Herbal Products (Phytochemicals)

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Objectives

• Describe the legal status and regulation of herbal products
• Know problems in evaluation and use of herbal products
• Describe the clinical usefulness, side-effects, mechanisms of action and potential interactions of commonly used herbal products
• Understand the dangers of certain herbal products

Public’s Perception of Herbals

• Natural products are intrinsically safe
• Sold without a Rx
• Products are reviewed & approved by the FDA
• No warning labels on the products

Economics of Dietary Supplements

• 1999 herbal sales were estimated at anywhere from 5 to 17 billion
• Mainstream pharmaceutical companies entering the market
• Some food and beverage companies add herbals to their products

Full Circle?

• 2000 B.C. Here, eat this root.
• 1000 A.D. That root is heathen. Here, say this prayer.
• 1850 A.D. That prayer is superstition. Here, drink this potion.
• 1940 A.D. That potion is snake oil. Here, swallow this pill.
• 1985 A.D. That pill is ineffective. Here, take this antibiotic.
• 2000 A.D. That antibiotic is artificial. Here, eat this root.

What Is a Dietary Supplement?

Defined in Dietary Supplement Health and Education Act (DSHEA) of 1994.
Product taken by mouth containing “dietary ingredient” to supplement diet.
“Dietary ingredients”: vitamins, minerals, herbs/other botanicals, amino acids, and other substances (e.g., enzymes, organ tissues, glandulars, metabolites).
Dietary supplements can also be extracts or concentrates, tablets, capsules, softgels, gelcaps, liquids, or powders.
They can also be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet.
Dietary supplements are in a special category under the general umbrella of “foods,” not drugs, and requires that every supplement be labeled a dietary supplement.
Legal Status of Herbal Products

Different set of FDA regulations than those covering "conventional" foods and drug products (prescription and OTC).

Generally not patentable
• natural products have long history of use for medical applications
• rigorous evaluation of safety and efficacy usually lacking

Dietary Supplement Health and Education Act of 1994 (DSHEA)

A. Manufacturer
• responsible for ensuring dietary supplement is safe before marketing.
• ensures product label information is truthful and not misleading.
• generally, does not need to register with FDA nor get FDA approval before producing or selling dietary supplements.

B. FDA
• responsible for taking action against any unsafe dietary supplement product after it reaches the market.
• post-marketing responsibilities include monitoring safety (e.g. voluntary dietary supplement adverse event reporting, and product information, e.g. labeling, claims, package inserts, and literature).

C. The Federal Trade Commission regulates dietary supplement advertising.

How Do Herbs Differ From Drugs?

• Not in our education or experience
• Different FDA categories
• Constituents - very complex
• Plant constituents vary
  – Soil, weather, storage, manufacturing process
• Active ingredient often unknown
• Several constituents may be responsible for effects
• Not pure
• Unknown pharmacology & toxicology
• Nonstandard indications

Problems: Evaluation and Use of Herbal Products

Few properly conducted studies of safety and effectiveness and lack of long-term studies “natural” does not equal “safe”
avoid in children, elderly, people with chronic diseases
lack of reproductive studies -- avoid in pregnant and nursing women

Identification of active constituents (or “balance” of constituents)

Standardization/comparison of products on basis of active constituents is probably preferable quantity of plant material (less reliable)

Manufacturing practices
widely variable across industry
quality control often lacking

Toxicological Concerns

• Poisonings
• Allergies
• Adverse reactions
• Herb-drug interactions
• Contamination
Overall Caveats

- FDA does not evaluate herbal products for safety, effectiveness, or purity.
- Most potential risks and/or advantages are unknown.
- No regulated manufacturing standards.
- Herbal/health supplements have been contaminated with toxic metals or other drugs.
- Herbal/health supplements should be purchased from a reliable source to minimize the risk of contamination.
- Talk to your doctor if you are pregnant or could become pregnant.
- Teratological effects are unknown.
- Do not take without first talking to your doctor if breast-feeding.
- Do not give to a child without first talking to the child's doctor.

Questions to Ask Patients Who May Be Taking Herbal Products

Are you taking an herbal product, herbal supplement or other "natural remedy?"
If so, are you taking any prescription or nonprescription medications for the same purpose as the herbal product?
Have you used this herbal product before?
Are you allergic to any plant products?
Are you pregnant or breast-feeding?

