

Five Herbs Commonly Encountered in a Clinical Setting

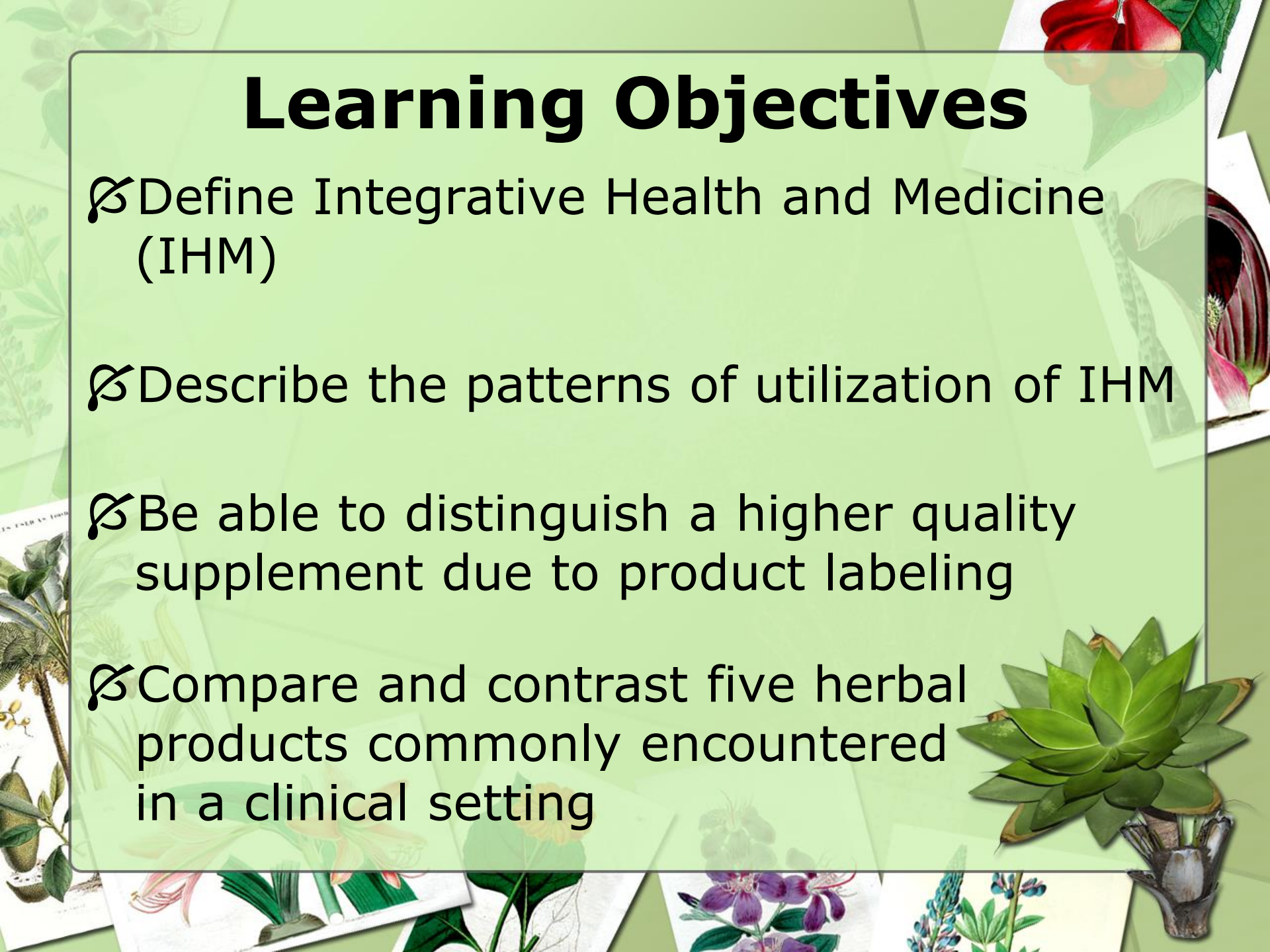
Linda White Tribute

*Monika Nuffer, PharmD
School of Pharmacy*



Learning Objectives

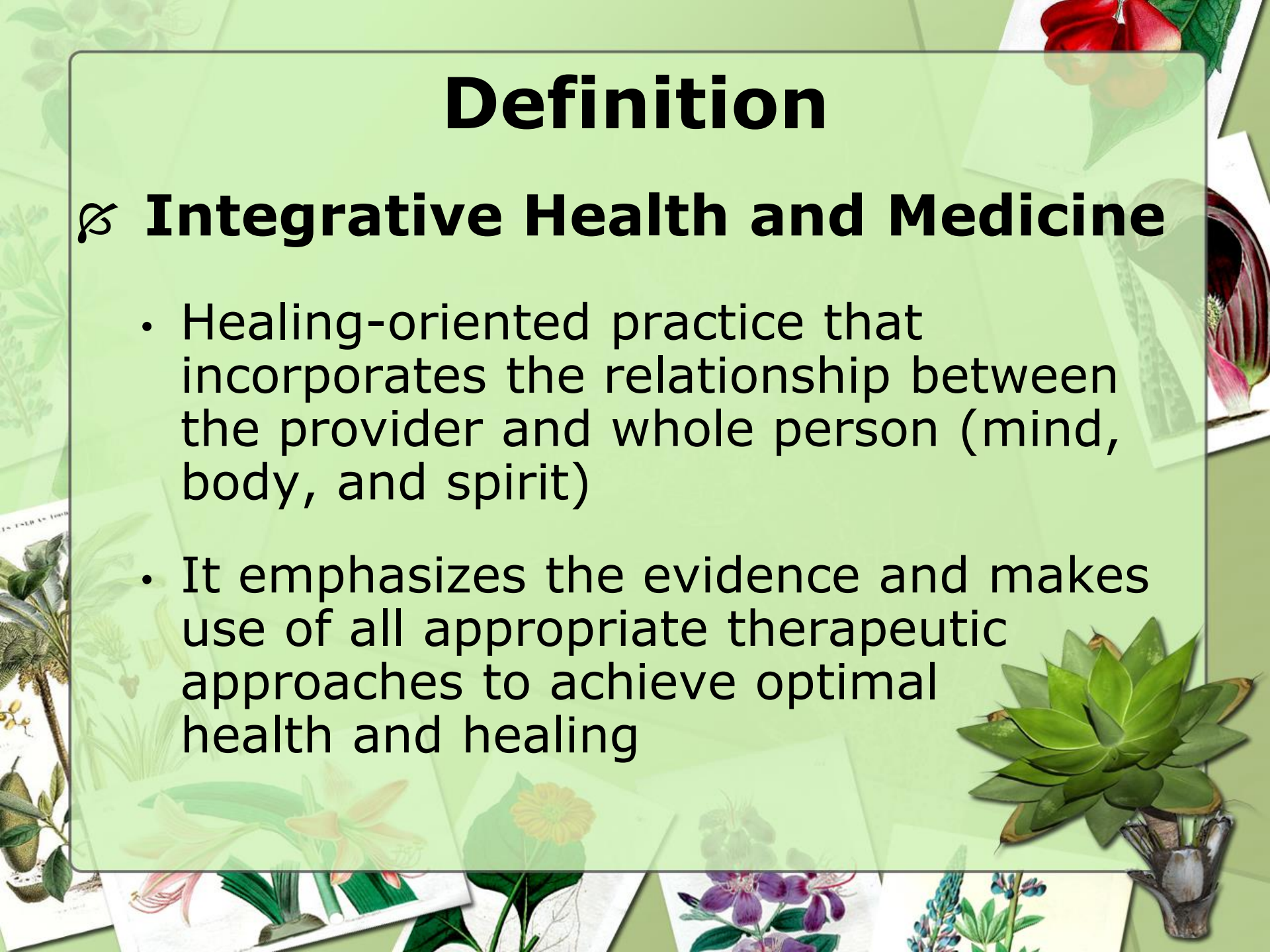
- ✧ Define Integrative Health and Medicine (IHM)
- ✧ Describe the patterns of utilization of IHM
- ✧ Be able to distinguish a higher quality supplement due to product labeling
- ✧ Compare and contrast five herbal products commonly encountered in a clinical setting



Definition

⌘ Integrative Health and Medicine

- Healing-oriented practice that incorporates the relationship between the provider and whole person (mind, body, and spirit)
- It emphasizes the evidence and makes use of all appropriate therapeutic approaches to achieve optimal health and healing



Statistics

⌘ Utilization

- Adult American population 33.2%
- Children American population 11.6%
- Women more than men
- Patient with higher education and income
- **72 % patients didn't report IHM use to health care provider ***

⌘ Cost in 2014

- \$ 6.4 billion US dollars
- Estimated \$115 billion globally by 2020

Why People Use IHM

- ✧ Dissatisfied with the results of conventional therapy
- ✧ Lack of disease curing of conventional therapy
- ✧ Dramatic reports from media
- ✧ Patient empowerment
- ✧ Focused on spiritual and emotional wellbeing



What Patients Believe...

- ⌘ Natural is better than synthetic
- ⌘ Patients don't consider herbs as "drugs"
- ⌘ Herbs don't have side effects
- ⌘ Herbs are regulated, standardized, and safe
- ⌘ Used for thousands of years



