



Herbal Medicine: An Introduction

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WHAT ARE HERBS?

Herbs are “Crude drugs of vegetable origin used to treat various diseases (usually chronic) in order to attain or maintain health.”¹

The popular notion of herbs is that they are a benign and “natural” alternative to expensive pharmaceuticals.

HOW ARE HERBS DIFFERENT FROM OTHER DRUGS?

In the United States, products which are sold with or without a prescription must meet certain standards. These include safety, efficacy, purity and bioavailability. Bioavailability means that when you take the drug, it will reach an effective (therapeutic) level in your body. A drug may be safe and effective, but if it never reaches an effective level in your body, you might as well not take it. The drug must also be listed in an official source such as the United States Pharmacopoeia or the National Formulary.

These standards are regulated by the Food and Drug Administration, which sets the standards for any product sold with the claim to cure or treat disease. Although herbs have been used for centuries, most have not undergone the rigorous and expensive testing required by the FDA to be “official.”

Official drugs also have specific names, so they cannot be confused with any other drugs. Herbs, on the other hand, tend to be sold under vague and regional names. Snakeroot, for example, is a term that can apply to at least 6 different plants.¹ The same applies to ginseng.¹ There are many varieties of ginseng, and not all are equivalent. In the U.S. herbs are sold labeled as food supplements and not as drugs. As a result, purity, quality, and identity may vary greatly from product to product.

HOW DID THE GOVERNMENT GET INVOLVED?

The reasons why we have a Food and Drug Administration (FDA) go back to the turn of the century. At that time, anyone could concoct a preparation using anything at all and sell it as a “cure-all.” Most of the time, the

stuff was just worthless or, at most, owed its effect more to its alcohol content than to anything else. Some products were actually dangerous-in effect, poisons.

In 1906, the Food and Drugs Act was passed, aimed at curbing the worst of the frauds and charlatans. In 1912, the Act was amended to prohibit misbranding and adulteration of drugs. That is, you couldn't sell an “all vitamin tonic” if it was mostly whiskey with little vitamin content, and you couldn't claim it was “pure spring water” when it actually came from the city pump.

Safety and efficacy were not addressed until 1937. At that time, the S.E. Massengill Company of Bristol, Tennessee, marketed an Elixir Sulfanilamide.

Sulfanilamide was an approved antibiotic but it had to be dissolved in a solution (“vehicle” is the fancy term) so that people could measure and take a dose. The vehicle used was diethylene glycol—similar to antifreeze and very toxic. As a result, 105 people died of kidney failure before anyone realized that the diethylene glycol was the culprit.¹ This led to the Federal Food, Drug and Cosmetic Act (1938), requiring drugs entering interstate commerce to be proven safe.¹ All components had to be safe, not just the drug itself.

The Durham-Humphrey Act of 1951 separated drugs into 2 classes: Prescription and Non-prescription.² Drugs which were generally deemed safe for use in an unsupervised manner were classed as Non-prescription, or Over the Counter (OTC), and could be purchased by the consumer without a prescription. The rest were classed as drugs requiring medical supervision and placed under Prescription status. These could only be purchased with a prescription and only from a pharmacist.

Only drugs approved by the FDA are legal in

the United States and they must fall into one of the two categories mentioned above. Drugs that are legal in other countries but not in the United States may be brought into this country only if they are legally obtained (or prescribed) in the country where they are legal and then only in quantities for the individual's personal use.

In 1962, the Kefauver-Harris Amendment required that all drugs (and their component parts) be both safe and effective.¹ This move was largely in response to the thalidomide tragedy. Although marketed in Europe for 10 years, thalidomide was finally identified as a teratogen (causing birth defects). Drugs marketed prior to 1938 were “grandfathered” in, but those sold between 1938 and 1962 had to prove both safety and efficacy. Since efficacy was difficult to prove, many drugs were withdrawn from the market. The same amendment also tightened requirements on the manufacturing end of the pharmaceutical industry, requiring clean premises and equipment, uncontaminated processing, purity of ingredients, and rigorous testing.²

The Division of Medical Sciences of the National Academy of Sciences - National Research Council organized a Drug Efficacy Study which lasted from 1962 to 1969.¹ In 1972, 17 panels were formed to look at 17 different therapeutic classes of drugs, including the OTC class, in which herbs and herbal products would have been included.¹ Since the number of products to be evaluated was huge, the panels relied extensively on clinical trials and “in vitro” (laboratory) studies. For most herbals, such studies did not exist. As a result, herbals lost their “official” status and were considered “misbranded” if they were sold with any claims for the prevention or treatment of disease.¹

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WHAT MAKES A PRODUCT “OFFICIAL”?

