

6.3 Likelihood of Use Studies among Tobacco Users and Non-Users

6.3.1 Background

The 2012 FDA MRTPA Draft Guidance ([FDA MRTPA Draft Guidance 2012](#)) states that applications should contain evidence to inform FDA's evaluation of the effects of modified risk advertising on the likelihood that:

- Current tobacco users will start using the product ("Switching");
- Those not currently using tobacco will start using the product ("initiation");
- Tobacco users who adopt the product will switch to other tobacco products that are higher risk to the individual ("Gateway Effects");
- Consumers will use the product in addition to other tobacco products ("dual use"); and
- Users who may have otherwise quit using tobacco products will instead use the product ("Diversion from Quitting").

In accordance with the FDA's MRTPA Draft Guidance, RJRT conducted three likelihood of use studies to assess the effects of the proposed modified risk advertising for Camel Snus on current tobacco users' and non-users' likelihood to use Camel Snus and, among those who were likely to use, their intended pattern of use (*i.e.*, switch completely, use in addition to other tobacco products, or use instead of quitting) ([FDA MRTPA Draft Guidance 2012](#)). Evaluation of likelihood of use among current tobacco users also included an assessment of potential quitters (expected to quit all tobacco products within 9 months). Evaluation among those not currently using tobacco included both never tobacco users and former tobacco users. Full study reports, study protocols, and raw data for each of the three executions are submitted with this Application.

To evaluate likelihood of use in response to the proposed advertising, respondents were randomized to be shown either the Camel Snus advertisements¹ with the proposed modified risk messaging (the test condition) or a Camel Snus advertisement that did not contain the proposed modified risk messaging (the control condition). Respondents were then asked to rate their likelihood to purchase Camel Snus in order to try it (on a scale of 1-to-10, 1=definitely would not; 10=definitely would). Participants who rated their likelihood to purchase Camel Snus in order to try it as a 2 or greater – that is, those who expressed any interest at all in Camel Snus – were asked further questions about their intended behavior.

¹ The proposed advertisements were created solely for this Application and are not currently used for Camel Snus.

The primary outcome for the three likelihood of use studies was the rated likelihood of purchase for personal trial of Camel Snus, and the estimated percentage of respondents projected to actually purchase Camel Snus. Estimates of the percentage of respondents who would actually purchase the product were derived from the stated likelihood to purchase ratings using an empirically-derived algorithm. The translation of intention to purchase for trial ratings into empirically derived purchase probabilities is useful, as estimates of likelihood of use are critical inputs to the Dynamic Population Modeler, DPM (+1), and the estimation of the net population health impact of a modified risk tobacco product.

6.3.2 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – First Execution of Consumer Testing

6.3.2.1 Study Methods – Execution 1

6.3.2.1.1 Sample

An online study was conducted with a sample of 14,511 U.S. adults whose age (at least 18+) made them legally eligible to purchase tobacco in their jurisdiction of residence. The sample was drawn randomly from the Research Now online panel of approximately three million individuals in the U.S. Quota sampling was used to promote representativeness of the sample with respect to gender, age, race/ethnicity, education, and geographic region. The sample for each of the two conditions (test and control) (see below) was separately weighted to match the demographics of the U.S. population. A detailed description of the sampling and weighting is available in the study protocol ([Protocol Identifier: RO-BR-2014-03 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users](#)) and the final study report (*Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report*), respectively.

Quota sampling was done to obtain approximately 5,000 respondents in each of three current or non-current tobacco user groups of interest:

1. Current regular tobacco users (n=4,497), self-defined as currently using tobacco regularly or occasionally;
2. Former regular tobacco users (n=4,972), self-defined as having used tobacco regularly in the past but not a current user (whether regular or occasional); and
3. Never regular tobacco users (n=5,042), self-defined as having never regularly used tobacco.

To mask the purpose of the study, the screening questions about tobacco use were embedded with questions about regular use of other products, namely beer or malt-based beverages, bottled water, nutritional supplements/vitamins, or tobacco products. "Regular use" and "occasional use" were self-defined. For each product, participants were asked: "Would you consider yourself to be – or to have been at any time in the past – a "regular user" of any of the

following products? We leave it to you to define regular use.” Response options were “Yes, I am or was a regular user” and “No, I have never been a regular user.” All respondents who said they had ever been a regular user of tobacco products were then asked “Focusing only on the present, how would you currently describe yourself, relative to each of the following categories?”. Response options for each of the product categories were “current non-user,” “current occasional user,” and “current regular user.”

Potential quitters (n=805) are a subset of current regular tobacco users who do not expect to be using any tobacco product 9 months from the time of the survey. A time frame of 9 months was used to define expected quitting, because this matched the interval over which product purchases were assessed to develop the algorithm to project purchase rates.

Data analysis was also performed for other subgroups: cigarette smokers (as a subset of tobacco use groups), who are the primary target for modified risk advertising; young adults (18-24), because of their potential openness to change; and white males, who are currently the most common users of smokeless tobacco products.

The sample was balanced between the test condition (those who viewed advertisements with the proposed modified risk messaging) and control condition (those who saw advertisements without the proposed modified risk messaging) such that there were 7,253 in the test condition (2,248 current regular tobacco users, 2,483 former regular tobacco users, and 2,522 never regular tobacco users) and 7,258 in the control condition (2,249 current regular tobacco users, 2,489 former regular tobacco users, and 2,520 never regular tobacco users).

6.3.2.1.2 Procedures

An online study was conducted November 24 through December 22, 2014. Respondents were screened for demographics and use of tobacco products, as described above. Qualified respondents (aged 18-75, legally eligible to purchase tobacco in their state of residence, and not current users of Camel Snus) were entered into the study.

6.3.2.1.3 Message Exposure

Respondents were randomized in a 1:1 ratio within tobacco user group to be shown either an advertisement for Camel Snus with the proposed modified risk messaging or a control Camel Snus advertisement that did not have the modified risk messaging. Each advertisement consisted of three separate color images. The three images appeared one above the other on the same screen, and respondents were instructed to scroll down to view all the product information. Questions about the respondents’ intentions followed on separate screens, and respondents were not able to go back to review the advertisement. The proposed modified risk Camel Snus advertisement was identical to that tested in the comprehension and perceptions study for this advertisement execution (Execution 1).

The test advertisement included three images, the first of which contained the statement “Swap the Smoke for More Freedom and Less Risk.” The second image provided product

information (what it is, how to use it, how it is different), and the third image provided information on the benefits of switching completely from cigarettes to Camel Snus. The control advertisement also included three images, the first of which contained the statement “Swap the Smoke for More Freedom.” The second image provided product information (what it is, how to use it), and the third image provided additional product information (how it is different) and why a smoker should switch (no hassle, no smoke smell, etc.) ([Protocol Identifier: RO-BR-2014-03 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users](#)). The bottom fifth of all images in both the test and control conditions included one of the four government-mandated warning label statements, which were randomly rotated.

Respondents in the test condition saw the proposed modified risk advertisement, which contained risk-related information, as well as additional information about how Camel Snus (and tobacco products generally) should and should not be used. In addition, the advertisement included other health-related information that is not modified risk or risk-related messaging. In the control condition, the advertisement included benefits of switching to Camel Snus (*i.e.*, no hassle, no lingering smoke smell, more freedom) but did **not** mention any reduction in disease risk, nor did it include other health-related messages that are included in the test advertisement. See [Table 6.3.2-1](#) below for the messages included in the test and control advertisements.

Table 6.3.2-1: Comparison of the Messages Included in the Advertisements for the Test and Control Conditions (Execution 1)

| Test Advertisement | Control Advertisement |
|--|--|
| Page 1 | |
| Swap the smoke for more freedom & less risk | Swap the smoke for more freedom |
| Picture of a smashed cigarette butt appears next to the Camel Snus package | Picture of a smashed cigarette butt appears next to the Camel Snus package |
| <i>1 of 4 government-mandated warning label statements for snus</i> | <i>1 of 4 government-mandated warning label statements for snus</i> |
| Pages 2 and 3 | |
| What is Camel Snus? <ul style="list-style-type: none"> Camel Snus (rhymes with “moose”) is finely ground premium tobacco in a soft fleece pouch. | What is Camel Snus? <ul style="list-style-type: none"> Camel Snus (rhymes with “moose”) is finely ground premium tobacco in a soft fleece pouch. |
| <ul style="list-style-type: none"> Like all tobacco products, Camel Snus contains nicotine and is addictive. | |
| How is it different? <ul style="list-style-type: none"> Many smokeless tobacco products, like dip and chew, are fermented loose tobacco. | How is it different? <ul style="list-style-type: none"> Many smokeless tobacco products, like dip and chew, are fermented loose tobacco. |
| <ul style="list-style-type: none"> Sure, they’re smoke-free, but they can get messy and require spitting. | <ul style="list-style-type: none"> Sure, they’re smoke-free, but they can get messy and require spitting. |

| Test Advertisement | Control Advertisement |
|--|--|
| <ul style="list-style-type: none"> Snus is different. It's smoke-free, mess-free and spit-free. | <ul style="list-style-type: none"> Snus is different. It's smoke-free, mess-free and spit-free. |
| <ul style="list-style-type: none"> Camel Snus is heat-treated, not fermented, and crafted with four main ingredients: tobacco, water, salt and flavoring. | <ul style="list-style-type: none"> Camel Snus is heat-treated, not fermented, and crafted with four main ingredients: tobacco, water, salt and flavoring. |
| <p>How do I use it?</p> <ul style="list-style-type: none"> Slide a pouch under your upper lip. | <p>How do I use it?</p> <ul style="list-style-type: none"> Slide a pouch under your upper lip. |
| <ul style="list-style-type: none"> Taste the real, premium tobacco. | <ul style="list-style-type: none"> Taste the real, premium tobacco. |
| <ul style="list-style-type: none"> Dispose of the pouch in the trash when you are finished. | <ul style="list-style-type: none"> Dispose of the pouch in the trash when you are finished. |
| <ul style="list-style-type: none"> Smokers who use Camel Snus instead of cigarettes can significantly reduce their health risks from smoking. | |
| <p>No smoke = less risk</p> | |
| <p>Smokers who switch completely from cigarettes to Camel Snus can significantly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease.</p> | |
| <p>Scientific studies have shown that Camel Snus contains fewer carcinogens than cigarette smoke.</p> | |
| <p>Camel Snus is smoke-free, so there are no second-hand smoke risks for those around you.</p> | |
| <p>I'm a smoker. Why would I switch?</p> | <p>I'm a smoker. Why would I switch?</p> |
| <p>No smoke means...</p> | <p>No smoke means...</p> |
| <ul style="list-style-type: none"> No lingering smoke smell | <ul style="list-style-type: none"> No lingering smoke smell |
| <ul style="list-style-type: none"> More freedom | <ul style="list-style-type: none"> More freedom |
| <ul style="list-style-type: none"> Fewer carcinogens | |
| <ul style="list-style-type: none"> Less risk for you and those around you | |
| <ul style="list-style-type: none"> No hassle | <ul style="list-style-type: none"> No hassle |
| <p>No tobacco product is safe.^{**}</p> | |
| <ul style="list-style-type: none"> However, smokers who use Camel Snus instead of cigarettes can significantly reduce their health risks from smoking. | |
| <ul style="list-style-type: none"> Like all tobacco products, Camel Snus | |

| Test Advertisement | Control Advertisement |
|---|---|
| contains nicotine and is addictive. | |
| <ul style="list-style-type: none"> Adults who do not use or have quit using tobacco products should not start.** | |
| <ul style="list-style-type: none"> Minors and pregnant women should never use tobacco products.** | |
| <ul style="list-style-type: none"> If you're a smoker concerned about the health risks from smoking, the best choice is to quit.** | |
| <ul style="list-style-type: none"> A good place to begin is talking with a healthcare provider.** | |
| <ul style="list-style-type: none"> But if you're not going to quit using tobacco products, you should think about switching to Camel Snus. | |
| <i>1 of 4 government-mandated warning label statements for snus</i> | <i>1 of 4 government-mandated warning label statements for snus</i> |

** Indicates information contained only in the test advertisement that is **not** considered to be modified risk information but does convey health-related messages that are not in the control advertisement.

6.3.2.1.4 Assessment

Following exposure to either the test or control advertisement, respondents were asked about their likelihood to purchase with the question “Assuming the product were available today, how likely would you be to purchase Camel Snus in order to try it?” The response scale ranged from 1 (“definitely would not purchase it to try”) to 10 (“definitely would purchase it to try”). Among those who expressed any interest at all in trying Camel Snus (*i.e.*, rated their likelihood to purchase as 2 or greater on the 10-point scale), additional questions were asked to assess the following: 1) how they intended to use Camel Snus (*i.e.*, instead of their current tobacco product, in addition to their current tobacco product, in place of some of their current tobacco product, or don’t know); 2) how likely they would be to switch back to their current tobacco product after trying Camel Snus (response scale ranged from 1 = not at all likely to 10 = very likely); and 3) how likely they would be to switch to a different tobacco product [that presents more risk, such as cigarettes] after trying Camel Snus (response scale ranged from 1 = not at all likely to 10 = very likely). Potential quitters who expressed interest in trying Camel Snus (*i.e.*, rated their likelihood to purchase as 2 or greater on the 10-point scale) were asked an additional question about their reason for interest in Camel Snus (to help them quit, to use in situations where their current tobacco product cannot be used, just curious about it, or don’t know). Respondents finished the survey with questions about intentions to quit tobacco use in the future (current tobacco users) or to take up tobacco use (former and never tobacco users).

6.3.2.1.5 Analysis

The primary objective of this study was to estimate the likelihood of use for Camel Snus, with and without advertising that contains the proposed modified risk messaging, among consumers overall and among the three tobacco user groups (current, former, and never tobacco users). Factorial Analysis of Variance (ANOVA) was employed to test differences in mean intent ratings and projected purchase rates between tobacco user groups, by test versus control groups. The main effect of user group reflects differences in interest in Camel Snus among groups different in tobacco use status (across test and control conditions). The main effect of test vs. control groups reflects the differences due to the different advertisements, across tobacco use groups. The interaction effect reflects the differential effect of test vs. control advertisements for different tobacco use groups. When a significant interaction effect was noted, it was followed by simple-main-effects t-tests to determine where (*i.e.*, in which tobacco use groups) the test vs. control differences were significant.

An *a priori* power analysis showed that the study had approximately 80% power to detect mean differences in projected purchase rate of roughly 1% across the arms for the primary analyses by tobacco user groups. *Post-hoc* power analyses based on the observed data distributions showed that all but one of the analyses had at least 80% power to detect small effects ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report, p. 28, footnote 22](#)), with effect sizes ranging from .03 to .1. An exception was analysis of young adults by potential quitter status, which had smaller sample sizes, and had 80% power to detect an effect size of 0.15.

Likelihood of use were also estimated and tested for several subgroups thought to be relevant to evaluating participants' responses to the proposed modified risk advertising: young adults (ages 18-24 years) and white males (overall and by tobacco user subgroup), and cigarette smokers. Data are presented as mean ratings of likelihood to purchase for trial and 95% confidence intervals. Significant differences were assessed with t-tests

6.3.2.1.6 Estimating actual purchase

Since stated *intent* to purchase does not always translate into *actual* purchase, a predictive algorithm was developed to transform the 'likelihood to purchase for personal trial' ratings into projected purchase rates for the tobacco product. This algorithm was developed by comparing *pre-launch* survey ratings of likelihood to purchase a tobacco product (a new brand of cigarettes) with actual (self-reported) purchase of the product *post-launch*. This comparison to actual purchase enables the creation of a conversion algorithm that can project purchase for trial of *future* new products based on pre-market survey ratings of likelihood to purchase. The algorithm was used in this study to transform the scaled ratings of likelihood to purchase into projected purchase estimates, taking into account the observation that likelihood of purchase ratings from groups defined by age and tobacco use had slightly different relationships to actual subsequent purchase. Thus, although derived from the underlying likelihood to purchase ratings, the projected purchase probabilities may have a different distribution.

The algorithm was validated in a separate study and tested in two additional studies, one of which included a Camel Snus product as the test product ([Bachand and Sulsky 2013](#)). The algorithm was valid for predictions of cigarette and non-cigarette tobacco purchase, but it consistently overestimates actual purchase for trial. Also, the algorithm predicts trial, not necessarily persistent product use beyond trial use. Therefore, the algorithm estimates the likely *maximum* rates of actual purchase and use ([New Tobacco Product "Likelihood" Study: An Algorithm to Predict Usage of New Tobacco Products Prior to Market Launch – Methodological Report](#)).

The algorithm generates a probability of purchase for each respondent, based on their likelihood of use ratings. Data on projected purchase are presented as percentages and 95% confidence intervals. Significant differences were assessed with t-tests.

6.3.2.2 Study Results – Effect of the Modified Risk Advertising on Likelihood of Use

The results summarized below are based on the [Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – First Execution of Consumer Testing – Amended Final Report](#).

6.3.2.2.1 Demographics

The weighted demographics for the test and control conditions were identical and mirror the U.S. population: 51% female, 25% 18-30 years old, 37% 31-50 years old, and 38% 51-75 years old. The geographic representation was 18% from the Northeast, 21% Midwest, 37% South, and 23% West. Non-Hispanic whites made up 66% of each group with 16% Hispanic, 12% Non-Hispanic black, and 8% non-Hispanic Asian or other race. Less than half (41%) had a high school education or less; 29% had some college, and 30% had a bachelor degree or more education. There were no demographic differences between the test and control samples.

6.3.2.2.2 Tobacco Use History

Among current regular tobacco users in the study, the majority (test: 62% [59.8%-64.2%]; control: 61% [58.7%-63.3%]) smoked cigarettes² every day. An additional 19% (17.3%-20.7%) in the test condition and 20% (18.2%-21.8%) in the control condition smoked cigarettes some days. A minority of current tobacco users used smokeless tobacco every day (test: 5% [3.9%-6.1%]; control: 4% [2.9%-5.1%]) or some days (test: 4% [3%-5%]; control: 5% [4%-6%]). Only 1% (0.6%-1.4%) in the test or control condition used snus every day, but a slightly greater percentage used (a non-Camel brand) snus some days (test: 3% [2.2%-3.8%]; control: 5% [4%-6%]).

² Respondents were considered cigarette smokers if they smoked manufactured cigarettes. Only 31 respondents (14 test condition, 17 control condition) indicated smoking roll-your-own cigarettes; these were counted as tobacco users but not cigarette smokers.

Former tobacco users in this study were predominantly former cigarette smokers (test: 93% [91.8%-94.2%]; control: 94% [92.9%-95.1%]). Equal proportions in the test and control conditions were former smokeless tobacco users (11% [9.5%-12.5%]) or former snus users (3% [2.2%-3.8%]).

6.3.2.2.3 Mean Intent Ratings for Purchasing Camel Snus and Projected Rates of Actual Purchase

Respondents in the test and control conditions were asked to rate their likelihood “to purchase Camel Snus in order to try it” on a scale from 1 (definitely would not purchase to try) to 10 (definitely would purchase to try) after viewing the test or control advertisement. Among the entire sample of test and control respondents, the mean rating of likelihood to purchase for trial was 1.7 (95% CI: 1.66-1.74) on the 10-point scale, and not significantly different ($p>0.05$) between test and control. These intent-to-purchase ratings were used to project purchase rates. For the sample as a whole, the estimated rate of purchase for those in the control condition was 1.3% (0.9%-2.1%), the same as in the test condition (1.3%, 0.9%-2.0%) ($p>0.05$).

