



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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U.S. finds metals in herbal pills

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Nearly all of the herbal dietary supplements tested in a U.S. government investigation contained trace amounts of lead and other contaminants, and some supplement sellers made illegal claims that their products could cure cancer and other diseases, investigators found.

The levels of heavy metals — including mercury, cadmium and arsenic — did not exceed thresholds considered dangerous, the investigators found.

However, 16 of the 40 supplements tested contained pesticide residues that appeared to exceed legal limits, the investigators found. In some cases, the U.S. government has not set allowable levels of those pesticides because of a paucity of scientific research.

Investigators found at least nine products that made apparently illegal health claims, including a product containing ginkgo biloba that was labeled as a treatment for Alzheimer's disease and a product containing ginseng labeled as a treatment to prevent diabetes and cancer.

They also described a sales clerk at a supplement specialty store who claimed that a garlic supplement could be taken instead of blood pressure medication.

Any product that claims to treat, cure, prevent or mitigate a disease is considered a drug and must go through strict regulatory reviews.

In recent years, a vast majority of supplement suppliers have located overseas—principally in China. Nearly all of the vitamin C and many other supplements consumed in the United States are made from ingredients made in Chinese plants. Those plants are almost never inspected by the U.S. Food and Drug Administration because the agency is not required to do so, has little money to do so and does not view the plants as particularly risky.

The report, which was prepared by the Government Accountability Office, was provided to The New York Times and was made public at a Senate hearing Wednesday. Its release comes two weeks before the Senate is scheduled to begin debate on a landmark food safety bill that is expected to substantially increase the U.S. government's authority over food manufacturers. The International Herald Tribune is the global edition of The Times.

But it is uncertain how tough the bill will be on supplement manufacturers, and it has been the subject of fierce lobbying.

Congressional staff members familiar with the process said the bill was unlikely to include provisions

opposed by supplement manufacturers. deputy commissioner at the F.D.A., said in an interview that he was not concerned about the safety of the supplements tested by the G.A.O. investigators.

But Dr. Sharfstein noted that the agency had recently announced a recall of Vita Breath, a dietary supplement that it said might contain hazardous levels of lead.

Steve Mister, president of the Council for Responsible Nutrition, a trade association representing the dietary supplement industry, said it was not surprising that herbal supplements contained trace amounts of heavy metals, because those substances are routinely found in soil and plants.

“I don’t think this should be of concern to consumers,” Mr. Mister said.

Senator Herb Kohl, a Wisconsin Democrat who will preside over the hearing Wednesday of the Senate Special Committee on Aging, said that while improvements had been made in recent years in the oversight of supplements, “the F.D.A. needs the authority and tools to ensure that dietary supplements are as safe and effective as is widely perceived by the Americans who take them.” Among the witnesses at the hearing will be Dr. Tod Cooperman, president of ConsumerLab.com, a company that has tested more than 2,000 dietary supplements made by more than 300 manufacturers and has found that one in four have quality problems. According to Dr.

Cooperman’s written testimony, the most common problems are supplements that lack adequate quantities of the indicated ingredients and those that are contaminated with heavy metals.

Travis T. Tygart, chief executive of the U.S. Anti-Doping Agency, wrote a letter to the committee saying that some athletes had been rendered ineligible for international competitions because they took supplements that contained steroids not listed on the products’ labels.

There are thousands of supplements available for sale that contain steroids or other harmful ingredients, he wrote.

“The F.D.A. is operating in a regulatory environment that is simply too burdensome to allow for effective post-market regulation of these products,” Mr.

Tygart wrote.

In 1994, Congress passed legislation that allowed supplement makers to sell products without first getting approval from the F.D.A. for their ingredients or for basic health claims. But scientific organizations have warned repeatedly since then that the F.D.A. should do more to ensure that the supplements are safe and that their health claims are substantiated.

Mr. Mister said supplement sellers tested ingredients before using them, but he agreed that testing could not ensure quality. He called on Congress to provide the F.D.A. with more money to inspect overseas and domestic supplement plants. “I think you’ll see more and more inspections,” Mr. Mister said.

He said that a few companies made illegal health claims for their supplements, but that the industry was trying to police those. “I occasionally see these late-night commercials with health claims that make my blood boil,” he said.

Dr. Sharfstein said the F.D.A. had increased enforcement actions against supplements spiked with prescription drugs like Viagra. And he said the agency had taken action against supplement makers that made broad health claims.

“We don’t want people to think they’re treating a disease with something that hasn’t been proven to do that,” he said.