

House Government Reform Committee

hearing on

The Regulation of Dietary Supplements:
A Review of Consumer Safeguards

March 9, 2006

Statement for the Record
Submitted by the



American Society of
Health-System Pharmacists®

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The American Society of Health-System Pharmacists (ASHP) respectfully submits the following statement for the record of the House Government Reform Committee hearing entitled, “Regulation of Dietary Supplements: A Review of Consumer Safeguards.”

ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term-care facilities, and other components of health systems. For more than 60 years, ASHP has helped pharmacists and pharmacy technicians who practice in hospitals and health systems improve medication use and enhance patient outcomes.

According to a survey conducted by the Centers for Disease Control and Prevention, approximately 40 percent of the American public consumes dietary supplements.¹ ASHP believes widespread, indiscriminate use of dietary supplements presents substantial risks to public health. ASHP therefore encourages its members to integrate awareness of dietary supplement use into their everyday practice and to increase efforts to prevent interactions between dietary supplements and drugs. Current federal regulation of the manufacturing and labeling of dietary supplements, however, fails to address the substantial risks posed to public health, leaving both consumers and providers with limited reliable information to make informed decision about dietary supplement use.

In the attached “ASHP Statement on the Use of Dietary Supplements,” the Society lays out concerns regarding the current framework for regulating dietary supplements and makes recommendations to help consumers and providers make informed decisions.

ASHP recommends that Congress amend the Dietary Supplement Health Education Act of 1994 (DSHEA) to:

- Require that dietary supplements undergo FDA approval for evidence of safety and efficacy,
- Mandate FDA-approved dietary supplement labeling that describes safe use in a clear, standardized format, including the potential for interaction with medications and cautions for special populations,
- Require FDA to promulgate and enforce good manufacturing practices for dietary supplements,
- Require that dietary supplements meet FDA-established standards for identity, strength, purity, and quality, and
- Empower FDA to establish and maintain an adverse event-reporting system specifically for dietary supplements, and require dietary supplement manufacturers to report suspected adverse reactions to FDA.

The time for congressional action is now. This is true particularly in light of a recent ruling issued by the United States District Court for the District of Utah Central Division,

¹ National Health and Nutrition Examination Survey (6/2002), accessed at www.cdc.gov/nchs/data/nhanes/databriefs/dietary.pdf.

in which the court questions the FDA's authority to monitor and regulate dietary supplements. The court overturned the FDA's ban on dietary supplements containing ephedrine alkaloids of 10 mg or less per daily noting that the FDA failed to prove that the risk identified by the FDA are associated with the intake of low doses. The duty currently falls on the FDA to establish a significant risk of illness or injury by a preponderance of the evidence.

ASHP supports congressional efforts to close loopholes in the DSHEA to ensure that consumers and providers have the information necessary to assess the safety and effectiveness of dietary supplements. ASHP appreciates the opportunity to share our views with the committee and stands ready to work with you on this important legislation.