

HERBAL DRUGS: IS NATURAL ALWAYS SAFE?

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Commenting on herbal medicine and their safety is a very daunting task. Herbal medicine is the world's most ancient form of medicine. Every ancient civilisation used plants for healing and much of this knowledge is still used today. Around three-quarters of the world's population, especially those in developing countries, rely on herbal medicine. Huge numbers of people take herbs and vitamins, but very little is known scientifically about either their effectiveness or their safety. It is assumed by the public that something that is "natural" must be safe, but it should be kept in mind that when you take an herb that you are ingesting a chemical that has a biologically active function.

Herbal medicine uses plant as whole or its parts to treat illness, relieve common ailments and restore health. Some traditional systems also use mineral and animal products. Almost quarter of all modern prescription drugs, including aspirin, are derived from plant sources. The medicinal part of the plant is harvested or extracted and then either dried for use in teas or made into ointments, powders, pills, capsules, lozenges, pessaries or liquid tinctures. Traditional herbal medicine treats the whole person rather than individual symptoms, and a prescription is individually formulated to stimulate the body's natural healing powers.

The medicinal properties of different plants have been identified by trial and error - and later through scientific investigation - over many centuries. The 16th century alchemist Paracelsus believed the appearance of a plant gave clues as to what it could be good for medicinally. This theory is known as the '**doctrine of signatures**'. Chinese herbal medicine classifies herbs according to their taste and effect on different internal organs and acupuncture meridians. In Western herbal medicine, each medicinal plant is thought to contain ingredients that prevent side effects as well as those that cure. For this reason, Western herbalists believe it's better to use ingredients from parts

of the whole plant rather than just isolated individual ingredients, as is common in modern pharmaceuticals.

Safety first

Millions of people take herbal supplements because they want to ingest something safe and healthy. Just because a herb is natural doesn't mean it's safe. Some plants are highly toxic if taken in large dosages, or may have side effects when combined with other herbs or medicines. It is mostly believed that **"Every herb is a blessing from God. All are pure and natural for our benefit"**.

Allopathic drugs, to come to market, must undergo hundreds of millions of dollars of clinical testing to prove their efficacy and measure their toxicity. Almost none of the herbs in common use today have been tested scientifically in the way that prescription drugs have been tested. Only in recent times have universities and private industry taken these traditional uses and run clinical studies to determine how they might be working or have worked in the past and predict what they might be useful for in the future. Between 25% and 50% of pharmaceutical drugs on the market today are derived directly from, or from a model of, a plant chemical. This plant chemical cannot be used directly as it comes from nature because it cannot be patented and protected financially, so the chemical must be altered into a new entity, an analog, and then tested for efficacy and toxicity. If this new chemical works and isn't too poisonous, it is entered into the hundreds of millions of dollars of testing to bring a new drug to market.

The herbs in themselves, as whole herbs, are generally much milder, generally not toxic, take longer to work, and are much more complicated than pharmaceutical drugs. Pharmaceuticals are monostructures; that is they contain one single chemical. Herbs can contain hundreds and hundreds of chemicals, each doing something different in the bodies, often times offsetting toxicities. But some herbals are more potent than some allopathic or prescription drugs. They are more likely to cause problems if taken incorrectly. E.g., strychnine, morphine, digitalis.

Poor-quality herbs may contain contaminants or only small amounts of the active ingredient. Certain oriental herbal formulations may contain animal products taken from protected species.

How do we know that what is on the label is what is in the bottle with herbs?

Bottles of the same herb from different manufacturers can vary a lot. This aspect of commercially available herbal preparations is not well regulated. You can pick up two bottles of St. John's Wort, and you can be getting two completely different medicines. This is the greatest problem that faces herbal medicine today.

Herbal medicines, once found only in health food stores, are now sold in supermarkets, mass-market drugstores, and even via trickily produced infomercials. This has resulted into making herbal remedies are big business. Surprisingly enough, young people are fueling that increase.

