# WORKING PAPER

# Effects of Strength of Science Disclaimers on the

# Communication Impacts of Health Claims

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**ABSTRACT**

In this paper we investigate the communication impacts of various schemes for conveying information about the certainty of the scientific evidence supporting a health claim that appears on a food product label. Disclaimers about the level of scientific evidence supporting a health claim have been recommended by recent Court decisions as a remedy for otherwise potentially misleading claims. We evaluate four possible schemes for conveying the strength of science supporting a health claim. Two experimental schemes rely on specific wording and word order, and use claim language similar to that used in FDA's interim guidance for qualified health claims. The other two experimental schemes use report card grades to convey strength of science.

For the experiment, we selected four dietary substance/disease relationships (calcium/osteoporosis, omega-3 fatty acids/heart disease, selenium/cancer and lycopene/cancer) to represent a range of scientific certainty. These "health claims" did not necessarily reflect authorized health claims allowed under FDA regulations or qualified health claims already considered by the agency. For each hypothetical health claim, we also identified an everyday food product that contained the identified nutrient and met all or most qualifying and disqualifying criteria for other nutrients (calcium/orange juice, omega-3/tuna, selenium/eggs, and lycopene/spaghetti sauce). Each respondent was randomly assigned to an experimental condition where he/she saw two different products consecutively. One of the products showed a label with one of the four following conditions (No Claim, Nutrient Content Claim, Unqualified Health Claim stated with "may", Unqualified Health Claim stated without "may"). Some respondents were first briefed about the scientific evidence for one of the health claims and later saw the product label for the Nutrient Content Claim condition for the relevant nutrient ("Full Information" condition). The other product showed a disclaimer from one of the four schemes that convey the strength of science that is appropriate for the level assigned to the hypothetical claim being tested or one level above or below this level. The order and combinations of presented products were counterbalanced to avoid possible bias in the

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estimation of experimental effects. Respondents answered questions about the perceived certainty of science for the claim and about perceived health benefits for the product.

The results suggest that text sentences using adjectives do not correctly convey to respondents the intended strength of science. The schemes using report card grades did convey the intended strength of science, but report card grade disclaimers had unintended effects on respondents' perceptions of scientific certainty relative to unqualified claims, such that respondents attributed more certainty to claims with disclaimers than those without disclaimers. Finally, there was evidence that respondents' perceptions of product health benefits were not diminished by conveying greater scientific uncertainty for a claim. In some cases conveying more scientific certainty for a claim actually led to more negative perceptions of product health benefits. This overall pattern of results suggests important caveats on the possible effectiveness of strength of science disclaimers.

# Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims

Health claims are regulated statements on food product labels. They describe a relationship between a food or component of food and reduction in the risk of a disease or health-related condition (21 U.S.C. 343(r)(1)(B); 21 CFR 101.14(a)(1) and (2)). On one hand, they represent to the consumer the state of science about the effects of dietary intake of particular nutrients on the likelihood of reducing the risk of certain diseases and, on the other hand, they imply that the product may help provide the suggested health benefits. Neither assertion is trivial or self-evident. There is little space on the label to provide supporting information, and little opportunity to seek more at the time consumers see the claim. Consumers may have varying amounts of relevant prior information to help them evaluate the dual assertions about the science and the product. To consumers, health claims appear as stylized communications that rely on convention and background knowledge to be understood.

The special communication status of health claims on food product labels lies in possible consumer presumptions about the truthfulness of the dual assertions made by the claim. Because food labels are regulated contexts for communication between manufacturers and customers, there may be a presumption that both assertions are true based on the fact that the health claim appears on the label.

The regulatory history of health claims in food labeling attests to this concern (Hutt, 1986). The 1993 regulations implementing the Nutrition Labeling and Education Act (NLEA; 21 CFR 21 101.14) adopted the congressionally mandated standard of "significant scientific agreement" (SSA) to limit authorized health claims in food labeling to those dietary substance/disease relationships where, based on the totality of publicly available scientific evidence, there is significant scientific agreement among qualified experts that the claim is supported by such evidence. The intent was to ensure that health claims that consumers saw in food labeling would deserve confidence and be unlikely to be reversed by additional scientific information. The 1993 regulations also required that products bearing a health claim meet minimal nutritional standards and not exceed certain disqualifying levels for key nutrients so that any product bearing a claim would deserve its presumptive role in contributing to a healthy diet. However, the approach of deciding whether a claim was misleading or not based on FDA's evaluation of whether the scientific evidence met the significant scientific agreement standard was overturned in court (*See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999)).

The *Pearson* decision rejected FDA's approach in part because the agency did not meet its burden of justifying a restriction on health claims that do not meet the SSA standard (i.e., a specific claim was not shown to be misleading). Moreover, the court criticized FDA's approach for not considering the possibility that disclaimers about the quality of science underlying the claim could remedy any potential harm. Following the *Pearson* decision, FDA revised its process for reviewing health claim petitions. This process includes a consideration of health claims in food labeling that do not meet the SSA

standard, when such "qualified health claims" accurately communicate the level of scientific support for the claim. Recently, FDA instituted an interim system for communicating qualified health claims in food and dietary supplement labeling based on a four-level system to classify health claim petitions in terms of the strength of science supporting the claim. (Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data (68 FR 41387, July 11, 2003); Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements (68 FR 41387, July 11, 2003)).

The intent of the present study is to assess the relative effectiveness of different ways of communicating the strength of science underlying a food label health claim using different possible wordings or graphic presentations of strength of science disclaimers to implement a four-level scheme (i.e., unqualified health claim statement and three-levels of qualified health claim statements).[1]

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[1] Throughout this research report "unqualified health claim" or "health claim" refers to a health claim statement of the form "X may reduce the risk of Y," and "qualified health claim" refers to a health claim statement accompanied by a disclaimer. As used herein, the terms are not intended to encompass the more complex definitions and requirements provided in FDA's regulations.

## Experimental Variables

Strength of Science (SS) Disclaimer Schemes

There are many possible ways to construct disclaimers to communicate the degree of scientific support for a health claim. The present study looks at four possible schemes, two similar to those currently being used by manufacturers under FDA's interim guidance for qualified health claims and two other alternatives. Within each scheme, the top level is an unqualified health claim (i.e., without an SS disclaimer), similar to how authorized claims that meet SSA are currently presented on product labels.[2] Each scheme also defines three levels of disclaimers below this top level. Two schemes (Point/Counterpoint and Embedded[3]) rely on text sentences with different grammatical structure and adjectives to communicate the levels of scientific support for the claim. Two schemes use a familiar A-B-C-D report card grade to communicate the level. The Report Card-Text scheme uses text to describe the system and the letter grade assigned ("B", "C" or "D") to the qualified health claim statement. The Report Card-Graphic scheme uses a visual depiction of the report card grading scheme where the claim's grade is indicated by a checkmark next to the B, C or D box. Table 1 describes each of the

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[2] The unqualified health claim is stated simply, for example "Calcium may reduce the risk of osteoporosis." For research purposes, other information typically included in authorized health claims is not included, both to ensure a focus on the strength of science information and because this information would be identical across experimental conditions.

[3] Point/Counterpoint claims are worded with the statement of the relationship first, followed by the disclaimer, e.g., "Selenium may reduce the risk of cancer but the scientific evidence is promising but not conclusive." Embedded claims are stated with the disclaimer first, e.g., "Promising but not conclusive scientific evidence suggests that selenium may reduce the risk of cancer."

disclaimer schemes used in the study. Appendix 1 shows examples of test labels for each

of the four schemes.

