Herbs and Alternative Supplements - Heart Help or Hype?

Introduction

Do you occasionally drink herbal tea? Ever buy a jar of minced garlic at the grocery store? Sometimes add spices or herbs to foods you cook? Then you too are among the 33% of Americans who use herbal products. As you can see, surveys and studies that define use of herbal products use vague criteria. Herbal products can be effective for a variety of conditions if used in the proper context. For many herbal remedies it takes daily - often multiple daily - doses over the course of many weeks to gain the desired effect. Herbs, for the most part, aren't a quick or easy therapy. Here are some interesting statistics:

• Herbals are the primary source of healthcare treatment for 80% of the world's population - World Health Organization.

• One in three Americans, or about 60 million people, spends an average of $54 on herbals a year, totaling $3.24 billion - Prevention Magazine survey

• Almost 70% of German doctors prescribe herbal supplements for their patients - Reuters News Service

Such impressive statistics may leave those who haven't tried herbal therapies wondering - what am I missing? Statistics can be misleading, so let's probe a little deeper into this topic.

It's true that a large percent of the world's people rely on herbal or botanical remedies. Most don't have any other choice. Basic healthcare and pharmaceutical drugs are simply not available in many sections of the world. If you're poor and can't afford medication, you do what you can including using local roots, herbs and potions. If 70% of German doctors prescribe herbal products, that leaves 30% who don't prescribe them. We're given no information on how frequently this 70% recommend herbs over pharmaceuticals - once a year, once a day, with every patient? In 1995, herbal prescriptions accounted for just 7% of all prescription medications covered by

public health insurance in Germany. This figure sheds a little more light on the frequency of herbal practice by German physicians. Of course, many herbal products are also available over-the-counter in Germany.
We also have the category of alternative supplements, which aren't necessarily herbals, or vitamin/mineral supplements. Many alternative supplements are drugs - they're just regulated differently. Some examples of alternative supplements would be: arginine, PABA, DHEA, creatine, glucosamine, fish oil capsules, and cholestin. Because a product has been popular and on the market for years doesn't mean it's safe or effective. How much do you really know about the supplements you take? People usually spend more time researching their next car or computer purchase than selecting their supplements.

Don't be afraid to call a manufacturer's toll free numbers and ask questions. The National Council for Responsible Health Information (formerly the National Council Against Health Fraud) investigated performance-enhancing claims made by supplement companies. Here's what they found:

• Misrepresentation: Often manufacturers use information that is not 100% accurate. Advertising and public relations firms frequently determine what claims and slogans to use.
• Research currently underway: When asked for research data, many companies say they are in the process of conducting research. If they can't or won't give specific details or put you in touch with researchers, be wary.
• Not for public review: When you are denied access to documentation for label and marketing claims, it's likely they don't have any back-up.
• Testimonials: Everybody loves a good story. Celebrities, sports personalities and even politicians have been used in this popular sales technique. Testimonials are usually paid endorsements.
• Patent or Patent Pending: The manufacturer thinks their product is unique or special. It may be. That doesn't mean it is effective or safe.
• Inappropriately referenced material: A lengthy list of research studies looks impressive. Often, studies cited are poorly designed, don't prove anything, have never been published or reviewed, don't relate to the topic, or may not even exist.

Many of the alternative supplements have one thing in common, they are relatively new supplements. They don't have the history of herbal products or the wealth of investigation and research supporting many of the vitamins and minerals. This doesn't make them bad; we just know less about how they may or may not act to improve or impair health.

HERB APPEAL

Use of herbal preparations in Western cultures began to boom in the early 1990s. You can now purchase exotic herbs and combinations of botanicals in retail outlets ranging from supermarkets to superstores. In 1994 the estimated the market for botanical medicines was approximately $1.6 billion. Americans are expected to spend $4.3 billion in 1999 on herbal supplements that promise to do everything from lifting depression and shrinking swollen prostates to fighting colds and easing stress.

Time magazine's November 23, 1998, issue featured a cover story on the big business behind herbal supplements. Wall Street investment groups

are now sponsoring conferences on how to buy into lucrative botanical medicine companies just as they did with the biotechnology companies a dozen years ago. Some analysts suggest herbal products will maintain yearly growth rates of 12 - 20% for the next several years. Growing herbs is big business too. Herbs for health are grown in the US for export to European and Asian countries. Currently, 43 US approved drugs are derived from herbs.

Herbal remedies are appealing. Plants are living, fresh and green - the very essence of natural. They might seem safer and gentler than synthetically manufactured pills. Using "herbs to heal" sounds better than "taking drugs." Drugs are perceived as negative because of their potential for harm and abuse. Why else would pharmaceutical companies be required to print all the warnings, side effects and negative study results when they advertise their products? As with most debates the issues aren't so simple.

Arsenic, nicotine, heroin, salmonella and alcohol are all 100% natural botanicals and can be toxic or fatal. It all depends on the dose. The ancient philosopher

Top-Selling Herbs in the United States

	$ in millions	Percent of Annual Growth since July 1998
Gingko	138	140+
St. John's Wort	121	2,180+
Ginseng	98	26+
Garlic	84	27+
Echinacea	33	151+
Saw Palmetto	27	138+
Grapeseed	11	38+
Kava	8	473+
Evening Primrose	8	104+
Echinacea/Goldenseal	8	80+
Cranberry	8	75+
Valerian	8	35+
All others	1	
Total	663.4	

Where we buy supplements*

Pharmacy or drug store	32%
Grocery store or supermarket	23%
Direct mail order or personal sales	17%
Health food store	11%
Vitamin supplement store	11%
Club/warehouse store	8%
Health food supermarket	6%

Source: Natural Foods Merchandiser, February/March 1998

*Totals exceed 100 percent as some buy from more than one source.

