

BEFORE THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

In the Matter of
Assessing Consumer Perceptions of Health Claims;
Public Meeting; Request for Comments

Docket No. 2005N-0413

Comments of the Staff of
the Bureau of Economics,
the Bureau of Consumer Protection,
and the Office of Policy Planning
of the Federal Trade Commission

January 17, 2006*

*These comments represent the views of the staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission. They do not necessarily represent the views of the Federal Trade Commission or any individual Commissioner. The Commission has, however, voted to authorize the staff to submit these comments. Questions or comments concerning this document may be addressed to Dennis Murphy (202-326-3524 or dmurphy@ftc.gov) or Pauline Ippolito (202-326-3447 or pippolito@ftc.gov) in the Bureau of Economics.

I. Introduction

On November 17, 2005, the Food and Drug Administration (“FDA”) held a public meeting to present findings of five recent studies of consumer perceptions of qualified and unqualified health claims for conventional foods and dietary supplements. In the meeting announcement, FDA also sought public comment on (1) available research and the implications of the research for further consumer studies and (2) other approaches that might convey effectively to consumers the strength of science supporting health claims.¹ The staff of the Federal Trade Commission’s Bureau of Economics, Bureau of Consumer Protection, and Office of Policy Planning (“FTC staff”) is pleased to submit this comment in response to FDA’s request for public comment.

In this comment, the FTC staff identifies five findings from the studies that may help guide future research in this area. These findings are: (1) Current FDA language for qualified and unqualified claims does not communicate the intended levels of scientific certainty to consumers; (2) The current language the FDA uses to communicate an unqualified Significant Scientific Agreement claim does not convey strong scientific certainty to consumers; (3) The FTC staff’s research indicates that language may be crafted that will differentiate clearly among differing levels of scientific certainty; (4) The “report card” formats perform consistently well in ranking scientific certainty; and (5) Consumer interpretation of the individual qualified claims that researchers have tested varies widely. The comment then suggests several ways in which researchers might build on these findings.

¹ Assessing Consumer Perceptions of Health Claims; Public Meeting; Request for Comments, Docket No. 2005N-0413, 70 Fed. Reg. 60749, 60750-51 (Oct. 19, 2005) (hereinafter “FDA Public Meeting”).

A. The FDA Approach to Regulating Qualified Health Claims

The FDA currently evaluates the scientific evidence supporting health claims in food and dietary supplement labeling pursuant to an interim process using a four level system.² Level “A” health claims are *unqualified* claims for which there is “significant scientific agreement” (“SSA”) that the diet-disease relationship is valid. Levels “B”, “C”, and “D” claims correspond to *qualified* health claims for which the level of comfort regarding the scientific support for a given diet-disease relationship is progressively weaker.³

² FDA statutes and regulations permit health claims on labels for both food and dietary supplements if they are supported by "significant scientific agreement" ("SSA") among qualified experts based on publicly available scientific evidence. 21 U.S.C. 343(r)(1)(B); 21 C.F.R. 101.14(a)(1) and (2). In 1999, the U.S. Court of Appeals for the D.C. Circuit considered a constitutional challenge to the FDA's denial of four health claims for dietary supplements that were not supported by SSA. *See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). The FDA asserted that it could prohibit these claims because they had the potential to mislead consumers, but the court rejected this argument. The court held that the FDA had violated the First Amendment by denying these claims without proof that disclosures would not have sufficed to cure the potential for deception. After the *Pearson* decision and another related case, *Whitaker v. Thompson*, 248 F.Supp.2d 1 (D.D.C. 2002)), the FDA adopted an interim process that allows marketers to convey truthful, non-misleading health claims for both foods and dietary supplements that indicate the level of scientific support for the claim.

³ *Guidance for Industry and FDA: Interim Evidence-based Ranking System for Scientific Data*, 68 Fed. Reg. 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 Fed. Reg. 41387 (July 11, 2003).

