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

In the Matter of Food Labeling: Health Claims; Dietary Guidance
Docket No. 2003-0496

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

January 26, 2004*

*** These comments represent the views of the staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission. They are not necessarily the views of the Federal Trade Commission or any individual Commissioner. The Commission has, however, voted to authorize the staff to submit these comments.**

I. INTRODUCTION

The Food and Drug Administration (FDA) has issued an Advance Notice of Proposed Rulemaking (ANPR) to solicit views on qualified health claims.[1] The FDA is currently reviewing qualified health claims pursuant to an interim enforcement policy that allows marketers to communicate truthful, non-misleading health claims for foods and dietary supplements when appropriately qualified to indicate the level of scientific support for the claim. The agency adopted this policy to provide consumers a greater range of information on ways to improve their health and to respond to court rulings establishing that consumers have a First Amendment right to truthful health information even if that information is not supported by significant scientific agreement.[2]

In the ANPR the FDA solicits views as to which permanent approach to qualified health claims the agency should adopt.[3] It is considering three alternative proposals. Option 1, which is based on the interim approach, would require marketers to petition the FDA for approval of qualified health claims, and, after public comment, the agency would indicate whether it intended to exercise its law enforcement discretion to challenge the claim. Option 2 would require notice and comment rulemaking for each qualified health claim. Option 3 would regulate qualified health claims on a post-market basis. The FDA is also considering adopting an evidence-based ranking system for qualified health claims and it seeks any current empirical research findings relevant to consumer interpretation of qualified health

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[1] 68 Fed. Reg. 66040 (Nov. 25, 2003).

[2] *See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002).

[3] ANPR at 66040.

claims.[4]

FTC staff supports FDA's initiative because it is likely to increase the flow of truthful, non-misleading health information to consumers, while at the same time maintaining strong protections against deception. Because effective consumer protection requires that such claims be considered from the standpoint of the consumers receiving them, we also strongly support the FDA's commitment to use empirical evidence to guide its regulatory and policy choices. In brief, this comment notes:

- The FDA's interim approach to qualified health claims appears to recognize the importance of protecting consumers from deception, promoting truthful, non-misleading commercial speech, and ensuring flexibility in accommodating changes in science.
- FTC staff believes that Option 1, which would codify the interim approach, is an acceptable approach, although more experience with the approach and further consumer research are needed to reach definite conclusions about its merits.
- Consumer research conducted by FTC staff suggests that consumers can distinguish between levels of scientific support, but that strongly worded qualifiers are needed to avoid deception. This is particularly true when fashioning qualifiers such as those proposed for so-called "C" and "D" claims when the level of scientific support is weak.
- The FDA's evidence-based ranking system appears to maintain marketers' incentives to further develop the science in support of their claims.

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[4] *Id.*

II. BACKGROUND

The Federal Trade Commission has considerable expertise in food and dietary supplement advertising and labeling issues. The FTC enforces the Federal Trade Commission Act,[5] which prohibits deceptive or unfair acts or practices in or affecting commerce.[6] The FTC considers the prevention of deceptive health-related advertising claims to be one of its highest priorities and has challenged deceptive health claims about foods and dietary supplements in numerous cases. FTC staff has also studied the effect of advertising regulation on consumers and competition[7] and examined the role of advertising in conveying health information to consumers.[8] Finally, FTC staff participated as members of the Task Force on Consumer Health Information for Better Nutrition that formulated the recommendations to the FDA that are explored in the ANPR, and staff submitted comments

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[5] 15 U.S.C. § 45 *et seq*.

[6] *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, while the FTC has primary responsibility for ensuring that their advertising is truthful and not misleading. Working Agreement Between FTC and FDA, 4 Trade Reg. Rep. (CCH) ¶ 9,850.01 (1971).

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

[8] *See, e.g.,* Dennis Murphy *et al., A Generic Copy Test of Food Health Claims in Advertising* (1998).

on a number of FDA food advertising and labeling issues – including two in the past year.[9]

At its core, the Commission's mission is to protect consumer sovereignty by addressing practices that impede consumers' ability to exercise informed choice in the marketplace. Preventing deception while fostering the free flow of truthful and non-misleading information to consumers is key to this mission. Accordingly, the Commission strives to stop deception without imposing unduly burdensome restrictions that might chill information useful to consumers in making purchase decisions.[10] Because truthful and non-misleading information is also critical for competition, the Commission has been vigilant to oppose overly broad restrictions on the provision of such information, whether imposed by government or private organizations.[11]

Generally, regulatory approaches that narrowly tailor restrictions against false or misleading claims, coupled with vigorous law enforcement, will result in greater dissemination of truthful, non-misleading information. In contrast, broad restrictions on the

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[9] *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), *available at* www.ftc.gov/be/v040003text.pdf; *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 or Disclosure Statements*, Docket No. 03N-0076 (Oct. 9, 2003), *available at* www.ftc.gov/os/2003/10/fdafattyacidscommenttext.pdf.

