Experimental Study of Consumer Response to Health Claims and Disclaimers
About the Relationship between Selenium and Risk of Various Cancers

0910-NEW

SUPPORTING STATEMENT

B. Statistical Methods

1. Respondent Universe and Sampling Methods

The population of interest is those who use supplements. Data provided by the nationally representative Health Information National Trends Survey (HINTS; Ref. 1) suggest that individuals over age 50 have a higher overall prevalence of cancer in general, and a higher prevalence of most of the specific cancers that are the subject of an existing QHC for selenium (Ref. 2), but do not systematically differ from individuals in other age groups with respect to their patterns of cancer-related perceptions.

The sampling frame for this study is Synovate's online Consumer Opinion Panel ("ePanel"); Synovate is the agency's contractor for this study. The target sample size for the experimental study is 1,200 respondents. U.S. male panelists who are 55 years of age and older and married U.S. female panelists who are 50 years of age and older will be invited to participate until the following quotas are met: 800 men who are 55 years or older and 400 married women who are 50 years or older.

By targeting participants in this age range and with these characteristics, the study is expected to maximize efficient use of the limited resources allocated to the project by yielding a greater amount of information pertinent to people who are more likely to take a selenium supplement. To that end, the study will aim for increased representation of potential selenium users by targeting a sample that includes at least 400 participants who have taken a selenium supplement at least once. Because the rate of selenium use in the general population is estimated to be low overall, but somewhat higher among men than women (Refs. 3 and 4), the sample will consist of a greater proportion of men. In addition, the screening process for the online consumer panel will limit female participants to those who report being married, and women enrolled in the study will be asked to provide information about their spouses' use of selenium in addition to their own.

Respondents for the cognitive interviews will be recruited from commercial databases of residents in the Washington, D.C. metropolitan area. We will recruit approximately 15 respondents over 50 years of age to make sure at least 9 of them will show up for the interviews. In addition, we will attempt to recruit one or more male respondents over 50 years of age who have ever used selenium and/or other dietary supplements.

As discussed in Section A2, we will test hypotheses related to between-label differences with respect to perceptions of, and behavioral intentions related to, claims about selenium's potential to reduce the risk of certain cancers. We will impose no a priori

direction of differences, if any (i.e., we assume all tests are two-tailed). The target sample size will yield approximately 100 observations for each of 12 experimental conditions. We expect that this will provide adequate power (i.e., $\alpha = 0.05$, $\beta = 0.2$) to identify main effects of a medium size and two-way interaction effects of a large size.

The study will use a convenience sample of self-selected members of an established online consumer panel, rather than a probability-based sample. The agency does not intend to generate nationally representative results or precise estimates of population parameters from this study. Nonetheless, the study design will yield valid and quantitative estimates of differences in consumer responses caused by variations between the different labels.

2. Procedures for the Collection of Information

The contractor will recruit and screen potential respondents for the cognitive interviews via telephone. The recruitment will target men and women who are 50 years of age or older. Eligible respondents will be asked to complete the draft questionnaire independently. Then, a moderator will interview each participant about how he or she interpreted certain questions and the process by which the participant selected his or her responses.

For the experimental study, eligible members of the ePanel (i.e., men 55 years or older and married women 50 years or older) will be invited by email to a dedicated Website to complete the study online. We estimate that it will take respondents about 10 minutes to complete the study.

The order of the question topics appearing in the questionnaire is displayed in Table 1.

