Play It Safe When Choosing Vitamins and Supplements

Millions of consumers believe taking dietary supplements each day helps them to feel their best and stay healthy. Although most are safe, some groups are calling for tighter government regulations to ensure these vitamins and supplements undergo rigorous quality assurance testing before they’re placed on the market.

David O’Dell, graduate Nursing program director at South University — West Palm Beach, says that the U.S. Food and Drug Administration (FDA) does not evaluate the contents of vitamins and supplements, but it does regulate the quality of the products.

“For example, if a batch of vitamins was contaminated, the FDA would step in and demand that they be removed from shelves and work with the manufacturing company to remedy the problem,” O’Dell says. “They do respond to any major adverse reaction.”

O’Dell says that the FDA does not regulate vitamins and supplements in the same manner seen on prescriptions and over-the-counter medications.

Duffy MacKay, N.D., vice president of Scientific & Regulatory Affairs, at the Council for Responsible Nutrition (CRN), says that dietary supplements are regulated as a category of food by the FDA, under the Dietary Supplement Health & Education Act (DSHEA) of 1994.

“The Federal Trade Commission (FTC) also regulates supplements, both for the marketing and advertising of these products,” MacKay says.

Are Government Regulations Strict Enough?

O’Dell says the industry that produces vitamins and supplements is self-regulated by the Good Manufacturing Practices (GMP) and the U.S. Pharmacopoeia (USP).

“These are quality assurance organizations,” O’Dell says. “All manufacturing companies that produce vitamins and supplements are responsible for product testing and should be reviewed by independent third-party companies to verify quality.”

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O’Dell says that groups interested in the quality of vitamins and supplements have pushed to have the FDA take over the quality control of vitamins and supplements, but these efforts have been met with strong resistance.

“Some say that the FDA would be good for the general health of consumers,” O’Dell says. “Others point out that the FDA has made errors in evaluating and releasing prescription medications that ended up being very harmful to some consumers. The debate continues.”

Some experts think it is highly unlikely that the FDA will take control of the regulation of vitamins and supplements.

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“It's unlikely that Congress will tighten the regulations very much because the supplement industry has powerful allies in Congress and millions of customers who will lobby against any more restrictions,” says David Schardt, senior nutritionist, at the Center for Science in the Public Interest.

Analyzing the Safety of Vitamins and Supplements

MacKay believes the current regulation process is safe for consumers.

“Dietary supplements are properly regulated by both the FDA and the FTC, and in such a way that consumer access to healthful products is balanced with minimizing safety risks,” MacKay says. “The overwhelming majority of supplement products on the market are both safe and beneficial, and consumers can
have confidence that, if purchasing a reputable brand, they are getting a high quality supplement product."

The Government Accountability Office (GAO), disagrees that vitamins and supplements are properly regulated.

“In our 2009 report, we found that consumers are vulnerable to risks posed by potentially unsafe products,” says Lisa Shame, director of Natural Resources and Environment at GAO.

“Although FDA has used varied approaches, such as analyzing adverse events and conducting inspections, to identify safety concerns and has taken some actions, such as detaining certain potentially unsafe imported products, in response to these concerns, several factors limit FDA’s ability to further identify and act on safety concerns,” Shame says.

Schardt also believes that although most supplements are safe, they should face stronger regulations.

“While some supplements may be important for some people — calcium, vitamin D, folic acid, and vitamin B-12 for example, millions of consumers are wasting their money on other unproven supplements,” Schardt says.

Making Dietary Supplements Safer for Consumers

MacKay says the CRN urges the FDA to take swift action against companies illegally selling products falsely claiming to be dietary supplements.

“FDA has the authority under the law to take strong action against any companies not following the law and our organization repeatedly urges FDA to use that enforcement authority,” MacKay says. “For example, last December the dietary supplement industry joined with FDA to warn consumers about products that contain pharmaceutical ingredients and are illegally being sold as dietary supplements.”

In its 2009 report, Shame says GAO made a few recommendations to enhance the FDA’s oversight of dietary supplements and foods with added dietary ingredients. These include requesting more information on the companies and products it is required to regulate, dedicating more resources to dietary supplement oversight activities, and increasing its ability to efficiently and effectively remove a product from the market.

MacKay says there are a number of things consumers can do to ensure they are purchasing a high quality supplement product.

“Consumers should also manage their expectations for what a supplement can and cannot do — supplements are meant to supplement the diet, and be used in combination with other healthy habits, such as getting a healthy diet and plenty of exercise,” MacKay says. “Don’t seek out a supplement product advertising dramatic, instant, or drug-like effects — and question supplements being advertised as such.”

MacKay suggests that consumers read the CRN fact sheet, “One Dozen Tips for Consumers,” before purchasing a supplement.

O’Dell says that doing research on supplements before purchasing them can teach consumers valuable information, such as if they will react badly with other foods, products, or prescribed medications.

“Everyone should discuss all vitamins and supplements with their health care provider or pharmacist to assure that no adverse reactions occur as a result of taking what could be considered an innocent pill,” O’Dell says.

Schardt says that consumers should only purchase supplements from reputable companies.

“Buy from major companies or retailers they trust, like Centrum or Target or many others like them,” Schardt says. “These companies are responsible and have too much to lose by selling unsafe products. Consumers can also subscribe to ConsumerLab.com, a website that analyzes supplements for quality.”