Black Cohosh (Cimicifuga racemosa)

Uses
- Ease menopause symptoms
- Ease menstrual discomfort
- Rheumatism
- Cough
- High cholesterol levels
- Hardening of the arteries

Do not take if ever been diagnosed with breast cancer

Overdose symptoms might include nausea
- Dizziness
- Seizures
- Visual disturbances
- Reduced pulse rate
- Increased perspiration
- Stomach upset (common side effect with therapeutic doses)

Chamomile (Matricaria recutita)

Uses
- Reduce flatulence and/or diarrhea
- Treat travel sickness
- Produce mild sedation
- Reduce restlessness and irritability
- Treat the common cold
- Treat fevers
- Reduce cough
- Liver and gallbladder complaints
- Increase appetite

Also been used topically
- Reduce inflammation of the skin, mouth, and throat
- Reduce nasal inflammation and discharge
- Treat wounds and burns

Chamomile Side Effects

Side Effects
- Serious uncommon
- Other less serious side effects have not been reported.
- Allergic reactions

Do not take
- With warfarin or other blood thinners
- If allergic to ragweed, asters, chrysanthemums, celery, or other plants
Echinacea

**PURPORTED USES**

- Common cold
- Immunostimulation
- Infections
- Viral infections
- Wound healing

Not recommended for use by people with multiple sclerosis, white blood cell disorders, collagen disorders, HIV / AIDS, autoimmune disorders, or tuberculosis.

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**In Vitro Effects**

- stimulates phagocytosis
- enhances mobility of leukocytes
- stimulates TNF and interleukin 1 secretion from macrophages and lymphocytes
- improves respiratory activity
- Non-specific T cell activation may occur via binding of the polyacetylene fraction of echinacea binding to cell surface carbohydrate receptors resulting in antiviral and immunostimulant activity
- May also have antiinflammatory, local anesthetic, and antibacterial activity

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**Echinacea: Side Effects & Drug Interactions**

Do not use different formulations together because of overdose risk

**Side Effects**

- Fever
- Nausea or vomiting
- Allergic Reactions

May alter actions of other medicines that affect the immune system

- Steroids (e.g., betamethasone, dexamethasone, cortisone)
- Cyclosporine
- Methotrexate
- Other immune system suppressants.

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**Echinacea failed to reduce cold duration**

Echinacea failed to improve URIs in Children

**Feverfew (Tanacetum parthenium)**

**Uses**

- Prevention of migraine headaches.
- Prevention and treatment of asthma, rheumatoid arthritis, painful menstrual periods, inflammatory skin conditions such as psoriasis, toothache, and insect bites.

**Potential Drug Interactions**

- warfarin (Coumadin)
- aspirin, NSAIDs (e.g. ibuprofen, naproxen)

**Side effects**

- Allergic reactions
- Dry or sore tongue, loss of taste, unpleasant taste
- Indigestion, flatulence, nausea or vomiting.
- Following discontinuation: nervousness, tension headache, insomnia, stiffness, joint pain, and tiredness.

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**Echinacea Failed to Improve URIs in Children**

Table 2: Comparison of Treatment Outcomes in Upper Respiratory Tract Infections (URIs) Treated With Echinacea and Placebo

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Echinacea Group (n = 327 URIs)</th>
<th>Placebo Group (n = 370 URIs)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of symptoms, median (IQR), d</td>
<td>9 (8-10)</td>
<td>9 (8-10)</td>
<td>.89</td>
</tr>
<tr>
<td>Severity of symptoms, median (IQR)</td>
<td>10 (6-13)</td>
<td>9 (8-12)</td>
<td>.09</td>
</tr>
<tr>
<td>Days of fever, mean (SE)</td>
<td>3.0 (1.5)</td>
<td>3.0 (1.3)</td>
<td>.99</td>
</tr>
<tr>
<td>Peak severity of symptoms, mean (SD)</td>
<td>0.0 (0.2)</td>
<td>0.1 (0.3)</td>
<td>.06</td>
</tr>
<tr>
<td>No. of days of peak severity, mean (SD)</td>
<td>1.60 (0.8)</td>
<td>1.66 (1.1)</td>
<td>.97</td>
</tr>
<tr>
<td>Parental assessment of severity, No. (%)</td>
<td>153 (49.3)</td>
<td>170 (45.3)</td>
<td>.57</td>
</tr>
<tr>
<td>Moderate</td>
<td>128 (38.0)</td>
<td>157 (42.8)</td>
<td>.67</td>
</tr>
<tr>
<td>Severe</td>
<td>48 (14.6)</td>
<td>40 (10.9)</td>
<td>.05</td>
</tr>
</tbody>
</table>