Table 1. Characteristics of Tested Strength of Science Disclaimer Schemes

| Disclaimer Scheme | Point/ Counterpoint | Embedded | Report Card Text | Report Card Graphic |
|---|---|---|---|---|
| Presentation Style | Text Statement | Text Statement | Text Statement | Text Statement Graphic Report Card |
| Health Claim(HC)/SS Disclaimer Order | SS Disclaimer after HC | SS Disclaimer First | SS Disclaimer after HC | SS Disclaimer after HC |
| Level A (SSA) | Unqualified HC | Unqualified HC | Unqualified HC | Unqualified HC |
| Level B | "…promising but not conclusive…" | "…promising but not conclusive…" | "…gave it a 'B' rating based on a scale from A (strongest evidence) to D (weakest evidence)…" | Four-level box with "B. Moderate Evidence" checked |
| Level C | "…limited and inconclusive…" | "…limited and not conclusive…" | "…gave it a 'C' rating based on a scale from A (strongest evidence) to D (weakest evidence)…" | Four-level box with "C. Some Evidence" checked |
| Level D | "…very limited and preliminary…" | "…very limited and preliminary…" | "gave it a 'D' rating based on a scale from A (strongest evidence) to D (weakest evidence)…" | Four-level box with "D. Little Evidence" checked |

Claim/Product Pairings and Assignment of Disclaimer Level Conditions to

Claim/Product Pairings

To ensure as much realism as possible, we selected for study four diet-disease

relationships that could serve as possible examples of each level of scientific

support and paired them with a food product that contains the identified

nutrient or food component and meets all or most qualifying and

disqualifying criteria for other nutrients with the hypothetical health claim.

Our objective was to test experimental claims that consumers would perceive

as plausible; the specific language tested does not necessarily reflect claims

currently considered under regulation or FDA's interim guidance for qualified

health claims.  In general, whether consumers view a claim/product

combination as plausible depends on what they already know about the claim

and the product.  Similarly, for a claim to seem plausible, the disclaimer level

presented on the label needs to be reasonably consistent with what consumers

perceive is the scientific evidence for the claim.

The four experimental health claims tested represent a range of scientific certainty, from

an authorized health claim that meets the SSA standard to three claims where the

available evidence was considered to be increasingly limited.  However, they do not

represent qualified health claims that at the time the study protocol was developed had

been evaluated under FDA's interim guidance.

Each substance/disease relationship was paired with a familiar food product that consumers would perceive as appropriate to bear the claim. Table 2 describes each of the substance/disease relationships and product pairings used in the study. The experimental claims we developed to represent B, C, and D level health claims are referred to as "correct." We did not include disclaimer conditions that deviated too far from this "correct" level to minimize the likelihood that some respondents would find the claims implausible, for example, a C or D level disclaimer for the relationship between calcium and osteoporosis. Therefore, the experimental design limited conditions to claim levels one level higher and one level lower than the "correct" level of that relationship. Table 3 shows the health claims and disclaimer level conditions tested for each of the four claim/product pairs.

Table 2. Characteristics of Claim/Product Pairings Used in the Study

| Substance/Disease Relationship | Calcium/ Osteoporosis | Omega-3 fatty acids/ Heart Disease | Selenium/ Cancer | Lycopene/ Cancer |
|---|---|---|---|---|
| **Product** | Calcium-fortified Orange Juice | Light Tuna in Water | Fresh Eggs | Spaghetti Sauce |
| **"Correct" Claim Level** | Unqualified Health Claim | Level B | Level C | Level D |
| **Health Claim Statement** | "Calcium may reduce the risk of osteoporosis." | "Omega-3 fatty acids may reduce the risk of heart disease." | "A diet high in selenium may reduce the risk of cancer." | "The antioxidant lycopene may reduce the risk of certain cancers, including prostate cancer in men." |

Note:  Associated nutrient content claims:  "High in calcium"; "180mg omega-3 fatty acids", "High in selenium", and "20 mg lycopene."  Nutrient content claims where a Daily Value (DV) has been established may use terms such as "high" to describe the amount of the nutrient per serving, provided the amount meets FDA criteria for the term. Nutrients without a DV are permitted to state the quantitative amount per serving (e.g., 20mg lycopene) but are not permitted to include the nutrient in the Nutrition Facts Panel (NFP) (21CRS101.13(i)(3)).  In this study, calcium and selenium have DVs and the amounts meet the regulatory definition for the term "high."  Omega-3 fatty acids and lycopene do not have DVs established and therefore are stated in terms of quantitative amount per serving and do not appear in the NFP.

Table 3.  Disclaimer Levels Tested for Each Claim/Product Pairing

| Claim/Product Combinations | Calcium/ Osteoporosis Orange Juice | Omega-3 / Heart Disease Tuna fish | Selenium/ Cancer Eggs | Lycopene/ Cancer Spaghetti Sauce |
|---|---|---|---|---|
| Unqualified Claim | Yes | Yes | Yes | Yes |
| Level B Claim | Yes | Yes | Yes | No |
| Level C Claim | No | Yes | Yes | Yes |
| Level D Claim | No | No | Yes | Yes |

Controls to Assess Communication Effectiveness

Communication effectiveness depends on both the direction and magnitude of impact of

the communication.  In order to assess the direction and magnitude of impact of

disclaimers, they need to be compared to other conditions, such as the absence of a claim

and the presence of a claim, as viewed by experts or informed consumers (Russo, Metcalf & Stephens, 1981). The present study includes multiple controls in order to maximize its usefulness to the policy dialogue about how to design effective disclaimers. In addition to the primary controls of "No Claim" and an "Unqualified Health Claim", the study uses several additional control conditions to assist in gauging the magnitude and direction of the effects of disclaimers.

Five separate label conditions are included in the study as controls:

1. No Claim (front label has neither a health claim nor a nutrient content claim).

2. Nutrient Content Claim (front label contains a nutrient content claim or quantitative disclosure for the relevant nutrient).

3. Unqualified Health Claim (front label contains the relevant health claim that states that the nutrient "may reduce the risk of" the relevant disease or health-related condition).

4. Unqualified Health Claim without "may" (front label contains the relevant health claim without "may" (e.g., "X reduces the risk of Y")).

5. Full Information ( respondents read a one page summary of the scientific evidence for the one of the four substance/disease relationships before seeing a label with the relevant nutrient content claim)

Given the dual messages inherent in food label health claims, the impact of different kinds of disclaimers need to be measured by what a disclaimer conveys about the scientific support for the substance/disease relationship, as well as what it conveys about product health benefits.  Table 4 describes the questions used in the study to assess the performance of strength of science disclaimers.

Table 4. Communication Outcome Measures

| Measure Name | Scientific Certainty | Relevant Health Benefit | Other Health Benefits | Importance in Diet |
|---|---|---|---|---|
| **Concept Measured** | Perceived certainty of science supporting claim | Perceived likelihood that the product has the relevant health benefit | Perceived likelihood that the product has other specific health benefits | Perceived importance of food as part of a healthy diet. |
| **Question Wording** | Based on what the label says or suggests, how certain is the scientific evidence that eating foods that contain [relevant nutrient] will reduce the risk of [relevant health condition]? | How likely is it that eating this food as a regular part of one's diet would reduce the risk of [relevant health condition]? | How likely is it that eating this food as a regular part of one's diet would reduce the risk of [3 specific health conditions not mentioned in the claim]? | How important would this food be as part of a healthy diet? |
| **Response Scale** | 1-7, 1=Very Uncertain; 7=Very Certain | 1-7, 1=Very Unlikely; 7 = Very Likely | 1-7, 1=Very Unlikely; 7 = Very Likely, Average of 3 responses | 1-7, 1=Not at all Important, 7 = Very Important |
| **Timing of Question** | After seeing front panel | After seeing both front panel & NFP | After seeing both front panel & NFP | After seeing both front panel & NFP |

The introductory wording of the perceived scientific certainty question, "Based on what
the label says or suggests…" was modified to say, "Based on what you know..." for
respondents who viewed a control label that did not show a health claim.  This ensured
that all respondents could answer the scientific certainty question (otherwise a likely

response would be, "It doesn't say anything about scientific certainty").  The responses of

those exposed to the No Claim control label provide an indication of consumers' prior

beliefs regarding the substance/disease relationships.

