# Herbal Medications - Issues Related To Their Use - Part I

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## Objectives

1. Explain when, why, and by how much the use of herbal products by Americans increased in the United States.
2. Describe the proposed mechanisms of action for the herbal products reviewed in this article and the primary reason why people use them.
3. Discuss which herbal products reviewed in this article should be used with caution in patients with hypertension, epilepsy, and immune disorders, and in those taking certain medications.
4. Discuss which herbal products reviewed in this article should not be used prior to surgery, near delivery by pregnant women, or in conjunction with other drugs that may decrease the ability of blood to clot.

## Article

### Issues Related to the Use of Herbal Medications – Part I

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**Background and History:**

To start, hundreds of herbal ingredients are in existence and alone or in combination make up thousands of products that can be purchased by the public without a prescription. One of the purposes of this article (and others that will follow in the series) is to inform nurses about some of the medical effects that can be seen with certain products. It is important to remember that a large portion of prescription and non-prescription drugs come from herbs or are derivatives of herbs. Therefore, many herbs can produce an effect on an individual medically when taken internally. Furthermore, nurses and everyone in the healthcare field should understand why these have become so popular. We should not take the stance that they are all hocus-pocus and ineffective. On the contrary, some have been shown to be effective; however, some have not been shown to be effective.

As background, the sale of drugs to the public has been occurring for hundreds of years. In the 1800's and even early 1900's, there were traveling salesmen that promoted "miracle drugs". These "miracle drugs" could have been simple sugar water, whereas others may have been something addicting such as alcohol or opiates. In 1927 the Food, Drug, and Insecticide Administration was formed in the United States for the purpose of protecting the public from charlatans. The Insecticide portion was later moved to a different area in the government leaving us with the Food and Drug Administration or FDA, as we know it today.

In 1938, the goal of the FDA was changed by an Act passed in Congress. Under this original Act of 1938, drugs (both prescription and non-prescription) had to prove safety before they could be sold to the public. However, in 1961 it was discovered that drugs could be teratogenic (produce birth defects) when taken by pregnant women in the first trimester. It was determined that Thalidomide (a drug used for treating anxiety and nausea in Europe) had produced

severe limb defects in the newborns of women who had used the drug in the first trimester of pregnancy. In 1962, Congress passed an amendment to the original Act, which required that drugs had to be "effective" as well as "safe" before they could be sold to the public.

Therefore, in the mid to late 1960's, the FDA began to evaluate the effectiveness of all drugs that had been approved since 1938 "as being safe". This in depth review initially began with prescription drugs. The review of over-the-counter (OTC) drugs began in 1972. These review processes are still ongoing. In the mid to late 1980's, the FDA began to review herbal products. However, this changed when "The Dietary Supplement Health and Education Act of 1994" was passed, which removed the FDA's authority to regulate "dietary supplements". Herbal medicines and natural remedies are classified as "dietary supplements" and thus are no longer reviewed by the FDA.

The passage of this 1994 Act in conjunction with other factors has resulted in an explosion in the use of herbal products by people in the United States. Americans spent an estimated 3 to 4 billion dollars on herbal medicines and "natural remedies" in the year 2000, an increase of 10 fold from 1994. An estimated 80 million Americans used an herbal medication in the year 2000, excluding vitamins. As with nearly everything in medicine, there are pros and cons to what has occurred.

Under the current FDA system, all prescription and OTC drugs must go through a rigorous research and development process to prove that a drug is "safe and effective". In addition, there are restrictions on what can be placed on the label. For the most part, this results in good protection for the public. The downside is that the drugs become much more expensive, can usually only be obtained through a physician, and are delayed in their release for marketing to the public (a problem for good products that are needed in treating difficult medical problems, i.e. HIV, etc.). In essence, it is a balance between patient convenience and need to that of safety and efficacy.

For herbal medicines and natural remedies, there is no FDA process. Therefore, currently there is no testing that is required before a product is released and proof of effectiveness is not mandatory. Proof of safety is also not required from the maker; instead the FDA has to prove that the product is unsafe. Proof of product purity and accuracy in the amount of active ingredient from pill to pill is not required. Furthermore, there are no standards on the accuracy and amount of information that is to be supplied on the label. Thus, herbal products are easier to obtain by the public and are much less expensive when compared to prescription drugs. However, in some respects we have reverted back to a system that predates 1927. A few recalls have occurred with herbal products. For example, the FDA has asked that some Chinese Herbs for treating diabetes be removed because glyburide and phenformin were detected. In addition, a few herbs for improving circulation were removed because aristolochic acid was detected, a chemical that can permanently destroy the kidneys.

