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FILE: ▪ Dietary Supplements
▪ Food & Drug Administration (FDA)
▪ Dietary Supplement Health & Education Act (DSHEA)

HC 110642-275

Date: February 28, 2005

RE: Should Dietary Supplements Be Further Regulated?

Hileman B. Reining in dietary supplements: food additives critics demand changes in the law governing supplements. *Government & Policy.* 2004;82(25):21–23.

On June 8, 2004, the United States Senate held a hearing on the Dietary Supplement Health & Education Act of 1994 (DSHEA). When it was enacted, DSHEA classified dietary supplements as foods, not food additives, which exempted them from having to prove their safety or efficacy. Had they been defined as food additives, they would have fallen under the mandate of the Federal Food, Drug and Cosmetic Act (FFDC), which requires that manufacturers of food additives, drugs, and medical devices prove their products are safe before they can be sold. Dietary supplements represent an $18 billion industry and more than 29,000 products.

At the hearing, the majority of people testifying advocated reform of DSHEA. Critics of DSHEA included Ronald M. Davis, an American Medical Association (AMA) board of trustees member; Bruce Silverglade, director of legal affairs for the Center for Science in the Public Interest; and Anthony L. Young, general counsel for the American Herbal Products Association (AHPA), a trade association. One criticism is that supplement manufacturers are not required to report adverse effects to the Food and Drug Administration (FDA), such as death and illnesses caused by their products. In contrast, manufacturers of drugs must report such events. Since the FDA has the authority to ban dangerous products, the authors note that gathering the number and type of adverse reactions for dietary supplements has been difficult, thus posing a dilemma.

Another criticism of the current law is that DSHEA does not require testing of products going to market to ensure that they actually contain the ingredients listed on the label. In one study of 24 ginseng products, one-third of the products contained no active ingredients (presumably ginsenosides) at all, according to the authors. Contamination with heavy metals or other ingredients not on the label is also a concern. DSHEA called for the establishment of new Good Manufacturing Practices (GMP) for the dietary supplement industry; however,

these guidelines were not proposed by the FDA until 2003. (Until these GMPs for dietary supplements are finalized by the FDA, manufacturers of supplements are required to meet the same GMPs as those used by processors of conventional food products.)

Robert E. Brackett, director of FDA's Center for Food Safety & Applied Nutrition, and Annette Dickinson, Ph.D., president of the Council for Responsible Nutrition, a dietary supplements trade association, defended the law as it currently stands. They testified that the law merely needs to be enforced, not changed.

Senate bill 722 was introduced in 2003 by Senator Durbin (D-Ill.), ranking minority member of the oversight subcommittee of the Committee on Governmental Affairs. This bill requires premarket approval for stimulants, "a class of supplements that presents some of the greatest problems" and mandatory reporting of dietary supplement adverse events to the FDA.

—John Neustadt, ND4

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