

Food and Nutrition Labeling Group

April 4, 2000

American Association of
Family and Consumer Sciences

American Association of
Retired Persons

American Cancer Society

American College of Preventive
Medicine

The American Dietetic Association

American Heart Association

American Institute for
Cancer Research

American Public Health Association

American Society for Nutritional
Sciences

Center for Science in the
Public Interest

Citizens for Public Action on
Blood Pressure and Cholesterol

Consumer Federation of
America

National Consumers League

Society for Nutrition Education

Association of American Medical
Colleges

Mr. Joseph A. Levitt
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Dear Mr. Levitt:

We, the undersigned members of the Food and Nutrition Labeling Group -- a coalition of 15 consumer and public health organizations including the American Dietetic Association, the American Cancer Society and the American Association of Retired Persons -- wish to provide our views on the Food and Drug Administration's (FDA) "Strategy for Implementation of *Pearson Court Decision*."

In its decision, the U.S. Court of Appeals for the District of Columbia Circuit held that unless certain exceptions apply, the First Amendment prevents the FDA from prohibiting the use of a health claim that does not meet the "significant scientific agreement standard" if the use of a disclaimer in conjunction with the claim prevents consumer deception, 164 F.3d 650 (D.C. Cir. 1999).

Some food and dietary supplement companies may view that decision as a "green light" to make health claims based on preliminary studies and inconclusive results. The FDA, therefore, should implement the Court's holding in *Pearson* in a manner that prevents companies from using the First Amendment as a shield to make health claims based on unsound science.

Coordinating Committee:

American Association of Retired Persons *Larry White* (202) 434-3800

American Cancer Society *Nancy Hailpern* (202) 661-5700

American Dietetic Association *Stephanie Patrick* (202) 371-0500

American Heart Association *Brian Williams* (202) 758-7900

Center for Science in the Public Interest *Bruce Silverglade* (202) 332-9110

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A. The Court's Holding Should Only be Applied to Dietary Supplements, not Foods.

As a threshold matter, we support the approach taken by the FDA in its "Strategy for Implementation of *Pearson* Court Decision," 64 Fed. Reg. 67289 (Dec. 1, 1999). The strategy applies the court's decision exclusively to dietary supplements. This is appropriate, since the *Pearson* decision involved health claims for dietary supplements, not foods. Health claims for dietary supplements and foods have been treated differently by Congress since 1990. In enacting the Nutrition Labeling and Education Act (NLEA), Congress gave the FDA authority to apply different standards and procedures with respect to the approval of health claims for dietary supplements and foods, 21 U.S.C. § 403(r)(5)(D). Congress continued this distinction four years later when it enacted the Dietary Supplement Health and Education Act (DSHEA). Most recently, Congress demonstrated the importance of this distinction by passing the Food and Drug Administration Modernization Act, which authorizes health claims for foods based on authoritative statements of government agencies other than the FDA. A similar provision was not enacted for dietary supplements.

The FDA has also distinguished between foods and dietary supplements when designing and enforcing regulatory programs. For example, if a structure/function claim is made for a food product, the FDA requires that the claim relate to the nutritive value of the substance that is the subject of the claim, 62 Fed. Reg. 49859-61 (Sept, 23, 1997). The FDA does not apply the same requirement to dietary supplements. Accordingly, the FDA should apply the decision in *Pearson* only to health claims for dietary supplements and not for food.

B. The FDA Should Defer Action on Petitions for New Dietary Supplement Health Claims that do not Meet the "Significant Scientific Agreement" Standard.

We support the FDA's decision in its "Strategy for Implementation of *Pearson* Court Decision" to deny, without prejudice, petitions for new dietary supplement health claims that do not meet the "significant scientific agreement" standard until the agency's rulemaking to reconsider its general rules for dietary supplement health claims is complete. The FDA must determine when the use of qualifying disclaimers is appropriate before it approves new health claims based on the regulatory approach favored by the Court. The FDA should defer action on specific petitions for new claims and first complete action on amendments to its general rules for claims. In this way, the FDA can better ensure that consumers are provided with informational label statements that will help them distinguish between product claims that are based on a relatively high degree of scientific certainty and those that are not.

This approach is certainly the most equitable. It protects the First Amendment rights of petitioners who cannot currently meet the significant scientific agreement standard by allowing them to refile petitions for new claims without prejudice once final rules for using a qualifying

statement in conjunction with a claim are in place. At the same time, it maintains the level of protection from misleading claims that is currently provided to consumers until the agency completes changes to its general rules for health claims. It is also consistent with the approach that the agency has taken with respect to other regulations issued pursuant to the NLEA.

