How Safe Are Diet Supplements?

FDA regulation is weak, so private watchdogs are stepping in

BY JOHN CAREY

JENNIFER ANGER WAS JUST looking for a bit more energy. So the 25-year-old graphic designer took the recommended dose of Zantrex-3, a dietary supplement billed on the Internet as "America's hottest n Super Pill," offering rapid weight los and incredible energy." She got something very different. "My heart started pounding. I thought I was having a heart attack," she says. When that symptom subsided, she was left with a splitting headache.

Anger was stunned that a popular supplement could have such a powerful effect. But Dr. Tod Cooperman isn't surprised. His company, ConsumerLab.com LLC, tests dietary supplements to see what's actually in them. The Zantrex-3 that he analyzed in late 2005 contained a huge amount of caffeine per daily dose: 1,223 milligrams. That's a bigger jolt than you would get from 35 cans of Classic Coke or 12 cups of espresso. "There is a shocking quantity in some of these products," says Cooperman.

Zantrex-3's maker, Basic Research Zoller Laboratories, said in a statement: "At no time do we try to conceal either the xanthine content [caffeine-like substances] or the huge energy boost." The company adds: "Every bottle...cautions those who are sensitive to stimulants to consult with their physician prior to taking Zantrex-3." Still, such Web sites as www.fitnessinfomercialreview.com, where customers report experiences, are full of tales like Jennifer Anger's.

The stories raise a host of issues about the safety and quality of products sold by the $20.3 billion dietary supplement industry and the seeming failure to regulate them. ConsumerLab, which, for a fee, also offers seals of approval for companies whose products pass the tests, has found that 25% of the products it tests fail in some way. Some lack the claimed ingredients or levels of ingredients. Others are laced with contaminants. Cooperman has found lead in ginkgo and magnesium supplements, toxic chromium in a weight-loss product, and lacking active ingredients in others (table).

COOPERMAN decided to test products and put out the results

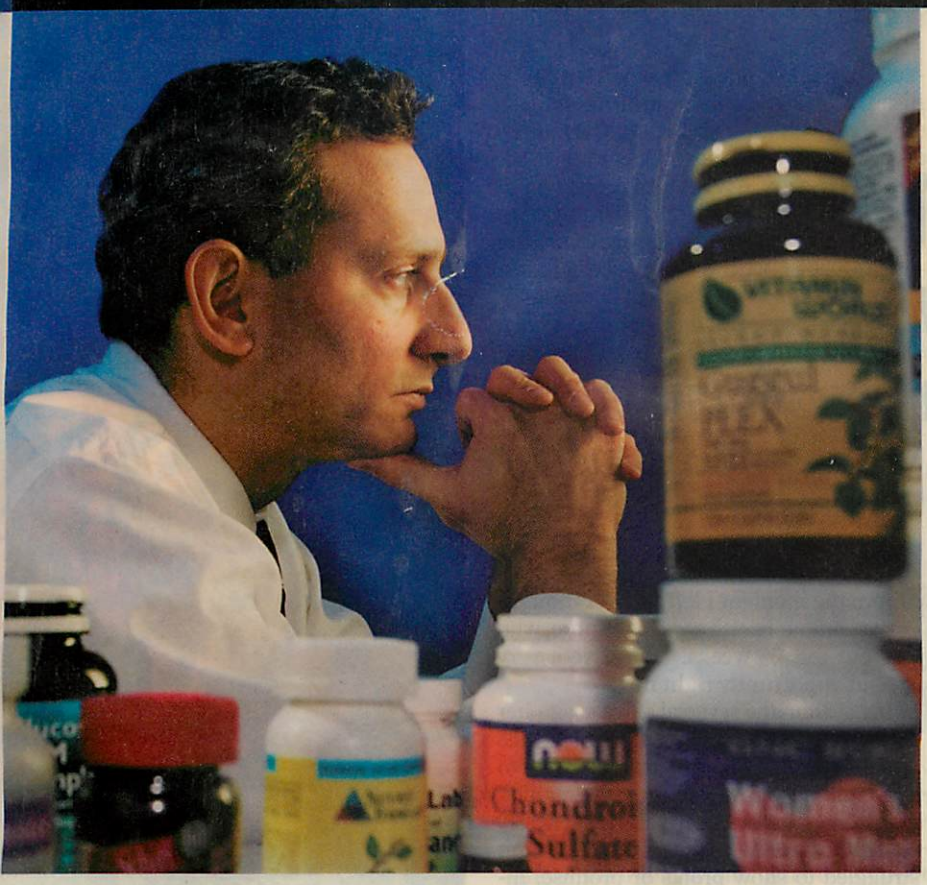
BusinessWeek has learned that key lawmakers led by Senator Dick Durbin (D-Ill.) are near a deal for a new law requiring companies to report to the Food & Drug Administration serious adverse events involving supplements. That would limit harm from a dangerous product. In the meantime, Cooperman's private efforts cast a stark light on the sprawling health supplement industry, which is still struggling to gain credibility. And they show how commercial attempts to fill the regulatory vacuum can stir up a hornet's nest. "What ConsumerLab is doing is literally extortion," accuses Jarrow L. Rogovin, president of Los Angeles supplement maker Jarrow Formulas LLC. "They are a viper at the mother's breast." Jarrow recalled a line of ginkgo products on Dec. 28, after Cooperman's company discovered that the supplements lacked the advertised amounts of active substances. Jarrow says that a Chinese supplier was at fault.