Paracelsus summarized it best, "Everything is poison. There is nothing without poison. Only the dose makes a thing a poison." As with any nutritional supplement or drug, herbal products can and do have side effects. Botanicals are not inherently safer than other types of remedies. Some plants are harmless or beneficial if you use the berries or flowers, but the leaves can kill you - or vice versa.

From the dawn of history herbs have been known as medicines with the power to cure or alleviate a host of afflictions. The famous "Ebers Papyrus" contains an Egyptian physician's herbal remedies written over 35 centuries ago. The pharmacologic treatment of disease is grounded in the use of herbs. The cocoa shrub from the New World yielded cocaine - the prototype for modern local anesthetics. The bark of Cinchona species yielded quinine, a drug still important in the treatment of malaria. Salacylic acid from willow bark was extracted and refined into aspirin. Echinacea was listed in the US drug formulary before the discovery of antibiotics.

Most herbal remedies do not give immediate results. This can be confusing for the many Americans who seek simple solutions for health problems. Therapeutic effects from botanicals often appear only after weeks or months of continued use. When you visit the doctor for something urgent - you expect immediate relief and recovery.

We also want easy solutions - a pill to swallow just once a day - no injections, multiple medicines or complicated dosing schedules. If you've ever had an infant or toddler with an ear infection, it was thrilling to learn there's a new medicine you can give just once a day for five days. It's not easy to get four, equally spaced doses of gooey pink medicine into a squirming child on ten consecutive days. The most common complaint from physicians is that as soon as a child starts to improve on antibiotics, parents stop the medicine. But most herbal products don't have simple dosage regimens. Europeans and Asians are far more likely to take their herbal tonic as a tea or tincture. Multiple daily doses are common. Often, it takes several weeks to notice any improvement. Herbal and botanical remedies are not simple, easy alternatives.

Herbal products are prepared in a variety of ways. Only a scant number of scientific studies have been conducted using herbal products found on American store shelves. When research shows that a particular herb is beneficial there are many factors to consider before you buy:

- What part of the plant was used?
- What form of the herb was studied?
- What were the marker or standardized ingredients?
- What dose was taken?
- How many times per day?
- How many days did treatment last?
- Is a similar product available in the US?
- How many people were in the study?
- Who were these people and are they similar to you?

NIGHTMARE ON HERB STREET

The herbal marketplace is a regulatory mess. There are no federal standards for botanicals to ensure dose, safety or purity. Many products are standardized according to industry guidelines that differ from producer to producer. Herbal products and botanicals generally don't contain calories, fiber, vitamins or minerals.

Therefore, no RDA or DRI guidelines exist for them. Herbal remedies are usually marketed for their "acclaimed" drug effect, but are not regulated as drugs.

The US Dietary Supplement Health Education Act (DSHEA) uses both "herbs" and "botanicals" when referring to herbal supplements. The more accurate term is botanical, meaning a substance derived from plants or a vegetable drug - especially in its crude state. Herbs, botanically speaking, refer to plants with a non-woody stem that die back in winter. The DSHEA laws of 1994 forbids advertising that implies herbal products treat or prevent specific illnesses. But advertising, product labeling and news reports still claim that "St. John's Wort treats depression" or use "echinacea to prevent colds."

Right now there are four pathways to sell herbal products in the US. A supplier can choose any or all of these distribution channels - each with different requirements.

1. Herbs can be sold as foods. You probably have some in your kitchen right now. They include flavoring spices (parsley, sage, rosemary and thyme) candied ginger, minced garlic, jalapeno peppers and more. Some of these products require Nutrition Facts labeling on the package, some do not. Only those that have significant nutrient value of basic vitamins and minerals must carry this label.

2. Herbal products can be sold as dietary supplements and make claims as to their effect on the structure or function of the human body. These claims are permitted as long as the company has adequate documentation. The FDA is not permitted to request or review this evidence. In addition, any product that makes a structure or function claim must print a disclaimer on their package: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." Search out the smallest print on the label - that's where you'll usually find this note.

3. Some herbal remedies are sold as over-the-counter medication. This permits the use of more specific therapeutic claims - similar to some drug claims. This doesn't mean that the identical product can't also be sold as a dietary supplement, but they must have different labeling.

4. The newest regulatory category available for botanicals is through the Investigational New Drug/New Drug Application (IND/NDA) process of the FDA. Until recently only the US pharmaceutical industry had access to this option. According to the FDA's Center for Drug Evaluation and Research (CDER), there are 50 botanicals or botanical formulas holding active IND applications.

Some herbal companies plan to seek Food and Drug Administration approval to sell their most effective herbs as prescription drugs. That way, doctors and consumers wary of unregulated supplements could choose, for a little higher price, a fully tested and regulated medicinal version. There already is scientific data from Germany that particular herbs have beneficial drug-like effects. Germany's data prompted our National Institutes of Health to finance a study comparing St. John's Wort to the prescription antidepressant Zoloft. The study is designed to determine which product will better help moderately depressed Americans. Such careful

studies are new for the US supplement industry, but more are planned.