Why have herbal medications become so popular? Many answers to this question have been offered, however, the true answer is probably a combination of factors. The following list contains some of the more common responses to this question.

1. Many Americans have lost faith in the medical profession so let's try something natural.
2. If it's "natural", it must be safe (but people should remember that opium, marijuana, tobacco, and poison mushrooms are natural!)
3. Natural remedies might be the treatment that can be used for a medical disorder in cases where the standard healthcare system says, "no other treatment is available", or "everything we can do has been done", or "the only way we can treat you is with xyz drug" (a drug that often has significant side effects, for example, chemotherapy treatments, etc.).
4. Over 1000 books have been published on "how to stay healthier" by using herbal medicines and natural remedies. "With this much literature in print, there must be some truth!"

**Current Knowledge on Herbal Drugs:**

Many of the herbal products have been studied, however, the majority of these reports come from Europe or Asia. In addition, the majority of studies are not randomized and placebo-controlled. However, because of the huge increase in usage in the past few years, the number of needed studies to determine safety and effectiveness have begun to increase. Still, very few studies if any have been performed on the potential effects of herbal products when used during pregnancy. In addition, no studies to date have ever determined whether herbal medicines have a teratogenic risk if taken in the first trimester.

Extensive herbal medication usage has been ongoing in Europe for a long period of time compared to that of the United States. In the early 1980's, Germany developed its "Commission E" (CE), which was a 24-member group of physicians, pharmacists, toxicologists, and pharmacologists that reviewed the literature on 380 herbs and published monographs on their conclusions. This review process occurred from 1983 to 1995. The World Health Organization (WHO) has also started to review some herbal medications and is creating monographs. Twenty such monographs have been completed with an additional 30 due by the end of 2001 to 2002. Currently, there are no ongoing reviews in the United States by an organized group of researchers. The information regarding the herbs in this article comes from Commission E and WHO reports as well as the most recent literature.

**Herbal Medication Usage in the United States:**

The top selling herbal medicines in the United States as of 2000 are seen in the list below:

1. Ginkgo Biloba
2. St. John's Wort
3. Ginseng
4. Garlic
5. Echinacea
6. Saw Palmetto
7. Kava Kava
8. Grape Seed
9. Cranberry
10. Valerian Root
11. Evening Primrose
12. Bilberry
13. Milk Thistle
14. Ginger

Because of the shear number of Americans who use herbal medicines, it is imperative that nurses learn more about these remedies and that they alter their present history taking to include a specific question regarding the use of any herbal or "natural remedy" product. The herbal drugs discussed in this article are the first 5 on the list, number 12, and number 14.

**Ginkgo Biloba:**

Ginkgo Biloba is currently the number one selling herbal product in the United States. It has several other names including Madenhair, Silver Apricot, Duck Foot, and Kew. People primarily use this herbal medication for improving memory, to treat leg pain caused by circulation insufficiency (claudication), and for treating altitude sickness. However, many other uses have been reported in Chinese medicine and folk medicine including the treatment of bronchitis, sexual dysfunction, and to improve liver and gallbladder function.

Several randomized placebo-controlled studies have been performed to date regarding improvement in memory and the treatment of claudication, most of which show that it is effective (though some have not shown benefit). However, the studies showing effectiveness primarily used the standardized dry leaf extract by acetone and water. Its proposed mechanism of action is that it decreases blood viscosity and thereby improves flow. Improved blood flow to the central nervous system may also improve memory.

Ginkgo is also a potent inhibitor of Platelet-Activating Factor (PAF) and thereby decreases the ability of blood to clot. Because of this action, Ginkgo should not be used prior to surgery or near delivery (if pregnant). In addition, its use with other drugs or herbs that might affect clotting is also not recommended including aspirin, non-steroidal anti-inflammatory agents, heparin, or warfarin (Coumadin), along with some of the other herbal products mentioned in this article.

There have been a few case reports suggesting that Ginkgo might be associated with seizures, though this has not been confirmed to date. If a relationship exists, it might be that Ginkgo in some patients lowers the seizure threshold in people who are prone to having seizures. Therefore, it is not recommended for use by patients with epilepsy.

