

GAO Investigation Concerning Herbal Dietary Supplements Fuels Legislative Debate: Does FDA Need More Authority to Protect Elderly Consumers?

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On May 26, 2010, the Special Committee on Aging of the U.S. Senate (the Committee) held a hearing entitled, "Dietary Supplements: What Seniors Need to Know," in response to a recent U.S. Government Accountability Office (GAO) investigation which found that sellers of certain retail dietary supplement products commonly used by the elderly relied on deceptive and unfounded disease-related claims to market their products, encouraging consumers to use such products to prevent or treat diabetes, cancer, heart disease, Alzheimer's disease, and other serious conditions. The GAO investigation also found that most of the herbal supplement products tested were contaminated with heavy metals such as lead, or pesticide residues. Some of the products tested contained residues of pesticides that are banned in the United States. [For more information on the GAO investigation, see below].

The Adequacy of FDA's Existing Legal Authority and Prospects for Reform

In response to the GAO findings, Senator Herb Kohl's opening statement stressed that it is "obvious" that "more must be done" to protect consumers of dietary supplement products, urging that the Senate move forward to ensure that "meaningful provisions" addressing dietary supplements be included in the pending FDA Food Safety and Modernization Act (S. 510), which would expand FDA food safety regulatory authority under the Federal Food, Drug, and Cosmetic Act (FDCA). Prior to floor consideration, the Senate bill is expected to be modified to include provisions requiring dietary supplement manufacturers to register their companies and products with FDA annually and, additionally, to provide the Agency with the authority to recall supplements suspected of being dangerous. Senator Kohl has advocated provisions that would:

- Require dietary supplement product labels to include warnings about potential side effects, adverse interactions with prescription drugs, and other health hazards;
- Increase FDA oversight over dietary supplement products to minimize the risk from dangerous contaminants; and
- Ensure that as FDA's authority expands, FDA resources will be adjusted appropriately.

Senate consideration of the FDA Food Safety and Modernization Act could take place as early as this month. Similar legislation was passed by the House in July 2009 (H.R. 2749, the Food Safety Enhancement Act).

Of note, Senators McCain (R-AZ) and Dorgan (D-ND) introduced S. 3002, the Dietary Supplement Safety Act of 2010, in February of this year. Their stand alone bill would amend the FDCA to "more effectively regulate dietary supplements that may pose safety risks unknown to consumers." At this time, while related provisions are likely to be added to the Senate's food safety legislation, the comprehensive measure introduced by Sens. McCain and Dorgan is not expected to be incorporated.

Principal Deputy FDA Commissioner, Dr. Joshua Sharfstein's hearing testimony highlighted FDA priorities and key challenges presented by herbal dietary supplement products, including:

- Products that are marketed as "dietary supplements" which contain the same active ingredients found in FDA-approved drug products (e.g., sexual enhancement and weight loss supplements);
- Dietary supplement products promoted with unsubstantiated and illegal disease-related claims which "may encourage consumers to self-treat for a serious disease without the benefit of a medical diagnosis or treatment" (e.g., cancer, asthma, arthritis, hypertension, H1N1 flu); and
- Unsafe dietary supplement products containing a combination of ingredients ("it is challenging to identify causal connections between specific ingredients and adverse effects").

Dr. Sharfstein's testimony outlined FDA's legal authority to regulate dietary supplement products, highlighting key limitations:

- "FDA does not approve dietary supplements before they reach the consumer;"
- With the exception of "new dietary ingredients," "a firm does not have to provide FDA with evidence on safety before it markets its products;"
- "Manufacturers register their facilities but do not register their products with FDA;" and
- "There is no authoritative list of ingredients that were marketed prior to 1994, which creates a significant challenge to FDA" in enforcing the premarket notification requirements that apply only to new dietary ingredients."

The GAO Investigation

In response to the Committee's request, GAO conducted an investigation to determine (1) whether sellers of herbal dietary supplements are relying on deceptive or questionable claims to market their products, and (2) whether certain herbal supplements in the marketplace are contaminated with harmful substances. The GAO investigation focused on 22 retailers of herbal dietary supplements. GAO investigators posed as elderly consumers and asked a series of questions of the sales staff relating to the health risks and benefits associated with dietary supplement products. GAO also had an accredited laboratory test 40 different herbal dietary supplement products for contamination by heavy metals (lead, arsenic, mercury, cadmium) and certain pesticides (organochlorine and organophosphorous), targeting the herbal products that are most commonly consumed by the elderly: chamomile, Echinacea, garlic, ginkgo biloba, ginseng, peppermint, saw palmetto, and St. John's wort.

Key findings of the GAO investigation were reported in testimony presented to the Committee, including the following:

- Sellers made unfounded representations suggesting that consuming herbal dietary supplement products would prevent, treat, and/or mitigate serious disease conditions, including cardiovascular disease, cancer and tumors, obesity, diabetes (reduce glycemia), Alzheimer's disease and dementia.
- Sellers made unfounded representations suggesting that elderly consumers could rely on herbal dietary supplements to treat serious medical conditions in lieu of prescription medications, putting consumer health at risk.
- Sellers failed to encourage consumers to consult their health care provider before taking herbal dietary supplement products and failed to disclose conditions under which consumption of the dietary supplement would be medically contraindicated or would require medical monitoring, based on NIH guidance. Examples:
 - Garlic supplements can have adverse effects for consumers who are taking certain drugs for the treatment of cancer or diabetes, and is not recommended for the treatment of hypertension.
 - Ginseng supplements can have adverse effects for consumers who are taking drugs for the treatment of breast and uterine cancer, and is not recommended for the treatment of diabetes.
 - Gingko biloba supplements can have adverse effects for consumers who are taking aspirin regularly.

The GAO testimony also reported that chemical contaminants were found in 37 of the 40 herbal dietary supplement products that were tested, but none of the contaminants were present in amounts that were sufficient to present a risk of acute toxicity to consumers. Sixteen of the 40 supplements tested contained violative pesticide residues, and 4 samples contained residues of pesticides that are prohibited in the United States.

GAO has provided FDA and FTC with information gathered during its investigation, including the names of companies engaged in deceptive or questionable marketing practices and/or selling contaminated products.

Kelley Drye & Warren LLP

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