Medicinal Chemistry 420  
(2 credits)  
Alternative and Complementary Medicines  

Thursdays 1:30-3:20  Room T747  
http://courses.washington.edu/medch420/  
Gary Elmer, H172j Health Sciences, 543-2055,  
elmer@u.washington.edu  

Lecture Topics  

- Sept 29  
  Introduction  
  Herbal Products 1  
  Gary Elmer  
- Oct 5  
  Tour of the Medicinal Herb Garden (A-K)  
  Herbal Products 2 (L-Z)  
  Doug Ewing  
- Oct 12  
  Tour of the Medicinal Herb Garden (L-Z)  
  Herbal Products 2 (A-K)  
  Gary Elmer  
- Oct 19  
  Herbal Products 3  
  Gary Elmer  
- Oct 26  
  Herbal Products 4  
  Gary Elmer  
- Nov 2  
  Herbal Products 5  
  Other Dietary Supplements  
  Gary Elmer  
- Nov 9  
  Toxic Herbals  
  Sid Nelson  
- Nov 16  
  Herbal-Drug Interactions  
  Other Dietary Supplements  
  Gary Elmer  
- Nov 23  
  Holiday  
- Nov 30  
  Probiotics  
  Homeopathic Products  
  Gary Elmer  
- Dec 7  
  Effective Herbal Counseling  
  Darleen Wilson
Requirements for Credit

• Research paper
  – Short (4-6 double spaced pages, not including references) and up-to-date
  – Write on an herbal or other dietary supplement NOT covered in class. We will cover the “top 20” herbs (see slides for list), probiotics, DHEA, glucosamine, chondroitin, melatonin, CoQ10, and homeopathic products.
  – If taking Pharm 309, the guidelines specified for the research paper for this course and a 3.0 grade on the paper will be accepted. See http://courses.washington.edu/pharm309.
  – If not taking 309, write the paper following guidelines for the paper for Pharm 309 (see above) except you do not need to indicate the database search source location of your cited references.
  – Due date will be Nov 20.

Weekly Quiz

• Every week there will be a brief (~5 questions) quiz. The time allowed will be 10-15 min.
• quiz will be based on lecture material presented in the previous class.
• You can drop one quiz with the lowest score.
• There will be no “make-up” quiz if you are absent.
• At least a 70% on all possible quiz points and a “pass” on the research paper will be needed to get credit for this credit/no credit course.
General References on Herbal Products
(comprehensive monographs)

- The Review of Natural Products. *Facts and Comparisons Publishing Group*, St. Louis MO. 2004. Available at the UW Bookstore. Also available online through the UW at (http://healthlinks.washington.edu/contentBrowser.jsp?ctype=1)

- Natural Medicines Comprehensive Database
  Excellent database, the “gold standard”, available in print version ($92/yr) or online ($92/yr). Online updated “daily”. Available online at UW at (http://healthlinks.washington.edu/contentBrowser.jsp?ctype=1)


Books


- Essential Guide to Herbal Safety
  Simon Mills and Kerry Bone.. 2005
  Elsevier –new and excellent. $65

- The ABC Clinical Guide to Herbs

Periodicals and Newsletters on Herbal Products

—“HerbalGram” published by the American Botanical Council and the Herb Research Foundation; PO Box 201660, Austin TX 78720

Useful Internet Web sites

- Consumerlab.com. Consumerlab is evaluating dietary supplements for quality, a worthy goal. To see the complete evaluations, there is a subscription fee of $17.95/yr. The subscription will also provide you access to The Natural Pharmacist, an excellent database of monographs on herbals and other dietary supplements. www.consumerlab.com
Useful Internet Web sites

- Office of Dietary Supplements, NIH. Mandated by DSHEA, their mission is to promote research and provide objective information on dietary supplements. Link to IBIDS database on scientific literature on dietary supplements and other databases. Use is free to all.  http://ods.od.nih.gov

- American Herbal Products Association. Trade Association with links to member companies and publications. Also access to HerbMed database providing some references on herbals. Not always up to date, however. Useful general site. http://www.ahpa.org/

