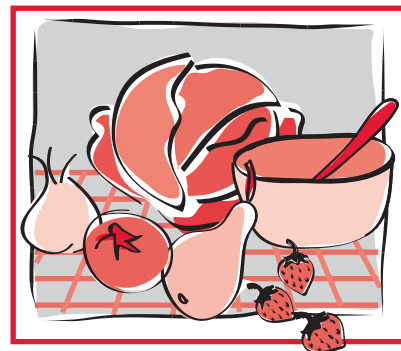


Dietary Supplements: Herbals and Botanicals

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by L. Bellows and R. Moore*

Herbals and botanicals have been used medicinally for thousands of years. Once thought of as ‘traditional medicine’ used by native or ancient cultures, herbal medicine has emerged as a popular complementary and alternative medicine (CAM), or supplement to modern medicine. The herbal market is growing steadily at about 20% each year, and it is estimated that in the United States alone the sale of botanical dietary supplements exceeded \$5.3 billion in 2011. Herbal and botanical supplements are the leading type of CAM for both adults and those under the age of 18. Despite the natural origin of many herbals and botanicals, these substances are considered dietary supplements and should be taken with caution, as their use may result in negative side-effects.

What are Dietary Supplements?

Dietary supplements include vitamins, minerals, herbs, amino acids, enzymes, and other substances that may be ‘supplemented,’ or added to the diet, in order to complete dietary needs or to make up for a nutrition deficiency. These substances are not intended to replace a healthy diet. Dietary supplements may be found in many forms including pills, capsules, powders, drinks, or energy bars. For more information on other forms of dietary supplements, see fact sheet [Dietary Supplements: Vitamins and Minerals](#).

Herbal and botanical supplements are plants used for oral medicinal purposes, and include the flower, leaf, root, and seed of the plant. Herbs and botanicals are sold as dietary supplements, which are regulated differently than pharmaceutical drugs and are sold under the terms: ‘herbals,’ ‘herbal products,’ ‘herbal medicines,’ and ‘herbal remedies.’ Supplements are not required to go through

the same stringent testing as over the counter (OTC) and prescribed medicine, and are not regulated as closely by the Food and Drug Administration (FDA).

Why Take Herbal and Botanical Supplements?

Many consider herbs and botanicals to be natural and therefore healthier and gentler than conventional drugs, even though 30% of all prescription drugs are of herbal origin. Many use herbs and botanicals for a variety of medical conditions, as well as for overall health and well-being. For others, herbal use is grounded in traditions passed down from generation to generation or recommended by folk healers. See Table 1 for the top ten most commonly used herbal supplements.

How Are Herbs Regulated?

Herbal products, similar to vitamin and mineral supplements, are classified by the FDA as dietary supplements, not drugs. As a result, they are not tested for safety or efficacy, and can be marketed at any time without scientific research and without approval from the FDA. The FDA can take regulatory action on an herbal product only after it has received a sufficient number of reports of ill effects, and can demonstrate that the product is unsafe. The FDA can then recommend that the product be withdrawn from the market and/or labeled to reflect potential side effects.

Summary of Herbal Regulation

- Herbs are not standardized, and doses differ between herb capsules and from product to product.
- The active ingredients vary depending on the plant part (flower, root, seeds, nuts, bark, branch), plant form (dried, extract, tincture, tea) and plant species.

Quick Facts

- Herbals and botanicals are sold as dietary supplements and regulated differently than pharmaceutical drugs.
- The Food and Drug Administration (FDA) does not test herbs for safety or efficacy.
- Products that are described as “natural” are not always safe.
- There is no data to suggest that herbs are more beneficial than conventional drugs for treating illnesses.
- The best prescription for disease prevention is a healthy lifestyle.

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Some herbal products may contain impure ingredients (such as lead), and less active ingredients than claimed on the label.

- If a manufacturer follows certain protocols for extracting or drying herbs, they can include United States Pharmacopoeia (USP) or Natural Formulary (NF) on their label. This label does not ensure that doses are similar or that the product is safe, it only provides assurance that the product was properly manufactured and contains the ingredients listed on the label.
- The most rigorous stamp of approval is from Consumer Lab (CL). CL conducts independent tests of products for identity and potency (proper labeling), purity (any contaminants), and consistency (the same identity, potency and purity from one batch to the next). Products that pass their tests contain a CL stamp of approval.
- For information on how to identify nutrition fraud, see fact sheet [Nutrition Misinformation: How to Identify Fraud and Misleading Claims](#).

