

# Tighter Regulation of Supplements Is Urged

BY MICHELE G. SULLIVAN

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

The report, issued in March 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,



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DR. ALTMAN

and labeling of these products. The GAO investigation into supplement safety was made at the request of Congress.

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 ([www.gao.gov/new.items/d09250.pdf](http://www.gao.gov/new.items/d09250.pdf)).

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 dan-

gerous, the agency is hamstrung—it 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 before marketing with the enactment of the Dietary Supplement Health and Education Act of 1994 (DSHEA) ([www.cfsan.fda.gov/~dms/diet-sup.html](http://www.cfsan.fda.gov/~dms/diet-sup.html)). Before passage of the DSHEA, which went a long way toward deregulating the dietary supplement industry, the ingredients of dietary supplements were regulated under the 1958 Food Additive Amendments to the Federal Food, Drug, and Cosmetic Act.

Dietary supplements fall within the definition of complementary and alternative medicine (CAM). An earlier federal report issued by the Centers for Disease Control and Prevention found that use of CAM is widespread. For example, when patients with arthritis become frustrated by lack of pain relief, they often turn to dietary supplements.

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."

Similar quality control problems led Congress to request the investigation about 18 months ago, said Lisa Shames, the GAO's director of Food Safety and Agriculture Issues. "There has been a lot of congressional interest into how FDA was implementing the requirements [for oversight of dietary supplements and herbal products], especially the requirement for reporting adverse events," she said in an interview.

One of the paper's key findings is that adverse events are probably significantly underreported, she said. 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



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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."

The report also called on the FDA to require more information from manufacturers about the ingredients in their products. "There is a real lack of information that FDA needs," Ms. Shames said. "Herbal products are not registered by the companies that produce them, and companies are not required to tell FDA what product they sell."

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.

The report didn't even touch on manufacturing issues, which are controlled by a set of laws that until recently left manufacturing oversight to the companies, with little government regulation. In 2007, the FDA

finalized its Good Manufacturing Practice regulations, which will require quality control measures for all domestic manufacturers and foreign manufacturers that distribute in the United States. But the law is being phased in by company size, with the smallest companies having until June 2010 to come into full compliance.

Dr. Altman noted that the medical literature contains virtually no data on which brand of supplements or herbal preparations most closely resemble their labeling. Nor is country of manufacture a good guideline, Dr. Altman said.

The unreliability of labeling puts both physicians and patients in a bind, he said. "It 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. I try and steer my patients toward brands I have personally investigated and feel comfortable with, but there are no databases that contain this information, so people can't make informed choices." ■

## FDA Approval Does Not Bar Suits, Supreme Court Rules

BY ALICIA AULT

In an eagerly anticipated opinion, the U.S. Supreme Court has upheld a lower court ruling that Food and Drug Administration approval does not give pharmaceutical companies immunity from product liability lawsuits.

The justices voted 6-3 to affirm the judgment of the Vermont Supreme Court that federal law did not preempt Diana Levine's claim of inadequate warning on the label of promethazine (Phenergan). Ms. Levine received the drug by intravenous push and subsequently lost her arm. She was awarded \$6.7 million by a Vermont jury.

A majority of justices rejected the ar-

gument by Wyeth Pharmaceuticals Inc., maker of Phenergan, that it was impossible for the company to simultaneously comply with both federal and state laws and regulations.

Wyeth could have unilaterally strengthened the label at any time without input or clearance from the FDA, wrote the justices, concurring with the lower court opinion. And, the company's argument that following the duty to warn under state law would have interfered with the FDA's power to preempt state law was "meritless," according to the majority opinion.

Justice Clarence Thomas voted with the majority, agreeing that Wyeth could have changed its label and complied with

both state and federal laws. But he said that he did not agree with the majority's more far-reaching conclusions about preemption, specifically a tendency to override state laws when they were perceived to be an impediment to enforcing federal statutes.

Justice Samuel Alito and Justice Antonin Scalia, joined by Chief Justice John Roberts, dissented, writing in their opinion that "this case illustrates that tragic facts make bad law. The Court holds that a state tort jury, rather than the Food and Drug Administration, is ultimately responsible for regulating warning labels for prescription drugs." That premise is not consistent with previous rulings, they wrote.

Indeed, just last year the U.S. Supreme Court ruled in *Riegel v. Medtronic Inc.*, that FDA approval conferred special protection against product liability suits involving medical devices.

The Pharmaceutical Research and Manufacturers of America said that it was still reviewing the opinions in *Wyeth v. Levine*.

"We continue to believe that the expert scientists and medical professionals at the FDA are in the best position to evaluate the voluminous information about a medicine's benefits and risks and to determine which safety information to include in the drug label," PhRMA Senior Vice President Ken Johnson said in a statement. ■