Are herbal medicines safe to use?

Yes, herbal medicines can be acceptably safe to use with care. It is important to remember, however, that natural does not necessarily mean safe. Different ways of risk: for example,

- if the patient information is insufficient; or
- if the remedy is made to low standards.
- If it is adulterated or contaminated with heavy metals or pharmaceutical ingredients.
- Carries a possible risk of side effects or of interacting with other medicines.

There are hundreds of herbal preparations available. Some are safe, some are effective, and some are neither. Even doctors may have no idea what is actually in these products. Compounding the confusion is the fact that the FDA does not regulate the supplement and herbal medicine industries because herbs are classified as foods, not drugs. But just because something is labeled "all natural" doesn't mean that it is safe. For example, one popular supplement, *ma huang*, marketed as a weight-loss aid, has been linked with kidney stones, hypertension, anxiety, and even death in some cases. The herbs kava and comfrey have been linked to serious liver damage. Some herbal supplements have been found to be contaminated with metals, unlabeled prescription drugs, microorganisms, or other substances.

Guidelines for Using Herbal Remedies

1. Because herb/drug interactions can occur, always tell your doctor if you are using and/or thinking about using an herbal remedy.

2. Be aware that just because something is "natural" does not mean that it is safe.
3. Note that lack of standardization can result in differences among particular products, and even among different batches of a particular brand.
4. Do not use herbal remedies in pregnancy.
5. Never use larger than the recommended dose.
6. Long-term use of herbal remedies should be avoided except under the supervision of a healthcare provider.
7. Avoid herbal remedies with known toxic effects and known side effects, such as ma huang.
8. Any illness that does not get better in a reasonable time requires medical attention. If symptoms persist, see your doctor.
9. Many herbal medicines are taken by drinking a tea. Avoid concentrating or over-steeping a tea remedy.
10. An herbal treatment that does not work, even if it won't hurt you, could delay getting necessary medical treatment. Don't waste time further....
11. A "natural" product from a plant is not necessarily better than the same chemical produced in a laboratory.
12. Some herbal products contain active ingredients that can produce unexpected side effects (for example, Saw palmetto contains estrogen, a female hormone).

Examples of potentially harmful plant remedies:

Herb	Potential Toxic Effect
Borage (<i>Borago officinalis</i>)	Skin irritation
Calamus (<i>Acorus calamus</i>)	Skin irritation, stomach upset, may cause cancer
Chaparral (<i>Larrea indentata</i>)	Liver damage
Comfrey (<i>Symphytum officinale</i>)	Liver damage
Ephedra; Ma-huang (<i>Ephedra sinica</i>)	Agitation, high blood pressure, rapid heart beat, convulsions
Germander (<i>Teucrium chamaedrys</i>)	Liver damage
Life root (<i>Senecio aureus</i>)	Liver damage
Pennyroyal (<i>Mentha pulegium</i>)	Liver damage. Concentrated oil can cause convulsions, shock, and multi organ failure
Sassafras (<i>Sassafras albidum</i>)	Liver damage. Concentrated oil can cause hallucinations, trembling, shock, and possibly cancer.

Some Herbal Medicine Products Contain Potentially Toxic Amounts of Heavy Metals. An analysis of a sample of Ayurvedic herbal medicine products (HMP) found that 20 percent contained metals such as lead, mercury and arsenic at levels that could be toxic if taken as directed, according to a study in the December 15 issue of *The Journal of the American Medical Association*. The researchers found that 14 (20 percent) of the 70 HMPs contained lead, mercury and/or arsenic, and that if taken as recommended by the manufacturer, each of these could result in heavy metal intake above the published regulatory standards. Lead was found in 13 HMPs; mercury in 6 HMPs; and arsenic in 6 HMPs. Half of the HMPs containing potentially toxic heavy metals were recommended for children. The 14 HMPs containing heavy metals were manufactured by 11 different companies. Of the 30 stores visited, 24 sold at least one heavy metal-containing HMP. If such is the case in a developed country like USA, then the situation in developing country like India can be imagined. The presence of heavy metals in Ayurvedic HMPs and the numerous reports of associated toxicity may have important public health, clinical, and policy implications.

