

Public Dockets Comments Summary

The Task Force on Consumer Health Information for Better Nutrition established public docket 03N-0069 to receive views and comments from interested stakeholders. The Task Force is especially interested in learning about stakeholder views on the following questions that were asked at the stakeholder meetings:

1. What body of scientific evidence do you think should be adequate for a qualified health claim?
2. What types of safety concerns should be factored into FDA decision-making?
3. What specific claims do you think are currently ready for consideration under the new guidance?
4. On what issues are disclaimers valuable, or not valuable, in preventing consumers from being misled, and do you have data to support your view?
5. What kinds of empirical data should FDA rely upon to show that consumers are, or are not, misled by claims?
6. Should conventional foods and dietary supplements be treated the same or treated differently, and why?

Public docket 03N-0069 closed on Tuesday, May 27, 2003.

Comments to Docket: 03N-0069 FDA Task Force on Consumer Health Information for Better Nutrition

Summary of Selected Comments Submitted to the Docket

Note: The comments sent to the docket that addressed the 6 questions that FDA requested comments on are summarized below. The comments submitted to the docket that did not address the 6 questions are included as an attachment. Please note that several comments were submitted to docket # 02D-0515 that was opened for "Guidance for Industry - Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements." They are included in this summary.

American Dietetic Association (June 3, 2003)

1. What body of scientific evidence do you think should be adequate for a qualified health claim?

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Health claims authorized for foods and dietary supplements should be based on the totality of the publicly available scientific evidence, including results from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles. For a statement to be valid or scientifically sound, it cannot be preliminary or speculative. For example, if just any statement in a publication from a scientific body were allowed to form the basis for a qualified health claim, misleading and potentially harmful statements could appear on food labels. A sufficient body of evidence must exist to avoid confusing millions of consumers and losing their trust.

For determining the body of evidence needed for a qualified health claim, ADA recommends a methodology similar to the one ADA has adopted for use with evidence-based guides for practice. This grading system, consisting of "strength" grades I-IV, are described by Myers et al in the September 2001 issue of Journal of the American Dietetic Association. A system like the one described by Greer et al. determines the weight of evidence in favor of, or the extent to which evidence submitted supports, a qualified claim. This system was developed to communicate the strength of evidence with health care professionals. Whether the terminology or concepts would be understood by consumers is unknown.

2. What types of safety concerns should be factored into FDA's decision-making?

Government standards and guidelines should help prevent excessive nutrient intakes from fortified foods and dietary supplements. At present there is little regulation to guide the amount of nutrients in highly fortified foods, meal replacements, or oral nutritional supplements. Several resources are available to help address the safety of non-nutrients, which are often included in dietary supplement products and are increasingly being included in food products as well. Clearly, a methodology is needed for determining whether consumption of a nutrient does or does not put the public, especially sub-groups deemed to be at high risk such as children, pregnant women, the elderly and the immunocompromised, in danger. Side effects should be evaluated, particularly unusual side effects not normally reported but with serious consequences just the same. The product should not have serious side effects.

Furthermore, a modeling methodology needs to be established to account for actual consumer behavior, not just the effects of consuming the substance according to directions on the label.

3. What specific claims do you think are currently ready for consideration under the new guidance?

ADA does not have recommendations on which qualified health claims are ready for consideration.

4. On what issues are disclaimers valuable, or not valuable, in preventing consumers from being misled, and do you have data to support your view?

Our Nutrition Trends Survey addresses the global question of whether information on labels influences behavior. Fifty-four percent of respondents stated he or she purchased a product due to information on a nutrition label, suggesting labels do matter. This supports our belief that consumers want understandable, useable and credible information on both food products and dietary supplements.

5. What kinds of empirical data should FDA rely upon to show that consumers are, or are not, misled by claims?

ADA recommends pre-market research of consumer perceptions of the various label layouts, designs and effectiveness of communication strategies be conducted prior to the qualified claim's approval. For example, FDA should require, at a minimum, focus groups reflective of the sample of consumers to whom a claim is targeted. FDA also should consider information gathered by the Federal Trade Commission's (FTC) research on disclosure statements.

6. Should conventional foods and dietary supplements be treated the same or treated differently, and why?

Health claims for conventional foods and health claims for dietary supplements should meet identical standards for sound scientific agreement. With respect to qualified health claims, the same evidence-based system to determine the weight of scientific evidence supporting such a claim should be used for both dietary supplements and conventional foods. While it is clear that dietary supplements and conventional foods are not alike in every way, FDA should mandate a single standard for qualified claims and apply it to both dietary supplements and conventional foods. Use of a single standard and system is less likely to confuse consumers and will make them better able to identify if products may be beneficial to them.

Jonathan Emord on behalf of Julian M. Whitaker, M.D. and Wellness Lifestyles, Inc. d/b/a American Longevity (April 24, 2003)

1. What body of scientific evidence do you think should be adequate for a qualified health claim?

The question presumes that a defined level of scientific evidence can serve as a general standard or rule for allowance of qualified health claims. That presumption is in error. In *Pearson v. Shalala*, (D.C. Cir. 1999), the agency tried to convince the Court of Appeals that "significant scientific agreement" defined a standard for claim allowance and that were the FDA to find such agreement not present, it had no First Amendment obligation to permit a health claim to be made with disclaimers. The

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Court rejected that argument. Inconclusiveness of science does not make a claim suppressible under the First Amendment; rather, it merely begs the ultimate First Amendment question: Can the claim be qualified or disclaimed in a way that will eliminate misleadingness? If it can be rendered nonmisleading through the addition of a disclaimer, qualification, or warning statement, it must be... Viewed from the vantage point of what FDA must prove in order to meet its First Amendment burden to justify claim suppression, one may readily see that so long as the claim is backed by some scientific evidence and a disclaimer can suffice to eliminate misleadingness, the claim must be allowed with that disclaimer.

2. What type of safety concerns should be factored into FDA decision making?

Safety is an issue only if the product is not lawfully saleable as a dietary supplement under the Food Drug and Cosmetic Act (due to adulteration). If a petitioner were to seek agency health claim approval for a dietary supplement that contained ingredients that were adulterated, then the FDA would fulfill its statutory duty without offense to the First Amendment by denying the petition. That is because the denial would be based on the unlawful status of the product, a statutory determination that can be rendered without regard to the content of what is communicated. If, however, the dietary supplement contained ingredients lawfully saleable but known to cause adverse effects in a subset of the American population or to cause adverse effects at some level of ingestion, then the FDA would act properly by requiring an appropriate disclaimer but improperly by denying the petition. That is because use of a disclaimer in such a circumstance is an obvious, less speech restrictive alternative to outright suppression and, thus, constitutionally required.

3. What specific claims do you think are currently ready for consideration under the new guidance?

The potential claims are as numerous as the credible evidence on nutrient-disease relationships contained in the publicly available scientific literature. Few, if any, commenters will likely volunteer the precise claims they wish to submit because those decisions involve proprietary concerns, scientific research, and business planning that many prefer not to divulge publicly before actually filing a petition.

A significant reduction in the time expended for claim review would likely increase private resort to use of the health claim petition process and would thereby fulfill the purposes of the statute and of the health information for better nutrition initiative by increasing the quantity and variety of accurate health information available to consumers. A significant reduction in review time would also quite likely reduce the incentive for, and thus the number of, unapproved claims in the market, redounding to the benefit of consumers due to a reduction in the number of false or unsubstantiated market claims.

4. On what issues are disclaimers valuable, or not valuable, in preventing consumers from being misled, and do you have data to support your view?

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The Supreme Court and the lower federal courts define disclaimers, qualifications, and warning statements as the only means available to the government to alter potentially misleading commercial speech, speech the Court has held protected by the First Amendment.

Government is thus left with a choice of either mandating or not use of a disclaimer, qualification, or warning statement in those instances where it can prove the existence of a potential to mislead. Because a health claim is, by statutory definition, one that cannot enter the market without FDA approval, market survey data is of little use in ascertaining whether consumers will be misled once the claim has entered the market. That is because the presence of the claim in the market has its own edifying effects.

The Court of Appeals and the lower federal courts expect FDA to rely on empirical evidence, not supposition, as a basis for finding the existence of a potential to mislead.