[10] *See, e.g.*, FTC Policy Statement Regarding Advertising Substantiation, 49 Fed. Reg. 31000 (1984) (substantiation factors include benefits of a truthful claim and costs of a false or misleading claim, thus balancing the goal of preventing deception with the need to ensure access to truthful information and vigorous competition).

[11] *See, e.g., American Medical Ass'n*, 94 F.T.C. 701, 993-96 (1979), *enforced as modified*, 638 F. 2d 443 (2d Cir. 1980), *aff'd per curiam by an equally divided court*, 455 U.S. 676 (1982) (challenge to the association's prohibition on physician advertising).

dissemination of information do stop false or misleading information but can also deprive consumers of useful information and impede their ability to exercise informed choice.[12] Empirical evidence, described more fully in prior FTC comments filed with the FDA,[13] suggests that the effects of government restrictions on claims for foods and dietary supplements are consistent with these general principles.[14]

III. FDA APPROACH TO REGULATING QUALIFIED HEALTH CLAIMS

The FDA requests comment evaluating the merits of three alternative proposals for regulating qualified health claims for foods and dietary supplements. As noted above, Option 1 would codify the current interim procedures and evidence-based ranking system and require that marketers petition the FDA for approval of qualified health claims.[15] The petition would be made available to the public, and the agency would issue a letter indicating whether it intended to exercise its law enforcement discretion to challenge the claim. The FDA would

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[12] *See 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 in the Matter of Request for Comment on First Amendment Issues*, Docket No. 02N-0209 (2002), *available at* www.ftc.gov/os/2002/09/fdatextversion.pdf.

[13] *See, e.g.*, FTC Staff Comments, *supra* note 7.

[14] *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).

[15] The ANPR explicitly states that the FDA would codify the evidence-based ranking system into a regulation under Option 1. See ANPR at 66042. The ANPR is silent about whether the FDA would use the evidence-based ranking system if it adopted Option 2 or Option 3. If the FDA adopts Option 2 or Option 3, it should explore whether adopting the evidence-based ranking system under these options could benefit consumers.

evaluate the science supporting the underlying substance-disease relationship and assign a ranking to the claim depending on the level of scientific support. Option 2 would mandate formal notice and comment rulemaking for each requested qualified health claim. A marketer would petition the FDA for approval of a qualified health claim; the agency would then publish the proposed claim for public comment and would approve it if the claim as qualified were supported by significant scientific agreement. Option 3 would have the FDA "treat qualified health claims as wholly outside the NLEA and regulate them solely on a postmarket basis, if they are false or misleading."[16]

We believe that the best regulatory approach to qualified health claims should accomplish two main objectives. First, the approach should maximize the ability of sellers to disseminate truthful and non-misleading information to consumers, while adequately protecting consumers from false or misleading information. Second, because the approach must accommodate claims based on emerging science, it should be flexible enough to allow the claims to be modified as the science changes without the cost and delay of a formal rulemaking.

The FTC staff believes that the ANPR sets forth the correct factors for the FDA to consider in evaluating the merits of the three options the agency has put forward.[17] We also believe that Option 1 – based largely on the FDA's current interim approach – is an acceptable approach,[18] although more experience with the approach and further consumer

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[16] ANPR at 66042.

[17] *Id*. at 66042-43.

[18] The ANPR requests comment on the "meaning and/or relevance" of the "competent and reliable scientific evidence" standard in the context of the FDA's interim

research are needed to reach definite conclusions about its merits. Although options 2 and 3 have clear conceptual advantages, each also has important implications for resources and fits differently with the FDA's authority. The FTC staff, however, takes no position on whether Option 2 or Option 3[19] (or some other alternative) better fits the FDA's mission, resources, and authority.