**Efficacy and Safety of Echinacea in Treating Upper Respiratory Tract Infections in Children A Randomized Controlled Trial**

Taylor et al., *JAMA*. 2003;290:2824-2830.
Garlic

**Used orally**
- as an antioxidant
- to reduce cholesterol and triglycerides
- to reduce hardening of the arteries and blood clotting
- to reduce blood pressure; to prevent cancer
- to protect the liver
- as an antibiotic, antiviral, and antifungal
- to increase the effects of the immune system
- to reduce blood sugar levels
- to reduce menstrual pain

**Topical Uses**
- corns
- warts
- calluses
- ear infections
- muscle pain
- nerve pain
- arthritis
- sciatica

**Drug Interactions**
- decreases blood warfarin
- hypoglycemia with chlorpropamide

Ginseng: Ancient Remedy, Modern Medicine?

Ginseng

**Uses**
- cancer preventive
- alleviation of menopausal symptoms (hot flashes)
- anti-inflammatory
- improve the body's resistance
- increase vitality
- increased immune function
- treatment of cardiovascular diseases
- improvement of cognition
- enhanced physical performance
- enhanced sexual function

But the efficacy of ginseng could not be established beyond doubt for any of these indications

Ginger

**Uses**
- treatment and prevention of motion sickness
- increase appetite
- reduce stomach acidity
- reduce severe nausea in pregnancy

**Side Effects**
- uncommon
- allergic reactions

Avoid while taking
- any heart medicine
- any medication to control blood sugar (e.g., insulin, glipizide)
- warfarin (Coumadin)
- aspirin
- NSAIDs

Ginkgo biloba

**Active constituents of leaves:**
- flavonoid glycosides and ginkgolides
- Potent antioxidant
- Enhances peripheral, cerebral, and ocular circulation

**Uses**:
- Enhances memory in Alzheimer's and age-related dementias
- No memory enhancement in healthy individuals > 60 years
- (JAMA, 8/21/03).
- Enhances cerebral and ocular blood flow.
- Alleviates congestive symptoms of premenstrual syndrome.
- Prevention of altitude sickness.
- Treatment of cerebrovascular dysfunctions and peripheral vascular disorders.

**Ginkgo Side Effects & Drug Interactions**

Ginkgo seeds and fruit pulp are toxic, can cause a severe reaction including skin redness, swelling, blistering, and itching for 7-10 days

**Serious Side Effects**
- allergic reaction
- irregular heartbeats
- muscle spasms or cramps;
- seizures
- loss of consciousness

**Less Serious Side Effects**
- headache
- dizziness
- stomach upset

**Drug Interactions**
- warfarin (Coumadin)
- aspirin
- NSAIDs (e.g., ibuprofen, naproxen)
- heparin
- antioxidants

**Overdose**
- seizures
- a loss of consciousness
- possibly death.
Ginseng Side Effects

- Sleeping problems
- Swelling or fluid retention
- Headache
- Abdominal discomfort

Drug Interactions

- Any heart or blood pressure medicines
- Medicine controlling blood sugar (e.g., insulin, glipizide, glyburide)
- Warfarin
- Aspirin
- NSAIDs (e.g., ibuprofen, naproxen)
- Heparin

Antiflammatory

St. John’s Wort (Hypericum perforatum)

- Cancer treatment
- Cardiovascular disease
- Cognitive improvement
- GI disorders
- Weight loss
- Hypertension

Constituents

- Caffeine
- Flavonoids, theaflavin
- Methylxanthines: Theophylline, theobromine, and theanine
- Polyphenols: Gallic acid and catechins: gallocatechin (GC), epigallocatechin (EGC), epicatechin (EC), and epigallocatechin gallate (EGCG)
- Polysaccharides
- Proanthocyanidins (tannins)
- Vitamins: Ascorbic acid, tocopherol
- Other: Fluoride, chlorophyll, organic acids

Uses

- Treatment of anxiety
- Insomnia
- Irritability
- Skin inflammation
- Inflamed muscles and joints
- Nerve and muscle pain
- Skin wounds

Purported Mechanisms of Action

- Antiflammatory and anti-inflammatory properties tannins
- Antioxidant and anti-oxidative properties: flavonoids