Performance Standards for Effective Disclaimers Schemes

To evaluate the effectiveness of the disclaimer schemes, the research had to empirically

define relevant performance standards.  These performance standards were specified in

advance to make explicit how we would measure communication effectiveness and the

interpretation of these tests.  We used the following three performance standards:

1.  Linear effect of disclaimer levels.  The perceived strength of science conveyed by

    a disclaimer should decrease significantly as the disclaimer says the evidence is

    weaker, i.e., consumers should correctly comprehend the intended meaning of the

    disclaimer.  An appropriate analytic test for this performance standard would be a

    significant linear effect of disclaimer level on the perceived strength of science

    measure.

2.  Compensatory effect of disclaimers.  A disclaimer appropriate for the "correct"

    level of scientific evidence (appropriate disclaimer) should produce strength of

    science perceptions in the opposite direction from the effect of an unqualified

    health claim compared to a "No Claim" condition (i.e., the disclaimer should act

    to moderate the positive effect of an unqualified health claim).  The appropriate

    analytic test would be to estimate the planned comparisons between (1) no claim

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versus unqualified claim conditions, and (2) unqualified claim versus appropriate disclaimer conditions, then to compare the direction and magnitude of these two planned contrasts.

3.  Product perception consistency.  The effect of an appropriate disclaimer on perceptions of product health benefits should parallel its effect on perceptions of scientific support.  The effect of disclaimer level on product perceptions may be attenuated for product benefits not specifically mentioned in the claim or for more global product evaluations, but there should not be significant reversals. Significant reversals would indicate that consumers are making incorrect inferential judgments from the disclaimer, i.e., a communication failure.  The same analytic approach used above should be applied to the measures of perceived product health benefits, comparing claims with appropriate disclaimers to No Claim and Unqualified Health Claim conditions.

In addition to these basic performance standards for an effective disclaimer scheme, there are a number of other empirical questions relevant to evaluating the effectiveness of disclaimers relative to different possible control conditions.

1.  What is the effect of omitting the auxiliary verb "may" from the unqualified statement of the health claim?

2.  Does a nutrient content claim on a food label have the same effect as a health claim?

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3. What is the effect of briefing consumers about the level of scientific support for a given substance/disease relationship before they see a product that contains the relevant nutrient?

**Interview Protocol**

We collected data at five regional shopping malls (Detroit, Los Angeles, Philadelphia, Atlanta, and White Plains, New York), using a shopping mall intercept methodology. Eligible respondents were 18 years old or older who were responsible for at least half of the household food shopping and able to read words in the required print size. Each site met specified screening quotas for age and sex.

Once respondents agreed to participate, they were randomly assigned to an experimental condition. Each site administered an entire replicate of 384 experimental conditions designed to counterbalance the order of presentation and product type. In all, there are 1,920 respondents, each of whom reviewed two products (one a control condition and one a disclaimer condition), thereby contributing two observations each to the design.

At the beginning of the session respondents were told, "We are conducting a study for the U.S. Food and Drug Administration (FDA) about food and food labels. Today you will be looking at some food labels for everyday food products. We are less concerned about how the labels look than with what they say. None of these products are currently available for sale but they are similar to products you may have seen or purchased." The

quarter of respondents in the "Full Information" condition first read a one-page summary about the scientific evidence for one of the four substance/disease relationships and answered a couple of questions to ensure they paid attention to the information presented to them.

Respondents were handed the front panel label of one product, asked to look it over, and then answered the perceived strength of science question (Certainty).  Next, they were given the back panel label which showed the Nutrition Facts Panel, looked it over, and answered the perceived product benefit questions (Relative Benefit, Other Health Benefits, and Importance).  This procedure was repeated for the second product.  A constraint was imposed on the possible label conditions that respondents saw such that one of them was always a disclaimer condition (i.e., a B, C, or D level disclaimer) and one of them was always a control condition (i.e., no nutrient content or health claim, a nutrient content claim only, or an unqualified health claim with or without "may").  All possible combinations of the two products that were seen and their order of presentation were crossed with product, control, and disclaimer conditions to minimize any possible bias of order and product combination on experimental effects.

After looking at and answering questions about the two products, respondents answered a few background questions including race, household status, age, education level,  and household health status (i.e., "Have you or has anyone *currently living in your household* ever had ... (heart disease, diabetes, high blood pressure, cancer or osteoporosis?")).

**Analysis**

The experimental design for the study is a partial factorial design. Claim/Product (4) is fully crossed with Control Conditions (5) and Disclaimer Scheme (4). Disclaimer level (3) is nested within Claim Product as described in Table 3. Control Conditions, however, are independent of Disclaimer Scheme. As noted above, each respondent contributes one observation to a control condition and one observation to a disclaimer condition. Order of presentation of products and product combinations are counterbalanced across experimental conditions.

The key analyses are based on a General Linear Model (GLM) to estimate the effects of experimental variables on the four communication outcome measures (SAS Institute, Inc., 1989). Individual difference variables were included as covariates. Specific planned contrasts were used to estimate the linear trend effect of disclaimer level and to estimate certain planned contrasts between label conditions within each claim/product pairing (see SAS Institute, Inc. 2005). To facilitate the presentation of the results, outcome measure scores were normalized within each product/claim level so that the overall mean for each measure for a given product equals zero, with a standard deviation of plus or minus one. Under this normalization procedure, label condition means represent standardized effect sizes.

## RESULTS

**Analyses of Three Key Performance Standards**

1.  Linear effects of disclaimer level

As noted earlier, to be considered effective, a strength of science disclaimer scheme for

health claims must be able to produce a significant linear effect of disclaimer level on

consumer perceptions of scientific certainty. Figure 1 presents the means for perceived

scientific certainty by disclaimer level for each of the four schemes tested in the study.

The figure shows that the Point/Counterpoint and Embedded schemes failed to show a

linear downward trend by disclaimer level, a critical performance standard for an

effective disclaimer scheme.

Figure 1.



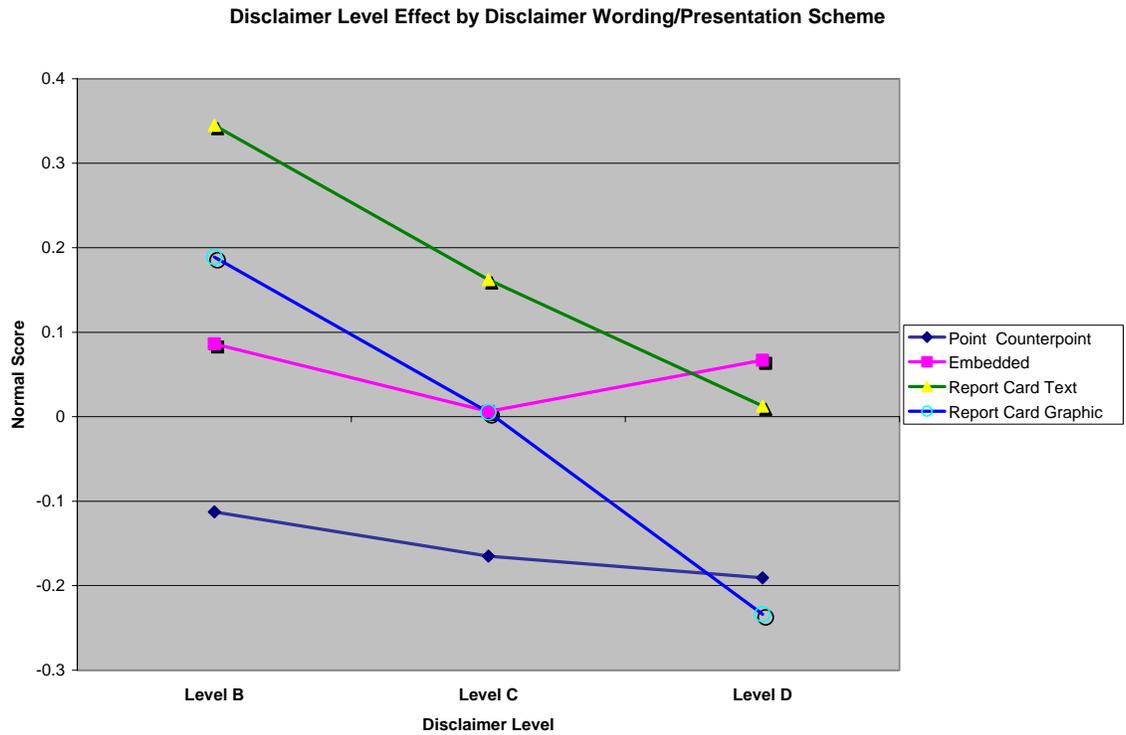Disclaimer Level Effect by Disclaimer Wording/Presentation Scheme