6.3.2.2.4 Tobacco Use Status

The benefit to public health of a modified risk tobacco product is achieved when it is adopted by current users of tobacco products that pose greater health risks. Conversely, adoption of Camel Snus by non-users of tobacco confers risk. Therefore, it is important that statements made about the modified risk product not attract non-users of tobacco (former and never users).

Rated likelihood of use. The ratings of the likelihood to purchase Camel Snus were significantly higher ($p<0.0001$) among current regular tobacco users than among former and never tobacco users (Table 6.3.2-2). There was no difference between the advertisements and no interaction, suggesting that the proposed modified risk advertisement neither increased nor decreased interest across the board or in particular tobacco use groups.

Table 6.3.2-2: Likelihood to Purchase Ratings and Projected Purchase Rates by Current Tobacco Use Status

| Likelihood to Purchase Ratings (1-10) by Current Tobacco Use Status Mean (95% CI) | | | |
|--|-------------------------------|------------------------------|------------------------------|
| | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 3.1 (2.97-3.23) (n=2,248) | 1.6 (1.53-1.67) (n=2,483) | 1.4 (1.35-1.45) (n=2,522) |
| Control (without proposed modified risk messaging) | 3.0 (2.87-3.13) (n=2,249) | 1.6 (1.53-1.67) (n=2,489) | 1.4 (1.34-1.46) (n=2,520) |

| Projected Purchase Rates (%) by Current Tobacco Use Status % (95% CI) | | | |
|--|-------------------------------|-------------------------------|-------------------------------|
| | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 5.9% (4.3%-8.2%) (n=2,248) | 1.2% (0.6%-2.4%) (n=2,483) | 0.3% (0.2%-0.5%) (n=2,522) |
| Control (without proposed modified risk messaging) | 5.8% (4.2%-8.0%) (n=2,249) | 1.2% (0.6%-2.4%) (n=2,489) | 0.3% (0.2%-0.5%) (n=2,520) |

Projected purchase rates. Projected purchase rates were significantly higher ($p < 0.0001$) among current regular tobacco users – 4 times higher than among former tobacco users, and almost 20 times higher than among never tobacco users. The group to which the proposed modified risk advertising is targeted (current regular tobacco users) was most likely to be interested in purchasing Camel Snus. The projected purchase rates among those not currently using tobacco – the population for which the product is *not* intended – were low in both arms and were not increased (or decreased) by the proposed modified risk advertising.

6.3.2.2.5 Potential Quitters

A concern about modified risk advertising is that it might attract tobacco users who expect to or are likely to quit all tobacco use, potentially diverting or delaying them from quitting. Accordingly, the effect of the proposed modified risk advertising was tested among tobacco users who were potential quitters (expected to quit all tobacco products within 9 months).

Rated likelihood of use. The ratings for intent to purchase among current tobacco users who were potential quitters (test: $n=430$; control: $n=375$) were significantly lower ($p < 0.0001$) than the ratings of tobacco users who were not potential quitters (Table 6.3.2-3). Effects were similar across test and control advertisements, and there was no interaction effect, meaning that the differences between the test and control advertisements did not differ by tobacco use status.

Projected purchase rates. The projected rates of purchase were significantly ($p < 0.0001$) lower (by about one-third) among current tobacco users who were potential quitters were than among current users who were not potential quitters. There was no effect of the advertisement on intent to purchase or projected purchase by potential quitting status ($p > 0.05$).

Table 6.3.2-3: Likelihood to Purchase Ratings and Projected Purchase Rates among Current Tobacco Users by Quitting Status

| Likelihood to Purchase Ratings (1-10) among Current Tobacco Users by Quitting Status Mean (95% CI) | | | |
|---|--------------------------------------|-----------------------------|-------------------------------|
| | Current Regular Tobacco Users | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 3.1 (2.97-3.23) (n=2,248) | 2.3 (2.05-2.55) (n=430) | 3.3 (3.16-3.34) (n=1,818) |
| Control (without proposed modified risk messaging) | 3.0 (2.87-3.13) (n=2,249) | 2.2 (1.94-2.46) (n=375) | 3.1 (2.96-3.24) (n=1,874) |
| Projected Purchase Rates (%) among Current Tobacco Users by Quitting Status % (95% CI) | | | |
| | Current Regular Tobacco Users | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 5.9% (4.3%-8.2%) (n=2,248) | 4.2% (2.9%-6.0%) (n=430) | 6.4% (4.6%-8.8%) (n=1,818) |
| Control (without proposed modified risk messaging) | 5.8% (4.2%-8.0%) (n=2,249) | 4.0% (2.8%-5.8%) (n=375) | 6.1% (4.4%-8.5%) (n=1,874) |

The proposed modified risk advertising did not differentially increase the appeal of Camel Snus to potential quitters. In fact, potential quitters were much less interested in Camel Snus regardless of the advertising they were randomized to view. These findings suggest that, among current tobacco users, Camel Snus is less appealing to potential quitters, and that the proposed modified risk advertising does not increase appeal to potential quitters.

6.3.2.2.6 Cigarette Use Status

The results above assessed likelihood to purchase among respondents based on their use of any tobacco product. Since the proposed modified risk advertising targets cigarette smokers in particular (a group using a product with significantly greater risk than snus), it was important to assess the impact of the modified risk advertising on this group specifically, as well as among former and never smokers, for whom this product is not intended.

Rated likelihood of use. Interest in purchasing Camel Snus was significantly higher ($p < 0.0001$) among current regular smokers than among both former smokers and never smokers (Table 6.3.2-4). Interest among current regular smokers was significantly higher ($p < 0.05$) among those who viewed the proposed modified risk advertisement compared to current smokers who saw the control advertisement, but there was no effect of the advertisement among former or never smokers ($ps > 0.05$). Accordingly, there was a significant ($p < 0.05$) interaction, confirming that the test advertisement had a greater effect on current cigarette smokers than on former and never smokers. The modified risk advertisement specifically increased interest in Camel

Snus among current cigarette smokers without increasing interest among former or never cigarette smokers.

Projected purchase rates. The projected rate of purchase among current regular smokers was significantly higher ($p < 0.0001$) than the projected rates of purchase for former and never smokers (Table 6.3.2-4). The proposed modified risk advertising did not increase the appeal to former or never smokers, nor did it demonstrate an interaction (*i.e.*, it did not differentially appeal to former or never smokers).

Table 6.3.2-4: Likelihood to Purchase Ratings and Projected Purchase Rates by Current Cigarette Use Status

| Likelihood to Purchase Ratings (1-10) by Current Cigarette Use Status | | | |
|--|---|---------------------------------------|--------------------------------------|
| Mean (95% CI) | | | |
| | Current Regular Cigarette Users | Former Regular Cigarette Users | Never Regular Cigarette Users |
| Test (with proposed modified risk messaging) | 3.0 [†] (2.85-3.15) (n=1,624) | 1.9 (1.82-1.98) (n=2,818) | 1.4 (1.35-1.45) (n=2,811) |
| Control (without proposed modified risk messaging) | 2.8 (2.66-2.94) (n=1,631) | 1.9 (1.82-1.98) (n=2,836) | 1.4 (1.34-1.46) (n=2,791) |
| Projected Purchase Rates (%) by Current Cigarette Use Status | | | |
| % (95% CI) | | | |
| | Current Regular Cigarette Users | Former Regular Cigarette Users | Never Regular Cigarette Users |
| Test (with proposed modified risk messaging) | 5.8% (4.2%-8.0%) (n=1,624) | 2.1% (1.3%-3.4%) (n=2,818) | 0.4% (0.2%-0.7%) (n=2,811) |
| Control (without proposed modified risk messaging) | 5.4% (3.8%-7.5%) (n=1,631) | 2.2% (1.4%-3.6%) (n=2,836) | 0.4% (0.2%-0.7%) (n=2,791) |

[†] Statistically significant versus control.

These findings demonstrate that the proposed modified risk advertising for Camel Snus did not inappropriately appeal to those for whom the product is not intended (former smokers and never smokers) but that the proposed modified risk advertising did modestly increase rated interest in purchasing among current cigarette smokers.

6.3.2.2.7 Potential Quitters

Rated likelihood of use. Current regular cigarette smokers who were potential quitters rated their likelihood to purchase Camel Snus significantly lower ($p < 0.0001$) than current cigarette smokers who were not potential quitters (Table 6.3.2-5) in both arms of the study. This finding suggests that adding the proposed modified risk advertising to Camel Snus does not differentially appeal to smokers who are expecting to quit (no interaction).

Projected purchase rates. In both arms of the study, the projected rates of purchase for smokers who were potential quitters were significantly lower ($p < 0.0001$) than they were for cigarette smokers who were not expecting to quit tobacco use (Table 6.3.2-5). There was no interaction effect between the advertisement and smoking status, meaning that the modified risk advertisement did not differentially appeal to potential quitters.

Table 6.3.2-5: Likelihood to Purchase Ratings and Projected Purchase Rates by Quitting Status among Current Cigarette Users

| Likelihood to Purchase Ratings (1-10) by Quitting Status among Current Cigarette Users | | |
|---|-----------------------------|-------------------------------|
| | Mean (95% CI) | |
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 2.3 (1.99-2.61) (n=264) | 3.2 (3.03-3.37) (n=1,360) |
| Control (without proposed modified risk messaging) | 2.1 (1.79-2.41) (n=235) | 2.9 (2.74-3.06) (n=1,396) |
| Projected Purchase Rates (%) by Quitting Status among Current Cigarette Users | | |
| | % (95% CI) | |
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 3.9% (2.7%-5.7%) (n=264) | 6.2% (4.5%-8.5%) (n=1,360) |
| Control (without proposed modified risk messaging) | 3.7% (2.6%-5.4%) (n=235) | 5.6% (4.0%-7.8%) (n=1,396) |

These findings suggest that smokers who are expecting to quit smoking will not be particularly attracted by the modified risk messaging in the proposed advertisement.

6.3.2.2.8 Young Adults – Overall

Young adults (aged 18-24) are a group of particular interest for several reasons. Their present tobacco use patterns may not be as stable as those of older adults. Consequently, those young adults who are not presently using tobacco products may begin using tobacco products in the future, making it important to assess whether a modified risk tobacco product is attractive to this group. On the other hand, those young adults who *are* currently using tobacco products may not be as committed to continued smoking as older smokers and may be more amendable to switching to a lower risk product. The younger a person is when they reduce their exposure to the harmful constituents in tobacco and tobacco smoke, the lower their lifetime health risk from use (Jha *et al.* 2013). Finally, the responses of young adults may be a proxy indicator for responses by those under legal purchase age. Therefore, appealing to young adult tobacco users with a reduced risk product may greatly reduce their lifetime disease risk. At the same time, advertising should not increase appeal to the young adults who are not using tobacco, to avoid increasing the prevalence of tobacco use.

Rated likelihood of use. Young adults who were current regular tobacco users were significantly ($p<0.0001$) more interested in purchasing Camel Snus than were young adult former and never regular tobacco users (Table 6.3.2-6). The difference in interest in purchasing Camel Snus was significantly greater ($p<0.05$) in young adult current tobacco users who saw the modified risk advertisement compared to those who saw the control advertisement, and there was a significant advertisement-by-tobacco-use group interaction ($p<0.05$). These findings suggest that, among young adults, the proposed modified risk advertising does not attract non-tobacco users but differentially attracts current tobacco users.

Projected purchase rates. Projected rates of purchase among young adults were significantly greater for current tobacco users than for former and never regular tobacco users ($p<0.0001$). Further, there was a significant advertisement-by-tobacco-use group interaction among current tobacco users ($p<0.05$), due to the fact that projected rates of purchase were significantly greater among current tobacco users who viewed the proposed modified risk advertisement than among those in the control condition ($p<0.05$) (Table 6.3.2-6). Specifically, the test advertisement increased likely purchase among young adult tobacco users, but not among former and never tobacco users. These findings suggest that the proposed modified risk advertising differentially attracted the young adults who could benefit from switching to a modified risk product (current regular tobacco users) while not differentially appealing to young adults who were not currently using tobacco products.

Table 6.3.2-6: Likelihood to Purchase Ratings and Projected Purchase Rates among Young Adults by Current Tobacco Use Status

| Likelihood to Purchase Ratings (1-10) among Young Adults by Current Tobacco Use Status | | | | |
|---|--------------------------------|---|-------------------------------------|------------------------------------|
| Mean (95% CI) | | | | |
| | All Young Adults | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 2.2 (1.99-2.41) (n=462) | 4.8 [†] (4.29-5.31) (n=181) | 3.0 (2.26-3.74) (n=69) | 1.6 (1.4-1.8) (n=212) |
| Control (without proposed modified risk messaging) | 2.1 (1.87-2.33) (n=416) | 4.1 (3.55-4.65) (n=163) | 2.2 (1.54-2.86) (n=53) | 1.7 (1.45-1.95) (n=200) |
| Projected Purchase Rates (%) among Young Adults by Current Tobacco Use Status | | | | |
| % (95% CI) | | | | |
| | All Young Adults | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 2.5% (1.7%-3.7%) (n=462) | 12.9% [†] (9.3%-17.5%) (n=181) | 3.1% (1.2%-7.5%) (n=69) | 0.3% (0.2%-0.6%) (n=212) |
| Control (without proposed modified risk messaging) | 2.1% (1.4%-3.2%) (n=416) | 10.6% (7.6%-14.7%) (n=163) | 2.1% (0.8%-5.3%) (n=53) | 0.4% (0.2%-0.7%) (n=200) |

[†] Statistically significant versus control.

6.3.2.2.9 Young Adult – Potential Quitters

As with all tobacco users who are potential quitters, it was important to assess specifically the interest of young adults who are potential quitters in purchasing Camel Snus.

Rated likelihood of use. Young adult current tobacco users who were potential quitters were significantly ($p < 0.05$) less likely than those who were not potential quitters to be interested in purchasing Camel Snus. There was no interaction between quit intent and test versus control condition, meaning that the difference between the test and control advertisements did not differ by intent to quit. These results suggest that the proposed modified risk advertising did not differentially attract those who were expecting to quit tobacco use, and had its greatest appeal among those who were not expecting to quit their tobacco use.

Projected purchase rates. The projected rates of purchase were in the same direction as the interest ratings. Young adult potential quitters were significantly less likely to purchase Camel Snus than young adults not expecting to quit tobacco ($p < 0.05$) (Table 6.3.2-7). Numerically, the test advertisement increased likely purchase among those not expecting to quit smoking, but not among those expecting to quit. However, this effect was not statistically significant. The effect was similar for both the test and control advertisements, and there was no interaction.

Table 6.3.2-7: Likelihood to Purchase Ratings and Projected Purchase Rates by Quitting Status among Young Adults

| Likelihood to Purchase Ratings (1-10) by Quitting Status among Young Adults Mean (95% CI) | | |
|--|--------------------------------|----------------------------------|
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 3.6 (2.5-4.7) (n=29) | 5.0 (4.44-5.56) (n=152) |
| Control (without proposed modified risk messaging) | 3.1 (1.7-4.5) (n=22) | 4.2 (3.61-4.79) (n=141) |
| Projected Purchase Rates (%) by Quitting Status among Young Adults % (95% CI) | | |
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 8.4% (5.8%-12.0%) (n=29) | 13.7% (9.9%-18.5%) (n=152) |
| Control (without proposed modified risk messaging) | 8.4% (5.9%-11.8%) (n=22) | 11.0% (7.8%-15.2%) (n=141) |

These results among young adults indicate that the proposed modified risk advertising did not differentially attract those who were potential quitters.

6.3.2.2.10 White Males – Overall

Interest in purchase among white males was assessed because they have traditionally been the primary users of smokeless tobacco products in the U.S. (USDHHS 2014).

Rated likelihood of use. White males who were current tobacco users were significantly more interested in purchasing Camel Snus than were white male former and never tobacco users (p<0.0001) (Table 6.3.2-8). This was true for respondents who saw either the test or control advertisement.

Projected purchase rates. Projected rates of purchase among white males overall was similarly not affected by the proposed modified risk advertising, but projected rates of purchase were significantly greater for among current regular tobacco users than among former and never tobacco users (p<0.0001) (Table 6.3.2-8).

Table 6.3.2-8: Likelihood to Purchase Ratings and Projected Purchase Rates among White Males by Current Tobacco Use Status

| Likelihood to Purchase Ratings (1-10) among White Males by Current Tobacco Use Status Mean (95% CI) | | | | |
|--|----------------------------------|--------------------------------|--------------------------------|--------------------------------|
| | White Males | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 1.9 (1.82-1.98) (n=2,199) | 3.6 (3.36-3.84) (n=649) | 1.8 (1.67-1.93) (n=757) | 1.4 (1.31-1.49) (n=793) |
| Control (without proposed modified risk messaging) | 1.9 (1.82-1.98) (n=2,207) | 3.4 (3.16-3.64) (n=651) | 1.7 (1.57-1.83) (n=780) | 1.4 (1.3-1.5) (n=776) |
| Projected Purchase Rates (%) among White Males by Current Tobacco Use Status % (95% CI) | | | | |
| | White Males | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 1.9% (1.3%-2.9%) (n=2,199) | 7.3% (5.3%-9.9%) (n=649) | 1.6% (0.8%-3.1%) (n=757) | 0.3% (0.2%-0.5%) (n=793) |
| Control (without proposed modified risk messaging) | 1.9% (1.3%-2.9%) (n=2,207) | 7.1% (5.2%-9.7%) (n=651) | 1.5% (0.8%-3.1%) (n=780) | 0.3% (0.2%-0.5%) (n=776) |

These findings demonstrate that white male current tobacco users, one of the groups more likely to use Camel Snus, are interested in purchasing the product for trial, and the proposed modified risk advertising increased interest within this group.

White males who do not currently use tobacco expressed little interest in purchasing it, and the modified risk advertising had no effect on their interest. There were lower rates of projected purchase for the groups (former and never tobacco users) for which the product is not intended, suggesting that the interest in Camel Snus among white males is fairly confined to those who

are more likely to obtain a reduction in risk by using it, and that the proposed modified risk advertising did not differentially attract those for whom it is not intended.

6.3.2.2.11 White Males – Potential Quitters

Rated likelihood of use. White male current tobacco users who were potential quitters were significantly less interested in purchasing Camel Snus than those who were not potential quitters ($p < 0.05$) (Table 6.3.2-9). There was no significant differential effect of the test advertisement (*i.e.*, interaction), but the numerical trend was for the test advertisement to decrease interest among those expecting to quit, and increase interest among those not expecting to quit. This suggests that the proposed modified risk advertising is not negatively impacting potential quitters’ decisions with regard to their continued use of tobacco products.

Projected purchase rates. The projected rates of purchase for white male potential quitters were significantly lower than the projected rates of purchase for while male current tobacco users who were not potential quitters ($p < 0.01$) (Table 6.3.2-9). As in the raw ratings, there was no differential effect of the test advertisement.

