

6.2.: EFFECT OF MARKETING ON CONSUMER UNDERSTANDING AND PERCEPTIONS

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6.2. EFFECT OF MARKETING ON CONSUMER UNDERSTANDING AND PERCEPTIONS

6.2.1. Purpose

Section 911(h)(1) of the FD&C Act states that;

“The Secretary shall require for the marketing of a product under this section that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products.”

USSTC seeks authorization to communicate a modified risk claim informing adult cigarette smokers that switching completely to the candidate product from cigarettes reduces the risk of lung cancer. Section 6.2 summarizes the evidence with regard to existing consumer perceptions about the risks of Copenhagen® Snuff Fine Cut (candidate product) and presents primary research on the development and testing of consumer understanding of the proposed modified risk claim.

Millions of adults continue using tobacco products, including approximately 2.3 million adult smokeless tobacco (ST) consumers who also smoke.¹ An accurate message conveying the risk difference between tobacco products is vital so that adult tobacco consumers (ATC) can make informed decisions. Further, as stated in the recent commentary by Borland “[h]elping people develop a better understanding of relative risks is likely to maximize the public health benefit” (Borland, 2018).

As presented in Section 6.1, the overwhelming scientific, medical, and public health consensus confirms that moist smokeless tobacco (MST) products, including those widely available in the U.S., are substantially less hazardous than cigarettes.² Despite the substantial compelling epidemiological evidence that ST products are less risky than cigarettes, existing research on risk perceptions (Section 6.2.2) shows that the vast majority of ATC perceive ST products as equally or more harmful than cigarettes.

Our proposed modified risk claim emphasizes the utility of complete switching and informs ATC regarding differences in lung cancer risk between the candidate product and cigarette smoking. We focus on lung cancer, since cigarettes are the most prevalent tobacco product used; this is the most serious and fatal disease in smokers; and the claim is supported by sound scientific evidence. According to the [Surgeon General Report](#), smoking is directly responsible for more than 80% of lung cancer deaths (2014).

¹ We refer to the population of ST consumers that also smoke cigarettes as “Dual Users.” This population is heterogeneous and we do not differentiate between levels of dual usage, which may consist of regular smokers that occasionally use ST or regular ST users that smoke cigarettes occasionally. [Appendix 3.2-1](#).

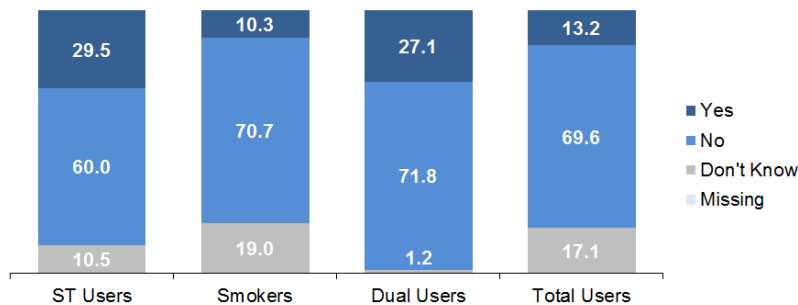
² See, e.g., M. Zeller et al., The Strategic Dialogue on Tobacco Harm Reduction: a vision and blueprint for action in the United States, 18 *TOBACCO CONTROL J.* 324-32 (2009); D.K. Hatsukami et al., Developing the science base for reducing tobacco harm, 9 *NICOTINE & TOBACCO RES.* S546 (2007).

Section 6.2.3 describes our research program encompassing claim development and testing. Section 6.2.5 then presents results from our Claim Comprehension and Intentions (CCI) Study (Appendix 7.3.2-1) evaluating comprehension of the claim and the effect of the claim on risk perceptions among (1) adult current tobacco consumers who use MST, cigarettes, or both products; and (2) adult nonusers of tobacco products, including never-users of tobacco and former tobacco users. The CCI Study results demonstrate that respondents understand the proposed modified risk claim; that exposure to this claim does not alter perceptions regarding absolute and relative risk; and that our proposed claim does not lead to misperceptions that use of the candidate product is without risk or a safe alternative to quitting tobacco use.

6.2.2. Consumer Beliefs about the Health Risks of Using Smokeless Tobacco

Despite substantial and compelling epidemiological evidence that ST products are far less risky than cigarettes (Section 6.1), many ATC wrongly believe that ST products are as harmful as cigarettes, or even more harmful. For example, in the PATH (Population Assessment of Tobacco and Health) WAVE 1 survey, the vast majority of smokers (90%) said that ST is as or more harmful than cigarettes.³ Similar findings are evident in the 2015 HINTS (Health Information National Trends) survey (Figure 6.2-1), where a vast majority of smokers (71%) and dual users (72%) do not believe that ST is less harmful than cigarettes.

Figure 6.2-1: Proportion of Adult Tobacco Consumers that Believe that ST is Less Harmful than Cigarettes



Source: Data from ALCS analysis of the 2015 National Cancer Institute Health Information National Trends Survey (HINTS). Proportions represent responses to the question: “In your opinion, do you think that some smokeless products, such as chewing tobacco, snus and snuff, are less harmful to a person’s health than cigarettes?”

Definitions: “ST users” include individuals who had used smokeless tobacco (ST) at least 20 times and were using every day or some days at the time of the assessment but did not smoke cigarettes at the time of the assessment

³ Source: ALCS Analysis of PATH Wave 1 (Sept ‘13- Dec ‘14) Adult Public Use File. In PATH, “Don’t Know” is not included in the valid response set. ST defined as loose snus, moist snuff, dip, spit, or chewing tobacco.

(n=60). “Smokers” include individuals who had smoked at least 100 cigarettes and were smoking cigarettes every day or some days at the time of the assessment, but did not use ST at the time of the assessment (n=467). “Dual users” include those who met lifetime criteria for both ST and cigarettes and were using both products every day or some days at the time of the assessment (n=21). ST included chewing tobacco, snus, snuff, or dip.

NOTE: Numbers may not total 100% due to rounding.

These observations corroborate previous reports that most cigarette smokers believe ST to be of equal or greater risk to their health than cigarettes (O'Connor, Hyland, Giovino, Fong, & Cummings, 2005; O'Connor et al., 2007; Smith, Curbow, & Stillman, 2007; Tomar & Hatsukami, 2007) (Section 7.5.7-1 and Section 7.5.7-2). Table 6.2-1 summarizes the published literature on risk perceptions of ST use.

Table 6.2-1: Summary of the Literature on ST Risk Perceptions

Authors (Date)	Findings Related to Risk Perceptions of ST	Percent Risk Misperception
(Haddock, Lando, Klesges, Peterson, & Scarinci, 2004)	Evaluated perceived risk reduction by switching to smokeless. 75% reported “no risk reduction” and only 2% reported “large risk reduction.” Authors found increased smoking cessation among those who perceived risk reduction for smokeless tobacco (ST).	75%
(O'Connor et al., 2005)	Among smokers (aware of ST) 10.7% agreed, 82.9% disagreed, 6.4% responded that they “did not know” in relation to the belief that ST products are less harmful than smoking.	83%
(Smith et al., 2007)	Study examined perceived harm of smokeless products and cigarettes and found that 89.3% perceived dip /chew to be “as harmful” or “more harmful” than cigarettes.	89%
(Tomar & Hatsukami, 2007)	Among HS seniors, 58.7% perceived ST to have equal or greater risk of harm than cigarettes.	59%
(O'Connor et al., 2007)	Across all Waves/Countries, 13% adult smokers agreed that there are any ST that are less harmful than cigarettes. At Wave 3 among AS, 7.6% in the U.S., 9.7% in Canada, 11.7% in U.K., and 11.7% in Australia agreed that any ST products are less harmful.	>87%
(Peiper, Stone, van Zyl, & Rodu, 2010)	In a survey of faculty, greater than 80% perceived ST to be “high risk” and less than 4% perceived “low” risk. Relative to cigarette smoking 36% believed ST was riskier and 50% no difference in risk.	86%
(Borland, Cooper, McNeill, O'Connor, & Cummings, 2011)	Perception that some ST are “a lot less harmful” ranged from less than 20% in the U.S. and Canada to 40% or less in the U.K. and Australia.	60-80%
(Callery, Hammond, O'Connor, & Fong, 2011)	Among four products tested, 30-60% reported perceptions of “less harmful.” Of the six conditions tested, 15-38% reported that ST was “more harmful.”	40-70%