Table 5 presents the tests of significance for the linear effect of disclaimer level on respondent perceptions of scientific certainty for each disclaimer scheme.

Table 5 Linear Effect of Disclaimer Level by Disclaimer Scheme

|  | Estimate | Error | t Value | Pr > \|t\| |
|---|---|---|---|---|
|  |  |  |  |  |
| Point/Counterpoint | 0.053 | 0.109 | 0.47 | 0.636 |
| Embedded | -0.021 | 0.108 | -0.19 | 0.848 |
| Report Card (text) | 0.241 | 0.106 | 2.28 | 0.023 |
| Report Card (graphic) | 0.331 | 0.108 | 3.08 | 0.002 |

As Table 5 shows, the only schemes that meet the minimal requirement for an effective disclaimer scheme are those that use report card grades to convey strength of science.

2.  Compensatory effects of "correct" level disclaimers

The second critical performance standard for an effective disclaimer scheme is that a disclaimer that matches the "correct" SS level for the substance/disease claim should be able to counteract to some degree the communication effect of an unqualified health claim.  The expected pattern is a positive effect of a health claim relative to a No Claim control coupled with a negative or compensating effect of an appropriate disclaimer.  Figure 2 presents the estimated effect on perceptions of scientific certainty of an Unqualified Health Claim relative to a No Claim condition and the estimated effect of an appropriate disclaimer relative to the Unqualified Health Claim condition for each claim/product pairing.  Since the Point/Counterpoint and Embedded disclaimer schemes did not show significant linear effects of disclaimer level (Table 5), they are not included in this analysis.

Figure 2.

**Unqualified Health Claim and Disclaimer Effects on Perceived Scientific Certainty**
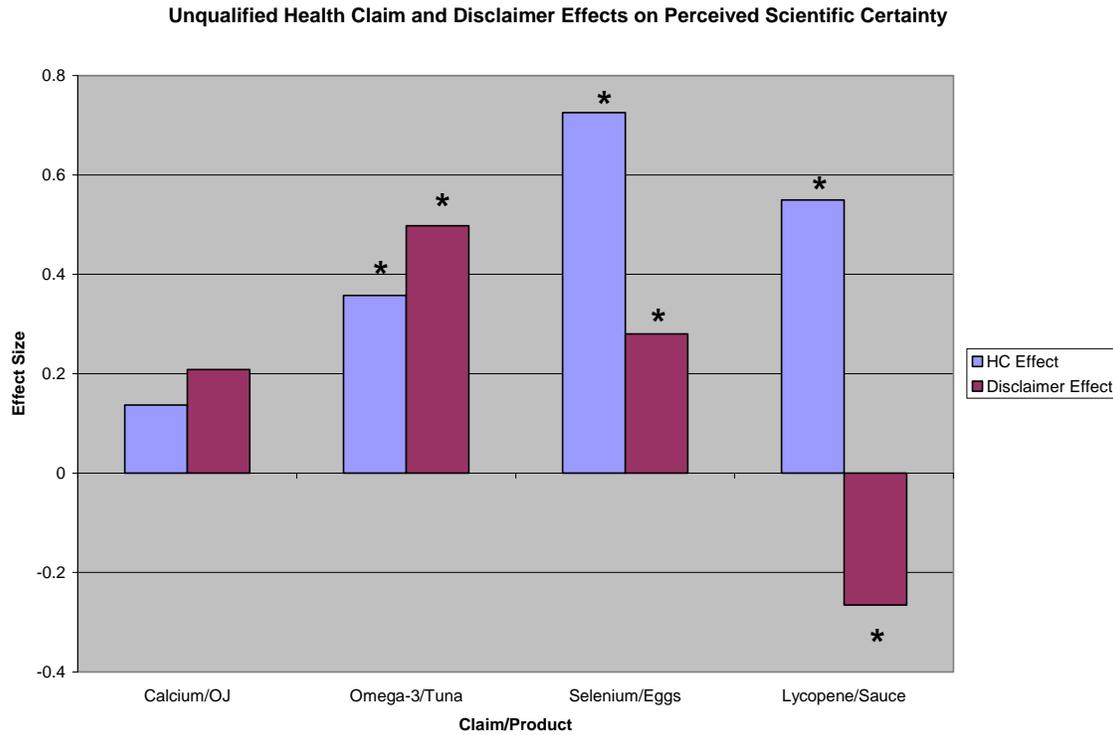


\* $p \leq .05$

Unqualified Health Claim conditions compared to labels with No Claim conditions ("Health Claim Effect") have the expected positive impact on consumers perceptions of scientific certainty (F (1, 2752) = 7.6, p ≤ .0001). Calcium/Orange Juice is the only claim/product pairing that does not show a significant positive impact of the Unqualified Health Claim condition. The calcium claim is also the most familiar and most scientifically supported claim. The results show that the positive impact of an unqualified health claim on perceived scientific certainty is strongest for the less familiar claims.
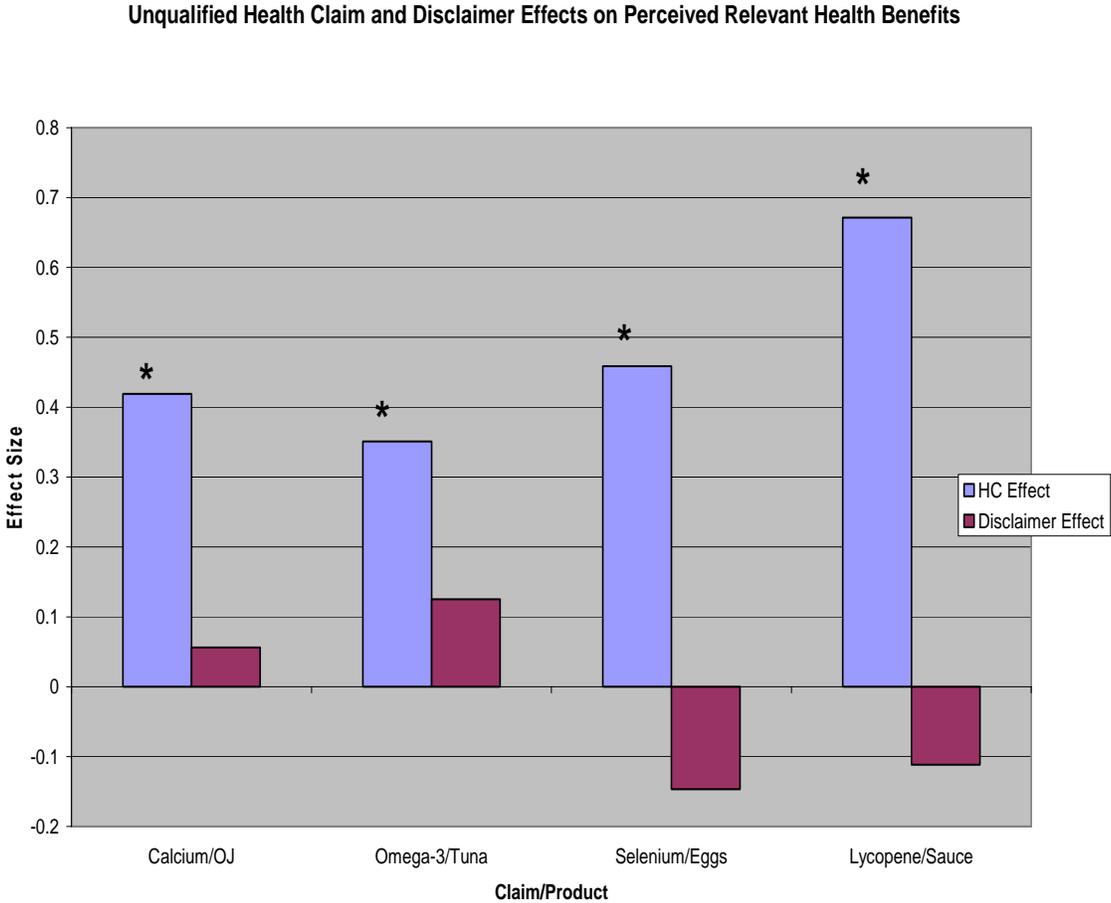
Strength of science disclaimers do not perform as expected. When product labels have a level of disclaimer that is appropriate for the qualified health claim, (i.e., when the B-level claim has a B-level disclaimer, the C-level claim has a C-level disclaimer, and the D-level claim has a D-level disclaimer), or when the A-level claim has a B-level disclaimer,[4] the impact of the disclaimer is usually positive instead of negative. In the cases of Omega-3/Tuna and Selenium/Eggs the positive impact is statistically significant. Only the D-level disclaimer for Lycopene/Spaghetti Sauce has the expected negative effect on consumers' perceptions of scientific certainty.

