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**Perceptions and Behavioral Intentions Study for *General Snus*®
Cognitive Testing Report**

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2. BACKGROUND AND OVERVIEW

In November 2015, Swedish Match North America, Inc. (SMNA) received U.S. market authorization for *General Snus*[®]. In June 2014 SMNA submitted modified risk tobacco product applications (MRTPAs) for *General Snus*[®] smokeless tobacco products. SMNA has elected to submit an amended MRTPA for its *General Snus*[®] product line. A Perceptions and Behavioral Intentions Study for *General Snus*[®] will be conducted to determine how proposed modified risk claims impact various cohorts of adult consumers' perceptions of health risks of using *General Snus*[®] and their behavior intentions regarding tobacco use. This study will be submitted to the FDA as part of the *General Snus*[®] MRTPA amendment.

The overarching research question for the Perceptions and Behavioral Intentions Study for *General Snus*[®] can be stated as follows: How does the presence of a statement claiming benefits of *General Snus*[®] usage over cigarette smoking (the MRTP claim) affect intentions and behaviors of tobacco/nicotine product (TNP) use, when compared to the absence of that same claim? The question will be studied among both TNP users and non-users (all of whom are of legal age to use TNP in their residential geography). The effectiveness of the three proposed MRTP claims will be studied in the context of a single exposure to a *General Snus*[®] description provided in a video advertisement, each with one of the three proposed claims or absence of a claim.

User and non-user groups for this study include the following cohorts:

- Never users of TNP from legal age to 24 years of age
- Never users of TNP older than 24 years of age
- Former cigarette smokers from legal age and older
- Current cigarette smokers from legal age to 24 years of age
- Current cigarette smokers older than 24 years of age
- Current smokeless tobacco users from legal age and older

Before executing the Perceptions and Behavioral Intentions Study for *General Snus*[®] on-line survey, cognitive interviews were conducted to assess how respondents understand, interpret, and answer each survey question. The cognitive testing research² adhered to the Office of Management and Budget (OMB) Statistical Policy Directive No.2 Addendum: Standards and Guidelines for Cognitive Interviews¹.

This report describes the cognitive interview research.

3. METHODS

3.1. Materials and Process

To ensure that the materials were appropriate and sufficiently clear to consumers, the Perceptions and Behavioral Intentions Study online survey was tested among 19 respondents across two rounds of qualitative in-depth, in-person, cognitive interviews. Round 1 was conducted in Seattle, WA and Round 2 in Philadelphia, PA. The second round of cognitive interviews was conducted two weeks after the initial round to

allow for survey revisions between rounds. Cognitive interviews were up to 60 minutes in duration and each respondent received \$125 in a Visa Pre-Paid Card as compensation for the time spent.

Kantar Health developed the materials needed for the cognitive interviews; this included informed consent forms, recruitment screener, and cognitive interview guide. All materials were reviewed and approved by Sterling Institutional Review Board and SMNA in advance of recruiting and conducting interviews. Interviews across both markets were administered by the same interviewer who was trained by Kantar Health's VP and Lead of Qualitative Services who is certified to conduct cognitive interviews by the Odum Institute / University of Chapel Hill. Study team members from Kantar Health and the sponsor, SMNA, were present to observe the cognitive interviews and attended both rounds of research.

Interviews were conducted utilizing a concurrent interviewing methodology, where respondents were interviewed question by question rather than retrospectively after completion of the full survey. The interview was conducted using a programmed electronic survey that respondents completed on a laptop computer, while the interviewer, using a separate screen, monitored survey responses. The Kantar Health and SMNA study team viewed a separate screen in the observer room to track the respondents' progress while completing the survey. Interviews in both rounds of research were audio recorded and a third-party vendor, MRT Babbletype, collated responses into a cognitive analysis grid to provide data for systematic analysis. This ensured that the findings represent the full range of responses to each question.

During the cognitive interview respondents viewed a video advertisement (video) for *General Snus*®. The videos were created such that each showed only one of 3 test claims or was absent any modified risk claim, thus serving as the control. Each video also showed one of 4 warning statements and one of 2 flavors of *General Snus*® on the product package shown in the video. The video shown to each respondent was randomly selected..

Interviews were conducted applying the “think aloud” technique whereby respondents stated their interpretation of the question and how they arrived at a response. Additional scripted probes were administered verbally, by the interviewer, to elicit desired comprehension information that was not anticipated to emerge from the “think aloud” approach.

After Round 1, the interviewer, Kantar Health, and SMNA observers participated in a cognitive interview debrief to develop recommendations for revisions to survey questions to implement in Round 2 testing. Questions where 30% or more of the sample in Round 1 could not demonstrate a logical thought process for arriving at their answer or misinterpreted the intent of the question and/or terminology were revised for greater clarification and to be tested in Round 2.