It is thus most prudent (and, in fact, essential from a First Amendment standpoint) for each claim to be evaluated based on its plain language meaning. If in light of the scientific evidence reviewed, the plain meaning of the claim conveys a misleading connotation or omits material, then a succinct, accurate and tailored disclaimer, qualification, or warning statement may be added to avoid misleadingness.

Moreover, under the First Amendment, government has no constitutional power to suppress a true message on the basis that recipients of the message do not comprehend it.

5. What kinds of empirical data should FDA rely upon to show that consumers are, or are not, misled by claims?

As explained above, the relevant empirical data in the prior restraint context of health claims exists in all publicly available scientific literature germane to the claim and in the plain language of the claim. With that information in hand, FDA may determine if the claim as worded is backed by credible evidence, does not convey a misleading connotation, and does not omit material information necessary to avoid misleadingness. If the language of the claim may mislead or if a material omission is present that could mislead, then FDA may require the addition of a reasonable disclaimer, qualification, or warning to avoid the misleading connotation. As stated above, empirical data from the market will not provide accurate consumer perception information concerning nutrient/disease information not present in the market. As explained above, the First Amendment forbids government censorship of truthful communication on the basis that the recipient cannot comprehend or misunderstands the message.

6. Should conventional foods and dietary supplements be treated the same or treated differently, and Why?

The First Amendment applies equally to commercial speech concerning dietary supplements and foods. Nutrient-disease claims for both should be treated under the same First Amendment standard; the Pearson decision and its progeny rest on First Amendment principles that apply to all manner of commercial speakers. Consequently, there is no sound legal basis for affording any less First Amendment protection to nutrient-disease claims for foods than nutrient-disease claims for dietary supplements. Claims for each should be evaluated under the same First Amendment standard.

The Consumer Healthcare Products Association (CHPA) and the Council for Responsible Nutrition (CRN) – May 27, 2003

The Consumer Healthcare Products Association (CHPA) and the Council for Responsible Nutrition (CRN) support this effort. One question posed was whether conventional foods and, dietary supplements should be treated the same or treated differently. The purpose of the present comment submitted by CHPA and CRN is solely to address some aspects of this issue.

As the Task Force seeks to identify ways to encourage communication of high quality, science-based nutrition information to consumers about health claims, it should bear in mind that health information is also conveyed through structure/function claims. Indeed, the average consumer does not know whether a particular claim for a food or dietary supplement is a health claim or a structure/function claim. In 2000, however, FDA took a position that can be expected to create consumer confusion about structure/function claims for conventional foods and dietary supplements with nutritive value. This position is inconsistent with FDA's new policy goal to provide enhanced nutrition information for consumers to help them improve their health.

For at least five years following passage of the Dietary Supplement Health and Education Act, FDA took the position that dietary supplements having nutritive value are also "food," independent of their status as dietary supplements, for purposes of Section 201(g)(1)(C) of the FDC Act. Therefore, structure/function claims for dietary supplements having nutritive value could be made without the disclaimer and notification requirements of Section 403(r)(6) of the Act.

On January 6, 2000, however, without notice and without an explanation of the need for its action, the agency abruptly reversed itself. In the preamble to the final rule on structure/function claims, FDA declared that claims made for dietary supplements with nutritive value would have to bear the disclaimer, and that the notification and other regulatory requirements would have to be met, or the dietary supplements would be subject to regulation as drugs. In February 2000, CHPA and CRN petitioned the agency to reconsider and reinstate its prior position.

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The FDA position requiring structure/function disclaimers for dietary supplements with nutritive value is directly at odds with the agency's new policy initiative on Consumer Health Information for Better Nutrition. In light of this new initiative, as well as for the reasons set forth in our previous submissions, CHPA and CRN urge the agency to reconsider and reverse the decision to require structure/function disclaimers and notification for dietary supplements with nutritive value.

Council for Responsible Nutrition (May 27, 2003)

1. What body of scientific evidence do you think should be adequate for a qualified health claim?

The courts have made it clear that there are First Amendment issues raised when FDA prohibits health claims that are not false and misleading but that fail to meet the NLEA standard of being supported by significant scientific agreement.

CRN believes it is important that qualified health claims be supported by credible evidence, and that the disclaimer not be used as an excuse for permitting claims that are not well supported. The Federal Trade Commission's application of its standard of "adequate and reliable scientific evidence," may provide the most relevant example of an appropriate standard that permits a wide variety of statements to be made while still requiring a solid basis for the claims.

CRN is concerned about the "good news, bad news" format FDA has adopted for expressing qualified claims. These claims (start out with an affirmative, unqualified statement and then essentially say that FDA does not believe it. This construction seems unlikely to provide consumers with a good understanding of the nature of the support that exists for the statement or the reasons for FDA's unfavorable view of the claim. We urge the agency to consider a more unified and informative statement as an alternative.

FDA tentatively plans to approach qualified health claims by requiring that a petitioner begin by submitting a request for an unqualified claim. Only if FDA concludes that an unqualified claim cannot be approved will the agency move on to considering a qualified claim. CRN joins other food industry associations in urging FDA to avoid unnecessary duplication of effort both for industry proponents and for the agency by permitting the direct submission of a petition for a qualified health claim.

2. What type of safety concerns should be factored into FDA decision making?

CRN believes the agency's current policy of requiring that the food substance that is the subject of a health claim be "lawful" is sound. Clearly it is important for the agency and the industry to work together to ensure themselves as well as the public that consumers can safely increase consumption of the substance that is the subject of the health claim.

3. What specific claims may currently be ready for consideration under the new guidance?

CRN has not prepared a list of claims that companies may currently be considering. However, a review of some recent reports suggests several possible qualified claims that may be of interest. For example, B vitamins may play a role in protecting cognitive function and reducing the risk of dementia. Vitamin D certainly plays a role, along with calcium, in reducing the risk of osteoporosis, and there is also evidence supporting a role for vitamin K. Chromium may aid in controlling blood glucose levels in the general population or specifically in persons with diabetes. Antioxidants, including vitamin C, may delay onset of cataracts, and carotenoids such as lutein may reduce the risk of macular degeneration. Magnesium may play a role in protecting against hypertension and cardiovascular disease.

Going beyond the area of vitamins and minerals, there are some dietary supplements that currently bear structure/function statements but that may be eligible for qualified health claims relating to specific disease conditions. For example, glucosamine and chondroitin 3 sulfate may help reduce the risk of arthritis, and ginger may protect against motion sickness. We recognize that in both of these cases, the eligibility of the substance under the general requirements for health claims must also be considered.

5. What kinds of empirical data should FDA rely upon to show that consumers are, or are not, misled by claims?

No Comments submitted.

6. Should conventional foods and dietary supplements be treated the same or treated differently, and why?

Dietary supplements are a subcategory of foods, and have been so for as long as they have been marketed.

When NLEA was passed in 1990, it provided that there could be distinct systems established for regulating health claims for conventional foods and dietary supplements, but FDA concluded that the same standard and procedure should apply to both. Therefore, under the existing regulatory system, it is appropriate that dietary supplements and conventional foods should be treated the same for purposes of qualified claims as well as regular health claims, to the extent that they have the same capability for delivering a given benefit. FDA has taken this approach in its evaluation of NLEA health claims up to now, as is appropriate.

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When a health claim relates to the increased consumption of a particular nutrient or other food substance and when the substance can be provided either by a conventional food or a supplement, both should be eligible for the claim. FDA has already taken this approach with regard to health claims for calcium in reducing the risk of osteoporosis, for example, as well as in several other health claims and qualified claims.

CRN sees no rationale for excluding conventional foods from eligibility for qualified health claims, and we applaud the new Commissioner's decision to extend eligibility for qualified health claims to conventional foods.

While equal treatment should guide FDA's actions in considering health claims and qualified claims, that is not to say there may not be some instances in which a claim will not apply equally to all products or to all categories of products.

There may well be other instances in which some health claims and qualified claims should not be available to all products or all forms of a nutrient. CRN believes this should have been the case with respect to the folic acid health claim. Virtually all of the evidence on folic acid and neural tube defects is based on the benefits of supplemental folic acid. This claim could have been and probably should have been limited to dietary supplements and fortified foods providing 400 mcg of folic acid per serving and should not have been made available for conventional foods providing only a small fraction of this amount, in a less bioavailable form.

