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

0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The need for this collection of information derives from the Food and Drug Administration's (FDA's) regulation of the labeling of food products under the Federal Food, Drug, and Cosmetic Act, as amended by the Nutrition Labeling and Education Act of 1990 (NLEA). NLEA regulations establish general requirements for voluntary health claims, i.e., statements in food labeling that characterize the relationship between a food substance and a disease or health-related condition (21 CFR 101.14(a)(1)). Under the petition process for new health claims (21 CFR 101.70), petitioners must submit scientific evidence supporting a proposed health claim to FDA for review. If FDA determines that there is significant scientific agreement (SSA) among experts that the proposed health claim is supported by the totality of publicly available evidence, FDA issues a regulation authorizing the claim (21 CFR 101.14(c)-(d)). Health claims must be "complete, truthful, and not misleading" (21 CFR 101.14(d)(2)(iii)) and must "enable[] the public to comprehend the information provided and to understand the relative significance of such information in the context of a total daily diet" (21 CFR 101.14(d)(2)(v)).

In response to *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), FDA issued guidance on an interim review process for health claims that do not meet the SSA standard for the issuance of a regulation authorizing the claim (Ref. 1). These claims, referred to as "qualified health claims" (QHCs), include a disclaimer or other qualifying language to distinguish them from claims that meet the SSA standard and to prevent consumers from being misled about the level of scientific evidence supporting the claim (Ref. 2). When FDA reviews a QHC petition and determines that the proposed claim is supported by credible evidence and that it can be qualified to prevent consumers from being misled, the agency issues a letter stating its intent to exercise enforcement discretion for the use of the QHC in food labeling.

In 2003, FDA issued a letter of enforcement discretion for two QHCs for dietary supplements containing selenium (Ref. 3):

> Claim 1: "Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive."

> Claim 2: "Selenium may produce anticarcinogenic effects in the body. Some scientific evidence suggests that consumption of selenium may produce anticarcinogenic effects in the body. However, FDA has determined that this evidence is limited and not conclusive."

In 2008, FDA received a petition requesting enforcement discretion for additional selenium QHCs. FDA's response to the 2008 petition was challenged (*Alliance for Natural Health v. Sebelius*, 714 F. Supp. 2d 48 (D.D.C. 2010)), and a settlement was reached whereby FDA agreed to exercise enforcement discretion for QHCs for selenium and reduced risk of bladder, prostate, colon, rectal, and thyroid cancers (Ref. 4). In lieu of the "certain cancers" and "anticarcinogenic effects" QHCs, the plaintiffs agreed to accept a QHC that listed all five site-specific cancers. However, FDA is reevaluating the 2003 selenium QHCs that use the phrases "certain cancers" and "anticarcinogenic effects" (see 72 FR 72738, 72739-40; Dec. 21, 2007) and, based on past experience, it is likely that the agency will continue to receive petitions for health claims containing those phrases. Prior research has not investigated how consumers interpret labeling claims using phrases such as "certain cancers" and "anticarcinogenic effects," or whether qualifiers, such as a listing of site-specific cancers, would eliminate potential deception. The agency therefore proposes an experimental study to examine consumer reactions to health claims using those phrases, with and without various disclaimers.

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.

2. Purpose and Use of the Information Collection

The objective of this proposed study is to collect quantitative data to examine consumer interpretations of two dietary supplement labeling claims, "selenium may reduce the risk of certain cancers" and "selenium may produce anticarcinogenic effects in the body," with and without various disclaimers. Previous studies conducted by FDA and others have examined consumer understanding of hypothetical QHCs and QHCs that have been the subject of a letter of enforcement discretion. The primary goal of the previous studies was to evaluate ways to communicate the strength of scientific evidence supporting a claim (Ref. 5 through 8). None of these prior studies investigated whether labeling claims using phrases such as "certain cancers" and "anticarcinogenic effects" may cause consumers to have unjustified perceptions about the effects of a dietary supplement or food, or how such misperceptions may affect behavioral intentions. The agency therefore proposes this study to support its objective of assuring that QHCs used in food labeling are complete, truthful, and not misleading (see Appendix A).

To answer the primary research questions, the study will test whether the following null hypotheses hold:

(1) There is no difference in behavioral intentions related to, or beliefs about, selenium's potential to reduce the risk of all forms of cancer between consumers who view a selenium claim and consumers who do not view a selenium claim;

(2) There is no difference in behavioral intentions related to, or beliefs about, selenium's potential to reduce the risk of a cancer for which there is no credible evidence of risk reduction between consumers who view a selenium claim and consumers who do not view a selenium claim;

(3) There is no difference in behavioral intentions related to, or beliefs about, selenium's potential to reduce the risk of all forms of cancer between consumers who view a selenium claim and consumers who view a selenium claim plus a disclaimer;

(4) There is no difference in behavioral intentions related to, or beliefs about, selenium's potential to reduce the risk of a cancer for which there is no credible evidence of risk reduction between consumers who view a selenium claim and consumers who view a selenium claim plus a disclaimer;

(5) There is no difference in behavioral intentions related to, or beliefs about, selenium's potential to treat or completely prevent cancer between consumers who view the "anticarcinogenic effects" claim and consumers who do not view this claim;

(6) There is no difference in behavioral intentions related to, or beliefs about, selenium's potential to treat or completely prevent cancer between consumers who view the "anticarcinogenic effects" claim and consumers who view the "anticarcinogenic effects" claim plus a disclaimer;

(7) There is no difference in erroneous beliefs about cancer between consumers who view a claim about selenium and consumers who do not;

(8) There is no difference in erroneous beliefs about cancer between consumers who view a claim about selenium and consumers who view the same claim paired with a disclaimer.