Side Effects

- Headache
- Abdominal pain and gas
- Nausea
- Insomnia
- Anxiety
- Hypertension

Purported Uses

- Cancer prevention
- Cancer treatment
- Cardiovascular disease
- Cognitive improvement
- GI disorders
- Weight loss
- Hypertension

Adverse Reactions

- Nausea and GI upset, possibly due to tannin content
- Insomnia, irritability, and nervousness can occur due to caffeine content
- Skin irritation
- Skin rash

Green Tea

Constituents

- Caffeine
- Flavonoids, theaflavin
- Methylxanthines: Theophylline, theobromine, and theanine
- Polyphenols: Gallic acid and catechins: gallocatechin (GC), epigallocatechin-3-gallate (EGCG)

Uses

- Cancer prevention
- Cancer treatment
- Cardiovascular disease
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- GI disorders
- Weight loss
- Hypertension

Purported Mechanisms of Action

- Antiflammatory activity of green tea, polyphenol content: Chemopreventive: catechin epigallocatechin-3-gallate (EGCG)
- Anticancer activity of green tea, polyphenol content: Chemopreventive: catechin epigallocatechin-3-gallate (EGCG)
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### St. John’s Wort Side Effects and Warnings

**Side Effects**
- Increased skin sensitivity to sunlight
- Rash
- A feeling of fullness in stomach
- Constipation

**Drugs to Avoid**
- MAO inhibitors (e.g., Nardil, Parnate)
- Serotonin reuptake inhibitors (e.g., Prozac, Paxil, Zoloft)
- Tricyclic antidepressants (e.g., Elavil, Norpramin, Tofranil)
- Bupropion (Wellbutrin, Zyban)
- HIV/AIDS protease inhibitors (e.g., Crixivan, Norvir)
- HIV/AIDS nonnucleoside reverse transcriptase inhibitors (e.g., Rescriptor, Viramune).

*Do not take perioperatively*

### Purported Mechanisms of Action

**Antidepressant activity:**
- Hypericin (MAO inhibitor)?
- Weak inhibition of catechol-O-methyl-transferase (COMT) and limited reuptake of norepinephrine: whole plant extract
- Inhibits the reuptake of serotonin, dopamine, norepinephrine, GABA, and L-glutamine: Hyperforin

Analgesic and CNS activity: bioflavonoid content.

### Saw Palmetto (Serenoa repens)

**Uses**
- Benign prostatic hypertrophy (BPH)
- Relieve difficult urination that may be associated with BPH
- Relieve the symptoms of an irritable bladder

**Side effects**
- Allergic reactions (uncommon)
- Cramping
- Nausea
- Diarrhea
- Headache

*Do not take this medication without first talking to your doctor if*
- Cancer of the prostate
- Breast cancer
- Other sex hormone-related disease or disorder
- Pregnant (may alter hormonal activity)

### Purported Mechanisms of Action

**Antiandrogenic**
- Liposterolic extract of the berries reduced the uptake of both testosterone and DHT (dihydrotestosterone) by more than 40% does not induce changes in the level of testosterone or other hormones in the plasma itself.
- Reduces the conversion of less active testosterone to the more active DHT by inhibiting the enzyme steroid 5 alpha reductase.

**antiandrogenic properties, anti-inflammatory and antiedematous activity**
- Inhibition of the cyclooxygenase and 5-lipoxygenase pathways thereby preventing the biosynthesis of inflammation-producing prostaglandins and leukotrienes.

### Valerian (Valerian officinali)

**Uses**
- Anxiety
- Restlessness
- Insomnia
- Mental strain
- Lack of concentration
- Excitability
- Stress
- Headache
- Nervous stomach cramps
- Uterine spasticity
- Menopause
- Pain
- Emotional distress that may occur with menstruation.

**Side Effects**
- Headache,
- Excitability
- Restlessness or uneasiness
- Sleeplessness
- Dilated pupils
- Irregular heartbeats or other heart problems
- Allergic reactions

### Severe Adverse Events: Examples

- Hepatotoxicity
- Kava Kava
- Germander
- Chaparral
- Comfrey
- Strokes
- Ma hung
- Yohimbe
### Kava (Piper methysticum)

**Uses**
- Induce and improve sleep
- Decrease anxiety, nervousness, stress, and restlessness

**Interacts with substances that cause drowsiness**
- Antidepressants
- Alcohol, sedatives
- Pain relievers
- Anxiety medicines
- Muscle relaxants

**Overdose Symptoms**
- Tiredness
- Sleepiness
- Poor coordination

### Consumer Advisory (3/25/02): Kava Dietary Supplements

Associated with liver-related injuries – including hepatitis, cirrhosis, and liver failure.

