Not Food, Not Medicine: Understanding Dietary Supplements

What Are They, and How Are They Regulated?

By Gregory Alford

Type "asthma cures" into your favorite search engine and you'll discover thousands of high-tech hucksters claiming their "all natural" cures for asthma ranging from ginger water to exotic tree bark from the Philippines. The proliferation of Web sites touting "miracle cures" for asthma and allergies that work in as little as one week dovetails with a growing interest in legitimate complementary and alternative medicine (CAM). In its 2005 report titled, *Complementary and Alternative Medicine in the United States,* the Federal Institutes of Medicine reports more than one-third of adults state that they have pursued some form of CAM treatment, such as herbal remedies and acupuncture.

Using herbs and other natural substances to fashion potions to treat illness and disease is a practice that dates back thousands of years. Today, herbal products can be purchased in thousands of retail outlets. The Natural Marketing Institute reports that dietary supplements including vitamins, minerals, and herbal remedies sold in retail stores rose 6% in 2003 to $19 billion. It estimates that 1500 herbal and botanical products are now available in retail outlets.

Although many people take herbal and vitamin formulas for medical purposes, the federal government does not consider them medicines. Even herbs containing ephedra, which was used to treat asthma in the early and mid-20th century and has a long history of causing injury and death, is still legal.

Government Oversight Scarce

The Dietary Supplement Health and Education Act of 1994 (DSHEA) restricts the US Food and Drug Administration's (FDA) control over dietary supplements and expands the meaning of the term "dietary supplements" beyond essential nutrients to include gin-

seng, kava, garlic, fish oils, herbals, botanicals, enzymes, and amino acids. As a result, "dietary supplements are not regulated by the Food and Drug Administration the same way prescription and over-the-counter medications are," says Joan Pleuss, registered dietician and Bionutrition Research Manager at the Medical College of Wisconsin in Milwaukee. "They do not have to meet the same standards for safety, effectiveness, and what the FDA calls 'good manufacturing practices.' "

Instead, dietary supplements are considered more like food in that their manufacturers and distributors are largely responsible for ensuring the safety of their products. Once a product enters the marketplace, the FDA does have the authority to take action against any dietary supplement product that presents a significant or unreasonable risk of illness or injury. However, in 2004, the Supreme Court invalidated the FDA's action of removing ephedra from the market citing that it had overstepped its regulatory authority.

Supplement marketing is drawing considerable attention from both the medical community and the federal government. The DSHEA prohibits supplement labels or marketing materials from claiming the product can treat, prevent, diagnose, or cure specific diseases. The FDA can take action against companies that violate marketing rules, but the number of companies making illegal claims on the Internet makes enforcement of this law problematic.

In 2003, the *Journal of the American Medical Association* published a survey of health claims made on Web sites touting dietary supplements. The survey found that "the public may be misled by vendors' claims that herbal products can treat, prevent, diagnose, or cure specific diseases." It found that 81% of supplement retail Web sites examined made at least one health claim. More than half of those sites contained illegal claims. The study authors concluded that "more effective regulation is required to put this class of therapeutics on the same evidence-based footing as other medicinal products" (*JAMA* 2003;290:1505-9).

Triggering Allergic Reactions

"I think there are useful substances in some herbs," says Marianne Frieri, MD, PhD, director of Allergy Immunology Training, and Clinical Immunopathology at Nassau County Medical Center in East Meadow, NY. "But there is a lot of misleading information and contaminated products on the market at the current time. What is needed are more controlled, double-blind peer-reviewed studies to provide more information about the effects of herbs on health and disease processes."

Some supplements, such as cayenne and St. Johns Wort, can interact with medications used to treat asthma, including the drug theophylline. Furthermore, she adds that an important but often overlooked aspect of

What to Know Before Taking A Supplement

According to Clifford W. Bassett, MD, Attending, Department of Immunology and Allergy, Long Island College Hospital, NY, people with the following medical conditions may be at higher risk for side effects associated with herbal supplements:

- **High blood pressure**
- **Blood clotting problems**
- **Thyroid disease**
- **Enlarged prostate**
- **Glaucoma**
- **Parkinson's disease**
- **Stroke**
- **Heart disease**
- **Epilepsy**

Dr. Bassett provides the following tips to provide assistance in the use of medicinal herbal remedies:

- **Never give dietary supplements or herbal remedies to children without consulting a pediatrician**
- **People about to undergo surgery must inform their doctor regarding the use of herbs**
- **Do not take supplements during pregnancy or while breast-feeding, as they could have effects on your baby**
- **Let your medical provider know which supplement you are using as some may have an interaction with prescription and over-the-counter medications**