Why aren't more companies running scientific trials? There's little incentive to spend up to $500 million on tests that can take 10 to 15 years to complete. That's the process new drugs must complete. But unlike most prescription or over-the-counter drugs, plant material such as an herb can't be patented. Drug manufacturers only profit if they can patent the process used to create, isolate or modify a drug. Competitors are not permitted to copy patented drugs. If a botanical company finances scientific studies about the effectiveness or safety of an herb, competing brands would be able to capitalize on the results.

If healing herbs were always as effective as the spin-offs patented by the drug companies there would be no reason to produce pharmaceutical drugs. Many herbal products are not better or safer than pharmaceuticals. A case in point is aspirin (a derivative of the active component of willow bark.) Aspirin is much gentler on your stomach and easier to swallow than natural willow bark. Both products work, but aspirin has fewer negative side effects. In Herbs of Choice, Varro Tyler calculated you would need to brew 10 cups of the highest quality willow bark tea to make the equivalent of a single aspirin tablet. If you substitute ordinary white willow bark, you'd need 70 cups to substitute for one aspirin.

Almost all synthetic drugs are first tested in laboratory animals before they are tested on people. Animal experimentation greatly speeds up scientific research and points to potential harm or side effects. By contrast, herbal remedy support is often linked to casual observation of what happened to particular individuals. Convincing evidence to support mainstream herbal therapy using US products has not been completed. It's difficult to draw conclusions from studies of other countries that test doses and forms of herbal products not available in the US. Consumers should demand, at the very least, evidence that shows which options are safe and actually deliver the results they promise. According to the Food and Nutrition Science Alliance (FANSA), too few herbal products list the contraindications on their labels to warn consumers of potential ill effects. Responsible manufacturers voluntarily provide this information.

Aside from DSHEA, which went into effect in 1994, manufacturers of herbal supplements are forbidden to advertise that their products treat or prevent specific illnesses. Aside from that, the industry is mostly unregulated. Given the dramatic increase in volume and variety of dietary supplement advertising in recent years, FTC staff has issued guidelines to clarify long-standing FTC policies and enforcement practices related to dietary supplement advertising. You're left on your own to find out what herbs are used for, how much you need and what any possible side effects might be.

Handy Hotline to the FTC 1-202-382-4357 to file a complaint regarding herbal supplements and advertising.

Germany is often praised as the world model for successful regulations and use of botanical medicines. The German rules permit herbs and botanicals to be sold either as self-selected or prescription drugs. Their

government requires absolute proof of their safety and a reasonable certainty that herbs will they do what they promise. The words "reasonable certainty" are extremely important. They require some scientific and clinical evidence be provided prior to approval. These requirements are not the same as would be necessary for a new chemical entity. "Their system is the best because it encourages research," says leading US herb expert Dr. Varro E. Tyler. "The literature is reviewed. They do trials." Because the German system is based in science, consumers are more satisfied and are guaranteed to receive a quality product with proven results.

That is not the case in the United States, where almost anyone can sell herbal supplements and claim it contains an herbal ingredient. US consumers are largely dependent on the good will or integrity of manufacturers. Now that reputable US manufacturers and trusted German supplement companies have entered the market, more reliable, science-based products are becoming available. In late 1998, the USP released the first voluntary US standards for the potency of nine herbal products. Manufacturers that follow these standards can add the letters NF, for national formulary, to their labels. NF is like the Good Housekeeping Seal of Approval for herbal remedies.

BUYING BETTER BOTANICALS

You can't rely on health food sales staff or even pharmacists for accurate information about both the risks and benefits of the herbal remedies they sell. An informal survey reported at the March 1999 meeting at the American Society for Clinical Pharmacology and Therapeutics in San Antonio found that neither pharmacists or health food retailers provided much accurate information on herbal products. For example, almost half didn't know any of the negative side effects of St. John's Wort and valerian root. Since you are on your own when purchasing herbs, here are some tips to follow:

Buy "standardized" preparations.
Standardized means that an herb has been processed so that every pill or capsule contains the same amount of one or more chemical "markers" (not necessarily the active ingredient). It will be listed as a certain percentage of the ingredients. Look for the USP National Formulary (NF) approval on labels.
Choose products that give specific and clear information on dosing. Don't use guesswork to determine how much you need. Start with the smallest recommended dose.
Buy from a reputable company that researches its products. Check with as many sources as you can to find out which companies are good. Supplements imported from Germany tend to be high quality, as do the newer ones from US pharmaceutical companies. Find out what brands are being used in US clinical trials. You can do this by noting the journal source of published research and going on-line to find out which brands were used in the trials.
The Los Angeles Times commissioned a laboratory analysis of ten brands of St. John's Wort. Three were found to have no more than half the potency listed on the label, and another four had less than 90% of the labeled amount. One of the lowest scoring products, with about 20% of the labeled potency, was from Sundown Herbals, a division of Rexall, the nation's #1

distributor of dietary supplements. The other two lowest scores were from Pure Source and Futurebiotics. (Associated Press Article, August 31, 1998)

Don't hunt for bargains. Budget-priced herbal supplements are typically lower quality. As more mainstream companies enter the herbal marketplace prices will come down. In the meantime, purchase name brands you can trust.