The proposed study is part of FDA's continuing effort to enable consumers to make informed dietary choices and eat healthful diets. Results of this case study will be used to further the agency's understanding of how consumers may interpret "certain cancers" and "anticarcinogenic effects," phrases that appear in a number of health claims that are authorized by regulation, as well as in some QHCs for which the agency has issued a letter of enforcement discretion. Results of the study will not be used to develop population estimates.

3. Use of Improved Information Technology and Burden Reduction

   The quantitative portion of the proposed information collection will recruit respondents and conduct experiments via the Internet. To help design and refine the questionnaire, FDA also plans to conduct nine in-person cognitive interviews.

   In comparison to telephone or in-person data collection modes, the Internet mode of data collection minimizes respondent burden, increases speed and reduces costs of administration, and avoids the potential for interviewer bias. Web-based data collections also minimize possible data entry errors and expedite the timeliness of data processing. Compared to face-to-face interviews and mailed surveys, web-based surveys are less intrusive and less costly.
4. Efforts to Identify Duplication and Use of Similar Information

   The proposed experimental study is not duplicative of existing information. Although prior research has examined consumer understanding of various QHCs and disclaimers conveying the strength of scientific evidence supporting some of those claims (Ref. 5 through 8), none of these studies has investigated whether labeling claims using phrases such as "certain cancers" and "anticarcinogenic effects" may cause consumers to have unjustified perceptions about the effects of a dietary supplement or food, or how such misperceptions may affect behavioral intentions.
5. Impact on Small Businesses or Other Small Entities

   No small businesses will be involved in this collection.

6. Consequences of Collecting the Information Less Frequently

   This is a one-time data collection. Without this study, FDA will not have the needed information to understand to what extent consumers may be misled by claims that use the phrases "certain cancers" and "anticarcinogenic effects" and, to the extent that consumers are misled, whether this can be mitigated with disclaimers. The information from this study will help the agency to better understand the potential consumer impact of these claims and will help inform FDA's ongoing evaluation of the scientific evidence underlying these claims.
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   There are no special circumstances for this collection of information.
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   In the Federal Register of January 27, 2012 (77 FR 4329), FDA published a 60-day notice requesting public comment on the proposed collection of information. The agency received one comment that dealt with topics outside the scope of the proposed collection of information described in the 60-day notice. Therefore, the comment is not addressed here.
9. Explanation of Any Payment or Gift to Respondents

Cognitive interview participants will be recruited from a commercial database of residents in the Washington, D.C. metropolitan area. As an incentive, each respondent will be offered the government-wide standard of $40 to participate in the one-hour interview.

Study respondents will be recruited from members of Synovate's Consumer Opinion Panel. Members have voluntarily agreed to join the panel and participate in regular online surveys conducted by Synovate. Synovate offers panelists two main incentive programs: Sweepstakes and a Points Rewards Program. The sweepstakes draw is conducted quarterly or monthly, depending on the market. Panel members receive an entry into the draw for registering for the panel, and for each survey they complete during this time period. Each time a member completes a survey, the individual is automatically entered into the current month's drawing to win one of the following cash prizes: one cash prize of $1,000, 10 prizes of $100, 15 prizes of $50, 30 prizes of $25, and 150 prizes of $10. In the Points Rewards Program, panelists earn points for every survey they complete and can redeem these points for cash in their native currency. Panelists receive 50 points for every survey minute anticipated. One thousand points = $1.

10. Assurance of Confidentiality Provided to Respondents

All data will be kept private to the extent permitted by law. The study instrument will include a statement explaining this to respondents.

No personally identifiable information will be sent to FDA. The independent contractor will keep all information that can identify individual respondents separate from the data provided to FDA. The information will be kept in a secured fashion that will not permit unauthorized access. These methods will all be approved by FDA's Institutional Review Board (Research Involving Human Subjects Committee) prior to collecting any information.

An independent contractor for FDA, Synovate, will collect the data and will not provide FDA with identifying information on the respondents. Interviewing staff are required to sign a pledge of confidentiality that reinforces confidentiality requirements of the study and states that any procedural violation that jeopardizes a respondent's privacy will be grounds for immediate termination and possible legal action. Once response editing and interview validation are completed for the survey data, respondents' names and other identifying information will be permanently dissociated from interview data.