The United States Pharmacopoeia (USP) and the National Formulary (NF) are accepted as the legal standards for all drugs sold in the United States. These volumes set specific definitions for biological potency, biological availability, percentages of ingredients, solutions, tablet and capsule characteristics, exact name, chemical formula, type of inert ingredients, safety, efficacy, and so on. The “label” is the official product statement detailing the chemical description, use, activity in the body (kinetics), contra-indications, side effects, known adverse reactions, appropriate dosages, procedure for over dosage, and consumer information. The company manufacturing and marketing the drug can be held legally liable for this information.

WHERE DOES THAT LEAVE HERBS?

The final word on OTC products was released in 1990. Because so many herbals could not be proven safe and effective through clinical trials, it was ruled that they could not be sold with any claim of medicinal value. (The other side of this coin is that since clinical studies and trials are so expensive, the new drug is protected with a patent. Herbals being what they are, they cannot be patented. A manufacturer cannot recoup the money spent on studies; therefore, there is no incentive to even try.) Since the FDA has such stringent requirements for a product to be marketed as a treatment or cure for a specific ailment, all labeling relating to the treatment of specific conditions was removed from herbs in 1990.

The FDA does maintain 3 lists of Herbal categories:

- Generally Recognized as Safe (GRAS)
- Herbs of Undefined Safety
- Unsafe Herbs

As a further downside, since the herbals are not official, and are sold without any claims on their labeling, they are not really subject to any regulation in the United States. This means, unless you buy from a very reputable manufacturer, you may not be buying what you think you are buying.

POINTS WORTH PONDERING:

1 Since plant names are non-specific (e.g., snakeroot and ginseng, mentioned above), you may believe you are buying a plant product known for its high concentration of medicinally active substances, while you are actually getting a cheaper, easier to obtain but worthless “cousin.” You pay the premium price in any case.

2 Not all parts of the same plant are equal. The active component may concentrate more in one part of the plant than another. If the concentration is higher in the leaves than in the roots, and the product you purchase is ground-up root, you may be paying “leaf” prices for a “root” product. Toxicity can be a more serious problem. Toxic compounds may concentrate in one part of the plant more than others. If you purchase a product containing significant portions of the toxic part, you may become very ill. An example is Comfrey. Some varieties of Comfrey contain high concentrations of toxic compounds, particularly in the roots. Only the leaves of *Syphytum officinale* L. are medicinally useful and then only externally.¹

3 Environment greatly influences plants. Too or too little sun, too much or too little moisture can affect how the plant grows, and growth characteristics influence the amount of active ingredient present when the plant is harvested. The timing of harvesting also influences the concentration of active compound. Some herbs are more potent in spring, some in the summer, some in the fall. Unfortunately, this information is not on the product’s label.

4 Since there are no standards regarding purity, some products are adulterated with other substances. For instance, herbals have been found to include non-steroidals such as ibuprofen (Motrin®, Advil®).³ Others may contain aspirin, caffeine, ephedrine, even diazepam (Valium®).^{3,4} Since ingredients like these do not appear on the label, you have no way of knowing if they are present, and no way of avoiding substances you may not want or to which you have an allergy. Buying diazepam without a prescription or government safeguards may sound “fun,” but a therapeutic dose may affect driving, or pre-employment drug screens—do you really want to explain how you tested positive for a drug you don’t take? Don’t buy an herb thinking you are getting a FDA-controlled OTC drug—you may get nothing at all (best scenario) or a toxic dose of something else entirely.

5 Imported Chinese herbs have been found contaminated with arsenic, mercury, and lead.⁴ Even herbals produced in the U.S. have been found to containing pesticide residues. Contamination may also occur from insects, rodent droppings, hair, and anything else which may be in the vicinity when the products is prepared. Volatile oils (from various sources) may be added to

herbal teas to enhance the flavor or aroma.¹ Again, these are not always mentioned on the label.