Authors (Date)	Findings Related to Risk Perceptions of ST	Percent Risk Misperception
(Capella, Taylor, & Kees, 2012)	This study examined relative risk perceptions of ST vs. cigarettes. The authors reported that pairing a Harm Reduction Statement with a warning led to mixed results.	Not reported
(Choi, Fabian, Mottey, Corbett, & Forster, 2012)	Some participants thought smokeless products were just as harmful or more harmful.	Not reported
(Sami et al., 2012)	In focus groups of smokers on perceptions of ST and harm reduction, some “perceived [ST] as more ‘unhealthy’ than cigarettes.”	Not reported
(Wray, Jupka, Berman, Zellin, & Vijaykumar, 2012)	In young adult focus groups on perceived risk, the authors reported “varying levels of risk.”	Not reported
(Borland et al., 2012)	Correct perception of ST as “a lot less harmful” after fact sheet intervention was 27.1% in the US, 28.3% in Sweden, 35.8% in Australia and 53.3% in the UK.	78-93% (pre-intervention)
(Biener, Nyman, Stepanov, & Hatsukami, 2014)	In an online survey of tobacco control professionals, about 30% incorrectly answered that ST is more harmful than cigarettes; unclear how many believe ST and cigarettes are equally harmful.	>30% (pre intervention)
(Bahreinifar, Sheon, & Ling, 2013)	In focus groups of smokers, the authors reported that most seemed skeptical about whether or not snus was a safer than cigarettes.	Not reported

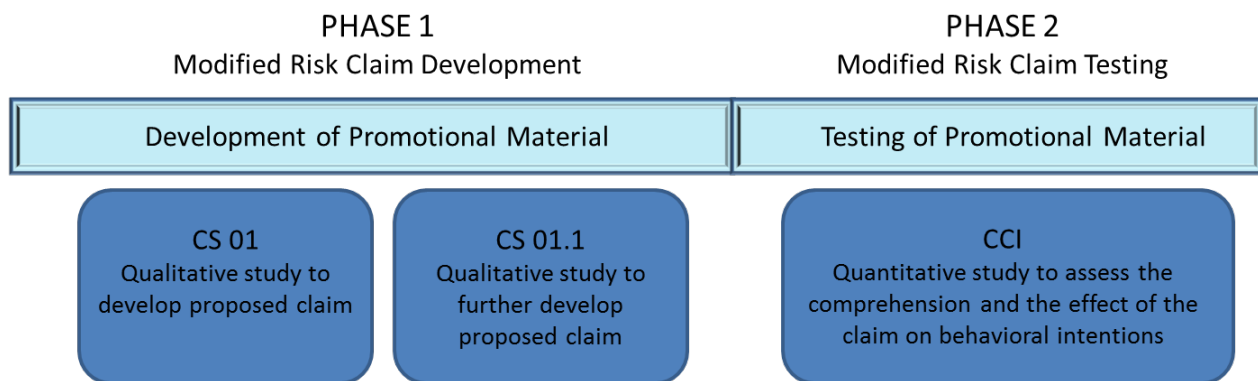
In addition to being false, these misperception may have consequences. Borland states, “[I]f people underestimate the real risk differential, they are likely to be at greater risk of moving to or remaining with smoking because they may perceive less or no perceived risk reduction without affecting the reduction in benefit. In short, there is a risk that the strategy of downplaying relative risks may end up resulting in the very thing it was designed to avoid; more smoking than there would otherwise be” (Borland, 2018). In order to overcome consumer misperception of the real risk differential between tobacco products, successful communication of accurate relative risk information is essential (Kozlowski & Sweanor, 2018; Levy, 2018; Niaura, 2018). ATC who are unwilling or unable to quit cigarettes, including dual users of cigarettes and ST, will experience a benefit if they understand this relative risk information and ultimately switch completely to the candidate product. Correcting misperceptions about the relative risk of cigarettes and ST products could be an important first step in persuading certain AS over time to completely switch to ST.

6.2.3. Overview of Consumer Perception and Behavior Program For Modified Risk Claim Development and Testing

ALCS designed a perception and behavior program to develop and test various potential modified risk claims as shown in Figure 6.2-2. As a first step towards developing the claims language, we evaluated possible claims for clarity, relevance, believability, and understanding. Once selected, based on criteria described in Section 6.2.3.2 below, we

assessed the final proposed modified risk claim for consumer comprehension and understanding of the significance of the claim in the context of total health and in relation to specific diseases and health-related conditions associated with the use of the candidate product.

Figure 6.2-2: Perception and Behavior Program for Development and Testing of a Modified Risk Claim



6.2.3.1. Phase 1: Development

We first developed consumer-centric, modified risk claims language, supported by the scientific evidence, based on careful review of the published epidemiology and our analysis of the linked mortality datasets, presented in Section 6.1. During the claims language development phase, ALCS conducted two studies ([Appendix 7.3.3-1 CS01 Claims Qualitative Study](#), [Appendix 7.3.3-2 CS01.1 Claims Qualitative Study](#)) to determine claims language combinations that ATC would find clear, understandable, relevant, and believable. Based on our analysis (see Section 6.2.4.1) of the information, we selected the following proposed modified risk claim:

“IF YOU SMOKE CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer.”

While this claim met the criteria for testing phase inclusion, many participants still associated ST products to be as risky as cigarettes due to other perceived negative implications to total health and specific diseases (e.g., mouth cancer) ([Appendix 7.3.3-2; Overall Responses Section, Pg. 14](#)).

Also, of note, we chose to begin our claim language with a headline: **“IF YOU SMOKE, CONSIDER THIS.”** We paid much attention to the construct of our headline, because of its key role and various functions it must serve. The most important function of a headline is attracting the reader’s attention and making them interested in the rest of the message. Research ([Hafer & White, 1989](#)) ([Belch & Belch, 1993](#)) has shown the headline is generally what people first look at in a print ad followed by the illustration. However, that only 20% of

readers go beyond the headline and read the body copy. Thus, in addition to attracting attention, the headline must provide the reader with sufficient reason to read the copy portion of the ad. Our headline also performs a segmentation function by engaging the attention and interest of consumers who would most likely to buy the candidate product, i.e., adult smokers. We also chose a command format. Command headlines range from gentle or polite suggestions to strong statements regarding appropriate behaviors or actions. As noted by (Belch & Belch, 1993), these types of headlines are particularly effective when the advertiser has something important or new to tell the target audience.

6.2.3.2. Phase 2: Testing

During the testing phase, ALCS conducted the CCI Study to evaluate adult tobacco users' and nonusers' (former and never tobacco users) comprehension of the proposed modified risk claim, risk perceptions for the candidate product, and the effect of the modified risk claim statement in the context of general advertising⁴ on behavioral intentions (CCI Study; Appendix 7.3.2-1).

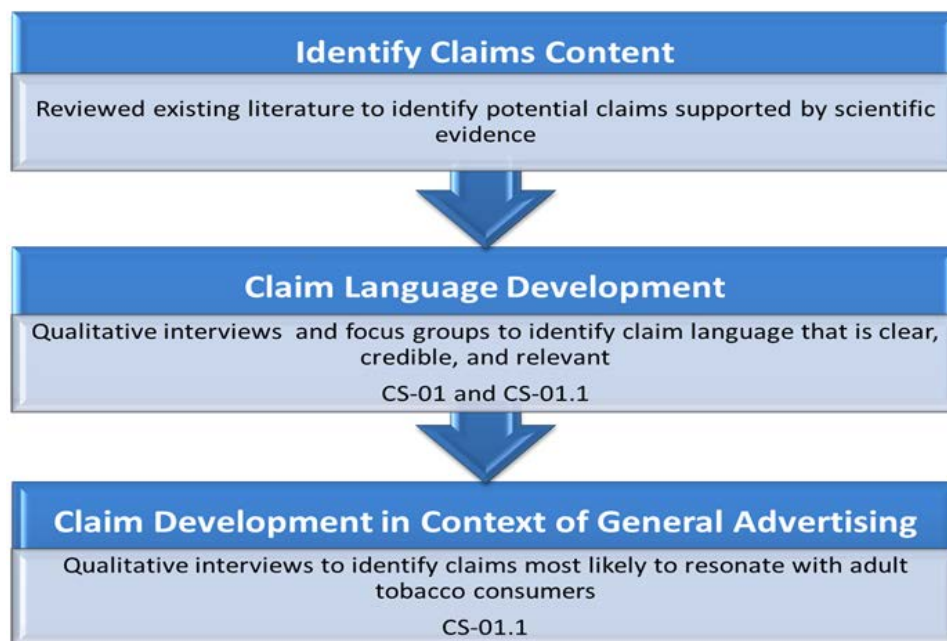
The CCI Study results demonstrated that adult tobacco users and nonusers understand the claim (e.g., study participants correctly interpret the message of the claim statement in the context of the advertising material), and the proposed modified risk claim does not mislead tobacco users and nonusers to believe that the candidate product eliminates all risk to health.

