Effects of FDA Authorized Smokeless Tobacco Claims among US Adults who Smoke Cigarettes

NCT Number: NCT06927700

Protocol and Statistical Analysis Plan

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Study Protocol

Purpose/Specific Aims

This study is an online survey experiment conducted with adults who smoke cigarettes (ages 21+) to examine their reactions to Modified Risk Tobacco Product (MRTP) advertising claims authorized by the Food & Drug Administration (FDA) for two smokeless tobacco brands (General Snus and Copenhagen), which describe the lower risks of these products compared to cigarette smoking. The overall aim is to examine the potential impact of FDA authorized modified risk claims about select smokeless tobacco products on smokers' perceptions about and interest in using these products, and to examine whether perceptions are influenced by the claim type (reference to reduced risks for lung cancer only versus multiple diseases) and brand source.

Hypotheses / Research Question(s)

We hypothesize that those exposed to ads with any authorized MRTP claim will report lower product harm perceptions and higher interest in using the product than those in the no-claim condition. We will explore whether the Multiple Diseases claim results in stronger effects than the Lung-Only claim, and if this interacts with brand. We will also explore differences in perceived ad and claim strength/persuasiveness based on claim type.

Research Design and Methods

We contracted with the research company Ipsos (as a fee-for service contract) to implement an online cross-sectional survey (designed by our research team) with a national sample of 1257 adults who smoke cigarettes (ages 21+). Participants were invited by Ipsos from their national panel of research participants (KnowledgePanel). In terms of Inclusion Criteria, the study was limited to adults (age 21 and over) who are current established cigarette smokers (i.e., smoked 100 cigarettes in their lifetime and now smoke every day or somedays), based in the US, and who have chosen to complete their Ipsos research panel surveys in English. Invited participants who were interested and eligible for the online survey provided online consent before proceeding to the main survey. Eligible participants who began the survey first completed questions about their smoking history, then were randomized by Ipsos' online survey platform to one of six ad conditions for an embedded 2x3 (Brand x Claim type) between-subjects experiment. In each condition, participants viewed 4 smokeless tobacco ads (with a set viewing time of 8 seconds each) before completing outcome measures in the survey. At the end of the survey, all participants were shown a debriefing page, explaining the study objectives and any relevant manipulations/deceptions per their condition. The median completion time was 12 minutes.

Independent Variables, Interventions, or Predictor Variables

The main independent variables are Claim Type (3 conditions) and Brand (two conditions). Participants were randomized to one of six ad conditions in an embedded 2x3 (Brand x Claim type) between-subjects experiment. In each condition, participants viewed 4 ads that varied by two main factors (independent variables): Brand (Copenhagen or General Snus) and MRTP Claim type (None; Reduced risk of multiple diseases; Reduced lung cancer only). We adapted Copenhagen's FDA authorized MRTP claim for the "Lung-Only" claim conditions, and General Snus' FDA authorized claim for the "Multiple Diseases" conditions. We identified real Copenhagen and General Snus ads and manipulated these as needed per the relevant conditions. Arm descriptions:

- Group 1 (General Snus-Control Ads): Participants in this group viewed 4 ads for the brand General Snus that did not include a modified risk claim.
- Group 2 (General Snus-Multiple Disease Ads): Participants in this group viewed 4 ads for the brand General Snus that included a modified risk claim about the lower risk of multiple diseases.
- Group 3 (General Snus- Lung Ads): Participants in this group viewed 4 ads for the brand General Snus that included a modified risk claim about the lower risk of lung cancer only.
- Group 4 (Copenhagen-Control Ads): Participants in this group view 4 ads for the brand Copenhagen that did not include a modified risk claim.
- Group 5 (Copenhagen-Multiple Disease Ads): Participants in this group viewed 4 ads for the brand Copenhagen that included a modified risk claim about the lower risk of multiple diseases.
- Group 6 (Copenhagen- Lung Ads): Participants in this group viewed 4 ads for the brand Copenhagen that included a modified risk claim about the lower risk of lung cancer only.

Dependent Variables or Outcome Measures

Based on the comparative risk content and premise of the claims, the primary outcome measures (asked after ad viewing) focus on perceived harmfulness/risks of the viewed ST products in general and compared to cigarettes, and participants' interest and intentions to use the viewed products. Secondary outcomes include recall of whether the ads made any risk comparisons with cigarettes, a comprehension question about the need for complete product switching to receive any reduced risk benefits, and ratings of the ads' perceived strength and persuasiveness (e.g., novelty, importance, credibility, believability of the information). Participants in the claim conditions are also shown and asked to rate the claim they viewed in the ads on similar measures of perceived claim believability and persuasiveness.

Statistical Analysis Plan

Analytic approach. Our primary hypothesis is that those exposed to ads with any authorized MRTP claim will report lower product harm perceptions and higher interest in using the product (primary outcomes) than those in the no-claim condition. We will also explore whether the Multiple Diseases claim results in stronger effects than the Lung-Only claim, and if this interacts with Brand. We will conduct a series of two-way ANOVA tests to examine main effects of Claim type and Brand, and Claim type X Brand interactions, with post-hoc analyses comparing both claim types (Lung only and Multiple Diseases) with the non-claim control groups. If a ClaimType x Brand interaction exists, we will stratify results by brand. We will also explore whether effects on use intentions vary by gender, given historical preferences for smokeless tobacco use by males versus females. For secondary outcomes, we will similarly use two-way ANOVA tests to examine main effects of Claim type and Brand (and Claim type X Brand interactions) on the perceived strength/persuasiveness of the ads and claims viewed. We will use chi-square tests to examine associations with intervention group and claim recall, and claim comprehension. We will use descriptive statistics to describe participant characteristics and the prevalence of participants' ever use of the products and exposure to the authorized claims prior to the study.

Sample size and power. With a sample size of 1200 and assuming no interaction by brand, we would have 400 subjects in each claim type group (No claim; Lung-only; Multiple Diseases) for evaluation of Claim type main effects on our primary outcomes. With this sample size, alpha set at 0.05 and a power level of 0.90, we estimate being able to detect effect sizes as small as approximately $\omega^2 = 0.01$.* If we stratify by a two-way factor (i.e., brand) so that group sizes are 200, this minimum detectable effect size increases to 0.02.

Data Preparation. Prior to performing analyses, standard data screening/cleaning procedures will be applied. These procedures will (1) screen the data for data recording errors, (2) check for outliers, (3) assess the extent and pattern of missing data, and (4) check that appropriate assumptions of normality are met whenever necessary. In all analyses, the assumptions underlying the application of all the statistical methods that are used will be examined, principally using standardized residuals, influence diagnostics, and graphical displays. Where needed, appropriate transformations will be applied to ensure that data meet model assumptions. We will first use descriptive statistics to detail the demographics and tobacco history of the sample. We will test for equivalency of key characteristics across study conditions to ensure that randomization was successful.

Missing data: The most effective approach to eliminating biases and inefficiency caused by missing data is to collect complete data. We will follow best practices for survey design to minimize missing data. Where possible we will use established and previously used measures. The study team will review all drafted survey instructions, measures and response options, to help ensure they can be understood, and be understood accurately and consistently. We will not ask sensitive questions, be mindful of survey question order and make use of relevant skip logic. We will limit the survey length to 10-15 minutes to minimize respondent fatigue and facilitate response completeness. Some participants may still refuse to answer certain questions. During analysis, we will examine levels of missing, which we anticipate to be very low based on our previous work (0-~3% per variable). In resulting manuscripts, we will provide numbers or percentages of key outcomes with missing data as appropriate, particularly for any potential variables with higher levels of missing data.