



Dangerous supplements: Still at large

If you can buy it at a clean, well-lighted store, if it's "all natural," it's not going to do you serious harm, right? That's what many Americans assume about dietary supplements. But while most supplements are probably fairly benign, *Consumer Reports* has identified a dozen that according to government warnings, adverse-event reports, and top experts are too dangerous to be on the market. Yet they are. We easily purchased all 12 in February 2004 in a few days of shopping online and in retail stores.

These unsafe supplements include Aristolochia, an herb conclusively linked to kidney failure and cancer in China, Europe, Japan, and the U.S.; yohimbe, a sexual stimulant linked to heart and respiratory problems; bitter orange, whose ingredients have effects similar to those of the banned weight-loss stimulant ephedra; and chaparral, comfrey, germander, and kava, all known or likely causes of liver failure. (For a complete list of the "dirty dozen," see [12 supplements to avoid](#).)

U.S. consumers shelled out some \$76 million in 2002 for just three of these supplements: androstenedione, kava, and yohimbe, the only ones for which sales figures were available, according to the Nutrition Business Journal, which tracks the supplement industry.

The potentially dangerous effects of most of these products have been known for more than a decade, and at least five of them are banned in Asia, Europe, or Canada. Yet until very recently, the U.S. Food and Drug Administration had not managed to remove a single dietary supplement from the market for safety reasons.

After seven years of trying, the agency announced a ban on the weight-loss aid ephedra in December 2003. And in March 2004 it warned 23 companies to stop marketing the body-building supplement androstenedione (andro).

Despite these actions against high-profile supplements, whose dangers were so well known that even industry trade groups had stopped defending them, the agency continues to be hamstrung by the 1994 Dietary Supplement Health and Education Act (DSHEA, pronounced *de-shay*). While drug manufacturers are required to prove that their products are safe before being marketed, DSHEA makes the FDA prove that supplements on the market are *unsafe* and denies the agency all but the sketchiest information about the safety record of most of them.

"The standards for demonstrating a supplement is hazardous are so high that it can take the FDA years to build a case," said Bruce Silverglade, legal director of the Center for Science in the Public Interest, a Washington, D.C., consumer-advocacy group.

At the same time, the FDA's supplement division is understaffed and underfunded, with about 60 people and a budget of only \$10 million to police a \$19.4 billion-a-year industry. To regulate drugs, annual sales of which are 12 times the amount of supplement sales, the FDA has almost 43 times as much money and almost 48 times as many people.

"The law has never been fully funded," said William Hubbard, FDA associate commissioner for policy and planning. "There's never been the resources to do all the things the law would command us to do."

The agency has learned that it must tread carefully when regulating supplements. The first time it tried to regulate the dangerous stimulant ephedra, in 1997, overwhelming opposition from Congress and industry forced it to back down.

As a result, the FDA is sometimes left practicing what Silverglade calls "regulation by press release"--issuing warnings about dangerous supplements and hoping that consumers and health practitioners read them.

There are signs of hope. The FDA has said that if the ban on ephedra holds up against likely legal challenges, it plans to go after other harmful supplements. Legislation has been introduced to strengthen the FDA's authority under DSHEA and give the agency more money to enforce the act.

But the supplement marketplace still holds hidden hazards for consumers, especially among products that aren't in the headlines.

CR Quick Take

A CR investigation found that many dangerous supplements can easily be purchased in stores and online. Many of these supplements have been banned in other countries. Why can't the U.S. Food and Drug Administration ban these products now?

We found that regulatory barriers created by Congress, supplement-industry pressure, and a lack of resources at the FDA have resulted in major risks for consumers.

- These widely available dietary supplements (see [12 supplements to avoid](#)) may cause cancer, severe kidney or liver damage, heart problems, or even death. They should be avoided by consumers.
- These supplements are sold under a profusion of names, making it difficult for consumers to know what they're purchasing.
- Most also appear in combination products marketed for a broad array of uses, such as aphrodisiacs, athletic-performance boosters, and treatments for anxiety, arthritis, menstrual problems, ulcers, and weight loss.

"Consumers are provided with more information about the composition and nutritional value of a loaf of bread than about the ingredients and potential hazards of botanical medicines," said Arthur Grollman, M.D., professor of pharmacological sciences at the State University of New York, Stony Brook, and a critic of DSHEA.

