

0508 00 MAY -3 P3:09

**TESTIMONY**

**Testimony of  
Stacey A. Zawal  
Vice President, Scientific and Regulatory Policy  
Grocery Manufacturers of America, Inc.  
FDA Public Meeting, Washington, DC**

April 4, 2000

## **GMA Testimony, Food and Drug Administration Public Meeting, Implementation of Pearson v. Shalala Decision**

Thank you for the opportunity to testify this afternoon. The Grocery Manufacturers of America (GMA) is the world's largest association of food, beverage, and consumer brand companies and as such our member companies have a deep interest in the FDA implementation of the decision in Pearson v. Shalala and the provisions that authorize disease claims for food products. GMA commends the agency for providing a public forum to address how the Pearson decision will be implemented and to consider whether to permit health claims about an effect on an existing disease.

### **The Pearson Decision Applies to Conventional Food**

Although the Pearson decision involved four disease claims that arose in the context of dietary supplements, it applies to all food – and not just dietary supplements. Nothing in the Pearson decision limits the impact of the court's analysis to dietary supplements. To ensure a fair, balanced and efficient policy development process, it is incumbent upon FDA to consider directly conventional foods along with dietary supplements. Indeed, the Notice acknowledges that the treatment of health claims with respect to dietary supplements is directly relevant to conventional foods.

The agency's apparent intent to consider these issues solely in the context of dietary supplements is ill-conceived. FDA misses a valuable opportunity to use its resources efficiently by considering a single set of issues once in connection with both dietary supplements and conventional foods. This concurrent approach also facilitates timely development of policies. Ultimately, these policies will be applied to conventional foods. It is, therefore, rational and prudent to directly consider conventional foods when such policies are developed.

We also object to FDA's determination that it will not consider foods in connection with its implementation of Pearson due to purported limits on its statutory authority and because Pearson only involved dietary supplements. This viewpoint is incorrect as a matter of law, and represents unsound public policy. FDA's continued preference to read the First Amendment protections narrowly to the facts of the Pearson case is short-sighted. FDA should not postpone consideration of these important issues in the context of conventional foods until ordered to do so by a Federal court.

### **The Disease Claims Provisions of the FD&C Act Apply to Treatment as Well as Prevention of Disease**

Claims in the labeling of a food that "characterizes the relationship of any nutrient . . . to a disease . . ." are authorized in the Act. There is no limitation in this provision to the "prevention" of disease.

00N-0598

TS26

Some nutrient/disease relationships involve treatment as well as prevention. For example, a person with hypertension is often put on a low sodium diet as part of a treatment regimen. Similarly, patients with osteoporosis are prescribed calcium for treatment, people with cardiovascular disease are prescribed a diet of low fat and dietary fiber as part of a treatment program, and so forth. There is, in short, no bright line between prevention and treatment in the field of diet and disease.

In its Federal Register notice, FDA contends that the disease prevention or treatment characteristic of a food must be based upon its nutritional value. It is, moreover, directly contrary to judicial precedent. The court in *Nutrilab, Inc. v. Schweiker* concluded that food is consumed "primarily for taste, aroma, or nutritive value" but that "To hold as did the district court that articles used as food are articles used solely for taste, aroma or nutritive value is unduly restrictive . . ." Thus, food may be comprised of nutritive and nonnutritive materials, or completely from nonnutritive materials, and there is no statutory requirement that the value of a food in preventing or treating disease must be derived from the nutritive components.

#### Conclusion

For the reasons stated above, FDA should proceed promptly to implement the Pearson decision for all forms of food -- including conventional food, medical food, and any other categories of food, as well as dietary supplements -- and should recognize that the disease claims provisions in Section 403(r)(1)(B) of the FD&C Act include the treatment as well as the prevention of disease.

---

#### Staff Contacts

- Stacey A. Zawel

#### Press Contacts

- Brian T. Sansoni

#### Related GMA Documents dealing with - DIETARY SUPPLEMENTS

##### COMMENT

- o April 27, 2000 GMA Petition to FDA: Withdraw, Revise Pearson v. Shalala Implementation Strategy, Re Disease Claim Rules
- o March 28, 2000 Guidance on Significant Scientific Agreement
- o February 7, 2000 GMA Petition to Food and Drug Administration: Reconsideration and Stay of Action, Structure/Function Claims
- o August 5, 1999 Comments to FDA, Re Structure/Function Statements, Disease Claims
- o May 11, 1999 Disease Prevention Claims and Nutrient Descriptors Based Upon Authoritative Statements of Federal Health Agencies and the National Academy of Sciences
- o September 23, 1998 Structure/Function Statements

##### NEWS RELEASE

- o April 27, 2000 GMA Petition: FDA Should Immediately Withdraw, Revise Unconstitutional Disease Claims Rules
- o April 4, 2000 FDA Policy For Disease Prevention Claims Should Be Applied To All Foods, Not Just Supplements
- o February 10, 2000 GMA Requests FDA To Halt Action On Disease Claim Rules; Group Says Rule "Tantamount to Ban on Commercial Speech"
- o January 5, 2000 GMA: FDA "Moves in Right Direction", Allows Communication of Health Information to Consumers
- o May 11, 1999 GMA: "TIME IS RIPE" FOR FDA TO RECONSIDER AND REVISE

**HEALTH CLAIMS APPROVAL PROCESS**

**TESTIMONY**

- o **April 4, 2000 GMA Testimony, Food and Drug Administration Public Meeting, Implementation of Pearson v. Shalala Decision**

[Back](#)

---

[Home Page](#) | [About GMA](#) | [News](#) | [Public Policy](#) | [Industry Affairs](#) | [Products & Services](#)  
[Member & Brand Links](#) | [Facts & Figures](#) | [Search the Site](#) | [Members Only](#) | [Contact Us](#)

Copyright © 1995 - 2000 Grocery Manufacturers of America. All rights reserved.