

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

Comments on Food Labeling; Dietary )  
Supplement Health Claims: Public )  
Meeting Concerning Implementation )  
of *Pearson* Court Decision and Whether )  
Claims of Effects on Existing Diseases )  
May Be Made as Health Claims )  
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Docket No. 00N-0598

Submitted by the

Center for Science in the Public Interest

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**Re: Food Labeling; Dietary Supplement Health Claims: Public Meeting  
Concerning Implementation of *Pearson* Court Decision and Whether Claims  
of Effects on Existing Diseases May Be Made as Health Claims  
[Docket No. 00N-0598]**

The Center for Science in the Public Interest<sup>1</sup> submits these comments on the implementation of the decision by the U.S. Court of Appeals for the District of Columbia Circuit in *Pearson v. Shalala*<sup>2</sup> to supplement our presentation at the April 4, 2000 hearing on this topic. Our comments will specifically address the questions raised in the March 16, 2000 *Federal Register* notice.

**Issue One: Implementation of the *Pearson* Court Decision**

*1. What is the best regulatory approach for protecting and promoting the public health? Specifically, what approach to regulating health claims will: (a) Protect consumers from fraudulent and misleading claims; and (b) provide reliable, understandable information that will in fact reduce the incidence of diseases? By what criteria should implementation options be judged?*

The best regulatory approach for protecting and promoting the public health is to make

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<sup>1</sup> CSPI is a non-profit consumer organization supported by almost 1,000,000 members that has worked since 1971 to improve national health policies.

<sup>2</sup> 164 F.3d 650 (D.C. Cir. 1999).

“public health” the starting point for determining whether a particular health claim should be approved in the absence of significant scientific agreement that the evidence supports the claim.

No health claim which is supported by less than significant scientific agreement should be approved if:

- It focuses on essential organs such as the heart, lung, brain and liver; risk factors for serious diseases such as cancer and heart disease; or other serious health conditions such as asthma, birth defects, diabetes, HIV, and Alzheimer’s disease.
- It is foreseeable that consumers may, based on a preliminary claim, forego a proven dietary or medical therapy in favor of a dietary supplement that may or may not be beneficial to health.
- Consumers, based on their own observations, cannot determine whether a claim is true.
- Scientific evidence supporting a claim is outweighed by quantitatively or qualitatively superior evidence.
- Empirical evidence shows that the disclaimer is insufficient to protect consumers from deception.

*2. Can qualifying language (including disclaimers) be effective in preventing consumers from being misled by health claims based on preliminary or conflicting evidence? If so, what are the characteristics of effective qualifying language? How should the agency determine what constitutes an appropriately qualified claim? If the available information is not sufficient to answer these questions, what research needs to be done, and who should be responsible for doing it? The agency encourages those commenting to submit empirical data on the effectiveness of qualifying language.*

CSPI does not believe that disclaimers can be effective in preventing consumers from being misled by health claims based on preliminary or conflicting evidence. For example, the Federal Trade Commission (FTC) found that where disclaimers were used to inform consumers that a product high in one beneficial nutrient also contained high levels of another nutrient that could increase the risk of a diet-related disease, almost half of those surveyed “apparently

misconstrued the dietary warning as a favorable commentary on the quantity of sodium or saturated fat in the advertised products.”<sup>3</sup> We believe that the FDA needs to conduct its own research to determine whether appropriate disclaimers can be used to communicate effectively to consumers that the evidence is preliminary.

As will be discussed in more detail in our response to Question 3, we believe that the *Pearson* court’s decision created three broad exceptions from its primary holding that the FDA must *consider* the use of a disclaimer in conjunction with claims not supported by significant scientific agreement. We can envision few, if any instances in which the approval of a health claim not supported by significant scientific agreement would not be false and misleading, regardless of the disclaimer used.

Nonetheless, we believe it is important to describe the type of disclaimer that would be appropriate if the FDA determines that a claim that does not meet significant scientific agreement standard can still be made. The FDA should require a disclaimer such as:

**“The U.S. Food and Drug Administration has not found the following statement to be adequately substantiated.”**

The disclaimer should come before the health claim and be in a typeface as large and as conspicuous as the promotional statement.