Examples of FDA SSA and Qualified Health Claims

| <u>FDA Scientific Ranking⁴</u> | <u>Health Claim Statement</u> |
|--|---|
| Level A (SSA standard - high level of comfort) | “Diets rich in calcium may reduce the risk of osteoporosis.” |
| Level B (moderate/good level of comfort) | “Omega-3 fatty acids may reduce the risk of heart disease but the scientific evidence is promising but not conclusive. ” |
| Level C (low level of comfort) | “A diet high in selenium may reduce the risk of cancer but the scientific evidence is limited and inconclusive. ” |
| Level D (extremely low level of comfort) | “The antioxidant lycopene may reduce the risk of certain cancers, including prostate cancer in men, but the scientific evidence is very limited and preliminary. ” |

FDA’s recent consumer research tested the “B”, “C”, and “D” level health claims in the chart above, and a slightly shortened version of the SSA claim.⁵

B. Research Presented at the November Meeting

At the meeting, FDA presented the findings of its copy test of 1,920 consumers, which examined the performance of health claims in labeling for four fictional food products using two language-only formats and two “report card” formats.⁶ The International Food Information

⁴ Descriptions of FDA scientific rankings from *Guidance for Industry and FDA: Interim Evidence-based Ranking System for Scientific Data* and *Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements*, *supra* note 3.

⁵ Brenda M. Derby & Alan S. Levy, *Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims* 8-10 (U.S. Food and Drug Administration, Working Paper No. 1, 2005).

⁶ *Id.* See also Brenda M. Derby & Alan S. Levy, *Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims* (Nov. 17, 2005) (slide presentation at FDA Public Meeting), available at <http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00004-Derby.pdf>.

Council (“IFIC”) Foundation presented findings of an internet-based survey of 5,642 consumers, which tested the same health claim formats as those examined by FDA.⁷ Staff of the Federal Trade Commission (“FTC”) discussed findings from a series of copy tests dating back to 1998. This research, which involved approximately 1300 consumers, tested qualified health claims in print advertising.⁸ Ratapol P. Teratanavat and Neal H. Hooker (“Teratanavat-Hooker”), researchers from The Ohio State University, discussed two computer-based experiments that studied how a sample of 372 college students interpreted qualified and unqualified health claims in food product labeling.⁹ Finally, Karen Russo France and Paula Fitzgerald Bone (“France-Bone”), faculty members at West Virginia University, presented findings from copy test research of 359 consumers who examined one unqualified and one qualified “B” level health claim on the labels of two fictional dietary supplements.¹⁰

⁷ IFIC Foundation, *Qualified Health Claims Consumer Research Project Executive Summary* (Mar. 2005), available at <http://www.ific.org/research/qualhealthclaimsres.cfm>. See also Wendy Reinhardt Kapsak, *Assessing Consumers’ Perceptions of Health Claims* (Nov. 17, 2005) (slide presentation at FDA Public Meeting), available at <http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00006-kapsak.pdf>.

⁸ Dennis Murphy *et al.*, *A Generic Copy Test of Food Health Claims in Advertising*, Federal Trade Commission (1998); R. Dennis Murphy, *Consumer Perceptions of Qualified Health Claims in Advertising* (Federal Trade Commission, Working Paper No. 277, 2005). See also Pauline M. Ippolito, *Qualified Health Claims* (Nov. 17, 2005) (slide presentation at FDA Public Meeting), available at <http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00005-ippolito.pdf>.

⁹ Neal H. Hooker, *Do People Understand Qualified Health Claims? Evidence from Experimental Studies* (2005) (manuscript on file with Ohio State University). See also Neal H. Hooker & Ratapol P. Teratanavat, *Qualified Health Claims: Food for Thought?* (Nov. 17, 2005) (slide presentation at FDA Public Meeting), available at <http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00008-hooker.pdf>.

¹⁰ Karen Russo France & Paula Fitzgerald Bone, *Policy Makers’ Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Labels*, 39 J. CONSUMER

II. FTC Experience

The FTC has significant expertise in food and dietary supplement advertising and labeling issues. The FTC enforces the Federal Trade Commission Act,¹¹ which prohibits deceptive or unfair acts or practices in or affecting commerce.¹² A high priority of the FTC is bringing law enforcement actions to prevent deceptive claims in health-related advertising.¹³ The Commission strives to achieve this goal in a manner that will not impose unduly burdensome

AFFAIRS 27 (2005). *See also* Karen Russo France & Paula Fitzgerald Bone, *Policy Makers' Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Labels* (Nov. 17, 2005) (slide presentation at FDA Public Meeting), *available at* <http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00007-France.pdf>.

¹¹ 15 U.S.C. § 45 *et seq.*

¹² *Id.* The FTC and the FDA have overlapping jurisdiction to regulate the advertising, labeling, and promotion of foods, over-the-counter drugs, cosmetics, and medical devices. Under a long-standing liaison agreement between the agencies, the FDA exercises primary responsibility for regulating the labeling of these products, and the FTC has primary responsibility for ensuring the advertising of these products is truthful and not misleading. Working Agreement Between FTC and FDA, 4 Trade Reg. Rep. (CCH) ¶ 9,850.01 (1971).