IV. QUALIFICATION OF HEALTH CLAIMS

The ANPR seeks information on how to qualify health claims adequately to convey to consumers the level of scientific support for the claims. The FTC staff recognizes that developing proper qualifying language is necessary if the FDA's health claims initiative is to succeed. Well-grounded empirical evidence of how consumers would interpret the qualifiers is essential to determine whether the health claims, as qualified, can be conveyed in a way that is truthful and non-misleading. Moreover, marketers' incentives to petition for

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evidence-based ranking guidance, which the FDA would implement under Option 1. *See* ANPR at 66045. The FTC typically requires "competent and reliable scientific evidence" to substantiate efficacy or safety claims for health-related claims for products like foods, OTC drugs, supplements, and devices. The FTC does not impose any fixed formula regarding the number or type of studies required to meet the standard, or any specific parameters for sample size and study duration. The Commission examines both the validity of individual studies and the surrounding context of the scientific literature to determine whether the weight of the evidence supports a particular claim. *See* FTC Bureau of Consumer Protection, *Dietary Supplements: An Advertising Guide for Industry* (1998), at Sections B.1-5. The competent and reliable scientific evidence standard has limited relevance under the evidence-based ranking system, however: because the FDA reviews the scientific support for a claim before it is disseminated and assigns the appropriate ranking qualifying the level of support, a reasonable consumer would expect it to have only the level of support that the FDA ranking indicated.

[19] Option 3 calls for the FDA to review health claims after dissemination, as the FTC does, to ensure that the claims are not false or misleading. We believe that such a post-dissemination model has been effective for the Commission, given its mission, authority, and resources. The FDA, however, has a different mission, authority, and resources. *See* ANPR at 66043 (comparing the FTC and the FDA's investigative powers).

approval of health claims and to sponsor science are stronger if qualifiers distinctly signal the level of scientific support for a claim to consumers.

A. FTC Staff Research Results

Since 1998, the FTC staff has conducted extensive consumer survey research testing qualified health claims.[20] The FTC staff has tested ads on approximately 1,300 consumers as part of copy testing to provide guidance about which types of qualifying language are most effective in conveying limitations on the science supporting health claims. This research suggests that qualifiers must be carefully crafted to be effective.

The copy tests suggest that consumers can distinguish between claims that are qualified to convey differing levels of scientific certainty. Consumers thought that ads with unqualified claims, such as "Scientists have proven that taking antioxidant vitamin supplements reduces the risk of certain kinds of cancer," were the most certain. Consumers also understood more qualified claims, such as "It looks promising, but further research is needed," as being significantly less certain. Consumers further recognized that the most highly qualified claims were the least certain of all.

The copy tests also suggest that very strong qualifiers for health claims may be needed to convey an accurate impression to consumers if the supporting science for the diet-disease relationship is weak. FTC staff tested ads concerning the relationship between the use of antioxidant vitamin supplements and a reduced cancer risk under the assumption that the science supporting this relationship is weak. When consumers were shown an ad with mild or

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[20] Results of the 1998 copy tests were published in Murphy, *supra* note 6. Results from the subsequent copy tests require further analysis and review, but preliminary analysis of that data indicates that the results are broadly consistent with the 1998 results.

moderate qualifiers regarding the science supporting this relationship, most consumers thought that scientists were relatively sure that antioxidant vitamin supplements reduced the risk of cancer. To make consumer perception consistent with the weaker level of scientific support, stronger qualifiers (e.g., "Most studies have failed to show that antioxidant vitamin supplements reduce the risk of cancer") were necessary.

The FTC staff's copy tests are assessing the efficacy of various qualifiers in particular ads with health claims. In contrast, the FDA here is attempting to identify standard qualifiers that would work for all health claims on labels involving the same category of supporting science. Because the impression that consumers take away from a claim sometimes varies based on the context in which it is made, the FDA faces a difficult task in identifying qualifiers that will be effective on a variety of labels. Nevertheless, the FTC staff's copy tests of various qualifiers in particular ads should provide useful insight to the FDA in accomplishing this task.

It may be that even stronger qualifiers may not be adequate in some circumstances to convey an accurate impression if the supporting science is weak. Because companies typically do not use these claims in their advertising, FTC staff has relatively limited experience in assessing the adequacy of qualifiers for claims that are supported by weak science.[21] In the absence of additional well-designed and well-conducted consumer research, it is thus not clear that qualifiers can be identified that will convey an accurate impression of health claims for which the scientific support is weak.

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[21] This may be because such highly qualified claims concerning the efficacy of a product may not be likely to cause consumers to purchase the product or because of other reasons, such as concerns about legal liability.