*3. Is there a way to preserve the existing regulatory framework for health claims consistent with the First Amendment?*

Yes. The U.S. Court of Appeals held in *Pearson v. Shalala* that based on the

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<sup>3</sup> Federal Trade Commission, *Generic Copy Test of Food Health Claims in Advertising*, Nov. 1998, E 3-4.

administrative record before it, the FDA must *consider* whether the use of a disclaimer would eliminate the potential for deception before it decides to prohibit health claims not supported by significant scientific agreement. The Court, therefore, was not requiring that the FDA must approve all health claims accompanied by a disclaimer. Rather, it was *requiring* that once the FDA determines that a claim is not supported by significant scientific agreement, it must then *evaluate* whether a disclaimer could turn an otherwise false and misleading claim into a truthful and non-misleading statement.

The Court, however, created several major exceptions to its overall holding and discussed situations in which disclaimers would not be sufficient to prevent consumer deception. These include situations in which:

- Permitting a health claim not supported by significant scientific agreement would threaten consumer health and safety;
- Scientific evidence supporting a health claim is outweighed by evidence that is qualitatively or quantitatively superior;
- Empirical evidence demonstrates that a disclaimer is insufficient to protect consumers from deception.

These exceptions to the Court's holding significantly limit the number and types of health claims that can be made in the absence of significant scientific agreement. These exceptions are more fully discussed in the legal memorandum attached as Appendix A.

*4. If health claims are permitted based on a standard less rigorous than significant scientific agreement, what is the best way to distinguish among claims supported by different levels of evidence so that consumers are not misled? Does the word "may" in existing health claims accurately communicate the strength of the evidence supporting claims that meet the significant scientific agreement standard or should other language be used?*

The word "may" does not accurately communicate the strength of the scientific evidence

for claims not supported by significant scientific agreement because that word is already used to qualify approved health claims that are supported by significant scientific agreement.

The FDA should conduct consumer research to determine if and how health claims not supported by significant scientific agreement can be qualified to prevent consumer deception and injury to health. The FDA should also consider alternative approaches to permitting health claims not based on significant scientific agreement. One approach could be to permit such claims only if the manufacturer agrees to a bond or trust fund that could be used to pay for corrective advertising if later studies demonstrate that the preliminary claim is not valid.

*5. If health claims are permitted based on a less rigorous standard, what actions can be taken to provide incentives to manufacturers to conduct further research on emerging substance-disease relationships?*

One incentive to manufacturers to conduct further research could involve setting a date by which preliminary claims must be supported by significant scientific agreement or discontinued. Failure to comply with the deadline would constitute misbranding. The manufacturer could also be required to conduct research within a specified period of time aimed at determining whether the claim is valid.

*6. The Pearson opinion mentions circumstances in which FDA might be justified in banning certain health claims outright (e.g., where the evidence in support of the claim is outweighed by evidence against the claim, or where the evidence supporting the claim is qualitatively weaker than the evidence against it.)*

*(a) How should FDA determine when evidence supporting a claim is outweighed by evidence against the claim?*

*(b) How should FDA determine when evidence supporting a health claim is qualitatively weaker than the evidence against the claim?*

It is difficult to separate qualitative and quantitative factors when considering the validity

of scientific evidence. Both factors must be considered when evaluating the soundness of the science behind a claim. In either case, the FDA should determine that there is clear and convincing scientific evidence in support of a claim that is not likely to be reversed by new scientific studies.

*(c) Are there other circumstances in which health claims are inevitably misleading and cannot be made non-deceptive by qualifying language?*

As indicated in our discussion in response to Question 1, claims raising health and safety concerns are inherently misleading under the following circumstances; (1) the claim relates to essential bodily organs or serious health conditions; (2) it is foreseeable that consumers may forego a proven dietary or medical therapy in favor of a dietary supplement that may or may not be beneficial to health; or (3) when consumers, based on their own observations, cannot determine whether a claim is true.