¹³ For example, the FTC has brought law enforcement actions against food companies that allegedly made deceptive claims about the health benefits of their products. *See, e.g., Tropicana Products, Inc.*, C-4145 (Aug. 19, 2005) (consent order); *KFC Corp.*, C-4118 (Sept. 17, 2004) (consent order). *See also Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the FTC in the Matter of Request for Comments on Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims; Reopening of the Comment Period*, Docket Nos. 1994P-0390 and 1995P-0241, at 3 (July 27, 2004); *Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the FTC in the Matter of Food Labeling: Health Claims; Dietary Guidance*, Docket No. 2003-0496, at 4 (Jan. 26, 2004).

restrictions that might chill information useful to consumers in making purchasing decisions.¹⁴

Likewise, FTC staff has studied the effect of advertising regulation on consumers and competition¹⁵ and has examined the role of advertising in communicating health information to consumers.¹⁶ As noted above, since 1998 FTC staff has conducted extensive consumer survey research on qualified health claims, including advertising copy tests on over 1,300 consumers, to study which types of qualifying language most effectively convey limitations in scientific support for diet-disease relationships.

¹⁴ See, e.g., FTC Policy Statement Regarding Advertising Substantiation, appended to *Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984) (substantiation factors include benefits of a truthful claim and costs of a false claim, thus balancing the goal of preventing deception with the need to ensure access to truthful information and vigorous competition).

¹⁵ See Pauline Ippolito & Janis Pappalardo, *Advertising Nutrition & Health: Evidence from Food Advertising 1977-1997*, FTC Staff Report (2002); Pauline Ippolito & Alan Mathios, *Information and Advertising Policy: A Study of Fat and Cholesterol Consumption in the United States, 1977-1990*, FTC Staff Report (1996); Pauline Ippolito & Alan Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market*, FTC Staff Report (1989); John Calfee & Janis Pappalardo, *How Should Health Claims for Foods Be Regulated? An Economic Perspective*, FTC Staff Report (1989).

¹⁶ Murphy *et al.* (1998) and Murphy (2005), *supra* note 8.

Finally, FTC staff has commented on several FDA food advertising and labeling issues¹⁷ and participated on the Task Force on Consumer Health Information for Better Nutrition, which formulated recommendations on FDA's proposed regulatory approach to qualified health claims.

Based on its experience and research in this area, FTC staff submits this comment in response to FDA's request for public comment on the implications of available research for future research on qualified health claims. The comment first presents what we believe to be principal findings of the research presented at the November meeting and then discusses possible ways in which further research on health claims might build on these findings.

III. Principal Findings of Research Presented at the Public Meeting

Our review of the five studies presented at the public meeting has identified at least five findings that may have important implications for future research. Many of these findings are common to most or even all of the studies, and therefore should be considered robust.

Finding #1: The current FDA language for qualified and unqualified claims does not communicate the four intended levels of scientific certainty to consumers.

All of the studies tested examples of language that FDA has approved tentatively for qualified health claims in labeling. Four of the five studies tested FDA claims that spanned more

¹⁷ See, e.g., *Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the FTC in the Matter of Food Labeling: Health Claims; Dietary Guidance*, Docket No. 2003-0496 (Jan. 26, 2004); *Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the FTC in the Matter of Obesity Working Group; Public Workshop: Exploring the Link Between Weight Management and Food Labels and Packaging*, Docket No. 2003N-0338 (Dec. 12, 2003); *Comments of the Staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the FTC in the Matter of Food Labeling: Trans Fatty Acids in Nutrition Labeling: Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote on Disclosure Statements*, Docket No. 03N-0076 (Oct. 9, 2003).

than one level of scientific certainty. These “language-only” claims do not employ any symbols or letter grades to describe the level of certainty the claim is intended to communicate. The IFIC and FDA studies tested the largest number and broadest range of these claims.

The IFIC research included a “sorting” exercise that produced strong evidence that the current FDA language does not function as intended. In this experiment, consumers compared four of the FDA claims, one from each of the four levels of scientific certainty (“A” through “D”). Only 22 percent of the participants could sort the four claims in the correct order of scientific certainty.¹⁸

The more formal copy test portions of the FDA and IFIC studies asked respondents to rate the scientific certainty conveyed by a given claim on a 7-point scale that ranged from (1) “very uncertain” to (7) “very certain.” Unlike the IFIC sorting exercise, in these tests different groups of consumers saw different claims and could not compare the language side by side. Neither study found a statistically significant relationship between the average certainty scores that respondents gave the various claims and the level of certainty the claims were intended to convey.¹⁹ That is, consumers who saw a label with a higher level FDA claim did not on average choose scores that were higher than scores chosen by consumers who saw a lower level FDA claim. In the Teratanavat-Hooker research, the average certainty ratings that college students assigned to an FDA unqualified “A” health claim did not differ significantly from the average

¹⁸ IFIC Foundation (Mar. 2005), *supra* note 7, at 5. Further, one-third of the consumers rated the “D” claim (weakest science) as conveying the highest level of certainty.