- Dr. Duke’s databases. Database on plants and their chemical constituents with biological activities. Dr. James Duke is a well known authority on ethnobotany. http://www.ars-grin.gov/duke

Free Electronic Newletters

- Dietary Supplement/Food Label News from the FDA http://www.cfsan.fda.gov/~dms/infonet.html


- Arbor Clinical Nutrition Updates (Dr. Tony Heilman) http://arborcom.com
1000 year old “Patterson Bundle”, a Native American bundle of medicinal herbs. HerbalGram 2002;55:35-41

Herbal Products

• sales of about $14 billion $ in USA for dietary supplements
• sales of about 4 billion $ in USA for botanicals
• Mass market herbal sales increased dramatically in the 1990s but have dropped in recent years. Total sales from all channels have generally shown a slow increase.
• In 1990 5.8% used “alternative medicines”
• In 2002, 25.2% used “alternative medicines”
• most do not tell their “traditional” provider what they are taking and many take alternative and complementary products together with allopathic drugs

Another Survey on Public Use of Alternative Medicines

- 1,584 S. Carolina adults
- 44% had used CAM within the year
- 25% used alternative medicines within the year
- 62% reported CAM medicines were “extremely or very effective”
- 87.8% would recommend to a friend
- 4% had bad experience
- 63% did not tell MD (15% MD recommended)

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Dietary Supplement Education Alliance Survey (Harris Interactive)
July 2001

- N=1022
- 59% take dietary supplements on a regular basis
- 46% take multivitamins
- 23% take herbal and specialty products (15% botanicals, 8% non botanical supplements)
- 95% indicate satisfaction; 75% very satisfied or extremely satisfied
- 25% wrong about expecting immediate results from herbals
- Only 49% consult with health care providers about taking supplements
- Most believe they have sufficient information on using supplements
Distribution of the $4.96 Billion European Market for Over-the-Counter Herbal Medicines in 2003.

The remaining $132 million in sales was divided among Portugal, Hungary, Ireland, Slovakia, Finland, and Norway. Data are from IMS Health. The spending per capita (calculated on the basis of the manufacturers' prices to wholesalers and recent United Nations projections of 2003 populations) was $25.00 in Germany, $18.80 in France, $9.50 in Italy, $6.50 in Poland, $3.60 in the United Kingdom, $4.10 in Spain, $12.30 in Belgium, $13.00 in Switzerland, $10.90 in Austria, $5.00 in the Netherlands, and $7.40 in the Czech Republic.
Most Common Uses for Herbal Products and Alternative Medicines

• Musculoskeletal Complaints
  • arthritis (glucosamine/chondroitin)

• CNS
  • fatigue (ginseng and others)
  • insomnia (valerian)
  • anxiety/depression (kava, chamomile, skullcap, St. John’s Wort)

• Colds/flu/immune (echinacea, goldenseal, atragalus, pau d’arco)

• Men (saw palmetto, pygeum)

• Women (black cohosh, soy, evening primrose)

• Circulation (ginkgo, garlic)

Types of Herbal and Alternative Medicines

• “Crude” dried herbs *
• “European” Phytopharmaceuticals
  – extracts
  – standardized extracts *
• Traditional Chinese Medicines*
• Ayurvedic Medicines
• Homeopathic Medicines*
• Functional Foods/Neutraceuticals *
• Probiotics **
• “other” dietary supplements (e.g. melatonin)
NEW-AGE PRODUCTS FOR FEELING GREAT

Gellus™ gives you two enjoyable products to normalize your intestinal function.

- A unique fermented apricot peach whey drink.
- A slightly fermented dairy product of a new kind, tasty even when unflavored and easy to eat with a spoon.

The new ingredient common to both Gellus products is the agreeable and palatable bacterial strain, Lactobacillus GG.

Both are low-lactose HYLA products.
Only a pinch of fructose is used as a sweetener and the fermented dairy product has a low fat content (1.5%).

LOW-LACTOSE FERMENTED DAIRY PRODUCT

Good on its own. A fresh natural taste. Delicious with berries or museli. At breakfast and as a snack.

