GAO Calls for More Regulation of Supplements

BY MICHELE G. SULLIVAN

The days when the dietary supplements industry is allowed to regulate itself may be numbered following release of a federal report addressing growing concerns about the dietary supplement industry.

The report by the Government Accountability Office calls on the Food and Drug Administration to expand adverse event reporting and increase its efforts to educate the public about the safety, efficacy, and labeling of these products.

According to the 77-page report, the FDA should be tracking all levels of adverse events related to the use of dietary supplements and herbs, not just severe events. And, the report noted, despite the 2007 requirement for improved manufacturing practices, the FDA still lacks even the most basic ability to track the quality of dietary supplements.

Companies that manufacture the products are not required to identify themselves as such or to provide the FDA with information about the products, including the product name and ingredients, the report said. And if a product is found to be dangerous, the agency can only ask for a voluntary recall, as it did in December when Star Caps, a popular weight-loss supplement, was found to contain prescription-strength levels of the diuretic bumetanide.

The FDA lost its authority to regulate the ingredients of dietary supplements prior to marketing with the enactment of the Dietary Supplement Health and Education Act of 1994 (DSHEA). Before then, they were regulated under the 1958 Food Additive Amendments to the Federal Food, Drug, and Cosmetic Act.

The issue of quality control has bothered Dr. Roy Altman for years. Supplements and herbal preparations designed to promote joint health and relieve pain are some of the most popular products on the market, grabbing almost as big a market share as weight-loss products, he said in an interview. "We are looking at probably $40-$60 billion spent on over-the-counter arthritis supplements each year," he said, but noted that "this is only a fraction of what is spent on prescribed arthritis medications."

Some of these products probably do have a beneficial effect in patients with rheumatic disorders, said Dr. Altman, professor of rheumatology at the University of California, Los Angeles. The problem is identifying which products actually contain what the label promises, and nothing else. "We, and a group of colleagues from Canada, once tested 10 different glucosamine products sold in the U.S. Four of them didn't even have glucosamine in them, and of the remaining six, four had much less than was stated on the product label."

One of the paper's key findings is that adverse events are probably significantly underreported, said Lisa Shames, the GAO's director of Food Safety and Agriculture Issues. In December 2007, the FDA began requiring manufacturers of dietary supplements and herbal preparations to report all serious adverse events related to the use of their products. "Since then, FDA has had a threefold increase in the number of events reported, but the big question is whether this is all the events that are happening," Ms. Shames said. From January through October 2008, the FDA received 948 reports of adverse events, compared with 298 over the same time frame in 2007. "FDA recently estimated that the true number of adverse events could be well over 50,000 each year. We recommended that the FDA require reporting of all adverse events, regardless of their severity."

'There is no way of really knowing for certain what you're getting' when you buy a dietary supplement.

DR. ALTMAN

The agency should also increase its efforts to educate the public about the safety of supplements, the report concluded. "People think all these products are safe and approved by the FDA, and of course, this isn't the case," Ms. Shames said.

Dr. Altman noted that the medical literature contains virtually no data on which brand of supplements or herbal preparations most closely resemble their labeling. "You might think you are better off buying something that was made in the U.S., but in reality a lot of those are manufactured in China and then repackaged in the U.S.," Dr. Altman said.

The unreliability of labeling "does present a real dilemma, because even if it's a safe product, like glucosamine, and you'd like to use it, there is no way of really knowing for certain what you're getting."

Dr. David Riley, founder of the Integrative Medicine Institute in Santa Fe, N.M., said that "most of the products produced in the U.S. and Europe meet more stringent manufacturing requirements than those produced in China and India."

Products imported from those countries have a history of poor quality. In fact, a recent study rather spectacularly showcased the problem, Dr. Riley said. Researchers obtained 190 Ayurvedic medicines from Internet sources and determined their components by x-ray fluorescence spectroscopy. They found that 20% contained some level of toxic metal (lead, mercury, or arsenic). U.S.-manufactured products were just as likely to be contaminated as were those made in India (22% vs. 19%).

But alternative medicine, like allopathic medicine, is based on a balance of risk and benefit, Dr. Riley pointed out. Still, herbal preparations are generally more benign than prescription medications. "I think it's important that people don't assume that 'natural' products are 100% safe, but the risks are still very low," he said. ■