¹⁹ Derby & Levy, *supra* note 5, at 21; IFIC Foundation (Mar. 2005), *supra* note 7, at 5-8.

rating given an FDA “D” level claim.²⁰ Finally, in the France-Bone study, participants did not rate an FDA “A” claim as more certain than an FDA “B” claim.²¹ In short, these results suggest that the current FDA language for qualified claims does not distinguish adequately between the levels of science supporting these claims.

Finding #2: Consumers do not perceive the current FDA SSA claim to convey strong scientific certainty.

Research to date has found consistently that consumers believe that SSA claims are supported by less science than is in fact the case.²² This discounting of what is intended to be the strongest claim available in labeling greatly increases the difficulty of crafting qualified claims that differentiate varying levels of scientific certainty below the level of significant scientific agreement.

Evidence of this discounting can be found in all of the studies that conducted relevant tests. In the FDA study, the average scientific certainty score for the various SSA claims ranged from 3.9 to 4.8 on a 7-point scale.²³ The IFIC study findings are similar.²⁴ The Teratanavat-Hooker study recorded an average certainty rating of 4.11 out of a possible seven points for the

²⁰ Hooker, *supra* note 9, at 19.

²¹ France & Bone, *supra* note 10, at 45.

²² The format for this claim is: “Diets rich in substance X may reduce the risk of disease Y.”

²³ Analysis is based on data provided to FTC staff by FDA staff. Removing the “may” from this claim made very little difference in the certainty scores. The maximum average score achieved was still only about 4.8.

²⁴ Again, the highest average rating for the SSA claim was 4.8 and the lowest recorded average score was only 2.8 out of a possible seven points. (Analysis is based on data provided to FTC staff by IFIC staff.)

FDA SSA claim.²⁵ Finally, the average certainty scores in the France-Bone study for the two tested FDA SSA claims were 3.5 and 4.0 on a six-point scale.²⁶

In part, these scores may reflect basic consumer skepticism of promotional claims, however worded.²⁷ As we detail below, however, consumers gave higher certainty ratings to other approaches to unqualified claims, including a strongly worded “proof” claim used in FTC staff’s copy test research and a “report card” format claim tested in the IFIC study.

Finding #3: The results of the FTC staff’s copy tests indicate that it is possible to craft language that differentiates clearly among differing levels of scientific certainty.

During the past 10 years, the FTC staff has conducted a series of four copy tests of qualified health claims in advertising. These tests incorporated several approaches to measuring consumer perception of the degree of support for a qualified health claim, including a 5-level rating scale in the early tests and a 7-point scale in the most recent research. Over the course of this research, FTC staff tested four levels of health claims – one unqualified claim and three successively more qualified claims – all appearing in print ads for a fictional antioxidant vitamin supplement. The unqualified claim, referenced hereafter as the “proof” claim, used very strong language to convey a high level of scientific certainty for the efficacy of antioxidant vitamins in reducing the risk of cancer. The relevant portion of the text stated:

²⁵ Hooker, *supra* note 9, at 35.

²⁶ France & Bone, *supra* note 10, at 44 (Table 2, Cell 2).

²⁷ See, e.g., Calfee, J.E., & Ringold, D.J., *The Seventy Percent Majority: Enduring Consumer Beliefs about Advertising*, 13 J. PUBLIC POLICY AND MARKETING: 228-238 (1994).

Scientists have now proven that supplements containing these same antioxidant vitamins also reduce the risk of cancer. It's a fact!

Although this claim very likely overstates the degree of certainty scientists would accord a diet-disease relationship, it was included for experimental purposes in the early testing to provide a firm basis for determining whether it was feasible to devise qualifying language that could communicate a lower level of certainty to consumers.²⁸ A “mildly” qualified claim used language intended to convey a “weight-of-the-evidence” level claim similar to FDA’s current “B” level claim.²⁹ The qualifying language stated that the evidence “looks promising, but scientists won’t be sure until longer term research is completed.” A stronger “qualified” claim cautioned that:

It’s too early to tell for sure. Some studies have failed to show that these vitamins protect against cancer. Longer term research is needed.