Round 2 interviews followed the same process utilizing the “think aloud” technique and additional scripted probes. Round 2 focused on ascertaining if survey question changes from Round 1 achieved universal understanding of the intent of each of the questions. Upon completion of Round 2, the same consensus process was used to determine if saturation was reached. Saturation was achieved, when for each question 80% or more of the respondents in Round 2 verbalized a logical thought process when answering the question that fit with the intent of the question.

This report summarizes both the issues identified with “comprehension, retrieval, decision-judgement, and response across all subjects”² as well as the subsequent survey changes made to mitigate each issue.

3.2. Recruitment Procedures

Recruitment of respondents was a convenience sample. A qualification screener was developed by Kantar Health, approved by SMNA and used to select respondents representative of the population of interest in the Perceptions and Behavioral Intentions research with respect to age, gender, race/ethnicity, and TNP use or non-use. Fieldwork Research Seattle and Schlesinger Research Philadelphia recruited respondents by screening their local databases of consumers.

Tables 1 and 2 provide respondent demographic characteristics and TNP quota group classification for both rounds of cognitive interviews.

Table 1: Round 1 Cognitive Interview Respondents

Interview	Gender	Age	Ethnicity	Cohort Definition
1	Male	42	Caucasian	Current smokeless tobacco user from legal age and older
2	Male	55	Caucasian	Current cigarette smoker older than 24 years
3	Male	24	Caucasian	Never tobacco user from legal age to 24 years of age
4	Male	26	Asian	Never tobacco user older than 24 years of age
5	Female	48	Caucasian	Current cigarette smoker older than 24 years
6	Female	21	Caucasian	Current cigarette smoker from legal age to 24 years of age
7	Male	28	Mixed	Current smokeless tobacco user from legal age and older
8	Female	30	Caucasian	Former cigarette smoker from legal age and older
9	Female	38	Caucasian	Never tobacco user older than 24 years of age

Table 2: Round 2 Cognitive Interview Respondents

Interview	Gender	Age	Ethnicity	Cohort Definition
1	Female	40	African American	Never tobacco user older than 24 years of age
2	Female	23	Caucasian	Never tobacco user from legal age to 24 years of age
3	Male	30	Caucasian	Current smokeless tobacco user from legal age and older
4	Female	29	Caucasian	Former cigarette smoker from legal age and older
5	Female	52	Caucasian	Former cigarette smoker from legal age and older
6	Male	50	Caucasian	Current smokeless tobacco user from legal age and older
7	Female	24	African American	Current cigarette smoker from legal age to 24 years of age
8	Male	50	African American	Current cigarette smoker older than 24 years of age
9	Female	56	African American	Current cigarette smoker older than 24 years of age
10	Female	55	African American	Former cigarette smoker from legal age and older

4. FINDINGS

4.1. Overall Findings – Round 1 Interviews

Issues identified in Round 1 cognitive interviews in Seattle, October 25th and 26th, 2017 are listed in Table 3 below. Questions identified as having issues were revised for testing in Round 2.

Table 3: Survey Changes after Round 1

Original Survey Question	Description of Problem	Survey Change
S21. Assuming you complete all of the survey, you will receive the honoraria mentioned in the survey invitation for your time.	Unknown term – Many respondents did not understand the term, ‘honoraria’.	Assuming you complete all of the survey, you will be compensated for your time and opinions, as mentioned in the survey invitation.
A8. If a typical person has never used tobacco or nicotine products, what is the chance that this person would suffer from the following health conditions during his/her lifetime? <i>NOTE: question was repeated for 8 health conditions</i>	Terminology Issue - ‘Poor overall health’ was an ambiguous term and impeded comprehension of the question.	Changed ‘Poor overall health’ to ‘Serious health problems’. <i>This change was also made for A9, C2, C3 and C3a.</i>
A9. If a typical person smokes cigarettes every day but uses no other tobacco products , what is the chance that this person would suffer from the following health conditions during his/her lifetime? <i>NOTE: question was repeated for 8 health conditions</i>	Comprehension issue – There was confusion about the difference between questions A8 and A9. Comprehension and readability would be improved by reversing the order of the question and add emphasis to ‘smokes’ in A9.	If a typical person <u>SMOKES</u> cigarettes every day but uses no other tobacco products , what is the chance that this person would suffer from the following health conditions during his/her lifetime (repeat for 8 health conditions)?