Table 6.3.2-9: Likelihood to Purchase Ratings and Projected Purchase Rates by Quitting Status among White Males

| Likelihood to Purchase Ratings (1-10) by Quitting Status among White Males Mean (95% CI) | | |
|---|--------------------------------|---------------------------------|
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 2.7 (2.21-3.19) (n=116) | 3.8 (3.53-4.07) (n=533) |
| Control (without proposed modified risk messaging) | 3.0 (2.43-3.57) (n=93) | 3.5 (3.24-3.76) (n=558) |
| Projected Purchase Rates (%) by Quitting Status among White Males % (95% CI) | | |
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 5.1% (3.6%-7.2%) (n=116) | 7.8% (5.7%-10.5%) (n=533) |
| Control (without proposed modified risk messaging) | 5.8% (4.1%-8.2%) (n=93) | 7.3% (5.3%-9.9%) (n=558) |

These findings suggest that the proposed modified risk advertising is not likely to increase interest in or purchase of Camel Snus by white males who are expecting to quit tobacco use.

6.3.2.2.12 Reasons for Using Camel Snus

Since tobacco users who are interested in quitting tobacco altogether are not the intended population for a modified risk tobacco product, respondents who were potential quitters, yet indicated any likelihood at all of trying Camel Snus (*i.e.*, rating their interest at 2 or greater on the 1-to-10 scale; test: n = 144; control: n = 115), were asked what their reason was for wanting to try Camel Snus. The distribution of reasons given did not differ according to study arm. Approximately one-third, in both study arms (test: 35% [26.3%-43.7%]; control: 30% [20.3%-39.7%]), stated their reason was “to help me quit.” This finding suggests that there are some potential quitters who viewed Camel Snus as a potential gateway *out* of tobacco use.

The most commonly cited reason given by potential quitters for interest in trying Camel Snus was curiosity, which was cited by nearly half the potential quitters (test: 42% [33.1%-50.9%]; control: 45% [34.5%-55.6%]), equally across study arms. Thus, the proposed modified risk advertising did not differentially trigger curiosity to try Camel Snus. If curiosity about Camel Snus leads to switching to Camel Snus from a product with greater risk, such trial may also benefit users and the public health.

Some respondents indicated that their reason for considering use of Camel Snus was because it might “allow me to use in situations where I cannot use my current product.” This response was equally common in response to the proposed modified risk advertisement and the control (test: 11% [5.5%-16.5%]; control: 14% [6.7%-21.3%]).

Overall, these results suggest that exposure to the proposed modified risk advertising for Camel Snus did not differentially invoke adverse motives for trying Camel Snus among current tobacco users who were potential quitters.

6.3.2.2.13 Intended Use among Smokers Not Expecting to Quit

Use of Camel Snus would provide the greatest health benefit to cigarette smokers who switch completely to snus from cigarettes. In order to assess how likely this change might be, respondents who expressed any interest at all in Camel Snus – those who rated their likelihood to purchase Camel Snus as a 2 or higher on the 1-to-10 scale – were asked how they would use Camel Snus. Response options included “instead of my current tobacco product,” “in addition to my current tobacco product,” “in place of some of my current tobacco product,” and “don’t know.”

Among current regular cigarette smokers who were not expecting to quit tobacco use, 14% (11.1%-16.9%) in the test condition and 11% (8.4%-13.6%) in the control condition indicated that they would use Camel Snus *instead of* cigarettes (*i.e.*, stop use of cigarettes and use snus only) and a third (test: 34% [30.0%-38.0%]; control: 35% [30.8%-39.2%]) said they would use it in place of some of the tobacco they currently consumed. Approximately one-third in both conditions (test: 32% [28.1%-35.9%]; control: 37% [32.7%-41.3%]) did not know how they would use Camel Snus. There were some cigarette smokers who said they would add Camel Snus to their current tobacco use (test: 20% [16.7%-23.3%]; control: 18% [15.6%-20.4%]),

regardless of which advertisement they saw. Thus, some respondents interested in using Camel Snus thought they would use it in ways that are not optimal. However, exposure to the proposed modified risk advertising did not materially increase the proportion that would do so.

6.3.2.2.14 Switching to Smoking After Using Camel Snus

Among those who may use Camel Snus, it is important to evaluate the likelihood that they might subsequently switch (or switch back) to smoking, which would increase their health risk. This is particularly important for those who are not using tobacco at the time they started using Camel Snus.

Current regular cigarette smokers who stated that they would use Camel Snus *instead of* cigarettes rated their likelihood to switch back to cigarettes after trying Camel Snus on a 10-point scale (1 = not at all likely, 10 = very likely). Those exposed to the proposed modified risk advertising were directionally less likely to switch back to cigarettes (5.9; 5.41-6.39) than those not exposed to the proposed modified risk advertising (6.5; 5.95-7.05), though the differences were not significant. In any case, the data suggest that exposure to the proposed modified risk advertising does not increase the risk of reverting to smoking after trying Camel Snus.

Former regular tobacco users who expressed any interest at all in trying Camel Snus (*i.e.*, they rated their likelihood to purchase Camel Snus a 2 or higher) were then asked to rate how likely they would be to switch to a different tobacco product after trying Camel Snus. Those who viewed the proposed modified risk advertising assessed their likelihood of switching to another tobacco product significantly lower (3.3; 3.03-3.57) than those who saw the control advertisement (4.3; 4.01-4.59) ($p < 0.00001$). This suggests that the proposed modified risk advertising would tend to deter resumption of smoking.

The intentions of never regular tobacco users are important to examine since movement of this group, which is at the lowest health risk given their abstinence from tobacco, into higher-risk tobacco use (such as smoking) would be an adverse public health impact. This has been discussed as the "gateway" effect. Never regular tobacco users who expressed any interest in purchasing Camel Snus (at least 2 on the 1-to-10 scale) rated their likelihood to switch to another tobacco product significantly lower (3.5; 3.19-3.81) if they had seen the proposed modified risk advertisement than if they had seen the control advertisement (4.1; 3.79-4.41) ($p < 0.05$). Thus, the modified risk advertising appears to impede (and not promote) progression from use of Camel Snus to products such as cigarettes that pose more risk. Along with the finding that the proposed modified risk advertising does not attract increased interest among those who never used tobacco, this finding suggests modified risk advertising for Camel Snus is unlikely to lead to "gateway" effects that might result in increased smoking.

6.3.2.3 Conclusions

Modified risk tobacco products provide a potential health benefit to those who switch to them from tobacco products that pose a greater risk to health. The likelihood of use study was conducted to determine whether the proposed modified risk advertising for Camel Snus would

appeal to those for whom it would provide a benefit, in the form of reduced health risk (*i.e.*, current cigarette smokers), and, most importantly, whether the modified risk advertising would have unintended consequences by differentially attracting those for whom use would not be beneficial (non-smokers and smokers expecting to quit). In addition, the study evaluated whether the anticipated modes of use would be consistent with a public health benefit (*i.e.*, as a replacement for a greater risk product among those who are not interested in quitting tobacco completely).

Overall, interest in Camel Snus was greatest among current cigarette smokers, especially among those not expecting to quit, for whom switching to Camel Snus would confer a benefit. Among the small number of potential quitters who expressed any interest in purchasing Camel Snus, approximately one-third indicated that their motive for trying it was “to help me quit.” These results are reassuring that the proposed modified risk advertising is not likely to keep smokers interested in quitting from doing so.

Among current regular smokers not intending to quit smoking who expressed an interest in using Camel Snus, approximately half intended to replace some or all of their cigarettes with Camel Snus. About one in five, though, said they would add it to their current cigarette consumption. Such behavior could mitigate the overall population health benefit of a modified risk product.

There was interest in purchasing Camel Snus among white male current tobacco users, a group that has traditionally been more willing to use smokeless tobacco products in general. Among this group, those expecting to quit all tobacco use were less likely than those not interested in quitting tobacco to express interest in purchasing Camel Snus and had significantly lower projected purchase rates than those expecting to continue using tobacco. These findings suggest that the proposed modified risk advertising did appeal to white males who use tobacco and are not interested in quitting while not attracting those who are interested in quitting tobacco.

Young adults are a group whose current tobacco use patterns may not yet be fully established. Therefore, those young adults who are not presently using tobacco products may not be resistant to taking up tobacco use, and those who are presently using may be more open to switching to a lower risk product. The younger a person is when they reduce their exposure to the harmful constituents in tobacco and tobacco smoke, the lower their lifetime health risk from use (Jha *et al.* 2013). Therefore, appealing to young adult tobacco users with a reduced risk product can greatly lower their lifetime disease risk. In this study, young adults who were already using tobacco showed the highest level of interest in trying Camel Snus of all the groups studied. Further, the proposed modified risk advertising had specific differential appeal to young adult current tobacco users compared to former or never tobacco users. Young adults who were not expecting to quit tobacco were more interested in purchasing Camel Snus than young adults who were expecting to quit. These findings suggest that Camel Snus may have some benefit for young adults already using tobacco and help alleviate some concern about potentially inappropriate interest among young adults in this modified risk tobacco product.

The study measured the effects of a single exposure of the proposed modified risk advertisement for Camel Snus during the course of a survey, as opposed to the effects of multiple exposures over time in the real world in the context of advertising. Importantly, motivating smokers to switch to snus may rest on persuading them that snus is truly safer and able to reduce harm to them. Research shows that both smokers and non-smokers have pre-existing misconceptions about the risk of smokeless tobacco use relative to smoking, thinking that smokeless use is at least as hazardous as smoking (Fong *et al.* 2016; Kaufman *et al.* 2014; Kiviniemi and Kozlowski 2015; Regan *et al.* 2012). Data from the comprehension and perceptions studies of the proposed modified risk advertising for Camel Snus also suggested this. Thus, it may take multiple exposures, and consistent messages from multiple sources, including sources more credible than a tobacco company advertisement, for smokers to appreciate the potential of Camel Snus to reduce their health risk.

After this single exposure to an advertisement, interest in Camel Snus was modest. This is consistent with the literature on use of snus in the U.S. (King *et al.* 2012). Exposure to the proposed modified risk advertising did not differentially attract interest from any of the groups for whom snus use could increase risk: never tobacco users, former tobacco users, or current tobacco users expecting to quit. The modified risk advertising also did not increase the likelihood that former smokers who might adopt Camel Snus would return to smoking or that non-tobacco users who might try Camel Snus would progress onto cigarette smoking (*i.e.*, "gateway" effects). Thus, the data strongly suggest that the proposed modified risk advertising would not cause harm, and is likely to encourage trial among current smokers which would benefit individual and population health.

6.3.2.4 Limitations and Strengths

Like any study, this study had some limitations. The sample was drawn from an opt-in online panel, and thus may not be fully representative of the U.S. population, not all of whom have internet access or join panels. However, strong majorities of Americans are now online (Perrin and Duggan 2015), and online panels can produce reasonable estimates (Farrell and Petersen 2010). Moreover, the sample was recruited and weighted to represent the demographics of the U.S. population.

The proposed modified risk advertising is intended to be used in multiple marketing platforms and media, but here it was viewed via an online, on-screen display in a research context. However, such methods are often used to evaluate communications (Sullivan *et al.* 2015), and there is little reason to think the results are not generalizable to other media.

The study measured the effects of a single exposure of the proposed modified risk advertisement for Camel Snus during the course of a survey, as opposed to the effects of multiple exposures over time in the real world in the context of advertising. Importantly, motivating smokers to switch to snus may rest on persuading them that snus is truly safer and able to reduce harm to them. Research shows that both smokers and non-smokers have pre-existing misconceptions about the risk of smokeless tobacco use relative to smoking, thinking that smokeless use is at least as hazardous as smoking (Fong *et al.* 2016; Kaufman *et al.* 2014;

Kiviniemi and Kozlowski 2015; Regan *et al.* 2012). Data from the comprehension and perceptions studies of the proposed modified risk advertising for Camel Snus also suggested this. Thus, it may take multiple exposures, and consistent messages from multiple sources, including sources more credible than a tobacco company advertisement, for smokers to appreciate the potential of Camel Snus to reduce their health risk. Similarly, exposure to multiple messages about the importance of switching completely from smoking to Camel Snus could promote appropriate health-protective behavior.

Projected estimates of likely Camel Snus purchase for trial were derived from a model based on and validated in the context of cigarettes, rather than a smokeless product, and did not specifically test the link between stated interest and purchase in the context of modified risk advertising. Moreover, validation studies showed that purchase is over-estimated by the projection algorithm, though the differential purchase of different groups is accurately captured. Further, the algorithm models initial purchase for trial, and not long-term persistence, which is important to the expected harm-reduction benefit of switching to snus. A study (Carpenter *et al.* 2016) found that, among smokers who tried snus, 8% reported any use at the 6-month follow-up and 4% at the 12-month follow-up. Thus, the projected use data over-estimate the actual expected use, especially in the long-term. However, they should do so evenly across the different population groups examined, thus preserving the conclusion that the proposed advertisement does not differentially appeal to the groups that would not benefit from switching to Camel Snus. In any case, the raw "likelihood to purchase" data also lead to similar conclusions, so limitations of the projected purchase algorithm do not affect the reassuring conclusions.

The study also had considerable strengths. The sample was large, diverse, and sampled and weighted to match the demographics of U.S. adults. It included a broad range of demographics. The study included current, former, and never users of tobacco products, and also analyzed responses from important subgroups based on demographics and tobacco-use history. The data on rated likelihood of use were translated into projections of likely purchase, taking into account empirical observations about how such ratings translate into real-world behavior.

6.3.2.5 Summary – Execution 1

The study assessed interest in Camel Snus among a variety of populations when exposed to the proposed modified risk advertising. Overall, interest was modest. Importantly, the data suggest that the proposed modified risk advertising did not increase the appeal of the product to populations where adoption of it would increase harm rather than confer benefit—never smokers, former smokers, and tobacco users expecting to quit tobacco use. The data were also inconsistent with the concern that non-tobacco users (former users or never users) who try snus would progress to cigarette smoking. These data mitigate concerns about adverse effects on population health from the proposed modified risk advertising for Camel Snus. Moreover, the modified risk advertising differentially increased interest and projected purchase among current smokers, who stand to benefit from switching to Camel Snus, and not among former or never smokers. On balance, the data suggest that the proposed modified risk advertising

encouraging current smokers to switch to Camel Snus would likely result in benefits to population health.

6.3.3 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-users – Second Execution of Consumer Testing

6.3.3.1 Study Methods – Execution 2

6.3.3.1.1 Sample

An online study was conducted with a sample of 11,302 U.S. adults whose age (at least 18+) made them legally eligible to purchase tobacco in their jurisdiction of residence. The sample was drawn randomly from the Research Now online panel of approximately three million individuals in the U.S. Quota sampling was used to promote representativeness of the sample with respect to gender, age, race/ethnicity, education, and geographic region. The sample for each of the two conditions (test and control) (see below) was separately weighted to match the demographics of the U.S. population. A detailed description of the sampling and weighting is available in the study protocol ([Protocol Identifier: RO-BR-2015-04 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users - Second Execution of Consumer Testing](#)) and the final study report (*Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco users and Non-Users – Second Execution of Consumer Testing – Amended Final Report*), respectively.

Quota sampling was done to obtain at least 3,300 respondents in each of three current or non-current tobacco user groups of interest:

1. Current regular tobacco users (n=3,466), self-defined as currently using tobacco regularly or occasionally;
2. Former regular tobacco users (n=3,379), self-defined as having used tobacco regularly in the past but not a current user (whether regular or occasional);
3. Never regular tobacco users (n=4,457), self-defined as having never having regularly used tobacco.

To mask the purpose of the study, the screening questions about tobacco use were embedded with questions about regular use of other products, namely beer or malt-based beverages, bottled water, nutritional supplements/vitamins, or tobacco products. "Regular use" and "occasional use" were self-defined. For each product, participants were asked: "Would you consider yourself to be –or to have been at any time in the past – a "regular user" of any of the following products? We leave it to you to define regular use." Response options were "Yes, I am or was a regular user" and "No, I have never been a regular user." All respondents who said they had ever been a regular user of tobacco products were then asked "Focusing only on the present, how would you currently describe yourself, relative to each of the following

categories?”. Response options for each of the product categories were “current non-user,” “current occasional user,” and “current regular user.”

Potential quitters (n=497) are a subset of current regular tobacco users who do not expect to be using any tobacco product 9 months from the time of the survey. A time frame of 9 months was used to define expected quitting, because this matched the interval over which product purchases were assessed to develop the algorithm to project purchase rates.

Data analysis was also performed for other subgroups: cigarette smokers (as a subset of tobacco use groups), who are the primary target for modified risk advertising; young adults (18-24), because of their potential openness to change; and white males, who are currently the most common users of smokeless tobacco products.

The sample was balanced between the test condition (those who viewed advertisements with the proposed modified risk messaging) and control condition (those who saw advertisements without the proposed modified risk messaging) such that there were 5,647 in the test condition (1,733 current regular tobacco users, 1,689 former regular tobacco users, and 2,225 never regular tobacco users) and 5,655 in the control condition (1,733 current regular tobacco users, 1,690 former regular tobacco users, and 2,232 never regular tobacco users).

6.3.3.1.2 Procedures

An online study was conducted August 11 through September 30, 2015. Respondents were screened for demographics and use of tobacco products, as described above. Qualified respondents (aged 18-75, legally eligible to purchase tobacco in their state of residence, and not current users of Camel Snus) were entered into the study.

6.3.3.1.3 Message Exposure

Respondents were randomized in a 1:1 ratio within tobacco user group to be shown either an advertisement for Camel Snus with the proposed modified risk messaging or a control Camel Snus advertisement that did not have the modified-risk messaging³. Each advertisement consisted of three separate color images. The three images appeared one above the other on the same screen, and respondents were instructed to scroll down to view all the product information. Questions about the advertisement viewed followed on separate screens, and respondents were not able to go back to review the advertisement. The modified risk Camel Snus advertisement was identical to that tested in the comprehension and perceptions study for this ad execution (Execution 2).

³ Study Executions 2 and 3 shared a common control group. Thus, respondents were actually randomized into one of three arms, assigned to see the Execution 2 advertisement, the control advertisement, or the Execution 3 advertisement. This report addresses the Execution 2 advertisement and the control advertisement.

The test advertisement included three images, the first of which contained the statement “No Smoke, Less Risk, Choose Snus.” The second image provided product information (what it is, how to use it, how it is different), and the third image provided information on the benefits of switching completely from cigarettes to Camel Snus. The control advertisement also included three images, the first of which contained the statement “Choose Snus.” The second image provided product information (what it is, how to use it), and the third image provided additional product information (how it is different) and why a smoker should switch (no hassle, no smoke smell, etc.) ([Protocol Identifier: RO-BR-2015-04 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users - Second Execution of Consumer Testing](#)). The bottom fifth of all images in both the test and control conditions included one of the four government-mandated warning label statements, which were randomly rotated.