Finally, the most recent FTC staff copy tests included a more highly qualified “Box Disclaimer” advertisement that contained the following disclaimer set off inside a box:

There is much scientific debate about whether antioxidant vitamin supplements reduce the risk of some kinds of cancer. Most studies have failed to show that these vitamin supplements reduce the risk of cancer.

²⁸ Had the results shown no significant difference between consumer interpretation of this proof claim and the qualified claims, we could have concluded with some certainty that attempts to qualify health claims are unlikely to be effective.

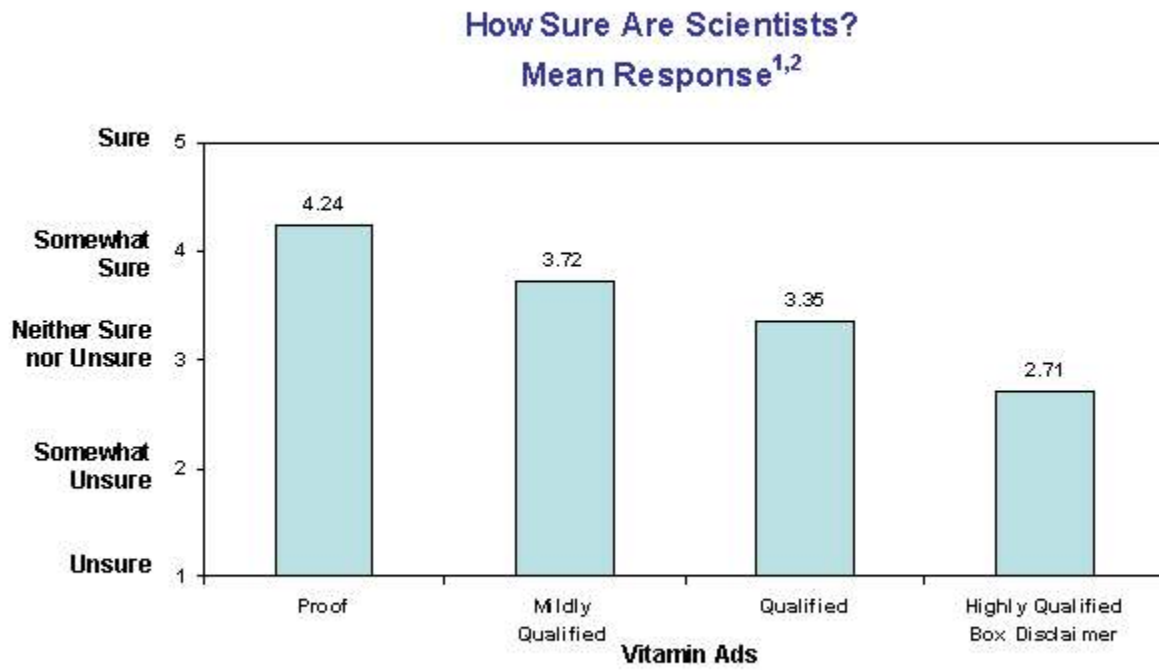
²⁹ At the time this claim was first tested in 1998, the science supporting the relationship between antioxidant vitamin supplements and a reduced cancer risk arguably could have been rated at a level “B.” Over the course of the FTC’s series of copy tests, however, the science weakened to a “C” level.

Figure 1 shows the average certainty scores that respondents assigned to these claims using a 5-point scale.³⁰ On average, consumers were able to discern clear differences in the level of certainty communicated by these claims. As intended, the average certainty scores decline consistently as the level of intended qualification increases, *i.e.*, as the science becomes less certain. It is also clear from comparing the results for the proof and mildly qualified claim that even a small degree of qualification can reduce consumers' certainty ratings substantially.³¹

³⁰ Murphy (2005), *supra* note 8 at 22. The mean score for the Highly Qualified Box Disclaimer is from an earlier unpublished copy test performed in July 2002.

³¹ An analysis of the distribution of ratings across the five certainty choices shows that 58 percent of respondents seeing the proof claim thought that scientists were “sure” about the efficacy of antioxidant vitamin supplements, whereas only 22 percent of respondents seeing the mildly qualified claim thought that the science was “sure.” For the qualified claim and the highly qualified box disclaimer test ads, the figures for “sure” were, respectively, ten percent and five percent.

Figure 1



¹ All differences are significant in one-tailed tests.

² Consumers were asked to rate certainty on a 1-5 scale as shown.

Finding #4: The “report card” formats performed consistently well on the ranking tests.

