Fight over ephedra safety intensifies

by Linda Marsa
Los Angeles Times

Wes Siegner is trying to save ephedra, the herbal stimulant that is under attack from a chorus of critics who say it is dangerous to your health. Even opponents of the lobbyist marvel at his victories so far, but it is looking more and more as if he is fighting a losing battle.

Siegner's task grew more difficult last month with news of a federal investigation of Metabolife International, a leading seller of ephedra in the United States. The fate of Metabolife, and of ephedra generally, is likely to influence the broader debate over the effectiveness and safety of herbs, sports drinks, diet pills and hundreds of other products for which Americans spend about $4.2 billion annually.

" Siegner's job is to protect the industry, and thus far he's succeeded," says Dr. Sidney M. Wolfe, director of Public Citizen's Health Research Group, a consumer watchdog group in Washington, D.C., that has called on the Food and Drug Administration to take ephedra off the market. "But time is running out."

The anti-ephedra forces are gaining momentum as government regulators, health officials, scientists and consumer groups push for tougher regulation of the herb or its removal from the market altogether. These critics, including the influential American Medical Association, say ephedra, the active ingredient in hundreds of energy boosters and diet products, is a health hazard. They cite evidence linking it to heart attacks, strokes, seizures--and more than 100 deaths.

Seven states already have enacted tough new rules regarding the sale of ephedra products. The Canadian government in January issued a national recall of supplements containing ephedra. The National Football League and the National Collegiate Athletic Association have outlawed the use of performance-enhancing supplements that contain ephedra, partly due to safety concerns.

The growing number of serious medical problems linked to the herbal stimulant, ranging from dizziness, headaches, heart palpitations and high blood pressure to heart attacks, seizures, strokes and death, threatens not only to derail ephedra but to engulf the entire dietary supplement industry.

And then, last month the Justice Department launched a criminal probe into whether executives at San Diego-based Metabolife International made false statements about the existence of 13,000 consumer complaints of serious health problems, at least 80 of which included deaths, seizures, heart attacks or other medical emergencies.

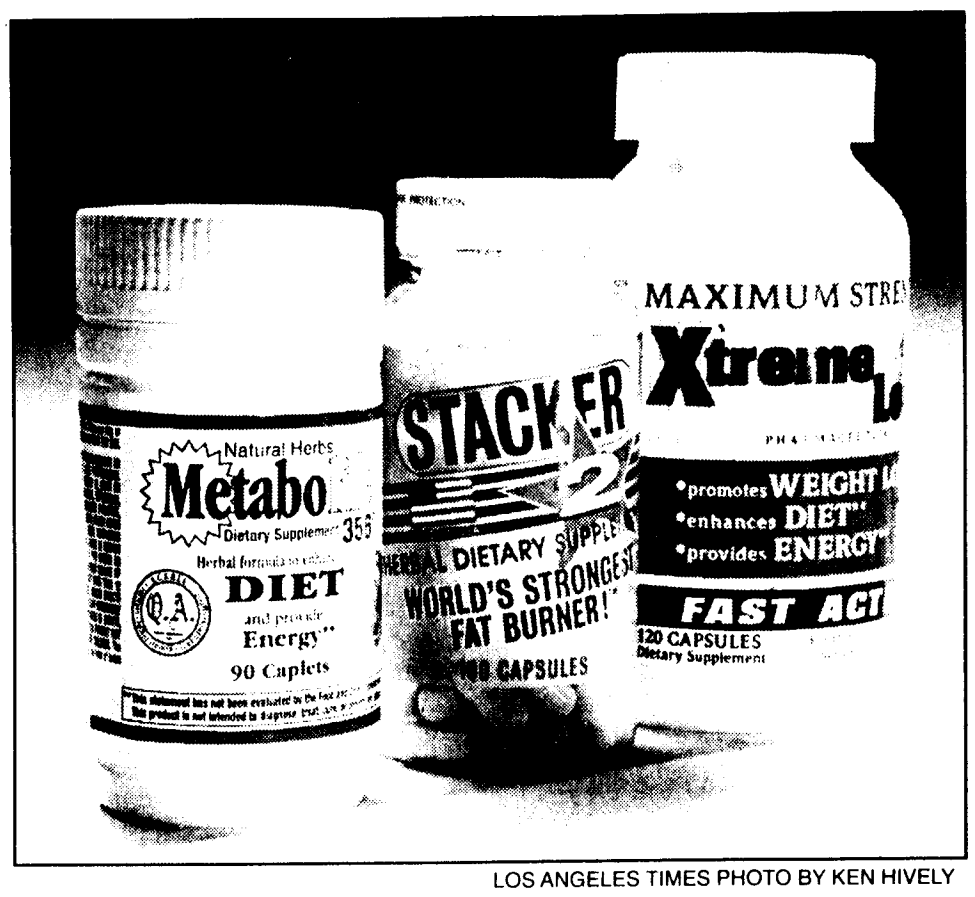
The FDA has sought unsuccessfully for years to obtain these reports, which Metabolife refused to provide until the government opened its investigation. In the jargon of health regulators, such incidents are commonly referred to as "adverse events."