**St. John's Wort:**

St. John's Wort is the number 2 selling herbal product in the United States. It has several other names including Hypericum, Klamath Weed, Demon Chaser, and Goatweed. People primarily use this herbal medication for treating anxiety, mild to moderate depression, and sleep disorders. Other reported uses have included the treatment of headache and gastric indigestion.

Several randomized placebo-controlled studies have been performed to date regarding the use of St. John's Wort in treating mild to moderate depression and or anxiety. Many of these showed that the product was effective (though again, some have not shown benefit). Its proposed mechanism of action is that it inhibits the uptake of certain neurotransmitters including serotonin, norepinephrine, and dopamine. It also appears to have mild monoamine oxidase (MAO) inhibiting effects. Therefore, it appears to have an action similar to a selective serotonin reuptake inhibitor (SSRI). However, whether it effectively crosses the blood-brain barrier is not fully known.

Because of its potential SSRI mechanism of action, the use of this drug with other SSRI drugs (such as Prozac, Paxil, Zoloft, Luvox, and Celexa) and MAO inhibitors is not recommended. In addition, because it can increase levels of dopamine and norepinephrine, its use in patients with hypertension (especially if not well controlled) should be monitored closely. St John's Wort has also been shown to decrease the effectiveness and or blood levels of digoxin, theophylline, reserpine, and the HIV protease inhibitor – Indinavir.

**Ginseng:**

Ginseng has become the third most purchased herbal product in the United States, despite the lack of well-controlled studies. It actually comes in three major forms, which are Asian or Panax, American, and Siberian. Other names for the Panax form include: Chinese, Korean, Japanese, Oriental, or red ginseng, as well as Ren Shen, Seng and Sang. The American ginseng is also known as Canadian, Wisconsin, Ontario, and North American ginseng. The wild form is very difficult to find. The Siberian ginseng is also known as Ciwujia, Devil's Bush, Eleuthero Ginseng, and Thorny Pepperbush.

For the most part, people use ginseng for boosting vitality and to fight fatigue. However, many other uses have been reported in Chinese medicine and folk medicine including the treatment of diabetes, headaches, and intestinal disorders. Only a few randomized placebo-controlled studies have been performed and the results vary on its effectiveness. Its proposed mechanism of action is that it stimulates nicotinic receptors. It also may lower blood glucose levels and increase blood pressure in some individuals.

All three major forms appear to have anti-platelet effects and thereby can decrease the ability of blood to clot. Therefore, ginseng should not be used prior to surgery or near delivery if pregnant, and should not be used with other drugs or herbs that might affect clotting including aspirin, non-steroidal anti-inflammatory agents, heparin, or warfarin (Coumadin), along with some of the other herbal products mentioned in this article.

Because it might lower blood glucose levels in some individuals, it should be used with caution in patients with diabetes (especially those using insulin or other glucose altering drugs because of an added effect) and in patients who have difficulty with hypoglycemia. This herb should also be used with caution in hypertensive patients, especially the Siberian form.

**Garlic:**

Garlic is the number four selling herb in the United States and has been around for centuries. Other names for this herb are Camphor of the Poor, Nectar of the Gods, Stinking Rose, and Rust Treacle. People use this product primarily for improving circulation, lowering blood lipid levels, and for lowering blood pressure. Many other uses have been proposed including the treatment of menstrual disorders, earaches, diarrhea, colds and flu, and numerous other ailments.

Several randomized placebo-controlled studies have been performed regarding efficacy in lowering blood lipid levels and blood pressure, but the results vary. Its proposed mechanism of action is that it may inhibit certain enzymes in cholesterol biosynthesis thereby decreasing blood lipid levels. It also may stimulate the production of endothelium-derived relaxation factor and thus promote vasodilation.

Garlic can also inhibit platelet aggregation and enhance fibrinolytic activity thereby decreasing the ability of blood to

clot. Therefore, garlic should not be used prior to surgery or near delivery if pregnant, and should not be used with other drugs or herbs that might affect clotting including aspirin, non-steroidal anti-inflammatory agents, heparin, or warfarin (Coumadin), along with some of the other herbal products mentioned in this article.