Are Herbs and Botanicals Effective?

Current research shows limited health benefits from taking herbal and botanical supplements, and no conclusive evidence that herbals should be used to treat or prevent any type of medical condition. There is no data to suggest that herbs are more beneficial than conventional drugs for treating illnesses. However, there is enough evidence to support the limited use of herbs and botanicals under the guidance of a medical professional. The body of well-controlled research is growing, but the short-term and long-term benefits and risks, as well as active or beneficial ingredients are still largely unknown.

To address this uncertainty, federal law states that herbs cannot claim to prevent, diagnose, treat or cure a condition or disease. Herbs may carry health-related claims about effects on the "structure or function of the body" or "general well-being" that may result from the product. This definition is very loose and gives rise to misleading health claims. The consumer is ultimately responsible for checking their validity and avoiding products with fraudulent claims.

Are Herbs and Botanicals Safe?

Though many herbs are considered safe, some have hazardous side effects especially in children, pregnant women, or those with underlying medical conditions and diseases. Herbals and botanicals have the potential to interact with prescription medications, over-the-counter drugs, vitamins and minerals. For example, ginkgo taken with ibuprofen may lead to spontaneous and/or excessive bleeding. High doses of garlic may enhance the effects and adverse effects of anticoagulant and antiplatelet drugs, including aspirin, clopidogrel (Plavix), enoxaparin (Lovenox), and others. Herbs are not as closely regulated as drugs and other medications, though they are often used for similar purposes. Herbs are not recommended in place of medical treatment or conventional medicine for chronic conditions or diseases, such as severe depression, diabetes, hypertension, and heart disease. Herbs also are not recommended for those who may be immuno-compromised (such as the elderly or those with HIV), those with kidney damage or liver disease, anyone who may be undergoing surgery or other invasive procedures, pregnant or lactating women, or children under the age of six.

To date, the FDA provides a warning for the following herbs which are considered toxic, and given their side effects, should be avoided:

- *Aristolochic Acid*—kidney damage and a carcinogen. It may be found in products with guan mu tong, ma dou ling, birthwort, Indian ginger, wild ginger, colic root, and snakeroot.
- *Chapparal*—irreversible liver damage.
- *Comfrey*—liver toxicity, carcinogenic effects, and damage to fetus if used during pregnancy.
- *Ephedra/ma huang* (ephedra sinca)—hypertension, myocardial infarction (MI), seizure, stroke, psychosis.
- *Germander*—liver damage and death.
- *Kava*—liver damage, especially risky for those with liver problems.
- *Lobelia* (Indian tobacco)—breathing problems, rapid heartbeat, low blood pressure, coma, or death.
- *Magnolia-stephania preparation*—kidney disease and permanent kidney failure.
- *Willow bark*—Reye's syndrome in children, and allergic reaction in adults.

- *Wormwood*—seizures, numbness of legs and arms, delirium, and kidney failure.
- *Yohimbe*—hypotension (low blood pressure), heart conduction disorders, kidney disorders, nervous system disorders, death.

Summary

Consumers should be informed in order to protect themselves from questionable health products and services. The following are tips intended to help one become more aware of the risks associated with taking herbal and botanical supplements:

- Determine whether an herbal supplement is truly needed.
- Stay informed by researching the product to determine: safety, validity of claims, dosage, most effective form, plant part, species, time frame of use, side effects, counter indications with other supplements or medications, and reasonable price.
- Inform a doctor, pharmacist and other health care professionals of any herbs being considered or routinely used. Consult them with any questions.
- Choose brands that have been tested for consistency in dosage by looking for the United States Pharmacopoeia (USP), National Formulary (NF), or Consumer Lab (CL) symbols.
- Read the product label and follow the instructions closely.
- Use herbal products only for minor conditions and only on a short-term basis. If a condition is serious or chronic, consult a medical professional.
- Discontinue use if adverse side effects are experienced.
- Avoid herbal therapies if you suffer from certain conditions or under certain circumstances. (See the section located above: 'Are Herbs and Botanicals Safe?')
- Do not take herbal products known to be toxic. The list in this fact sheet may not include all potentially toxic herbs, so check the resources listed in this fact sheet regularly, for additional toxic herbs.
- The best prescription for disease prevention is a healthy lifestyle that includes a diet high in whole-grains, fruits and vegetables, and low in fat. Physical activity also plays an important role in reducing one's risk for disease.