*7. What safety information is necessary to prevent a health claim from being misleading? For example, such information might include side effects, drug and food interactions, and segments of the population who should not use the product or who should consult a physician before doing so. When a product may have adverse effects unrelated to the subject of a scientifically valid health claim, is the claim misleading? Under what circumstances if any, should the product be allowed to bear the claim?*

We believe that a claim is misleading if the product may have adverse effects unrelated to the subject of a scientifically valid claim. The valid claim creates a presumption in the minds of consumers that the product has been approved by the FDA, is safe under its intended conditions of use, and does not present any other hazards to health.

8. *What actions should the agency take to ensure that consumers receive all relevant information about the safety of products that bear health claims and about research on product safety?*

Health claims should not be approved for products that cannot be used safely by consumers.

**Issue Two: Whether Claims of Effects on Existing Diseases May be Made as Health Claims**

CSPI does not believe it is appropriate to address the issues raised by this question at this time. Allowing health claims to be made for existing diseases would significantly broaden the scope of permissible health claims at a time when the statutory scheme is already facing a number of serious issues that need to be resolved. Agency resources should be directed at resolving the problems that have already arisen before it considers whether an additional category of claims should be allowed.

Numerous difficulties have arisen in connection with the use of claims made solely for risk reduction. For example, one of the most controversial issues concerns the dividing line between structure/function claims and health claims (drug claims). An agency task force led by the Center for Drug Evaluation and Research (CDER) is attempting to issue guidance on this issue.

A second issue is the fact that companies are using the structure/function claim as a means of avoiding the regulatory process associated with obtaining approval for a health claim. For example, Kellogg recently began making a structure/function claim linking the adequate intake of folate, B6 and B12 to a healthy cardiovascular system. This is really a thinly disguised health claim that requires pre-approval by the FDA. Kellogg knew that it was not going to get

this approval, however, because the FDA previously denied a request for approval of a similar health claim on February 6, 2000.

A third issue that has arisen is the question of what constitutes *nutritive value*. Health claims may not be made for either food or dietary supplements unless the claim relates to the nutritive value of the substance that is the subject of the claim.<sup>4</sup> Given the fact that many herbals do not have any nutritive value, the Agency is being pressured to reconsider its definition. The issue also arises with respect to structure/function claims because foods, unlike supplements, must also meet the nutritive value requirement.

These issues must be resolved before the FDA considers permitting claims of effects on existing diseases. It makes little sense to expand the universe of claims that will be affected by a multitude of known regulatory problems until these problems are resolved.

Respectfully submitted,

  
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<sup>4</sup> 58 Fed. Reg. 2,478, 2,499 (Jan. 6, 1993); 62 Fed. Reg. 49859-60 (Sept.23, 1997); 21 C.F.R. § 101.14(b)(3)(I).

## APPENDIX A

### **I. The FDA is not obligated to consider using the disclaimer approach when a preliminary health claim raises health and safety concerns.**

At the outset, it should be emphasized that the Court's overall holding was premised on the basis that the supplements at issue in the case do not "in any fashion threaten consumers' health and safety."<sup>1</sup> However, there has been a steady stream of reports concerning the hazards of dietary supplements. The Washington Post, for example, ran this front page article last month that proclaimed "Herbal Products Boom Take Human Toll."<sup>2</sup> The government apparently did a poor job of bringing this type of information to the Court's attention, and the Court simplistically assumed that supplements in general posed no hazard. In light of this naive assumption, the relevance of the Court's primary holding is quite limited. As the Court noted, "the government may have more leeway in choosing suppression over disclosure as a response to the problem of consumer confusion where the product *affects health*."<sup>3</sup> Health claims for dietary supplements that are not supported by significant scientific agreement can have an adverse impact on health in several different ways.

#### **A. The FDA need not consider using the disclaimer approach where claims relate to essential bodily organs or serious health conditions.**

Under the Court's opinion, the FDA need not and should not consider using the

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<sup>1</sup> *Pearson* at 656.

<sup>2</sup> Guy Gugliotta, *Health Concerns Grow Over Herbal Aids; As Industry Booms, Analysis Suggests Rising Toll in Illness and Death*, Wash. Post, Mar. 19, 2000, at A1, A22.