6 Consistency is frequently lacking. A manufacturer of aspirin must guarantee that if the label says “100 MG”, each tablet must contain no less than 95 MG and no more than 105 MG in the tablet. No such requirement exists for herbals.¹ Percentages of the labeled content actually contained in the product vary wildly, with 0% not uncommon.

Common Sense: Buy only from a reputable supplier.

But aren’t herbs sold in Europe without all this fuss?

Yes, to some extent. The German Bundesgesundheitsamt (Federal Health Agency) began evaluating the safety and efficacy of herbal medicines in Germany in 1978.¹ Commission E was the agency established to carry out this task. Since then, the Commission has published about 435 monographs regarding the safety and efficacy of various herbs. The findings of Germany’s Commission E are probably the most accurate and scientific available to date and are rapidly becoming a standard of reference for herbs.¹ Inclusion in the Commission E reports makes a drug “official” in Germany and many other European countries. The monographs, which are available in English, cover approved uses, contra-indications, side effects, adverse reactions, drug interactions, and other specific information necessary to rational product selection.⁶

ISN’T ALL THIS CAUTION JUST A PLOT BY THE AMA?

Not really. There is legitimate concern among health care practitioners about the safety and quality of herbals. There is also, too often, a lack of knowledge. The use of plant products and herbals is not generally taught in medical school and rarely in pharmacy school.

Originally, all medicines were derived from herbal sources. The effective use of medicines, however, depends heavily on being able to standardize doses, and, as we have discussed, plants vary tremendously. With the progress of technology in the twentieth century, it became possible to isolate a plant’s active chemical compound, reliably reproduce that compound in the lab, standardize it, and then mass produce the compound for use as a medicine. Digitalis, quinine, caffeine and many anti-cancer agents

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are derived from plant sources.

Most of the response of the health care profession is in reaction to paraherbalism. Paraherbalism is a term coined by Dr. Tyler^{1,5} to describe people who tend to disregard all scientific evidence and rely instead upon mysticism and a belief that only natural products can be effective and safe. That these beliefs are extremely popular can be seen in the proliferation of popular books and other publications on herbals. Recurrent themes of paraherbalism include:^{1,5}

- Herbs cannot harm, only cure.
- Whole herbs are more effective than the isolated active components.
- Natural and Organic are superior to synthetic.
- The Doctrine of Signatures is meaningful.
- Astrology is significant.
- Animal tests are not applicable to humans.

These themes are worth looking at more closely:

HARMLESSNESS

In regard to the harmlessness of herbs, it is well known that plants can contain very toxic ingredients. Examples include ricin (Castor bean), cicutoxin (hemlock),⁷ muscarine alkaloids (amanita mushrooms),⁷ and aconite (monkshood). Other common natural-but-toxic plants are poison ivy, oleander, and autumn crocus.

Whole vs. Isolated Components, Superiority of Natural and Organic

Remember, modern medicine got its start because scientists saw the value of isolating and administering the pure medicinal compound without its being diluted or counteracted by other compounds present in the “natural” plant. A pure chemical compound is just that—a single molecule. That molecule is the same whether it is produced by chemical reactions in the lab or distilled from the plant. Your body doesn’t know the difference as long as the chemical structure is identical.

DOCTRINE OF SIGNATURES

The Doctrine of Signatures is an ancient belief that a plant is shaped like the part of the body it is supposed to heal. This is the origin of legends that certain fruits and vegetables are aphrodisiacs. Yet, the shapes of useful plants have little relationship to the parts of the body receiving the benefit. Foxglove, from which we derive digitalis, looks nothing like the heart. The Pacific Yew, from which Taxol[®] (for breast cancer) is

derived, looks like a tree. Similarly, kidney beans are not useful for renal disease.

ASTROLOGY

A true believer in astrology and astrological influences may perceive some benefit; however, there is little evidence to support the effects of astrology.

ANIMAL TESTS

There are some compounds which truly have different effects in different animal species. This is why testing is required in several species prior to testing in humans. But in general, if it poisons animals, it poisons humans. If a cure can be effected in animals, cures should also be effected in humans.

POPULAR HERBS

Echinacea

• Traditional uses: prevention of colds, flu; immune system booster; immune system stimulant.

• Side effects include nausea and vomiting; tingling sensation on tongue.

