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Mar. 14, 2000

Christine J. Lewis, Ph.D.
Acting Director
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Washington, D.C. 20204

Dear Acting Director Lewis;

I received your Mar. 3 fax about a public meeting on April 4 relating to the implementation of Pearson v. Shalala and another issue on health claims. I have class on April 4 and will not be able to attend.

I made comments about the implementation of Pearson in my March 25, 1999 Testimony to the House Government Reform Committee. I have enclosed a copy in case you can include it in the record of input for the meeting. I also have expanded my views in a section in an article on Constitutionalizing Food and Drug Law which is to be published shortly in 74 Tulane Law Review 815 (2000).

I hope this is of assistance.

Sincerely yours,

Margaret Gilhooley
Professor of Law

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TESTIMONY OF PROF. MARGARET GILHOOLEY OF SETON HALL LAW SCHOOL
HEARING OF THE HOUSE COMMITTEE ON GOVERNMENT REFORM
ON DIETARY SUPPLEMENTS, MARCH 25, 1999

I am Margaret Gilhooley. I teach at Seton Hall Law School and was a member of the Commission on Dietary Supplement Labels. I appreciate the opportunity to testify on DSHEA and whether FDA is carrying out its intent.

1. Criteria to Identify Disease Claims. DSHEA permits dietary supplements to make structure and function claims but not disease claims. Under FDA's proposed rules (63 Fed. Reg. 23624), disease claims include references to specific diseases, but not more general references to body systems or functions. Thus, FDA tentatively regards as appropriate a claim that a supplement "helps maintain cardiovascular function," "inhibits platelet aggregation," and "helps maintain a healthy cholesterol level."

I believe FDA's criteria are too narrow. General references to bodily functions can still imply usefulness to prevent disease conditions, and especially so when the claims refer to bodily organs and functions that normally receive medical attention. The Commission members disagreed about appropriate claims for

supplements, and some of us found "troubling" and "problematic" claims:

"ostensibly relating to 'normal bodily functions' that actually imply the need to remedy an underlying abnormal or unhealthy state and statements mentioning organs (e.g. heart, liver, and prostate) or systems (e.g. circulatory) associated with major clinical conditions. P. 36-37 (emphasis added).

In my view, a claim to "maintain normal" cardiovascular function (or similar claims) implies a need to use the product to prevent an abnormality, an abnormality which would be a disease. Moreover, when a claim relates to a matter beyond the ability of the consumer to assess from their own experience, the potential to be misled increases.

I think the FDA proposal needs to be revised to restrict supplement claims that relate to the maintenance of bodily conditions and functions closely associated with the occurrence of disease and beyond the ability of the consumer to evaluate.

2. Need to Identify an Understandable "Dietary" Relationship. The FDA proposal recognizes as an appropriate "structure and function" statement for a dietary supplement a claim that the product "improves absentmindedness." In my view this claim should not be viewed as an appropriate claim for a "dietary" ingredient, There are no foods that affect absentmindedness, and this claim is not one for the role of a dietary ingredient or a dietary supplement in any meaningful sense. That claim should not be

permissible for the same reason that a claim on a dietary supplement to be an "oral contraceptive" would not be permissible--the claim is simply not one for the effects of a "dietary" ingredient.

The FDA rule should preclude structure and function claims for supplements unless the claim had an understandable "dietary" relationship. Products can be sold simply as dietary supplements, but when they go beyond that to make a structure and function claim, the statement should relate to the role of the dietary ingredient in the diet in achieving effects like those associated with the effects of foods. An appropriate dietary claim would be that the supplement is a substitute source for effects like those produced by foods in the diet. For example, a supplement might claim that it provides energy, has a wake-up effect like coffee or a calming effect like tea.

3. Health Claims and Dietary Supplements. The Commission recommended that the process for approval of health claims should be the same for dietary supplements and conventional foods, and supported "the concept of fairness" under which the requirements for health claims are the same for foods and for dietary supplements. P. 34-35. While FDA had already adopted this approach, a recent decision by the D.C. Circuit Court of Appeals has found constitutional and legal difficulties with FDA's actions. *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

Under the court decision, the FDA regulations are unconstitutional in failing to allow supplements to make a health

claim even when there is no significant scientific agreement to support the claim, so long as the supplement bears a disclaimer about the inconclusiveness or other limits of the supporting evidence, and the lack of FDA approval. I will not comment upon the constitutional law aspects of the decision, but will point out the important decision FDA will have to make on remand in determining what constitutes an adequate disclaimer to adequately inform consumers with respect to particular claims. In my view, in addition to the other disclaimers, consideration needs to be given to stating on the label that there is "no significant scientific agreement" to support the claim. The level of scientific agreement that supports a claim is important to scientists in evaluating a claim, and should be disclosed in order to adequately inform consumers.

