More Careful Scrutiny Encouraged for Purification and Quantitative Testing of Nutritional Supplements

Recent case of selenium toxicity points to need for FDA to toughen regulations for supplements

by Gary Witman, MD

MacFarguhar et al have written an excellent article in the Feb. 8, 2010 edition of the Archives of Internal Medicine entitled "Acute Selenium Toxicity Associated with a Dietary Supplement." They report that in 2008 a chiropractor in Florida noted common symptoms of gastrointestinal illness and hair loss among several of his patients. In response to these symptoms these patients had doubled the dose of a dietary supplement they have purchased at the chiropractic office. Due to excellent surveillance work performed by the local health department and the Food and Drug Administration the dietary supplement was identified as the common exposure among all affected persons.

The product causing the selenium toxicity was a blend of 16 vitamins, 12 elements with labeled concentrations, 58 trace elements, 18 amino acids and 3 essential fatty acids, Coenzyme Q10 and antioxidants, all suspended in an ionic colloidal liquid. While the product labeling indicated that it contained 200ug of selenium per fluid ounce, the testing performed by the FDA determined that the actual concentration of selenium was 40,800 ug per fluid ounce, or more than 200 times the labeled concentration. Furthermore, the chromium concentration was 17 times the labeled concentration.

Of great concern is that there is no proven antidote nor curative treatment for selenosis due to an overdose of selenium. Treatment consists of stopping the exposure and providing supportive care for symptoms.

At present, dietary supplements such as vitamins, minerals and herbal products are not subject to premarket review or approval for safety, efficacy or Good Manufacturing Practices. Under the Federal Food, Drug and Cosmetic Act the manufacturer of a finished dietary supplement is responsible for ensuring the safety and the quality of the final product, which includes all ingredients received from suppliers. That responsibility includes testing of received ingredients, including premixed ingredients and the final product.

Had the manufacturer been held to standards used in the pharmaceutical industry this outbreak may have been prevented.

In total more than 200 individuals developed acute selenium toxicity.

The expansion of the dietary supplement industry has exceeded our ability to monitor and regulate. In 1994 there were 4000 different dietary supplements on our shelves, and today that number exceeds 75,000. Over the last 15 years the industry has grown from $4 billion to $ 25 billion in sales.

DAI encourages the Food and Drug Administration Center for Food Safety and Nutrition to allocate more of their resources for the monitoring of dietary supplements, and ensure quality control in raw materials, purification and honest labeling and packaging.

You may be asking yourself "what the heck are these guys at writing about when they are a company which manufactures and distributes adsorbents". You may be correct in asking this question, but then you would be missing the point.

DAI is in the business of providing products and solutions for the separation and purification of materials critical in the manufacture of drugs and nutritional supplements. We provide specialized activated aluminas used to remove pyrogens and other harmful materials which are untoward consequences of manufacturing as well as providing superior silica and alumina adsorbents essential in the purification of marine and plant alkaloids which are critical for drug production.

We seek to have the most secure nutraceutical and pharmaceutical supplies available globally, and if we take our eye off the "8-ball" we will allow processing issues to occur, which if unchecked may lead to untoward harm.

The Food and Drug Administration was established to assure the safety of the food and drug supply in this country, and its jurisdiction and controls need to be strengthened to assure that no harm is allowed to occur. We make products to assure the safety of the food and drug supply. We are concerned scientists, and safety and health remain our paramount priorities.

Gary Witman, MD