What's in That Bottle?

In 25% of products it's not what the label claims, tests show. Some examples:

PRODUCT	PROBLEM
GINKGO BILOBA Supposed to improve memory	Three of 13 products tested were contaminated with lead; 7 of 13 lacked the claimed amounts of ingredients
WEIGHT LOSS PRODUCTS E.g. Ripped Fuel, Zantrex-3	Some contained high amounts of caffeine, plus 5 of 11 products tested didn't contain enough of their key ingredients
HORNY GOAT WEED Aimed at sexual dysfunction	All four tested products were either contaminated with lead or lacked the claimed amount of the active substance
CHROMIUM May help in diabetes	One supplement contained a toxic form of chromium; others had less—or more—chromium than listed on the bottle
MULTIVITAMINS	Most were O.K., but some lacked the full amounts of claimed ingredients, or contained lead, or didn't dissolve when swallowed

Data: ConsumerLab.com



CHRIS CASABURI

The turmoil over supplements stretches back to a 1994 law in which Congress decided that the products, unlike pharmaceuticals, don't have to be pre-approved by the FDA. Nor must the FDA test them for safety, efficacy, or even quality control.

The law created a fast-growing industry. Now, even President George W. Bush takes supplements: multivitamins, omega-3 fatty acids, and glucosamine and chondroitin to ease stiffness in his joints. There are still questions about whether the thousands of products work. But more important, is the quality up to snuff? "People think these things are regulated...but it's pretty much like the Wild West," says New York nutritionist Erica Ilton.

BITE THE BULLET

EXPERTS SAY THAT most products contain what the label indicates. Yet even industry leaders concede that there are too many times when this isn't true. "There are still a lot of fly-by-nighters out there. It is a problem the industry is still struggling with," says A. Wes Siegner Jr. of Hyman, Phelps & McNamara, who has served as general counsel for dietary supplement trade associations.

In recent years, the Federal Trade Commission has cracked down on egregious marketing. But the FTC has no authority over manufacturing quality, and it can't quash all the dubious claims. "Let's just say that I have job security," says Richard Cleland, assistant director of the FTC's division of advertising practices. "It doesn't take too long on the Internet to figure out there is still a problem out there." The FDA is empowered to take supplements it can prove are dangerous off the market, such as those containing ephedra—but it rarely has.

Nonprofit USP sets voluntary quality standards for makers

That's why Tod Cooperman saw an opportunity. After medical school, he was more interested in business than in doctoring and was eager to get better information to consumers. The first company he started, CareData Reports Inc., rated health-maintenance organizations and managed-care plans. (It is now owned by J.D. Power & Associates—like *BusinessWeek*, a unit of The McGraw-Hill Companies). After selling CareData, he looked around "for another situation where consumers had no sense of how to distinguish good from bad products," he says.

Dietary supplements fit the bill, even if Cooperman started with no business model. "I just bit the bullet and decided to buy products, test them, and put out the results for free," Cooperman recalls. "But immediately we found an audience for this kind of information."

ConsumerLab currently has about $1 million in annual revenues and 25,000 subscribers. "I don't recommend anything that has not been tested," says nutritionist Ilton. Colorado engineer Peter Wagner, 56, found the site about a year ago, and he quickly became a believer: "I read some of the reports and said: 'Man alive!' Some of the stuff out there is junk."

Consumer advocates say Cooperman is offering vital information, but they believe he's a poor substitute for real FDA regulation. "It's a sad commentary when we have a private-sector lab...doing what should have been part of the law long ago," says Dr. Sidney Wolfe, director of Public Citizen's Health Research Group.

Yet that's a rave review compared with the reaction of supplement makers. After ConsumerLab testing found excessive amounts of lead in a popular children's vitamin, L'il Critters Gummy Vites, the industry's chief trade association, the Council for Responsible Nutrition (CRN), went on the offensive. In January, 2005, it complained to the FTC that Cooperman's enterprise misleads "consumers into believing that ConsumerLab is operating in the public interest," when its "entire business model represents an egregious form of consumer fraud and deception." Preposterous, retorts Cooperman. The attacks are an example of trying to shoot the messenger, he says. The FTC declined to investigate, and now Cooperman is suing CRN for libel.

Even if they dislike ConsumerLab, though, many supplement makers see a need for third-party evaluators. Pharmavite LLC, makers of "Nature Made" and other products, and several other major companies have signed up with the U.S. Pharmacopoeia, a nonprofit group that sets quality standards. For a fee, the USP will test supplements and enforce rigorous manufacturing standards. "The USP mark is front and center on every one of our Nature Made labels," says Tom Zimmerman, Pharmavite's vice-president of business development.

CRN and others also have been asking the FDA to issue long-awaited *rules* requiring higher-quality manufacturing processes. Meanwhile, consumers can follow the example of Eileen Begley. The Monterey (Calif.) Realtor, 53, won't buy a supplement until she checks ConsumerLab's tests. "It's a nice feeling that I'm not just taking snake medicine," she says.