6.2.4. Modified Risk Claim Development Phase

During the development phase, we (Figure 6.2-3) (1) identified potential modified risk claims content; (2) developed claims language with ATC; and (3) tested modified risk claims in the context of advertisements to identify those generally resonating⁵ with ATC.

⁴ We use the terms advertising materials to refer to the materials presented during research containing proposed modified risk claims.

⁵ We generally define resonance as having enough personal meaning to result in consideration of a behavior change (in this instance switching from cigarettes to MST).

Figure 6.2-3: Modified Risk Claims Development**6.2.4.1. Claims Language Development & Assessment**

We conducted two qualitative studies:

- CS-01: Claims Language Development ([Appendix 7.3.3-1](#)), n=63; and
- CS-01.1: Claims Language Assessment ([Appendix 7.3.3-2](#)), n = 22.

The first qualitative study, CS-01: Claims Language Development, consisted of five focus groups of adult male smokers who did not reject MST and dual users of MST and cigarettes (n = 63). The study participants engaged in a sorting exercise to combine separate parts of potential claims language (e.g. switching completely, using exclusively), which covered a range of respiratory and cancer-related diseases and behaviors, into full statements, which they then evaluated as a group. The results of those focus groups indicated that claims language must follow some general principles in order to be credible:

1. The message must be strong, but language should not be so strong that it is unbelievable.
2. The message needs to be congruent with what people already believe to be true about the health risks of ST products (e.g., the claims should not conflict with the warning statements).
3. The message cannot be alienating (e.g., referring to “exclusive use of this product” was alienating to consumers; whereas, “switching completely” was considered strong without being overly alienating).
4. The message must be easy to understand (e.g., the terms “COPD” and “emphysema” were not well understood by the participants).

The second study, CS-01.1 ([Appendix 7.3.3-2](#)), used one-on-one interviews (n=22) among adult male smokers who did not reject MST (i.e., those saying they are “neutral,” “somewhat willing,” or “very willing” to try MST at some point in the future) and dual users of cigarettes and MST. CS-01.1 evaluated participants’ understanding of the claims language and the impact to risk perceptions and behavioral intentions related to modified risk claims. During the study, participants combined different parts of a potential claim to form one claim that they felt was understandable, relevant, and fully compatible. The interviewer then asked questions about their understanding of claim parts, risk perceptions, and behavioral intentions.

The interviews conducted in CS-01.1 resulted in the following findings as part of the claims development process:

1. Although participants disliked introductory claim language such as “switching completely” and “exclusive use,” these messages were understood to mean 100% replacement of cigarettes with MST; whereas terms like “as an alternative” or “use instead of” were not interpreted to mean 100% replacement.
2. Only a few participants said that the claim message they developed during the research would positively affect their intent to use MST.
3. Fewer than half of the participants said that the claim might affect their perceived risk to health from using MST.
4. The majority of participants questioned the credibility and/or believability of various claim statements (e.g., general health), saying that a given claim statement could contradict the warning statement, while others saw claim statements (e.g., mouth cancer) as a tradeoff between health risks associated with MST and cigarette smoking.

Importantly, across the CS-01 study series, while only a few participants stated positive changes in intention to use MST, they were typically dual users. Additionally, while participants viewed multiple claim statements throughout the interview, the research involved only a single exposure occasion.

The results of the CS-01 study series further suggest that individuals’ beliefs about the risk of ST are likely to influence their interpretation of potential claim language. As referenced by [Slovic \(1987\)](#), “New evidence appears reliable and informative if it is consistent with one’s initial beliefs; contrary evidence tends to be dismissed as unreliable, erroneous, or unrepresentative.”⁶

Additionally, some adult smokers believe the risks to health from cigarettes and MST are equivalent. However, when evaluating a specific risk tradeoff, social or ideological concerns come into consideration. For example, during our claims development research, the visible aspects of contracting mouth cancer through ST made this risk a stronger negative than the risk of lung cancer.

⁶ R. Nisbett and L. Ross. *Human Inference: Strategies and Shortcomings of Social Judgment* (Prentice-Hall, Englewood Cliffs, NJ, 1980).

While understanding that there may be positive rationale for the inclusion of other claims, we selected the claims language based on:

1. its relevance and understanding to the individual smoker;
2. its level of clarity and believability relative to other claims tested; and
3. robust scientific evidence substantiating the proposed modified risk claim.

6.2.4.2. Summary of Modified Risk Claim and Advertising Material Development

Through our modified risk claims development, we created advertising with the proposed modified risk claim for testing shown in Figure 6.2-4. Additionally, our qualitative studies suggest comprehension of the claim language by ATC. We also selected “switching completely,” since the majority of the ATC in the CS-01.1 ([Appendix 7.3.3-2](#)) interpret this term to mean 100% replacement of their cigarettes with the candidate product, without feeling alienated by the switching language (CS-01, [Appendix 7.3.3-1](#)).

Figure 6.2-4: Proposed Modified Risk Claim and Advertisement



Through our research, we also concluded that this claim, when presented in the context of advertising (e.g., including warnings and product imagery):

- conveys accurate information, supported by the scientific evidence;
- is understandable and relevant to ATC; and
- would not lead consumers to believe that the candidate product is without risk.

6.2.5. Modified Risk Claim Testing

FDA provides additional clarification to the Section 911(h)(1) statutory requirement in Section VI(A)(4) of the 2012 MRTPA Draft Guidance by providing the following recommendation:

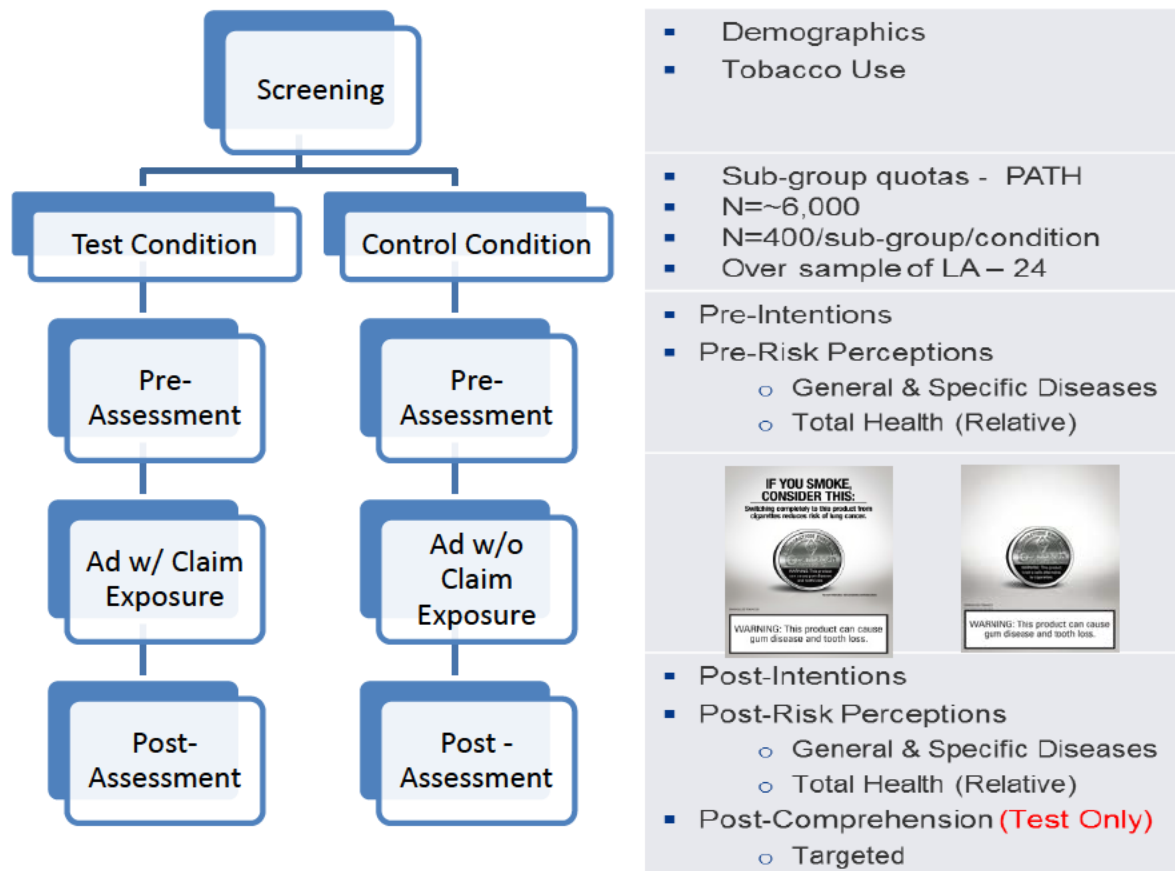
“The scientific studies submitted by the applicant should inform FDA’s evaluation of the tobacco product’s marketing on consumer perception and understanding, including:

The ability of consumers to understand the modified risk claims and the significance of the information in the context of one’s health;

Consumers’ beliefs about the health risks of using the product relative to other tobacco products, including those within the same class of products;

Consumer beliefs about the health risks of using the product relative to cessation aids; and
Consumer beliefs about the risks of using the product relative to quitting all tobacco use.”