The difficulties of using disclaimers to inform consumers is illustrated by the National Cancer Institute's decision to end a study of the effects of beta carotene supplements. The study was ended early when investigators concluded not only that the supplements were not helpful but also that there was "a hint of possible harm" in increasing a cancer risk. See "Studies Find Beta Carotene, Used by Millions, Doesn't Forestall Cancer or Heart Disease," New York Times, p. A 16, Jan. 16, 1996. Disclaimers may simply not be adequate to convey the information.

The Court of Appeals was also concerned that FDA provide a better articulation of the meaning of "significant scientific agreement." The Commission report has a discussion that may be of

some assistance. The report pointed out ways that the FDA process can be improved, including by holding scientific conferences and workshops. P. 34-35. The report also notes that there is scientific literature concerning the ways of evaluating a body of scientific evidence that involves uncertainties and matters of judgment. P.31.

The Commission also recognized the difficulty in doing research to support health claims, because of the chronic nature of the conditions, and the inappropriateness of direct experimentation for many claims. See p. 31. These factors make the evaluation of the claims more difficult and also make the existence of significant scientific agreement important in determining whether there is sufficient support.

The Court of Appeals found inadequate FDA's explanations for why the agency found particular claims lacking in scientific support. The decision highlights the importance of FDA making a careful examination of the evidence for each claim, and providing a full and well-documented explanation if the agency finds the support inadequate.

4. Safety Substantiation. Consumers use dietary supplements because they assume the supplements are safe--as safe as foods. The supplements are not, however, subject to the requirements for general recognition or FDA approval that provides assurance of the safety of other food ingredients. FDA bears the burden of proof to show that a product poses a significant risk. The Commission report indicates the difficulties and resource burdens involved in

meeting this standard. P. 22.

Supplement manufacturers should have a legally-enforceable affirmative obligation to do the testing needed to establish that supplements are safe. If they do not do safety testing, the manufacturer should put a warning on the label that the safety of the supplement has not been substantiated. Such a measure would not involve pre-market approval by FDA. I recommended in the Commission report that FDA require this warning to prevent deception, but FDA has not acted on this measure.

5. *Pharmanex v. Shalala*. I understand that the Committee is also interested in views on the District Court decision in *Pharmanex v. Shalala*, 1999 U.S. Dist. Lexis 1659 (D. Utah 1999). DSHEA excludes from the definition of dietary supplements "an article that is approved as a new drug" unless FDA, by rule, provides otherwise. The court found that this exclusion applied only to finished drug products, and not to a supplement that contains the active ingredient of an approved new drug. The decision emphasizes the textual language, and prior cases, and views Congress' purpose as leaving the existing law in place with respect to the basis for determining drug intent.

The length and detail of the definitional exclusion suggests Congress' purpose may have been broader. A commentary on DSHEA indicates that the exclusion covers "ingredients" and that Congress had a wider purpose to protect research investment, and to guard against the marketing of supplements containing botanical ingredients such as those in *Taxol*:

"Under this provision, ingredients first marketed as new drugs would not be dietary supplement ingredients....The purpose behind the provision was to protect bona fide new drug ingredients as well as research investment into natural ingredients for use in new drugs.[Footnote] At the time of negotiations leading to the enactment, another concern was that abortifacient ingredients and anti-neoplastic agents derived from botanicals, such as taxophen, might be marketed as dietary supplements." See Bass & Young, DSHEA:A Legislative History and Analysis 36 (1996).

The provision for FDA regulatory review and approval of the marketing of these supplements provides a forum to consider the labeling of the product and all the factors that can be considered in determining a manufacturer's intent. Congress may have believed this additional review was needed in the unusual case in which a supplement has the same active ingredient found in a marketed new drug sold by prescription.

The impact of the Supreme Court cases cited by the District Court was to expand FDA's ability to regulate products as drugs, and the impact of the Pharmanex decision is to narrow FDA's authority to regulate a supplement as a drug. This difference in impact may need further consideration in determining Congress' intent.

6. Determining DSHEA's intent. Finally, there is debate about whether FDA is carrying out the intent of DSHEA. But the

underlying reason why it is hard to resolve that issue is because DSHEA is an enigma. The provisions are ambiguous, and can be interpreted various ways. Thus, while I believe FDA can, and should, do more to guard against inappropriate claims, and to ensure that manufacturers substantiate safety, I recognize that not all will agree that FDA has that authority under DSHEA. If FDA does not have this authority, in my view, Congress should revisit DSHEA and provide clear criteria to limit inappropriate claims and give FDA stronger authority to ensure the safety of supplements.

I ask that a full copy of my testimony be included in the record of the hearing. I would be glad to answer questions or to provide further information.

Thank you.