3. Consistent Product Perceptions

Figures 3, 4, and 5 present the same analyses for the other communication outcome measures: perceived relevant product health benefits, other product health benefits, and rated product health importance. Each measure shows the same pattern of results in varying degrees. Health claims have positive effects relative to the no claim condition for "Perceived relevant product health benefits" (Figure 3), $(F (1, 2748) = 7.8, p \leq .0001)$ and for "Other perceived health benefits" (Figure 4), $(F (1, 2598) = 3.2, p \leq .01)$. For "Perceived product healthfulness" (Figure 5), $(F (1, 2872) = 1.5, p \leq .15)$, the health claim effect reaches statistical significance only in the case of Lycopene/Spaghetti Sauce. At the same time, appropriate disclaimers do little, if anything, to reverse these effects. As Tables 3-5 show, in all cases the disclaimer effect is not significant.
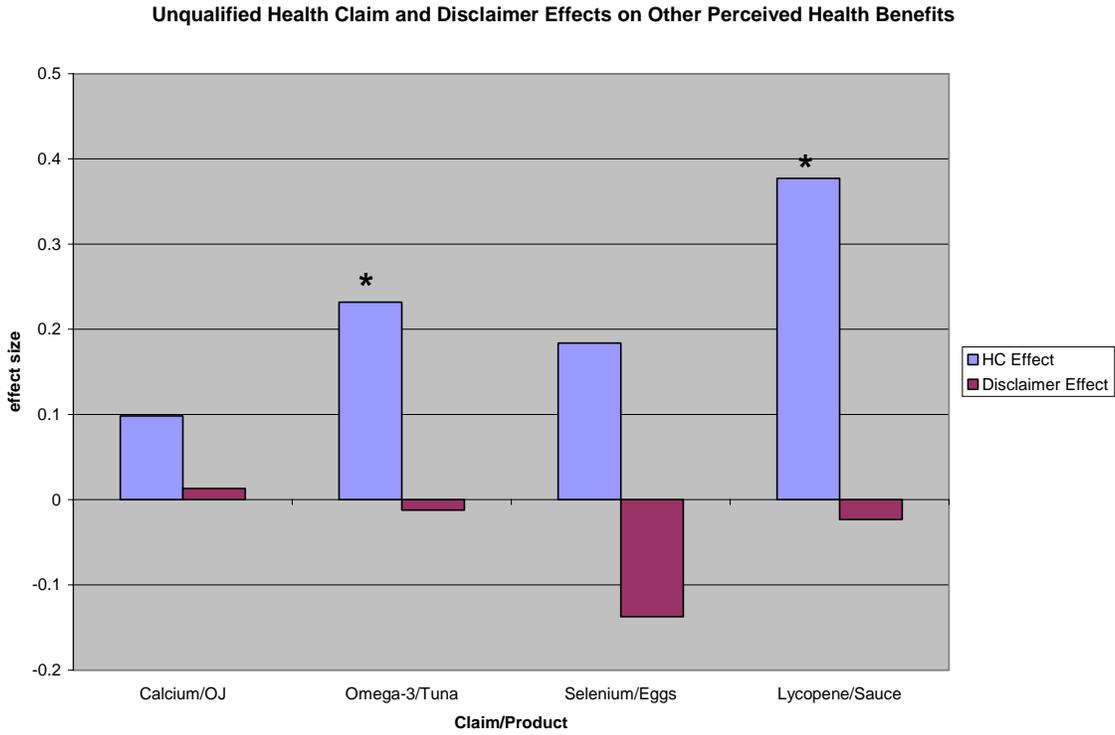
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[4] In this study, the calcium/osteoporosis claim represents an authorized (i.e., A level) health claim, but to maintain consistency with current regulations for authorized health claims we did not identify the unqualified claim condition with an "A" in either of the report card schemes.
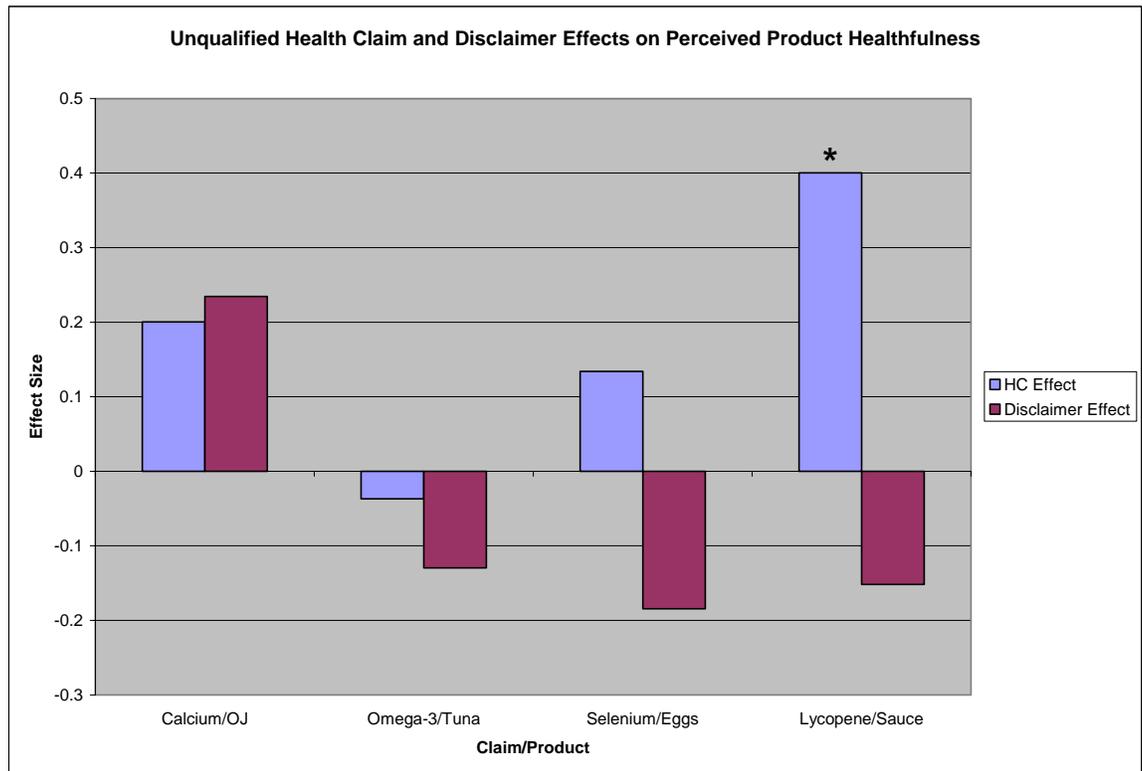
Figure 3.