American Medical Association (May 23, 2003)

Note: The American Medical Association (AMA) offered comments on "qualified" health claims to the Food and Drug Administration's (FDA) Task Force on Consumer Health Information for Better Nutrition but did not respond to the six questions as requested.

The AMA would like to express its opposition to the FDA's intent, as expressed in its December 2002 Guidance for Industry, to allow qualified health claims in the labeling of conventional foods. The AMA also wishes to re-affirm its longstanding concerns about the inadequate regulation of dietary supplement products and to restate its views on health claims made for these products.

The FDA has stated that allowing qualified health claims for conventional foods would provide better health information for consumers. The AMA disagrees and urges the FDA to rescind its December 2002 Guidance. The AMA opposes the use of qualified health claims in the labeling of conventional foods for three reasons:

First, the AMA does not believe the FDA has the regulatory authority to allow qualified health claims in the labeling of conventional foods. The AMA believes

that the FDA lacks the authority to lower the significant scientific agreement standard by which health claims in the labeling of conventional foods are to be judged.

Second, the AMA opposes the FDA's decision to allow a lower standard - the so-called weight of the scientific evidence standard - to be used in deciding a health claim. The AMA believes the significant scientific agreement standard is appropriate for health claims on conventional foods. This standard provides reasonable assurance to a consumer that the health claim is accurate because the claim is supported by a significant body of scientific evidence. In contrast, under its December 2002 Guidance, the FDA would allow qualified health claims in the labeling of conventional foods based on a lesser weight of the scientific evidence standard. The AMA believes a weight of the scientific evidence standard should not be used because the evidence to support the qualified health claim under this standard would be equivocal. For example, beta-carotene was shown to lower the frequency and severity of experimental cancer induced in animals. In addition, high intakes of fruits and vegetables rich in carotenoids were associated with a reduced risk of developing cancer in humans. Thus, under the weight of the scientific evidence standard, the FDA might have approved a qualified health claim that fruits and vegetables rich in beta-carotene reduce the risk of cancer. A subsequent randomized, controlled clinical trial assessing the effect of beta-carotene on the development of lung cancer in high-risk Finnish men with a history of smoking, however, found a significant increase in the rate of lung cancer among the beta-carotene supplemented group. The AMA has serious concerns, therefore, that a weight of the scientific evidence could lead to conventional foods, which are consumed by the entire population of the United States, being allowed to carry health claims that have a reasonable chance of being erroneous. This would be an unsound public health policy. It is noteworthy that the FDA rejected the beta-carotene-cancer risk health claim based on the significant scientific agreement standard (see FDA's December 1999 Guidance).

Third, the AMA also opposes qualified health claims in the labeling of conventional foods because such claims would not be helpful to, and actually could confuse consumers. An educated consumer will not know whether to believe or not to believe the claim. An uneducated consumer likely will not understand the claim, but also may erroneously just accept that the qualified health claim is valid (i.e., the food product reduces the risk of a certain disease). For example, the FDA appears to have authorized "qualified" health claims for six dietary supplements, including folic acid-neural tube defects, omega-3 fatty acids-coronary heart disease, B vitamins-coronary heart disease, selenium-certain cancers, phosphatidylserine-cognitive dysfunction and dementia, and antioxidant vitamins-certain cancers. While the qualified health claims approved to date by FDA may be factually accurate, the AMA does not believe these claims are helpful to consumers in selecting products to improve their health.

Finally, the AMA's interpretation of the December 2002 Guidance is that FDA will allow health claims in the labeling of conventional foods if either the significant scientific agreement standard is met or, for a qualified health claim, if the weight of the scientific evidence standard is met. The AMA believes that this will only further confuse consumers. For any given claim, consumers will not know how valid the claim is because they will not know what the level of scientific evidence is to support the claim.

The AMA remains deeply concerned about the quality, safety, and efficacy of dietary supplement products, especially herbal remedies. The AMA has communicated its concerns to the FDA in numerous letters over the past four years and has testified before Congress on this issue. The primary problem is the "Dietary Supplement Health and Education Act of 1994" (DSHEA), which fails to provide for adequate regulatory oversight of dietary supplement products by the FDA. In that regard, our House of Delegates (AMA's policy-making body) has asked the AMA to work with Congress to modify DSHEA to require that dietary supplements and herbal remedies, including those products already in the marketplace, undergo FDA approval for evidence of safety and efficacy, meet standards established by the United States Pharmacopoeia (USP) for identity, strength, quality, purity, packaging, and labeling, and meet FDA postmarketing requirements to report adverse events, including drug interactions. In the absence of modifications to current federal law, the AMA urges the FDA to aggressively regulate dietary supplements to the fullest extent permitted by law in order to fulfill its obligation to protect the health of the American public.

The best regulatory approach for protecting and promoting the public health is for the FDA to mandate a single standard - the significant scientific agreement standard - for health claims that would apply to both conventional foods and to dietary supplements. This continuity is necessary to prevent confusion among consumers and to allow them to intelligently and confidently identify conventional food and dietary supplement products that may reduce the risk of a disease or health-related condition.

The AMA maintains its vigorous opposition to the lesser weight of the scientific evidence standard for dietary supplement health claims, as originally proposed by the FDA in October 2000 and reaffirmed by the Agency in its December 2002 Guidance. Consistent with our views on qualified health claims for conventional foods, to allow qualified health claims for dietary supplements based on preliminary or equivocal evidence fails to protect the health of the American people. Moreover, it will be next to impossible for consumers to understand the differences between structure/function claims, health claims, and qualified health claims on dietary supplement labels that, according to the Office of the Inspector General (OIG), are already limited in their ability to guide and inform consumers about appropriate use of supplements. The FDA should change its policy and adamantly insist that failure to meet the significant scientific agreement standard, as described in the December 1999 Guidance, satisfies the circumstances under

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the *Pearson* opinion in which FDA is justified in banning certain health claims for dietary supplements. Specifically, the AMA believes that if there is insufficient evidence to support a health claim based on the significant scientific agreement standard, then this should be interpreted as evidence against the claim outweighing evidence for the claim and, therefore, provide justification for denial of the claim.

The AMA also vigorously opposes the expansion of health claims for dietary supplements to include effects on an existing disease. Despite its shortcomings, the DSHEA was very explicit in distinguishing a dietary supplement from a drug. Thus, if a manufacturer wishes to make a claim that its product is intended to diagnose, cure, mitigate, treat, or prevent a disease, the product would have to be classified as a drug and be subject to the drug regulatory process.

In prior correspondence, the AMA has urged the FDA to ensure that consumers readily understand the differences between drug products and dietary supplement products (particularly herbal remedies) so each type of product is used appropriately. It is imperative, therefore, that the FDA not allow health claims for dietary supplements to include effects on an existing disease because it will blur the distinction between a drug and a dietary supplement and elevate the level of confusion among consumers regarding appropriate therapies. The AMA believes that health claims for dietary supplements should be limited to reducing the risk of a disease or health-related condition in the general population (or a significant subpopulation) when the product has met the significant scientific agreement standard.

Conclusion: The AMA strongly opposes allowing qualified health claims in the labeling of both conventional foods and dietary supplements. Claims based on equivocal scientific data are not helpful to consumers in selecting products to improve their health. Rather, qualified health claims are likely to be confusing and potentially misleading, regardless of disclaimers. With regard to conventional foods, the AMA does not believe the FDA has the statutory authority to allow qualified health claims and urges the FDA to rescind its December 2002 Guidance. The AMA recognizes that the *Pearson* court decision has further compromised the FDA's ability to regulate dietary supplements. However, the AMA believes that failure of a dietary supplement health claim to meet the significant scientific agreement standard (per the FDA's December 1999 Guidance) should be interpreted as evidence against the claim outweighing evidence for the claim and, therefore, provide justification for denial of the claim.

AARP (May 27, 2003)

AARP appreciates this opportunity to present its views on the guidance document, issued by the Food and Drug Administration (FDA) in December 2002 that allows labels of conventional foods and dietary supplements to include "qualified" health claims.