<sup>3</sup> *Pearson* at 659 (emphasis added).

disclaimer approach if a proposed health claim not based on significant scientific agreement pertains to an essential organ or a serious health condition. This would include, for example, claims regarding the heart, lung, brain and liver. This exception to the Court's holding also pertains to claims regarding serious health conditions including risk factors for cancer and heart disease, as well as asthma, birth defects, diabetes, HIV, and Alzheimer's disease. The Court recognized that in situations where either consumer health or safety is involved, claims supported by preliminary scientific evidence would be inappropriate even if accompanied by a disclaimer.

The Court's holding on this point is well-grounded. For example, in the 1990's beta carotene supplements were being promoted by the supplement industry as substances that might reduce the risk of cancer. Preliminary epidemiological studies had demonstrated a promising link between the consumption of beta carotene rich foods and a reduced risk of cancer. Clinical studies conducted afterwards, however, showed strong evidence of *no* benefit from beta carotene supplements and indicated that the use of such products by smokers might actually increase their risk of lung cancer.<sup>4</sup> Additional clinical studies funded by the National Institutes of Health confirmed these findings and led the researchers to discontinue the studies.<sup>5</sup>

Therefore, it is essential that claims that a substance can reduce the risk of a serious disease like cancer should only be permitted where significant scientific agreement exists; under the Court's holding, the FDA is not obligated to permit such claims on the basis of preliminary evidence.

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<sup>4</sup> National Cancer Institute, Press Release, *Beta Carotene and Vitamin A Halted in Lung Cancer Prevention Trial*, Jan. 18, 1996.

<sup>5</sup> *Id.*

**B. The FDA need not consider using the disclaimer approach when it is foreseeable that consumers may, based on a preliminary claim, forego a proven dietary or medical therapy in favor of a dietary supplement that may or may not be beneficial to health.**

As the Court recognized, the FDA may choose to suppress claims not supported by significant scientific agreement instead of permitting them with a disclaimer in situations where a supplement “affects health.”<sup>6</sup> Preliminary claims for dietary supplements that may or may not be beneficial can cause injury to health if consumers choose them over proven dietary or medical therapies. Thus under the Court’s holding, the FDA is not obligated to permit preliminary health claims with a disclaimer if the claim would lead consumers to rely on an unproven dietary supplement instead of a proven dietary or medical therapy.

A survey conducted by *Prevention Magazine* with technical assistance from the FDA estimates that consumers often substitute unproven dietary supplements for proven therapeutic approaches even in the absence of preliminary health claims. According to this survey, 22.8 million consumers used dietary supplements *instead* of prescription medicine, and 30.3 million used herbal remedies *instead* of an over-the-counter drug. Thus, it is evident that supplements -- which largely have not been tested for safety and efficacy -- have already replaced many prescription and over-the-counter drugs that have been demonstrated to be safe and effective. The use of preliminary health claims would surely exacerbate this trend and cause additional injury to consumer health. As the Prevention survey concluded:

Already, an estimated 11.9 consumers have experienced adverse reactions from using herbal remedies, and 6.5 million have had problems of this kind when using specialty

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<sup>6</sup> *Pearson* at 659.

supplements.<sup>7</sup>

To permit health claims to be made on a basis other than significant scientific agreement presents an unnecessary and unjustified threat to consumer health, especially when the claim may encourage consumers to forego a proven dietary or medical treatment in favor of a supplement that may or may not work. In such situations, the use of a disclaimer approach is an insufficient means of protecting consumer health and safety, and, under the Court's opinion, the FDA may instead prohibit the claim completely.

**C. The FDA need not consider using the disclaimer approach when consumers, based on their own observations, cannot determine whether a claim is true.**

Consumers who rely on preliminary health claims and take dietary supplements promoted for conditions that are difficult to self-diagnose have no way of knowing whether the products are working. The use of preliminary health claims not supported by significant scientific agreement is particularly dangerous in such cases because they may lead consumers to rely on treatments that may not be effective. The Court's decision in *Pearson* does not require the FDA to approve preliminary claims with a disclaimer if the health and safety of consumers are threatened as they are in this situation.