The report card approach to communicating scientific certainty uses a letter grade (from “A” to “D”) rather than a verbal description to describe the certainty of the science supporting a given health claim. The FDA and IFIC studies used two formats to present the letter grade. In the “report card text” version, a health claim supported by, say, a “C” level of science is followed by the statement:

FDA evaluated the scientific evidence and gave it a “C” rating, based on a scale from A (strongest evidence) to D (weakest evidence).

A second approach, called the “report card graphic,” uses four levels of boxes with the appropriate box checked off. These boxes are labeled, from top to bottom: “A: Strong Evidence;” “B: Moderate Evidence;” “C: Some Evidence;” and “D: Little Evidence.” Figure 2 presents an example of a “D” level report card graphic label used in the FDA copy test.³²

In FDA’s research, the average certainty scores for both versions of the report card format tracked the intended level of certainty for the “B” through “D” claims. FDA did not test an “A” level report card claim, but instead used a shortened version of the current language-only format for an SSA claim. (“Substance X may reduce the risk of disease Y.”) Interestingly, the “B” level report card scores were consistently higher than the SSA claim scores, which may be another indication that the current unqualified language is not communicating a sufficiently high level of scientific certainty.³³

³² Derby & Levy, *supra* note 6, at 10.

³³ Derby & Levy, *supra* note 5, at 23; Analysis is based on data supplied to FTC staff by FDA staff.



Figure 2

Graphic Report Card Scheme

The antioxidant lycopene may reduce the risk of certain cancers, including prostate cancer in men.

| FDA Rating of Scientific Evidence | |
|-----------------------------------|-------------------------------------|
| A. Strong Evidence | <input type="checkbox"/> |
| B. Moderate Evidence | <input type="checkbox"/> |
| C. Some Evidence | <input type="checkbox"/> |
| D. Little Evidence | <input checked="" type="checkbox"/> |

NET WT. 1lb. 9.75oz. (730g)



The IFIC research, which, unlike the FDA test, included report card formats for “A” level claims, found that consumers could distinguish reliably among the four levels of qualification when shown labels using the same report card graphic format used by the FDA. With the report card text format, respondents could distinguish between two levels (A-B and C-D).³⁴ In absolute terms, the Report Card “A” average certainty scores were consistently higher than the corresponding average language-only SSA claims.³⁵ Finally, the Teratanavat-Hooker study tested an “A” and “D” level report card graphic format in combination with the corresponding current FDA language-only claim, and also tested the current FDA language standing alone. Respondents could distinguish the claims when the report card graphic was included, but could not distinguish when the claim was presented in language form only.³⁶ Again consistent with the findings of other research, the mean certainty rating for the report card version of the unqualified health claim was significantly higher than for the FDA unqualified claim standing alone (5.02 vs. 4.11 on a 7-point scale).³⁷

Finding #5: Consumer interpretation of qualifying language varies widely.

In its most recent research, the FTC staff tested three possible qualified claims for antioxidant vitamin supplements and a reduced risk of cancer, including the very strong “Box Disclaimer” discussed earlier. Consumers were asked “How certain is the evidence?” FTC staff used a 7-point scale for these ads. The average certainty scores for the three ads (3.33 to 4.04 on

³⁴ IFIC Foundation (Mar. 2005), *supra* note 7, at 6-7.

³⁵ Data provided to FTC staff by IFIC staff.

³⁶ Hooker, *supra* note 9, at 19 and graph at 38.

³⁷ *Id.* at 35.