Siegner, a lanky man with a plaintive face, looks more like the high school biology teacher he once was than an Ivy League-educated lobbyist whose role is to rebut the arguments of scientists and politicians alike. Although he says he has no need to take ephedra, he would do so "in a heartbeat." In conversation, the 50-year-old Buffalo-born lawyer never strays far from his essential--and, clearly, well-practiced--message.

"Adverse events don't prove causality," he says. "These are a random set of events that happened to people who happened to be taking ephedra."

When millions of people use a product--any product--the law of averages dictates that a certain percentage of them will have heart attacks, strokes and seizures, which may or may not be linked to use of the product. Only a rigorous scientific study, say experts, in which one group is taking the supplement and another is using a placebo or dummy pill, can prove a direct connection. Otherwise the evidence is circumstantial.

The Metabolife investigation "makes the situation more difficult," says Siegner, who contends that it diverts attention from the more important issue of ephedra safety. Siegner has led the industry's so-far effective campaign to keep ephedra products on the market by raising doubts about the link between ephedra and medical problems, and by challenging industry critics at every turn. Even though doctors still aren't sure if ephedra is dangerous, the supplement makers that Siegner represents contend that these products are safe when used as directed on the label.



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Ephedra, a stimulant contained in many weight-loss supplements, is under pressure to be removed from the market due to adverse side effects in some individuals.

But critics point to the mounting evidence of serious side effects. This has prompted some lawmakers, such as Sen. Richard Durbin, D-Ill., to push for stricter regulation of dietary supplements, which could hurt the industry by squeezing out smaller companies, driving up prices and curtailing availability of products.

So far, Siegner and the supplement industry have managed to blunt many government efforts to restrict the availability of ephedra, including repeated attempts by the FDA to regulate the herb over the last five years. Efforts by Siegner and the Dutko Group, a high-profile Washington, D.C., lobbying group, along with nearly $4 million in contributions to both the Democratic and Republican parties and to Washington politicians during the past decade, have so far largely thwarted attempts at stricter regulation.

Siegner, whose specialty is product-liability cases, was hired in 1997 as a lobbyist for the American Herbal Products Association, a trade group whose members include such industry heavyweights as Herbalife, Nature's Way and Weider Nutrition. The Ephedra Education Council, the industry's public relations arm, was formed later by a consortium of ephedra makers, including Rexall Sundown, General Nutrition Cos. and Twin Laboratories.

In 1997, when the FDA sought to limit dosages of ephedra and require warning labels on products, Siegner helped persuade Congress to order a General Accounting Office audit. The GAO concluded that the FDA's proposed rules were based on only 13 cases of adverse events, and that the data in those reports were too sketchy to blame them on ephedra, scuttling any regulatory action.

Since passage of the Dietary Supplement Health Education Act in 1994, supplement makers have not had to prove that their products--herbal or otherwise--are safe and effective before they put them on the market. The law, in effect, mandates that the FDA assume that supplements are harmless until proved otherwise, according to Christine L. Taylor, director of the FDA's Office of Nutritional Products, Labeling and Dietary Supplements in Rockville, Md. To remove a supplement from the market, the agency must demonstrate that it is dangerous.

After the release of the GAO report, the FDA asked University of California, San Francisco researchers to review 140 adverse-event reports received by the agency between June 1997 and March 1999. In an article published in the New England Journal of Medicine in December 2000, they concluded that 87 of the medical problems reported, including 10 deaths, 17 strokes and seizures, and 13 cases of permanent impairment, were likely caused by supplements containing ephedra.

In response, the Ephedra Education Council gathered its own panel of prominent research scientists to look at the product's safety data. The group concluded that the "available information" did not demonstrate a causal relationship between ephedra and serious medical emergencies when the herb was used in the industry's recommended individual dosage of 25 milligrams, and no more than 100 milligrams a day.

As debate continues over who's right about ephedra safety, the federal government has stepped in to try to clarify matters. The U.S. Department of Health and Human Services in June asked researchers at Rand Corp., an influential think tank based in Santa Monica, Calif., to review 1,300 ephedra-related medical emergencies. The Rand report is expected to be released this fall, after which the federal health agency will determine if additional research is needed.