A QUESTION OF SAFETY

Supplement-industry advocates say the ephedra ban demonstrates that DSHEA gives the FDA enough power to protect consumers from unsafe products. "I don't think there's anything wrong except that FDA has only recently begun vigorous and active enforcement of the law," said Annette Dickinson, Ph.D., president of the Council for Responsible Nutrition, a major trade association for the supplement industry.

But critics of DSHEA think the ban illustrates the extremes to which the FDA must go to outlaw a hazardous product.

When the agency initially tried to rein in ephedra use in 1997, after receiving hundreds of reports of adverse events, it sought not an outright ban but dosage restrictions and sterner warning labels. The industry mounted a furious counter-attack, including the creation of a public-relations group called the Ephedra Education Council and a scientific review from a private consulting firm, commissioned by Dickinson's trade group, that concluded ephedra was safe. After the U.S. General Accounting Office said the FDA "did not establish a causal link" between taking ephedra and deaths or injuries, the agency was forced to drop its proposal.

SUFFERED SEIZURE

Gretchen Fitzgerald, age 21, Fort Collins, Colo.

PROBLEM She took Xenadrine EFX "thermogenic" diet pills to boost her energy while studying for final exams, believing they were safe because they were labeled ephedra-free. After three weeks of taking the product she had a seizure. The neurologist consulted told her the bitter orange in the Xenadrine was the probable cause. Xenadrine's manufacturer did not return our phone calls. Since going off the Xenadrine, Fitzgerald has had no further problems.



The industry continued to vigorously market and defend ephedra. Metabolife International, a leading ephedra manufacturer, did not let the FDA know that it had received 14,684 complaints of adverse events associated with its ephedra product, Metabolife 356, in the previous five years, including 18 heart attacks, 26 strokes, 43 seizures, and 5 deaths. It took the pressure of congressional and Justice Department investigations to get the company to turn over the complaints in 2002. Then Steve Bechler, a pitcher for the Baltimore Orioles, died unexpectedly in 2003 while taking another ephedra supplement, Xenadrine RFA-1. With sales suffering from the bad publicity, manufacturers began to replace ephedra with other stimulants such as bitter orange, which mimics ephedra in chemical composition and function.

"All of a sudden Congress dropped objections to an ephedra ban and started demanding the FDA act," said Silverglade.

To amass the necessary scientific evidence that it hoped would satisfy the demanding standard set by DSHEA, the FDA took aggressive action: It commissioned an outside review from the RAND Corporation, analyzed adverse-event reports, and pored over every available shred of scientific evidence.

"We've gone the whole nine yards to collect and evaluate all the possible evidence," Mark McClellan, commissioner of the FDA, said in announcing the ban. "We will be doing our best to defend this in court, and if that's not sufficient, it may be time to re-examine the act."

DRUGS VS. SUPPLEMENTS

In an October 2002 nationwide Harris Poll of 1,010 adults, 59 percent of respondents said they believed that supplements must be approved by a government agency before they can be sold to the public. Sixty-eight percent said the government requires warning labels on supplements' potential side effects or dangers. Fifty-five percent said supplement manufacturers can't make safety claims without solid scientific support.

They were wrong. None of those protections exist for supplements--only for prescription and over-the-counter medicines. Here are the major differences in the safety regulations:

Testing for hazards. Before approval, drugs must be proved effective, with an acceptable safety profile, by means of lab research and rigorous human clinical trials involving a minimum of several thousand people, many millions of dollars, and several years.

In contrast, supplement manufacturers can introduce new products without any testing for safety and efficacy. The maker's only obligation is to send the FDA a copy of the language on the label (see [Supplement labels](#)).

"Products regulated by DSHEA were presumed to be safe because of their long history of use, often in other countries," said Jane E. Henney, M.D., commissioner of the FDA from 1998 to 2001. "As their use dramatically increased in this country after the passage of DSHEA, the presumption of safety may have been misplaced, particularly for products other than traditional vitamins and minerals. Some, like ephedra, act like drugs and thus have similar risks."

KIDNEYS FAILED

Beverly Hames, age 59, Beaverton, Ore.