Table 1. Structure of the study

Section	Topic
A	Eligibility for study inclusion (including selenium use)
B	Label responses, intentions to use selenium supplements, and other perceptions to compare how selenium is rated when labeled with different claims and/or disclaimers – perceived likelihood that selenium may reduce the risk of all forms of cancer, perceived likelihood that selenium may reduce the risk of a cancer for which there is no credible evidence of risk reduction, perceived likelihood that selenium may treat or completely prevent cancer, intentions to use selenium, beliefs about how selenium use may affect cancer, and perceptions of the understandability and trustworthiness of the information displayed. Participants will be assigned to view one label (e.g., no claim, or one claim in the presence or absence of a disclaimer) according to their randomly selected experimental condition assignment.
C	Beliefs, knowledge, and perceptions about cancer
D	Perceptions of dietary supplements
E	Experience with dietary supplements
F	Knowledge about dietary supplements and how they are regulated

G	Demographics, health status, and other covariates

Participants will view a randomly assigned label accompanied by a product identity caption (e.g., "Selenium Dietary Supplement"), but no brand names (either fictitious or real) will be included. Appendix A lists the proposed claims and disclaimers to be evaluated; Appendix B provides sample label mock-ups. Dependent measures will include perceived likelihood that selenium may reduce the risk of all forms of cancer, perceived likelihood that selenium may reduce the risk of a cancer for which there is no credible evidence of risk reduction, perceived likelihood that selenium may treat or completely prevent cancer, intentions to use selenium, beliefs about how selenium use may affect cancer, and perceptions of the understandability and trustworthiness of the information displayed (Section B in Table 1 above). Responses on the dependent measures will be compared across the experimental conditions.

Auxiliary measures will be collected and used to help understand participants' responses to the label (Sections C through G in Table 1 above). The planned measures include beliefs, knowledge, and perceptions about cancer; perceptions of, experience with, and knowledge about dietary supplements; and health status and demographics.

3. Methods to Maximize Response Rates and Deal with Non-response

To maximize response rates, we will conduct cognitive interviews and pretests to help improve understandability of the questionnaire, to reduce participant burden, and to enhance interview administration. We will keep the study questionnaire at a reasonable length to minimize non-completion.

In addition, the contractors will (1) identify FDA as the sponsor of the study and state the purpose of the study in their invitation and reminder to encourage participation (see Appendix C for reminder); (2) provide an email address and a toll-free number for prospective participants to inquire about the authenticity of the interview and other questions; and (3) monitor all interviews and sample assignment and solve any problems daily throughout the course of the collection of information.

4. Test of Procedures or Methods to be Undertaken

FDA plans to perform two tests to minimize collection burden on respondents and improve quality of collected information. The first test consists of cognitive interviews; the primary purpose of these interviews is to understand the thinking processes that respondents use to answer the survey questions.

The second test is field pretests focusing more on the length of the questionnaire and respondent burden. The contractor who is responsible for the data collection will administer the full questionnaire to 60 adult members of Synovate's web-based consumer panel shortly after OMB approval of the collection of information.

Some fine-tuning of the data collection activity may result from the cognitive interviews or the pretests, but substantive changes are not expected. This proposed information collection requests OMB approval for these described cognitive interviews and pretests.

We will submit a non-substantive change to OMB for the main collection. That change request will include a summary of the results of the cognitive testing and the pre-test, a summary of any changes to the survey procedures or data collection instruments, along with a final version of all of the materials to be used in the main collection. We will alert the OMB desk officer when those materials are submitted so that the clearance can be processed expeditiously.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

   David Lambert, PhD, Synovate has been consulted on statistical aspects of the study. Serena Lo, PhD, CFSAN, will lead the analysis of the data.

Reference

1. National Cancer Institute, Health Information National Trends Survey, 2007, available at http://hints.cancer.gov/
2. U.S. Food and Drug Administration, "Settlement Reached for Qualified Health Claims Relating Selenium to Reduced Risk of Prostate, Colon, Rectal, Bladder, and Thyroid Cancers," 2011, available at http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm256940.htm
3. Bailey, R.L., J.J. Gahche, C.V. Lentino, et al., "Dietary Supplement Use in the United States, 2003-2006," Journal of Nutrition, vol. 141, pp. 261-266, 2011.
4. Radimer, K., B. Bindewald, J. Hughes, et al., "Dietary Supplement Use by US Adults: Data from the National Health and Nutrition Examination Survey, 1999-2000," American Journal of Epidemiology, vol. 160, pp. 339-349, 2004.