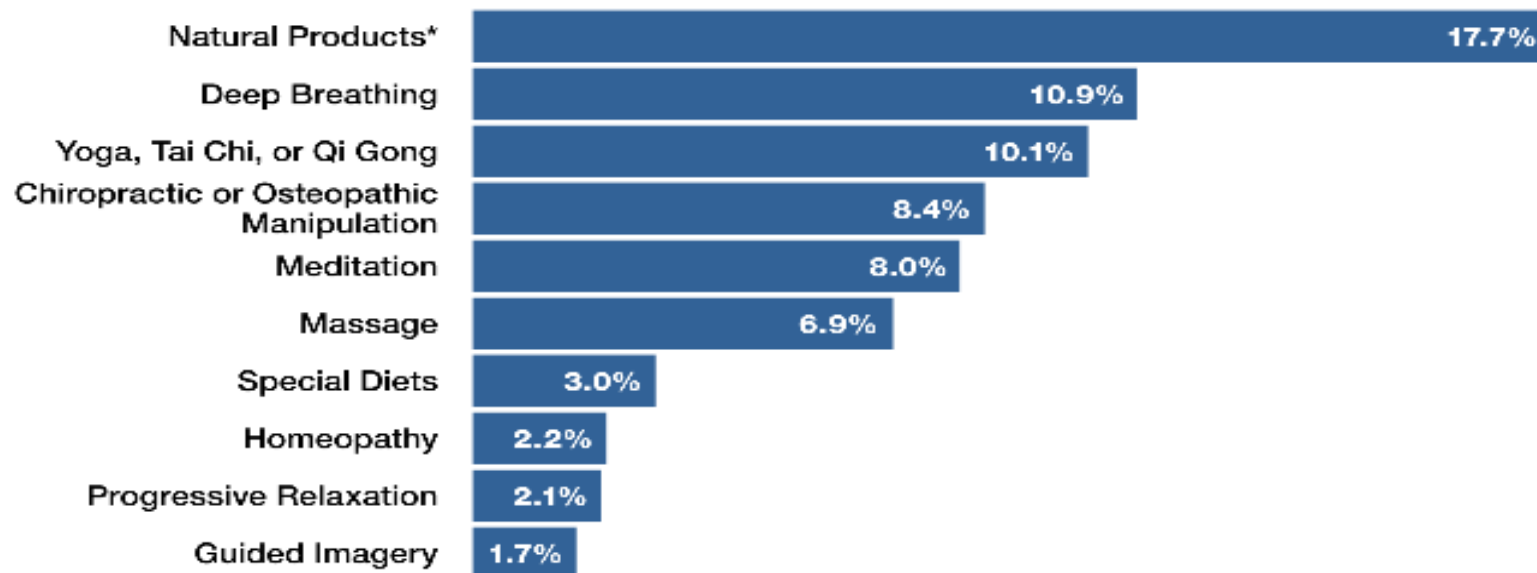
IHM Domains



Use of Complementary Health Approaches in the U.S.

National Health Interview Survey (NHIS)

10 most common complementary health approaches among adults—2012



*Dietary supplements other than vitamins and minerals.

Source: Clarke TC, Black LI, Stussman BJ, Barnes PM, Nahin RL. Trends in the use of complementary health approaches among adults: United States, 2002-2012. National health statistics reports: no 79. Hyattsville, MD: National Center for Health Statistics; 2015.

U.S. Department of Health & Human Services • National Institutes of Health

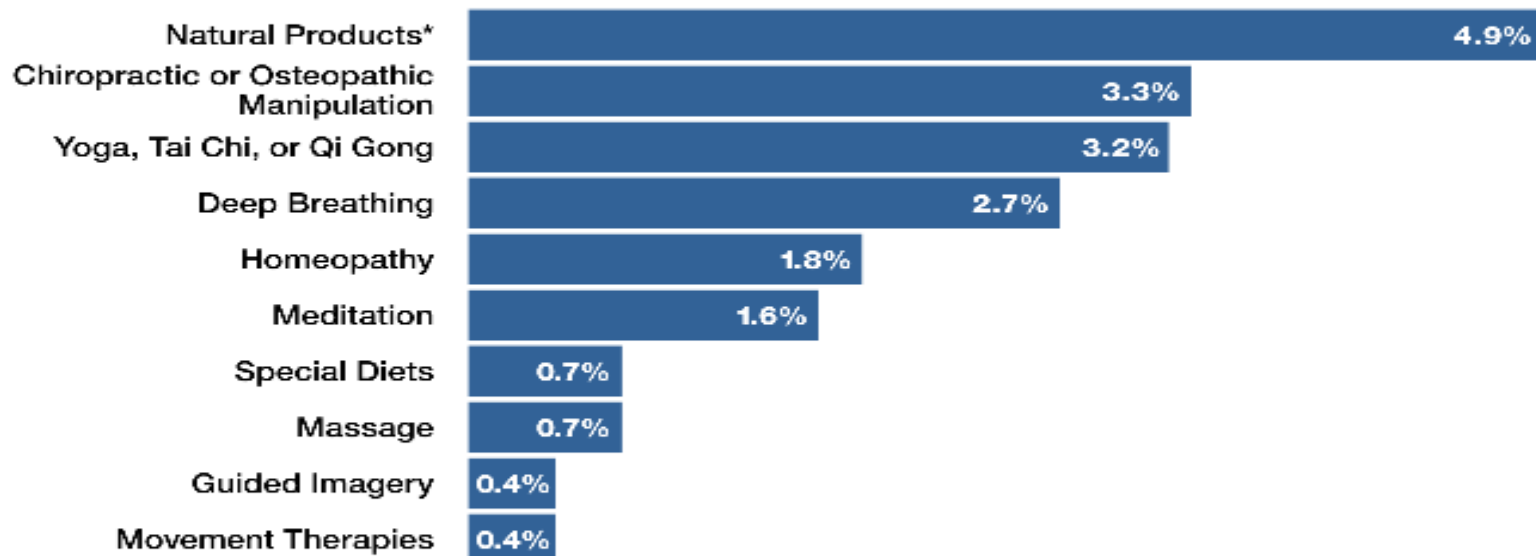


nccih.nih.gov

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U.S. Department of Health & Human Services • National Institutes of Health