Choose solid products rather than the liquid-based tinctures. Most liquids are not standardized. Many active ingredients are less stable in liquid form. Creating a tincture is a simple process of infusing herbs in alcohol, while an extract requires heating and greater concentration of the original material.

Check expiration dates. Since herbs are plant-based, they can quickly lose potency. It has long been advised to toss out any kitchen herbs and spices after 6 months. Currently there are no standards for evaluating the shelf life of herbal products. Choose products with imprinted expiration dates when possible. Like other medicines, store in a cool, dry place.

COMMON MYTHS ABOUT HERBS

Herbal products have been used for their health benefits throughout history. In ancient times, people used herbals because there were few alternatives. Knowledge about herbal remedies was carefully passed down until two to three generations ago when western medicine became the norm. Information almost reached the vanishing point in the rush to modern medicine. Renewed interest in the 1990's sparked a response that was more enthusiastic than knowledgeable. Consumers today are taunted with information then warned not to apply it. Although there are a variety of modern healthcare options available today, the use of herbals is growing. Herbs are now being used in conjunction with traditional pharmacological-based medicines to help maintain health. The benefits of herbals are just beginning to be verified in clinical studies, and scientists are discovering the key ingredients in herbs responsible for their beneficial effects.

Nevertheless, myths persist:

Herbs can't harm, only heal. Some of the most toxic substances on earth are made from plants, for example, strychnine. The most common side effects of toxic herbs are quite vague and are similar to those acquired from drugs, the flu or viral infections. You can develop allergic reactions, cramps, diarrhea, dry mouth, digestive system upset, headache, nausea, and vomiting from taking some herbal products. A significant portion of all currently used pharmaceutical drugs are derived, either directly or indirectly, from active ingredients that have been taken from plants. In spite of this fact:

- 80% of consumers think there is a low risk of side effects or problems with natural remedies.
- 84% rated synthetic drugs as having a moderate to high risk for potential side effects or harm.

Whole herbs are more effective than isolated active ingredients. Many herbs contain a variety of compounds - some helpful and some toxic. Many isolated ingredients from plants become mainstream medicines. They are sometimes safer and more effective when isolated. Penicillin is a good example. Obtained from a mold by the Department of Agriculture during World War II, all of its descendants are single chemicals made by the pharmaceutical industry. The vast

majority of prescription drugs and many over-the-counter medicines are based on single chemicals. Most of these satisfy standards defined by the USP and provide the best control of dose, effect and purity.

All herbs are the same - from my backyard or around the world. When an herb does provide some benefit you need a standardized formula or home "recipe" that carries a consistent dose of the active ingredients that make it work. Wine flavor and quality vary from vineyard to vineyard and melons from one field are sweet while those from another are tasteless. These same variations in climate and growing conditions affect the ingredients in any particular herb. Different species of the same plant may not have the same beneficial effect you desire. Some local co-ops or specialty stores may sell pure strains of herbs or seeds for home gardeners.

Herbs have been used safely for years - no testing is needed. The assumed safety of most herbs is a result of historical tradition - not testing. Testing is "a step in the right direction," said Dr. H.B. Matthews of the National Institutes of Health, at a meeting in 1998 where scientists demanded better quality control from the booming herbal industry. Matthews cautioned that the companies haven't yet proved that their testing methods work and there are no standardized tests. The herb industry is attempting to counter growing complaints about dietary supplements' quality and effectiveness by turning to science. There is a fledgling movement that encourages use of pharmaceutical-style testing to ensure you get what you pay for.

The doctrine of signatures has merit. This ancient belief states that the shape of a plant part determines its therapeutic value. For example, kidney beans are kidney shaped and should cure all types of kidney disease. Walnuts have a ridged surface similar to your brain - they should help with all types of brain disorders. These beliefs are unfounded and research in this area is unlikely.

The Western medical establishment is trying to discredit and discourage use of herbs. There is no conspiracy here - just a lack of knowledge. Most health professionals don't have the time to learn about other systems and styles of caring for your health. After many years of formal training and daily practice, today's health care workers would have to add another new set of professional skills to become proficient at herbal therapies. Not only that, they are expected to set aside the scientific foundation of their training and adopt new treatment options based on testimonials and consumer demand. Some of the first US commissioned scientific studies of botanicals are just being released in the traditional method of peer-reviewed research publications. As more scientific verification of herbal medicines is available, the easier it will be for health professionals to choose them as practice options.

QUALITY PRODUCTS

The cup of coffee you make might be twice as strong as your neighbor’s. The mix of chemicals in your morning brew depends on many variables: the type of coffee, quality of the water, kind of pot or percolator, brewing time and temperature. This chemical combination changes if you make a pot of coffee at 6:00 am and keep it warm all morning for refills. The many variations in this theme illustrate some

To help protect yourself from inferior or unsafe herbal products:

- Look for ingredients in products with the USP NF notation, which indicates the manufacturer followed National Formulary standards established by the US Pharmacopoeia.
- Realize that the label term "natural" doesn't guarantee that a product is safe or free from chemicals. "Think of poisonous mushrooms," says Elizabeth Yetley, Ph.D., director of FDA's Office of Special Nutritionals. "They're natural."
- Consider the name and reputation of the manufacturer or distributor. Supplements made by a nationally known food and drug manufacturer, for example, have likely been made under tight controls because these companies already have manufacturing standards in place for their other products.
- Write or phone supplement manufacturers for more information. Ask the company about the conditions under which its products were made.