Nutrient content/100 grams:
- energy: 270 kJ
- protein: 4.3 g
- fat: 1.5 g
- carbohydrates: 8.3 g
- lactose, less than: 1.5 g
- calcium: 150 mg

FERMENTED APRICOT-PEACH WHEY DRINK

A refreshing fruity taste. Try it first thing in the morning or anytime during the day.

Nutrient content/100 ml:
- energy: 260 kJ
- protein: 1.4 g
- fat: 0.1 g
- carbohydrates: 12.5 g
- lactose, less than: 1 g
Top 20 Selling Herbals - Mass Market, 52 weeks ending Jan 2, 2006
HerbalGram 2006;71:64

<table>
<thead>
<tr>
<th>Product</th>
<th>M $</th>
<th>% change</th>
<th>rank in 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. garlic</td>
<td>27</td>
<td>-3.3</td>
<td>1</td>
</tr>
<tr>
<td>2. echinacea</td>
<td>21</td>
<td>-11</td>
<td>2</td>
</tr>
<tr>
<td>3. saw palmetto</td>
<td>19</td>
<td>-5.4</td>
<td>3</td>
</tr>
<tr>
<td>4. ginkgo</td>
<td>17</td>
<td>-15</td>
<td>4</td>
</tr>
<tr>
<td>5. cranberry</td>
<td>16</td>
<td>+17</td>
<td>6</td>
</tr>
<tr>
<td>6. soy</td>
<td>15</td>
<td>-17</td>
<td>5</td>
</tr>
<tr>
<td>7. ginseng</td>
<td>11</td>
<td>-6.2</td>
<td>7</td>
</tr>
<tr>
<td>8. black cohosh</td>
<td>10</td>
<td>-10</td>
<td>8</td>
</tr>
<tr>
<td>9. St. John’s wort</td>
<td>9.0</td>
<td>-1.3</td>
<td>9</td>
</tr>
<tr>
<td>10. milk thistle</td>
<td>8.3</td>
<td>+6.8</td>
<td>10</td>
</tr>
<tr>
<td>11. Green tea</td>
<td>5.7</td>
<td>+94</td>
<td>13</td>
</tr>
<tr>
<td>12. Evening primrose oil</td>
<td>5.3</td>
<td>-13</td>
<td>11</td>
</tr>
<tr>
<td>13. valerian</td>
<td>3.4</td>
<td>-0.4</td>
<td>12</td>
</tr>
<tr>
<td>14. Horny goat weed</td>
<td>2.2</td>
<td>-1.4</td>
<td>16</td>
</tr>
</tbody>
</table>

Red indicates risk for drug interactions

Top 20 Selling Herbals - Mass Market, 52 weeks ending Jan 2, 2006
HerbalGram 2006;71:64

<table>
<thead>
<tr>
<th>Product</th>
<th>M $</th>
<th>% change</th>
<th>rank in 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>15. grape seed</td>
<td>2.2</td>
<td>-7.1</td>
<td>15</td>
</tr>
<tr>
<td>16. bilberry</td>
<td>2.1</td>
<td>-10</td>
<td>16</td>
</tr>
<tr>
<td>17. Red clover</td>
<td>1.7</td>
<td>-26</td>
<td>17</td>
</tr>
<tr>
<td>18. Yohimbe</td>
<td>1.5</td>
<td>-16</td>
<td>18</td>
</tr>
<tr>
<td>19. Horse chestnut seed</td>
<td>1.2</td>
<td>-15</td>
<td>19</td>
</tr>
<tr>
<td>20. ginger</td>
<td>0.9</td>
<td>+6</td>
<td>20</td>
</tr>
</tbody>
</table>

Total (all herbs) 249 -3.7

Red indicates herbs risk for drug interactions

Note: total herbal sales are estimated at $4.2 billion

The above figures include only sales from food stores, drug stores, and mass market retailers but with Wal-Mart figures not included. It does not include warehouse buying clubs, convenience stores, natural foods stores, multilevel marketers, health professional sales, mail order or internet sales.
### Total Estimated Herb Sales for All Channels