During Phase 2 of the program ([Figure 6.2-5](#)), we addressed these recommendations by testing the understanding and risk perceptions among users and nonusers of tobacco products in relation to the proposed modified risk claim and advertising developed during Phase 1.

Figure 6.2-5: Modified Risk Claim and Advertising Testing Design

6.2.5.1. Validation of items in the survey instrument

Below, we briefly describe the CCI Study design ([Appendix 7.3.2-1](#)), which either used items sourced ([Appendix 7.3.2-10](#) Item Tracking Matrix) from the literature or validated based on an internally conducted validation study. The following appendices provide further detail on item validity ([Appendix 7.3.3-8](#)).

Our validation study used a survey instrument developed as part of a comprehensive consumer perception and behavior assessment program. ALCS validated the scales derived from the survey items measuring behavioral intentions and absolute risk perceptions in accordance with FDA 2009 Guidance on Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. The validation study comprised multiple waves of cognitive interviewing, followed by a large-scale, quantitative phase, during which we established key psychometric properties (e.g. test-retest reliability, construct validity) on validation and cross-validation samples. In addition to classical test theory methodology, we employed item response theory to establish appropriate item functioning and to demonstrate little to no bias across key demographic characteristics. We further validated the items on a large, demographically diverse sample of tobacco users and non-users, including, but not limited to, cigarette smokers, electronic cigarette users, and ST

users. While the study incorporated stimuli related to e-cigarettes, the questions tested apply to the CCI study given that:

1. the items were validated on a demographically diverse sample of tobacco users including ST users;
2. the content of the items from the validation study is exactly the same as the content of the items in the CCI study, except for reference to the candidate product;
3. the items functioned appropriately for both tobacco users and never users; and
4. the items functioned similarly between key demographic characteristics (e.g., males and females).

We also adapted scales measuring relative risk perceptions, attitudes, and beliefs from previously published scientific literature (as listed in [Appendix 7.3.3-7](#)). In subsequent sections (see Section [6.2.6](#), Section [6.2.8](#), and Section [6.2.9](#)), we describe the results of the CCI Study related to specific FDA recommendations for testing consumer understanding and perceptions. Where applicable, we provide additional context through published literature.

6.2.5.2. CCI Study Design Overview

ALCS conducted the CCI Study to assess (1) comprehension⁷ of the proposed modified risk claim; (2) intentions⁸ to try, use, dual use, and switch to the candidate product; and (3) intentions to quit smoking or quit tobacco use, among adult users and nonusers (former- and never-users) of tobacco products. This research also examined risk perceptions⁹ associated with the use of the candidate product ([Appendix 7.3.2-1](#)). We discuss the CCI Study intention outcome measures in Section [6.3](#) and Section [6.4](#).

CCI Study measures relevant to this section included:

- comprehension of the claim;
- understanding of the modified risk claim and the significance of the information in the context of one's health;
- perceptions about the health risks of using the product relative to other tobacco products, including those within the same class of products;
- perceptions about the health risks of using the product relative to cessation aids;
- perceptions about the risks of using the product relative to quitting all tobacco use; and
- ratings of believability of the advertising with the proposed modified risk claim in the presence of federally mandated rotating warnings.

To reflect the general population, participants were matched to the U.S. population using major demographic variables (gender, age, race/ethnicity, education, and region) based on

⁷ Primary outcome measure

⁸ Primary outcome measure

⁹ Secondary outcome measure

quotas from the PATH Study ([Appendix 7.3.2-1; Table 2](#)). This online study involved 5,871 adult (legal age to use tobacco products [LA] and older) users and nonusers of tobacco products from across the U.S., including 4,927 main sample participants and 944 over quota participants to increase the base size for LA-24 year olds, a population of interest to FDA¹⁰. We assigned participants to one of the six subgroups based on their current and prior use of tobacco products (Table 6.2-2). For the oversample of LA-24 year olds, the participants were assigned to one of two subgroups: LA-24 Users (n=419 in each of the Test and Control conditions) or LA-24 Nonusers (n=401 in Test and 403 in the Control conditions) ([Appendix 7.3.2-1; Table 5](#)). Additionally, those at risk for low health literacy were classified using the Single Item Literacy Screening (SILS) (n=217 in Test and n=182 in the Control conditions) ([Appendix 7.3.2-1; Table 5](#)).

Table 6.2-2: Sample Size by Subgroup

	Current Adult Tobacco Users				Adult Nonusers		Total Participants
	ASPQ	ASNPQ	Dual Users	MST Users	Former Users	Never Users	
Test Condition	406	398	422	432	402	402	2,462
Control Condition	401	403	418	439	404	400	2,465
Total	807	801	840	871	806	802	4,927

Source: [Appendix 7.3.2-1; Table 4](#)

ASPQ=Adult Smokers Planning to Quit; ASNPQ=Adult Smokers Not Planning to Quit; Dual Users=Cigarette Smokers and MST Users; MST=Moist Smokeless Tobacco

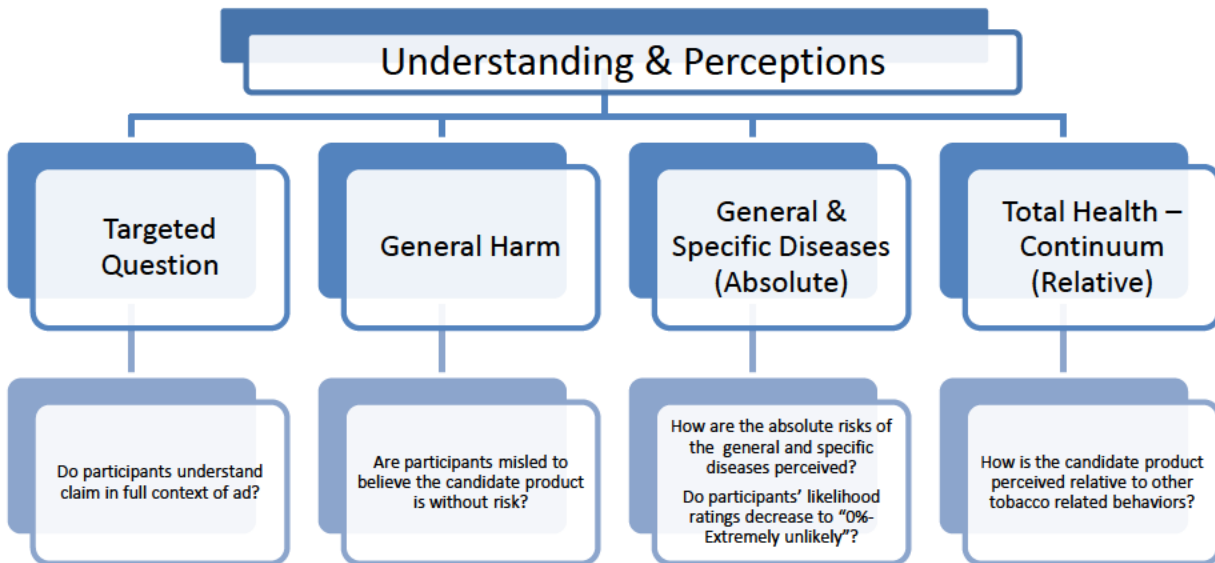
Dual and poly users of other tobacco products were included in all current adult tobacco user subgroups.

The CCI Study consisted of an experimental design with pre- and post- measures in two conditions: Test (advertising with proposed modified risk claim) and Control (same advertising material without the claim).