**Unqualified Health Claim and Disclaimer Effects on Perceived Relevant Health Benefits**



\* $p \leq .05$

Figure 4.



**Unqualified Health Claim and Disclaimer Effects on Other Perceived Health Benefits**

\* p ≤ .05

Figure 5.



**Unqualified Health Claim and Disclaimer Effects on Perceived Product Healthfulness**

* $p \leq .05$

**Other Research Questions**

<u>The impact of stating health claims with or without "may"</u>

Unqualified health claims use the word "may" to indicate the probabilistic and

multifactorial nature of the relationship between a substance and reduced risk of a disease

or health-related condition (e.g., a diet low in fat may reduce the risk of heart disease).

This usage is not intended to be interpreted as an implicit strength of science disclaimer,

but consumers may interpret it this way.  To determine whether the "may" usage conveys

strength of science, we included a study condition in which the unqualified health claim is stated without "may," i.e., " X reduces the risk of Y" instead of "X may reduce the risk of Y." Figure 6 presents the results of the comparison between the unqualified health claim wordings with and without "may."

Figure 6.



**Communication Impacts of Omitting "may" from Statement of Health Claim by Outcome Measures**
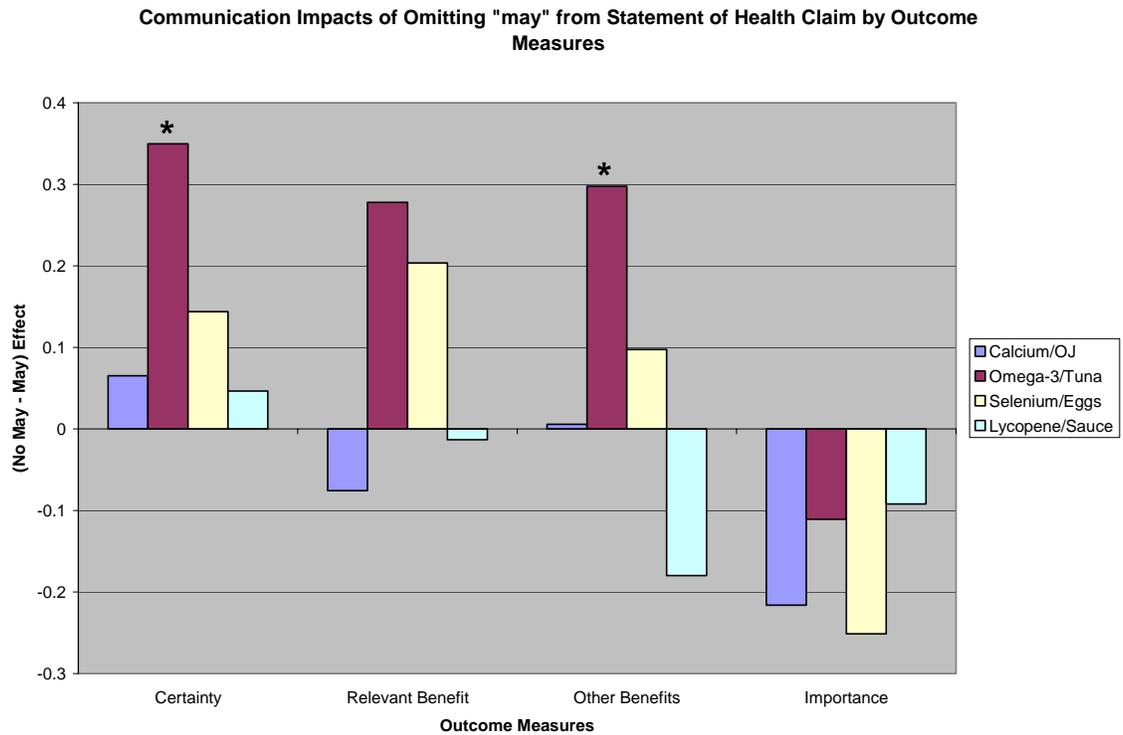
* p ≤ .05

As Figure 6 shows, the (No May – May) communication effects are mixed when collapsed across claim/product pairings, (Certainty, t = 1.93, ns; Relevant Health Benefit, t = 1.23, ns; Other Health Benefits, t = 0.78, ns: and Importance, t = -2.15. p ≤ .05). Expressing the substance/disease relationship without "may" leads to significantly lower

ratings of the perceived importance of the product to a healthy diet, an indication of an unexpected negative effect for health claims. The Omega-3/Tuna pairing is the only one of the four claim/product pairings that shows some positive effects of omitting "may" from the statement of the health claim.

Communication Impact of Unqualified Health Claims Relative to a Nutrient Content Claim

Health claims are assumed to be the most desirable type of product label claim because they make the strongest and most explicit assertions about possible product benefits of the product. However, in the marketplace there appear to be more nutrient content claims on product labels than authorized health claims, even when products would qualify for an authorized health claim (Ippolito and Pappalardo, Advertising Nutrition and Health, Bureau of Economics Staff Report, Federal Trade Commission, 2002; Geiger, 1998). Given the ubiquity of nutrient content claims in the marketplace, it seems prudent to consider nutrient content claims as a relevant control to evaluate the communication effectiveness of health claim statements.

Figure 7 presents the results of the comparison between the communication effects of an unqualified health claim or a corresponding nutrient content claim on a product label. Overall, an unqualified health claim communicates more positive views of the SS and the product benefits than does a corresponding nutrient content claim (Certainty $t = 4.9$, $p \leq$ .0001; Relevant Health Benefit, $t = 4.9$, $p \leq .0001$; Other Health Benefits, $t = 0.77$, ns;

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Importance, t = 2.6, p ≤ .01).  However, the positive impact of an unqualified health

claim is largely limited to less familiar substance/disease relationships.   The calcium

content claim, for example, has essentially the same communication impact on

respondents as does the familiar calcium/osteoporosis health claim.

