

**THE DIETARY SUPPLEMENT
HEALTH AND EDUCATION ACT OF 1994:
IT MAKES SENSE – LET’S MAKE IT WORK**

**Testimony of the Council for Responsible Nutrition
before the Oversight Subcommittee
of the Senate Governmental Affairs Committee**

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Senator Voinovich and Senator Durbin, the Council for Responsible Nutrition (CRN) appreciates the opportunity to appear before this Subcommittee to discuss the status of dietary supplement regulation ten years after passage of the Dietary Supplement Health and Education Act of 1994. CRN is a trade association representing the mainstream core of the dietary supplement industry. Our members include manufacturers and marketers of national brands as well as store brands of dietary supplements available to consumers through the mass market, natural food stores, direct sales, and mail order. Our members include the companies that make the finished products as well as the companies that supply the bulk ingredients such as vitamins, minerals, fatty acids, and botanicals.

PURPOSE OF DSHEA

DSHEA was passed for two reasons: to ensure that consumers would continue to be able to choose among a wide variety of safe dietary supplements, and to increase the

information available to consumers about the uses of dietary supplements. The past 10 years have demonstrated that these purposes are being fulfilled, as are other goals established by the law.

DSHEA was made necessary because FDA had a history of attempting to unreasonably restrict the formulation of dietary supplements and because Commissioner David Kessler appeared to be harking back to the notion of imposing broad restrictions. In the 1970's, FDA had finalized regulations that would have restricted vitamin and mineral supplements to no more than 150% of the daily reference amount. This would have meant a limit of only 90 mg for vitamin C, for example. These regulations were overturned by the courts and by legislation passed in 1976 that added Section 411 (vitamins and minerals) to the Food, Drug & Cosmetic Act.

In 1993, Commissioner Kessler 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 low multiples of the daily reference value,
- Nor permitting the sale of dietary supplements containing amino acids, and
- Treating most herbs and botanicals as inherently therapeutic and restricting them to sale as drugs.

This set off the storm of protest that ultimately resulted in the passage of DSHEA in 1994. DSHEA specified the types of ingredients that were to be permitted in dietary supplements and has been successful in maintaining access to a broad range of products.

On the information side, FDA in 1993 and 1994 was proposing to approve health claims for antioxidant vitamins and for fiber naturally occurring in foods, but not for dietary supplements providing exactly the same beneficial ingredients. Thus, it appeared the dietary supplements were unlikely to benefit from FDA's approach to health claims under the Nutrition Labeling and Education Act, and the industry sought some additional means of conveying information to consumers. DSHEA authorized Statements of Nutritional Support, including statements describing how a product affects the structure or function of the body. Companies making such statements are required to have substantiation and to notify FDA within 30 days. This provision was self-implementing and began to be utilized soon after DSHEA was passed. In January 2000, FDA finalized extensive rules defining the scope of appropriate structure/function statements, and today more than 10,000 letters of notification have been filed with FDA regarding such claims. Companies using such statements must also include a label disclaimer saying the claim has not been evaluated by FDA, in order to distinguish these statements from approved health claims. The disclaimer also says the product is not intended to diagnose, treat, cure or prevent disease, to distinguish the statements from approved drug claims.

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.

DSHEA DID NOT CHANGE THE REGULATORY STATUS OF DIETARY SUPPLEMENTS

Dietary supplements have always been considered as a subcategory of foods. This official categorization was not created by DSHEA, as some of our critics persist in asserting, but instead predates DSHEA by some 56 years. The FD&C Act of 1938 included dietary supplements within the category of foods for special dietary uses. FDA established a regulatory definition of such products in 1941, and that definition was incorporated into Section 411 of the Act by the vitamin amendments of 1976. The definition is extremely broad, covering vitamins and minerals but also all “other ingredients” intended for use in supplementing the diet.

DSHEA reconfirmed that dietary supplements were to continue to be regulated as foods and established a specific definition to clarify the categories of ingredients that were to be permitted in dietary supplements.

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” as safe hundreds of substances already being used in foods at the time those amendments were adopted. DSHEA established a premarket notification 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.

SAFE AND BENEFICIAL DIETARY SUPPLEMENTS

Health foods and dietary supplements have been popular with the American public for at least a hundred years, and today dietary supplements are used by 70% of the population at least some of the time and by 40 to 50% of the population on a regular basis. This is just as true in Iowa and Illinois as it is in New York and California. By far the most popular single product category is the multivitamin, with or without minerals, and several highly respected medical and nutrition authorities have recommended that it would make sense for virtually everyone to take a multivitamin. The Centers for Disease Control and Prevention are supporting a national initiative to encourage all women of childbearing age to take a multivitamin in order to get enough of the B vitamin folic acid to help protect them against having a baby with a neural tube defect such as spina bifida, the leading cause of childhood disability in this country.

Vitamin and mineral products account for \$7.7 billion in retail sales in the U.S. and represent 48% of sales for the entire \$16.2 billion dietary supplement category. Herbs and botanicals represent 26% of sales at \$4.28 billion. Specialty products account

for 15% at \$2.37 billion, and sports nutrition products represent 11% of sales at \$1.83 billion.

Were it not for two specific products that have been highly controversial over an extended period of time, the dietary supplement industry would be rightly recognized to have as good a safety record and as strong a benefit profile as any other food category. However, these two products -- ephedra and androstenedione – have unfortunately loomed so large as to almost characterize the industry in the minds of some. FDA is now addressing both issues aggressively. If current FDA actions are upheld, as we expect they will be, these two ingredients will no longer be an issue when the next Congress convenes in 2005, and hopefully we will be able to work together on different types of hearings -- hearings exploring the benefits of dietary supplements and the potential health care cost savings that could be realized if more people used supplements on a regular basis.