Respondents in the test condition saw the proposed advertisement, which contained modified risk information, as well as additional information about how Camel Snus (and tobacco products generally) should and should not be used. In addition, the proposed advertisement included other health-related information that is not modified risk or risk-related messaging. In the control condition, the advertisement included benefits of switching to Camel Snus (*i.e.*, no hassle, no lingering smoke smell, more freedom) but did ***not*** mention any reduction in disease risk, nor did it include other health-related messages that are included in the test advertisement. See [Table 6.3.3-1](#) below for the messages included in the test and control advertisements.

Table 6.3.3-1: Comparison of the Messages Included in the Advertisements for the Test and Control Conditions (Execution 2)

| Test Advertisement | Control Advertisement |
|--|--|
| Page 1 | |
| Choose snus. | Choose snus. |
| No smoke. | |
| Less risk. | |
| Picture of a smashed cigarette butt appears next to the Camel Snus package | Picture of a Camel Snus package only |
| <i>1 of 4 government-mandated warning label statements for snus</i> | <i>1 of 4 government-mandated warning label statements for snus</i> |
| Pages 2 and 3 | |
| What is Camel Snus? <ul style="list-style-type: none"> Camel Snus (rhymes with “moose”) is finely ground premium tobacco in a soft fleece pouch. | What is Camel Snus? <ul style="list-style-type: none"> Camel Snus (rhymes with “moose”) is finely ground premium tobacco in a soft fleece pouch. |
| <ul style="list-style-type: none"> Like all tobacco products, Camel Snus <u>contains nicotine</u> and <u>is addictive</u>. | |
| How is it different? <ul style="list-style-type: none"> Many smokeless tobacco products, like dip and chew, are fermented | How is it different? <ul style="list-style-type: none"> Many smokeless tobacco products, like dip and chew, are fermented loose tobacco. |

| Test Advertisement | Control Advertisement |
|--|--|
| loose tobacco. | |
| <ul style="list-style-type: none"> • Sure, they're smoke-free, but they can get messy and require spitting. | <ul style="list-style-type: none"> • Sure, they're smoke-free, but they can get messy and require spitting. |
| <ul style="list-style-type: none"> • Snus is different. It's smoke-free, mess-free and spit-free. | <ul style="list-style-type: none"> • Snus is different. It's smoke-free, mess-free and spit-free. |
| <ul style="list-style-type: none"> • Camel Snus is heat-treated, not fermented, and crafted with four main ingredients: tobacco, water, salt and flavoring. | <ul style="list-style-type: none"> • Camel Snus is heat-treated, not fermented, and crafted with four main ingredients: tobacco, water, salt and flavoring. |
| <p>How do I use it?</p> | <p>How do I use it?</p> |
| <ul style="list-style-type: none"> • Slide a pouch under your upper lip. | <ul style="list-style-type: none"> • Slide a pouch under your upper lip. |
| <ul style="list-style-type: none"> • Taste the real, premium tobacco. | <ul style="list-style-type: none"> • Taste the real, premium tobacco. |
| <ul style="list-style-type: none"> • Dispose of the pouch in the trash when you are finished. | <ul style="list-style-type: none"> • Dispose of the pouch in the trash when you are finished. |
| <ul style="list-style-type: none"> • Switch completely from cigarettes to Camel Snus. | |
| <p>No smoke = less risk</p> | |
| <p>Smokers who SWITCH COMPLETELY from cigarettes to Camel Snus can greatly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease.</p> | |
| <p>Scientific studies have shown that Camel Snus contains less of the harmful chemicals than cigarette smoke.</p> | |
| <p>Camel Snus is smoke-free, so there are no second-hand smoke risks for those around you.</p> | |
| <p>I'm a smoker. Why should I switch?</p> | <p>I'm a smoker. Why should I switch?</p> |
| <p>Switching to snus means . . .</p> | <p>Switching to snus means . . .</p> |
| <ul style="list-style-type: none"> • No lingering smoke smell | <ul style="list-style-type: none"> • No lingering smoke smell |
| <ul style="list-style-type: none"> • Less of the harmful chemicals found in cigarette smoke | |
| <ul style="list-style-type: none"> • Less risk for you and those around you | |
| <ul style="list-style-type: none"> • Hassle-free tobacco | <ul style="list-style-type: none"> • Hassle-free tobacco |
| <p>No tobacco product is safe.**</p> | |
| <ul style="list-style-type: none"> • Like all tobacco products, Camel Snus contains nicotine and is addictive. | |
| <ul style="list-style-type: none"> • Adults who do not use or have quit using tobacco products should not | |

| Test Advertisement | Control Advertisement |
|---|---|
| start.** | |
| <ul style="list-style-type: none"> • <u>Minors and pregnant women should never use tobacco products.</u>** | |
| <ul style="list-style-type: none"> • If you're a smoker concerned about the health risks from smoking, the best choice is to quit.** | |
| <ul style="list-style-type: none"> • A good place to begin is talking with a healthcare provider.** | |
| <ul style="list-style-type: none"> • But if you're not going to quit using tobacco products, you should think about switching to Camel Snus. | |
| <i>1 of 4 government-mandated warning label statements for snus</i> | <i>1 of 4 government-mandated warning label statements for snus</i> |

** Indicates information contained only in the test advertisement that is ***not*** considered to be modified risk information but does convey health-related messages that are not in the control advertisement.

6.3.3.1.4 Assessment

Following exposure to either the test or control advertisement, respondents were asked about their likelihood to purchase with the question “Assuming the product were available today, how likely would you be to purchase Camel Snus in order to try it?” The response scale ranged from 1 (“definitely would not purchase it to try”) to 10 (“definitely would purchase it to try”). Among those who expressed any interest at all in trying Camel Snus (*i.e.*, rated their likelihood to purchase as 2 or greater on the 10-point scale), additional questions were asked to assess the following: 1) how they intended to use Camel Snus (*i.e.*, instead of their current tobacco product, in addition to their current tobacco product, in place of some of their current tobacco product, or don’t know); 2) how likely they would be to switch back to their current tobacco product after trying Camel Snus (response scale ranged from 1 = not at all likely to 10 = very likely); and 3) how likely they would be to switch to a different tobacco product [that presents more risk, such as cigarettes] after trying Camel Snus (response scale ranged from 1 = not at all likely to 10 = very likely). Potential quitters who expressed interest in trying Camel Snus (*i.e.*, rated their likelihood to purchase as 2 or greater on the 10-point scale) were asked an additional question about their reason for interest in Camel Snus (to help them quit, to use in situations where their current tobacco product cannot be used, just curious about it, or don’t know).

Respondents finished the survey with questions about intentions to quit tobacco use in the future (current tobacco users) or to take up tobacco use (former and never tobacco users).

6.3.3.1.5 Analysis

The primary objective of this study was to estimate the likelihood of use for Camel Snus, with and without advertising that contains the proposed modified risk messaging, among consumers overall and among the three tobacco user groups (current, former, and never tobacco users).

Factorial Analysis of Variance (ANOVA) was employed to test differences in mean intent ratings and projected purchase rates between tobacco user groups, by test versus control groups. The main effect of user group reflects differences in interest in Camel Snus among groups different in tobacco use status (across test and control conditions). The main effect of test vs. control groups reflects the differences due to the different advertisements, across tobacco use groups. The interaction effect reflects the differential effect of test vs. control advertisements for different tobacco use groups. When a significant interaction effect was noted, it was followed by simple-main-effects t-tests to determine where (*i.e.*, in which tobacco use groups) the test vs. control differences were significant.

An *a priori* power analysis showed that the study had approximately 80% power to detect mean differences in projected purchase rate of roughly 1% across the arms for the primary analyses by tobacco user groups. *Post-hoc* power analyses based on the observed data distributions showed that all but one of the analyses had at least 80% power to detect small effects, with effect sizes ranging from 0.03 to 0.1 ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco users and Non-Users – Second Execution of Consumer Testing – Amended Final Report, p. 28, footnote 21](#)). An exception was analysis of young adults by potential quitter status, which had smaller sample sizes, and had 80% power to detect an effect size of 0.20.

Likelihood of use were also estimated and tested for several subgroups thought to be relevant to evaluating participants' responses to the proposed modified risk advertising: young adults (ages 18-24 years), white males (overall and by tobacco user subgroup), and cigarette smokers. Data are presented as mean ratings of likelihood to purchase for trial and 95% confidence intervals. Significant differences in ratings were assessed with t-tests.

6.3.3.1.6 Estimating Actual Purchase

Since stated *intent* to purchase does not always translate into *actual* purchase, a predictive algorithm was developed to transform the 'likelihood to purchase for personal trial' ratings into projected purchase rates for the tobacco product. This algorithm was developed by comparing *pre-launch* survey ratings of likelihood to purchase a tobacco product (a new brand of cigarettes) with actual (self-reported) purchase of the product *post-launch*. This comparison to actual purchase enables the creation of a conversion algorithm that can project purchase for trial of *future* new products based on pre-market survey ratings of likelihood to purchase. The algorithm was used in this study to transform the scaled ratings of likelihood to purchase into projected purchase estimates, taking into account the observation that likelihood of purchase ratings from groups defined by age and tobacco use had slightly different relationships to actual subsequent purchase. Thus, although derived from the underlying likelihood to purchase ratings, the projected purchase probabilities may have a different distribution.

The algorithm was validated in a separate study and tested in two additional studies, one of which included a Camel Snus product ([Bachand and Sulsky 2013](#)). The algorithm was valid for predictions of cigarette and non-cigarette tobacco purchase, but it consistently overestimates actual purchase for trial. The algorithm predicts trial, not necessarily persistent product use beyond trial use. Therefore, the algorithm estimates the *maximum* rates of actual purchase and

use ([New Tobacco Product "Likelihood" Study: An Algorithm to Predict Usage of New Tobacco Products Prior to Market Launch – Methodological Report](#)).

The algorithm generates a probability of purchase for each respondent, based on their likelihood of use ratings. Data on projected purchase are presented as percentages and 95% confidence intervals. Significant differences were assessed with t-tests.

6.3.3.2 Study Results – Effect of the Modified Risk Advertising on Likelihood of Use

The results summarized below are based on the [Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Second Execution of Consumer Testing – Amended Final Report](#).

6.3.3.2.1 Demographics

The weighted demographics for the test and control conditions were identical and mirror the U.S. population: 51% female, 25% 18-30 years old, 37% 31-50 years old, and 38% 51-75 years old. The geographic representation was 18% from the Northeast, 21% Midwest, 37% South, and 23% West. Non-Hispanic whites made up 66% of each group with 16% Hispanic, 12% Non-Hispanic black, and 8% non-Hispanic Asian or other race. Less than half (41%) had a high school education or less; 29% (control) and 30% (test) had some college, and 30% had a bachelor degree or more education. There were no significant demographic differences between the test and control samples.

6.3.3.2.2 Tobacco Use History

Among current regular tobacco users in the study, the majority (test: 66% [63.4%-68.6%]; control: 67% [64.4%-69.6%]) smoked cigarettes⁴ every day. An additional 18% (15.7%-20.3%) in the test condition and 17% (14.9%-19.1%) in the control condition smoked cigarettes some days. A minority of current tobacco users used smokeless tobacco every day (test: 4% [2.7%-5.3%]; control: 5% [3.7%-6.3%]) or some days (test: 7% [5.4%-8.6%]; control: 6% [4.5%-7.5%]). Only 2% (1.0%-3.0%) in the test condition and 1% (0.2%-1.8%) in the control condition used snus every day, but a slightly greater percentage used (a non-Camel brand) snus some days (test: 4% [2.8%-5.2%]; control: 5% [3.6%-6.4%]).

Former tobacco users in this study were predominantly former cigarette smokers (test: 94% [92.8%-95.2%]; control: 94% [92.8%-95.2%]). Nearly equal proportions in the test (7% [5.8%-8.2%]) and control (8% [6.7%-9.3%]) conditions were former smokeless tobacco users or former snus users (test: 2% [1.4%-2.6%]; control: 2% [1.2%-2.8%]).

⁴ Respondents were considered cigarette smokers if they smoked manufactured cigarettes. Only 34 respondents (17 test condition, 17 control condition) indicated smoking roll-your-own cigarettes; these were counted as tobacco users but not cigarette smokers.

6.3.3.2.3 Mean Intent Ratings for Purchasing Camel Snus and Projected Rates of Actual Purchase

Respondents in the test and control conditions were asked to rate their likelihood “to purchase Camel Snus in order to try it” on a scale from 1 (definitely would not purchase to try) to 10 (definitely would purchase to try) after viewing the test or control advertisement. The mean rating of likelihood to purchase for trial among respondents in the test condition was 2.0 (95% CI: 1.92-2.08) on the 10-point scale, which was significantly higher than the control condition (1.9 [95% CI: 1.83-1.97]) (p<0.05). These intent-to-purchase ratings were used to project purchase rates. For the sample as a whole, the estimated rate of purchase for those in the test condition was 1.7% (1.2%-2.5%), which was significantly higher than the control condition (1.5%, 1.0%-2.3%) (p<0.05).

6.3.3.2.4 Tobacco Use Status

The benefit to public health of a modified risk tobacco product is achieved when it is adopted by current users of tobacco products that pose greater health risks. Conversely, adoption of Camel Snus by non-users of tobacco confers risk. Therefore, it is important that statements made about the modified risk product not attract non-users of tobacco (former and never users).

Rated likelihood of use. The test advertisement attracted higher ratings of likelihood to purchase (p<0.05). Although the interaction was not significant, only current tobacco users showed a higher response to the test advertisement; former and never users did not. The ratings of the likelihood to purchase Camel Snus were significantly higher (p<0.0001) among current regular tobacco users than among former and never tobacco users (Table 6.3.3-2).

Table 6.3.3-2: Likelihood to Purchase Ratings and Projected Purchase Rates by Current Tobacco Use Status

| Likelihood to Purchase Ratings (1-10) by Current Tobacco Use Status | | | |
|---|---|------------------------------|-----------------------------|
| Mean (95% CI) | | | |
| | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 3.6 [†] (3.41-3.79) (n=1,733) | 1.6 (1.5-1.7) (n=1,689) | 1.7 (1.6-1.8) (n=2,225) |
| Control (without proposed modified risk messaging) | 3.3 (3.12-3.48) (n=1,733) | 1.6 (1.5-1.7) (n=1,690) | 1.7 (1.6-1.8) (n=2,232) |

| Projected Purchase Rates (%) by Current Tobacco Use Status % (95% CI) | | | |
|--|---|-------------------------------|-------------------------------|
| | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 7.8% [†] (5.7%-10.4%) (n=1,733) | 1.2% (0.6%-2.4%) (n=1,689) | 0.4% (0.2%-0.7%) (n=2,225) |
| Control (without proposed modified risk messaging) | 6.8% (5.0%-9.2%) (n=1,733) | 1.2% (0.6%-2.4%) (n=1,690) | 0.4% (0.2%-0.7%) (n=2,232) |

[†] Statistically significant versus control.

Projected purchase rates. Projected purchase rates were significantly higher for the test advertisement ($p < 0.01$) and among current regular tobacco users ($p < 0.0001$). A significant interaction emerges, indicating that the test advertisement differentially appealed to current tobacco users compared to former and never users ($p < 0.0001$). The group to which the proposed modified risk advertising is targeted (current regular tobacco users) was most likely to be interested in purchasing Camel Snus. The projected purchase rates among those not currently using tobacco – the population for which the product is *not* intended – were low in both arms and were not increased by the proposed modified risk advertising.

6.3.3.2.5 Potential Quitters

A concern about modified risk advertising is that it might attract tobacco users who expect to or are likely to quit all tobacco use, potentially diverting or delaying them from quitting. Accordingly, the effect of the proposed modified risk advertising was tested among tobacco users who were potential quitters (expected to quit all tobacco products within 9 months).

Rated likelihood of use. The ratings for intent to purchase among current tobacco users who were potential quitters (test: $n = 271$; control: $n = 226$) were significantly lower ($p < 0.0001$) than the ratings of tobacco users who were not potential quitters (Table 6.3.3-3). Among potential quitters, there was a significantly increased interest in purchase among those who saw the proposed modified risk advertisement than the control advertisement ($p < 0.05$).

Projected purchase rates. The overall projected rates of purchase were significantly higher in response to the test advertisement ($p < 0.001$), and significantly lower ($p < 0.0001$) among current tobacco users who were potential quitters than among current users who were not potential quitters. The interaction was not significant.

Table 6.3.3-3: Likelihood to Purchase Ratings and Projected Purchase Rates among Current Tobacco Users by Quitting Status

| Likelihood to Purchase Ratings (1-10) among Current Tobacco Users by Quitting Status Mean (95% CI) | | | |
|---|--|-----------------------------|---|
| | Current Regular Tobacco Users | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 3.6 [†] (3.41-3.79) (n=1,733) | 2.5 (2.15-2.85) (n=271) | 3.8 [†] (3.59-4.01) (n=1,462) |
| Control (without proposed modified risk messaging) | 3.3 (3.12-3.42) (n=1,733) | 2.2 (1.87-2.53) (n=226) | 3.5 (3.31-3.69) (n=1,507) |
| Projected Purchase Rates (%) among Current Tobacco Users by Quitting Status % (95% CI) | | | |
| | Current Regular Tobacco Users | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 7.8 [†] % (5.7%-10.4%) (n=1,733) | 4.4% (3.1%-6.3%) (n=271) | 8.4% (6.2%-11.2%) (n=1,462) |
| Control (without proposed modified risk messaging) | 6.8% (5.0%-9.2%) (n=1,733) | 3.9% (2.7%-5.7%) (n=226) | 7.2% (5.3%-9.7%) (n=1,507) |

[†] Statistically significant versus control.

These findings suggest that, among current tobacco users, Camel Snus is less appealing to potential quitters, and the proposed modified risk advertising did not differentially appeal to this group.

6.3.3.2.6 Cigarette Use Status

The results above assessed likelihood to purchase among respondents based on their use of any tobacco product. Since the proposed modified risk advertising targets cigarette smokers in particular (a group using a product with significantly greater risk than snus), it was important to assess the impact of the modified risk advertising on this group specifically, as well as among former and never smokers, for whom this product is not intended.

Rated likelihood of use. Interest in purchasing Camel Snus was significantly higher ($p < 0.0001$) among current regular smokers than among both former smokers and never smokers (Table 6.3.3-4), and the test advertisement generated greater interest ($p < 0.05$). There was a significant ($p < 0.05$) interaction, indicating that the test advertisement had differential appeal to current smokers. Interest among current regular smokers was significantly higher ($p < 0.05$) among those who viewed the proposed modified risk advertisement compared to current smokers who saw the control advertisement, but there was no effect of the advertisement among former or never smokers.

Projected purchase rates. The projected rate of purchase was significantly higher ($p < 0.05$) among current regular smokers than among both former smokers and never smokers (Table 6.3.3-4), and the test advertisement generated greater projected purchase rates ($p < 0.001$). There was a significant ($p < 0.0001$) interaction, indicating that the test advertisement had differential appeal to current smokers. Projected purchase among current regular smokers was significantly increased ($p < 0.05$) among those who viewed the proposed modified risk advertisement compared to current smokers who saw the control advertisement, but there was no effect of the advertisement among former or never smokers.