First, FDA's decision to allow health claims on the labels of conventional foods should meet the statutorily mandated standard. The Federal Food Drug and Cosmetic Act (FFDCA), as amended by the Nutrition Labeling and Education Act (NLEA) of 1990, authorizes FDA to approve health claims for conventional foods "only if the Secretary determines, based on the totality of the publicly available scientific evidence . . . the claim is supported by such evidence."

Until it issued the guidance document at issue here, FDA has consistently, repeatedly, and appropriately limited the Pearson decision to dietary supplements, the products that were at issue in this case. The FFDCA treats conventional foods and supplements differently in a number of instances, including where health claims are at issue: the statute requires that health claims for conventional foods be supported by "significant scientific agreement," but leaves to FDA the determination of the appropriate standard for supplement claims. The guidance document reverses FDA policy, without providing any reasonable rationale or justification for the change. Without such a basis, FDA's reversal constitutes the type of "arbitrary and capricious" action that is generally prohibited under the Administrative Procedure Act.

Second, the decision should follow the statutorily prescribed health-claim procedure for approving qualified health claims. The FFDCA generally allows only those health claims that are established by regulations developed through a notice-and-comment procedure.

Third, FDA's reliance on the Federal Trade Commission's (FTC) approach to health claims in advertisements in allowing qualified claims on product labels is misplaced. The FTC itself, in its Enforcement Policy Statement for Food Advertising, clearly distinguishes its authority under the Federal Trade Commission Act from that of the FDA. With the enactment of the NLEA, the FTC acknowledges that FDA was granted an "expanded and unique" jurisdictional mandate, which gives its regulations a "broader purpose" than just preventing false and misleading claims. The FDA is also charged with educating consumers about the importance of diet to health. We believe that this additional authority justifies a different approach to health claims, as do the differences in consumer perception between information that appears on product labels and that which is included in advertisements.

In addition, we question FDA's assessment that the FTC has been "successful" in policing the marketplace for misleading food advertising. While the EPS contains a thorough discussion of what constitutes "adequate qualification" for health claims that are not supported by "significant scientific agreement, the FTC has failed to bring a single case applying this policy, despite the fact that numerous petitions requesting Commission action in this area have been filed.

Moreover, in its guidance document, FDA cites in numerous instances a study by the FTC's Bureau of Economics, Advertising Nutrition & Health: Evidence from Food

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Advertising 1977 - 1997. This study is of limited usefulness, however, because it reviewed only print advertisements and did not include television ads, which the authors acknowledge are a bigger source of health claims.

Finally, while AARP applauds FDA's desire to provide consumers with more diet-related information to help them improve their health, we believe that the agency is far too sanguine regarding the potential for health claims to provide this information.

AARP believes that there are better ways for FDA to provide consumers with ready access to diet-related information that they could use to improve their health. One such way would be to quickly finalize the proposed rule requiring the listing of trans fat content in the Nutrition Facts panel. In addition, FDA should explore ways to revise nutrition labeling to better educate consumers about the risks of obesity. One approach could be to highlight, through bold face type or other graphic elements, the calorie content of food products. Another could be to include, adjacent to the Nutrition Facts panel, a statement such as: "The most effective way to achieve and maintain a healthy weight is to limit your caloric intake and increase your physical activity."

The remainder of our comments will focus on some of the specific questions posed by FDA.

1. What body of scientific evidence do you think should be adequate for a qualified health claim?

As discussed above, in order to be consistent with FFDCA, the level of scientific support for a health claim should be "significant scientific agreement."

2. What types of safety concerns should be factored into FDA's decision-making?

If FDA allows qualified health claims for conventional foods, then it must require (as it does for standard health claims) that the use of the substance that is the basis of the claim be "safe and lawful" under the FFDCA. In determining the safety of the substance, FDA should consider not only the number of people who might be injured by the substance, but also the seriousness of the harm. This approach would authorize FDA to prohibit a claim for a substance that might impact relatively few people, but where the injury could be significant. Moreover, we urge the agency to consider both the inherent safety of the substance itself as well as the potential for serious harm as a result of interactions between the substance and other products, such as prescription and over-the-counter (OTC) drugs. If FDA determines that this interaction is not serious enough to warrant prohibiting a qualified health claim, then the agency should require that the label include a warning that alerts consumers to the potential problem.

No comments submitted on Question 3.

4. On what issues are disclaimers valuable, or not valuable, in preventing consumers from being misled, and do you have data to support your view?

For a thorough response to this question, we direct FDA to comments we filed in Docket 02N-0209 in September 2002, relating to First Amendment issues. We are submitting a copy of those comments and the studies cited therein along with these comments. Our review of legal, social science and marketing research found that practical consumer experience with disclaimers and similar qualifying language calls into question whether such language does what it is intended to do: eliminate misleading impressions and remedy consumer confusion. We urge the agency to examine the theory of "information overload," which suggests that, when faced with an overabundance of data, consumers will completely ignore most or all of the information presented to them. In addition, FDA should look at the FTC's use of "affirmative disclosures" in advertising. At least one study relating to ads for OTC drugs concluded that the disclosure statements developed by the FTC would be widely misunderstood by large segments of the population.

In 2002, AARP conducted an omnibus telephone survey. Respondents were read two different claims:

"Increased consumption of foods like grape juice that are rich in antioxidants may reduce the risk of some cancers;" and

"Preliminary evidence suggests that increased consumption of foods like grape juice that are rich in antioxidants may reduce the risk of some cancers but further research is necessary."

They were then asked to compare the two claims in terms of the level of scientific support. Remarkably, 52 percent of respondents thought that the second claim (which included the type of "qualifying language" that the FTC suggests is acceptable) was supported by more scientific evidence than the first, with 16 percent believing the opposite, and 22 percent thinking that the claims had the same level of scientific support. This perplexing result demonstrates the need for further research in this area.

FDA should also examine the use of qualifying language, in the form of disclaimers, in other areas, such as trademark law. A recent review of trademark disclaimer cases found that, in those cases in which disclaimers were examined empirically, they generally were found to be ineffective at alleviating consumer confusion.

5. What kinds of empirical data should FDA rely upon to show that consumers are, or are not, misled by claims?

If FDA approves qualified health claims for conventional foods, then we believe it is appropriate to require that the party seeking approval of the claim provide empirical evidence that the specific disclaimer would eliminate any consumer confusion. As the FTC has cautioned, "it is important to recognize . . . that subtle changes in the

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wording or placement of claims and qualifying disclosures could have a significant impact on consumers' understanding."

We urge FDA to require that a specific qualified claim be tested on real consumers in real-life situations before it is approved. FDA should review the testing methods used in various areas (e.g., FTC and trademark cases) and identify acceptable testing methodologies. We also believe that any proposed qualified claim should be tested on a wide range of consumers – including those of different ages and different educational levels.

6. Should conventional foods and dietary supplements be treated the same or treated differently, and why?

The NLEA gave FDA the authority to choose an appropriate standard for health claims for dietary supplements, and the agency's decision to apply the same standard to supplements as it does to conventional foods ("significant scientific agreement") was struck down in court. As a result, dietary supplement labels can currently include "qualified" health claims.

Rather than having a standard for health claims that is more permissive than that used for conventional foods, we believe that at least some dietary supplements products - those that pose safety problems - should have a stricter health-claim standard. For example, we believe that it would clearly be misleading to allow an ephedra product to include a health claim, such as "reduces the risk of obesity," on its label. The safety risks associated with this product are definitely related to its health benefit and must be factored into a decision regarding whether to allow a health claim on the product label. In this example, the safety risks of the product outweigh the health benefit, and therefore a health claim should not be allowed. Moreover, ephedra's risks are so serious that the addition of qualifying language or other disclaimers would not be sufficient to eliminate the misleading impression created by the claim.

Reliance on misleading health claims can have a more insidious effect. Not only might consumers lose confidence in the particular product, but they may also become skeptical about all health-related information that is included on product labels and in advertisements. The same result can occur when health claims are based on "preliminary evidence." The problem here is that all too often, "preliminary evidence" is ultimately proven wrong. A 2002 report by the Institute of Medicine of the National Academy of Sciences uses the experience with beta-carotene to illustrate this problem.