Source: FDA Consumer. September/October 1998.

of the problems of self-medication with botanicals. It's difficult to get a consistent dose.

The United States Pharmacopoeia Convention (USP) was established more than 175 years ago when most medicines were obtained from the garden. Some physicians formed this alliance when they realized that the medicinal effects of extracts of plants, such as purple foxglove, varied greatly depending on how they were prepared. Differences in plant variety, garden soil, climate, method of preparation and other factors produced a medicine that was far from uniform. The organization was founded to provide recipes and standards that would result in more uniform medicines having more predictable effects. Doses came to be defined better.

Dietary supplements are subject to looser standards of dose, efficacy, labeling, purity and safety than those required for medicines by the Food and Drug Administration. Only if harm has been proven, can the FDA investigate a supplement.

Ginger and valerian are not approved as drugs in the US, but are used in Europe and Australia for nausea and insomnia, respectively. These materials are derived from roots and each contains at least 50 distinct chemicals. Neither the active ingredients nor how they relieve nausea or insomnia is known.

Poor manufacturing practices are not unique to dietary supplements, but the growing market for supplements in a less restrictive regulatory environment creates the potential for supplements to be prone to quality-control problems. For example, the FDA has identified several problems where some manufacturers were buying herbs, plants and other ingredients without first adequately testing them to determine whether the product they ordered was actually what they received or whether the ingredients were free from contaminants.

SAFETY CLASSIFICATIONS

The American Herbal Products Association (AHPA) publishes the Botanical Safety Handbook (BSH) list of almost 600 herbs and botanical products sold in the US market.

BSH has created a standardization of the safety of these herbal products by developing four classes of herbs with a grading for their relative safety and potential toxicity.

Safety Ratings for Herbs

Class 1: Herbs that when used appropriately, can be safely consumed

Class 2: Herbs for which the following restrictions apply, unless otherwise directed by an expert qualified in the use of the described substance:

- 2a: for external use only
- 2b: not to be used during pregnancy
- 2c: not to be used while breast-feeding
- 2d: other specific restrictions

Class 3: Herbs for which enough information is known to recommend the following labeling:
"To be used only under the supervision of an expert qualified in the appropriate use of this substance." The label must include proper information on the dose, contraindications, potential side effects and drug interactions and any other relevant safety information.

Class 4: Herbs for which insufficient data is available for classification.

Source: Botanical Safety Handbook

SUPPLEMENT SAVVY

Have you ever ventured into a casino? Dim lights, smoky air and a rainbow of flashy games entice you to part with your money. You might wonder if the slots are rigged or the dealers crooked; yet the seductive promise of walking away a winner can be difficult to resist. This same image comes to mind when stalking the supplement shelves. Though the lighting is better and smoking prohibited - you usually don't know what you're getting into; but hopes are high for choosing a winner.

Although most people believe otherwise, supplements are one of the most loosely regulated products in America. In 1994, over two million Americans wrote or called congressional representatives and told them to back-off on supplement regulations being proposed by the Dietary Supplement Health and Education Act [DSHEA (duh-SHAY)]. Supplement manufacturers misled people into thinking that vitamin supplements would become as regulated as prescription drugs - in other words, limited or difficult to get. The public confusion and upset led to passage of a flimsy set of regulations that fail to provide even minimum standards of safety and truthfulness. Instead of requiring that all types of supplements be proven safe and effective, as is required for foods, drugs and additives, the Food and Drug Administration (FDA) must wait for proof that a product has caused serious harm or death before it can be pulled from the shelves.

DSHEA essentially gives dietary supplement manufacturers freedom to market more products as dietary supplements and provide information about their products' benefits on the label. No license, inspection or quality control is mandated. There are no government specifications for scientific testing of supplements. Each manufacturer can determine what type of testing, if any, will

Supplement manufacturers aren't required to completely list the ingredients included in their products. For example, researchers at Cedars-Sinai Bone Center in Los Angeles found that 10% of the older people they studied were taking toxic levels of vitamin D. Two of the supplements commonly used by those in the study (which happened to contain some of the highest levels of vitamin D) didn't even list vitamin D as an ingredient.

be done. Dosages are also set by product manufacturers, not the FDA.

Another example is of a weight lifter disqualified from international competition because he had ephedrine (a potentially harmful stimulant) in his system. In protest over the results of his drug-screening test, he sent his regular supplements to a laboratory for analysis. It was discovered that indeed the manufacturer had included ephedrine (a banned substance) in a supplement without listing it on the ingredient label.

The United States Pharmacopoeia (USP) sets standards for drug products. They recently established standards for individual and combination vitamin and mineral nutritional supplements. These standards detail quality practices for supplement manufacturers. Because the USP is a non-governmental organization, compliance with such standards are voluntary for supplements. However, USP standards for drug products are legally enforceable by the FDA. The USP notation on supplement labels is currently the best way insure product quality.