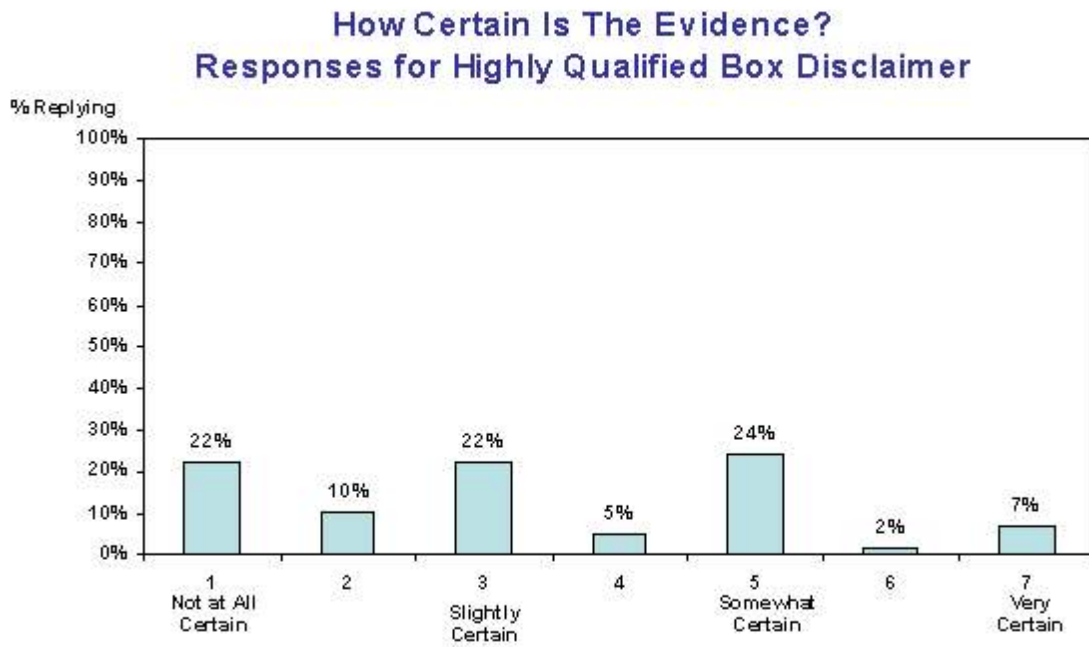
a 7-point scale) were at or below the midpoint of the scale, values that appear reasonable for a level of science that is below a weight-of-the-evidence standard. For any given claim, however, the scores that individual consumers chose did not cluster tightly around the average score. Instead, the choices were spread out across the scale.

As shown in Figure 3, an approximately equal proportion of consumers seeing the highly qualified Box Disclaimer chose option 1 (The science is “not at all certain”); option 3 (The science is “slightly certain”); and option 5 (The science is “somewhat certain..”). Further, one-third of the respondents rated the certainty of the science above the midpoint.³⁸ This suggests that these consumers may have overestimated the degree of scientific certainty for the antioxidant vitamin-cancer relationship, which, as indicated, is supported by less than the weight of the evidence.³⁹

³⁸ Murphy (2005), *supra* note 8 at 29.

³⁹ Although some variation in consumer interpretation of qualified health claims is inevitable given what are almost certainly broad differences in respondents’ background beliefs, the degree of variation observed in the research is nonetheless surprising, particularly for the heavily qualified claims, such as the Box Disclaimer, that incorporate very strong language intended to communicate a low level of certainty. It is possible that such a “disclaimer” runs counter to the basic efficacy claim being made for the product. Rather than qualifying the claim, the “disclaimer” may contradict it, leaving consumers in a difficult interpretative situation that is reflected in the wide variation in responses. See J. Howard Beales, Remarks Before the Food and Drug Law Institute’s Conference on Qualified Health Claims, at 8-9 (Jan. 14, 2004), *available at* <http://www.ftc.gov/speeches/beales/040114foodanddruglawinstitute.pdf>.

Figure 3



The distributions for the scientific certainty ratings in the FDA’s study also show wide variation in choices among consumers seeing the same label claim. This variation is evident for both the claims in language-only and report card format. For example, 40 percent of respondents seeing a Report Card Text “D” claim linking lycopene with a reduced risk of prostate cancer rated the certainty of the science at 5 or higher on the 7-point scale, and thus arguably were misled concerning the true level of scientific support. (Thirty-seven percent gave the science a score of 3 or lower, and the remainder (24%) chose the midpoint score of 4).⁴⁰ The results suggest that a qualified claim that, on average, communicates the correct level of scientific certainty may still mislead a substantial number of consumers.

IV. Implications for Future Research

The research findings discussed above have at least four implications for future research efforts on qualified health claims.

Implication #1: Other approaches to language-only claims should be explored.

Although the tested FDA language did not communicate differing levels of scientific support clearly, the results of FTC staff’s copy tests suggest that it may be possible to craft language-only claims that do perform satisfactorily. As emphasized above, one difficulty with the FDA’s current approach may be an insufficiently strong SSA claim. In particular, the SSA claim makes no mention of the high degree of scientific support for this class of diet-disease relationships.

⁴⁰ We did not have access to the underlying data for the other studies presented at the November 17 meeting and could not determine the degree of variation in the individual scores in that research.