National Center for
Complementary and
Integrative Health

nccih.nih.gov



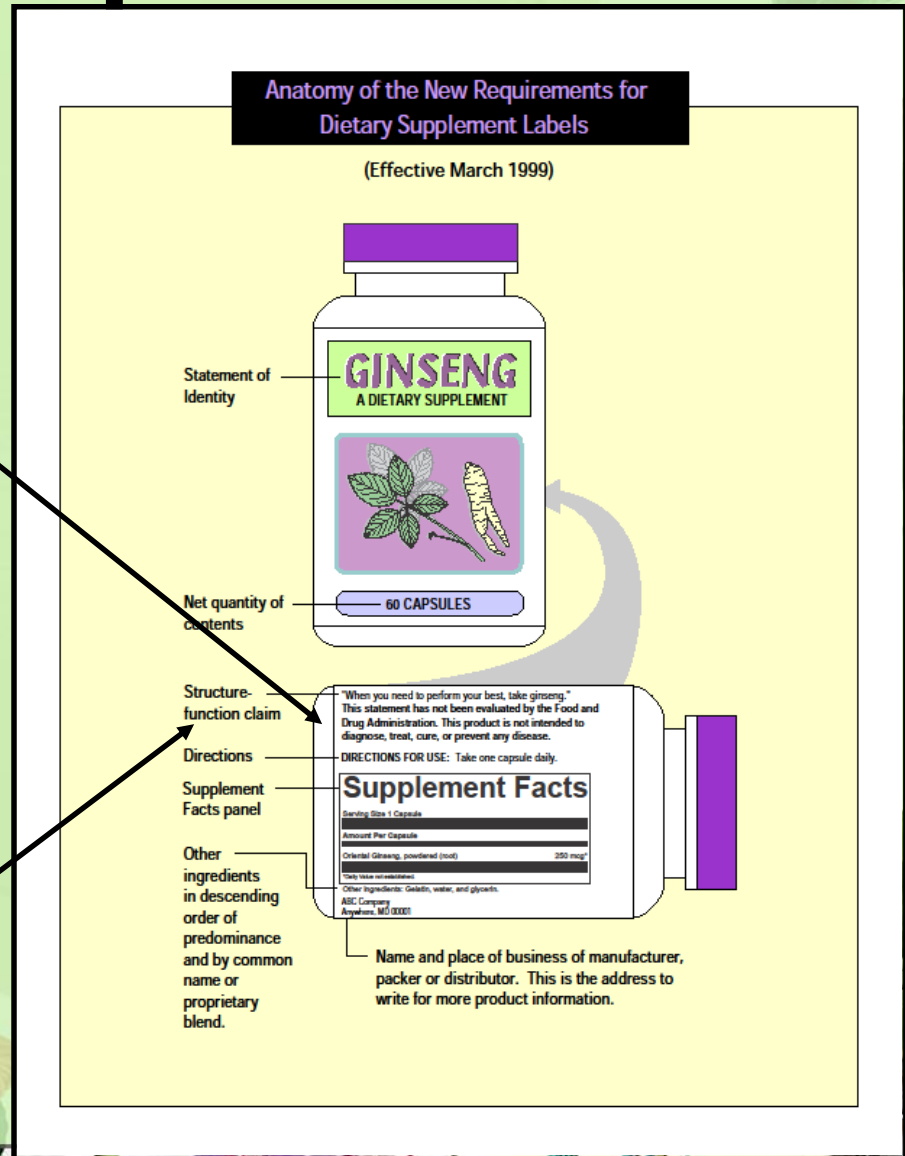
Labeling Requirements

Required Disclaimer

Structure-function claim

“This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease”

“When you need to perform Your best...take ginseng!”



Current Good Manufacturing Practices (cGMP)

Ø Food and Drug Administration (FDA) and Federal Trade Commission (FTC)

Ø June 2010

Ø More stringent practices

- Record keeping
- Quality control
- Testing
- Production
- Verify quality of raw materials
- Increase inspecting of facilities by FDA inspectors

Ø 483 inspection report

- Major breaches is due to record keeping

Supplement Seals of Approval

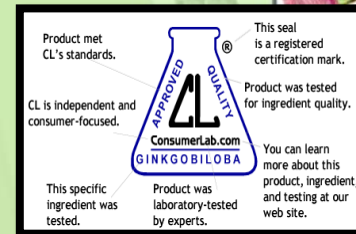
☞ Good Manufacturer Practices (GMPs)

- *Examples: Nature's Way, Country Life, Twin*



☞ Consumer Labs (CL)

- *Examples: Good Neighbor Pharmacy, Sundown*



☞ United States Pharmacopoeia (USP)

- *Example: Nature Made*



☞ National Sanitation Foundation (NSF)