PROBLEM Hames went to an acupuncturist in 1992 seeking a “safe, natural” treatment for an aching back. She got a selection of Chinese herbal products, at least five of which were later found to contain aristolochic acid. By mid-1994, she had symptoms of kidney failure, and in 1996 she underwent a kidney transplant. She must take anti-rejection drugs (below) for life. The herbs’ distributor said his Chinese suppliers had substituted *Aristolochia* for another herb without his knowledge.



The only exceptions to this “presumption of safety” are supplement ingredients that weren’t being sold in the U.S. when DSHEA took effect. Makers of such “new dietary ingredients” must show the FDA evidence of the products’ safety before marketing them. The FDA invoked that rarely used provision in its action against androstenedione. After years of allowing andro to be marketed without restriction, the agency declared that it was “not aware” that the supplement was used before DSHEA, so it couldn’t be sold without evidence of safety.

Disclosing the risks. Drug labels and package inserts must mention all possible adverse effects and interactions. But supplement makers don’t have to put safety warnings on the labels, even for products with known serious hazards.

We bought a product called Relaxit whose label had no warning about the kava it contained, even though the American Herbal Products Association, an industry trade group, recommends a detailed, though voluntary warning label about potential liver toxicity on all kava products.

Ensuring product quality. Drugs must conform to “good manufacturing practices” that guarantee that their contents are pure and in the quantities stated on the label. While DSHEA gave the FDA authority to impose similar standards on supplements, it took until 2003 for the agency to propose regulations--as yet not final--to implement that part of the law.

Contaminants, too, regularly turn up in supplements. In 1998 Richard Ko, Ph.D., of the California Department of Health Services reported that 32 percent of the Asian patent medicines he tested contained pharmaceuticals or heavy metals that weren’t on the label. In 2002, the FDA oversaw a voluntary manufacturer recall of a “prostate health” supplement called PC SPES that, according to tests by the California department, contained a powerful prescription blood thinner, warfarin.

Reporting the problems. By law, drug companies are required to tell the FDA about any reports of product-related adverse events that they receive from any source. Almost every year, drugs are removed from the market based on safety risks that first surfaced in those reports.

In contrast, supplement makers don’t have to report adverse events. Indeed, in the five years after DSHEA took effect, 1994 to 1999, fewer than 10 of the more than 2,500 reports that the FDA received came from manufacturers, according to a 2001 estimate from the inspector general of the U.S. Department of Health and Human Services. (Other sources of reports included consumers, health practitioners, and poison-control centers.) Overall, the FDA estimates that it learns of less than 1 percent of adverse events involving dietary supplements.

THE ‘NATURAL’ MYSTIQUE

Many makers market their supplements as “natural,” exploiting assumptions that such products can’t harm you. That’s a dangerous assumption, said Lois Swirsky Gold, Ph.D., director of the Carcinogenic Potency Project at the University of California, Berkeley, and an expert on chemical carcinogens. “Natural is hemlock, natural is arsenic, natural is poisonous mushrooms,” she said.

A cautionary example is aristolochic acid, which occurs naturally in species of *Aristolochia* vines that grow wild in many parts of the world. In addition to being a powerful kidney toxin, it is on the World Health Organization’s list of human carcinogens. “It’s one of the most potent chemicals of 1,400 in my Carcinogenic Potency Database,” Gold said. “People have taken high doses similar to the doses that animals are given in tests, and they both get tumors very quickly.”

KIDNEYS FAILED

Donna Andrade-Wheaton, age 40, Cranston, R.I.



PROBLEM

Andrade-Wheaton’s acupuncturist prescribed more than a half dozen Chinese herbal supplements to treat health conditions, including endometriosis. At least one of the products listed *Aristolochia* as an ingredient, even after the FDA issued a nationwide *Aristolochia* safety

The dangers of aristolochic acid have been known since at least 1993, when medical-journal articles began appearing about 105 patrons of a Belgian weight-loss clinic who had suffered kidney failure after consuming Chinese herbs adulterated with *Aristolochia*. At least 18 of the women also subsequently developed cancer near the kidney.

These findings prompted the FDA to issue a nationwide warning against *Aristolochia* in 2001 and to impose a ban on further imports of the herb. But in early 2004, more than two years after the import ban went into effect, *Consumer Reports* was able to purchase products online that were labeled as containing *Aristolochia*. In 2003, Gold identified more than 100 products for sale online with botanical ingredients listed by the FDA as known or suspected to contain aristolochic acid.