Used properly, herbal remedies can be a part of a healthy lifestyle, but they are not a replacement for regular exercise, a well-balanced diet, or adequate sleep.

Herbal Medicine, Uses & Abuses

In the absence of any regulatory authority, anyone who wants to grind up some herbs and put them in a capsule or compress them into a pill can sell them without any proof that they are either effective or safe. There is no assurance that the herbs you buy today will have the same potency as those you buy next month-even if they are bought from the same company. Herbs by their very nature are not "pure" substances. Their composition will vary according to the climate in which they were grown, the fertilizers that were used to grow them, the insecticides that were sprayed on them, etc. When you use an herbal medicine, you are ingesting not only a biologically active chemical, but all the other "junk" that may be mixed in with it. Recently it has come to light that some herbal products have even been found to contain animal byproducts used as "fillers". It's possible that these byproducts could be harmful, and possibly even place the consumer at risk of diseases such as Mad Cow Disease.

Another area of concern is the possibility of herb-drug interactions. This issue is vastly under researched. For example, when used alone ginseng has few serious side effects. When combined with Warfarin, its anti-platelet activity might cause excessive anticoagulation. The issue of other interactions between herbal remedies and synthetic drugs are certain to play a significant part in the discussion about the safety of phytomedicines.

Like many complementary therapies, herbal medicine aims to be holistic - it aims to treat the whole person, not just the symptoms, and to encourage the body to heal itself. Different parts of the same plant, such as the flowers or seeds, leaves or roots can have very different actions. Herbal medicine is not about isolating the active ingredients from a plant which is the way that conventional medicines are often derived.

Do they work?

There are herbal medicines available that claim to treat almost any common complaint, but there is usually limited scientific evidence that these work. Some herbal treatments are more established, and have undergone some clinical testing. These include:

- St John's wort, for the treatment of mild to moderate depression,
- black cohosh, for menopausal symptoms,
- echinacea, to reduce the symptoms of colds,
- garlic, to reduce blood cholesterol levels and potentially lower the risk of heart disease,
- ginger, to relieve nausea and vomiting,
- ginkgo biloba, to improve mental performance in people with Alzheimer's disease,
- hawthorn berries, for mild heart failure,
- horse chestnut, for chronic venous insufficiency,
- saw palmetto, for enlarged prostate.

However, the herbal medicines that are not listed may also be effective. The evidence for these is conflicting and further studies are needed.

If you have heart disease such as angina, high blood pressure or glaucoma, herbal treatments should not be taken without supervision from a trained herbalist or a doctor. Life

threatening illness are not suitable for treatment by a herbalist, such as epilepsy or heart problems or type 1 (insulin-dependent) diabetes.

Should you use it?

An associated risk is that by treating symptoms that are signals of a serious condition with herbal remedies, time is lost in giving tried and tested mainstream medicines.

Several other systems of medicine use herbal remedies as a main part of treatment, including Aromatherapy, Hindu Ayurvedic medicine and Chinese herbal medicine. Herbal medicine forms just one part of the Ayurvedic system and is used - along with yoga, massage, diet and meditation - to balance the body and increase "prana", or life energy. Chinese herbal medicine works on the same principles as acupuncture – herbs are used to boost or disperse energy. It is rare that a Chinese herbalist will prescribe just one herb. They are more likely to prescribe a complex cocktail of about ten different herbs.

Herbal medicines: Where is the evidence?

Sales of herbal medicines are soaring. In the United States, sales of herbal supplements are approaching \$4 billion a year. St. John's Wort, a herbal antidepressant, sales increased 2800% in one year. Faced with such figures, physicians need to be as educated in herbal treatments as they are in prescription drugs. There is no protection for the public against low quality and unsafe herbal remedies. For example, two recent cases of severe nephropathy caused by Chinese herbal tea. Because herbal supplements are not regulated, enormous variations exist in the quality. For example, Germany is often praised for high standards in quality control of herbal medicine industry. Yet when commercial products of Devil's Claw were tested, they found no consistency between batches.