Other documents submitted to this docket by AARP on May 28, 2003:

Comments by AARP in response to the May 16, 2002 Notice on First Amendment Issues. (originally submitted September 13, 2002)

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AARP Public Policy Institute – Data Digest article on Dietary Supplement and Older Consumers

AARP Label Study - conducted by telephone July 3-11 2002 among a nationally representative sample of 1013 respondents 18 years of age and older. Field work by ICR/International Communications Research of Media, PA.

“Cognitive Considerations In Designing Effective Labels For Presenting Risk Information” – Study By James R. Bettman, John W. Payne And Richard Staelin

“Comprehension Of Warnings And Resulting Attitudes” – By Elzbieta Lepkowska-White and Amy L. Parsons

“Grading the Report Card: Lessons from Cognitive Psychology, Marketing, and the Law of Information Disclosure for Quality Assessment in Health Care Reform” by Jason Ross Penzer, Yale J. on Reg., Winter 1995

“Brand Choice Behavior as a Function of Information Load” by Jacob Jacoby, Donald E. Speller, and Carol A. Kohn, Journal of Marketing Research, Vol. XI (February 1974), 63-9

“Perspectives on Information Overload” – by Jacob Jacoby, Journal of Consumer Research. vol. 10, March 1

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“Information Load” and Consumers” by Debra L. Scammon, THE JOURNAL OF CONSUMER RESEARCH, 1977

“Effects of Quality and Quantity of Information on Decision Effectiveness” by Kevin Lane Keller and Richard Staelin, THE JOURNAL OF CONSUMER RESEARCH

“The Information Overload Controversy: An Alternative Viewpoint” by Naresh K. Malhotra, Arun K. Jain & Stephen W. Lagakos, Journal of Marketing, Vol. 46 (Spring 1982). Z-37.

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The Economics of Labeling: An Overview of Issues for Health and Environmental Disclosures” by Mario F. Teisl and Brian Roe, Agricultural and Resource Economics Review, October 1998.

“Health Claims and Disclaimers: Extended Boundaries and Research Opportunities in Consumer Interpretation” by Marlys J. Mason and Debra L. Scammon, Journal of Public Policy and Marketing, Vol. 19 (1) (Spring 2000, 144- 150)

“Corrective Advertising and Affirmative Disclosure Statements: Their Potential for Confusing and Misleading the Consumer: by Jacob Jacoby, Margaret C. Nelson and Wayne D. Hoyer, Journal of Marketing, Vol 46 (Winter 1982), 61-72

“Not Manufactured or Authorized by . . . Recent Federal Cases Involving Trademark Disclaimers” by Jacob Jacoby and Maureen Morrin, 1998 American Marketing Association, Journal of Public Policy & Marketing, 1998 Spring, Legal Developments; Vol. 17, No. 1; Pg. 97

“Structural Characteristics of Televised Advertising Disclosures: A Comparison With the FTC Clear and Conspicuous Standard” by Mariea Grubbs Hay and Michael J. Starkey, Journal of Advertising, Volume XXII, Number 2, June 1993

“Action Plan for the Provision of Useful Prescription Medicine Information” by the Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, December 1996, the Keystone Center, Keystone, Colorado

Center for Science in the Public Interest (June 4, 2003)

CSPI believes that the Health Claims Initiative should be withdrawn because (1) the First Amendment of the U.S. Constitution does not require the use of “qualified” claims if the Congressionally mandated standard of “significant scientific agreement” (SSA) cannot be satisfied; (2) the use of such claims based upon an exercise of the Food and Drug Administration’s (FDA) “enforcement discretion” is contrary to the Nutrition Labeling and Education Act’s (NLEA) requirement that health claims for foods be issued pursuant to a notice and comment rulemaking proceeding or authoritative statement; (3) the FDA violates the Administrative Procedure Act (APA) by its decision to forego enforcement actions mandated by the Federal Food, Drug and Cosmetic Act against companies making “qualified claims;” and (4) the Initiative undermines the First Amendment rights that it attempts to protect. Despite CSPI’s misgivings about the Agency’s response to recent court decisions addressing First Amendment protections for commercial speech, we will, nonetheless, respond to the specific questions set forth by the Agency in its request for comments.

1. What body of scientific evidence do you think should be adequate for a qualified health claim?

We agree with the FDA's conclusion that if qualified claims are permitted for foods, they should be based on the weight of the scientific evidence as set forth in the December 2002 Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements. If claims are to be meaningful to consumers, they must be consistent with the available scientific evidence. Health claims will cease to have meaning if the FDA frequently approves qualified claims and just as frequently withdraws them in light of new scientific evidence.

We believe that the FDA should heed the warnings of the National Academy of Sciences' Institute of Medicine and be cautious in authorizing qualified claims. The IOM explained that: Claims about nutrient-disease relationships are more easily made than scientifically supported. Because the implications for public health are so important, caution is urged prior to accepting such claims without supportive evidence from appropriately designed, typically large clinical trials. The IOM stated that further study of an "appealing hypothesis" may result in a finding that the nutrient actually causes harm. For example, although preliminary evidence suggested that beta-carotene could reduce the risk of lung cancer, clinical intervention trials later demonstrated that beta-carotene supplements actually increased the risk of lung cancer in smokers.

Moreover, a newly released market analysis entitled "FDA Approved Health Claims in Food" concludes that one important factor influencing the purchase of products containing health claims is the degree to which consumers are skeptical of the claims because of past experience with nutrition advice that has been reversed, e.g., eat margarine/not butter followed by eat butter/not margarine. The report concludes, "codification of specific health claims through the FDA may result in a less suspicious public, one that is willing to eat more healthfully under the guidance of the government."

Thus, the new FDA policy may result in raising public suspicions about dietary advice and threaten the effectiveness of all health claims, including those based on significant scientific agreement.

2. What types of safety concerns should be factored into the FDA's decision-making?

Whenever a claim is being considered - whether it be a claim meeting the significant scientific agreement standard or a qualified claim, the FDA should consider the impact of the claim on the public's health. Among the questions that the agency should ask is whether the claim would encourage people to consume:

- A nutrient at levels that exceed the Upper Tolerable Intake Levels (UL) set by the National Academy of Sciences (NAS) or a supplement at levels that are unsafe
- A nutrient that puts some population groups at risk
- A nutrient that often occurs in the same foods as a detrimental substance
- A nutrient that might deter people from seeking medical evaluation or treatment

3. What specific claims do you think are currently ready under the new guidance?

We do not believe that any claims should be considered until the FDA conducts consumer research necessary to answer questions 4 and 5 below.

4. On what issues are disclaimers valuable, or not valuable, in preventing consumers from being misled, and do you have data to support your view?

Disclaimers are not helpful in informing consumers about the uncertainty of the science unless they are very detailed. As the Federal Trade Commission (FTC) staff found in its Generic Copy Test of Food Health Claims in Advertising: only strong disclaimers including explicit references to inconsistent study results or ongoing scientific debate “can have a significant impact on consumer perceptions of the level of proof underlying a health claim.”

Moreover, in an era of information overload, consumers may not read the disclaimer or may simply skim it without understanding its significance. For example, the Dietary Supplement Health and Education Act (DSHEA) requires that the label of any dietary supplement product that contains a “structure/function” claim include the following disclaimer: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.” One study involving the DSHEA-mandated disclaimer found that consumers do not interpret this disclaimer as so-called common sense would dictate. This study found that consumers evaluated the claim in diverse ways: several participants in the study were unaware of the lack of substantiation for the claims because they had either never read the disclaimer or had simply misread it to say that the FDA had in fact evaluated the claim.

A survey commissioned by AARP on dietary supplement use and knowledge among older consumers confirms that the DSHEA disclaimer may not function as intended. Most of the respondents in the study indicated that they had either never seen the disclaimer or did not know if they had ever seen it (59 percent).

Numerous other disclosures and disclaimers are mandated for various consumer products, and the FDA should thoroughly review all of the existing research on their effectiveness as part of this proceeding. CSPI believes that disclaimers and qualifying statements must be tested on consumers before determining, which, if any, should be included on product labels or in advertising. The court in the *Pearson* case acknowledges that empirical evidence has a role to play in determining the effectiveness of disclaimers and disclosures.