Donna Andrade-Wheaton, a former aerobics instructor in Rhode Island, learned those facts too late to save her kidneys. After taking Chinese herbs containing *Aristolochia* for more than two years, she suffered severe kidney damage; her kidney tissues were found to contain aristolochic acid. In late 2002, at age 39, she underwent a kidney

warning in 2001. She underwent a kidney transplant in September 2002 and must take anti-rejection drugs (below) for life.



transplant.

Andrade-Wheaton is suing both the acupuncturist who gave her the herbs and several companies that manufactured them. The acupuncturist declined to discuss the case on the record, and the manufacturer did not return our phone calls.

There's another widespread and false assumption about natural supplements: that they're always pure, unprocessed products of the earth. Because DSHEA permits the marketing of concentrates and extracts, supplement makers can and do manipulate ingredients to increase the concentrations of pharmacologically active compounds.

That's especially true of the many weight-loss supplements designed for "thermogenic" stimulant effects--boosting calorie expenditure by revving the metabolic rate.

On one Internet shopping tour, for instance, we bought a product called Thermorexin--"the Hottest new Thermogenic on the market!" Its label says it contains, among its 22 ingredients, 30 milligrams of theophylline derived from a black tea extract and the stimulant bitter orange. Sold as Theo-Dur and other brands, theophylline is a prescription drug and an effective asthma treatment, but most doctors seldom prescribe it because it can cause seizures and irregular heartbeats at relatively low doses.

Larry Berube, president of Anafit, Thermorexin's manufacturer, based in Orlando, Fla., described how the product's combination of ingredients was developed: "Once we find out that the FDA says it's OK, we put them together in the lab, run our tests, and do our trials, and if it comes up good, we capsule it, put it online and in the stores and sell it," he said.

Those tests involved asking fitness professionals to use the supplement, and measuring their heart rate and blood pressure, Berube said. The company doesn't use a control group, he said. Then "we go to the fitness discussion boards and let trainers and people know we have a new product and do they want to try it," he said. "And then they try it, and they report back." Berube said he has not heard of any bad reactions to Thermorexin.

The art and law of supplement labels



- “New 21st century ‘designer’ D-Bol (label above, top) is so potent it turns genetically average guys into supernatural studs no one messes with!”
- Xenadrine EFX (label above, left) “provides the most effective approach to losing weight ever developed!”
- “Thousands of testimonials” credit chaparral (label above, right) “for tumor remissions and complete cures. Other medical evidence indicates it is an anti-inflammatory and antimicrobial agent and a possible treatment for asthma.”

Does the government really allow supplement companies to make extravagant promises like those, which we found on Web sites promoting products we purchased? The answer is murky at best.

Under the 1994 Dietary Supplement Health and Education Act, manufacturers can’t claim that a product prevents or treats a disease or disorder. But they can say it affects the “structure and function” of the body--“supports healthy prostate function,” for example--or shows a “link” to a disease or disorder, and allow consumers to draw their own, often erroneous, conclusions. The FDA can require that a manufacturer change a label that it decides is making an unauthorized health claim.

DSHEA does say, confusingly, that supplement makers must be able to “substantiate” their claims. But it does not specify what that means, nor does it require that the evidence be shown to anybody, not even the FDA.

The Federal Trade Commission has the authority to punish companies whose ads are intentionally misleading. Unlike the FDA, it can force companies to give it documents substantiating suspect claims and order the products off the market if it decides that the substantiation isn’t sufficient. But it can’t move against a category of products, such as those containing ephedra, nor can it act against dangerous products that aren’t advertised to the public.

Since DSHEA’s passage, the FTC has brought more than 100 cases against supplement marketers for deceptive advertising. But “there are literally hundreds, perhaps thousands, of companies out there that probably deserve scrutiny,” said Richard Cleland, assistant director of the FTC’s division of advertising practices. “We don’t have the resources to look at every one.”

Twelve supplements you should avoid

The 12 supplement ingredients in this table have been linked to serious adverse events or, in the case of glandular supplements, to strong theoretical risks. They're all readily available on the Web, where our shoppers bought them both individually and in multi-ingredient "combination products." We think it's wise to avoid all of them. But the strength of that warning varies with the strength of the evidence and the size of the risk. So we've divided the dirty dozen into three categories: definitely hazardous, very likely hazardous, and likely hazardous.