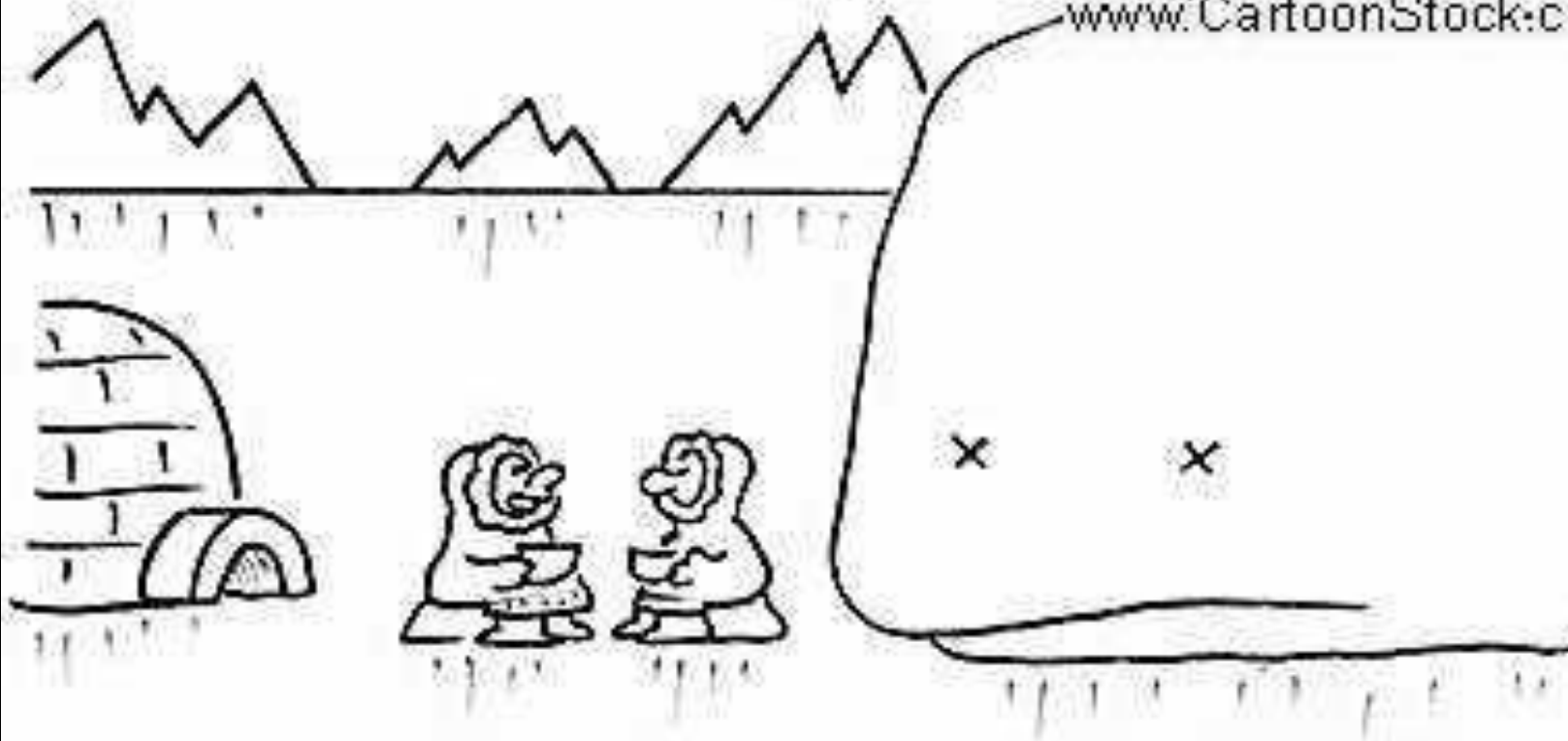
- *Example: GNC Nutritional Supplements*



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search ID: rman2433

"You know, we really should be taking vitamin supplements."

Echinacea

(Echinacea purpurea)



Echinacea

⌘ Indications:

- Common cold
- Upper respiratory infection

⌘ Mechanism of action:

- Immunomodulation

⌘ Efficacy:

- Schoop R et al. 2006 meta-analysis: Echinacea was effective in prevention of common cold symptoms after clinical inoculation compared to placebo $P < 0.43$



Echinacea

⚡ Adverse reactions:

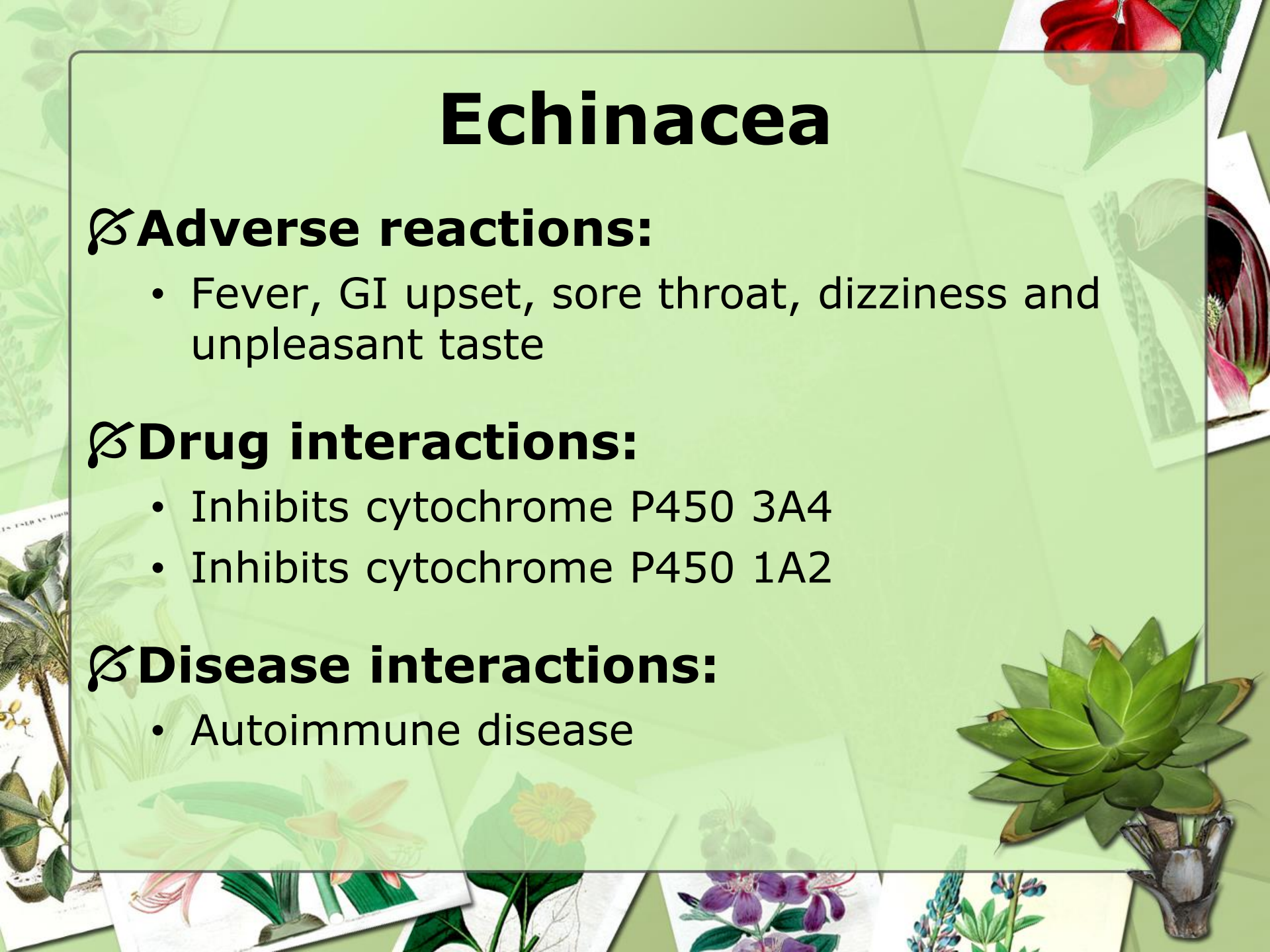
- Fever, GI upset, sore throat, dizziness and unpleasant taste