One possible solution to this problem would be to include an explicit description of the quality of the underlying evidence in each claim level. We show below an example of such a format using four levels of qualification. The FTC staff has not tested this language, and we provide the illustration only to stimulate thought on the type of language-only claims that might perform most effectively.

| <u>Claim Level</u> | <u>Claim</u> |
|--------------------|---|
| A. | Very strong evidence shows that a diet rich in substance X reduces the risk of disease Y. |
| B. | Promising evidence indicates that a diet rich in substance X reduces the risk of disease Y, but the evidence is not definite. |
| C. | Some evidence suggests that a diet rich in substance X may reduce the risk of disease Y, but the evidence is weak. |
| D. | Limited evidence suggests that a diet rich in substance X may reduce the risk of disease Y, but the evidence is very weak. |

Implication #2: Additional approaches similar to the report card format should be tested.

As discussed, the various studies found that the report card format was largely successful in communicating differing levels of scientific certainty to consumers. One potential difficulty with this approach, however, is that letter grades currently appear on certain product labels as a measure of product quality, *e.g.*, Grade A turkey, eggs, and butter. Marketers might therefore be reluctant to use any scientific certainty score below an “A” for fear consumers would construe the grade too broadly as a negative statement about overall product quality.⁴¹

⁴¹ It should be noted, however, that relevant charts included in IFIC’s November 17 presentation do not reveal strong evidence of any such undesirable “spillover” effects from the report card reporting system. These charts show, *inter alia*, the average ratings that consumers

The positive results for the report card format suggest that other simple scoring methods that do not rely on letter grades might also be successful and should be targeted for testing in future research projects. For example, certainty might be displayed on a thermometer-type scale, or perhaps using a system of stars, checkmarks, or numerical ratings. (The FDA may wish to consult with consumer education specialists in developing different ratings systems to test.) Alternatively, the letter grades might simply be removed from the report card graphic display, since the level of evidence corresponding to each box is already described in summary fashion (see Figure 2).

Implication #3: IFIC’s “sort test” can help allocate research resources

As discussed, IFIC found that FDA’s language-only claims could not pass a simple sorting test exercise where consumers saw all of the claims simultaneously and then attempted to rank the claims in the right order of intended scientific certainty. Relative to full copy tests, such a test is relatively inexpensive to perform and can quickly weed out claims that are unlikely to function as intended in subsequent formal copy testing. In particular, the sorting exercise will allow researchers to determine quickly whether other approaches to language-only claims should

gave for product quality and safety when shown only a nutrient content claim (which is labeled “control” in the charts), and the corresponding ratings for the test conditions where consumers saw an explicit health claim in report card text or graphic format. There are no statistically significant differences between any of the quality or safety ratings in the report card conditions and those in the nutrient content test conditions. This lack of differences suggests that marketers could make an explicit health claim, rather than the less informative nutrient content claim, without any adverse repercussions on consumer perceptions of product quality or safety. See IFIC Foundation (Mar. 2005), *supra* note 7, slides 6 and 7, available at <http://www.ific.org/research/upload/Slides.pdf>.

be explored. Accordingly, researchers may wish to include such a sorting exercise as a preliminary component of studies in this area.

Implication #4: Future research should examine the degree of variation in certainty ratings for a given test condition.

It is important that any system for qualifying claims meet the threshold ranking test that requires average ratings of scientific certainty for the various testing conditions to decline as the degree of qualification increases. As we noted in our discussion of the FTC staff and FDA staff copy tests, however, a large proportion of respondents seeing the same claim frequently selected scores that were considerably above or below the average score. Even if the average rating is considered consistent with the actual level of scientific support for the claim, the qualified language might still mislead or confuse a substantial number of consumers.⁴² A system of qualified claims that communicates the correct level of scientific certainty to a larger proportion of consumers would reduce this concern. Future researchers may wish, therefore, to address this issue explicitly.

V. Conclusion

The FDA is to be applauded for its important research on consumer interpretation of qualified health claims and for providing the opportunity for other researchers to present their findings in a public forum. The various studies have provided valuable insights into the performance of alternative approaches to conveying levels of scientific certainty in labeling and

⁴² The wide dispersion in ratings could also indicate that consumers were confused by the rating system itself. This issue might be explored in future research by using different rating systems to test the same claims. The degree of variation in responses found for each of the rating systems could then be compared to determine which rating system was easiest for consumers to understand.

advertising. In particular, the research suggests that FDA's current "language only" claims are not clearly communicating differences in scientific certainty. At the same time, certain findings indicate that it may be possible to craft language that will function more successfully in this regard.

Finally, the “report card” format was generally successful in communicating differences in scientific certainty, although a significant degree of disagreement was evident in consumer interpretation of the grades assigned to the claims. As discussed, these findings can help shape the next round of research in this important area of public policy.

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