• Overuse can actually suppress the immune system (through overstimulation).

• People suffering from immune disorders including lupus, AIDS, and rheumatoid arthritis SHOULD NOT USE!

• Do not use if allergic to sunflowers.

• Three different varieties of the Echinacea species have been studied. Both Button snakeroot and Missouri snakeroot have been substituted for Echinacea. Neither of these has any useful properties, but substitution is difficult to detect.

• The exact compound (or compounds) in Echinacea responsible for its action is unknown.

Garlic

• Traditional uses: as an anti-hypertensive; used to lower cholesterol; anti-inflammatory activity.

• Side effects: nausea; increased insulin (hypoglycemia); anti-platelet activity (bleeding may result).

• Will potentially interact with anti-coagulants.

• Should NOT be used in pregnancy.

• The principle active compound in garlic is allicin (this is also the smelly part).

• Although it is difficult to substitute something else for garlic (due to the distinctive smell) it is not impossible. “Odorless” garlic may have the allicin removed and may therefore be less effective.

St. John’s Wort

• Traditional uses: treatment of depression and anxiety; topically for burns.

• Adverse reactions include: dyspepsia, restlessness; rash from topical application.

• Certain foods and other drugs should be avoided. Foods to avoid include beer, aged cheese, red wine, yeast, pickled herring, etc. If you are taking these drugs, avoid St. John’s Wort. Drugs to avoid include antidepressants (MAOI class, TCA class, SSRI class), dextromethorphan (the DM in Robitussin DM), some parkinsonian medications. Your doctor or pharmacist can advise you.

• The active components are in the fresh leaves and flowering tops. One active component is hypericin, which gives the oil extract a reddish color. Hypericin is also implicated in the photo-toxicity associated with topical use.

Ginkgo bilboa

• Traditional uses; improve memory, treat asthma, peripheral vascular disease, Alzheimer’s.

• Side effects: headache, dizziness, vertigo, nausea, seizures (in children), diarrhea.

• May interact with anti-hypertensives, anti-coagulants, non-steroidal anti-inflammatory agents.

• An extract prepared from the leaves contains the active components, of which some have been identified. The commercial preparation is standardized to 24% flavone glycosides.

• Cross sensitivity with poison oak and poison ivy.

Saw Palmetto

• In Europe, popularly believed useful for treating benign prostatic hypertrophy.

• Adverse reactions include: headache, nausea, diarrhea, hepatitis.

• May interact with Proscar[®], Propecia[®].

• The active compounds are not water soluble, so teas made from the berries are ineffective.

• Be advised: the sale of non-prescription preparations, such as saw palmetto, for use in treating BPH is banned by the FDA due to the lack of efficacy studies. This is where the labeling issue becomes very important. It is also illegal for the person selling such products to claim the BPH can be treated using saw palmetto (or any other preparation).

• For your safety, have BPH diagnosed by a medical doctor. The problem could be pro-

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static cancer, not BPH, and self-treatment could delay anti-cancer therapy past the time it could be useful.

Ginseng

- Traditional uses: relieve stress, lower cholesterol, improve exercise performance, relieve symptoms of aging, relieve fatigue; an adaptogenic.
- Side effects include nervousness and irritability; also headache, diarrhea, insomnia.
- Use with caution in hypertension and during pregnancy; may interact with anti-coagulants.
- The species cultivated in the Orient is (both) *Panax ginseng* C.A. Mey and *P. schin-seng* Nees. The species cultivated in the United States is *P. quinquefolius* L. Because the demand in the Orient for the American species is so great, it has been overharvested to the point where it is now an endangered species. Cultivation, harvesting and sale are subject to intense regulation, making authentic ginseng difficult to obtain.
- Many of the active components have been identified, but good studies are difficult because ginseng contains dozens of components, some of which counteract each other. There are also many different plants called ginseng, with several species within the same genus. Studies to date have yielded non-specific and inconclusive data.
- Because the root is man-like in shape, the ancient Doctrine of Signatures implies that ginseng is appropriate for all of mankind's ills.

Kava Kava

- Traditional uses: treatment of mild to moderate anxiety, insomnia, depression; relieve pain, stress, restlessness.
- Do not take if you have Parkinson's Disease; may interact with other CNS depressants and alcohol.
- Other side effects include euphoria, visual disturbances, deafness.
- One commercial "Kava Kava" preparation, Kavatro!, is actually a combination of several herbs.