Table 6.3.3-4: Likelihood to Purchase Ratings and Projected Purchase Rates by Current Cigarette Use Status

| Likelihood to Purchase Ratings (1-10) by Current Cigarette Use Status | | | |
|--|--|---------------------------------------|--------------------------------------|
| Mean (95% CI) | | | |
| | Current Regular Cigarette Users | Former Regular Cigarette Users | Never Regular Cigarette Users |
| Test (with proposed modified risk messaging) | 3.7 [†] (3.48-3.92) (n=1,333) | 1.8 (1.69-1.91) (n=1,895) | 1.7 (1.6-1.8) (n=2,419) |
| Control (without proposed modified risk messaging) | 3.4 (3.2-3.6) (n=1,328) | 1.8 (1.69-1.91) (n=1,897) | 1.7 (1.61-1.79) (n=2,430) |
| Projected Purchase Rates (%) by Current Cigarette Use Status | | | |
| % (95% CI) | | | |
| | Current Regular Cigarette Users | Former Regular Cigarette Users | Never Regular Cigarette Users |
| Test (with proposed modified risk messaging) | 8.2 [†] % (6.0%-10.9%) (n=1,333) | 1.9% (1.2%-3.3%) (n=1,895) | 0.5% (0.3%-0.8%) (n=2,419) |
| Control (without proposed modified risk messaging) | 6.9% (5.1%-9.4%) (n=1,328) | 2.0% (1.2%-3.3%) (n=1,897) | 0.4% (0.3%-0.8%) (n=2,430) |

[†] Statistically significant versus control.

These findings demonstrate that the proposed modified risk advertising for Camel Snus did not inappropriately appeal to those for whom the product is not intended (former and never smokers) but that the proposed advertising did significantly and differentially increase rated interest in purchasing and projected rates of purchase among current cigarette smokers.

6.3.3.2.7 Potential Quitters

Rated likelihood of use. Among current, regular smokers, interest in purchasing Camel Snus was assessed by potential quitting status (intending to quit in the next 9 months). Current regular cigarette smokers who were potential quitters rated their likelihood to purchase Camel Snus significantly lower ($p < 0.0001$) than current cigarette smokers who were not potential quitters (Table 6.3.3-5), and the test advertisement generated higher ratings as well ($p < 0.001$). There

was no interaction between quitting status and the advertising viewed. This finding suggests that adding the proposed modified risk advertising to Camel Snus does not differentially appeal to smokers who are interested in quitting.

Projected purchase rates. In both arms of the study, the projected rates of purchase for current smokers who were potential quitters were significantly lower ($p < 0.0001$) than they were for cigarette smokers who were not expecting to quit tobacco use (Table 6.3.3-5), and the test advertisement generated higher projected purchase as well ($p < 0.05$). There was no interaction effect between the advertisement and smoking status, meaning that there were no differential effects of the advertisement across the two groups of smokers.

Table 6.3.3-5: Likelihood to Purchase Ratings and Projected Purchase Rates by Quitting Status among Current Cigarette Users

| Likelihood to Purchase Ratings (1-10) by Quitting Status among Current Cigarette Users | | |
|---|-----------------------------|--------------------------------|
| | Mean (95% CI) | |
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 2.5 (2.06-2.94) (n=184) | 3.9 (3.66-4.14) (n=1,149) |
| Control (without proposed modified risk messaging) | 2.3 (1.87-2.73) (n=155) | 3.5 (3.28-3.72) (n=1,173) |
| Projected Purchase Rates (%) by Quitting Status among Current Cigarette Users | | |
| | % (95% CI) | |
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 4.2% (2.9%-6.1%) (n=184) | 8.7% (6.5%-11.6%) (n=1,149) |
| Control (without proposed modified risk messaging) | 4.0% (2.7%-5.8%) (n=155) | 7.3% (5.4%-9.8%) (n=1,173) |

These findings suggest that smokers who are expecting to quit smoking will not be attracted by the modified risk messaging in the proposed advertisement.

6.3.3.2.8 Young Adults – Overall

Young adults (aged 18-24) are a group of particular interest for several reasons. Their present tobacco use patterns may not be as stable as those of older adults. Consequently, those young adults who are not presently using tobacco products may begin using tobacco products in the future, making it important to assess whether a modified risk tobacco product is attractive to this group. On the other hand, those young adults who are currently using tobacco products may not be as committed to continued smoking as older smokers and may be more amendable to switching to a lower risk product. The younger a person is when they reduce their exposure to the harmful constituents in tobacco and tobacco smoke, the lower their lifetime health risk from use (Jha *et al.* 2013). Finally, the responses of young adults may be a proxy indicator for responses by those under legal purchase age. Therefore, appealing to young adult tobacco

users with a reduced risk product may greatly lower their lifetime disease risk. At the same time, advertising should not increase appeal to the young adults who are not using tobacco, to avoid increasing the prevalence of tobacco use.

Rated likelihood of use. Young adults who were current regular tobacco users were significantly ($p < 0.0001$) more interested in purchasing Camel Snus than were young adult former and never regular tobacco users (Table 6.3.3-6). The difference in interest in purchasing Camel Snus was not significantly different ($p > 0.05$) between young adults who saw the modified risk advertisement compared to those who saw the control advertisement, and there was no difference between the advertisements, not any interaction. These findings suggest that, among young adults, the proposed modified risk advertising does not increase interest in Camel Snus among former and never regular tobacco users.

Projected purchase rates. The projected rates of purchase for young adult current regular tobacco users were significantly greater for those who viewed the proposed modified risk advertising than among those in the control condition ($p < 0.05$) (Table 6.3.3-6). Projected rates of purchase for current young adult tobacco users were significantly greater than for former and never regular tobacco users ($p < 0.0001$), and there was a significant advertisement-by-tobacco-use-status interaction ($p < 0.01$), meaning that the differences between the test and control advertisements differed across the groups. Specifically, the test advertisement increased projected among current tobacco users, not among former or never users. These findings suggest that, among young adults, the proposed modified risk advertising does not attract non-tobacco users but differentially attracts current tobacco users.

Table 6.3.3-6: Likelihood to Purchase Ratings and Projected Purchase Rates among Young Adults by Current Tobacco Use Status

| Likelihood to Purchase Ratings (1-10) among Young Adults by Current Tobacco Use Status | | | | |
|--|----------------------------|-------------------------------|------------------------------|-----------------------------|
| Mean (95% CI) | | | | |
| | All Young Adults | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 2.2 (1.9-2.5) (n=466) | 4.8 (4.05-5.55) (n=97) | 2.4 (1.51-3.29) (n=38) | 1.8 (1.47-2.13) (n=331) |
| Control (without proposed modified risk messaging) | 2.1 (1.84-2.36) (n=474) | 3.9 (3.14-4.66) (n=96) | 2.9 (1.8-4.0) (n=34) | 1.8 (1.52-2.08) (n=344) |

| Projected Purchase Rates (%) among Young Adults by Current Tobacco Use Status % (95% CI) | | | | |
|---|--------------------------------|--|-------------------------------|--------------------------------|
| | All Young Adults | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 2.2% (1.5%-3.3%) (n=466) | 13.3% [†] (9.6%-18.1%) (n=97) | 2.6% (1.0%-6.4%) (n=38) | 0.5% (0.3%-0.8%) (n=331) |
| Control (without proposed modified risk messaging) | 1.8% (1.2%-2.7%) (n=474) | 10.8% (7.7%-14.9%) (n=96) | 3.1% (1.2%-7.7%) (n=34) | 0.4% (0.2%-0.7%) (n=344) |

[†] Statistically significant versus control.

These findings suggest that the proposed modified risk advertising differentially attracted the young adults who could benefit from switching to a modified risk product (current regular tobacco users) while not differentially appealing to young adults who were not currently using tobacco products.

6.3.3.2.9 Young Adults – Potential Quitters

As with all tobacco users who are potential quitters, it was important to assess specifically the interest of young adults who are potential quitters in purchasing Camel Snus.

Rated likelihood of use. Overall, young adult current tobacco users who were potential quitters were significantly ($p < 0.0001$) less likely than those who were not potential quitters to be interested in purchasing Camel Snus. There was no interaction between quit intent and test versus control condition, meaning that the difference between the test and control advertisements did not differ by expectancy to quit. These results suggest that the proposed modified risk advertising did not differentially attract those who were expecting to quit tobacco use.

Projected purchase rates. The projected rates of purchase were in the same direction as the interest ratings. Young adult potential quitters were significantly less likely to be projected to purchase Camel Snus than young adults not expecting to quit tobacco ($p < 0.0001$) (Table 6.3.3-7). The effect was similar for both the test and control advertisements, and there was no interaction. However, the test advertisement resulted in significantly ($p < 0.05$) higher projected purchase rates.

Table 6.3.3-7: Likelihood to Purchase Ratings and Projected Rates of Purchase by Quitting Status among Young Adults

| Likelihood to Purchase Ratings (1-10) by Quitting Status among Young Adults Mean (95% CI) | | |
|--|----------------------------|-------------------------------|
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 2.4 (1.3-3.5) (n=15) | 5.2 (4.39-6.01) (n=82) |
| Control (without proposed modified risk messaging) | 1.8 (1.07-2.53) (n=14) | 4.3 (3.47-5.13) (n=82) |
| Projected Purchase Rates (%) by Quitting Status among Young Adults % (95% CI) | | |
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 5.4% (3.6%-8.2%) (n=15) | 14.4% (10.5%-19.4%) (n=82) |
| Control (without proposed modified risk messaging) | 4.0% (2.5%-6.3%) (n=14) | 11.8% (8.5%-16.2%) (n=82) |

These results among young adults indicate that the proposed modified risk advertising did not differentially attract those who were potential quitters.

6.3.3.2.10 White Males – Overall

Interest in purchase among white males was assessed because they have traditionally been the primary users of smokeless tobacco products in the U.S. (USDHHS 2014).

Rated likelihood of use. White males who were current regular tobacco users were significantly more interested in purchasing Camel Snus than were white male former and never tobacco users ($p < 0.0001$) (Table 6.3.3-8). Interest in purchase was not affected by the test advertisement.

Projected purchase rates. Projected rates of purchase among white males overall similarly was not affected by the proposed modified risk advertising. Across advertisements, projected rates of purchase were significantly greater for white male current regular tobacco users than among former and never tobacco users ($p < 0.0001$) (Table 6.3.3-8), and were not affected by the test advertisement.

Table 6.3.3-8: Likelihood to Purchase Ratings and Projected Purchase Rates among White Males by Current Tobacco Use Status

| Likelihood to Purchase Ratings (1-10) among White Males by Current Tobacco Use Status Mean (95% CI) | | | | |
|--|----------------------------------|--------------------------------|----------------------------------|--------------------------------|
| | White Males | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 1.9 (1.8-2.0) (n=2,645) | 3.4 (3.11-3.69) (n=718) | 1.4 (1.31-1.49) (n=1,007) | 1.6 (1.46-1.74) (n=920) |
| Control (without proposed modified risk messaging) | 1.8 (1.7-1.9) (n=2,666) | 3.2 (2.92-3.48) (n=710) | 1.4 (1.31-1.49) (n=1,011) | 1.5 (1.37-1.63) (n=945) |
| Projected Purchase Rates (%) among White Males by Current Tobacco Use Status % (95% CI) | | | | |
| | White Males | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 1.5% (1.1%-2.2%) (n=2,645) | 6.4% (4.7%-8.6%) (n=718) | 0.7% (0.4%-1.3%) (n=1,007) | 0.3% (0.2%-0.6%) (n=920) |
| Control (without proposed modified risk messaging) | 1.4% (1.0%-2.1%) (n=2,666) | 6.0% (4.4%-8.2%) (n=710) | 0.8% (0.4%-1.4%) (n=1,011) | 0.3% (0.2%-0.6%) (n=945) |

These findings demonstrate that white male current tobacco users, one of the groups more likely to use Camel Snus, is interested in purchasing the product for trial and has statistically significantly higher projected purchase rates than former and never regular tobacco users.

White males who do not currently use tobacco expressed little interest in purchasing it, and the modified risk advertising had no effect on their interest. There were lower rates of projected purchase for the groups (former and never tobacco users) for which the product is not intended, suggesting that the interest in Camel Snus among white males is fairly confined to those who are more likely to obtain a reduction in risk by using it, and that the proposed modified risk advertising did not differentially attract those for whom it is not intended.

6.3.3.2.11 White Males – Potential Quitters

Rated likelihood of use. White male current tobacco users who were potential quitters were significantly less interested in purchasing Camel Snus than those who were not potential quitters ($p < 0.0001$) (Table 6.3.3-9). Interest was not affected by which advertisement they saw.

Projected purchase rates. The projected rates of purchase for white male potential quitters were significantly lower than the projected rates of purchase for white male current tobacco users who were not potential quitters ($p < 0.0001$), and this was not affected by which advertisement they saw. This suggests that the proposed modified risk advertising is not differentially appealing to potential quitters (Table 6.3.3-9).

Table 6.3.3-9: Likelihood to Purchase Ratings and Projected Purchase Rates by Quitting Status among White Males

| Likelihood to Purchase Ratings (1-10) by Quitting Status among White Males Mean (95% CI) | | |
|---|-----------------------------|-------------------------------|
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 2.5 (2.02-2.98) (n=121) | 3.5 (3.18-3.82) (n=597) |
| Control (without proposed modified risk messaging) | 2.3 (1.79-2.81) (n=99) | 3.4 (3.09-3.71) (n=611) |
| Projected Purchase Rates (%) by Quitting Status among White Males % (95% CI) | | |
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 4.1% (2.9%-5.8%) (n=121) | 6.9% (5.1%-9.2%) (n=597) |
| Control (without proposed modified risk messaging) | 3.4% (2.3%-5.0%) (n=99) | 6.4% (4.7%-8.7%) (n=611) |

These findings suggest that the proposed modified risk advertising is not likely to increase interest in or purchase of Camel Snus by white males who are expecting to quit tobacco use.

6.3.3.2.12 Reasons for Using Camel Snus

Since tobacco users who are interested in quitting tobacco altogether are not the intended population for a modified risk tobacco product, respondents who were potential quitters yet indicated any likelihood at all of trying Camel Snus (*i.e.*, rating their interest at 2 or greater on the 1-to-10 scale; test: n=97; control: n=74) were asked what their reason was for wanting to try Camel Snus. In the test condition, 41% (29.1%-52.9%) stated their reason was “to help me quit.” Among those who saw the control advertisement, 27% (15.0%-39.0%) also stated their reason was “to help me quit.” This finding suggests that there are some potential quitters who viewed Camel Snus as a potential gateway *out* of tobacco use, and this was slightly more common (although not significantly) among those who saw the proposed modified risk advertising.

Curiosity was also commonly cited as a reason potential quitters gave for their interest in trying Camel Snus. Half (50%; 35.8%-64.2%) of those who saw the control advertisement and 38% (26.8%-49.2%) of those who saw the test advertisement cited curiosity as their reason for interest in trying Camel Snus. The proposed modified risk advertising did not differentially trigger curiosity to try Camel Snus among potential quitters. If curiosity about Camel Snus leads to switching to Camel Snus from a product with greater risk, such trial may also benefit users and the public health.

The proposed modified risk advertising did not increase interest in using Camel Snus because it might “allow me to use in situations where I cannot use my current product” (test: 8% [1.9%-14.1%]; control: 11% [2.5%-19.5%]).

Overall, these results suggest that exposure to the proposed modified risk advertising for Camel Snus did not differentially invoke adverse motives for trying Camel Snus among current tobacco users who were potential quitters.

6.3.3.2.13 Intended Use among Smokers Not Expecting to Quit

Use of Camel Snus would provide the greatest health benefit to cigarette smokers who switch completely to snus from cigarettes. In order to assess how likely this change might be, respondents who expressed any interest at all in Camel Snus – those who rated their likelihood to purchase Camel Snus as a 2 or higher on the 1-to-10 scale – were asked how they would use Camel Snus. Response options included “instead of my current tobacco product,” “in addition to my current tobacco product,” “in place of some of my current tobacco product,” and “don’t know.”

Among current regular cigarette smokers who were not expecting to quit tobacco use, 22% (18.1%-25.9%) in the test condition and 20% (16.0%-24.0%) in the control condition indicated that they would use Camel Snus *instead of* cigarettes (*i.e.*, stop use of cigarettes and use snus only). An additional 30% (26.0%-34.0%) in the test condition and 26% (22.1%-29.9%) in the control condition said they would use it in place of some of the tobacco they currently consumed. Slightly more than one-quarter in both conditions (test: 27% [23.1%-30.9%]; control: 26% [22.1%-29.9%]) did not know how they would use Camel Snus, and some cigarette smokers who said they would add Camel Snus to their current tobacco use (test: 22% [18.1%-25.9%]; control: 27% [23.0%-30.0%]). Thus, some respondents interested in using Camel Snus thought they would use it in ways that are not optimal. However, exposure to the proposed modified risk advertising did not increase the proportion that would do so ($p>0.05$).

6.3.3.2.14 Switching to Smoking After Using Camel Snus

Among those who may use Camel Snus, it is important to evaluate the likelihood that they might subsequently switch (or switch back) to smoking, which would increase their health risk. This is particularly important for those who are not using tobacco at the time they started using Camel Snus.

Current regular cigarette smokers who stated that they would use Camel Snus *instead of* cigarettes rated their likelihood to switch back to cigarettes after trying Camel Snus on a 10-point scale (1 = not at all likely, 10 = very likely). Those exposed to the proposed modified risk advertising were no more likely to switch back to cigarettes (7.3; 6.81-7.79) than those not exposed to the proposed modified risk advertising (7.1; 6.5-7.7). These findings suggest that exposure to the proposed modified risk advertising does not increase the risk of reverting to smoking after trying Camel Snus.

Former regular tobacco users who expressed any interest at all in trying Camel Snus (*i.e.*, they rated their likelihood to purchase Camel Snus a 2 or higher) were then asked to rate how likely they would be to switch to a different tobacco product after using Camel Snus. Those who viewed the proposed modified risk advertising were directionally less likely (3.9; 3.48-4.32) than those who saw the control advertisement (4.5; 4.07-4.93) to express interest in switching to another tobacco product after trying Camel Snus. Although these results are not statistically significant, they do suggest that the proposed modified risk advertisement does not encourage resumption of smoking compared to the control advertisement.

The intentions of never regular tobacco users are important to examine since movement of this group, which is at the lowest health risk given their abstinence from tobacco, into higher-risk tobacco use (such as smoking) would be an adverse public health impact. This has been discussed as the "gateway" effect. Never regular tobacco users who expressed any interest in purchasing Camel Snus (at least 2 on the 1-to-10 scale) rated their likelihood to switch to another tobacco product similarly regardless of which advertisement they viewed (test: 4.6; 4.19-5.01; control: 4.8; 4.46-5.14). Thus, the proposed modified risk advertising does not appear to promote progression from use of Camel Snus to products such as cigarettes that pose more risk. Along with the finding that the proposed modified risk advertising does not attract increased interest among those who never used tobacco, this finding suggests modified risk advertising for Camel Snus is unlikely to lead to "gateway" effects that might result in increased smoking.