Additional Resources

For more information and advice for choosing herbal and botanical products, see The National Institute of Health's (NIH) Office of Dietary Supplements website- *Botanical Supplement Fact Sheet*: <http://ods.od.nih.gov/factsheets/list-Botanicals/>

For in depth information regarding supplement regulation see the NIH Office of Dietary Supplements website: <http://ods.od.nih.gov/factsheets/BotanicalBackground-HealthProfessional/>

For more information on how to spot a false health claim, see the Federal Trade Commission (FTC) website: www.ftc.gov/bcp/edu/pubs/consumer/health/hea07.shtm

For information on recent supplement alerts and safety information, see the Food and Drug Administration (FDA) website: <http://www.fda.gov/ForConsumers/ConsumerUpdates/UCM2006894.htm>

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Table 1. Top ten most commonly used herbs.

Yes: Research supports efficacy/safety of this product when used appropriately. See disclaimer below.

Inconclusive: Not enough clinical evidence available to determine effectiveness.

No: Research finds that it is ineffective or unsafe.

Except where noted in comments, research indicates these 10 herbs appear to be safe *when used appropriately*.

Common name, source	Main uses and health claims: Is it effective?	Possible side effects	Comments
Echinacea (<i>Echinacea angustifolia</i>)	<ul style="list-style-type: none"> Reduce duration of colds: <i>No</i> Boost immune system: <i>No</i> Heal wounds: <i>No</i> 	<ul style="list-style-type: none"> GI symptoms including nausea, abdominal pain, diarrhea, and vomiting Allergic reactions (especially those allergic to the daisy/ aster family). 	<ul style="list-style-type: none"> Echinacea products are frequently mislabeled or may contain no Echinacea, or contaminated with selenium, arsenic, and lead. Do not consume if you have reduced immunity (HIV, lupus tuberculosis), or take medications that may be toxic to the liver (anabolic steroids).
Evening primrose oil (<i>Oenothera biennis</i>)	<ul style="list-style-type: none"> Reduce menopausal symptoms (hot flashes): <i>No</i> Reduce breast pain: <i>Yes</i> Treat eczema: <i>Yes</i> Treat ADHD: <i>No</i> Treat rheumatoid arthritis: <i>Inconclusive</i> Treat osteoporosis: <i>No</i> 	<ul style="list-style-type: none"> Well tolerated by most individuals; stomach upset and headache may occur. 	<ul style="list-style-type: none"> Good source of gamma-linolenic acid (GLA), an essential fatty acid, which may be responsible for the health benefits of evening primrose oil. May act as an anticoagulant – do not take with anticoagulant/ antiplatelet drugs including aspirin and ibuprofen.
Feverfew thin (<i>Tanacetum parthenium</i>)	<ul style="list-style-type: none"> Reduce migraines, headaches: <i>Yes</i> Treat arthritis: <i>Inconclusive</i> 	<ul style="list-style-type: none"> GI discomfort when taken orally. Mouth ulcers and inflamed mouth tissue when chewing leaf. 	<ul style="list-style-type: none"> May inhibit platelet activity – ask pharmacist/doctor before taking with anticoagulant/ antiplatelet drugs.
Garlic (<i>Allium sativum</i>)	<ul style="list-style-type: none"> Reduce the risk of heart disease: <i>Yes</i> Lower high blood cholesterol: <i>No</i> Lower high blood pressure: <i>Yes</i> Prevent cancer: <i>Inconclusive</i> Treat athlete's foot: <i>Yes</i> 	<ul style="list-style-type: none"> Safe for most individuals. Increase in bleeding. Breath or skin odor. Possible nausea, heartburn, or diarrhea at high doses. Topical garlic can cause skin irritation, blistering and burns. Asthma and other allergic reactions are possible. 	<ul style="list-style-type: none"> Fresh garlic is the best form. Garlic contains allicin. If consuming high doses of garlic, do not take blood-thinning, anticoagulant drugs, ginkgo, ginger, <i>Panax</i> ginseng, or high-dose vitamin E. Garlic may decrease the effectiveness of oral contraceptives and other drugs. Avoid taking 7 days prior to surgery.

