

PERSONAL HEALTH

Potential for Harm in Dietary Supplements

By JANE E. BRODY

A form of substance abuse rampant in this country is rarely discussed publicly or privately. It involves abusing legally sold dietary supplements — vitamins, minerals, herbals and homeopathic remedies — all of which can be sold over the counter without prior approval for safety and effectiveness.

Although there was much publicity about the hazards of ephedra, once widely used as a weight-loss aid until it was found to be deadly, many other heralded dietary supplements have the potential for harm, especially when taken in large doses or in various combinations with one another or with medically prescribed prescription drugs.

Still other problems can arise when these poorly regulated supplements are taken by people with known or hidden health problems or when patients fail to report their use to health professionals who treat them.

For example, Dr. Richard A. Nathan, a dental surgeon in San Francisco, wrote in January about a patient who needed a tooth extracted and minor periodontal surgery. She told Dr. Nathan that she was taking two drugs, for cholesterol and blood pressure, neither of which he said would present a problem to safe surgery and normal healing.

Thus, Dr. Nathan was perplexed when the patient returned five days later unhealed, with an unattached flap of tissue, severe bleeding and an infection.

“Based on my 30 years of experience, it looked as though the patient was an out-of-control diabetic or had a severely compromised immune system,” he told me. “Neither was the case. However, when I asked the patient again what medications she was taking, she admitted that she was on multiple — 18 to be exact — over-the-counter supplements, for a total of 43 pills and capsules a day.”

Six of these — green tea, grapeseed, ginkgo biloba turmeric, salmon oil and vitamin E, he said, “are known to increase bleeding due to inhibition of platelet aggregation,” the first step in forming a clot. Within a week after discontinuing all supplements, her mouth began to heal normally.

Problems Not Reliably Reported

While this case may represent an extreme, the problem is by no means an isolated one. No one knows how many such adverse effects befall supplement users, because there has been no reliable reporting system.

A new federal law requires supplement manufacturers to report serious adverse effects to the Food and Drug Administration, but it depends on consumers to call in reactions. Experts say most consumers are unlikely to relate health problems to a supplement they assume to be safe, and even if they do, they may be reluctant to report an adverse effect from a self-medicated substance.

Not so for Michael Alexander of San Francisco. In September, he wrote to Kaiser Permanente that a vitamin supplement he had regularly bought from the Kaiser pharmacy caused years of leg cramps, eventually diagnosed by a neurologist as vitamin B6-induced neuropathy. The supplement had 100 milligrams of B6, or 50 times the recommended daily amount. The ill effect developed even though Mr. Alexander cut each tablet in four parts and took “only” 25 milligrams daily.

According to a 2002 Harris poll, 70 percent of adults in the United States take vitamins, minerals, herbs or other supplements. Their use of supplements has been increasing, fed by the belief that they can make people feel better, give them greater energy, improve health and prevent and treat disease. Although some supplements are beneficial, others may or may not be. Others may be downright dangerous. Even so-called safe supplements can be hazardous in too large amounts or the wrong combinations.

Vitamins A, B6, B12, C, E and K; niacin; folic acid; calcium; magnesium; iron; and zinc can be hazardous when combined with various prescription drugs and over-the-counter remedies. Yet patients often fail to mention using such supplements to physicians.

“Consumers don’t realize that there’s a big difference between dietary supplements, homeopathic remedies and over-the-counter medications,” David Schardt, senior nutritionist for the Center for Science in the Public Interest, a watchdog group in Washington, said in an interview. “They’re all sold side by side in stores. Yet there’s a vast difference in the evidence for safety and effectiveness that manufacturers must have to sell them.”

Over-the-counter medications like ibuprofen, inhalers and reflux inhibitors have to be shown as safe and effective before the F.D.A. will let them be marketed. But thanks to the 1994 Dietary Supplement Health and Education Act, neither dietary supplements nor

homeopathic remedies are required to provide premarket evidence of safety and effectiveness. To remove such a product from the market, the F.D.A. has to prove that it is dangerous, a challenging task for the understaffed, budget-strapped agency.

Homeopathic Medical Claims

Homeopathic remedies slip under an even lower wire. While dietary supplements can make only structure and function claims, products labeled homeopathic — a designation decided by the industry, not the F.D.A. — can assert medical effects, Mr. Schardt explained. Thus, the homeopathic zinc supplement Cold-EEZE, claims to fight colds, but Cold-fX, sold as a zinc dietary supplement, cannot make such a claim.

Consumers are often swayed by reports of health benefits attributed to various supplements, and assume that they are risk free and can be safely taken in any amount. Although a small dose may be good, more is not necessarily better. In fact, it may be harmful. Megadoses of vitamins or minerals are no longer acting as nutrients but as drugs or, in some cases, as toxic agents.

For example, observational studies of people who eat foods rich in antioxidants like vitamins A and E and beta-carotene have suggested these substances improve health. But well-designed clinical trials found increased death rates among people who take them as supplements. And while low vitamin C doses can suppress harmful free radicals, very high doses promote their formation. The initial promise that vitamin E could protect against heart attacks and cancer failed to stand up to scientific scrutiny, which instead found that it increased the risk of heart failure.

Led by testimonials and articles in health food publications and on the Internet, consumers also tend to confuse structure and function claims with medical benefits. They are not the same. Just because beta-carotene in carrots aids normal vision does not mean it can correct nearsightedness. Or a substance for forming blood cells will not necessarily be useful to prevent or treat a disease of blood-forming tissue like leukemia.

A National Institutes of Health panel in May 2006 noted: “The F.D.A. has insufficient resources and legislative authority to require specific safety data from dietary supplement manufacturers or distributors before or after their products are made available to the public. The constraints imposed on F.D.A. make it difficult for the health of the American public to be adequately protected.” Caveat emptor.