Name (Also known as)	Dangers	Regulatory actions
DEFINITELY HAZARDOUS <i>Documented organ failure and known carcinogenic properties</i>		
Aristolochic acid (<i>Aristolochia</i> , birthwort, snakeweed, sangree root, sangrel, serpentaria, <i>asarum canadense</i> , wild ginger). Can be an ingredient in Chinese herbal products labeled fang ji, mu tong, ma dou ling, and mu xiang. Can be an unlabeled substitute for other herbs, including akebia, asarum, clematis, cocculus, stephania, and vladimiria species.	Potent human carcinogen; kidney failure, sometimes requiring transplant; deaths reported.	FDA warning to consumers and industry and import alert, in April 2001. Banned in 7 European countries and Egypt, Japan, and Venezuela.
VERY LIKELY HAZARDOUS <i>Banned in other countries, FDA warning, or adverse effects in studies</i>		
Comfrey (<i>Symphytum officinale</i> , ass ear, black root, blackwort, bruisewort, consolidae radix, consound, gum plant, healing herb, knitback, knitbone, salsify, slippery root, symphytum radix, wallwort)	Abnormal liver function or damage, often irreversible; deaths reported.	FDA advised industry to remove from market in July 2001.
Androstenedione (<i>4-androstene-3, 17-dione</i> , andro, androstene)	Increased cancer risk, decrease in HDL cholesterol.	FDA warned 23 companies to stop manufacturing, marketing, and distributing in March 2004. Banned by athletic associations.
Chaparral (<i>Larrea divaricata</i> , creosote bush, greasewood, hediondilla, jarilla, larreastat)	Abnormal liver function or damage, often irreversible; deaths reported.	FDA warning to consumers in December 1992.
Germander (<i>Teucrium chamaedrys</i> , wall germander, wild germander)	Abnormal liver function or damage, often irreversible; deaths reported.	Banned in France and Germany.
Kava (<i>Piper methysticum</i> , ava, awa, gea, gi, intoxicating pepper, kao, kavain, kawa-pfeffer, kew, long pepper, malohu, maluk, meruk, milik, rauschpfeffer, sakau, tonga, wurzelstock, yagona, yangona)	Abnormal liver function or damage, occasionally irreversible; deaths reported.	FDA warning to consumers in March 2002. Banned in Canada, Germany, Singapore, South Africa, and Switzerland.
LIKELY HAZARDOUS <i>Adverse-event reports or theoretical risks</i>		
Bitter orange (<i>Citrus aurantium</i> , green orange, kijitsu, neroli oil, Seville orange, shangzhou zhiqiao, sour orange, zhi oiao, zhi xhi)	High blood pressure; increased risk of heart arrhythmias, heart attack, stroke.	None

<p>Organ/glandular extracts(brain/adrenal/pituitary/placenta/other gland “substance” or “concentrate”)</p>	<p>Theoretical risk of mad cow disease, particularly from brain extracts.</p>	<p>FDA banned high-risk bovine materials from older cows in foods and supplements in January 2004. (High-risk parts from cows under 30 months still permitted.) Banned in France and Switzerland.</p>
<p>Lobelia (<i>Lobelia inflata</i>, asthma weed, bladderpod, emetic herb, gagroot, lobelie, indian tobacco, pukeweed, vomit wort, wild tobacco)</p>	<p>Breathing difficulty, rapid heartbeat, low blood pressure, diarrhea, dizziness, tremors; possible deaths reported.</p>	<p>Banned in Bangladesh and Italy.</p>
<p>Pennyroyal oil(<i>Hedeoma pulegioides</i>, lurk-in-the-ditch, mosquito plant, pilioleria, pudding grass, pulegium, run-by-the-ground, squaw balm, squawmint, stinking balm, tickweed)</p>	<p>Liver and kidney failure, nerve damage, convulsions, abdominal tenderness, burning of the throat; deaths reported.</p>	<p>None</p>
<p>Scullcap (<i>Scutellaria lateriflora</i>, blue pimpernel, helmet flower, hoodwort, mad weed, mad-dog herb, mad-dog weed, quaker bonnet, scutelluria, skullcap)</p>	<p>Abnormal liver function or damage.</p>	<p>None</p>
<p>Yohimbe (<i>Pausinystalia yohimbe</i>, johimbi, yohimbehe, yohimbine)</p>	<p>Change in blood pressure, heart arrhythmias, respiratory depression, heart attack; deaths reported.</p>	<p>None</p>

□ According to product labels.