Black Cohosh

- Traditional uses: treat symptoms of menopause, menstrual irregularities; treatment of PMS; has also been recommended as an anti-diarrheal and a cough suppressant.
- Adverse reactions: dyspepsia, hypotension, nausea, vomiting, headache, slow pulse.
- Avoid during pregnancy and lactation.

- Was one of the original ingredients in Lydia E. Pinkham's Vegetable Compound (along with alcohol).

- Alcoholic preparation of the herb was found effective by Germany's Commission E, for treatment of PMS and dysmenorrhea.

Valerian

- Traditionally uses: treat insomnia, anxiety, muscle tension, restlessness.
- Adverse effects include: headache, nausea, excitability, cardiac disturbances, emotional lability.
- Drug interactions are most likely with other CNS depressants and alcohol.
- Germany's Commission E has approved valerian as a mild sedative/hypnotic; the FDA is still awaiting clinical studies.

Horse Chestnut Seed

- Traditional uses: cure arthritis and rheumatism (by being carried in one's pocket); promote circulation in the legs, relieve varicose veins.
- Adverse effects include: diarrhea, cardiac irregularities, hypoglycemia, pruritis, nausea, vomiting; may color urine red.
- One active component is aescin. Aescin does have some diuretic effect and has been shown to reduce edema by stabilizing cell membranes and altering the transport of water and proteins. Return blood flow to the heart has also been shown to improve.
- Horse chestnut is used in Europe to treat chronic venous insufficiency; NOT approved in the U.S. for this condition.
- Swelling in the legs can be a sign of a serious problem. Have all swelling and pain in the legs evaluated by a medical doctor.

Aloe

- Traditional uses: externally for minor burns, sunburns; internally as a laxative.
- Side effects include: local irritation (external), diarrhea cramping (internal).
- The mucilainous gel for topical use and the juice used as a laxative come from different parts of the plant and should not be confused.
- Aloe may act by inhibiting bradykinin and thromboxane. There also appear to be anti-bacterial and anti-fungal activity. Different studies of aloe preparations on wound healing have yielded different results, some showing positive effects and some showing detrimental effects. Overall, aloe gel appears to be most beneficial for minor abrasions and burns.

Chamomile

- Traditional uses: topically as an anti-inflammatory agent; orally for indigestion, stomach discomfort, peptic ulcer, GI spasms; insomnia.
- Persons with allergies to ragweed, asters, or chrysanthemums should not use chamomile.
- Adverse reactions include: nausea, vomiting, contact dermatitis, severe allergic reactions.
- Chamomile is expensive and easy to adulterate; use only whole flower heads with few stems present.

Ginger

- Traditional uses: motion sickness, nausea, arthritis, muscle pains, migraines; appetite stimulant.
- May prolong bleeding times by inhibiting thromboxane and prostacyclin; the anti-emetic activity is due to local effect on the GI tract and not to any CNS activity.
- May interact with oral anticoagulants, calcium channel blockers.
- Adverse effects include nausea, CNS depression, cardiac arrhythmias.

Feverfew

- Traditional uses: migraine prophylaxis, fever reduction, arthritis pain.
- Appears to act as a serotonin antagonist (serotonin mediates migraine headaches); lowers the pain threshold.
- Adverse reactions: contact dermatitis, mouth ulcerations, nervousness, anticoagulation effects.
- For migraine, best if taken regularly; not very effective if the migraine has begun.
- May interact with anticoagulants, SSRIs (antidepressants).

Herbals: The Bottom line

- Buy herbs from a reputable source.
- Be sure all ingredients are clearly listed.
- Remember that herbs are for short-term use and for mild to moderate conditions; if symptoms persist or worsen, see a medical doctor.
- Certain conditions should be always evaluated by a medical doctor before taking any type of medication: pain, swelling, tenderness in the legs, symptoms of prostatic enlargement, unexplained vaginal bleeding, severe pain of any type, persistent cough or hoarseness, difficulty in swallowing, and persistent chest pain or heartburn, especially

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if accompanied by pain, numbness, or tingling in the jaw, shoulder or arm.

- Always inform your physician and pharmacist (and other health care practitioners taking a medical history) of all herbals and OTC medications you are taking.

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