Participants answered questions on risk perceptions before (pre-test) and after (post-test) viewing a product advertisement with or without the proposed claim. Participants in the claim exposure arm saw advertising material with the claim, and only these participants completed questions related to claim comprehension. While the study assessed various metrics,¹¹ this section focuses on the comprehension and risk perception results.

¹⁰ We chose to oversample this population because FDA in a meeting (Meeting # TC0001446 held on 2/26/2016) on Consumer Perception and Behavior Study Design for MRTPAs expressed an interest in understanding whether and how modified risk information may affect certain populations such as young adults (age 18-24).

¹¹ Section 6.3 and Section 6.4 include a summary of results with respect to intentions to try, use, dual use, switch, quit cigarettes and quit all tobacco.

Figure 6.2-6: Modified Risk Claim Comprehension and Risk Perception Overview

6.2.5.2.1. Measuring Claim Comprehension

Targeted Question: We measured comprehension of the information concerning the proposed modified risk claim in the CCI Study based on responses to the following targeted comprehension question (asked only in the Test condition):

- “Based **only** on the information shown in this ad, smokers who switch completely from cigarettes to Copenhagen® Snuff:
 - Increase the risk of lung cancer
 - Reduce the risk of lung cancer
 - Eliminate the risk of lung cancer
 - Do not know”

We classified participants as comprehending the claim message if they responded to the above questions with “reduce the risk of lung cancer.”

This measure assessed general understanding of the claim statement in context of the advertisement.

6.2.5.2.2. Measuring Risk Perception

We assessed the absolute and relative risk perceptions in the context of total health and in relation to diseases and health-related conditions associated with the use of tobacco products.

General Harm (Absolute) question: In both the Test and Control conditions, participants rated their perception of general harm associated with using the candidate product before exposure to the proposed modified risk claim and again after seeing the modified risk claim.

- “How harmful do you think using Copenhagen® Snuff is to a person’s health?”

- Not at all harmful
- Moderately harmful
- Very harmful”

This measure assessed risk perception of the proposed modified risk claim information in the context of total health. We assessed whether consumers could be potentially misled into believing that the candidate product was without risk, by assessing the proportion of participants responding that the candidate product was “not at all harmful” after exposure to the proposed modified risk claim statement compared to responses prior to exposure.

General and Specific Diseases (Absolute) question: To understand the significance of the claim information to a participant’s perception of possible diseases and health-related conditions associated with using the candidate product, participants rated the likelihood of certain health outcomes occurring from use of the candidate product. In both the Test and Control conditions, participants assigned likelihood for each of the following health outcomes on a scale of 0 to 100 percent, with 10 percent increments, both prior to exposure to the modified risk claim and again after seeing the claim.

- “Looking at the same list, how likely is it that these things will happen to a person who only uses Copenhagen® Snuff daily?”
 - Negatively impacts health
 - Mouth cancer
 - Lung cancer
 - Heart disease/heart attack
 - Nicotine addiction
 - Discolored teeth or decay

This measure provides additional information to assess how exposure to the proposed modified risk claim influences participants’ understanding of the impact to possible diseases and health related outcomes. We also assess whether the exposure to the proposed modified risk claim has the potential to mislead consumers to believe the candidate product is without risk by looking at the proportion of participants that decreases their ratings to “0%-extremely unlikely” after exposure.

Total Health – Continuum (Relative¹²) question: To assess perceptions of relative risk, participants rated several tobacco use behaviors for the risk they could pose to a person’s health. Participants rated each behavior on a seven-point, fully labeled scale, with the numeral one representing “not at all risky” and the numeral seven representing “extremely risky” with a “don’t know” option. In both the Test and Control conditions, questions were asked before exposure to the modified risk claim and again after seeing the modified risk claim:

¹² Items were asked on the same scale and individual tobacco-related behavior item ratings were then compared to each other.

- “Please rate each item for the risk you feel it could pose to a person's health;
 - Smoking 15 cigarettes daily;
 - Using half a can of Copenhagen® Snuff daily;
 - Using half a can of other smokeless tobacco (snuff or dip) daily;
 - Using only an FDA (Food and Drug Administration) approved over-the-counter smoking cessation medication, as directed, for quitting smoking (Nicorette® gum, the patch, etc.);
 - Completely quitting all tobacco use;
 - Never using tobacco products.”

This measure provides the relative assessment of the candidate product to other tobacco-related behaviors. We also assess whether the exposure to the proposed modified risk claim has the potential to mislead consumers to believe the candidate product is without risk by looking at the proportion of participants that decreases their rating for the candidate product to “1-not at all risky” after exposure.

6.2.6. Ability of Consumers to Understand the Proposed Modified Risk Claim and the Significance of the Information in the Context of One’s Health, Including Not Being Misled to Believe the Candidate Product is Without Risk

Our assessment addressed three questions:

1. Do the participants comprehend the proposed claim?
2. Do the participants believe the claim?
3. Are the participants either being misled by the claim into believing that the candidate product is without risk or generalizing the reduced risk message beyond the scope of the claim?

6.2.6.1. Claim Comprehension

The majority of the study participants, including those classified at risk for low health literacy, accurately comprehend that the claim conveys the message of reducing the risk of lung cancer upon switching completely from cigarettes to the candidate product.

Table 6.2-3 shows responses to the following Targeted Comprehension Question:

“Based **only** on the information shown in this ad, smokers who switch completely from cigarettes to Copenhagen® Snuff:

- Increase the risk of lung cancer
- Reduce the risk of lung cancer
- Eliminate the risk of lung cancer
- Do not know”

Table 6.2-3: Targeted Comprehension Question Response by Subgroup - Test Condition

% of Participants ¹	ASPQ	ASNPQ	Dual Users	MST Users	Former Users	Never Users	LA-24 Tobacco Users	LA-24 Tobacco Non-Users	Low Health Literacy	Normal Health Literacy
Base Size	406	398	422	432	402	402	419	401	217	2716
Increase the risk of lung cancer	20.44%	17.34%	8.06%	6.25%	19.90%	21.64%	14.56%	20.95%	15.67%	16.05%
Reduce the risk of lung cancer (CORRECT)	54.68%	61.31%	69.43%	69.68%	59.20%	58.71%	61.34%	57.11%	60.37%	61.56%
Eliminate the risk of lung cancer	7.14%	6.28%	8.06%	9.72%	3.98%	2.24%	8.35%	4.49%	10.14%	5.85%
Do not know	17.73%	15.08%	14.46%	14.35%	16.92%	17.41%	15.75%	17.46%	13.83%	16.53%

Source: [Appendix 7.3.2-1; Table 6](#)

ASPQ=Adult Smokers Planning to Quit; ASNPQ=Adult Smokers Not Planning to Quit; Dual Users=Cigarette Smokers and MST Users; MST=Moist Smokeless Tobacco

¹ Values shown as proportion of participants responding to each response option within the targeted question: “Based only on the information shown in this ad, smokers who switch completely from cigarettes to Copenhagen® Snuff.”

Overall, the majority of participants across all subgroups in the Test Condition understood the modified risk claim, by selecting the correct response, i.e., “*Reduces the risk of lung cancer.*” The response varied within the user subgroups ranging from 55% (in ASPQ) to 70% (in MST Users). A significant proportion of Dual Users (69%) selected the correct response. A similar proportion of Low Health Literacy (as classified by SILS¹³) (60%) and Normal Health Literacy (61%) participants identified the correct answer, providing further evidence regarding claim comprehension.

Importantly, the vast majority of participants (~90-98%) were not misled into believing that the candidate product eliminates the risk of lung cancer. Among all participants in the Test Condition, only 6% (181 of 2933) indicated that the candidate product eliminates the risk of lung cancer. In a recent publication, [Fix et al., \(2017\)](#) report similar observations during evaluation of modified risk statements associated with a commercial ST product; a proportion of the respondents (specific data not included in the manuscript) selected that the product has “no risk” after viewing the claim.

We gain additional insights into these respondents by further analysis of the ([Appendix 7.3.2-9; Table 6](#)) incoming beliefs among the (n=181) participants responding that the candidate

¹³ Participants were asked a single item health literacy screening question ([Morris, MacLean, Chew, & Littenberg, 2006](#)): “How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?”

product eliminates the risk of lung cancer. In this analysis, 19% (35 of the 181) already had incoming beliefs that the candidate product is *extremely unlikely* to cause lung cancer before they saw the proposed modified risk claim, which remained unchanged after seeing the proposed claim. Therefore, exposure to the claim did not change their prior risk perception and their response to the targeted question remained consistent with their incoming beliefs. The vast majority (71%) of the remaining respondents (129 of the 181) continued to believe that the candidate product has some likelihood of causing lung cancer both pre- and post-exposure. For this proportion of participants, a response of “eliminates” the risk of lung cancer is inconsistent with their beliefs about the candidate product both pre- and post-exposure.