Table 1. Top ten most commonly used herbs. (continued)

Common name, source	Main uses and health claims: Is it effective?	Possible side effects	Comments
Ginger (<i>Zingiber officinale</i>)	<ul style="list-style-type: none"> Prevent motion sickness: <i>Inconclusive</i> Reduce morning sickness: Yes Reduce nausea: <i>Inconclusive</i> Used as digestive aid: <i>Inconclusive</i> Treatment for rheumatoid arthritis, joint, and muscle pain: <i>Inconclusive</i> 	<ul style="list-style-type: none"> Well tolerated when used in small doses. High doses may cause abdominal discomfort, heartburn, diarrhea (most often may cause abdominal associated with powdered ginger. 	<ul style="list-style-type: none"> May increase the risk of bleeding - ask pharmacist/doctor before taking with anticoagulant/ antiplatelet drugs, garlic, ginko, taking with anticoagulant/ or <i>Panax ginseng</i>.
Ginkgo biloba (<i>Ginkgo biloba</i>)	<ul style="list-style-type: none"> Improve age-related memory impairment and dementia: <i>Inconclusive</i> Improve visual field in glaucoma and diabetic retinopathy: <i>Inconclusive</i> Lowering blood pressure, reducing hypertension: <i>No</i> 	<ul style="list-style-type: none"> Mild gastrointestinal (GI) upset, headache, dizziness, palpitations, constipation, and allergic skin reactions. Spontaneous bleeding. 	<ul style="list-style-type: none"> Decreases platelet activity and may increase risk of bleeding - do not take with anticoagulant/ antiplatelet drugs, garlic, ginger, or <i>Panax ginseng</i>.
Ginseng (<i>Panax ginseng</i>)	<ul style="list-style-type: none"> Improve cognitive function: Yes Enhance athletic performance: Yes Improve mood: <i>No</i> Lower blood glucose: Yes 	<ul style="list-style-type: none"> Side effects rare, especially when used short term in recommended doses. Headaches, gastrointestinal distress. Menstrual abnormalities, breast tenderness. Insomnia. 	<ul style="list-style-type: none"> Not recommended for people with autoimmune diseases, bleeding conditions, cardiac conditions, or diabetes. May decrease platelet activity - ask pharmacist/doctor before taking with anticoagulant/ antiplatelet drugs, garlic, ginko. Do not take with stimulants, including excessive caffeine.
Green tea extract (<i>Camellia sinensis</i>)	<ul style="list-style-type: none"> Reduces risk for cancer: <i>Inconclusive</i> Reduces risk for heart disease: <i>Inconclusive</i> Controls blood pressure: <i>Inconclusive</i>. 	<ul style="list-style-type: none"> Moderate intake of green tea extract is safe for most individuals. Nausea if consumed on an empty stomach. 	<ul style="list-style-type: none"> Interferes with iron absorption. Consult with a medical professional if taking anticoagulant medications.
St. John's wort (<i>Hypericum perforatum</i>)	<p>Orally:</p> <ul style="list-style-type: none"> Treat depression: <i>Inconclusive</i> Improve premenstrual syndrome: <i>Inconclusive</i> Treat obsessive compulsive disorder (OCD): <i>Inconclusive</i> Treat seasonal affective disorder (SAD): <i>Inconclusive</i> <p>Topically:</p> <ul style="list-style-type: none"> Used for wounds (inflammation), muscle aches, first-degree burns: <i>Inconclusive</i> 	<ul style="list-style-type: none"> Insomnia, anxiety, irritability, gastrointestinal (GI) discomfort, diarrhea, fatigue, dry mouth, dizziness, and headache. Photosensitivity. Hypomania in depressed patients. 	<ul style="list-style-type: none"> Not recommended for people with major depression, bipolar disorder, chronic depression, Alzheimer's disease, or ADHD. Do not take with antidepressants, barbiturates, or alcohol. Check with pharmacist/doctor about other potential herb-drug interactions. Women taking St. John's Wort and oral contraceptives concurrently should use an additional or alternative form of birth control.
Saw palmetto (<i>Serenoa repens</i>)	<ul style="list-style-type: none"> Treat benign prostatic hyperplasia: <i>Inconclusive</i> Improve overall prostate health: <i>Inconclusive</i> Enhance sexual vigor: <i>No</i> 	<ul style="list-style-type: none"> Well tolerated by most individuals. Dizziness, headache, and gastrointestinal complaints such as nausea, vomiting, constipation, and diarrhea. 	<ul style="list-style-type: none"> Check with pharmacist before using saw palmetto anticoagulant/ antiplatelet drugs, contraceptive drugs, or estrogens.

Disclaimer: Information concerning herbals and botanicals is constantly changing; therefore take all herbs with caution. Herbs generally are not recommended for people suffering from autoimmune disorders or liver disease, those undergoing surgery or other invasive medical procedure, pregnant or lactating women, or infants and small children. Use herbs only for minor conditions and only for the short-term. Discontinue if you experience any adverse side effects.