6.3.3.3 Conclusions

Modified risk tobacco products provide a potential health benefit to those who switch to them from tobacco products that pose a greater risk to health. The likelihood of use study was conducted to determine whether the proposed modified risk advertising for Camel Snus would appeal to those for whom it would provide a benefit in the form of reduced health risk (*i.e.*, current cigarette smokers), and, most importantly, whether the modified risk advertising would have unintended consequences by differentially attracting those for whom use would not be beneficial (non-smokers and smokers expecting to quit). In addition, the study evaluated whether the anticipated modes of use would be consistent with a public health benefit (*i.e.*, as a replacement for a greater risk product among those who are not interested in quitting tobacco completely).

Overall, interest in Camel Snus was greatest among current cigarette smokers, for whom switching to Camel Snus would confer a benefit. The test advertisement containing modified risk messages differentially attracted interest and projected purchase from current smokers, rather than from never or former smokers. It did not differentially appeal to those expecting to quit, and, indeed, overall interest in Camel Snus was substantially lower among those expecting to quit. Among the small number of potential quitters who expressed any interest in purchasing Camel Snus, over one-third indicated that their motive for trying it was "to help me quit." These results are reassuring that the proposed modified risk advertising is not likely to keep smokers interested in quitting from doing so.

Among current regular smokers not intending to quit smoking who expressed an interest in using Camel Snus, approximately half intended to replace some or all of their cigarettes with Camel Snus. About one in five, though, said they would add it to their current cigarette consumption. Such behavior could mitigate the overall population health benefit of a modified risk product.

There was interest in purchasing Camel Snus among white male current tobacco users, a group that has traditionally been more willing to use smokeless tobacco products in general. Among this group, those interested in quitting all tobacco use were less likely than those not interested in quitting tobacco to express interest in purchasing Camel Snus and had significantly lower projected purchase rates than those expecting to continue using tobacco. These findings suggest that the proposed modified risk advertising did appeal to white males who use tobacco and are not interested in quitting while not attracting those who are interested in quitting tobacco.

Young adults are a group whose current tobacco use patterns may not yet be fully established. Therefore, those young adults who are not presently using tobacco products may not be resistant to taking up tobacco use, and those who are presently using may be more open to switching to a lower risk product. The younger a person is when they reduce their exposure to the harmful constituents in tobacco and tobacco smoke, the lower their lifetime health risk from use (Jha *et al.* 2013). Therefore, appealing to young adult tobacco users with a reduced risk product can greatly lower their lifetime disease risk. In this study, young adult tobacco users showed the highest level of interest in trying Camel Snus of all the groups studied. Further, the proposed modified risk advertising had specific differential appeal to young adult current tobacco users. Young adults who were not expecting to quit tobacco were more interested in purchasing Camel Snus than young adults who were expecting to quit. These findings suggest that Camel Snus may have some benefit for young adults already using tobacco and help alleviate some concern about potentially inappropriate interest among young adults in this modified risk tobacco product.

The findings from this study generally suggest that there is low interest among all respondents in using Camel Snus, which is consistent with the literature on use of snus in the U.S. (King *et al.* 2012). Exposure to the proposed modified risk advertising did not differentially attract interest from any of the groups for whom snus use could increase risk: never tobacco users, former tobacco users, or current tobacco users expecting to quit. The modified risk advertising also did not increase the likelihood that former smokers who might adopt Camel Snus would return to smoking or that non-tobacco users who might try Camel Snus would progress onto cigarette smoking (*i.e.*, "gateway" effects). Thus, the data strongly suggest that the proposed modified risk advertising would not cause harm, and is likely to encourage trial among current smokers, which would benefit individual and population health.

6.3.3.4 Limitations and Strengths

Like any study, this study had some limitations. The sample was drawn from an opt-in online panel, and thus may not be fully representative of the U.S. population, not all of whom have

internet access or join panels. However, strong majorities of Americans are now online ([Perrin and Duggan 2015](#)), and online panels can produce reasonable estimates ([Farrell and Petersen 2010](#)). Moreover, the sample was recruited and weighted to represent the demographics of the U.S. population.

The proposed modified risk advertising is intended to be used in multiple marketing platforms and media, but here it was viewed via an online, on-screen display in a research context. However, such methods are often used to evaluate communications ([Sullivan et al. 2015](#)), and there is little reason to think the results are not generalizable to other media.

The study measured the effects of a single exposure of the proposed modified risk advertisement for Camel Snus during the course of a survey, as opposed to the effects of multiple exposures over time in the real world in the context of advertising. Importantly, motivating smokers to switch to snus may rest on persuading them that snus is truly safer and able to reduce harm to them. Research shows that both smokers and non-smokers have pre-existing misconceptions about the risk of smokeless tobacco use relative to smoking, thinking that smokeless use is at least as hazardous as smoking ([Fong et al. 2016](#); [Kaufman et al. 2014](#); [Kiviniemi and Kozlowski 2015](#); [Regan et al. 2012](#)). Data from the comprehension and perceptions studies of the proposed modified risk advertising for Camel Snus also suggested this. Thus, it may take multiple exposures, and consistent messages from multiple sources, including sources more credible than a tobacco company advertisement, for smokers to appreciate the potential of Camel Snus to reduce their health risk. Similarly, exposure to multiple messages about the importance of switching completely from smoking to Camel Snus could promote appropriate health-protective behavior.

Projected estimates of likely Camel Snus purchase for trial were derived from a model based on and validated in the context of cigarettes, rather than a smokeless product, and did not specifically test the link between stated interest and purchase in the context of modified risk advertising. Moreover, validation studies showed that purchase is over-estimated by the projection algorithm, though the differential purchase of different groups is accurately captured. Further, the algorithm models initial purchase for trial, and not long-term persistence, which is important to the expected harm-reduction benefit of switching to snus. A study ([Carpenter et al. 2016](#)) found that, among smokers who tried snus, 8% reported any use at the 6-month follow-up and 4% at the 12-month follow-up. Thus, the projected use data over-estimate the actual expected use, especially in the long-term. However, they should do so evenly across the different population groups examined, thus preserving the conclusion that the proposed advertisement does not differentially appeal to the groups that would not benefit from switching to Camel Snus. In any case, the raw "likelihood to purchase" data also lead to similar conclusions, so limitations of the projected purchase algorithm do not affect the reassuring conclusions.

The study also had considerable strengths. The sample was large, diverse, and sampled and weighted to match the demographics of U.S. adults. It included a broad range of demographics. The study included current, former, and never users of tobacco products, and also analyzed

responses from important subgroups based on demographics and tobacco-use history. The data on rated likelihood of use were translated into projections of likely purchase, taking into account empirical observations about how such ratings translate into real-world behavior.

6.3.3.5 Summary – Execution 2

The study assessed interest in Camel Snus among a variety of populations when exposed to the proposed modified risk advertising. Overall, interest was modest. Importantly, the data suggest that the proposed modified risk advertising did not increase the appeal of the product to populations where adoption of it would increase harm rather than confer benefit—never smokers, former smokers, and tobacco users expecting to quit tobacco use. The data were also inconsistent with the concern that non-tobacco users (former users or never users) who try snus would progress to cigarette smoking. These data mitigate concerns about adverse effects on population health from the proposed modified risk advertising for Camel Snus. Moreover, the modified risk advertising differentially increased interest and projected purchase among current smokers, who stand to benefit from switching to Camel Snus, and not among never or former smokers. On balance, the data suggest that the proposed modified risk advertising encouraging current smokers to switch to Camel Snus would likely result in benefits to population health.

6.3.4 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Third Execution of Consumer Testing

6.3.4.1 Study Methods – Execution 3

6.3.4.1.1 Sample

An online study was conducted with a sample of 11,305 U.S. adults whose age (at least 18+) made them legally eligible to purchase tobacco in their jurisdiction of residence. The sample was drawn randomly from the Research Now online panel of approximately three million individuals in the U.S. Quota sampling was used to promote representativeness of the sample with respect to gender, age, race/ethnicity, education, and geographic region. The sample for each of the two conditions (test and control) (see below) was separately weighted to match the demographics of the U.S. population. A detailed description of the sampling and weighting is available in the study protocol ([Protocol Identifier: RO-BR-2015-05 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users - Third Execution of Consumer Testing](#)) and the final study report (Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – *Third Execution of Consumer Testing – Amended Final Report*), respectively.

Quota sampling was done to obtain at least 3,300 respondents in each of three current or non-current tobacco user groups of interest:

1. Current regular tobacco users (n=3,468), self-defined as currently using tobacco regularly or occasionally;

2. Former regular tobacco users (n=3,379), self-defined as having used tobacco regularly in the past but not a current user (whether regular or occasional);
3. Never regular tobacco users (n=4,458), self-defined as having never having regularly used tobacco.

To mask the purpose of the study, the screening questions about tobacco use were embedded with questions about regular use of other products, namely beer or malt-based beverages, bottled water, nutritional supplements/vitamins, or tobacco products. "Regular use" and "occasional use" were self-defined. For each product, participants were asked: "Would you consider yourself to be – or to have been at any time in the past – a "regular user" of any of the following products? We leave it to you to define regular use." Response options were "Yes, I am or was a regular user" and "No, I have never been a regular user." All respondents who said they had ever been a regular user of tobacco products were then asked "Focusing only on the present, how would you currently describe yourself, relative to each of the following categories?". Response options for each of the product categories were "current non-user," "current occasional user," and "current regular user."

Potential quitters (n=479) are a subset of current regular tobacco users who do not expect to be using any tobacco product 9 months from the time of the survey. A time frame of 9 months was used to define expected quitting, because this matched the interval over which product purchases were assessed to develop the algorithm to project purchase rates.

Data analysis was also performed for other subgroups: cigarette smokers (as a subset of tobacco use groups), who are the primary target for modified risk advertising; young adults (18-24), because of their potential openness to change; and white males, who are currently the most common users of smokeless tobacco products.

The sample was balanced between the test condition (those who viewed advertisements with the proposed modified risk messaging) and control condition (those who saw advertisements without the proposed modified risk messaging) such that there were 5,650 in the test condition (1,735 current regular tobacco users, 1,689 former regular tobacco users, and 2,226 never regular tobacco users) and 5,655 in the control condition (1,733 current regular tobacco users, 1,690 former regular tobacco users, and 2,232 never regular tobacco users).

6.3.4.1.2 Procedures

An online study was conducted August 11 through September 30, 2015. Respondents were screened for demographics and use of tobacco products, as described above. Qualified respondents (aged 18-75, legally eligible to purchase tobacco in their state of residence, and not current users of Camel Snus) were entered into the study.

6.3.4.1.3 Message Exposure

Respondents were randomized in a 1:1 ratio within tobacco user group to be shown either an advertisement for Camel Snus with the proposed modified risk messaging or a control Camel Snus advertisement that did not have the modified-risk messaging⁵. Each advertisement consisted of three separate color images. The three images appeared one above the other on the same screen, and respondents were instructed to scroll down to view all the product information. Questions about the advertisement viewed followed on separate screens, and respondents were not able to go back to review the advertisement. The modified risk Camel Snus advertisement was identical to that tested in the comprehension and perception study for this ad execution (Execution 3).

The test advertising included three images, the first of which contained the statement “No Smoke, Less Risk, Choose Snus.” The second image provided product information (what it is, how to use it, how it is different), and the third image provided information on the benefits of switching completely from cigarettes to Camel Snus. The control advertisement also included three images, the first of which contained the statement “Choose Snus.” The second image provided product information (what it is, how to use it), and the third image provided additional product information (how it is different) and why a smoker should switch (no hassle, no smoke smell, etc.) ([Protocol Identifier: RO-BR-2015-05 Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users - Third Execution of Consumer Testing](#)). The bottom fifth of all images in both the test and control conditions included one of the four government-mandated warning label statements, which were randomly rotated.

Respondents in the test condition saw the proposed modified risk advertisement, which contained risk-related information, as well as additional information about how Camel Snus (and tobacco products generally) should and should not be used. In addition, the advertisement included other health-related information that is not modified risk or risk-related messaging. In the control condition, the advertisement included benefits of switching to Camel Snus (*i.e.*, no hassle, no lingering smoke smell, more freedom) but did **not** mention any reduction in disease risk, nor did it include other health-related messages that are included in the test advertisement. See [Table 6.3.4-1](#) below for the messages included in the test and control advertisements.

⁵ Study executions 2 and 3 shared a common control group. Thus, respondents were actually randomized into one of three arms, assigned to see the execution 2 advertisement, the control advertisement, or the execution 3 advertisement. This report addresses the execution 3 advertisement and the control advertisement.

Table 6.3.4-1: Comparison of the Messages Included in the Advertisements for the Test and Control Conditions (Execution 3)

| Test Advertisement | Control Advertisement |
|---|---|
| Page 1 | |
| Choose snus. | Choose snus. |
| No smoke. | |
| Less risk. | |
| Picture of a smashed cigarette butt appears next to the Camel Snus package | Picture of a Camel Snus package only |
| <i>1 of 4 government-mandated warning label statements for snus</i> | <i>1 of 4 government-mandated warning label statements for snus</i> |
| Pages 2 and 3 | |
| <p>What is Camel Snus?</p> <ul style="list-style-type: none"> Camel Snus (rhymes with “moose”) is finely ground premium tobacco in a soft fleece pouch. | <p>What is Camel Snus?</p> <ul style="list-style-type: none"> Camel Snus (rhymes with “moose”) is finely ground premium tobacco in a soft fleece pouch. |
| <ul style="list-style-type: none"> Like all tobacco products, Camel Snus contains nicotine and is addictive. | |
| <p>How is it different?</p> <ul style="list-style-type: none"> Many smokeless tobacco products, like dip and chew, are fermented loose tobacco. | <p>How is it different?</p> <ul style="list-style-type: none"> Many smokeless tobacco products, like dip and chew, are fermented loose tobacco. |
| <ul style="list-style-type: none"> Sure, they’re smoke-free, but they can get messy and require spitting. | <ul style="list-style-type: none"> Sure, they’re smoke-free, but they can get messy and require spitting. |
| <ul style="list-style-type: none"> Snus is different. It’s smoke-free, mess-free and spit-free. | <ul style="list-style-type: none"> Snus is different. It’s smoke-free, mess-free and spit-free. |
| <ul style="list-style-type: none"> Camel Snus is heat-treated, not fermented, and crafted with four main ingredients: tobacco, water, salt and flavoring. | <ul style="list-style-type: none"> Camel Snus is heat-treated, not fermented, and crafted with four main ingredients: tobacco, water, salt and flavoring. |
| <p>How do I use it?</p> <ul style="list-style-type: none"> Slide a pouch under your upper lip. | <p>How do I use it?</p> <ul style="list-style-type: none"> Slide a pouch under your upper lip. |
| <ul style="list-style-type: none"> Taste the real, premium tobacco. | <ul style="list-style-type: none"> Taste the real, premium tobacco. |
| <ul style="list-style-type: none"> Dispose of the pouch in the trash when you are finished. | <ul style="list-style-type: none"> Dispose of the pouch in the trash when you are finished. |
| <ul style="list-style-type: none"> Switch completely from cigarettes to Camel Snus. | |
| No smoke = less risk | |
| Smokers who SWITCH COMPLETELY from cigarettes to Camel Snus can greatly reduce their risk of lung cancer and respiratory disease. | |

| Test Advertisement | Control Advertisement |
|---|--|
| Scientific studies have shown that Camel Snus contains less of the harmful chemicals than cigarette smoke. | |
| Camel Snus is smoke-free, so there are no second-hand smoke risks for those around you. | |
| I'm a smoker. Why should I switch? | I'm a smoker. Why should I switch? |
| Switching to snus means . . . | Switching to snus means . . . |
| <ul style="list-style-type: none"> • No lingering smoke smell | <ul style="list-style-type: none"> • No lingering smoke smell |
| <ul style="list-style-type: none"> • Less of the harmful chemicals found in cigarette smoke | |
| <ul style="list-style-type: none"> • Less risk for you and those around you | |
| <ul style="list-style-type: none"> • Hassle-free tobacco | <ul style="list-style-type: none"> • Hassle-free tobacco |
| No tobacco product is safe.** | |
| <ul style="list-style-type: none"> • Like all tobacco products, Camel Snus <u>contains nicotine</u> and <u>is addictive</u>. | |
| <ul style="list-style-type: none"> • Adults who do not use or have quit using tobacco products should not start.** | |
| <ul style="list-style-type: none"> • <u>Minors and pregnant women should never use tobacco products.</u>** | |
| <ul style="list-style-type: none"> • If you're a smoker concerned about the health risks from smoking, the best choice is to quit.** | |
| <ul style="list-style-type: none"> • A good place to begin is talking with a healthcare provider.** | |
| <ul style="list-style-type: none"> • But if you're not going to quit using tobacco products, you should think about switching to Camel Snus. | |
| <i>1 of 4 government-mandated warning label statements for snus</i> | <i>1 of 4 government-mandated warning label statements for snus</i> |

** Indicates information contained only in the test advertisement that is ***not*** considered to be modified risk information but does convey health-related messages that are not in the control advertisement.

6.3.4.1.4 Assessment

Following exposure to either the test or control advertisement, respondents were asked about their likelihood to purchase with the question “Assuming the product were available today, how likely would you be to purchase Camel Snus in order to try it?” The response scale ranged from 1 (“definitely would not purchase it to try”) to 10 (“definitely would purchase it to try”). Among those who expressed any interest at all in trying Camel Snus (*i.e.*, rated their likelihood to purchase as 2 or greater on the 10-point scale), additional questions were asked to assess the following: 1) how they intended to use Camel Snus (*i.e.*, instead of their current tobacco

product, in addition to their current tobacco product, in place of some of their current tobacco product, or don't know); 2) how likely they would be to switch back to their current tobacco product after trying Camel Snus (response scale ranged from 1 = not at all likely to 10 = very likely); and 3) how likely they would be to switch to a different tobacco product [that presents more risk, such as cigarettes] after trying Camel Snus (response scale ranged from 1 = not at all likely to 10 = very likely). Potential quitters who expressed interest in trying Camel Snus (*i.e.*, rated their likelihood to purchase as 2 or greater on the 10-point scale) were asked an additional question about their reason for interest in Camel Snus (to help them quit, to use in situations where their current tobacco product cannot be used, just curious about it, or don't know).

Respondents finished the survey with questions about intentions to quit tobacco use in the future (current tobacco users) or to take up tobacco use (former and never tobacco users).

6.3.4.1.5 Analysis

The primary objective of this study was to estimate the likelihood of use for Camel Snus, with and without advertising that contains the proposed modified risk messaging, among consumers overall and among the three tobacco user groups (current, former, never tobacco users). Factorial Analysis of Variance (ANOVA) was employed to test differences in mean intent ratings and projected purchase rates between tobacco user groups, by test versus control groups. The main effect of user group reflects differences in interest in Camel Snus among groups different in tobacco use status (across test and control conditions). The main effect of test vs. control groups reflects the differences due to the different advertisements, across tobacco use groups. The interaction effect reflects the differential effect of test vs. control advertisements for different tobacco use groups. When a significant interaction effect was noted, it was followed by simple-main-effects t-tests to determine where (*i.e.*, in which tobacco use groups) the test vs. control differences were significant.