EPHEDRA

FDA issued a final regulation early this year that banned ephedra in dietary supplement products as of April 12, 2004. That rule is currently undergoing judicial review and has survived the first phase in which the court denied an injunction. This is viewed as an indication that it is likely to survive the entire process.

It is sometimes said that it took FDA ten years to take definitive action against ephedra, but this is not an accurate description of the process. From the time former Commissioner McClellan took office and decided to resolve this ongoing issue, it took the agency less than 2 years – lightning speed in terms of the regulatory process. The

earlier delays were due to false starts, wrong turns, and an unwillingness to actually use the provisions of DSHEA as Congress intended.

ANDROSTENEDIONE

Athletes have always and apparently will always seek out products and practices that have any potential whatsoever to improve performance. Sports organizations are vigilant in attempting to assure that performance is based on good nutrition, solid training, and healthy habits and not on the use of performance-enhancing products. U.S. and international sports authorities have established lists of banned substances, the use or detection of which will cause an athlete to be disqualified from competition, and these include anabolic steroids and some precursors of anabolic steroids. Androstenedione, one of those precursors, is marketed as a dietary supplement and has been blamed for the disqualification of some athletes. In order to address the issue of andro and other precursors “closer” to testosterone, CRN and the other industry trade associations are supporting Congressional legislation that will place a long list of these ingredients under the Controlled Substances Act and thus effectively remove them from the dietary supplement category. That legislation passed the House on June 3 and is expected to pass the Senate during this session. Separately, FDA has also taken action against a number of marketers of androstenedione, asserting that the ingredient is a “new dietary ingredient” for which there has been no premarket notification filed as required by DSHEA and about which there are safety concerns. Between the Congressional and FDA action, andro should be off the table as an issue of concern by the time the next Congress convenes.

ADVERSE EVENT REPORTING

In the course of the long and drawn-out controversy over ephedra, several issues have arisen that relate to the availability and interpretation of adverse event reports. Adverse event reports come to FDA from consumers, from health professionals, and from industry. For some drugs and for vaccines and medical devices, it is mandatory for companies that receive reports of serious adverse events to forward those reports to FDA. For OTC drugs subject to FDA monographs and for conventional foods and dietary supplements, companies are not subject to a mandatory reporting requirement. After one ephedra company denied having any adverse event reports and then later submitted thousands of them, there has been pressure to change the law to require companies to report adverse events – or at least serious adverse events – to FDA. If there were to be such a requirement, it would be important for it to contain at least the protections for reporting companies and for individuals that are included in the regulations applicable to other FDA-regulated categories. The legislative proposals currently on the table tend to exceed requirements applicable to pharmaceuticals and other product categories. CRN and the other trade associations are seriously considering this issue and are supporting a seminar sponsored by the University of Minnesota School of Pharmacy later this month to further explore ways of improving adverse event reporting for dietary supplements.

Another issue of importance is how adverse event reports can and should be used. FDA recognizes that the primary function of adverse event reports is to send up a signal of a potential problem that needs to be addressed. In the evaluation of adverse event reports for drugs, devices, and vaccines, it is well recognized that it is difficult and

sometimes impossible to determine whether there is a true relationship between the event reported and the product believed to be associated with it. There are well-established criteria for probing the likelihood of a true association, and it is recognized that in most cases clinical data or additional research will be needed to determine whether a given product may result in a given adverse effect. These same factors apply to the evaluation of adverse events relating to dietary supplements, and any legislation contemplated in this area must recognize these complications or at least not run roughshod over them. Some of the legislation on the table appears to assume that every adverse event is meaningful and is a true indictment of the product said to be associated with it, and this is simply not the case.

MOUNTAINS AND MOLEHILLS

The dietary supplement industry provides safe and beneficial products valued by over 150 million Americans as integral components of a healthy lifestyle. Those consumers tend to be somewhat better educated than the average consumer. Their ranks include dietitians, pharmacists, and physicians, as well as lawyers, waitresses, truck drivers, and even U.S. Senators.

The overwhelming majority of dietary supplement products are manufactured by responsible companies operating under stringent Good Manufacturing Practices and providing science-based formulations with substantiated claims. CRN considers these products and these companies to reflect the true nature of the dietary supplement industry. This true picture can be obscured when critics focus narrowly on a handful of fringe products and attempt to portray these as representative of the industry as a whole.

We are supporting FDA's efforts to deal with these fringe products, and we believe those efforts are proving effective. However, molehills are being made into mountains, and the smoke from the barrage of firepower being aimed at the fringes is obscuring and overwhelming any reasonable perception of the category as a whole. The broadside by *Consumer Reports* is an example of this lack of perspective, and CRN has described it as an effort to create a hurricane from a drop in the bucket. (See attachment.)

There are those who believe dietary supplements should be regulated like drugs. If this were the case, dietary supplements would also cost like drugs and perhaps be restricted in availability. Consumers have repeatedly spoken out in letters and calls and visits to their elected representatives, saying they want to be able to choose from a wide variety of dietary supplements for health promotion and disease prevention. CRN does not deny that some problems exist, and we have been and will continue to be working toward resolution of those problems. With any luck at all, most of those problems will be behind us when the new Congress convenes in January 2005, and we will be able to return to hearing rooms like this one to address positive questions such as the role of dietary supplements in improving the health of the population and ultimately in reducing health care costs associated with preventable conditions.