

TESTIMONY for the March 24, 2004 HEARING:

“10 Years after the Implementation of DSHEA: The Status  
of Dietary Supplements in the United States”

Subcommittee on Human Rights and Wellness  
Committee on Government Reform  
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### **Hearing Testimony**

“10 Years after the Implementation of DSHEA: The Status of Dietary Supplements in the United States”

Prepared by Annette Dickinson, President, Council for Responsible Nutrition

Mr. Chairman and members of the Committee, thank you for the opportunity to testify before the Committee on Government Reform, Subcommittee on Human Rights and Wellness - 10 Years After the Implementation of DSHEA: The Status of Dietary Supplements in the United States. My name is Annette Dickinson and I am the president of the Council for Responsible Nutrition (CRN).

CRN represents the mainstream core of the dietary supplement industry, including suppliers of dietary supplement ingredients as well as manufacturers and marketers of branded and private label products available to consumers through all distribution channels -- mass market, health food stores, mail order, and direct sales. CRN members adhere to a strong code of ethics, comply with dosage limits and manufacture dietary supplements to high quality standards under good manufacturing practices.

### **Introduction**

The Dietary Supplement Health and Education Act was passed in 1994 for two primary reasons: to ensure that consumers would continue to have access to a wide variety of safe dietary supplements and to provide consumers with more information about the dietary supplements they purchase.

The past 10 years have demonstrated that these purposes are being fulfilled, as are other goals established by the law.

### **Access to Products**

In 1993, FDA published an Advance Notice of Proposed Rulemaking suggesting numerous restrictions that might be placed on dietary supplements, including

- Limiting the dosage of vitamins and minerals to a small multiple of the RDA,
- Not permitting the sale of dietary supplements containing amino acids,
- Treating most herbs and botanicals as inherently therapeutic and restricting them to sale as drugs.

DSHEA was passed in part to avoid these arbitrary restrictions, by establishing a broad and specific definition listing several classes of permissible dietary supplement ingredients. Today, consumers have access to a wide variety of safe dietary supplements, and category sales have continued the steady rate of increase they have enjoyed since at least the 1970s. Thus, DSHEA has been successful in assuring broad consumer access.

### **Access to Information**

In order to provide consumers with more information about the uses of dietary supplements, DSHEA permitted marketers to make Statements of Nutritional Support, including structure/function statements -- that is, statements describing how a product affects the structure or function of the body. These statements may be used in labeling, subject to the following provisions:

- The marketer must have substantiation that the statement is truthful and not misleading.
- FDA must be notified within 30 days that the statement is being made.

- The product label must include a disclaimer that distinguishes the statement from FDA-approved health claims and from FDA-approved drug claims.

Companies began using Statements of Nutritional Support as soon as DSHEA was passed, and FDA issued extensive rules on structure/function statements in January 2000. As of today, more than 10,000 letters of notification have been submitted to FDA, and the agency has responded to about 10% of the statements with “courtesy letters” advising companies that the claim submitted was not appropriate, either because FDA viewed it as a disease claim or because the product involved was not in fact a dietary supplement.

The ten most commonly utilized types of structure/function statements in the marketplace have to do with immune function, heart health, antioxidant effects, gastrointestinal function, healthy joints, cognitive function, men’s health issues, weight loss or metabolism, energy or endurance, and women’s health issues. Consumers have a vital interest in receiving more information about these topics, and DSHEA was successful in devising a means of providing that information in product labeling.

### **Nutrition Labeling**

In its implementation of the Nutrition Labeling and Education Act, FDA initially proposed to require companies to label dietary supplements as though they were conventional foods. Under this proposal, herbal products for example would have been required to show the amount of protein, fat, and carbohydrate in the product, even though all three values would almost always be zero. Further, those herbal products would not

have been permitted to list any of their active components, but would have been required to show the amount of vitamins A and C and the amount of calcium and iron they contained. A product like glucosamine and chondroitin sulfate would have been subject to similar requirements. Since this approach would not have provided consumers with useful information about dietary supplements other than vitamin and mineral products, DSHEA required FDA to reconsider its approach to nutrition labeling for dietary supplements and to develop a more appropriate system. DSHEA further specified that the new system must permit the inclusion in the Facts Box of components other than vitamins and minerals.

FDA developed a revised approach, as required by DSHEA, and published final regulations on nutrition labeling for dietary supplements in September 1997. These regulations permit all relevant components to be listed in the “Supplement Facts” box, following the list of macronutrients and micronutrients, if any are present. Thus, DSHEA succeeded in the goal of creating a nutrition labeling format appropriate to the types of ingredients and components utilized in dietary supplements.

### **Good Manufacturing Practices**

DSHEA authorized FDA to establish Good Manufacturing Practices (GMPs) for dietary supplements, modeled after GMP regulations for foods. Until such regulations are finalized, dietary supplements are subject to the same GMPs that apply to conventional foods. The Council for Responsible Nutrition (CRN) had earlier established GMP guidelines for its membership, and those GMPs had formed the basis for the guidelines adopted by the U.S. Pharmacopeia for nutritional supplements. After the

passage of DSHEA, CRN approached FDA officials and inquired whether they intended to establish dietary supplement GMPs. They indicated they would like to do so, but lacked in-house expertise and would appreciate input from the industry. CRN convened a working group to draft appropriate GMPs and invited other trade associations to join in this effort. In November 1995, just over a year after the passage of DSHEA, the trade associations submitted a comprehensive draft that FDA published in February 1997 as an Advance Notice of Proposed Rulemaking. The proposal languished until the current administration published an extensive and problematic Proposed Rule in March 2003. Numerous comments were submitted during the official comment period, and even after the comment period several trade associations continued to work toward GMP language that could be jointly supported. On January 30, 2004, CRN, the American Herbal Products Association, and the National Nutritional Foods Association submitted a joint proposal that included specific recommended language for the GMPs. This document was also endorsed by the Consumer Healthcare Products Association. FDA is currently evaluating all the comments and is expected to issue a final rule in the near future. The new GMPs will provide a strong framework for ensuring the purity, identity, quality, strength and composition of dietary supplements, and CRN is pleased to have been able to contribute to this outcome by getting the ball rolling in 1995 and by submitting extensive comments and participating in development of the joint submission in 2003 and 2004.