Fast Facts

- The contents of many herbal products don't match the ingredients listed on their labels.
- In addition to their direct toxicity, herbal medicines may also cause dangerous problems by interacting with conventional drugs and reinforcing or antagonizing their actions.

Other natural remedies include minerals such as iron and calcium, and materials obtained from animal sources, such as glucosamine and chondroitin sulfate.

Are herbal medicines safe?

We simply don't know. Manufacturers are not required to perform safety studies before selling herbal or other natural products, nor are they required to maintain records of adverse events or to report them to the FDA. Many people incorrectly assume that remedies used for centuries must be safe. Unfortunately, we have learned in recent years that many traditional herbals have dangerous, and even fatal, side effects.

For instance, herbal medicines called birthwort or snakewort, made from extracts of *Aristolochia* plants, have been used all over the world for more than 1,000 years. We now know that these plants contain aristolochic acids, substances that can cause kidney failure and cancer of the kidney. Yet, herbal remedies that contain aristolochic acids can still be purchased in retail stores or on the Internet.

Herbal remedies for arthritis

Herbal remedies promoted for the treatment of arthritis include, ginger, Chinese Thunder God Vine, willow bark extract, feverfew, cat's claw and stinging nettle. While there is some evidence that ginger and willow bark extract may relieve pain, these remedies contain chemicals that are similar to conventional nonsteroidal anti-inflammatory compounds (NSAIDs) like naproxen and ibuprofen. NSAIDs may cause inflammation of the stomach and intestines. Further, they can interfere with blood clotting and lead to fluid retention, causing problems for people with high blood pressure or heart failure.

Chinese Thunder God Vine also relieves pain and inflammation, but chronic use may cause weakening of the immune system and bones (osteoporosis). In view of the lack of information about quality control, safety and effectiveness, the use of herbal remedies is not recommended.

Phytomedicine or Herbalist: What is it?

Phytomedicine or herbal medicine is the science, art, and exploration of using botanical remedies to treat illness. A French physician named **Henri Leclerc** (1870-1955) was the person who coined the term phytomedicine when he wrote numerous essays on the use of medicinal plants. Treatment of disease with plants has been around since ancient times. It has been used by the ancient Greeks, the Romans, early Egyptians, ancient India as well as Native American Indians.

A list of the ten fastest growing industries in the world would include herbal medicines. The interest in using herbal medicine spans all generations, but shows a definite spike in the elderly.

Herbalists believe that the body is a self-healing organism and that herbs should be chosen to enhance wellness, not simply relieve symptoms or treat disease. They look to reestablish a homeostatic balance in the body despite the varying environmental pressures.

For the most part, it would seem that herbal therapy addresses many chronic complaints that are only partially treated by conventional medicine and also everyday complaints in which people seek relief from a pill bottle. Again, instead of trying to block or reverse the process that produces disease, herbal therapy attempts to assist the body in search of wellness. The longer the condition exists, the longer it will take to restore the homeostasis or cause any change in the body.

Three 'Mis-es' Responsible for Unsafe Herbal Use

Dr. Varro Tyler from Columbia-Presbyterian indicated that the potential hazards of herbal medicines result in large part from misuse, misrepresentation and mislabeling. These "mis-es" would continue to plague users of herbal medicine until quality standards for herbal products are established and enforced.

Misuse refers to patient overdosing and concomitant drug consumption. Kava, for example, is used as an anxiolytic and a mild tranquilizer in dosing ranging from 60 to 120mg of kava pyrones daily. Some users may consume as much as triple this amount for extended periods of time without concern for the potential dangerous effects, which include malnutrition, liver and renal dysfunction and pulmonary hypertension.