**Echinacea:**

Echinacea is the number 5 selling herbal product in the United States. It has several other names including Purple Cone Flower, Black Sampson, Red Sunflower, Hedgehog, and Kansas Snakeroot. Three species are available for herbal usage, which are augustifolia, pallida, and purpurea. People primarily use this product for preventing and treating infections (especially the common cold and the flu) or it is used to boost the immune system.

Several randomized and placebo-controlled trials have been performed, but the results vary. It appears that the majority of studies do not show that Echinacea prevents the development of a cold or flu; however, it may decrease the severity and duration in some cases. Its proposed mechanism of action is that it stimulates cellular immune function by peripheral blood mononuclear cells, stimulates production of lymphokines, and has anti-inflammatory effects by inhibiting the enzyme, cyclooxygenase.

Very few adverse reactions to Echinacea have been reported. Its use is not recommended in patients with autoimmune diseases, multiple sclerosis, AIDS, and tuberculosis. It is felt by some researchers that a boost in certain areas of the immune system could exacerbate these diseases. In addition, it is not recommended for individuals who are taking immuno-suppressive drugs (because of its potential for an opposite effect).

**Bilberry**:

Bilberry is one of the top 20 selling herbal products in the United States despite the overall lack of clinical information. It has several other names including Whortleberry, Huckleberry, Hurtleberry, Dyeberry, Trackleberry, Airelle, Bleaberry, and Burren Myrtle. People use this product primarily for treating diarrhea, improving vision, and in treating inflammation of the mouth and throat. Folk medicine uses include "stimulating metabolism" and "purifying the blood".

Very few clinical studies have been performed to date and essentially no randomized placebo-controlled studies are found. Bilberry contains catechin tannins, which may be responsible for its possible astringent and anti-diarrheal effects. In addition, it can also inhibit platelet aggregation. Therefore, Bilberry should not be used prior to surgery or near delivery if pregnant, and should not be used with other drugs or herbs that might affect clotting including aspirin, non-steroidal anti-inflammatory agents, heparin, or warfarin (Coumadin), along with some of the other herbal products mentioned in this article.

**Ginger:**

Ginger is one of the top 20 selling herbal products in the United States and has also been around for centuries. People primarily use this product for the treatment of dyspepsia, motion sickness, and nausea and vomiting. Other uses reported in Chinese medicine include the treatment of rheumatism, malaria, baldness, poisonous snake bites, and as a diuretic.

Several randomized placebo-controlled studies have been performed regarding efficacy in preventing motion sickness, morning sickness, and preventing post-operative nausea and vomiting, but the results vary. Its proposed mechanism of action is basically uncertain, but its anti-emetic properties may involve a local effect in the gastrointestinal tract.

In larger doses, it appears to have an inhibitory effect on platelet aggregation. Therefore, ginger should not be used prior to surgery or near delivery if pregnant, and should not be used with other drugs or herbs that might affect clotting including aspirin, non-steroidal anti-inflammatory agents, heparin, or warfarin (Coumadin), along with some of the other herbal products mentioned in this article. Some researchers have stated that ginger should not be used for treating morning sickness; however, the reason for this warning is not certain.

**Herbs Not Recommended for Use Prior to Surgery or Near Delivery:**

1. Ginkgo Biloba
2. Ginseng

3. Garlic
4. Bilberry
5. Ginger (in large doses)

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Dr. Towers is currently Professor and Vice Chair of the Department of Obstetrics & Gynecology at University of Tennessee Medical Center Knoxville in the Division of Maternal-Fetal Medicine. He is still clinically active managing numerous high-risk pregnancies. He is also actively involved in research with over 90 publications in major medical journals. Though his research has spanned many areas in obstetrics, he has primary interests in drugs in pregnancy, infections in pregnancy, fetal heart monitoring, bleeding in pregnancy, and fetal lung maturity.

He has authored a book for consumers regarding the safety of over-the-counter medications that are used in treating the common cold entitled “I’m Pregnant & I Have a Cold – Are Over-the-Counter Drugs Safe to Use?” published by RBC Press, Inc. He is also one of the new Editors of the reference book for clinical care providers entitled “Drugs in Pregnancy and Lactation, published by Wolters & Kluwer.

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She received her BSN and then her MSN from Wichita State University followed by a postmaster’s Women’s Health Nurse Practitioner Certification from Arizona State University. She has provided several presentations regarding nursing concerns related to Women’ Health Care and has frequently lectured on normal and high-risk obstetrical issues. She has practiced clinically in Kansas, California, and Arizona.