

IN EVERY ISSUE

FDA Sets Rules for Dietary Supplements

BY KATY HUMAN

New regulations address what's in a supplement but not if it's safe or effective.

Cancer patients who take vitamins and other supplements to boost their nutrition status or fight nausea heard good news this summer: The Food and Drug Administration issued long-sought rules to make sure such substances are manufactured safely and contain what they promise.

Bottles of ginkgo biloba, beta-carotene, and vitamin B will soon sport labels that indicate exactly what is inside, including purity and strength, says FDA spokeswoman Kimberly Rawlings. Critics of the new rules, however, say they don't go far enough to protect people, including cancer patients, from adverse reactions of supplements with other drugs and treatments.

Americans spent almost \$22 billion on supplements last year, according to a *Nutrition Business Journal* report. Before August 24, 2007, the supplement industry was "regulated" but essentially protected under the Dietary Supplement Health and Education Act of 1994, which left the burden of proof with the FDA. Manufacturers weren't—and still aren't—required to demonstrate a product's safety and efficacy before it hits the market, which are strict requirements for conventional drugs. The FDA could, however, take action against companies when consumer complaints expose public health risks.

Now, supplement makers must test all their products' ingredients for purity, and have records of that testing available for FDA inspection for at least one year. Labels must indicate precise quantities and supplement makers must keep detailed records of the manufacturing process to prevent errors. The FDA also now requires that manufacturers report any adverse effects of their pills and liquids, Rawlings says, which should help her agency catch problem batches early.

The new rules will be phased in over the next three years and are likely to make supplements safer for many people, says Simon Yeung, a pharmacist and herbalist at Memorial Sloan-Kettering Cancer Center in New York. "I think most physicians are pleased with the new regulations," Yeung says. "But they still do not demand proof of efficacy, and that's a problem."

In 2002, Yeung and colleagues concerned about inappropriate supplement use created "About Herbs, Botanicals and Other Products," a website (www.mskcc.org/mskcc/html/11570.cfm) to inform consumers about the benefits and risks of most supplements.

"We know many cancer patients race to supplements after diagnosis, searching

for a cure, or to reverse the effects of chemotherapy or radiotherapy,” Yeung says. “But if you’re a cancer patient, you’re probably using multiple other drugs, so the potential for interaction is high, and some might be dangerous.”

The data from published research that Yeung and colleagues have amassed give pause. Ginkgo biloba extract, for example, can cause spontaneous bleeding by thinning the blood and should not be used before surgery. Antioxidants such as vitamin C may protect cancer cells as well as healthy cells from chemotherapy drugs, making chemotherapy less effective. And in one study, men taking heavy doses of multivitamins with zinc, selenium, or beta-carotene had an elevated risk for advanced and more aggressive prostate cancer. Controversy surrounds the use of vitamins and antioxidants, with mixed results from laboratory studies and a lack of controlled clinical trial data.

“At Memorial Sloan-Kettering, we usually advise against a patient using supplements. But we know some still do,” so it’s important for patients to tell their doctors what they’re taking, Yeung says.

The American Cancer Society has not taken a position on the new FDA supplement rules, but ACS nutrition director Colleen Doyle cautions cancer patients undergoing treatment to use vitamins and other supplements carefully. “More research is needed,” Doyle says. “But in the meantime, cancer survivors undergoing treatment should avoid exceeding 100 percent of the Recommended Daily Value for these nutrients during the treatment phase.”