Misrepresentation occurs when drug manufacturers distort or inflate the relative benefits from the products they distribute. A notorious example is Mexican yam, which was widely promoted as a natural progestin that would be safer than prescription estrogens and progestins for perimenopausal and postmenopausal women. A component of wild Mexican yam, diosgenin, is a progestin precursor- but only in the laboratory. However, when ingested or used topically it has no effect.

Mislabeleding, or improper identification, refers to instances where substitute herbs are included in a formulation. One example is a case of Siberian Ginseng that was thought to interact negatively with

a heart medication. However, it was found that this product was made with Chinese silk vine instead and thus misled the consumer in a potential dangerous fashion.

The fresh juice of aloe is effective in wound healing and burns while the dried juice is a cathartic. In high doses, aloe's strong laxative effect might be harmful to children or the elderly but is likely safe for most people.

On the other hand, some cancer clinics in Mexico have promoted laetrile. Laetrile, found in apricot pits, was restricted in this country as a cancer treatment a number of years ago because of its toxic nature. Research indicated that it was neither effective nor safe because the pits have a cyanide compound. Sassafras is likewise neither effective nor safe.

Coltsfoot may be effective for coughs but is not safe. Research has revealed that all of the plant including the leaves and the flowers contain a compound poisonous to the liver and that coltsfoot has produced cancerous tumors of the liver when rats were fed high doses.

About 1 in 6 herbal remedies is considered unsafe while the safety of a similar number has not been proven. In other words, 37 percent of the herbal remedies are either known to be unsafe or their safety is unknown.

Tests by independent laboratories of herbal products have revealed that they vary greatly in the amounts of active ingredients present. Also the bulk fillers used may or may not be safe. Unfortunately, many producers have poor quality control standards.

The future of herbal drugs is shadowed by the pervading lack of regulatory control. Although research is being done, it is very limited and buyers are often left on their own to decide what is safe and effective for them. Doctors along with other professionals are now working on untangling this herbal maze.

The Safety of Herbal Products, Hope versus Hype

Many people believe in the safety of herbal products because they are "natural". Because herbal products are classified as dietary supplements, not drugs, and face none of the premarket hurdles that drugs must clear, consumers have no assurance of safety or effectiveness. Therefore, herbal preparations on the market, besides the possible dangers cited above, could be poor quality or

contaminated. The journal American Family Physician pointed out that some herbal remedies contained lead, arsenic and steroids.

A recent article in the Journal of American Family Physician states “several deaths related to ephedrine-containing products have led some states to impose a ban on their sale.” Guarana (a form of caffeine) was listed as an ingredient also. The combo of Guarana and Muhuang is more likely to cause high blood pressure, stroke or even death. It also contains Ginseng, which can cause insomnia, depression, headaches, palpitations, and high blood pressure. Finally, the product contains Chromium Picolinate, which has been shown to cause chromosomal damage in animal studies and kidney failure in one woman.

What can you do to learn more? Do your research. Talk to your doctor and herbalist.

Study the benefits and risks of a chosen herb and find out the chance it could be adulterated.

Further reading :

BOOKS

- *Herbs of Choice: The Therapeutic Use of Phytomedicinals* by Varro Tyler
- *The American Pharmaceutical Association Practical Guide to Natural Medicines* by Andrea Peirce
- *The Green Pharmacy* by James A. Duke
- German Commission E monographs - American Botanical Council www.herbalgram.org

WEB SITES

- www.consumerlab.com, a free resource on plant to drug interactions and their safety.
- Columbia University Medical Center's Fact Sheets on Alternative Medicine at www.acpmcnet.columbia.edu/dept/rosenthal/factsheets.html
- The National Institute of Health's National Center for Complementary and Alternative Medicine at www.altmed.od.nih.gov/nccam
- The U.S. Food and Drug Administration's Dietary Supplement Information Page at www.cfsan.fda.gov/~dms/supplmnt.html
- American Botanical Council at www.herbalgram.org

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