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Herbal Remedies ~ Therapeutic or Fraudulent?

Sales of natural supplements are among the world's largest growing economic sectors. Congress estimated sales of $1 billion in 1999 with an expected growth rate of 10 percent. While nearly half of the amount is spent on essential vitamins and minerals, the remainder is spent on a panacea of herbal products that make a wide array of claims.

Here's what the law allows…

☞ Products can go on the market without testing for efficacy, unless they contain a new dietary ingredient, where pre-market review for safety data is required by law.

☞ Companies have the responsibility to ensure that products are safe.

☞ Supplements don't have to be manufactured according to specifications, although the FDA does intend to issue regulations in the near future.

☞ Claims are permitted on the packages as long as the claims are truthful and not misleading. Manufacturers are required to tell consumers that their health claims have not been reviewed by the FDA, but there is no requirement that they make that message stand out.

☞ The label may not have supportive evidence behind it.

☞ FDA approval is not needed for package or marketing claims. Medicinal claims are not allowed.

☞ Simply put, the FDA does not approve supplement safety.

So buyers beware.

Traditionally dietary supplements are products made of one or more of the essential nutrients, such as vitamins, minerals, and amino acids. They fall under the 1958 *Food Additive Amendments* to the **Federal Food, Drug, and Cosmetic Act**. In 1990 the *Nutrition Labeling and Education Act* added herbs or other botanicals and substances such as enzymes, organ tissue, glandulars, and metabolites to the term dietary supplement. Dietary supplements may also include extracts or concentrates. They come in an array of forms, such as tablets, capsules, soft gels, gel caps, liquids, or powders. Regardless every supplement is treated as a food and must be labeled a dietary supplement.

The Dietary Supplement and Health Education Act of 1994 was enacted to establish a new framework for assuring safety, including guidelines for use on non-medicinal claims, ingredient and nutrition labeling, and the establishment of good manufacturing practice regulations. A new **Commission of Dietary Supplement Labels** and an **Office of Dietary Supplements** was formed within the National Institutes of Health in response to the law.

ODS has developed the *International Bibliographic Information on Dietary Supplements* (IBIDS) database. IBIDS is a database of scientific literature on dietary supplements (http://ods.od.nih.gov/health_information/ibids.aspx). The *Food & Nutrition Information Center* contains general dietary supplement information and a resource list (http://www.nal.usda.gov/fnic/etext/ds_general.html). Additional information is available from the *Food and Drug Administration's* (FDA) web site (http://www.cfsan.fds.gov).

There are differences between herbal supplements and FDA-approved medications. A drug is intended to diagnose, cure, mitigate, treat, or prevent diseases. Before they are marketed, drugs must undergo clinical studies. The clinical studies must meet strict criteria that determine a drug's effectiveness, safety, interaction, possibilities, and appropriate dosages. FDA then reviews the data and authorizes a drug's use before it is marketed. There are many areas of the world, including Great Britain and Europe, which have been collecting data on herbs as medicines for years. These studies, however do not meet the strict criteria approved by FDA. In many instances, these studies are the basis for clinical study on an herb's medicinal effects in the United States.

Since FDA views dietary supplements as food, dietary supplement manufacturers simply ensure that the products they put on the market are safe. But FDA does not review or approve supplement ingredients or products before marketing. Once marketed, it is up to FDA to prove the dietary supplement is unsafe before it can restrict the product's use.

Herbs are natural products that contain an array of chemicals with concentrations that vary depending on the genetics of the plants, growing conditions, plant parts used, harvest time, preparation, and storage. An herbal product sold as a dietary supplement that is labeled as a treatment or cure for a specific disease or condition, would be considered an illegal drug. FDA oversees safety, manufacturing, and product information, while the **Federal Trade Commission** regulates the advertising of all dietary supplements.

Herbs are categorized and defined by several disciplines.

Culinary professionals think of herbs as vegetable products that add flavor or aroma to food.

Botanists restrict the meaning of herbs to non-woody, seed-producing plants that grow, and then die during repeated growing seasons.

Medically, herbs are most accurately defined as crude drugs of vegetable origin utilized for the treatment of disease states, often of a chronic nature, or to attain or maintain a condition of improved health. The primary concern regarding the use of herbals is that people self-medicate rather than seek traditional therapy from a physician.

Herbal Supplement Use

A number of studies have shown that certain herbs may help people with health concerns, from headaches to high cholesterol. Some herbs even have the potential to become the next quinine, aspirin, or digitalis - all drugs that were originally derived from plants.

If you decide you want to use herbs, you face a formidable obstacle. There is no guarantee that the supplements are what they say they are, and in most cases no one really knows what will happen if you take them. You have no way to be sure:

- if a plant's active ingredients are actually in the herbal pills you buy;
- that a supplement's active ingredients are in a form your body can use;
- whether the dosage makes any sense;
- what unknown ingredients are in the pills;
- whether the pills are safe; and
- whether the next bottle of those same pills will have the same ingredients.

The manufacturers may not know this information either. Because herbal supplements are regulated as food, manufacturers are not required to do the testing or quality control that is standard protocol for prescription drugs.

No herb should be a substitute for established disease therapy. Potential use should be discussed with appropriate health care professionals. Consider changes to your diet or lifestyle that might accomplish your goals.

If you do take herbal supplements and experience any unusual symptoms, allergies, rashes, or other problems, stop taking the product at once. The FDA advises consumers to contact their physician, who should then call the Agency's MedWatch hotline at (800) FDA-1088. Health care professionals can report problems that may be related to FDA-regulated products.

References

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Herbs that Can Harm

The Food and Drug Administration has identified a number of herbs that can cause serious harm. Some including those that follow are still sold under various names:

Aristolochic acid is an ingredient in Chinese weight loss products. It has caused kidney failure, often leading to death. The FDA warned consumers and industry in April 2001.

Androstenedione is an anabolic steroid precursor that is converted into testosterone in the body. Steroids are reported to build stronger and more muscles. The FDA warned 23 companies to stop manufacturing, marketing, and distributing in March 2004.

Chaparral is sold as tea and in tablet and capsule form. It is promoted as a blood purifier, cancer cure, acne treatment, and natural antioxidant. Chaparral has caused numerous cases of liver disease and death. The FDA warned consumers in December 1992.

Comfrey is sold as tea, tincture, poultice, lotion, and in tablet and capsule form. Comfrey taken orally has been linked to liver damage, with at least one death reported. Animal studies indicate that lung, kidney, and gastrointestinal problems are also possible so the FDA advised its removal from the market in July 2001.

Ephedra, also known as ma huang and epitonin, contains stimulants found in asthma drugs and decongestants. It is promoted for weight control and energy boosting. Energy-boosting formulas, sometimes with caffeine, can augment the adverse effects. Ephedra can raise blood pressure and cause nerve damage, muscle injury, psychosis, stroke, and memory loss. Deaths have occurred prompting the FDA to ban herbal products containing ephedra effective December 2003.

Kava is promoted as a tea and in capsule form as a muscle relaxer and stress reliever. The FDA warned consumers in March 2002 of possible liver damage and death.

Lobelia acts like nicotine, though less potent. It can stimulate or depress the autonomic nervous system. Even a small amount of dried lobelia can reduce breathing, drop blood pressure, induce sweating and rapid heart beat, and cause coma and death. Adverse-event reports have been made to the FDA.

Yohimbe is sold as a men's aphrodisiac. An overdose may cause weakness and nervous stimulation, followed by paralysis, fatigue, stomach disorders, and ultimately, death. Adverse-event reports have been made to the FDA.

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