There are several key measures that are important in making sure that vitamin and mineral tablets and capsules do the job you expect them to. The following quality indicators are based on USP laboratory testing standards:

• Disintegration measures how fast a tablet or capsule breaks into small pieces. Smaller piece size makes it easier for the ingredients to dissolve. If a tablet or capsule does not break down within a certain amount of time, it may pass through your body without being absorbed. Water-soluble vitamins should disintegrate in less than 45 minutes (uncoated) or in less than 60 minutes (coated.)

• Dissolution gages how fast and how much of a vitamin or mineral dissolves in a fluid that is similar to your digestive tract. USP standards track pyridoxine when testing multivitamins. Their standards require that 75% be dissolved within 60 minutes.

• Strength is the amount of a specific vitamin or mineral substance in each tablet or capsule. To meet USP product quality standards, the amount present must be within a narrow range of the amount declared on the label.

• Purity is controlled by USP standards that set a range for acceptable

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impurities that can result from contamination or degradation of the product during processing or storage.

• Expiration dates must be imprinted on the package. When the date is past due the nutrient ingredients in a bottle or package of supplements may no longer meet USP standards of purity, strength, and/or quality.

It's been widely reported that you can test your own supplements at home for disintegration. But home experiments using water or vinegar don't come close to copying the conditions in your stomach or at a laboratory.

THE CLAIM GAME

DSHEA allows dietary supplements to carry "structure or function" claims, but not statements that imply their products can treat, diagnose, cure or prevent disease. All structure or function claims must be based on scientific information about using supplements to maintain health. However, the term "scientific" is defined by the supplement manufacturer or their advertising agency. Thumb through magazine ads for supplements and you'll see that almost anything counts as scientific in the minds of the companies that are challenged to market these products.

Benefit claims have always been a controversial feature of dietary supplement labeling and manufacturers rely on claims to sell products. Can you trust them? DSHEA and previous food labeling laws allow supplement manufacturers to use three types of claims. Nutrient-content claims and health claims follow rules similar to those required for food products. Nutrition support claims, which include "structure-function claims," are unique to supplement products. As with food products, nutrient levels required for any claims are based on DVs and not RDAs.

Nutrient-content claims describe the level of a nutrient in a food or dietary supplement. For example, a supplement containing at least 200 milligrams of calcium per serving could carry the claim "high in calcium" since it provides at least 20% of the DV for calcium. A supplement with at least 12 mg per serving of vitamin C could state on its label, "Excellent source of vitamin C."

Health claims indicate a link between a food or substance and a disease or health-related condition. The FDA preauthorizes these claims based on a review of the scientific evidence or authoritative statements from certain scientific bodies, such as the National Academy of Sciences, that shows or describes a well-established diet-to-health link. As of this writing, a few of the approved claims that appropriate supplements may use include:

• folic acid and a decreased risk of neural tube defect-affected pregnancy (if the supplement contains sufficient amounts of folic acid).
• calcium and a lower risk of osteoporosis (if the supplement contains sufficient amounts of calcium).
• psyllium seed husk (as part of a diet low in cholesterol and saturated fat) and a lower risk of coronary heart disease (if the supplement contains sufficient amounts of psyllium seed husk).

Examples of prohibited claims for a dietary supplement include "protects against cancer," "treats hot flashes," and "reduces nausea associated with chemotherapy." If you find dietary supplements whose labels state or imply that the product can help diagnose, treat, cure, or prevent a disease (e.g., "cures

cancer" or "treats arthritis"), remember that the product is being marketed illegally as a drug and has not been evaluated for safety or effectiveness.

Nutrition support claims describe a link between a nutrient and the deficiency disease that can result if the nutrient is lacking in the diet. For example, an iron supplement label could state that iron prevents anemia. When these types of claims are used, the label must mention the prevalence of the nutrient-deficiency disease in the United States.

Structure-function claims refer to the supplement's effect on the body's structure or function, including its overall effect on a person's well being. Examples of structure-function claims are:

- calcium builds strong bones.
- antioxidants maintain cell integrity.
- fiber maintains bowel regularity.

Manufacturers can use structure-function claims without FDA authorization. Structure-function claims are be easy to spot because, on the label, they must be accompanied with the disclaimer "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

In an effort to correct these problems, the FDA is trying to update DSHEA. "Consumers want access to dietary supplements, but also need reliable information about the products they are consuming," announced William Schultz, FDA's Deputy Commissioner for Policy in explaining the proposed changes. "By clarifying for manufactures what types of claims can and cannot be made on a dietary supplement label, this new proposal helps consumers make more informed and wiser choices."

The Federal Trade Commission (FTC), not the FDA, regulates claims made in the advertising of dietary supplements. In recent years, the FTC has taken a number of enforcement actions against companies whose advertisements contained false and misleading information. Erroneous claims that

Anatomy of the New Requirements for Dietary Supplement Labels

Information that was first required on supplement labels in March, 1999 includes:

- Statement of identity (e.g., "vitamin C")
- Net quantity of contents (e.g., "100 capsules")
- Optional structure-function claim must include the warning "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."
- Directions for use (e.g., "Take one capsule daily.")
- Supplement facts panel (lists serving size, amount, and active ingredient).
- Other ingredients in descending order of predominance and by common name or proprietary blend.
- Name and place of business of manufacturer, packer or distributor. This is the address to write for more product information.