But information indicating that the FDA has not reviewed a claim does not help consumers at all. It does not provide them with due certainty that claims inducing them to buy a product are justified. Nor does the fact that the claim states that it is based on preliminary evidence offer the consumer helpful advice. The consumer

cannot evaluate the various studies that have been done to reach a rational conclusion as to whether it is worth buying the product.

It is a far cry from a disclaimer that basically tells consumers “caveat emptor” - the FDA has abdicated its responsibility to ensure the reliability of a health claim.

5. What kinds of empirical data should the FDA rely upon to show that consumers are, or are not, misled by claims?

Focus groups are a useful first step to determine if further research is needed. The focus groups that have been conducted so far show that disclaimers do not function effectively. Thus, such studies need to be supplemented with telephone surveys and mall intercept studies.

As part of these studies, the FDA needs to obtain definitive data on consumer expectations with respect to health claims. For example, it must determine: (1) whether consumers pay attention to health claims; (2) to what extent the presence of a health claim influences the purchasing decision; (3) whether consumers believe that claims are approved by the FDA; (3) whether their buying decision depends on the perception that a claim has government approval; (4) whether consumers would be less likely to buy a product that had a preliminary health claim than one meeting the SSA standard; and (5) whether they will read and comprehend disclaimers.

The FDA also should research whether distinguishing between structure/function claims and health claims for regulatory purposes is helpful to consumers. It is no secret that prior to the implementation of the Health Claims Initiative, manufacturers whose claims could not meet the significant scientific agreement standard or contained disqualifying levels of particular nutrients could present virtually the same claims reworded as structure/function claims.

Moreover, in 1999, nine FDA focus groups found that consumers could not tell the difference between structure/function claims and health claims. Nor are consumers aware of the legal and evidentiary distinctions between them. Consumer understanding of these distinctions has not improved in the four years since those focus groups were convened. This problem is discussed in the cover story of the June 2003 Nutrition Action Healthletter published by CSPI.

6. Should conventional foods and dietary supplements be treated the same or treated differently, and why?

Each category should be treated differently. Although everyone has to eat, only 50-60% of consumers use supplements. Consumers who take supplements may be more health conscious than consumers who do not. Furthermore, dietary supplements are typically sold as pills or capsules. In contrast, food is sold whole or processed and is consumed for its taste as well as its nutritive value. Practically all foods are safe for children over two years of age to consume (other than those that

present choking hazards). In contrast, only some dietary supplements are safe for children to consume. Thus, these two product categories present different health considerations and should be regulated accordingly.

Additional Statement provided with Comments by CSPI

7. The Federal Trade Commission's policy is not an appropriate model for qualified claims.

The FDA has felt compelled in this proceeding to emulate the policies of the FTC. However, other than one action last year, the FTC has not obtained a single cease and desist order against a food advertiser for making false and misleading health claims since it issued its Enforcement Policy Statement (EPS) on Food Advertising in 1994 - more than eight years ago! Moreover, the FTC has ignored numerous complaints about false and misleading health claims in food ads that have been brought to its attention by CSPI and others. We thus question the FTC's commitment to consumer protection in this area and are dismayed that the FDA would want to follow that agency's policies. Moreover, the FTC staff's latest study of health claims, Advertising Nutrition & Health Evidence from Food Advertising 1977-97, is filled with shortcomings and methodological deficiencies, and should not be relied on to guide regulatory policy.

The FDA's deference to and reliance on FTC policy is also improper because of the significant difference in each of the agencies' missions. This distinction was spelled out clearly by Congress in the legislative history of the NLEA, the statute itself, and by the FTC in its EPS issued in response to the FDA's implementation of the new law.

The House Committee on Energy and Commerce explained the specific purposes behind the NLEA: Health claims supported by . . . significant scientific agreement can reinforce the Surgeon General's recommendations and help Americans to maintain a balanced and healthful diet. A distinct section of the NLEA, section 2(c), entitled "Consumer Education," requires the FDA to educate consumers about the availability of nutrition labeling and the importance of such information in maintaining healthy dietary practices.

The FTC has also recognized the scientific expertise of the FDA and discussed its intention to give "great weight" to the FDA's scientific determinations in matters of nutrition and health. It is, therefore, disturbing that given its broader mandate to educate and its greater scientific expertise, the FDA is essentially assuming the narrower mission of the FTC, deferring to its limited scientific expertise and limiting its goals to preventing false and misleading claims.

Simply informing the public that scientific evidence is preliminary does not educate Consumers. Instead of taking a "buyer beware" approach, the FDA should be using

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its scientific expertise to educate consumers about truly valid claims that can be relied on to improve their health.

Lastly, the FDA's reliance on the FTC legal standard for consumer deception and court decisions enunciating that the FDA's only duty is to protect "a reasonable person" are inappropriate since they do not represent current law involving misbranding.

The FDA is well aware that courts reviewing misbranding violations on product labels have - with rare exception - interpreted the FDCA as protecting "the ignorant, the unthinking, and the credulous consumer." In the Guidance, the FDA cites some of these cases but then concludes that the "reasonable consumer" approach is "the appropriate standard" based in part on a 1951 case, U.S. v. 88 Cases, Birely 's Orange Beverage. It ignores the fact that the most widely followed cases on this issue are far more recent than the Birely case.

The FDA's reliance on Supreme Court language quoted in *Bolger v. Young Products Corporation* is also inappropriate because that case involved advertising not labeling.

The First Amendment cases discussed by the FDA ignore the fundamental distinctions between labeling and advertising. Food labeling is mandatory. Product labels are required to list ingredients, nutrition facts, net weight, a product identity statement, and the location of the manufacturer, packer or distributor. Print size and placement requirements are imposed. Because of these requirements, consumers have come to rely on labels to be accurate and dependable.

In contrast, there is no requirement that any attributes of food products be advertised. Superlative claims about the attributes of particular products are the norm and are often considered by regulatory officials to constitute "puffing." Thus, it is inappropriate for the FDA to base regulatory policies dealing with labeling on those developed for the purposes of regulating food advertising.

Conclusion

For the foregoing reasons, CSPI believes that the Health Claims Initiative should be withdrawn. In the event that this does not occur, the FDA needs to obtain appropriate consumer survey data to help the Agency determine the most effective way of protecting the public from misleading claims and educating consumers about diet and health. Qualified health claims for foods should not be authorized before such data is obtained.

Representative Henry Waxman et al (letter to Dr. McClellan, May 27, 2003)

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Reps. Henry Waxman (D-Calif.), Edward Markey (D-Mass.), David Price (D-N.C.), Jeff Bingaman (D-N.M.) and Sen. Barbara Boxer (D-Calif.) submitted comments to Dr. McClellan protesting the FDA's recent guidance issued late last year that would allow qualified health claims for food. The letter states the new policy constitutes "an illegal assertion of authority."

Mr. Waxman et al state that in taking this action, the FDA has rejected the scientific standard required by governing statute, and that this has been long sought by the food industry.

The congressional letter says that the action "is not only a step backward for truthful, credible food labels, but an unprecedented assertion of authority on the part of the executive branch to ignore a specific congressional mandate."

The letter cites the 1990 Nutritional Labeling and Education Act, saying that the law requires FDA to stick with the previous standard for food health claims, which says a claim must be supported by "significant scientific agreement."

"As authors of the NLEA, we strongly oppose this guidance document," the congressional members said, and called it "a serious setback for truthful advertising and an invitation for misleading claims on foods."

Mr. Waxman et al request FDA to rescind the December 20, 2002 guidance. Because the guidance was issued without notice and comment or process of any kind, it can be rescinded immediately.

Comments Submitted to Docket 02D-0515

Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements

The Grocery Manufacturers of America, The Snack Foods Association, The Institute of Shortening & Edible Oils, Inc., and The National Restaurant Association (May 16, 2003)

The Associations submitted a draft regulation that would establish a premarket notification, rather than a premarket approval program under which FDA would review proposed qualified health claims for food labeling. It would apply to health claims that do not meet the statutory standard of "significant scientific agreement" of the Federal Food,

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Drug, and Cosmetic Act (FD&C Act) but that do meet the lower standard of credible scientific evidence established in the *Pearson* litigation.

