

American Medical Association

Physicians dedicated to the health of America



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April 18, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

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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 American Medical Association (AMA), representing approximately 300,000 physicians and physicians-in-training, is pleased to comment on two topics pertaining to health claims in dietary supplement labeling: implementation of the *Pearson* court decision and whether claims about an effect on an existing disease may be made as health claims (65 Fed. Reg. 52, pp. 14219-14223 (March 16, 2000)).

The AMA is concerned about the quality, safety, and efficacy of dietary supplement products, especially herbal remedies. Many of the AMA's concerns have been communicated to the FDA in four previous letters, dated August 28, 1998, May 27, 1999, August 4, 1999, and August 19, 1999.

The AMA believes that the primary problem is the Dietary Supplement Health and Education Act of 1994 (DSHEA), which fails to provide for adequate regulatory oversight of these 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 Pharmacopeia (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 believes the FDA must aggressively regulate dietary supplements to the fullest extent of permitted by law, in order to fulfill its obligation to protect the health of the American public. The following AMA comments pertaining to health claims in dietary supplement labeling reflect this view.

Implementation of the Pearson Court Decision

The AMA believes that the best regulatory approach for protecting and promoting the public health is for 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.

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The **significant scientific agreement standard**, as described in the FDA's *Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements* (December 22, 1999), appears adequate, provided a health claim only refers to reducing the risk of a disease or health-related condition in the general population or a significant subpopulation (e.g., "diets low in saturated fat and cholesterol may reduce the risk of heart disease" [21 CFR 101.75]). For all other disease-related claims, a dietary supplement should be considered a drug (see Sec. 201(g)(1)(B) of the Food, Drug & Cosmetic Act) and satisfy the more rigorous **substantial evidence standard** that applies to drugs (see Sec. 505(d) of the Food, Drug & Cosmetic Act).

The AMA vigorously opposes a lesser standard for dietary supplement health claims. To allow health claims based on "preliminary or conflicting evidence" fails to protect the health of the American people. The FDA must 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. Specifically, the AMA believes that if there is insufficient evidence to support a health claim, then this should be interpreted as evidence against the claim outweighing evidence for the claim and justifies denial of the claim.

If the FDA is unsuccessful in making the above argument and the *Pearson* opinion forces the FDA to allow "qualifying language" for dietary supplement health claims that fail to meet the significant scientific agreement standard, it will be most unfortunate for consumers. However, if the FDA has no other alternative, the AMA recommends that the qualifying language be a boxed Warning statement prominently displayed on the label of the dietary supplement product. The following language is proposed:

WARNING: The Food and Drug Administration has determined that there is insufficient scientific evidence to support the health claim(s) being made for this product. Thus, this product may be of no benefit or even be harmful to some individuals.

The AMA is strong in its view that this is the only type of qualifying language that clearly states there is insufficient evidence to support the health claim and that also will gain the attention of consumers.

In its March 16, 2000 *Federal Register* request for comments, the FDA asks for guidance on information about safety of dietary supplement products that bear health claims. In prior correspondence (enclosed), the AMA has stated that the FDA must ensure that dietary supplements are of high quality and have a safety profile that warrants direct purchase by consumers without health professional supervision. To assure dietary supplement quality, the AMA has asked the FDA to rely on the USP to set standards for identity, strength, quality, purity, packaging, and labeling and, to develop specific Good Manufacturing Practices (GMP) regulations for these products. To assure safety, the AMA has asked the FDA to adopt a vigorous Adverse Event Reporting program for dietary supplements and to take necessary action when safety problems are identified. This would include requiring dietary supplement manufacturers to include safety information (i.e., warnings, contraindications, precautions, and adverse reactions) on the labels of dietary supplements to protect consumers.

Whether Claims of Effects on Existing Diseases May Be Made As Health Claims

The AMA 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. This law clearly states that dietary supplements are deemed to be foods except for purposes of Sec. 201(g) of the Food, Drug & Cosmetic Act. Dietary supplements are not intended to diagnose, cure, mitigate, treat, or prevent any disease. 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 (i.e., require FDA review and approval prior to marketing and meet the substantial evidence standard).

In prior correspondence (enclosed), 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. Drug products have a known benefit/risk ratio based on rigorous scientific study and premarket regulatory review by the FDA. In contrast, knowledge about the benefit/risk ratio of dietary supplements is far less certain. Dietary supplement products should not be used inappropriately by consumers to treat diseases or delay individuals with diseases from obtaining a diagnosis and appropriate drug treatment from a physician.

Thus, it is imperative 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. Such an action by the FDA clearly would be in conflict with its mission to protect the health of the public. 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).

In conclusion, the AMA continues to believe that the DSHEA fails to provide adequate regulatory oversight of dietary supplement products by the FDA and modifications to the current federal law are necessary. However, in the absence of modifications to the law, the AMA believes the FDA must pursue a regulatory strategy that will help the FDA meet its primary responsibility to protect the health of the public. With regard to health claims, the AMA urges the FDA to require the same standard of "significant scientific agreement" to dietary supplements as it does for conventional foods. Furthermore, the AMA vigorously opposes the expansion of health claims for dietary supplements to include effects on an existing disease.

The AMA appreciates the opportunity to comment on this important issue and would be pleased to discuss its concerns and recommendations regarding dietary supplements more fully with the FDA. Please direct any questions or comments to Margaret Garikes in our Washington Office, at 202-789-7409.

Sincerely,



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