Figure 7

**Communication Impacts of an Unqualified Health Claim Relative to a Content Claim**
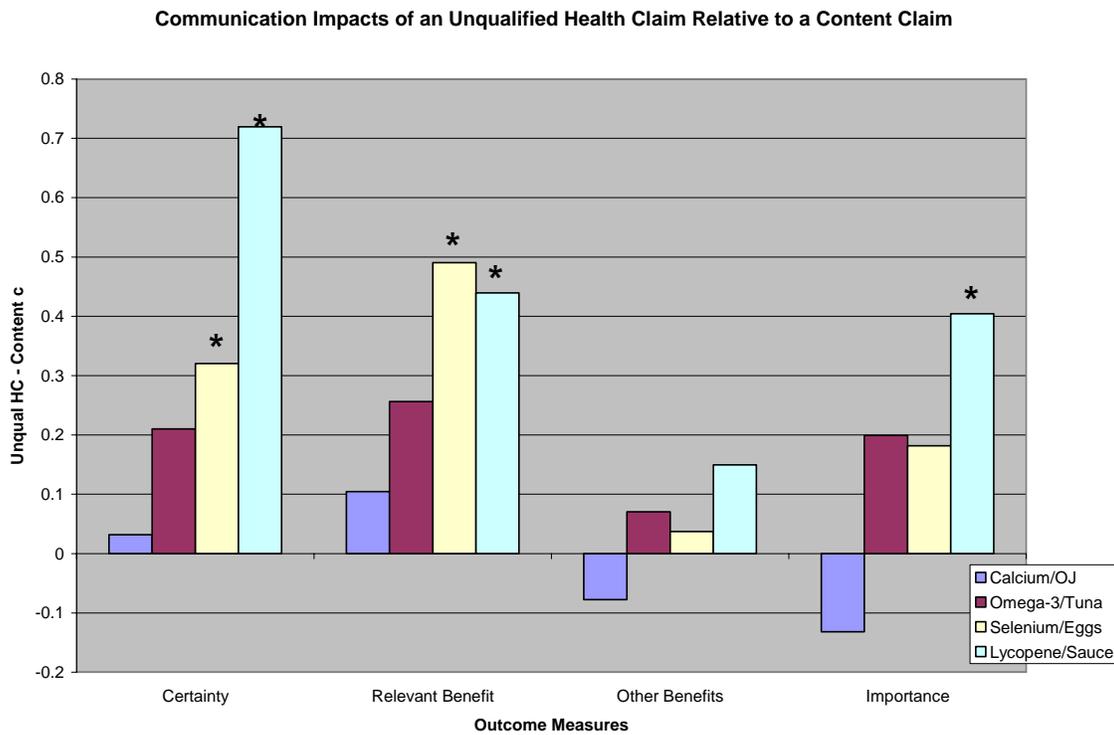


* p ≤ .05

## Communication Impacts of the "Full Information" Condition

Consumers will usually have prior beliefs about the strength of science underlying a

given health claim before they see such a claim on a food product label.  An interesting

control for evaluating the impacts of disclaimers is the situation where consumers are

briefed about the current state of science for one of the four health claims. Subjects in

this condition represent "educated" consumers who have more knowledge about the

science underlying the claim than an average consumer. In the study, respondents in the

"Full Information" condition see a product label with a nutrient content claim after

reading a one-page summary about the state of scientific evidence supporting the relevant

health claim (the order of presentation was counterbalanced, so half the respondents in

the Full Information condition viewed the relevant product label as their first product

while the other half viewed it as their second product).

Figure 8 presents the results for the mean communication impacts of the Full Information

control condition relative to a product label with an unqualified health claim. Reading a

one-page scientific summary produces more scientific certainty about the

substance/disease relationship than simply seeing the health claim on a product label

(Certainty, $t = 3.97$, $p \leq .0001$). This is particularly true when the scientific summary is

mainly positive (e.g., Calcium/Osteoporosis, Omega-3/Heart Disease), but even when the

scientific summary highlights major weaknesses in the scientific evidence, respondents

consider the conveyed state of evidence to be no worse than what is conveyed by an

unqualified health claim. Respondents in the Full Information condition perceive and

understand products with a nutrient content claim in the same way that typically

uninformed consumers perceive and understand products with unqualified health claims

(Relevant Benefit $t = 1.4$, ns; Other Benefits, $t = .04$, ns; Importance, $t = 0.62$, ns). In a

sense, the "Full Information" condition produces the same phenomenon observed

naturally for the well-known Calcium/Osteoporosis claim; i.e., effective communication

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equivalence between a nutrient content claim and a health claim (see Figure 2).  This

seems likely to occur with any health claim in the marketplace once the public has

become educated about the scientific support of the claim.

Figure 8.

**Communication Impacts of Full Information Relative to an Unqualified Health Claim on Product Label**
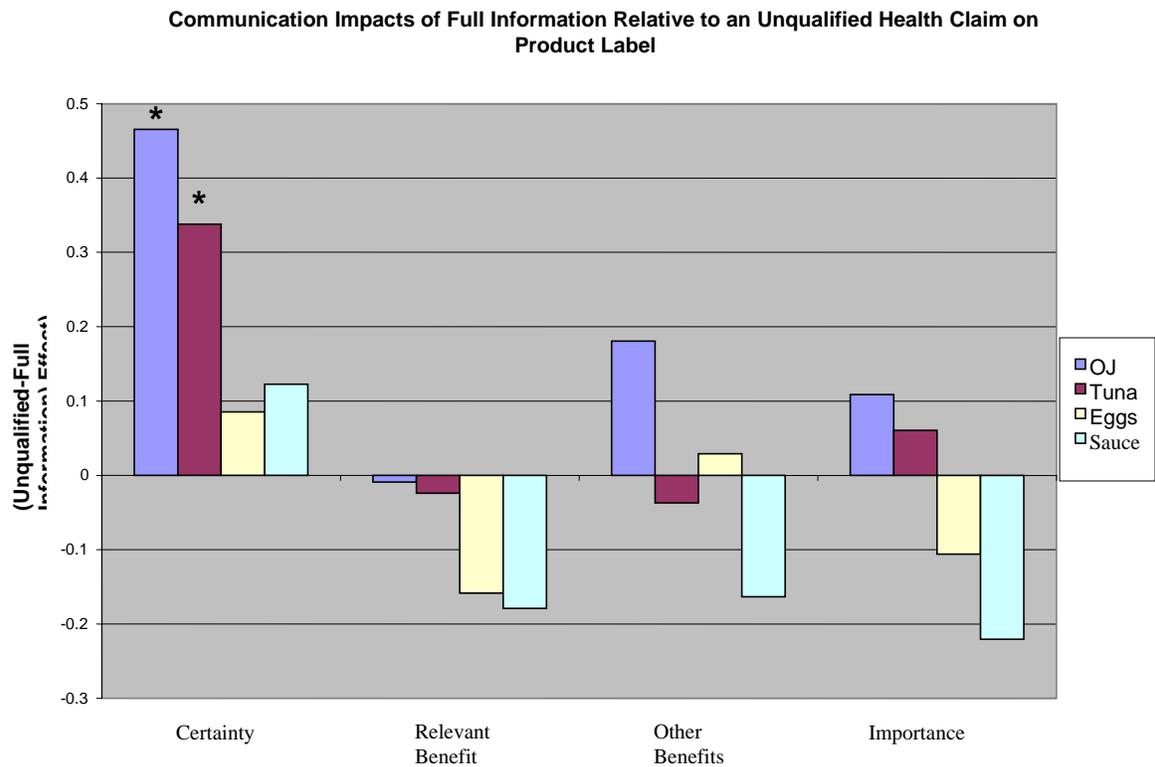


\* $p \le .05$

Individual Differences

Table 6 presents the parameter estimates and t-tests for selected individual difference

variables from the GLM solution.  The analysis shows that age, prior awareness of health

effects of specific nutrients, and education are consistently related to the communication

impacts of product label health claims.  Respondents with greater awareness of the health

effects of a nutrient are more likely to react positively to an associated health claim (i.e.,

stronger ratings of scientific certainty, more positive ratings of the relevant health benefit

and the importance of the food in the diet).  Respondents who are between 30 and 45

years old are more likely to respond positively to health claims than other age groups.

Respondents with more education are apparently more skeptical of health claims than

those with less education.  Sex and health status do not appear to have consistent effects

on the communication impacts of food label health claims.