Source: Adapted from FDA Consumer, Sept./Oct. 1998

chromium picolinate was a treatment for weight loss and high blood cholesterol were removed. An action in 1997 targeted ads for an ephedrine alkaloid supplement because they understated the degree of the product's risk and featured a man falsely described as a doctor.

According to many professional groups, including the American Dietetic Association, consumer perception of supplement claims should also be part of the decision-making process. For instance, just what does "strengthen immunity" mean to the average supplement shopper? Preliminary research by the FDA shows that current health claims lead consumers to believe that products are likely to have positive health effects well beyond those promoted on the label.

Ads for supplements have powerful messages that play on your fears and exploit the desire to find an easy and "natural" solution to eating right. The FDA has little control over dietary supplements. This means that you have the responsibility for checking on the safety of dietary supplements and determining the truthfulness of any label claims.

Sport Fuel: Necessary or Not?

The explosive sports food market beckons elite athletes and everyday exercisers alike. But are these high-tech fuels really necessary for the average person? Probably not say sports medicine experts. What most athletes need is calories and water - plain and simple.

Sports Beverages

Hype: Touted as the ideal replacement for water loss during exercise.

Help: You can replace lost fluids with any liquid, but water is best unless you need or want extra calories. Eating any regular foods after exercise can replace lost sodium and stimulate thirst.

Harm: Constant consumption of sports drinks or any other beverage high in sugar can promote tooth decay if you don't brush your teeth frequently.

Energy Bars

Hype: Advertised as instant energizers.

Help: The bars are convenient to carry, but many are only reduced-fat candy bars with some added nutrients.

Harm: None really, except that some bars have close to 500 calories. Be sure to drink plenty of water to help improve nutrient absorption.

Protein Powders

Hype: Protein and amino acid supplements claim to enhance muscle development.

Help: None. Only physical training builds muscle.

Harm: Too much protein can be harmful and may stress your kidneys and lead to dehydration. Taking individual amino acids can also cause nutrient imbalances.

Goos and Gels

Hype: Quick energy (calories) for endurance athletes.

Help: The tubes and packets that hold these products are convenient for long distance runners and cyclists. Most are nutritionally equivalent to jelly or jam.

Harm: High-priced source of calories.

Glycerol

Hype: A way to "hyperhydrate" or store large amounts of water before training or competition.

Help: Glycerol, usually found in fatty foods, chemically attracts and holds water like a sponge.

Harm: May cause bloating and feelings of nausea. While glycerol does enhance fluid retention, there is no proof that this has a positive effect on athletic performance.

In 1999, the Federal Trade Commission (FTC) decided to give consumers a little assistance in evaluating advertising claims. The FTC released a business guide for the dietary supplement industry. For the first time ever, it's spelled out that anyone who "participates directly or indirectly in the marketing of dietary supplements has an obligation to make sure that claims are presented truthfully and to check the adequacy of the support." According to the FTC the amount and type of support needed will depend on a variety of factors. These factors include consumers' expectation of what a claim means, the specific claim being made, how claims are presented in the context of the entire ad, and how statements are qualified. In evaluating the adequacy of support for a claim, the FTC expects to consult with

experts in a wide variety of fields, including those with a background in botanicals and traditional medicines. FTCs definition of dietary supplements includes vitamins, minerals, herbal products, hormones and amino acids.

SUPPLEMENT PROFITEERS

It's not just the claims that are fraudulent, it's also the prices. In May 1999 the US Justice Department won its largest ever case, with fines of $725 million dollars, against several giant foreign drug and chemical companies for engaging in a worldwide conspiracy to raise and fix the prices of vitamins and other supplements. It's estimated that the inflated prices in effect since January of 1990 affected more than $5 billion of common products ranging from vitamins and enriched foods including milk, cereal and pet foods. The firms involved include Hoffman-LaRoche, BASF AG, and Lonza AG. More charges are expected to be filed as the case progresses.

The US market for vitamins and supplements is projected to be worth between $11 and $20 billion. The editor of Nutrition Business Journal estimates that mainstream physicians directly sold about $120 million worth of supplements to their patients last year. Chiropractors, homeopaths, naturopaths and other alternative practitioners sold $680 million in supplements from their offices.

For years the federal government has frowned upon doctors sending blood and urine samples to their own labs for analysis. The concern is that extra tests will be ordered to add profits to the balance sheet. The American Medical Association Code of Medical Ethics says physicians should not let their wallets influence what they prescribe. Would your doctor recommend supplements if they could make as much or more money from selling supplements as from an office visit?
Personal selling creates the lion's share of wealth in the supplement industry. Pyramid selling programs like Amway, Rexall and Shaklee allow anyone to sell supplements. These salespeople benefit personally when you take their advice as does the eager health food store employee who works on commission. If you've ever been asked to sell supplements you are

probably aware that more time and energy goes into training you to be a super-salesperson than knowing much about what you sell.

PROTECTING YOUR INVESTMENT

Here's how to get the most for your money:

• Choose only vitamin/mineral supplements designated as meeting USP guidelines to ensure you are getting a quality product that will deliver what's listed on the label.