Sources: Natural Medicines Comprehensive Database 2004 and Consumers Union's medical and research consultants.

What you can do

Sen. Richard Durbin, Democrat of Illinois, and Rep. Susan Davis, Democrat of California, have each introduced legislation that for the first time would require supplement manufacturers to disclose reports they receive of “serious” adverse events. Durbin’s bill also sets up a separate category for stimulants, which would have to receive FDA safety approval before being marketed, and reclassifies androstenedione and similar “steroid precursors” as controlled drugs. The Davis bill also strengthens the FDA’s powers to investigate emerging supplement safety problems. Davis’s bill exempts vitamins and minerals from its provisions. ([Consumers Union, publisher of *Consumer Reports*, supports both bills.](#))

Though the bills are still in committee, the supplement industry has mobilized in opposition. On its Web site and in flyers handed out at supplement stores, the National Nutritional Foods Association, a supplement retailers’ trade group, says the legislation “would significantly undermine many of the freedoms that American consumers of dietary supplements like you hold dear.”

The industry is supporting a more limited bill introduced by Sen. Orrin Hatch, Republican of Utah, and Sen. Tom Harkin, Democrat of Iowa, that would give the FDA an extra \$20 million this year, and more in subsequent years, to enforce DSHEA and would reclassify androstenedione and other steroid precursors as controlled drugs. Unlike the Durbin bill, however, this measure would exempt the steroid dehydroepiandrosterone, or DHEA, allowing it to continue to be marketed as an anti-aging product. Some \$47 million worth was sold in 2002, according to the Nutrition Business Journal.

Until the law is substantially changed and the FDA is adequately funded, you cannot rely on the federal government to ensure that dietary supplements are safe and effective. Here are some steps you can take to minimize your risk from any supplements you decide to take:

Stay away from the dirty dozen. All carry risks that in our view are unacceptable (see [12 supplements to avoid](#)). In combination products, you need to read the detailed ingredient list in the tiny print on the back. Who could otherwise guess, for instance, that Gaia Herbs’ PMS Day 14-28 capsules contain kava? (To the company’s credit, the label includes a warning about liver toxicity.)

Do not take daily doses of vitamins and minerals that exceed the safe upper limits. While vitamins and minerals are by far the safest and best-studied of supplements, it’s possible to overdose on some of them. For more information, see our October 2003 report on [fortified foods](#) (available to subscribers). Recommended allowances and safe upper limits can be found online at www.ific.org/publications/other/driupdateom.cfm.

Limit your intake of other supplements. Over the years, our medical and nutritional consultants have identified and tested a few products, other than standard multivitamins, with possible benefits and sufficiently low risks to recommend for general use: saw palmetto for benign enlarged prostate in men, glucosamine and chondroitin for arthritis, and fish-oil capsules (omega-3 fatty acids) for heart disease. (We plan to test additional supplements with potential benefits, such as probiotics.)

Tell your doctor about your supplements. “The Achilles’ heel of unregulated supplements is the risk created by herb-prescription drug interactions,” said Grollman, the pharmacologist at the State University of New York. “St. John’s wort, used to treat depression, for instance, may reduce the effectiveness of prescription drugs used by millions of Americans for hypertension, AIDS, heart failure, asthma, and other chronic diseases.”

Stay away from supplements for weight control. These products frequently contain several stimulants that have never been adequately tested separately, let alone in combinations. “I’d just as soon experiment with rats first rather than using the U.S. population as guinea pigs,” said Bill Gurley, Ph.D., professor of pharmaceutical sciences at the University of Arkansas.

Do your own research. Health-food-store clerks and marketers, alternative-medicine practitioners, herbal company Web sites, and even physicians are not necessarily knowledgeable about the scientific evidence regarding dietary supplements. These two Web sites contain reliable information: the National Institutes of Health site at ods.od.nih.gov/databases/ibids.html and Memorial Sloan-Kettering Cancer Center’s site at www.mskcc.org/mskcc/html/11570.cfm.

Watch for adverse events. Let your doctor know if you experience anything worrisome after starting a supplement. If your doctor concludes that the side effect may be related to the supplement, be sure to report it to the FDA, by calling 800-332-1088 or by visiting www.fda.gov/medwatch.