## **New Ingredients**

DSHEA “grandfathered” dietary supplement ingredients already on the market as of October 1994, in the same way the 1958 food additive amendments to the Food, Drug and Cosmetic Act “grandfathered” hundreds of substances already being used in foods at the time those amendments were adopted. DSHEA established a procedure that would be required for new ingredients used in dietary supplements in the future. Companies are now required to provide a notification to FDA regarding any new ingredient at least 75 days before marketing it, setting forth the basis for considering the ingredient to be “reasonably expected to be safe.” FDA has been receiving these notifications on a regular basis since the passage of DSHEA and has been giving them serious attention. A recent analysis by the American Herbal Products Association indicated that there have been 138 unique notifications filed, of which FDA has rejected 65, or almost half. The rejections are generally due to a company’s failure to sufficiently establish the identity of the ingredient or a failure to provide sufficient information to provide a basis for concluding that the ingredient is reasonably expected to be safe.

## **Commission on Dietary Supplement Labels**

DSHEA mandated the appointment by the President of a Commission on Dietary Supplement Labels, to provide advice to FDA on a number of issues. The Commission was appointed in 1995, met for a period of two years, and published its final report in November 1997. That report, unfortunately, has been largely ignored but it provides useful guidance that could still be helpful in defining, for example, the level of substantiation that should be required for structure/function statements. Among the seven

members of the Commission were two highly respected professors of nutrition (including the Chairman), the country's leading professor of pharmacognosy, a prominent professor of law who had previously served as an FDA counsel, and three persons directly or indirectly associated with the industry, including myself.

### **NIH Office of Dietary Supplements**

DSHEA required the establishment within the National Institutes of Health of an Office of Dietary Supplements (ODS), to encourage additional research and to serve as a source of expertise for FDA on issues relating to dietary supplements. This year, under the leadership of Dr. Paul Coates, ODS has a budget of \$20 million to support an aggressive research agenda relating to safety, benefits, and analytical methods. ODS also supports six botanical research centers at leading academic institutions and has sponsored numerous research conferences highlighting the evidence available regarding dietary supplements for specific populations such as women or the elderly or for particular purposes such as performance enhancement. Thus, DSHEA succeeded in creating a powerful mechanism within NIH for increasing research attention to dietary supplements and for engaging leading academic institutions in the task.

### **Problem Ingredients**

The biggest problems for the industry in the decade since the passage of DSHEA are only two in number, but these two have led to criticism so widespread as to undermine consumer confidence in the dietary supplement category as a whole. These are:

- The failure to resolve the issues surrounding ephedra until just this year, and
- The absence of action restricting the marketing of steroid hormone precursors until just this year.

FDA has recently finalized a regulation declaring ephedra products to be adulterated, using new authority provided under DSHEA to declare a product adulterated if it poses a “significant or unreasonable” risk of illness or injury. A legal challenge has been filed against the rule, and the courts will soon decide whether FDA’s rule is appropriate. Also, legislation has been introduced in both the Senate and the House that is expected to pass this year and that will classify androstenedione and a number of related substances as controlled substances. It is to be hoped that these actions will bring these issues to a resolution.

### **What Remains to be Done?**

DSHEA brought about a meaningful change in the way dietary supplements were regulated. Dietary supplements have always been regulated as a subcategory of foods, and DSHEA reaffirmed the appropriateness of this classification, but within the food category specific provisions were created for dealing with the unique aspects of dietary supplement regulation. FDA has implemented some of the provisions of DSHEA through extensive regulations on nutrition labeling for dietary supplements, on structure/function statements used for dietary supplements, and on GMPs for dietary

supplements. It cannot be said, however, that DSHEA has been fully implemented as of this tenth year following its passage.

DSHEA requires that companies submit notifications before marketing new ingredients, and those notifications must include information about the safety of the ingredients. FDA has been evaluating these submissions in a meaningful way, but there is no indication that the agency is monitoring the marketplace to ensure that new ingredients are not introduced without the filing of such notifications. This is an area that needs additional attention.

DSHEA permits marketers to use structure/function statements to describe the effects of dietary supplements, but also requires the companies to have substantiation that the statements are truthful and not misleading. The industry and the agency need to pay more attention to establishing guidance about the kind of substantiation needed. The Commission on Dietary Supplement Labels suggested that the substantiation be made public, in order to provide health professionals and consumers with more information about the basis of the claims, and this is a proposal worthy of further consideration.

One serious remaining challenge for the industry and for FDA is to put a stop to the marketing of street-drug knockoffs masquerading as dietary supplements. The agency has taken a number of actions against such products, but no sooner is one challenged than another emerges. There is a need for the industry and the agency to develop a highly visible partnership to attack this problem, in order to protect young people from unscrupulous marketers.

It is to be ardently hoped that the industry's second decade under DSHEA will be more peaceful than the first. With a few very difficult issues now resolved or about to be

brought to closure, the industry should have an opportunity as it moves forward to focus on the good news about the safety and benefits of most dietary supplements as positive components of a healthy lifestyle.