An *a priori* power analysis showed that the study had approximately 80% power to detect mean differences in projected purchase rate of roughly 1% across the arms for the primary analyses by tobacco user groups. *Post-hoc* power analyses based on the observed data distributions showed that all but one of the analyses had at least 80% power to detect small effects, with effect sizes ranging from .03 to .1 ([Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report, p. 28, footnote 21](#)). An exception was analysis of young adults by potential quitter status, which had smaller sample sizes, and had 80% power to detect an effect size of 0.21.

Likelihood of use were also estimated and tested for several subgroups thought to be relevant to evaluating participants' responses to the proposed modified risk advertising: young adults (ages 18-24 years) and white males (overall and by tobacco user subgroup), and cigarette smokers. Data are presented as mean ratings of likelihood to purchase for trial and 95% confidence intervals. Significant differences in ratings were assessed with t-tests.

6.3.4.1.6 Estimating Actual Purchase

Since stated *intent* to purchase does not always translate into *actual* purchase, a predictive algorithm was developed to transform the ‘likelihood to purchase for personal trial’ ratings into projected purchase rates for the tobacco product. This algorithm was developed by comparing *pre*-launch survey ratings of likelihood to purchase a tobacco product (a new brand of cigarettes) with actual (self-reported) purchase of the product *post*-launch. This comparison to actual purchase enables the creation of a conversion algorithm that can project purchase for trial of *future* new products based on pre-market survey ratings of likelihood to purchase. The algorithm was used in this study to transform the scaled ratings of likelihood to purchase into projected purchase estimates, taking into account the observation that likelihood of purchase ratings from groups defined by age and tobacco use had slightly different relationships to actual subsequent purchase. Thus, although derived from the underlying likelihood to purchase ratings, the projected purchase probabilities may have a different distribution.

The algorithm was validated in a separate study and tested in two additional studies, one of which included a Camel Snus product ([Bachand and Sulsky 2013](#)). The algorithm was valid for predictions of cigarette and non-cigarette tobacco purchase, but it consistently overestimates actual purchase for trial. The algorithm predicts trial, not necessarily persistent product use beyond trial use. Therefore, the algorithm estimates the likely *maximum* rates of actual purchase and use ([New Tobacco Product "Likelihood" Study: An Algorithm to Predict Usage of New Tobacco Products Prior to Market Launch – Methodological Report](#)).

The algorithm generates a probability of purchase for each respondent, based on their likelihood of use ratings. Data on projected purchase are presented as percentages and 95% confidence intervals. Significant differences were assessed with t-tests.

6.3.4.2 Study Results – Effect of the Modified Risk Advertising on Likelihood of Use

The results summarized below are based on the [Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users – Third Execution of Consumer Testing – Amended Final Report](#).

6.3.4.2.1 Demographics

The weighted demographics for the test and control conditions were identical and mirror the U.S. population: 51% female, 25% 18-30 years old, 37% 31-50 years old, and 38% 51-75 years old. The geographic representation was 18% from the Northeast, 21% Midwest, 37% South, and 23% West. Non-Hispanic whites made up 66% of each group with 16% Hispanic, 12% Non-Hispanic black, and 8% non-Hispanic Asian or other race. Less than half (41%) had a high school education or less; 30% had some college, and 30% had a bachelor degree or more education. There were no significant demographic differences between the test and control samples.

6.3.4.2.2 Tobacco Use History

Among current regular tobacco users in the study, the majority (test: 65% [62.2%-67.8%]; control: 67% [64.4%-69.6%]) smoked cigarettes⁶ every day. An additional 18% (15.7%-20.3%) in the test condition and 17% (14.9%-19.1%) in the control condition smoked cigarettes some days. A minority of current tobacco users used smokeless tobacco every day (test: 5% [3.6%-6.4%]; control: 5% [3.7%-6.3%]) or some days (test: 6% [4.6%-7.4%]; control: 6% [4.5%-7.5%]). Only 1% (0.4%-1.6%) in the test condition and 1% (0.2%-1.8%) in the control condition used snus every day, but slightly greater percentage used (a non-Camel brand) snus some days (test: 5% [3.7%-6.3%]; control: 5% [3.6%-6.4%]).

Former tobacco users in this study were predominantly former cigarette smokers (test: 95% [93.9%-96.1%]; control: 94% [92.8%-95.2%]). Nearly equal proportions in the test (8% [6.7%-9.3%]) and control (8% [6.7%-9.3%]) conditions were former smokeless tobacco users or former snus users (test: 2% [1.2%-2.8%]; control: 2% [1.2%-2.8%]).

6.3.4.2.3 Mean Intent Ratings for Purchasing Camel Snus and Projected Rates of Actual Purchase

Respondents in the test and control conditions were asked to rate their likelihood “to purchase Camel Snus in order to try it” on a scale from 1 (definitely would not purchase to try) to 10 (definitely would purchase to try) after viewing the test or control advertisement. The mean rating of likelihood to purchase for trial among respondents in the test condition was 2.0 (95% CI: 1.92-2.08) on the 10-point scale, which was significantly higher than the control condition (1.9 [95% CI: 1.83-1.97]) ($p < 0.05$). These intent-to-purchase ratings were used to project purchase rates. For the sample as a whole, the estimated rate of purchase for those in the test condition was 1.7% (1.1%-2.5%), which was significantly higher than the control condition (1.5%, 1.0%-2.3%) ($p < 0.05$).

6.3.4.2.4 Tobacco Use Status

The benefit to public health of a modified risk tobacco product is achieved when it is adopted by current users of tobacco products that pose greater health risks. Conversely, adoption of Camel Snus by non-users of tobacco confers risk. Therefore, it is important that statements made about the modified risk product not attract non-users of tobacco (former and never users).

Rated likelihood of use. The ratings of the likelihood to purchase Camel Snus were significantly higher ($p < 0.0001$) among current regular tobacco users than among former and never tobacco users (Table 6.3.4-2), and higher among respondents who saw the test advertisement ($p < 0.01$).

⁶ Respondents were considered cigarette smokers if they smoked manufactured cigarettes. Only 38 respondents (21 test condition, 17 control condition) indicated smoking roll-your-own cigarettes; these were counted as tobacco users but not cigarette smokers.

Further, there was an interaction ($p < 0.05$) such that the test advertisement increased rated interest among current users but not among never or former users.

Table 6.3.4-2: Likelihood to Purchase Ratings and Projected Purchase Rates by Current Tobacco Use Status

| Likelihood to Purchase Ratings (1-10) by Current Tobacco Use Status | | | |
|--|---|-------------------------------------|------------------------------------|
| Mean (95% CI) | | | |
| | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 3.7 [†] (3.51-3.89) (n=1,735) | 1.6 (1.5-1.7) (n=1,689) | 1.7 (1.6-1.8) (n=2,226) |
| Control (without proposed modified risk messaging) | 3.3 (3.12-3.48) (n=1,733) | 1.6 (1.5-1.7) (n=1,690) | 1.7 (1.6-1.8) (n=2,232) |
| Projected Purchase Rates (%) by Current Tobacco Use Status | | | |
| % (95% CI) | | | |
| | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 7.5% [†] (5.6%-10.2%) (n=1,733) | 1.4% (0.7%-2.6%) (n=1,689) | 0.4% (0.2%-0.7%) (n=2,226) |
| Control (without proposed modified risk messaging) | 6.8% (5.0%-9.2%) (n=1,733) | 1.2% (0.6%-2.4%) (n=1,690) | 0.4% (0.2%-0.7%) (n=2,232) |

[†] Statistically significant versus control.

Projected purchase rates. Projected purchase rates were significantly higher ($p < 0.001$) among current regular tobacco users than among former and never tobacco users, and higher ($p < 0.001$) among those who saw the test advertisement. An interaction ($p < 0.001$) showed that the test advertisement differentially and specifically increased projected purchase among current tobacco users, compared to former or never users. The group to which the proposed modified risk advertising is targeted (current regular tobacco users) was most likely to be interested in purchasing Camel Snus. The projected purchase rates among those not currently using tobacco – the population for which the product is *not* intended – were low in both arms and were not increased by the proposed modified risk advertising.

6.3.4.2.5 Potential Quitters

A concern about modified risk advertising is that it might attract tobacco users who expect to or are likely to quit all tobacco use, potentially diverting or delaying them from quitting. Accordingly, the effect of the proposed modified risk advertising was tested among tobacco users who were potential quitters (expected to quit all tobacco products within 9 months).

Rated likelihood of use. The ratings for intent to purchase among current tobacco users who were potential quitters (test: $n = 253$; control: $n = 226$) were significantly lower ($p < 0.0001$) than

the ratings of tobacco users who were not potential quitters (Table 6.3.4-3). Overall, ratings were higher in response to the test advertisement ($p < 0.05$), and this effect seemed to be concentrated in those not expecting to quit ($p < 0.0001$), but there was no interaction.

Projected purchase rates. The projected rates of purchase were significantly ($p < 0.0001$) lower among current tobacco users who were potential quitters than among current users who were not potential quitters. There was a significant effect of the test advertising within both groups, but no interaction.

Table 6.3.4-3: Likelihood to Purchase Ratings and Projected Purchase Rates among Current Tobacco Users by Quitting Status

| Likelihood to Purchase Ratings (1-10) among Current Tobacco Users by Quitting Status | | | |
|---|---|-----------------------------|---|
| Mean (95% CI) | | | |
| | Current Regular Tobacco Users | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 3.7 [†] (3.51-3.89) (n=1,735) | 2.6 (2.21-2.99) (n=253) | 3.8 [†] (3.6-4.0) (n=1,482) |
| Control (without proposed modified risk messaging) | 3.3 (3.12-3.42) (n=1,733) | 2.2 (1.87-2.53) (n=226) | 3.5 (3.31-3.69) (n=1,507) |
| Projected Purchase Rates (%) among Current Tobacco Users by Quitting Status | | | |
| % (95% CI) | | | |
| | Current Regular Tobacco Users | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 7.5% [†] (5.7%-10.4%) (n=1,735) | 4.5% (3.1%-6.3%) (n=271) | 8.0% (6.2%-11.2%) (n=1,482) |
| Control (without proposed modified risk messaging) | 6.8% (5.0%-9.2%) (n=1,733) | 3.9% (2.7%-5.7%) (n=226) | 7.2% (5.3%-9.7%) (n=1,507) |

[†] Statistically significant versus control.

These findings suggest that, among current tobacco users, Camel Snus is less appealing to potential quitters, and the proposed modified risk advertising only slightly increased the appeal to potential quitters and much less so than among current regular tobacco users not intending to quit tobacco use.

6.3.4.2.6 Cigarette Use Status

The results above assessed likelihood to purchase among respondents based on their use of any tobacco product. Since the proposed modified risk advertising targets cigarette smokers in particular (a group using a product with significantly greater risk than snus), it was important to assess the impact of the modified risk advertising on this group specifically, as well as among former and never smokers, for whom this product is not intended.

Rated likelihood of use. Interest in purchasing Camel Snus was significantly higher ($p < 0.0001$) among current regular smokers than among both former smokers and never smokers (Table 6.3.4-4). The test advertisement elicited significantly greater interest, and this reflected an effect of the test advertisement on current regular smokers, with no advertisement effect among former or never smokers ($ps > 0.05$), resulting in a significant ($p < 0.05$) interaction. That is, the test advertisement differentially appealed to current smokers, rather than to former or never smokers.

Projected purchase rates. The projected rate of purchase was significantly higher ($p < 0.0001$) among current regular smokers than among both former smokers and never smokers (Table 6.3.4-4). The test advertisement elicited significantly higher projected purchase, and this reflected an effect of the test advertisement on current regular smokers, with no advertisement effect among former or never smokers ($ps > 0.05$), resulting in a significant ($p < 0.05$) interaction. That is, the test advertisement differentially appealed to current smokers, rather than to former or never smokers.

Table 6.3.4-4: Likelihood to Purchase Ratings and Projected Purchase Rates by Current Cigarette Use Status

| Likelihood to Purchase Ratings (1-10) by Current Cigarette Use Status | | | |
|--|---|---------------------------------------|--------------------------------------|
| Mean (95% CI) | | | |
| | Current Regular Cigarette Users | Former Regular Cigarette Users | Never Regular Cigarette Users |
| Test (with proposed modified risk messaging) | 3.8 [†] (3.59-4.01) (n=1,354) | 1.9 (1.79-2.01) (n=1,886) | 1.7 (1.6-1.8) (n=2,410) |
| Control (without proposed modified risk messaging) | 3.4 (3.2-3.6) (n=1,328) | 1.8 (1.69-1.91) (n=1,897) | 1.7 (1.61-1.79) (n=2,430) |
| Projected Purchase Rates (%) by Current Cigarette Use Status | | | |
| % (95% CI) | | | |
| | Current Regular Cigarette Users | Former Regular Cigarette Users | Never Regular Cigarette Users |
| Test (with proposed modified risk messaging) | 8.0% [†] (5.9%-10.8%) (n=1,354) | 2.0% (1.3%-3.4%) (n=1,886) | 0.4% (0.3%-0.8%) (n=2,410) |
| Control (without proposed modified risk messaging) | 6.9% (5.1%-9.4%) (n=1,328) | 2.0% (1.2%-3.3%) (n=1,897) | 0.4% (0.3%-0.8%) (n=2,430) |

[†] Statistically significant versus control.

These findings demonstrate that the proposed modified risk advertising for Camel Snus did not inappropriately appeal to those for whom the product is not intended (former and never smokers) but that the proposed advertising did significantly increase rated interest in purchasing and projected rates of purchase among current cigarette smokers.

6.3.4.2.7 Potential Quitters

Rated likelihood of use. Among current regular smokers, interest in purchasing Camel Snus was assessed by potential quitting status (intending to quit in the next 9 months). Current regular cigarette smokers who were potential quitters rated their likelihood to purchase Camel Snus significantly lower ($p < 0.0001$) than current cigarette smokers who were not potential quitters (Table 6.3.4-5). The test advertisement elicited significantly ($p < 0.05$) higher ratings, but not differentially across groups (*i.e.*, no interaction). This finding suggests that adding the proposed modified risk advertising to Camel Snus does not differentially appeal to smokers who are interested in quitting.

Projected purchase rates. In both arms of the study, the projected rates of purchase for current smokers who were potential quitters were significantly lower ($p < 0.0001$) than they were for cigarette smokers who were not expecting to quit tobacco use (Table 6.3.4-5). The test advertisement resulted in higher projected purchase rates ($p < 0.05$). There was no interaction effect between the advertisement and smoking status, meaning that there were no differential effects of the advertisement across the two groups of smokers.

Table 6.3.4-5: Likelihood to Purchase Ratings and Projected Purchase Rates by Quitting Status among Current Cigarette Users

| Likelihood to Purchase Ratings (1-10) by Quitting Status among Current Cigarette Users Mean (95% CI) | | |
|---|-----------------------------|--------------------------------|
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 2.7 (2.22-3.18) (n=187) | 3.9 (3.67-4.13) (n=1,167) |
| Control (without proposed modified risk messaging) | 2.3 (1.87-2.73) (n=155) | 3.5 (3.28-3.72) (n=1,173) |
| Projected Purchase Rates (%) by Quitting Status among Current Cigarette Users % (95% CI) | | |
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 4.7% (3.4%-6.6%) (n=187) | 8.5% (6.3%-11.3%) (n=1,167) |
| Control (without proposed modified risk messaging) | 4.0% (2.7%-5.8%) (n=155) | 7.3% (5.4%-9.8%) (n=1,173) |

These findings suggest that smokers who are expecting to quit smoking will not be differentially attracted by the modified risk messaging in the proposed advertisement.

6.3.4.2.8 Young Adults – Overall

Young adults (aged 18-24) are a group of particular interest for several reasons. Their present tobacco use patterns may not be as stable as those of older adults. Consequently, those young

adults who are not presently using tobacco products may begin using tobacco products in the future, making it important to assess whether a modified risk tobacco product is attractive to this group. On the other hand, those young adults who are currently using tobacco products may not be as committed to continued smoking as older smokers and may be more amenable to switching to a lower risk product. The younger a person is when they reduce their exposure to the harmful constituents in tobacco and tobacco smoke, the lower their lifetime health risk from use (Jha *et al.* 2013). Finally, the responses of young adults may be a proxy indicator for responses by those under legal purchase age. Therefore, appealing to young adult tobacco users with a lower risk product may greatly reduce their lifetime disease risk. At the same time, advertising should not increase appeal to the young adults who are not using tobacco, to avoid increasing the prevalence of tobacco use.

Rated likelihood of use. Young adults who were current regular tobacco users were significantly ($p < 0.0001$) more interested in purchasing Camel Snus than were young adult former and never regular tobacco users (Table 6.3.4-6). The difference in interest in purchasing Camel Snus was not significantly different ($p > 0.05$) between young adults who saw the modified risk advertisement compared to those who saw the control advertisement, nor was there an interaction. These findings suggest that, among young adults, the proposed modified risk advertising does not differentially increase interest in Camel Snus among former and never regular tobacco users.

Projected purchase rates. The projected rates of purchase for young adults were significantly greater among current tobacco users ($p < 0.0001$) than former or never users (Table 6.3.4-6). The difference in interest in purchasing Camel Snus was not significantly different ($p > 0.05$) between young adults who saw the proposed modified risk advertising compared to those who saw the control advertisement, nor was there an interaction. These findings suggest that, among young adults, the proposed modified risk advertising does not differentially attract non-tobacco users.

Table 6.3.4-6: Likelihood to Purchase Ratings and Projected Rates of Purchase among Young Adults by Current Tobacco Use Status

| Likelihood to Purchase Ratings (1-10) among Young Adults by Current Tobacco Use Status Mean (95% CI) | | | | |
|---|----------------------------|-------------------------------|------------------------------|-----------------------------|
| | All Young Adults | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 2.2 (1.94-2.46) (n=443) | 4.3 (3.51-5.09) (n=80) | 3.8 (2.6-5.0) (n=33) | 1.8 (1.52-2.08) (n=330) |
| Control (without proposed modified risk messaging) | 2.1 (1.84-2.36) (n=474) | 3.9 (3.14-4.66) (n=96) | 2.9 (1.8-4.0) (n=34) | 1.8 (1.52-2.08) (n=344) |

| Projected Purchase Rates (%) among Young Adults by Current Tobacco Use Status % (95% CI) | | | | |
|---|--------------------------------|---------------------------------|--------------------------------|--------------------------------|
| | All Young Adults | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 1.8% (1.1%-2.7%) (n=443) | 11.5% (8.2%-15.8%) (n=80) | 4.6% (1.8%-10.8%) (n=33) | 0.4% (0.2%-0.7%) (n=330) |
| Control (without proposed modified risk messaging) | 1.8% (1.2%-2.7%) (n=474) | 10.8% (7.7%-14.9%) (n=96) | 3.1% (1.2%-7.7%) (n=34) | 0.4% (0.2%-0.7%) (n=344) |

These findings suggest that young adult current, regular tobacco users are interested in trying Camel Snus, but the proposed modified risk advertising did not differentially attract young adults who were not currently using tobacco products.

6.3.4.2.9 Young Adults – Potential Quitters

As with all tobacco users who are potential quitters, it was important to assess specifically the interest of young adults who are potential quitters in purchasing Camel Snus.