C. The FDA Should Fully Implement the Entire Decision of the Court, Including Exceptions to its Primary Holding.

The Court's holding in *Pearson* also contains several exceptions upon which the agency should rely to protect consumers from claims based on unsound science. First, the Court did not strike down the regulatory provision for dietary supplements that requires that health claims be based on "significant scientific agreement." Rather, the Court required the FDA to define significant scientific agreement and concluded that where the risk of consumer deception can be cured by the use of a disclaimer, the FDA *may* approve health claims that do not yet meet the significant scientific agreement standard. The FDA is *not* required to permit health claims with qualifying statements in every instance. The agency should thus issue guidelines indicating situations where disclaimers are not sufficient to protect consumers from deception.

Second, under the Court's decision, FDA is still permitted to prohibit health claims that do not meet the significant scientific agreement standard where consumer health and safety are threatened, *Pearson* at 655 and note 6. Many health claims directly or indirectly involve health and safety issues. For example, consumers who rely on supplements in lieu of proven medical treatments may seriously jeopardize their health. That is especially true for supplements bearing claims pertaining to the functioning of major body organs such as the brain, heart, lungs, liver and kidneys. The FDA should issue guidelines stating that it will prohibit health claims that do not meet the significant scientific agreement standard where "serious" risk to health and safety matters are involved.

Third, the Court said that the FDA could still prohibit health claims if the agency could demonstrate that a disclaimer was not sufficient to protect consumers from deception, *id.* at 660. The FDA should conduct consumer perception studies to investigate cases in which disclaimers effectively curtail deception.

Fourth, the Court said that the FDA can prohibit the use of health claims when evidence supporting a claim is outweighed by evidence that is qualitatively or quantitatively superior, *id.* at 660 and note 10. The FDA should provide clear guidance to industry on the scope of this aspect of the Court's decision.

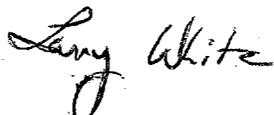
In situations where the Court's decision requires the FDA to permit a health claim that is not supported by significant scientific agreement, the FDA should require a disclaimer such as:

"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.

We urge the FDA to take these measures promptly.

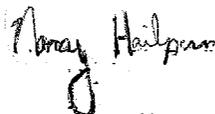
Sincerely,



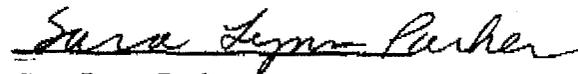
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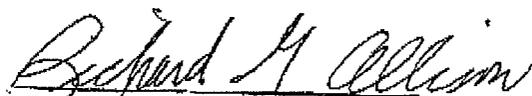
Nancy Hailpern
American Cancer Society



Sara Lynn Parker
Society for Nutrition Education



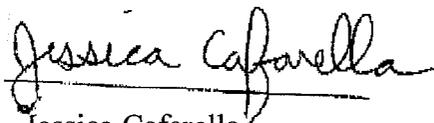
Stephanie Patrick
The American Dietetic Association



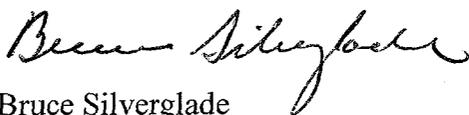
Richard Allison
American Society for Nutritional
Sciences



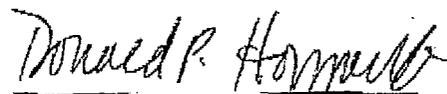
Brian Williams
American Heart Association



Jessica Caferella
American College of Preventive
Medicine



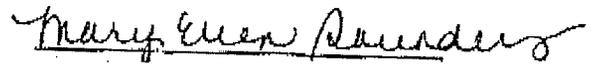
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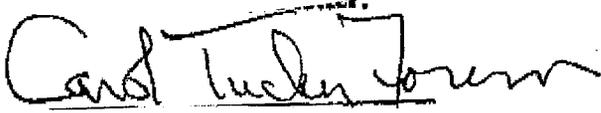
Donald Hoppert
American Public Health Association



Brett Kay
National Consumers League



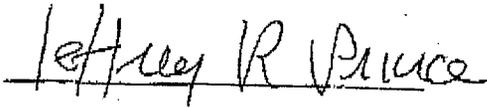
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