All data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

11. Justification for Sensitive Questions

The study will ask respondents their about their perceived health, prior diagnosis of and perceived susceptibility to cancer, and household income. This information is needed for

because these characteristics constitute key dimensions of potential variation among individuals likely to be exposed to, or to attend to, selenium products and/or qualified health claims related to cancer.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

To help design and refine the questionnaire, FDA plans to conduct cognitive interviews by screening 350 respondents in order to obtain 9 participants in the interviews, including two or more men who have used selenium or other dietary supplements. Each screening is expected to take 5 minutes (0.083 hour) and each cognitive interview is expected to take one hour. The total for cognitive interview activities is 38 hours (29 hours + 9 hours). Subsequently, we plan to conduct pretests of the questionnaire before it is administered in the study. We expect that 1700 invitations, each taking 2 minutes (0.033 hour), will need to be sent to panelists to have 60 of them complete a 10-minute (0.167 hour) pretest. The total for the pretest activities is 66 hours (56 hours + 10 hours). For the survey, we estimate that 45,000 invitations, each taking 2 minutes (0.033 hour) to complete, will need to be sent to the consumer panel to have 1,200 of its eligible members complete a 10-minute (0.167 hour) questionnaire. The total for the survey activities is 1,685 hours (1,485 hours + 200 hours). Thus, the total estimated burden is 1,789 hours. This estimate is 94 hours lower than the 1,883 hours published in the 60-day notice and reflects 23 more hours for the cognitive interview screener, 48 more hours for the pretest invitation, and 165 fewer hours for the survey invitation. These estimates were adjusted to be more reflective of the anticipated effort required to recruit, conduct cognitive interviews with, pretest, and survey participants with the desired characteristics. FDA's burden estimate is based on prior experience with research that is similar to this proposed study.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Portion of Study	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Cognitive interview screener	350	1	350	.083 (5 minutes)	29
Cognitive interview	9	1	9	1 (60 minutes)	9
Pretest invitation	1700	1	1700	.033 (2 minutes)	56
Pretest	60	1	60	.167 (10 minutes)	10
Survey invitation	45,000	1	45,000	.033 (2 minutes)	1,485
Survey	1,200	1	1,200	.167 (10 minutes)	200
Total					1,789

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $29,511 (1,781 x $16.57) at $16.57 per hour (the 2011 median wage rate in the U.S.) See http://www.bls.gov/oes/current/oes_nat.htm#00-0000.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The estimated total cost to the Federal Government for this information collection $200,000. This includes the value of a task order to execute the collection of information and the value of a Full-Time-Employee to manage the project.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

We plan to complete data collection and analysis within two years from the date of OMB approval. The planned schedule for the project is shown in Table 2.

The purpose of tabulation is to quantitatively analyze the data and summarize findings to meet the informational needs. Commonly accepted statistical techniques such as descriptive analysis, analysis-of-covariance (ANCOVA), and regression analysis will be used to analyze the experimental data.

Table 2. Project Schedule

Date	Activity
Within 3 days following OMB approval	Notification to contractor to proceed with data collection
Within 150 days following OMB approval	Completion of data collection
Within 6 months following OMB approval	Completion of data delivery by the contractor
Within 8 months days following OMB approval	Completion of preliminary analyses
Within 10 months following OMB approval	Beginning of review, clearance, and dissemination of preliminary findings

FDA will follow the agency's "Guidelines for Ensuring the Quality of Information Disseminated to the Public" strictly when disseminating the results of this study. In

describing the data collected and results of the analysis, FDA will clearly acknowledge that the experimental data does not provide nationally representative population estimates of consumer attitudes, knowledge, or behaviors but provides valid and quantitative estimates of differences across experimental conditions.

The dissemination of the study results may include internal briefings and reports, presentations and articles at trade and academic conferences, in professional journals, and posting on FDA Web site.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB approval and expiration date will be displayed on all materials associated with the study. No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

1. U.S. Food and Drug Administration, Guidance for Industry: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Foods and Human Dietary Supplements, 2003, available at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053832.htm
2. U.S. Food and Drug Administration, Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims, 2009, available at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm
3. U.S. Food and Drug Administration, "Selenium and Certain Cancers (Qualified Health Claim: Final Decision Letter) (Docket No. 02P-0457)," 2003, available at http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072780.htm
4. 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
5. Derby, B.M. and A.S. Levy, Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims, 2005, available at http://www.fda.gov/OHRMS/dockets/dockets/03N0496/03N-0496-rpt0001.pdf
6. Choinière, C. and L. Verrill, Experimental Studies of Qualified Health Claims: Consumer Inferences about Monounsaturated Fatty Acids from Olive Oil, EPA and DHA Omega-3

Fatty Acids, and Green Tea, 2009, available at http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm207549.htm

7. Hooker, N.H. and R. Teratanavat, "Dissecting Qualified Health Claims: Evidence from Experimental Studies," Critical Reviews in Food Science and Nutrition, vol. 48, pp. 160-176, 2008.

8. Kapsak, W.R., D. Schmidt, N.M. Childs, J. Meunier, and C. White, "Consumer Perceptions of Graded, Graphic and Text Label Presentations for Qualified Health Claims," Critical Reviews in Food Science and Nutrition, vol. 48, pp. 248-256, 2008.