Rated likelihood of use. Young adult current tobacco users who were potential quitters were significantly ($p < 0.0001$) less likely than those who were not potential quitters to be interested in purchasing Camel Snus. There was no difference between the test and control conditions, and no interaction between quit intent and test versus control condition, meaning that the difference between the test and control advertisements did not differ by intent to quit. These results suggest that interest in Camel Snus was higher among young adult current tobacco users who were not expecting to quit using tobacco, but the test advertisement did not differentially attract those who were expecting to quit tobacco use.

Projected purchase rates. The projected rates of purchase were in the same direction as the interest ratings. Young adult potential quitters were significantly less likely to purchase Camel Snus than young adults not expecting to quit tobacco ($p < 0.001$) (Table 6.3.4-7). The effect was similar for both the test and control advertisements, and there was no interaction.

Table 6.3.4-7: Likelihood to Purchase Ratings and Projected Purchase Rates by Quitting Status among Young Adults

| Likelihood to Purchase Ratings (1-10) by Quitting Status among Young Adults Mean (95% CI) | | |
|--|---------------------------|---------------------------|
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 1.4 (1.02-1.78) (n=11) | 4.6 (3.76-5.44) (n=69) |
| Control (without proposed modified risk messaging) | 1.8 (1.07-2.53) (n=14) | 4.3 (3.47-5.13) (n=82) |

| Projected Purchase Rates (%) by Quitting Status among Young Adults % (95% CI) | | |
|--|----------------------------|------------------------------|
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 3.2% (1.9%-5.4%) (n=15) | 12.4% (8.9%-17.0%) (n=82) |
| Control (without proposed modified risk messaging) | 4.0% (2.5%-6.3%) (n=14) | 11.8% (8.5%-16.2%) (n=82) |

These results among young adults indicate that the proposed modified risk advertising did not differentially attract those who were potential quitters.

6.3.4.2.10 White Males – Overall

Interest in purchase among white males was assessed because they have traditionally been the primary users of smokeless tobacco products in the U.S. (USDHHS 2014).

Rated likelihood of use. White males who were current regular tobacco users were significantly more interested in purchasing Camel Snus than were white male former and never tobacco users ($p < 0.0001$) (Table 6.3.4-8). There was no effect of the test advertisement and no interaction.

Projected purchase rates. Projected rates of purchase among white males overall was similarly not affected by the proposed modified risk advertising, but projected rates of purchase were significantly greater for white male current regular tobacco users than among former and never tobacco users ($p < 0.0001$) (Table 6.3.4-8). There was no effect of the test advertisement and no interaction.

Table 6.3.4-8: Likelihood to Purchase Ratings and Projected Purchase Rates among White Males by Current Tobacco Use Status

| Likelihood to Purchase Ratings (1-10) among White Males by Current Tobacco Use Status Mean (95% CI) | | | | |
|--|----------------------------|-------------------------------|------------------------------|-----------------------------|
| | White Males | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 1.9 (1.8-2.0) (n=2,641) | 3.5 (3.21-3.79) (n=708) | 1.3 (1.21-1.39) (n=1,013) | 1.6 (1.47-1.73) (n=920) |
| Control (without proposed modified risk messaging) | 1.8 (1.7-1.9) (n=2,666) | 3.2 (2.92-3.48) (n=710) | 1.4 (1.31-1.49) (n=1,011) | 1.5 (1.37-1.63) (n=945) |

| Projected Purchase Rates (%) among White Males by Current Tobacco Use Status % (95% CI) | | | | |
|--|----------------------------------|--------------------------------|----------------------------------|--------------------------------|
| | White Males | Current Regular Tobacco Users | Former Regular Tobacco Users | Never Regular Tobacco Users |
| Test (with proposed modified risk messaging) | 1.6% (1.1%-2.3%) (n=2,741) | 6.5% (4.7%-8.8%) (n=708) | 0.7% (0.4%-1.3%) (n=1,013) | 0.3% (0.2%-0.6%) (n=920) |
| Control (without proposed modified risk messaging) | 1.4% (1.0%-2.1%) (n=2,666) | 6.0% (4.4%-8.2%) (n=710) | 0.8% (0.4%-1.4%) (n=1,011) | 0.3% (0.2%-0.6%) (n=945) |

These findings demonstrate that white male current tobacco users, one of the groups more likely to use Camel Snus, is interested in purchasing the product for trial and has significantly higher projected purchase rates than former and never regular tobacco users.

White males who do not currently use tobacco expressed little interest in purchasing it, and the modified risk advertising had no effect on their interest. There were lower rates of projected purchase for the groups (former and never tobacco users) for which the product is not intended, suggesting that the interest in Camel Snus among white males is fairly confined to those who are more likely to obtain a reduction in risk by using it, and that the proposed modified risk advertising did not differentially attract those for whom it is not intended.

6.3.4.2.11 White Males – Potential Quitters

Rated likelihood of use. White male current tobacco users who were potential quitters were significantly less interested in purchasing Camel Snus than those who were not potential quitters ($p < 0.0001$) (Table 6.3.4-9). The test advertisement resulted in higher ratings, but there was no interaction.

Projected purchase rates. The projected rates of purchase for white male potential quitters were significantly lower than the projected rates of purchase for white male current tobacco users who were not potential quitters ($p < 0.0001$). There was no effect of the test advertisement and no interaction. This suggests that the proposed modified risk advertising is not negatively impacting potential quitters' decisions with regard to their continued use of tobacco products (Table 6.3.4-9).

Table 6.3.4-9: Likelihood to Purchase Ratings and Projected Purchase Rates by Quitting Status among White Males

| Likelihood to Purchase Ratings (1-10) by Quitting Status among White Males Mean (95% CI) | | |
|---|----------------------------|-------------------------------|
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 3.1 (2.42-3.78) (n=94) | 3.6 (3.29-3.91) (n=614) |
| Control (without proposed modified risk messaging) | 2.3 (1.79-2.81) (n=99) | 3.4 (3.09-3.71) (n=611) |
| Projected Purchase Rates (%) by Quitting Status among White Males % (95% CI) | | |
| | Potential Quitters | Not Potential Quitters |
| Test (with proposed modified risk messaging) | 5.2% (3.8%-7.2%) (n=94) | 6.7% (4.9%-9.0%) (n=614) |
| Control (without proposed modified risk messaging) | 3.4% (2.3%-5.0%) (n=99) | 6.4% (4.7%-8.7%) (n=611) |

These findings suggest that the proposed modified risk advertising is not likely to increase interest in or purchase of Camel Snus by white males who are expecting to quit tobacco use.

6.3.4.2.12 Reasons for Using Camel Snus

Since tobacco users who are interested in quitting tobacco altogether are not the intended population for a modified risk tobacco product, respondents who were potential quitters yet indicated any likelihood at all of trying Camel Snus (*i.e.*, rating their interest at 2 or greater on the 1-to-10 scale; test: n=94; control: n=74) were asked what their reason was for wanting to try Camel Snus. The pattern of answers differed between the test and control arms ($p < 0.05$). In the test condition, 49% (37.1%-60.9%) stated their reason was “to help me quit.” Among those who saw the control advertisement, 27% (15.0%-39.0%) also stated their reason was “to help me quit.”

Curiosity was also commonly cited as a reason potential quitters gave for their interest in trying Camel Snus. Half (50%; 35.8%-64.2%) of those who saw the control advertisement and 25% (13.8%-36.2%) who saw the test advertisement cited curiosity as their reason for interest in trying Camel Snus. Potential quitters in the test condition were more likely to select “to help me quit” and less likely to select “just curious about it” than potential quitters in the control condition. This finding suggests that there were some potential quitters who viewed Camel Snus as a potential gateway *out* of tobacco use, particularly among those who saw the proposed modified risk advertising.

The proposed modified risk advertising did not increase interest in using Camel Snus because it might “allow me to use in situations where I cannot use my current product” (test: 9% [1.4%-16.6%]; control: 11% [2.5%-19.5%]).

Overall, these results suggest that exposure to the proposed modified risk advertising for Camel Snus did not differentially invoke adverse motives for trying Camel Snus among current tobacco users who were potential quitters, and may have promoted cessation-oriented motives for trying Camel Snus.

6.3.4.2.13 Intended Use among Smokers Not Expecting to Quit

Use of Camel Snus would provide the greatest health benefit to cigarette smokers who switch completely to snus from cigarettes. In order to assess how likely this change might be, respondents who expressed any interest at all in Camel Snus – those who rated their likelihood to purchase Camel Snus as a 2 or higher on the 1-to-10 scale – were asked how they would use Camel Snus. Response options included “instead of my current tobacco product,” “in addition to my current tobacco product,” “in place of some of my current tobacco product,” and “don’t know.”

Among current regular cigarette smokers who were not expecting to quit tobacco use, 19% (15.4%-22.6%) in the test condition and 20% (16.0%-24.0%) in the control condition indicated that they would use Camel Snus *instead of* cigarettes (*i.e.*, stop use of cigarettes and use snus only). Slightly more than one-quarter in both conditions (test: 26% [21.7%-30.3%]; control: 26% [22.1%-29.9%]) did not know how they would use Camel Snus, and 32% (27.6%-36.4%) in the test condition and 26% (22.1%-29.9%) in the control condition said they would use it in place of some of the tobacco they currently consumed. There were some cigarette smokers who said they would add Camel Snus to their current tobacco use (test: 23% [18.7%-27.3%]; control: 27% [23.0%-30.0%]). Thus, some respondents interested in using Camel Snus thought they would use it in ways that are not optimal. However, exposure to the proposed modified risk advertising did not increase the proportion that would do so ($p>0.05$).

6.3.4.2.14 Switching to Smoking After Using Camel Snus

Among those who may use Camel Snus, it is important to evaluate the likelihood that they might subsequently switch (or switch back) to smoking, which would increase their health risk. This is particularly important for those who are not using tobacco at the time they started using Camel Snus.

Current regular cigarette smokers who stated that they would use Camel Snus *instead of* cigarettes rated their likelihood to switch back to cigarettes after trying Camel Snus on a 10-point scale (1 = not at all likely, 10 = very likely). Those exposed to the proposed modified risk advertising were no more likely to switch back to cigarettes (7.0; 6.49-7.51) than those not exposed to the proposed modified risk advertising (7.1; 6.5-7.7). These findings suggest that exposure to the proposed modified risk advertising does not change the risk of reverting to smoking after trying Camel Snus.

Former regular tobacco users who expressed any interest at all in trying Camel Snus (*i.e.*, they rated their likelihood to purchase Camel Snus a 2 or higher) were then asked to rate how likely they would be to switch to a different tobacco product after using Camel Snus. Ratings were similar between those who viewed the proposed modified risk advertising (4.4; 3.95-4.85) and those who saw the control advertisement (4.5; 4.07-4.93). The data suggest that the proposed modified risk advertising does not increase the likelihood that a former smoker will return to smoking compared to the control advertisement.

The intentions of never regular tobacco users are important to examine since movement of this group, which is at the lowest health risk given their abstinence from tobacco, into higher-risk tobacco use (such as smoking) would be an adverse public health impact. This has been discussed as the "gateway" effect. Never regular tobacco users who expressed any interest in purchasing Camel Snus (at least 2 on the 1-to-10 scale) rated their likelihood to switch to another tobacco product similarly regardless of which advertisement they viewed (test: 4.4; 4.02-4.78; control: 4.8; 4.46-5.14). Thus, the proposed modified risk advertising does not appear to promote progression from use of Camel Snus to products such as cigarettes that pose more risk. Along with the finding that the proposed modified risk advertising does not attract increased interest among those who never used tobacco, this finding suggests modified risk advertising for Camel Snus is unlikely to lead to "gateway" effects that might result in increased smoking.

6.3.4.3 Conclusions

Modified risk tobacco products provide a potential health benefit to those who switch to them from tobacco products that pose a greater risk to health. The likelihood of use study was conducted to determine whether the proposed modified risk advertising for Camel Snus would appeal to those for whom it would provide a benefit in the form of reduced health risk (*i.e.*, current cigarette smokers), and, most importantly, whether the modified risk advertising would have unintended consequences by differentially attracting those for whom use would not be beneficial (non-smokers and smokers expecting to quit). In addition, the study evaluated whether the anticipated modes of use would be consistent with a public health benefit (*i.e.*, as a replacement for a greater risk product among those who are not expecting to quit tobacco completely).

Overall, interest in Camel Snus was greatest among current cigarette smokers, for whom switching to Camel Snus would confer a benefit. Overall, interest in Camel Snus was greatest among current cigarette smokers, for whom switching to Camel Snus would confer a benefit. The test advertisement containing modified risk messages differentially attracted interest and projected purchase from current smokers, rather than from former or never smokers. It did not differentially appeal to those expecting to quit, and, indeed, overall interest in Camel Snus was substantially lower among those expecting to quit. Among the small number of potential quitters who expressed any interest in purchasing Camel Snus, approximately 40% indicated that their motive for trying it was "to help me quit." These results are reassuring that the

proposed modified risk advertising is not likely to keep smokers interested in quitting from doing so.

Among current regular smokers not intending to quit smoking who expressed an interest in using Camel Snus, approximately half intended to replace some or all of their cigarettes with Camel Snus. About one in five, though, said they would add it to their current cigarette consumption. Such behavior could mitigate the overall population health benefit of a modified risk product.

There was interest in purchasing Camel Snus among white male current tobacco users, a group that has traditionally been more willing to use smokeless tobacco products in general. Among this group, those interested in quitting all tobacco were less likely than those not interested in quitting tobacco to express interest in purchasing Camel Snus and had significantly lower projected purchase rates than those expecting to continue using tobacco. These findings suggest that the proposed modified risk advertising did appeal to white males who use tobacco and are not interested in quitting while not attracting those who are interested in quitting tobacco.

Young adults are a group whose current tobacco use patterns may not yet be fully established. Therefore, those young adults who are not presently using tobacco products may not be resistant to taking up tobacco use and those who are presently using may be more open to switching to a lower risk product. The younger a person is when they reduce their exposure to the harmful constituents in tobacco and tobacco smoke, the lower their lifetime health risk from use ([Jha et al. 2013](#)). Therefore, appealing to young adult tobacco users with a lower risk product can greatly reduce their lifetime disease risk. In this study, young adult tobacco users showed the highest level of interest in trying Camel Snus of all the groups studied. Further, the proposed modified risk advertising had specific appeal to young adult current tobacco users. Young adults who were not expecting to quit tobacco were more interested in purchasing Camel Snus than young adults who were expecting to quit. These findings suggest that Camel Snus may have some benefit for young adults already using tobacco and help alleviate some concern about potentially inappropriate interest among young adults in this modified risk tobacco product.

The findings from this single-exposure study generally suggest that there is low interest among all respondents in using Camel Snus, which is consistent with the literature on use of snus in the U.S. ([King et al. 2012](#)). Exposure to the proposed modified risk advertising did not differentially attract interest from any of the groups for whom snus use could increase risk: never tobacco users, former tobacco users, or current tobacco users expecting to quit. The proposed advertising also did not increase the likelihood that former smokers who might adopt Camel Snus would return to smoking or that non-tobacco users who might try Camel Snus would progress onto cigarette smoking (*i.e.*, "gateway" effects). Thus, the data strongly suggest that the proposed modified risk advertising would not cause harm, and is likely to encourage trial among current smokers, which would benefit individual and population health.

6.3.4.4 Limitations and Strengths

Like any study, this study had some limitations. The sample was drawn from an opt-in online panel, and thus may not be fully representative of the U.S. population, not all of whom have internet access or join panels. However, strong majorities of Americans are now online (Perrin and Duggan 2015), and online panels can produce reasonable estimates (Farrell and Petersen 2010). Moreover, the sample was recruited and weighted to represent the demographics of the U.S. population.

The proposed modified risk advertising is intended to be used in multiple marketing platforms and media, but here it was viewed via an online, on-screen display in a research context. However, such methods are often used to evaluate communications (Sullivan *et al.* 2015), and there is little reason to think the results are not generalizable to other media.

The study measured the effects of a single exposure of the proposed modified risk advertisement for Camel Snus during the course of a survey, as opposed to the effects of multiple exposures over time in the real world in the context of advertising. Importantly, motivating smokers to switch to snus may rest on persuading them that snus is truly safer and able to reduce harm to them. Research shows that both smokers and non-smokers have pre-existing misconceptions about the risk of smokeless tobacco use relative to smoking, thinking that smokeless use is at least as hazardous as smoking (Fong *et al.* 2016; Kaufman *et al.* 2014; Kiviniemi and Kozlowski 2015; Regan *et al.* 2012). Data from the comprehension and perceptions studies of the proposed modified risk advertising for Camel Snus also suggested this. Thus, it may take multiple exposures, and consistent messages from multiple sources, including sources more credible than a tobacco company advertisement, for smokers to appreciate the potential of Camel Snus to reduce their health risk. Similarly, exposure to multiple messages about the importance of switching completely from smoking to Camel Snus could promote appropriate health-protective behavior.

Projected estimates of likely Camel Snus purchase for trial were derived from a model based on and validated in the context of cigarettes, rather than a smokeless product, and did not specifically test the link between stated interest and purchase in the context of modified risk advertising. Moreover, validation studies showed that purchase is over-estimated by the projection algorithm, though the differential purchase of different groups is accurately captured. Further, the algorithm models initial purchase for trial, and not long-term persistence, which is important to the expected harm-reduction benefit of switching to snus. A study (Carpenter *et al.* 2016) found that, among smokers who tried snus, 8% reported any use at the 6-month follow-up and 4% at the 12-month follow-up. Thus, the projected use data over-estimate the actual expected use, especially in the long-term. However, they should do so evenly across the different population groups examined, thus preserving the conclusion that the proposed advertisement does not differentially appeal to the groups that would not benefit from switching to Camel Snus. In any case, the raw "likelihood to purchase" data also lead to similar conclusions, so limitations of the projected purchase algorithm do not affect the reassuring conclusions.

The study also had considerable strengths. The sample was large, diverse, and sampled and weighted to match the demographics of U.S. adults. It included a broad range of demographics. The study included current, former, and never users of tobacco products, and also analyzed responses from important subgroups based on demographics and tobacco-use history. The data on rated likelihood of use were translated into projections of likely purchase, taking into account empirical observations about how such ratings translate into real-world behavior.

6.3.4.5 Summary – Execution 3

The study assessed interest in Camel Snus among a variety of populations when exposed to the proposed modified risk advertising. Overall, interest was modest. Importantly, the data suggest that the proposed modified risk advertising did not increase the appeal of the product to populations where adoption of it would increase harm rather than confer benefit—never smokers, former smokers, and tobacco users expecting to quit tobacco use. The data were also inconsistent with the concern that non-tobacco users (former users or never users) who try snus would progress to cigarette smoking. These data mitigate concerns about adverse effects on population health from the proposed modified risk advertising for Camel Snus. Moreover, the proposed modified risk advertising differentially increased interest and projected purchase among current smokers, who stand to benefit from switching to Camel Snus, and not among never or former smokers. On balance, the data suggest that the proposed modified risk advertising encouraging current smokers to switch to Camel Snus would likely result in benefits to population health.