<p>C3. Which of the following products: daily use of only <i>General Snus</i>® or (repeat for 6 comparators) has the higher chance of causing each of the following health conditions (repeat for 8 health conditions)?</p>	<p>Comprehension issue – There was confusion about the intended comparisons between <i>General Snus</i>® and other products across the response choice scale, complicated by the ‘drag & drop’ response format used in the on-line survey.</p>	<p><i>Changed from the ‘drag & drop’ response format to a ‘fill in the blank’ format.</i></p> <p>C41a. Compared to the daily use of <u>only</u> (repeat for 6 comparators), the daily use of <u>only</u> <i>General Snus</i>® has a <u>much lower</u> chance, <u>a lower</u> chance, <u>the same</u> chance, <u>a higher</u> chance, <u>a much higher</u> chance (or don’t know, decline to answer) of causing (repeat for 8 health conditions)?</p>
<p>C3a. Assume two people who are exactly the same in every way, except one has decided to quit the use of all tobacco and nicotine products and the other has decided to quit the use of all tobacco and nicotine <u>except</u> for the daily use of <i>General Snus</i>®. Which one of these people have the higher chance of suffering each of the following health conditions _____?</p> <p><i>Note: this question repeated for 8 health conditions and 5 response choices.</i></p>	<p>Comprehension issue – There was confusion about the intended comparisons between <i>General Snus</i>® and other products across the response choice scale.</p>	<p><i>Revised the question to ‘a fill in the blank’ response format with simplified wording for the response options.</i></p> <p>C42a-h. Assume two people are exactly the same in every way, except one has decided to quit the use of all tobacco and nicotine products and the other has decided to quit the use of all tobacco and nicotine products <u>except</u> for the daily use of <i>General Snus</i>®.</p> <p>Which one of these people has the higher chance of suffering from <u>chronic bronchitis</u>?</p> <p>Complete the sentence below: Compared to the person <u>who has quit</u> all tobacco and nicotine products and uses nothing, the person who has quit all tobacco and nicotine products <u>except</u> for the daily use of <i>General Snus</i>® has (repeat for 8 health conditions)?</p>

Overall Findings – Round 2 Interviews

A minor issue identified in Round 2 of cognitive interviews in Philadelphia, November 7th and 8th, 2017 is listed in Table 4 below. There were no new substantive comprehension issues.

Table 4: Survey Changes after Round 2

Original Survey Question	Description of Problem	Survey change
<p>C42a-h. Assume two people are exactly the same in every way, except one has decided to quit the use of all tobacco and nicotine products and the other has decided to quit the use of all tobacco and nicotine products <u>except</u> for the daily use of <i>General Snus</i>®.</p> <p>Which one of these people has the higher chance of suffering from <u>chronic bronchitis</u>?</p> <p>Complete the sentence below:</p> <p>Compared to the person <u>who has quit</u> all tobacco and nicotine products and uses nothing, the person who has quit all tobacco and nicotine products <u>except</u> for the daily use of <i>General Snus</i>® has (repeat for 8 health conditions)?</p> <p><i>Note: This question repeated for 8 health conditions and 5 response choices.</i></p>	<p>Comprehension issue – There was confusion going from the introductory part of the question to the ‘complete the sentence’ part, especially with the repetition of having the introduction shown for each of the 8 health conditions, whereby understanding of the core question proved difficult.</p>	<p><i>Simplify the question by providing the introductory part of the question (‘two people exactly the same’) once upfront, instead of repeating it 8 times, and focus the remaining screens on the core question for each of the health conditions:</i></p> <p>For this next series of questions, assume two people are exactly the same in every way, except:</p> <ul style="list-style-type: none"> - One person has decided to quit the use of all tobacco and nicotine products and <u>use nothing</u>; and - The other has decided to quit the use of all tobacco and nicotine products <u>except</u> for the daily use of <i>General Snus</i>®.

4.2. Conclusion

The design and execution of Round 1 identified questions not functioning as intended. Revisions tested in Round 2, using the same

methodology as in Round 1, demonstrated improved comprehension of the questions. Saturation was achieved for all survey questions in Round 2. Simplifying question C42a-h by adding the one-time upfront instruction page improves readability but does not represent a comprehension issue that requires further testing.

The sample size was not designed to be projectable but was representative of the population that will be respondents in the quantitative phase in terms of age, gender, race/ethnicity, and TNP usage or non-usage. No difference in understanding the intent of the questions was evident based on age, gender, race/ethnicity, TNP usage or non-usage. No further testing is required.

5. REFERENCES

1. OMB Statistical Policy Directive No. 2 Addendum: Standards and Guidelines for Cognitive Interviews. Accessed October 12, 2016.
2. Boeije, H., Willis, G. The Cognitive Interviewing Reporting Framework (CIRF): Towards the harmonization of cognitive testing reports. In *Methodology: European Journal of Research Methods for the Behavioral and Social Sciences*. 2013;9(3): 87 – 95.