



NATIONAL CONSUMERS LEAGUE

1701 K Street, NW, Suite 1200, Washington, DC 20006

PHONE (202) 835-3323 FAX (202) 835-0747 www.nclnet.org

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FDA Public Meeting on Implementing the *Pearson* Court Decision and Other Health Claims Issues.

National Consumers League Testimony

Presented by

Brett Kay

Program Associate, Health Policy

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Good Afternoon. I want to thank the FDA for inviting me here to present the views of the National Consumers League, America's oldest nonprofit consumer advocacy organization. I believe that I can answer the question presented before this panel in one word, context. Consumers need information that makes sense to them; it needs to be in context.

What I mean by this is that much of the information and labeling of dietary supplements does not fully explain what it is intended to do, how it works, what are the best ways to take it, and what warnings or contraindications there may be. Without such information, consumers cannot make informed decisions. Health claims will only further confuse consumers if there are no qualifying statements. Just as in Direct-To-Consumer (DTC) Advertisements for prescription drugs, there must be fair balance about the risks and benefits, so to must health claims have a fair balance to explain the science and the claims being made.

According to a Louis Harris survey that NCL commissioned in 1999,¹ consumers feel labeling and product information have improved over the last decade and consumers feel their shopping skills have improved as well. This is the good news. With the passage of important consumer labeling laws such as the Nutrition Education Labeling Act (NLEA), consumers have much more information about the foods they eat, and most importantly, they have a context with which to judge it. After NLEA, consumers gained information about fat, saturated fat, fiber, cholesterol, and other nutritional components of food, and they learned why these were important and how they related the their health. The labeling was backed by a public education and awareness campaign. The health claims, if passed, will also need public campaigns to

¹ National Consumers League: Consumers and the 21st Century. Louis Harris & Associates, Inc. New York. 1999.

educated consumers about the relative value of such claims and how they affect consumer health and well being. In other words, they the new health claims will need to be put into context.

Now, for the bad news—when it comes to dietary supplements, we are still in pre-NLEA days. Consumers do not have the necessary information to make educated choices, and yet they are using dietary supplements in increasing numbers—most times without the supervision of a doctor, pharmacist, or other health professional.

Without some form of qualifying language, consumers do not have all of the facts. Let me give you two examples: Ginseng and Gingko. There are three types of ginseng--Asian, American, and Siberian--each with different properties and active ingredients. Many times, however, they are lumped together and marketed and sold simply as ginseng, with similar claims for its effects. Or, all three types are combined in to one product. According to traditional Chinese medicine, which treats according to balances in the body (yin/yang; hot/cold), Asian ginseng is regarded as a heating (yang) tonic, while American ginseng is a cooling (yin) tonic. Thus, they have opposite effects and purposes. What happens if they are combined? Do they cancel each other out, or do they have a synergistic effect, making one super potent? What if a consumer is looking for the cooling ginseng and instead takes the heating one? Without any information or qualifying statements, it is very difficult for consumers to make the right choice.

Let me give you one more example that is a bit more relevant to today's discussion. Gingko Biloba is currently marketed as a memory enhancer. The available research on gingko shows that it has some positive effects on people with Alzheimer's disease. None of the studies

has tested its effects on otherwise healthy people with general memory loss. Alzheimer's is a disease, and it cannot be extrapolated that just because ginkgo shows some improvements for this population that it will work for normal memory loss, which is not a disease. Unfortunately, consumers do not know this, and are taking ginkgo not for Alzheimer's, but for normal memory loss. Without some qualifying language addressing the clinical research, consumers may, at best, be wasting their money, and at worst, increasing their chances of harm—gingko is a blood thinner, and if a consumer is already on blood-thinning medicine such as coumadin or even aspirin, it make increase their chances of stroke or internal bleeding. Without such context, consumers may be misled by health claims.

The term dietary supplement is a bit misleading, especially in today's market. The name dietary supplement implies that the product is intended to supplement the diet by replacing or enhancing nutrients one does not get from their diet. However, this is not how supplements are being used or marketed. The paradigm has shifted and supplements are being used and thought of as medicines. Consumers are taking dietary supplements to treat diseases and health conditions such as depression, high cholesterol, prostate problems, hot flashes, arthritis, and the list goes on. This, despite the disclaimer that appears on the label stating the product is not intended to cure, treat, prevent, or mitigate any disease.

When consumers see a label claim, be it a structure/function claim, nutrient content claim, or health claim, they do not make the distinction that has been established by Congress, the FDA, and industry lawyers. Legal nuances are lost on the average consumer. They see a claim and assume the FDA has approved the product, that it is safe and effective. They also see

supplements as medicine, not foods. They are sold in the pharmacy section, often near the pharmacist counter in most drug stores and supermarkets, and they are packaged like many over-the-counter (OTC) medicines.

In order to ensure that consumers are not misled, consumers need clear language that is written in consumer-friendly terms--not legalistic jargon designed to straddle a regulatory hurdle—but to inform them about a product they are taking. Language similar to the Medication Guide (MedGuide) requirements approved by HHS Secretary Shalala in 1996 for prescription drug labeling for consumers is necessary.

MedGuide language is designed to provide context for consumers taking prescription medicines—the name of the drug, what it is used for, how to take it, what warnings and interactions to be aware of, the side effects—and it is done in clear language consumers can understand. The MedGuide format also calls for easy readability, including whiter space, bullets, clear fonts in black type on a white background and a standard format. These components are necessary and vital if consumers are to be able to glean the important messages. FDA recognizes that consumers need easily readable and consistently formatted labeling, having recently approved the new OTC labeling. Health claims for dietary supplements are going to need similar labeling so that consumers will be fully informed and not misled. Thank you once again for this opportunity to comment.