The FTC staff, like the FDA,[22] continues to conduct consumer research to identify specific language and other means to distinguish claims based on the level of scientific support. Among other things, our research is evaluating whether consumers take away an accurate impression from health claims for which the supporting science is weak. As the FTC staff completes its analysis of its test results, it will share these results with the FDA and the public.

B. Marketer Incentives to Make Qualified Health Claims

The ANPR seeks comment on "how to provide incentives for manufacturers to develop the data needed to obtain significant scientific agreement for an unqualified health claim."[23] We believe that the proposed evidence-based ranking structure itself provides some incentive for marketers to incur the cost of petitioning the FDA for approval of an unqualified or less-qualified claim or even to sponsor some research to support progressively less-qualified claims.

For example, a marketer that has to state on a label that "although there is scientific evidence supporting the claim, the evidence is not conclusive" to make a health claim (*i.e.*, a "B" claim under the FDA's interim approach)[24] would likely expect that consumers would be more interested in purchasing its product if it could make an unqualified health claim or "A"

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[22] *See* FDA, *Consumer Studies Research Agenda* (July 10, 2003), *available at* www.cfsan.fda.gov/~dms/nuttf-d.html.

[23] ANPR at 66043.

[24] On an interim basis, the FDA is assigning a letter ranking from A to D to all proposed health claims submitted for approval according to the particular level of science supporting the claim. Scientists have a high level of comfort that "A" – or unqualified – claims are valid, a moderate or good level of comfort that "B" claims are valid, a low level of comfort that "C" claims are valid, and an extremely low level of comfort that "D" claims are valid.

claim. Individual marketers, however, may not have sufficient incentive to undertake very costly independent research to gain approval for an unqualified health claim that relates to a class of foods generally, rather than specifically to their own brands.[25]

Preliminary results from the FTC staff's empirical research tentatively suggest that there may be much less incentive for marketers to incur costs to make highly qualified claims. The copy tests suggest that, particularly for highly qualified "C" or "D" claims in ads, such claims may not make consumers more likely to purchase the advertised product than if the ad contained no health claim at all. If such highly qualified claims in fact are not likely to increase product sales, marketers would have little incentive to commit resources to petition for or develop scientific support for "C" or "D" quality science when those claims likely will not have an effect on consumers' purchase decisions.

As recognized in the ANPR, there are many alternatives that the FDA could consider to help consumers distinguish between the levels of scientific support for health claims. The FDA might consider using attributions such as "FDA approved" or "FDA authorized" only

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[25] On the other hand, marketers may be less willing to fund research or spend to communicate claims about a class of foods generally, rather than their own brands. Marketers cannot use dietary guidance statements to link a substance and a disease because this link would make the statement a health claim. *See, e.g.,* ANPR at 66040, 66046. This limits their ability to communicate that a specific substance in that product is likely to have a health benefit, and manufacturers would be less likely to provide dietary guidance than to make qualified health claims. Therefore, from a regulatory perspective, dietary guidance statements are not a substitute for truthful, non-misleading qualified health claims. For discussion of the free rider problem and advertisers' incentives to communicate information, *see* J. Howard Beales, III, Richard Craswell, & Steven Salop, *The Efficient Regulation of Consumer Information*, 24 J.L. & Econ. 491, 503-04, 509 (1981).

with unqualified claims.[26] The FDA could eliminate the requirement that marketers use "may" in unqualified claims as in, "Calcium may reduce the risk of osteoporosis."[27] We support the FDA's plans to conduct research to test these and other possible qualifiers, and we intend to work closely with the FDA on consumer research relating to this issue.

V. CONCLUSION

The FDA's on-going efforts to develop an empirically-based approach to qualified health claims for food and dietary supplement labeling will likely benefit consumers and competition. We believe that the development and adoption of this approach will lead to better-informed consumers who will be able to select from a broader range of healthier products. We therefore support the FDA's efforts to develop such an approach.

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[26] Given that claims without SSA may well prove to be unfounded, this usage helps ensure that the value of such an attribution is not diluted by association with unfounded claims.

[27] Research conducted by the FTC staff indicates that vague qualifiers that a food or nutrient "may" have a certain health benefit have little or no impact on consumers' perception of the certainty of the science. Murphy, *supra* note 6; *see also* Richard Harris, *Inferences in Information Processing*, 15 The Psychol. of Learning and Motivation 81-128 (1981). To the extent consumers process "may" at all, we share the FDA's doubt that consumers understand it as meaning that the health claim holds true for some, but not all, people. *See* ANPR at 66043.

Respectfully submitted,

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