• Don't pay extra for "natural" supplements - they all work the same. Minerals are always natural since they can't be made from other substances. Vitamins present in food and plants are considered natural vitamins. Vitamins created in a laboratory are synthetic. There is no difference in most vitamin molecules whether they are synthetic or natural. Synthetic vitamins are usually less expensive, their potency can be better controlled and they may be purer or less contaminated with pesticides and fertilizers. On the other hand, natural vitamins may, by default, include other food components that are beneficial to health.

• Generics can be a good deal. National retailers like K-Mart, Target, and WalMart purchase supplements that are often identical to the higher priced name brands. Compare the labels.

• High potency claims on a supplement label will cost you more. Since "high potency" is not legally defined anyone can slap the term of the label of their supplement. It means nothing. Supplements work best when taken in several small doses spread throughout the day. That's because you can absorb more of a nutrient when your system isn't overloaded. When a high concentration of a nutrient enters your bloodstream, your kidneys work to quickly get rid of the excess. Taking a one-shot supplement isn't ideal, but it is convenient. Time-released supplements don't offer much of an advantage. Since vitamins and minerals are absorbed at different places in the gastrointestinal tract, it's highly unlikely that a time-released tablet will deliver each nutrient at the optimal time and place for absorption. Vitamin sprays and patches are sold in some parts of the US and Canada. Contrary to their marketing literature, it has not been proven that you can absorb more nutrients because they have been applied to your skin or sprayed inside your mouth.

• Take your multiple vitamin mineral supplements with food and water. You need fat and water to maximize nutrient absorption.

• Avoid frills and extras such as glandular products, hormones and amino acids. All of these add-ons can increase the cost of a supplement without a proven benefit. Supplements that include such products often do not completely label or disclose the total amounts of nutrients they contain and may result in potentially toxic doses.

• Check expiration dates. Never purchase supplements past their expiration dates - no matter how cheap they are. In fact, if a product is within 6 months of expiring you can be sure it's lost some of its stability and potency.

• Never store supplements anywhere in your bathroom. The heat and moisture variations may change the

One notable exception to this rule is vitamin E. The natural form of vitamin E (alpha-tocopherol) varies slightly from the synthetic versions (beta-, delta-, and gamma-tocopherol) and the nutrient is more effective in the natural form.

action of the vitamin or speed deterioration. Store supplements tightly capped and safely out of the reach of young children. Most supplements do best in a cool, dry place away from direct sunlight. A high shelf in the kitchen - away from the oven or stove - is usually a good choice.

ALTERNATIVE TO WHAT?

In 1993, a landmark study captured attention for today's alternative medicine movement. It was published in the prestigious New England Journal of Medicine. News stories based on this article proclaimed everyone was jumping into alternative medicine. It made you think - what am I missing out on?

Dr. David Eisenberg wrote a special article (not a clinical research paper): "Unconventional Medicine in the United States, Prevalence, Costs and Patterns of Use." The paper compiled results of a random telephone survey of 1,539. The 1,539 people included only those out of 2,295 households contacted where someone actually answered all of the questions asked. People were excluded who did not speak English, were physically or mentally incapacitated, refused to participate or hung up before finishing the survey. When the participants indicated they had a "bothersome or serious" health problem they were asked if they had seen their doctor for this condition in the last 12 months. Next, they were asked if they had used "any other kinds of therapies and treatments." A list of 16 unconventional therapies was read for each ailment that was noted. The person would say yes or no if they had tried each one. Here's the list in order of most frequently reported therapies:

- relaxation techniques
- chiropractic
- massage
- imagery
- spiritual healing
- commercial weight loss program
- lifestyle diets
- herbal medicine
- megavitamin therapy
- self-help groups
- energy healing
- biofeedback
- hypnosis
- homeopathy
- acupuncture
- folk remedies

These 16 categories included anyone who tried common options for improving their health. Just a few examples of activities that counted as "alternative" include: joining a Weight Watchers group, trying a low-fat diet, napping for relaxation, joining a support group, having a massage, trying to be positive about feeling better, or taking anything more than a one-a-day multivitamin supplement. Newspaper headlines screamed, One in Three People Use Alternative Medicine. The fire was lit.

In fairness to Dr. Eisenberg and his colleagues, their conclusions were quite different from the media reports. The researchers summarized: "Our observation that the majority of users of unconventional therapy did not discuss this therapy with their medical doctors suggests a deficiency in current patient-doctor relations. Medical doctors should begin to ask their patients about their use of unconventional therapy whenever they obtain a history. We suggest that medical schools include information about unconventional therapies and the clinical social sciences (anthropology and sociology) in their curriculums."

It should be added that more physicians are beginning to view diet, nutrition, relaxation, massage therapy, referral to self-help and

support groups as not only conventional - but essential therapy for people with chronic health problems.

EXPERT EVALUATION

If you have a chronic disease, complicated eating preferences, or just like the idea of checking out your food intake it's critical to find a reputable professional to help guide you. As with all trades or professions there is a range of competencies among those who practice. Team up with someone who has a strong academic and practical background in food, nutrition and health. They should be able to personalize suggestions and offer strategies right for you. The endorsement of special diets or nutrition products by people with a string of initials after their name should make you skeptical. Nutrition professionals shouldn't be endorsing specific products. Don't hand over your money to hucksters and celebrities, they may be great salespeople, but they are not usually great nutrition advisors.

Reference

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