The draft regulation provides that a qualified health claim must be supported by information that constitutes credible scientific evidence but that does not reach the statutory standard of significant scientific agreement that would justify an unqualified health claim. The definition acknowledges that a qualified health claim must either be worded, or qualified by explanatory information, disclaimers, or other qualification, to assure that the claim accurately conveys the supporting information and is not misleading. In many instances, the wording of a claim itself will incorporate a limitation or qualification, or will be accompanied by explanatory information, thus making frank disclaimers unnecessary. It is preferable to include the limitations and qualifications as a direct and integral *part of the claim, rather* than using disclaimers that conflict with the claim, because a claim that first *states* the matter positively and then qualifies it negatively will be far less understandable and useful to consumers.

The draft regulation includes a definition of "*credible scientific evidence.*" The standard of credible scientific evidence would be met by any scientific study that satisfies long - established principles of scientific investigation - e.g., a written protocol that describes the investigation in adequate detail, the informed consent of *the* test subjects, a statistical analysis of the results, and a written report reviewing the investigation and containing the conclusion. The type and quantity of evidence required to support a claim will depend on how the claim is worded, i.e., *on* exactly what claim is being made.

In determining whether a claim is misleading, the draft regulation adopts the "reasonable person" standard announced by FDA.

Whether a proposed health claim is a significant scientific agreement claim or a credible scientific evidence claim, it is subject to review by FDA, prior to use in the marketplace. There are sound public policy reasons, as well as legal authority, for establishing a separate premarket notification process for qualified health claims independent of the pre-market approval requirements for significant scientific agreement claims.

This is essentially the same procedure that FDA has in fact been following under the *Pearson* decision. Petitions for significant scientific agreement claims have been converted to the equivalent of qualified health claims notifications, and FDA has made its determinations through letters rather than through notice-and-comment rulemaking. This process is entirely lawful and need not be changed.

It would be burdensome and wasteful for both FDA and the regulated industry to require that a claim that the interested person knows does not meet the significant scientific agreement standard nonetheless be the subject of a full petition for such a claim, only to be turned down and there reconsidered as a qualified health claim. Instead, interested persons should be encouraged to submit a request directly for a qualified health claim where there is credible scientific evidence but not significant scientific agreement.

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A premarket notification procedure is more efficient and requires fewer resources at FDA. This is essentially the same procedure that FDA has in fact been following under the Pearson decision. Petitions for significant scientific agreement claims have been converted to the equivalent of qualified health claims notifications, and FDA has made its determinations through letters rather than through notice-and-comment rulemaking. This process is entirely lawful and need not be changed.

American Medical Association (February 21, 2003)

The American Medical Association (AMA) would like to express its opposition to the FDA's intent to allow qualified health claims in the labeling of conventional foods. The AMA also wishes to re-affirm its longstanding concerns about the inadequate regulation of dietary supplement products and to restate its views on health claims made for these products.

The AMA opposes the use of qualified health claims in the labeling of conventional foods for the following three reasons. First, the AMA does not believe the FDA has the regulatory authority to allow qualified health claims in the labeling of conventional foods because this decision is inconsistent with current federal law. The AMA believes that the FDA lacks the authority to lower the significant scientific agreement standard by which health claims in the labeling of conventional foods are to be judged.

The AMA also strongly opposes the FDA's decision to allow a lower standard - the so called weight of the scientific evidence standard - to be used in deciding whether a health claim can be placed on the labeling of a conventional food product.

Based on current law and regulation, health claims for conventional foods must meet a significant scientific agreement standard to be approved by the FDA to be placed on a product label. The AMA believes the significant scientific agreement standard is appropriate for health claims on conventional foods; this standard provides reasonable assurance to a consumer that the health claim is accurate because the claim is supported by a significant body of scientific evidence. In contrast, under its December 2002 Guidance, the FDA would allow qualified health claims in the labeling of conventional foods based on a lesser "weight of the scientific evidence standard." Thus, the AMA does not believe that conventional foods, which are consumed by the entire population of the United States, should be allowed to carry health claims that have a reasonable chance of being erroneous.

This is poor public health policy. It is worthy to note that the FDA rejected the beta-carotene-cancer risk health claim based on the significant scientific agreement standard.

The AMA also opposes qualified health claims in the labeling of conventional foods because such claims are not helpful to, and actually could confuse consumers. An educated consumer will not know whether to believe or not to believe the claim. An

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uneducated consumer may just accept that the qualified health claim is valid, and more likely will not understand it.

In the absence of modifications to current federal law, the AMA believes the FDA must aggressively regulate dietary supplements to the fullest extent permitted by law, in order to fulfill its obligation to protect the health of the American public.

The AMA believes that the best regulatory approach for protecting and promoting the public health is for the FDA to mandate a single standard for health claims that applies to both conventional foods and to dietary supplements. This continuity is necessary to prevent confusion among consumers and to allow them to intelligently and confidently identify conventional food and dietary supplement products that may reduce the risk of a disease or health-related condition.

The AMA vigorously opposes the lesser weight of the scientific evidence standard for dietary supplement health claims, as originally proposed by the FDA in October 2000 and re-affirmed by the Agency in its December 2002 Guidance. Consistent with our views on qualified health claims for conventional foods, to allow qualified health claims for dietary supplements based on preliminary or equivocal evidence fails to protect the health of the American people. The FDA should change its policy and adamantly insist that failure to meet the significant scientific agreement standard, as described in the December 1999 Guidance, satisfies the circumstances under the Pearson opinion in which FDA is justified in banning certain health claims.

The AMA also vigorously opposes the expansion of health claims for dietary supplements to include effects on an existing disease....because it will blur the distinction between a drug and a dietary supplement and elevate the level of confusion among consumers regarding appropriate therapies.

Consumer Federation of America (letter to Dr. McClellan, December 27, 2002)

The Consumer Federation of America is convinced this is bad news for consumers. This change will lower the bar for making food health claims and send the food industry down the path of confusing and misleading claims that has characterized dietary supplements in recent years. Whether it is food or supplements, consumers deserve health claims they can trust, supported by general scientific agreement. It serves no one's interest to fill grocery store shelves with products making health claims that could disappear with the next published study. This will only further confuse consumers and erode confidence in food labels. I urge you to rethink your decision. If current laws are not adequate to require significant scientific agreement for health claims, I suggest you propose legislation to amend NLEA to provide this protection for consumers.

Public Citizen and CSPI (April 10, 2003)

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Notwithstanding the statutory and regulatory prohibitions against making health claims that are not authorized by regulation (final or interim), the agency's December 2002 Guidance for Industry announces that the agency intends to forgo the rulemaking process for "qualified" health claims. That is, under the Guidance, health claims supported by the weight of scientific evidence but not by significant scientific agreement will be permitted, without notice-and-comment rulemaking, as long as the claims are qualified by a disclaimer.

Although the agency states that under this process qualified health claims are "subject to the statutory requirement of FDA authorization," that statement is not accurate. The statutory requirement of FDA authorization is a requirement of notice-and-comment rulemaking. The procedure announced in the Guidance takes qualified health claims outside of that authorization process and permits such claims to be made without any public process at all, let alone the notice-and-comment rulemaking prescribed by Congress.

The FDA's new policy undermines the protections afforded to consumers by encouraging companies to seek permission to make health claims based on preliminary evidence, as opposed to waiting until the evidence demonstrates the existence of significant scientific agreement.

The FDA has decided as a matter of policy to ignore the NLEA's procedural requirements and its own regulations.... And attempts to justify its departure from the statutory and regulatory requirements by characterizing its new policy as an exercise of "enforcement discretion." Put simply, neither the NLEA, current FDA regulations, nor *Pearson* give the FDA authority to disregard the requirement of notice-and-comment rulemaking before a health claim, whether qualified or unqualified, is permitted. Public Citizen and CSPI urge the agency to withdraw the December 2002 Guidance, not to sanction health claims (qualified or otherwise) unauthorized by regulation, and to continue its previous policy of enforcing the NLEA's procedural requirements, according to Congress's mandate and current regulations.

If the agency believes that its substantive regulations warrant revision in light of *Pearson*, it should initiate notice-and-comment rulemaking to amend them, subject to the requirements of the NLEA.

American Heart Association (May 27, 2003)

The American Heart Association (AHA) has reviewed with great interest the Consumer Health Information Initiative for Better Nutrition announced by Commissioner Dr. Mark B. McClellan in December 2002.