Table 6.        GLM Results for Individual Difference Effects on Communication
                Outcome Measures.

| | Scientific Certainty | | Relevant Health Benefit | | Other Health Benefits | | Importance | |
|---|---|---|---|---|---|---|---|---|
| | Beta | T-test | Beta | T-test | Beta | T-test | Beta | T-test |
| **Sex(male)** | -0.078 | -2.06* | -0.043 | -1.11 | 0.047 | 1.38 | -0.061 | -1.63 |
| **Age(18-29)** | -0.041 | -0.7 | 0.093 | 1.52 | -0.045 | -0.82 | -0.115 | -1.95 |
| **Age(30-45)** | 0.207 | 3.44** | 0.159 | 2.58* | 0.115 | 2.08* | 0.158 | 2.65* |
| **Age(46-60)** | 0.020 | 0.32 | 0.125 | 1.92 | 0.025 | 0.43 | 0.080 | 1.28 |
| **Health Status** | 0.014 | 0.88 | -0.024 | -1.49 | -0.023 | -1.57 | 0.007 | 0.41 |
| **Awareness** | 0.079 | 5.99*** | 0.042 | 3.12** | 0.010 | 0.84 | 0.057 | 4.35** |
| **Education** | -0.033 | -2.54* | -0.034 | -2.59* | -0.064 | 5.4*** | -0.036 | -2.84* |

$* p \leq .05$        $** p \leq .01$                $*** p \leq .001$

**Discussion**

None of the different ways tested to communicate the strength of science supporting a food label health claim performed very satisfactorily.  The ways that different disclaimer schemes failed, however, may help us understand why it is so difficult to communicate strength of science to consumers.  Text disclaimers that relied on plain English and adjectives (i.e., Point/Counterpoint and Embedded disclaimer schemes) failed the key communication test.  They did not reliably convey the intended level of scientific support for a health claim.  This suggests a need to better understand the operating assumptions that influence consumers' reactions to health claim statements and the ways consumers' assumptions and knowledge may affect their perceptions in this communication situation.

Even when strength of science disclaimers were easier to comprehend (i.e., with the familiar communication device of report card grade), they did not show the intended effects.  Report card grade disclaimer schemes successfully conveyed the intended ordering of scientific certainty, but they failed a compensatory effect test.  For example, when respondents saw B and C report card grade disclaimers appropriate for the "correct" level of scientific support for the claim, they became <u>more certain</u> about the scientific evidence supporting the claim than when they saw an unqualified ("A" level) health claim.   Rather than compensate for the effect of an unqualified claim, such qualified claims led to stronger effects in the same direction.   Similarly, strength of science disclaimers did not significantly diminish the impact of health claims on consumer perceptions of product health benefits.

The failure of report card grade disclaimers, which successfully convey the level of scientific support, to reverse the perceived certainty effects of unqualified health claims is especially worrisome. It raises questions, such as how can consumers understand the usual meaning of a report card grade of B or C to imply more certainty than their prior assumptions about the certainty of unqualified health claims? One possible explanation is that consumers may fail to recognize how much better the scientific evidence is for a health claim that meets the significant scientific agreement standard, such as those they currently see on food product labels, than it is for a claim that requires a disclaimer. Or it may be that their perceptions of the meaning of a B or a C letter grade is such that these disclaimers connote more certainty than their prior views about product label health claims in general. This communication failure would follow from consumers' inaccurate prior assumptions about the scientific support for unqualified health claims.

A problem of incorrect prior assumptions may be correctable through education, perhaps by explaining to consumers the implications of a health claim being unqualified or qualified by a SS disclaimer. This would require explaining to consumers the FDA's regulatory approach to health claims.

An attempt to update the consumer's prior assumptions at the time of reading the label, however, is functionally equivalent to a disclaimer and would need to be evaluated in the same way. For example, how would a consumer react if a label statement asserts that a health claim is more certain than the consumer previously thought it to be? This is

addressed in the present study with the comparison between stating an unqualified health claim with "may" and stating the unqualified health claim without "may." Stating an unqualified health claim without "may" conveyed somewhat greater scientific certainty (p ≤ .06) than the same health claim with "may;" it also led to a significant "boomerang effect" on one measure of perceived product health benefits, namely a flawed inferential judgment about the importance of the product as part of a healthy diet.

Another approach to dealing with incorrect prior assumptions might be to include unqualified health claims within the report card grade scheme. By giving unqualified health claims an explicit "A" grade, for example, the correct ordering of scientific certainty for health claims could be communicated for the full range of possible health claims. It should be noted that other health information found on food labels, such as structure-function claims or dietary guidance statements, fall outside this health claim approach.

A recent study by the International Food Information Council (IFIC, 2005) tested the approach of labeling unqualified health claims with an explicit report card grade of 'A.' IFIC found that although "A" grades conveyed significantly greater scientific certainty, they also produced some significant product preference reversals compared to health claims with lower report card grades (IFIC, 2005).

These findings suggest that consumers' prior beliefs about the certainty of science for a health claim are not easily supplanted by new information in the claim. These prior

beliefs apparently play an important role in determining how consumers understand and respond to health claims. When claims seem to convey more scientific certainty than respondents believed to be warranted by their prior beliefs, they reacted by attributing less positive health benefits to the product than they did when the claim conveyed less scientific certainty.

How can conveying more certainty about the science supporting a health claim cause negative effects on product perceptions? One would expect greater scientific certainty to signal more positive product characteristics. One possible explanation is based on the phenomenon of psychological reactance (Brehm, 1966; Ringold, 2002). Reactance is a well known social cognition phenomenon where people react negatively to what they perceive to be an inappropriate or exaggerated attempt to influence them. The crucial perspective applicable here is the idea that the claim/disclaimer on the product label is perceived by consumers as an explicit influence attempt. This suggests that rather than assuming that consumers view health claims/disclaimers on product labels as authoritative and authorless information, it may be that consumers think of health claims as marketing, intended to influence them to buy the product. In this view, when consumers have prior beliefs about either the product or the health claim, they are sensitive to product label claims which seem to be exaggerated or overblown. When the perceived discrepancy is sufficiently large, psychological reactance may result, and normal inferential effects of the claim on perceived product characteristics may be reversed. It may not be enough to convey greater scientific certainty about claims, even if they deserve it, if consumers see that as a basis to doubt the credibility of the claim.

From this perspective, the fundamental communication problem with strength of science disclaimers is not that they are incomprehensible, which they may be, or that consumers have incorrect prior beliefs about the scientific certainty of claims, which they may have, but rather that consumers see health claims and strength of science disclaimers as marketing information which may or may not deserve their trust.  Health claims and disclaimers that consumers see on product labels will sometimes provide helpful and useful information about product characteristics and nutrition science, but they also may be misleading.  In such a communication context, the first task of the label reader is to judge whether a claim deserves trust.  Rather than assume that disclaimers are authoritative (and authorless)  information about the science supporting the claim, consumers seem to see disclaimers as one more piece of evidence to help them decide whether the assertions being made about the product are plausible or misleading.

Analyzing health claims and disclaimers as marketing information manufacturers provide to promote their product seems to fit the data.  It would explain why consumers are generally skeptical about product label health claims—there is always the possibility that someone is trying to take advantage of your trust.  It explains why disclaimers don't reverse the effects of health claims—mild disclaimers may actually increase the perceived plausibility of claims because they seem to regard the disclaimer as a signal that the manufacturer is trying to be balanced and informative.  It explains why it is so hard to communicate levels of scientific certainty in a comprehensible way—if consumers don't care that much about scientific certainty of a claim except when it is

grossly discrepant from their existing views, they cannot be assumed to read this information with great care or attention. It helps explain why briefing respondents about the state of science for a given health claim before they see a product with a relevant content claim tends to make the content claim equivalent to an unqualified health claim, i.e., being briefed about the level of scientific support makes consumers react to a nutrient content claim as a plausible implied health claim. Finally, it helps explain why health claims have more positive effects when they are less familiar—when a health claim is unfamiliar the consumer has less of a knowledge basis that can serve to trigger a critical response.

A marketing perspective on label health claims also sheds light on the individual difference effects observed in the study. Respondents who are more knowledgeable about specific substance/disease relationships are more likely to be positively influenced by related health claims because these health claims are more likely to seem plausible in light of their prior knowledge. Similarly, respondents who are more educated are less likely to be positively influenced by health claims because more educated people tend to be more skeptical of what they see to be marketing claims.

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