**II. The FDA is not obligated to consider the disclaimer approach when scientific evidence supporting a claim is outweighed by quantitatively or qualitatively superior evidence.**

In *Pearson*, the Court stated that the FDA can prohibit preliminary health claims where

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<sup>7</sup> *Prevention Magazine's National Survey on Self-care Reveals 158 Million Consumers Use Dietary Supplements for Their Health and Spend Approximately \$8.5 Billion Each Year; Survey Also Reports That Widespread Use of Dietary Supplements May Cause Public Health Problems*, PR Newswire, Feb. 25, 2000.

the scientific evidence in support of the claim is outweighed by the evidence against the claim, or where the evidence supporting it is qualitatively weaker than the evidence against it. The Court's decision thus calls on the FDA to weigh and evaluate the scientific evidence in support of a claim. If studies in support of a claim are qualitatively weaker than studies siding against a claim, then the claim may be prohibited. Also, if the number of studies demonstrating that a claim is invalid is larger than the number of studies supporting the claim, the FDA may prohibit the claim completely. We believe this exception to the Court's primary holding is very broad and will apply to many of the decisions that the FDA will face in this area.

**III. The FDA is not obligated to consider permitting preliminary health claims with a disclaimer when empirical evidence shows that the disclaimer is insufficient to protect consumers from deception.**

The Court in *Pearson* stated that disclaimers would not be required where “empirical evidence that disclaimers similar to the ones . . . suggested. . . [by the court] would bewilder consumers and fail to correct for deceptiveness. . . .”<sup>8</sup>

The FDA should thus conduct research so that it can obtain empirical evidence demonstrating when disclaimers do not prevent consumer deception caused by health claims that fail to meet the significant scientific agreement standard. A study conducted by the FTC on health claims in advertising concludes that certain disclaimers are insufficient to protect consumers.<sup>9</sup> The FDA should conduct its own research on dietary supplement label claims.

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<sup>8</sup> *Pearson* at 659-660.

<sup>9</sup> E.g., Federal Trade Commission, Generic Copy Test of Food Health Claims in Advertising, Nov. 1998. For example, the FTC found that where disclaimers were used to inform consumers that a product high in one beneficial nutrient also contained high levels of

We note that under the Supreme Court doctrine in this area, a disclaimer approach is traditionally used to provide consumers with additional information to remedy a deceptive claim and help them choose between products or services. In the leading case, *Zauderer v. Office of Disciplinary Counsel*, an attorney had advertised that he accepted cases on a contingency basis with “no cost” to the client. The Supreme Court upheld an Ohio Bar rule requiring the lawyer to disclose that clients were still responsible for paying costs if the litigation were unsuccessful.

Similarly, in the dietary supplement area, a disclaimer providing additional information would be appropriate where there was significant scientific agreement that a substance produced a desired effect, but that other factors played an important role as well. For example, if the truthfulness of a health claim for an herbal substance is dependent upon consuming it with a diet low in fat, then that disclosure would be material to consumers.

The examples of the disclaimers suggested by the *Pearson* court, however,<sup>10</sup> do not provide consumers with any useful additional information to help them evaluate the safety and health benefits of a supplement. Simply informing consumers that the scientific evidence is inconclusive and/or that the FDA has not approved a claim merely constitutes a disclaimer of responsibility; such statements do not provide consumers with additional useful information that

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another nutrient that could increase the risk of a diet-related disease, almost half of those surveyed “apparently misconstrued the dietary warning as a favorable commentary on the quantity of sodium or saturated fat in the advertised products.” *Id.* at E. 3-4.

<sup>10</sup> “The FDA does not approve this claim” or “the evidence in support of this claim is inconclusive.” *Pearson* at 659.

remedies an otherwise misleading claim.<sup>11</sup> There is a vast difference between merely disclaiming responsibility and disclosing useful information that qualifies an otherwise deceptive statement. While the Court expressed confidence in the specific wording of the disclaimers that it suggested the FDA utilize, it did not “rule out the possibility”<sup>12</sup> that its suggested approach would “bewilder consumers and fail to correct for deceptiveness.”<sup>13</sup> It is, therefore, incumbent upon the FDA to conduct the necessary consumer research and resolve the Court’s uncertainty about its holding.

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<sup>11</sup> David C. Vladeck, *Devaluing Truth: Unverified Health Claims in the Aftermath of v. Shalala*, 54 Food and Drug L.J., 535-554 (1999).

<sup>12</sup> *Pearson* at 660.

<sup>13</sup> *Id.* at 659-60.