As a general principle, the AHA is guided by both its sound science and its interest in the public's health. In that regard, the AHA and FDA have many shared goals. In particular, the AHA strongly supports improving public nutrition through better information and with the corresponding need to assure that consumer information is

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reliable and, specifically, that health claims made for foods and dietary supplements are scientifically valid.

The AHA is pleased that the FDA is developing an agenda for consumer research, although the AHA is concerned that the initiative and new rules for health claims are being implemented prior to consumer research being done. In particular, it is important to have insight into what health messages consumers understand and what they do not understand in the context of short messages on labels and in advertising. Further, it is important to determine whether consumers will read and understand qualifiers or disclaimers accompanying health claims, and whether consumers will understand the overall intended message resulting from the combination of a health claim statement and a qualifying statement. Perhaps a mechanism of different levels or grades of health claims based upon different levels of scientific evidence could be considered as a method to help consumers better understand health claims. The AHA supports the FDA's adoption of the FTC's "reasonable consumer" standard in determining whether claims are misleading based on the principle that consumers can be active partners in their own healthcare and will likely behave in a manner promoting their health when given accurate health information.

The AHA is concerned about permitting health claims for foods to be made on the basis of the standard for making health claims for dietary supplements, noting the types of claims now being made for supplements. More information is desired about the impact or result of the "weight of scientific evidence" standard being applied to food health claims compared to the "significant scientific agreement" standard traditionally applied to food health claims. As well, the AHA desires more information about the type, nature and number of studies or statements considered to satisfy the weight of scientific evidence standard to substantiate making a qualified health claim as proposed by the Initiative. While there is an argument for having a single standard for health claims for foods and dietary supplements, the result must be to assure that the public can rely upon the health claims being permitted as scientifically valid, i.e., a claim is supported by a reasonable scientific conclusion based on an appropriate number of research studies or an appropriate study size conducted pursuant to acceptable scientific methodology and the claim is either valid for the general population or conspicuously limited to an identified population.

An essential element to implementing the proposed qualified health claims for foods under the weight of scientific evidence standard is the need for the FDA to dedicate sufficient resources for strengthened enforcement against misleading or unsubstantiated claims in food labeling. Our observation is that there is a need for heightened enforcement of health claims being made for dietary supplements currently being made under the weight of scientific evidence standard. While health claims for foods under the traditional significant scientific agreement standard has not resulted in the number of abuses as has been seen for supplements, presumably the FDA pre-approval process will help safeguard against inappropriate

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claims using the new standard. Additionally, it is suggested the FDA periodically reassess approved health claims, at least every 5 years, to assure their continuing scientific validity.

Consideration needs to be given to additional categories of health claims with scientific support, such as for omega-3 fatty acids; for oils lower in saturated fats like canola, flaxseed or soybean oils; and, perhaps, for nutrient density (i.e., proportion of nutrients per given unit of calories). Consideration also needs to be given to encouraging messages in labeling and promotional materials regarding portion size, appropriate balance between intake and expenditure of calories, and overall diet composition to help consumers create a healthier overall diet.

Support is given to the FDA's efforts to revise the Nutrition Facts panel to include a disclosure of trans fat. Further, there should be a disclosure for added sugars. Regarding added sugars, consideration also might be given to a disqualifying level for added sugars to preclude health claims being made as there currently is a disqualifying level for sodium content of foods.

The AHA will work with the FDA to assist in evaluating needed consumer research, evaluating such research outcomes, evaluating science and identifying science experts and resources, responding to FDA requests for input or advice, and identifying and disseminating nutrition education messages and tools to the public.

The American Heart Association thanks the Food & Drug Administration for focusing on increasing the dissemination of scientifically valid and understandable health information about foods and dietary supplements to the public, and for providing an opportunity for comment.

International Dairy Foods Association (May 29, 2003)

The International Dairy Foods Association (IDFA) notified the Food and Drug Administration (FDA) that it is joining the request from the Grocery Manufacturers of America (GMA) and five other food trade associations that FDA consider a proposal for regulations to establish a premarket notification program for qualified health claims for food labeling. IDFA fully endorses GMA's comments on "Proposed FDA Regulation to Establish a Premarket Notification Program for Qualified Health Claims for Food Labeling," filed to the docket earlier this month.

IDFA believes that GMA's proposed premarket notification for qualified health claims will provide an effective, efficient and transparent process to review potential health claims that do not meet the statutory standard of "significant scientific agreement" but that do meet the standard of credible evidence established by the Pearson litigation.

IDFA applauds the FDA's effort on its new initiative Consumers Health Information for Better Nutrition. We believe that FDA's guidance on qualified health claims can

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be enhanced with the proposed premarket notification process thus resulting in approach that will encourage the flow of high-quality science based information regarding the health benefits of conventional foods,

IDFA appreciates the opportunity to comment on the qualified health claim guidance and would welcome the opportunity to discuss these issues. We are also glad to answer questions or provide additional information.

Miscellaneous Comments to the Docket

Comment Number: EC -37

Commentor: Ms. Nancy Barnard Date/Time 2003-04-06 14:10:56

#6. Should conventional foods and dietary supplements be treated the same or treated differently, and why?

I do not feel conventional food and dietary supplements should be treated the same. Dietary supplements that are herbal, botanical, amino acids or enzymes are derived from products similar to many medications. Therefore the long-term effects of the products may not be clearly identified because they have not been thoroughly tested. Though there are unique situations where food can impact medication (broccoli – vitamin K on coumadin) these are relatively rare. The impact of dietary supplements (example – ephedra) are not as well tested and documented and the general public needs to be provided the opportunity to be informed regarding the potential risks.

Comment Number: EC -42

Commentor: Mrs. Tammy Pettit Date/Time 2003-04-09 20:46:20
Organization Slippery Rock University
Category Health Professional

#6. Should conventional foods and dietary supplements be treated the same or treated differently, and why?

I do not think that conventional foods and dietary supplements should be treated the same. Supplements are intended to add to a diet lacking in specific nutrients, vitamins, electrolytes, amino acids etc. The consumption of these supplements should be controlled in some way. Too much of any supplement could pose a risk to the consumer. It is my opinion that supplements be treated more like medication. The advice of a physician should be sought in most cases to help the consumer decide what dietary supplement would benefit them most.

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EMC-1

From: John and Dawn Hoogerbrugge [jdhoog@zbzoom.net]
Sent: Thursday, April 10, 2003 6:01 PM
To: FDADOCKETS@oc.fda.gov

5. What kinds of empirical data should FDA rely upon to show that consumers are, or are not, misled by claims?

Using empirical data to determine if consumers are, or are not, misled by claims is vital to obtaining accurate information. One kind of data that may provide insight is consumer-purchasing reports. If consumers believe that the claims made are accurate there should be an increase in the purchasing of the food or dietary supplement. Consumers also often ask their health care providers about foods or dietary supplements and the health claims made concerning these products. Because of this, health care providers may be able to provide information as to whether consumers are being misled. One other way is to conduct scientific research using simple random sampling or systematic sampling to survey consumer opinions or beliefs about health claims.

Comment Number: EC -43

Commentor: Mrs. Bernadette Moore Date/Time 2003-04-11 22:05:28
Category Health Professional
General Comments

5. What kinds of empirical data should FDA rely upon to show that consumers are, or are not, misled by claims?

The FDA should only look at empirical data when deciding whether or not the consumers are or are not misled by claims. Any other source of information would be unreliable. The FDA could follow sales of a certain product in question. If sales are good and continue to increase then consumers are usually not misled. Consumers have a tendency to obtain their information from medical personnel and pharmacists. This could also mean that the FDA could survey health care workers such as doctors and nurses. They could also get the drug companies involved with claims related to medications. The FDA could survey the consumers themselves about a claim. There are so many different ways the FDA can follow the consumer's beliefs about claims but reliable data is a must.

Comment Number: EC -44

Commentor: Mrs. Carolyn Roetering Date/Time 2003-04-13 22:45:19
General Comments

1. What body of scientific evidence do you think should be adequate for a qualified health claim?

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I feel that the body of scientific evidence that should be adequate for a qualified health claim should be obtained through randomized trials and clinical practice improvement studies.