Symptoms include jaundice and brown urine; also nausea, vomiting, light-colored stools, unusual tiredness, weakness, stomach or abdominal pain, and loss of appetite.

Consumers who use a kava-containing dietary supplement and who experience signs of illness associated with liver disease should also consult their physician.

Persons who have liver disease or liver problems, or persons who are taking drug products that can affect the liver, should consult a physician before using kava-containing supplements.

FDA urges consumers and their health care professionals to report any cases of liver and other injuries that may be related to the use of kava-containing dietary supplements.

### Ma huang (Ephedra)

- Also called squaw tea and Mormom tea of the genus Ephedra.
- Contains various chemical stimulants (e.g., ephedrine, pseudoephedrine and norpseudoephedrine) that are amphetamine-like chemicals used in OTC and prescription drugs, as well as various tannins and related chemicals. The concentrations of these alkaloids varies between species of Ephedra.
- Products often contain other stimulants (e.g., caffeine) which may increase the potential for adverse effects.
- Serious adverse effects, including hypertension, palpitation, neuropathy, myopathy, psychosis, stroke, and memory loss, have been reported to FDA with products containing Ma huang as ingredients.

### Ma huang (Ephedra) Purported Uses
- Asthma
- Bronchitis
- Common cold
- Cough
- Infections
- Promote urination
- Strength and stamina
- Weight loss

### Ma Huang: Drug Interactions

- **Aspirin**: May increase risk of cerebral hemorrhage.
- **Benzodiazepines and other sedatives**: Effects may be antagonized by ephedra.
- **Beta-adrenergic agonists**: May potentiate effects of beta-adrenergic agonists.
- **CNS stimulants**: May increase stimulatory effects.
- **Monoamine-oxidase inhibitors (MAO-I)**: Concomitant use can cause hypertensive crisis.
- **Theophylline**: May increase stimulatory effects.
- **Digoxin**: Concomitant use can cause arrhythmia.

### FDA Issues Regulation Prohibiting Sale of Dietary Supplements Containing Ephedrine Alkaloids and Reiterates Its Advice That Consumers Stop Using These Products

The Food and Drug Administration (FDA) today issued a final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids (ephedra) because such supplements present an unreasonable risk of illness or injury. The rule will become effective 60 days from the date of publication.

"This FDA rule reflects what the scientific evidence shows - that ephedra poses an unreasonable risk to those who use it," Health and Human Services Tommy G. Thompson said. "The regulations prohibit the sale of dietary supplements containing ephedra, and we intend to take swift action against anyone who puts consumers at risk by continuing to sell such products after the prohibition takes effect."

**FDA News**: February 6, 2004
Chaparral (Larrea tridentata)
- AKA creosote bush, is a desert shrub used as a traditional medicine by Native Americans.
- Marketed as a tea, tablet, capsule, and concentrated extract form
- Promoted as a natural antioxidant "blood purifier," cancer cure, and acne treatment.
- Associated with acute non-viral hepatitis (rapidly developing liver damage)
- In the majority of the cases reported thus far, the injury to the liver resolves over time, after discontinuation of the product.
- After FDA’s health warning, many distributors of chaparral products voluntarily removed the products from the market in December of 1992.
- Some chaparral products remain on the market, however, and other distributors who removed their products from the market are seeking to clarify the status of these products.

Comfrey (Symphytum officinale)
- Internal uses: stomach upset, stomach ulcers, hemorrhoids, and diarrhea
- External uses: bruises, sprains, burns, and swelling
- Used as a mouthwash and gargle for gum disease and sore throats.
- Contains pyrrolizidine alkaloids, that are firmly established to be hepatotoxins in animals.
- Comfrey and pyrrolizidine alkaloids associated with veno-occlusive disease (VOD), toxicity to other tissues, and are carcinogens.
- The adverse effects are entirely consistent with the known effects of comfrey ingestion described in the scientific literature.
- Should not be used as an ingredient in dietary supplements
- Federal Trade Commission (FTC) brought an enforcement action against a firm for marketing comfrey-containing products.
- FDA advises removal of comfrey products from the market (7/6/01)

Yohimbe (Pausinystalia yohimbe)
From tree bark.
Major alkaloid is yohimbine (an α₂ adrenergic antagonist)
Used for body building and "enhanced male performance."
Increases blood pressure and heart rate.
Serious adverse effects, including renal failure, seizures and death, have been reported to FDA with products containing yohimbe and are currently under investigation.
Side effects include central nervous system stimulation that causes anxiety attacks.
At high doses inhibits monoamine oxidase (MAO) inhibitor, so serious adverse effects when taken with tyramine-containing foods (e.g., liver, cheeses, red wine).
Should be avoided by individuals with hypertension, diabetes, and heart, liver or kidney disease.
Symptoms of overdosage include weakness and nervous stimulation followed by paralysis, fatigue, stomach disorders, and ultimately death.