Thus, the proportion selecting “eliminates the risk of lung cancer” on claim comprehension should be interpreted in the context of both incoming (pre-exposure) beliefs, as well as post-exposure perceptions of lung cancer risk from use of the candidate product. Additionally, we observe in our Claims Development studies that an individual’s pre-existing beliefs may influence their incorrect comprehension of a modified risk statement, which is consistent with the findings by other researchers (Borland, 2018; Fix et al., 2017; Slovic, 1987).

6.2.6.2. Claim Believability

While most AS understand the claim, they do not find it believable, providing additional evidence that incoming beliefs influence comprehension. A majority of the participants in the MST User subgroups – Dual Users (67%) and MST Users (62%) – either agree or strongly agree that the ad is believable (Appendix 7.3.2-9; Table 3). In contrast, the majority of the participants in the AS subgroups – ASPQ (57%) and ASNPQ (54%) – as well as ~70% of the Nonusers subgroups (Former Users, Never Users and LA-24 Nonusers), strongly disagree, disagree, or neither agree nor disagree that the ad is believable. Trustworthiness has been widely considered an important factor in believability of reduced risk messaging regarding tobacco products. Adult tobacco consumers will not believe the information provided by the manufacturer, however they will trust such communication if disseminated by public health agencies like FDA and CDC (Weaver et al., 2017). Fix et al., (2017) reported similar observations where respondents were skeptical and found advertisements with modified risk messages to be less truthful.

6.2.6.3. Is the Claim Misleading

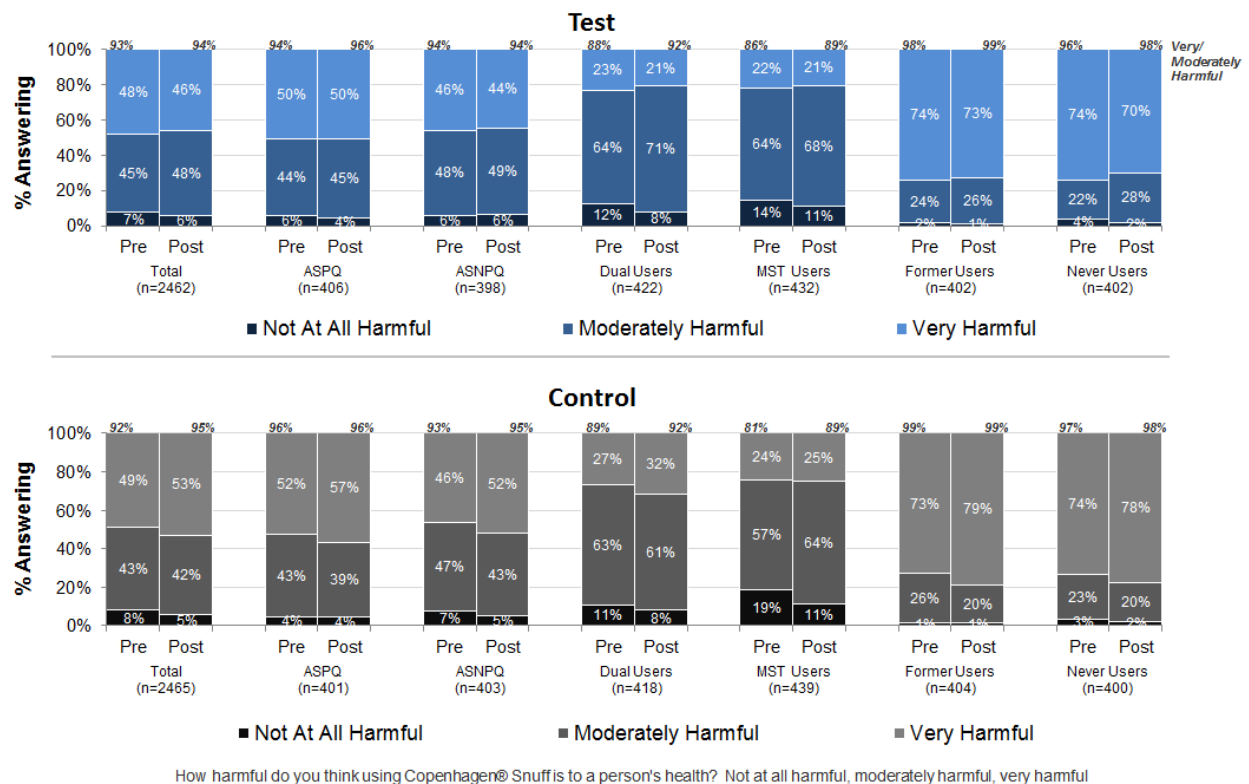
We investigated whether the claim is misleading by first assessing perceptions of general harm of the candidate product after exposure to the claim to determine if the claim led study participants to believe that the candidate product is without harm. Second, we determined whether the respondents generalized the reduced risk message to other diseases, beyond lung cancer, by evaluating changes in risk perceptions of general and specific diseases.

Based on responses to the general harm question, we conclude that study participants were not misled into believing that the candidate product is without harm. Most participants continue to associate harm with the candidate product in the context of one’s total health after exposure to the modified risk claim. As shown in Figure 6.2-7, when assessing the general harm of the candidate product, a vast majority (89%-99%) of participants associated some level of harm (“moderately harmful” or “very harmful”) with using the candidate

product after exposure to the proposed modified risk claim. Furthermore, very few participants perceive the candidate product as having no harm, and viewing the proposed claim did not increase the perception that the candidate product is “Not at all harmful” in any subgroup.

To further understand the effect of the claim, we calculated the proportion of participants who changed their rating for “Using half a can of Copenhagen® Snuff daily” from >1 (somewhat or extremely risky) at pre-test to “1 Not at all risky” at post-test ([Appendix 7.3.2-9](#); [Table 5](#)). The proportion of participants who changed their answer was similar for both the Test and Control conditions, providing further evidence that the claim is not misleading.

Figure 6.2-7: General Harm Associated with the Candidate Product Pre-Post for Test and Control



Source: [Appendix 7.3.2-1](#); [Table 64](#)

ASPQ = Adult Smokers Planning to Quit; ASNPQ = Adult Smokers Not Planning to Quit; MST = Moist Smokeless Tobacco

We also conclude that the claim did not mislead study participants into generalizing the reduced risk message beyond lung cancer -- the disease referenced in our proposed claim. We determined the proportion of participants in each subgroup who rated six health outcomes as less likely to happen at post-test, relative to pre-test, in both conditions. No statistically significant differences were found for any of the six general and specific diseases

among ASPQ, ASNPQ, Dual Users, Never Users, and LA-24 Users between the Test and Control conditions (Table 6.2-4).

In Former Users and LA-24 Nonusers, a significantly higher proportion responded that lung cancer is less likely to occur after viewing the advertisement in the Test condition (with the claim) compared to the Control condition (without the claim). This observation was isolated to responses on lung cancer (specified in the claim) and general health (negatively impacts health) for LA-24 Nonusers and just to lung cancer for Former Users (Table 6.2-4).

However, we observed no corresponding changes in behavioral intentions for these subgroups.

Thus, we conclude that the vast majority of study participants were not misled after reviewing the modified risk claim into generalizing the reduced risk message to diseases beyond the specific lung cancer claim.

Table 6.2-4: Proportion of Participants for Whom Risk Perceptions Decreased After Viewing the Advertisement

Health Outcome	Condition	ASPQ	ASNPQ	Dual Users	MST Users	Former Users	Never Users	LA-24 Users	LA-24 Non-users
Negatively impacts health	Control	23%	19%	20%	22%	12%	11%	19%	11%
	Test	21%	23%	24%	20%	17%	17%	19%	20% ¹
Mouth cancer	Control	19%	19%	23%	19%	15%	14%	21%	13%
	Test	22%	20%	25%	23%	16%	18%	22%	20%
Lung cancer	Control	19%	20%	20%	15%	11%	14%	18%	15%
	Test	21%	24%	21%	21%	19% ¹	19%	21%	22% ¹
Heart disease/heart attack	Control	18%	18%	22%	22%	13%	13%	21%	17%
	Test	21%	25%	23%	24%	19%	16%	22%	22%
Nicotine addiction	Control	21%	17%	19%	21%	12%	11%	20%	12%
	Test	19%	16%	20%	17%	13%	16%	19%	18%
Discolored teeth or decay	Control	20%	17%	21%	21%	11%	13%	18%	14%
	Test	19%	17%	23%	20%	15%	18%	22%	17%

Source: [Appendix 7.3.2-9](#); [Table 7](#)

Note. ASPQ = Adult Smokers Planning to Quit; ASNPQ = Adult Smokers Not Planning to Quit; MST = Moist Smokeless Tobacco; LA: Legal age to purchase.

