



Essential Tremor (ET)

Buyer beware!

Dietary supplements not held to same standards as prescription drugs

The dietary supplement industry is booming. In fact, according to Nutrition Business Journal (NBJ), retail sales of dietary supplements, which the United States (US) Food and Drug Administration (FDA) define as “products containing vitamins, minerals, herbs or other botanicals (excluding tobacco), amino acids, or other substances intended to supplement the diet,” have seen double-digit growth during the past two years.

The reason, according to the NBJ, is a growing consumer interest in healthier products. Recent research has found that many supplements have great value in maintaining health, but there could be another reason that the sale of dietary supplements has grown rapidly while the rest of the economy has suffered.

According to Loren Israelsen, executive director of United Natural Products Alliance, a trade organization representing many of the world’s leading dietary supplement companies, at the NBJ 2009 Summit, “People can’t afford to get sick, and this is why many are turning to dietary supplements and other less-expensive health products.”

Even as early as 2003, before the recession, a survey of 2,000 grocery shoppers conducted by the Office of Dietary Supplements (ODS) at the National Institutes of Health in Bethesda, MD, found that Americans are using supplements to “self-medicate” with more than one third of respondents reporting that they use dietary supplements to treat conditions such as high blood pressure, heart disease, high cholesterol, diabetes, and obesity.

Dietary Supplements Are “Presumed to be Safe” but not Necessarily Effective

Many people incorrectly believe that dietary supplements are held to the same safety and effectiveness standards by the Food and Drug Administration (FDA) as prescription drugs. But according to the January 2009 US Government Accountability Office Report (GAO) to Congress dietary supplements are presumed to be safe” but not necessarily effective while prescription drugs must demonstrate safety and e effectiveness through a 12- to 15-year process involving human trials before receiving FDA approval and permission to market.

Once on the market, the FDA can move to have a dietary supplement banned, but they must have proof that a product is not safe. This proof comes in the form of reports of serious “adverse events, which the FDA characterizes as reactions requiring hospitalization or some form of medical intervention.

But the FDA has only required these reports since Dec. 22, 2007. During the first ten months of 2008, the FDA received 948 adverse event reports on dietary supplements, compared to only 298 from the previous time period in 2007. However, according to GOA, the FDA estimates that the actual number of total adverse events related to dietary supplements per year is more than 50,000.

Good Manufacturing Processes—A Step Forward, but Safety Issues Remain

While most dietary supplements, when tested, do contain the ingredients at the levels listed on their labels, in 2005 ConsumerLab, a for-profit testing laboratory, found that 25 percent—one in four—dietary supplements either lacked the claimed ingredients or levels of claimed ingredients or also contained unlisted contaminants.

In 2007 the US Department of Health and Human Services put out a set of standards, called Good Manufacturing Processes, or GMPs, for producing dietary supplements. These standards took full effect in June 2010, and mandate that dietary supplements be produced in a quality manner, not contain any contaminants or impurities, and be labeled with the actual ingredients in the product. But, according to Henry Miller and David Longtin of the Hoover Institution of Stanford University, a public policy think-tank, while a positive step forward in ensuring manufacturing standards and products contents, these standards “address only the identity, purity, and potency of the products, neglecting the fundamental question of whether the active ingredients themselves are safe and effective, and they offer no independent verification that the standards have been met.”

The bottom line? It remains a “buyer beware” dietary supplement market.

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Safety suggestions when choosing and using dietary supplements

According to the United States National Institutes of Health's Institute on Aging, consider the following when purchasing and using dietary supplements.

- Learn as much as you can about any dietary supplement you plan to use. Talk to your doctor or pharmacist, or to a registered dietitian. A supplement that helps someone else may not work for you.
- If you are checking websites, could the writer or group profit from the sale of a particular supplement?
- Just because something claims to be "natural" doesn't also mean it is safe or effective or even good for you. And it might make a medicine your doctor prescribed for you either weaker or stronger.
- Tell your doctor. They need to know about any dietary supplement you are thinking of using. Do not diagnose or treat a health condition without first checking with your doctor.
- Buy wisely. Choose brands that your doctor, dietitian, or pharmacist says are trustworthy. Don't buy dietary supplements with ingredients you don't need. Don't assume that more of something that might be good for you is even better for you.
- Check the science. Make sure any claim made about a dietary supplement is based on research. The manufacturer of the dietary supplement should be able to provide information on the safety and/or effectiveness of the ingredients.
- Remember that if something sounds too good to be true, it probably is.



Our Mission:

The IETF funds research to find the cause of essential tremor (ET) that leads to treatments and a cure, increases awareness, and provides educational materials, tools, and support for healthcare providers, the public, and those affected by ET.