⚡ Drug interactions:

- Inhibits cytochrome P450 3A4
- Inhibits cytochrome P450 1A2

⚡ Disease interactions:

- Autoimmune disease



Echinacea

⌘ Dosage:

- Crude extract: 6.75 mg (95% herb & 5% root)
2 tab tid
- Juice: 20 drops Q2hrs 1st day, then 20 drops tid
- Tea: 5-6 cups 1st day, then 1 cup x 5 days

⌘ Clinical pearls:

- Chrysanthemum family
- Included in the US National Formulary from 1916 - 1950
- Patient will have a tingling sensation on the tongue



Garlic (*Allium sativum*)



© Steven Foster

Garlic (*Allium sativum*)

⌘ Indications:

- Hypertension
- Hyperlipidemia

⌘ Mechanism of action:

- Allicin is the active ingredient
- Inhibits hepatic cholesterol synthesis
- Activates production of endothelium-derived relaxation factor to relax smooth muscle and vasodilation

Garlic (*Allium sativum*)

⌘ **Efficacy** - mix data

⌘ **Adverse reactions:**

- Halitosis, body odor, heartburn, and GI upset

⌘ **Drug interactions:**

- Anticoagulant
- Antiplatelet
- CYP3A4
- CYP2E1

⌘ **Herb interactions:**

- Ginger, Ginkgo and Vitamin E



Garlic (*Allium sativum*)

⌘ Dosage:

- DL: 1000 mg – 7200 mg/day
- HTN: 300-1500 mg qd
- 1 fresh clove (4 g)
- Standardized: 0.65 - 1.3 % allicin

⌘ Clinical pearls:

- When using fresh product needs to sit for 10 minutes chopped up prior to use for best results
- Generally recognized as safe (GRAS)
- Discontinue 2 - 3 weeks prior to surgery
- Products marketed as odorless, may not contain allicin

Ginger (*Zingiber officinale*)



<https://www.fragrantica.com>

Ginger (*Zingiber officinale*)

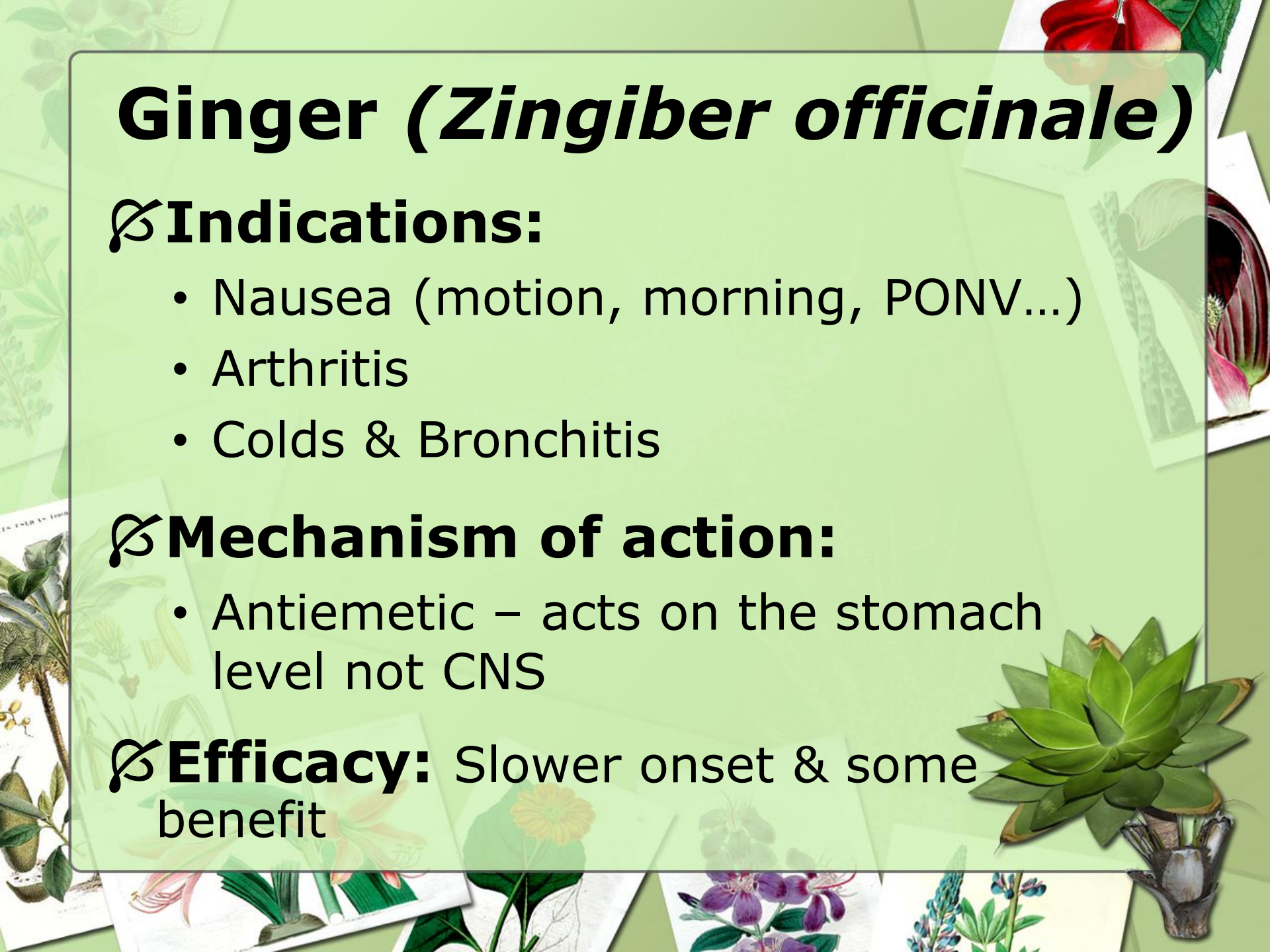
⌘ Indications:

- Nausea (motion, morning, PONV...)
- Arthritis
- Colds & Bronchitis

⌘ Mechanism of action:

- Antiemetic – acts on the stomach level not CNS

⌘ **Efficacy:** Slower onset & some benefit



Ginger (*Zingiber officinale*)

- ⌘ **Adverse reactions:** well tolerated
 - GI issues, heartburn, drowsiness
- ⌘ **Drug interactions:** Anticoagulants
- ⌘ **Herb interactions:**
 - Garlic, Ginkgo, Ginseng, Clove, Turmeric
 - Devils claw, Fenugreek, Ginseng, Guar gum
- ⌘ **Dosage:** 2-4 g dried rhizome powder
 - Motion sickness: 500 mg ½ - 1 hr. prior to travel & then every 2-4 hrs. prn
 - Pregnancy: max 1g daily & short term



Ginkgo (*Ginkgo biloba*)



Ginkgo biloba

⌘ Indications:

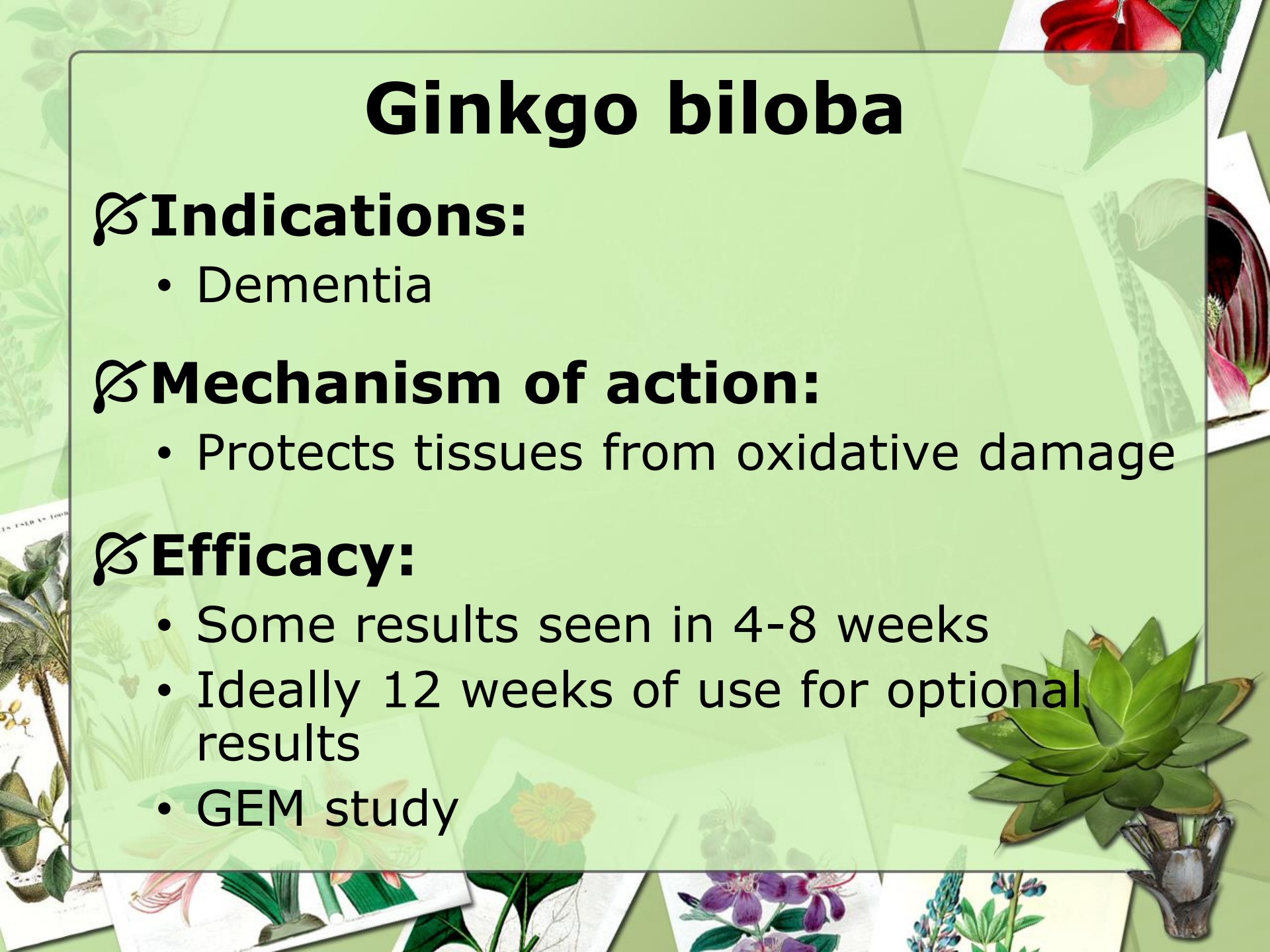
- Dementia

⌘ Mechanism of action:

- Protects tissues from oxidative damage

⌘ Efficacy:

- Some results seen in 4-8 weeks
- Ideally 12 weeks of use for optimal results
- GEM study



Ginkgo Biloba Efficacy

✂ Ginkgo Evaluation of Memory (GEM) Study

✂ **Design:** RDBPC, 6 year study, N = 3069, intervention was 120 mg bid ginkgo verses placebo

✂ **Outcome:** incident dementia and AD

✂ **Results:** was not effective in reducing the incidence rate of dementia (95% confidence interval [CI], 0.94-1.33; $P=.21$) or AD 1.16 (95% CI, 0.97-1.39; $P=.11$)

✂ Follow up to GEM study in 2009

JAMA. 2008;300(19):2253-2262

JAMA. 2009; 302:2663-2670

Ginkgo Biloba

⌘ Adverse reactions:

- GI, HA, dizziness, palpitations, and allergic skin reactions

⌘ Drug interactions:

- Antiplatelet and anticonvulsants

⌘ Herb interactions:

- Garlic, Ginger, Glucosamine
- St John's Wort

⌘ Disease interactions:

- Possible interference with fertility



Ginkgo Biloba

⌘ Dosage:

- 120 – 240 mg qd in divided doses
- Standardized leaf extract 24% ginkgo flavone glycoside and 6% terpene lactones

⌘ Clinical pearls:

- Discontinue 2 - 3 weeks prior to surgery



Ginseng (*Panax ginseng*)



Ginseng (*Panax ginseng*)

⌘ Indications:

- Adaptogen
- Diabetes
- Erectile Dysfunction

⌘ Mechanism of action:

- Increase serum cortisol
- Stimulate adrenal function

⌘ Efficacy:

- Use short term
- Some data ↓ risk of repeat colds in a season

Panax ginseng Efficacy

⌘ **Korean red ginseng (*Panax ginseng*) improves glucose and insulin regulation in well-controlled, type 2 diabetes: results of a randomized, double-blind, placebo-controlled study of efficacy and safety.**

⌘ **Design:** DBR crossover design, N = 19, 12 weeks, ginseng 2 g/meal verse placebo, adjunct to current diet and or medications

⌘ **Results:**

- No effects on HbA1c
- Patients maintained good glycemic control
- Safety and compliance were unchanged

Ginseng (*Panax ginseng*)

- ⌘ **Adverse reactions:** insomnia, BP changes, appetite loss, rash, dizziness and mood changes
- ⌘ **Drug interactions:** anticoagulants, diabetic meds, CYP 2D6 & 3A4
- ⌘ **Herb interactions:** Capsaicin, Chamomile, Feverfew, Garlic, Ginger and Bitter orange
- ⌘ **Disease interactions:** schizophrenia

Ginseng (*Panax ginseng*)

⌘ Dosage:

- Standardized > 7% ginsenoside
- ED: 900 mg tid
- DM: 3 – 8 grams 2 hours prior to meals
- Common Cold: 200 mg qd for 4 wks prior to vaccination and then 8 wks afterward

⌘ Clinical pearls:

- Generally recognized as safe (GRAS)
- Discontinue 2 - 3 weeks prior to surgery

Online Resources

Title	Location (Access)
Natural Medicine	http://www.naturaldatabase.com
National Center for Complementary and Alternative Medicine (NCCAM)	http://nccam.nih.gov
Florence G. Strauss-Leonard A. Wisneski Indigenous and Integrative Medicine Collection	http://hslibrary.ucdenver.edu/strauss
American Botanical Council	http://herbalgram.org/
Herb Research Foundation	http://herbs.org/
American Herbalist Guild	http://americanherbaistsquild.com
National Center for Homeopathy	http://www.homeopathy.org
United Plant Savers	http://www.unitedplantsavers.org
The Center for Integrative Medicine at University of Colorado Hospital	http://www.uch.edu/conditions/integrative-medicine/

Online resources

Title	Location (Access)
Micromedex	www.micromedex.com
UpToDate	www.uptodate.com
PubMed	www.ncbi.nlm.nih.gov/pubmed
Cochrane Collaboration	www.cochrane.org
Office of Dietary Supplements	www.ods.od.nih.gov
Mayo Clinic	http://www.mayoclinic.com/health/drug-information/DrugHerbIndex
Memorial Sloan-Kettering Cancer Center	http://www.mskcc.org/mskcc/html/11570.cfm
NOAH: New York Online Access to Health	http://noah-health.org/en/alternative/healing/herbal.html
Medline Plus	http://www.nlm.nih.gov/medlineplus/druginfo/herb_All.html
Food and Drug Administration	www.fda.gov

Conclusions

- ∅ The use of Integrative Health and Medicine is very prevalent in today's society
- ∅ Biological Based System therapies are the most utilized form of IHM
- ∅ Lack of FDA regulation necessitates informed decisions to find safe and effective products
- ∅ Health professionals must be educated about IHM or at least know where to find the information
- ∅ "Do no harm" approach

Questions



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