¹ Bold font indicates a statistically significant difference between the Control and Test conditions based on a chi-square test using Bonferroni-adjusted $\alpha = 0.05/6 = 0.008$.

Overall, the results indicate that the majority of participants understood the proposed modified risk claim, while not being misled by the claim either to believe the candidate product is without risk or to generalize the reduced risk message beyond the scope of the claim.

6.2.7. Beliefs About the Health Risks of Using the Product Relative to Other Tobacco Products, Including Those Within the Same Class of Products

6.2.7.1. Perceived Absolute Risk of the Candidate Product

The CCI Study corroborates previous reports that a large majority of ATC perceive ST products, including the candidate product, as harmful and single exposure to the proposed claim did not alter that perception. The CCI Study evaluated risk perceptions of the candidate product against six domains: “negatively impacts health,” “mouth cancer,” “lung cancer,” “heart disease/heart attack,” “nicotine addiction,” and “discolored teeth or decay.”

Exposure to the proposed modified risk claim did not alter the risk perception of the candidate product for lung cancer. Many of the participants in the AS subgroups (ASPQ and ASNPQ) had incoming beliefs that the candidate product is likely to result in lung cancer, which were unchanged after viewing the proposed claim. A smaller proportion (~40%) of the participants in the MST user subgroup (MST Users and Dual Users) also believed the candidate product was likely to cause lung cancer. A sizeable proportion¹⁴ of tobacco users (49% ASPQ, 38% ASNPQ, 28% Dual Users, 25% MST Users, 34% LA-24 Users) continued to believe that the candidate product was $\geq 70\%$ “Likely to cause Lung Cancer.” Although the scientific evidence supports the proposed modified risk claim, these data show that many tobacco product users in the study overestimate the risk of lung cancer from the candidate product. The deeply rooted misbeliefs about the harm of ST might be difficult to overcome from a single exposure. As suggested by other researchers, it is likely that there would need to be repeated exposures in order for the information to permanently alter beliefs, intentions, and to have any sustained influence on tobacco use behaviors (Borland et al., 2012).

Table 6.2-5 shows the average perceived risk likelihood for six general and specific diseases for the candidate product displayed across the six categories of users participating in the CCI Study. Overall, those participants currently using MST had lower perceptions of risk for the candidate product (risk likelihood ranging from 41% to 67%) compared to those who were not currently using MST. For example, ASPQ and ASNPQ had an average risk likelihood ranging from 53%-78%. All subgroups, however, showed similar trends in risk perceptions for general and specific diseases, which were generally unchanged among the study subgroups following exposure to the proposed modified risk claim. For example, all study participants rated a very high likelihood of mouth cancer, nicotine addiction, and discolored teeth or decay from using the candidate product, and exposure to the proposed claim did not alter these perceptions.

¹⁴Data shown in CCI Study Report ([Appendix 7.3.2-1](#))

Table 6.2-5: Average Ratings of Likelihood of Health Outcomes from Using the Candidate Product Daily, Only in the Claim Exposure Condition

Mean	ASPQ	ASNPQ	Dual Users	MST Users	Former Users	Never Users	LA-24 Tobacco Users	LA-24 Tobacco Non-users	Low Health Literacy	Normal Health Literacy
Base Size	406	398	422	432	402	402	419	401	217	2716
Negatively impacts health										
Pre-test	73.40	71.61	63.32	60.28	83.51	85.47	65.73	81.60	73.04	73.23
Post-test	75.07	70.68	63.96	61.25	84.58	85.20	68.02	80.50	73.78	73.61
Mouth cancer										
Pre-test	75.54	72.41	63.89	62.48	84.98	85.60	66.87	81.10	73.78	74.39
Post-test	77.12	72.49	64.22	63.08	84.68	85.27	68.62	80.92	74.24	74.59
Lung cancer										
Pre-test	59.70	53.57	42.87	38.87	64.15	70.12	45.73	63.89	56.82	55.22
Post-test	61.43	52.97	43.93	41.18	65.40	71.49	49.14	64.36	58.02	56.46
Heart disease/heart attack										
Pre-test	66.08	62.79	52.94	50.14	73.63	75.97	55.37	71.55	67.79	63.72
Post-test	68.97	61.23	54.34	50.72	74.68	77.44	57.45	71.80	68.30	64.67
Nicotine addiction										
Pre-test	74.70	75.58	69.17	67.82	88.13	86.10	68.78	81.10	76.13	76.68
Post-test	76.95	75.88	69.60	69.05	88.38	85.85	71.10	81.37	75.95	77.48
Discolored teeth or decay										
Pre-test	76.77	75.75	70.19	65.81	87.16	87.96	70.67	82.05	75.48	77.25
Post-test	78.25	76.26	68.96	66.83	87.09	87.21	71.41	82.24	75.12	77.47

Source: [Appendix 7.3.2-1; Table 56](#)

ASPQ = Adult Smokers Planning to Quit; ASNPQ = Adult Smokers Not Planning to Quit; MST = Moist Smokeless Tobacco; LA = Legal age to purchase tobacco

The proposed modified risk claim did not change the existing perceptions of *absolute* health risk among ATC for the candidate product. Additionally, participants understood that use of the candidate product presents risk and, in the case of both nonusers and adult smokers, these participants continue to perceive that there may be a high degree of risk for all health outcomes assessed. The findings from the CCI Study suggest that individuals understand the message of the proposed modified risk claim and do not misinterpret the message in the context of total health.

6.2.7.2. Perceived Risk of the Candidate Product Relative to Cigarettes and Other ST Products

Results from the CCI Study regarding the *relative* risk of other tobacco products also show that the proposed modified risk claim is not misleading. The CCI Study evaluated risk perceptions of the candidate product relative to cigarette smoking against six domains: “negatively impacts health,” “mouth cancer,” “lung cancer,” “heart disease/heart attack,” “nicotine addiction,” and “discolored teeth or decay.” We focused this comparison on cigarettes and MST use for several reasons: cigarette smoking is the most predominant form of tobacco use; MST dual use exists primarily with cigarettes (Section 3.2; Table 3.2-6); cigarettes are the most harmful of all the tobacco products; and our claim is directed toward smokers.

Participants rated the perceived risk of general and specific health outcomes from using the candidate product as similar to that of using cigarettes on three of the six items, specifically “negatively impacts health,” “nicotine addiction,” and “discolored teeth or decay.” Additionally, participants perceived mouth cancer likelihood as a greater risk when using the candidate product as compared to smoking. Participants rated the perceived risk of lung cancer from use of the candidate product as slightly lower than smoking cigarettes, on average. For pre- and post-exposure risk perceptions of cigarette smoking, see Appendix 7.3.2-1; Table 57.

We also assessed risks of the candidate product relative to cigarettes and other ST products in the CCI Study, Appendix 7.3.2-1. We report observations that are consistent for most subgroups; all subgroups believed smoking was riskiest, followed closely by using ST. Participants perceived the risks of using the candidate product and other snuff/dip/ST products to be almost identical.

Table 6.2-6: Average Rating of the Risk to One’s Health from Total Health-Continuum

Tobacco Usage Behavior ¹		ASPQ	ASNPQ	Dual User	MST User	Former User	Never User
		(N =393)	(N =390)	(N =407)	(N = 421)	(N =393)	(N =391)
Dipping half a can of Copenhagen Snuff daily	Pre-test	5.05	4.84	4.13	4.10	5.79	5.92
	Post-test	5.18	4.97	4.29	4.30	5.85	6.11
Dipping half a can of another snuff/dip/ST product daily	Pre-test	5.07	4.85	4.12	4.13	5.81	5.94
	Post-test	5.15	5.00	4.26	4.35	5.86	6.05
Smoking 15 cigarettes daily	Pre-test	5.43	4.96	4.81	5.25	6.09	6.39
	Post-test	5.62	5.11	4.87	5.27	6.23	6.45

Source: Appendix 7.3.2-1; Table 46a

ASPQ = Adult Smokers Planning to Quit; ASNPQ = Adult Smokers Not Planning to Quit; MST = Moist Smokeless Tobacco;

¹ 1 (Not at all Risky) to 7 (Extremely Risky) scale, with Do Not Know (DNK) option

In general, across all subgroups, single exposure to the proposed modified risk claim did not alter relative risk perceptions. The study participants ranked cigarette smoking as only slightly more risky than candidate product use or other ST products. Consistent with the previous discussion on misperceptions of relative risk, between 43% and 64% of CCI Study subgroup participants assigned the *same risk* to using the candidate product as they did to smoking cigarettes. Even a sizeable proportion of Dual Users (48%) and MST Users (43%) assigned the *same risk*. Between 6% and 19% of participants perceived the candidate product as *higher in risk* than smoking cigarettes (Appendix 7.3.2-1; Table 47).