Lobelia (Lobelia inflata)
Also known as Indian tobacco, contains pyridine-derived alkaloids, primarily lobeline.
Pharmacological actions similar to, though less potent than, nicotine.
Can cause either autonomic nervous system stimulation or depression.
Low doses produce bronchial dilation and increased respiratory rate.
Higher doses result in respiratory depression, as well as sweating, rapid heart rate, hypotension, and even coma and death. As little as 50 milligrams of dried herb or a single milliliter of lobelia tincture has caused these reactions.
Because of its similarity to nicotine, may be dangerous to susceptible populations, including children, pregnant women, and individuals with cardiac disease. But still found in dietary supplements that are marketed for use by children and infants, pregnant women, and smokers.

Germander (Teucrium genus)
Common name for a group of plants contained in medicinal teas, elixirs and capsules or tablets, either singly or in combination with other herbs.
Marketed for the treatment of obesity and to facilitate weight loss.
Since 1986, associated with at least 27 cases of acute nonviral hepatitis (liver disease), including one death.
In most cases, when the use of germander was stopped symptoms resolved gradually in most cases, approximately two of six months after withdrawal.
Although the constituent in germander responsible for its hepatic toxicity has not been identified, germander contains several chemicals, including polyphenols, tannins, diterpenoids, and flavonoids.
The French Ministry of Health has forbidden the use of germander in drugs. Its use has been restricted in other countries.

Willow Bark (Salix species)
- Long history of use as a pain reliever
- Little actual research has been done
- Used for its analgesic, antirheumatic, and antipyretic (fever-reducing) properties.
- The pharmacologically active component in willow bark is "salicin," which like Aspirin (acetylsalicylic acid) is converted to salicylic acid after ingestion.
- Although promoted as an "aspirin-free" analgesic, including in dietary supplement products for children, it shares the same chemical properties and the same adverse effects as aspirin.
Willow Bark Toxicity

- The "aspirin-free" claim is particularly dangerous on products marketed, without warning labels, for use by children and other aspirin-sensitive individuals.
- Major adverse effects: irritation of the gastric mucosa, Pregnancy (including stillbirth, bleeding, prolonged gestation and labor, and low-birth-weight infants), Reye syndrome.
- Salicylate intoxication (headache, dizziness, ringing in ears, difficulty hearing, dimness of vision, confusion, lassitude, drowsiness, sweating, hyperventilation, nausea, vomiting, and central nervous system disturbances in severe cases) may occur as the result of over-medication, or kidney or liver insufficiency.
- Hypersensitivity (approximately 5% population): itching, broncho-spasm and localized swelling (which may be life-threatening), can occur with very small doses of salicylates, and may occur even in those without a prior history of sensitivity to salicylates.

Jin Bu Huan

- Chinese herbal product whose label claims that it is good for "insomnia due to pain," ulcer, "stomachic (sic) neuralgia, pain in shrunken womb after childbirth, nervous insomnia, spasmotic cough, and etc."
- Reported to be responsible for the poisoning of at least three young children (ages 13 months to 2 2 years), who accidentally ingested this product. The children were hospitalized with rapid-onset, life-threatening bradycardia, and CNS and respiratory depression.
- Contains tetrahydropalmatine (THP), which causes in sedation, analgesia, and neuromuscular blockade (paralysis) in animals and the three children presented with these effects.
- Although the product label identified the plant source for Jin Bu Huan as Polygala chinensis, this appears to be incorrect and is more likely from the Stephania species.
- Stephania and Magnolia sold as a weight-loss treatment in Belgium and implicated recently as a cause of severe kidney injury in at least 48 women.

Take Home Points

- Describe the legal status and regulation of herbal products.
- Describe problems in evaluation and use of herbal products.
- Describe the apparent clinical usefulness of the most commonly used herbal products

Another Herb, Another Day