

**Congress of the United States**  
Washington, DC 20510

November 8, 2011

Mr. Gene L. Dodaro  
Comptroller General of the United States  
441 G Street, N.W.  
Washington, D.C. 20548

Dear Mr. Dodaro:

We write to ask the Government Accountability Office (GAO) to examine the Food and Drug Administration's adverse event reporting system, actions to address concerns about the safety of dietary supplements, and efforts to ensure consumers have useful information about the safety and efficacy of supplements.

As GAO reported in 2009, dietary supplements and foods containing added dietary ingredients, such as vitamins and herbs, constitute growing, multibillion dollar industries. Sales of dietary supplements alone reached approximately \$23.7 billion in 2007, the most recent year for which data are available. In addition, data from the 2007 National Health Interview Survey indicate that over half of all U.S. adults consume dietary supplements.<sup>1</sup> The Food and Drug Administration (FDA) regulates dietary supplements under provisions of the Federal Food, Drug, and Cosmetic Act.

Under the Dietary Supplement and Nonprescription Drug Consumer Protection Act, signed into law on December 22, 2006, manufacturers, packers, and distributors of dietary supplements in the United States are required to report information about serious adverse events associated with the use of dietary supplements to FDA. The effective date for complying with this requirement was December 22, 2007.

To facilitate adverse event reporting (AER) for any FDA-regulated products, FDA developed an interactive Web-based portal, called MedWatchPlus, which was intended to simplify the reporting process and reduce the time and cost associated with reviewing paper reports. For example, according to FDA documents, MedWatchPlus would simplify the reporting process by providing a single Internet portal for consumers, health care providers, and industry to report an adverse event. To date, however, it is unclear how the AER system is working in practice. Therefore, we ask GAO to address the following questions:

- (1) How many adverse event reports have been filed since 2007, the year AER requirements went into effect?
- (2) What kinds of supplements are most commonly implicated in AERs?
- (3) What kinds of adverse events have typically been reported?
- (4) What proportion of AERs are submitted by manufacturers, health providers, and consumers?
- (5) What steps is FDA taking to ensure that supplement manufacturers are reporting adverse events, as required by law?
- (6) How is FDA utilizing the AER system to inform its efforts to protect consumers?

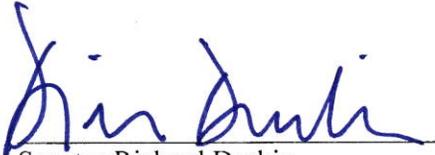
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<sup>1</sup> GAO, *Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding*, GAO-09-250 (Washington, D.C.: Jan. 29, 2009).

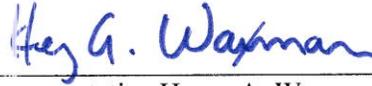
(7) To what extent has FDA implemented the recommendations GAO made in its 2009 report on dietary supplements?

Thank you for your attention to this important issue. Please contact Binta Beard of Mr. Durbin's office or Stacia Cardille of Mr. Waxman's staff to discuss this request and associated reporting time frames.

Sincerely,



Senator Richard Durbin  
Assistant Majority Leader  
United States Senate



Representative Henry A. Waxman  
Ranking Member  
Committee on Energy and Commerce  
United States House of Representatives