Relative to ST use, minimal changes in risk perceptions for using other dip/snuff daily were observed across the study participants (Appendix 7.3.2-1; Table 46a). These results indicate that study participants did not alter their risk perceptions for other dip/snuff after viewing the proposed claim. This will likely not change since the proposed claim is specifically directed to the candidate product. Additionally, most CCI Study participants perceived the candidate product to be equally risky to using other snuff/dip/ST products. Between 58% and 79% of participants perceived the candidate product and other snuff/dip/ST to be equally risky and did not change their perceptions after exposure to the modified risk claim (Appendix 7.3.2-1; Table 47).

Those participants not currently using tobacco products (former and never user subgroups) viewed the risks for each tobacco use behavior consistently higher than the subgroups of tobacco product users, both before and after exposure to the claim.

6.2.7.3. Summary of Health Risks of Using the Product Relative to Other Tobacco Products, Including Those Within the Same Class of Products

Overall, the CCI Study results show that after exposure to the proposed claim, beliefs about the risks of using the candidate product relative to using other tobacco products remain consistent. Overall, we conclude that:

- The modified risk claim resulted in minimal change in perception of *absolute* risk associated with using the candidate product.
- ATC continued to be misinformed and believe that cigarette smoking as only slightly more risky than the candidate product or other ST. The modified risk claim does not alter the *relative* risk perceptions of the candidate product.
- Adult users and nonusers of tobacco products (including LA-24) did not misinterpret advertising and labeling with the proposed claim and continue to perceive risks associated with using the candidate product. Furthermore, adult nonusers and former tobacco users continue to view using the candidate product as high risk, both pre- and post-exposure to the proposed modified risk claim.

6.2.8. Beliefs about the Health Risks of Using the Product Relative to Cessation Aids

The CCI Study also assessed risk perceptions relative to use of cessation medications. The study asked participants to rate “Using an FDA (Food and Drug Administration) approved over-the-counter smoking cessation medication, as directed, for quitting smoking (Nicorette®

gum, the patch, etc.)” in order to compare their perceptions of risk with the candidate product. Both tobacco users and nonusers rated the risks of using the candidate product to be higher than using an FDA-approved, tobacco-cessation medication ([Appendix 7.3.2-1](#)). After exposure to the modified risk claim, the majority of participants in our studies continued to believe that the candidate product poses more risk than tobacco-cessation medications.

Table 6.2-7: Average Risk Perception of Candidate Product Usage Compared with Smoking Cessation Aids in Claim Exposure Condition

Tobacco Usage Behavior ¹		ASPQ	ASNPQ	Dual User	MST User	Former User	Never User
		(N =393)	(N =390)	(N =407)	(N = 421)	(N =393)	(N =391)
Dipping half a can of Copenhagen Snuff daily	Pre-test	5.05	4.84	4.13	4.10	5.79	5.92
	Post-test	5.18	4.97	4.29	4.30	5.85	6.11
Using an FDA (Food and Drug Administration) approved over-the-counter smoking-cessation medication, as directed, for quitting smoking (Nicorette® gum, the patch, etc.)	Pre-test	3.65	3.18	3.04	3.02	3.66	4.00
	Post-test	3.93	3.46	3.17	3.09	3.88	4.14

Source: [Appendix 7.3.2-1; Table 46a](#)

ASPQ = Adult Smokers Planning to Quit; ASNPQ = Adult Smokers Not Planning to Quit; MST = Moist Smokeless Tobacco;

¹ Note: 1 (Not at all Risky) to 7 (Extremely Risky) scale, with Do Not Know (DNK) option – sample size includes DNK responses

6.2.9. Beliefs about the Risks of Using the Product Relative to Quitting All Tobacco Use

The CCI Study assessed participants’ perceptions of the risk of using the candidate product as compared to “Completely quitting all tobacco use” and “Never using tobacco products.” Both tobacco users and nonusers rated the risks of using the candidate product to be much higher than quitting all tobacco use or never using tobacco ([Table 6.2-8](#)).

The risk associated with quitting all tobacco products or never using tobacco products remained virtually unchanged following single exposure to the proposed modified risk claim. These results demonstrate that exposure to the modified risk claim does not result in a misinterpretation that the candidate product is comparable in risk to or less risky than quitting all tobacco products or never using tobacco.

Table 6.2-8: Average Risk Perception of Candidate MRTP Usage Compared with Quitting All Tobacco Use and Never Using Tobacco Products in Claim Exposure Condition

Tobacco Usage Behavior ¹		ASPQ	ASNPQ	Dual User	MST User	Former User	Never User
		(N =393)	(N =390)	(N =407)	(N = 421)	(N =393)	(N =391)
Dipping half a can of Copenhagen Snuff daily	Pre-test	5.05	4.84	4.13	4.10	5.79	5.92
	Post-test	5.18	4.97	4.29	4.30	5.85	6.11
Completely quitting all tobacco use	Pre-test	2.40	2.24	2.40	2.01	1.91	2.07
	Post-test	2.58	2.34	2.40	2.07	2.13	2.16
Never using tobacco products	Pre-test	2.24	2.17	1.99	1.71	1.87	1.69
	Post-test	2.44	2.28	2.00	1.84	1.88	1.82

Source: [Appendix 7.3.2-1; Table 46a](#)

ASPQ = Adult Smokers Planning to Quit; ASNPQ = Adult Smokers Not Planning to Quit; MST = Moist Smokeless Tobacco;

¹Note: 1 (Not at all Risky) to 7 (Extremely Risky) scale, with Do Not Know (DNK) option – sample size includes DNK responses

6.2.10. Summary of the Effect of Proposed Modified Risk Claim on Understanding and Risk Perceptions in Users and Nonusers of Tobacco Products

Adults have long-standing beliefs about the risks associated with ST, including that using ST is equally as or more risky than smoking cigarettes. These beliefs influence how they interpret and receive messaging, such as the proposed modified risk claim. For many participants, this information is inconsistent with their pre-existing attitudes, beliefs, and behavior, which may have influenced the comprehension and response to the proposed claim. The pre-post design of the CCI Study helped to mitigate the influence of participants' incoming beliefs on Test and Control differences and isolate the impact of the proposed modified risk claim in the context of the advertisement.

ATC did not find a single exposure to the advertisement with a modified risk claim entirely persuasive enough to change their risk perceptions. As suggested in other research, repeated exposures would likely be needed in order for the information to permanently alter beliefs, intentions, and to have any sustained influence on tobacco use behaviors ([Borland et al., 2012](#)). In order to persuade ATC to believe the proposed claim, we will have to overcome their skepticism of tobacco industry claims. The perceived credibility of the source of risk communication plays an important role in persuading consumers to change attitudes and behaviors ([Schmidt, Ranney, Pepper, & Goldstein, 2016](#)). In general, consumers view claims made by the industry with skepticism and mistrust, which could undermine their believability and pose serious challenges in engaging consumers in evidence-based decision making ([Carman et al., 2010](#)).

In summary, we observe that a single exposure to accurate information, in the form of our proposed claim, was not sufficient to correct these misperceptions in our study. We conclude that:

- Adult tobacco users and nonusers (including LA-24 year olds) understand and do not misinterpret the proposed modified risk claim and were not misled into extending the modified risk message to other diseases.
- Adult tobacco users and nonusers continue to believe that candidate product use poses risk to health.
- The proposed claim did not alter risk perceptions; they proved consistent with literature findings in showing similar perceived risks for both ST and cigarettes.
- The non-MST user subgroups (adult smokers, nonusers and former tobacco users) generally have higher perceived levels of risk from the candidate product than current MST users.

Overall, we conclude that the proposed modified risk claim “enables the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products.”¹⁵

6.2.11. Literature Cited

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¹⁵ Section 911(h)(1) of the FD&C Act

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