<table>
<thead>
<tr>
<th>Year</th>
<th>M $</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1994</td>
<td>2020</td>
<td></td>
</tr>
<tr>
<td>1995</td>
<td>2470</td>
<td>22</td>
</tr>
<tr>
<td>1996</td>
<td>2990</td>
<td>21</td>
</tr>
<tr>
<td>1997</td>
<td>3557</td>
<td>19</td>
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<td>1998</td>
<td>4002</td>
<td>13</td>
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<tr>
<td>1999</td>
<td>4110</td>
<td>3</td>
</tr>
<tr>
<td>2000</td>
<td>4260</td>
<td>4</td>
</tr>
<tr>
<td>2001</td>
<td>4397</td>
<td>3</td>
</tr>
<tr>
<td>2002</td>
<td>4276</td>
<td>-3</td>
</tr>
<tr>
<td>2003</td>
<td>4178</td>
<td>-2</td>
</tr>
<tr>
<td>2004</td>
<td>4320</td>
<td>3</td>
</tr>
<tr>
<td>2005</td>
<td>4410</td>
<td>2</td>
</tr>
</tbody>
</table>

Ref: HerbalGram 2006;71:64

### Herb Sales by Channel 2005

<table>
<thead>
<tr>
<th>Channel</th>
<th>M$</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mass market</td>
<td>713</td>
<td>-3.5</td>
</tr>
<tr>
<td>Natural and health food</td>
<td>1429</td>
<td>2.0</td>
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<tr>
<td>Direct sales</td>
<td>2268</td>
<td>4.0</td>
</tr>
<tr>
<td>Total</td>
<td>4410</td>
<td>2.1</td>
</tr>
</tbody>
</table>

Ref: HerbalGram 2006;71:64
Herb Sales by Category 2005

<table>
<thead>
<tr>
<th>Category</th>
<th>M$</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Herbs</td>
<td>2880</td>
<td>-0.7</td>
</tr>
<tr>
<td>Combination Herbs</td>
<td>1540</td>
<td>4.8</td>
</tr>
<tr>
<td>Total</td>
<td>4420</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Ref: HerbalGram 2006;71:64

Niacin (B3) 30 mg 1312 mg* Yerba Mate (leaf) SE Caffeine
Guarana (seed) SE Damiana (leaf, stem) SE Green Tea (leaf) SE Kola
Nut SE Schizonepeta (spica) SE Piper Nigum (fruit) SE Tibetan
Ginseng (root) SE Panax Ginseng (root) SE Maca Root SE Cocoa
Nut SE Thea Sinensis Complex (leaf) SE
Vitamin A (100% Acetate) 5000 IU, Vitamin C 1000 mg, Vitamin E 30 IU, Magnesium (Sulfate) 40 mg, Zinc (Sulfate) 8 mg, Selenium 15 mcg, Manganese 3 mg, Potassium 75 mg, Organic Herbal Extracts: Lonicera, Forsythia, Schizonepeta, Ginger, Chinese Vitex, Isatis Root, Echinacea 350 mg*, Amino Acids: Glutamine, Lysine 50 mg; 1 q 3h

Kaufman et al. JAMA 2002;287:337-344

<table>
<thead>
<tr>
<th>Rank</th>
<th>Herbal/Supplement</th>
<th>Men 18-44 y</th>
<th>Men 45-64 y</th>
<th>Men ≥65 y</th>
<th>Women 18-44 y</th>
<th>Women 45-64 y</th>
<th>Women ≥65 y</th>
<th>Total</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ginseng</td>
<td>4</td>
<td>4</td>
<td>&lt;1</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>3.3</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>GinGingiber extract</td>
<td>&lt;1</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>5</td>
<td>2.2</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Allum salivum</td>
<td>&lt;1</td>
<td>4</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>1.9</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Glucosamine</td>
<td>&lt;1</td>
<td>2</td>
<td>4</td>
<td>&lt;1</td>
<td>5</td>
<td>4</td>
<td>1.9</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>St. John's wort</td>
<td>&lt;1</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>&lt;1</td>
<td>1.3</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Echinacea augustifolia</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td>&lt;1</td>
<td>1.3</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Lecthin</td>
<td>&lt;1</td>
<td>&lt;1</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>1.1</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Chondroitin</td>
<td>&lt;1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Creatine</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.9</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Senecio repens</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>0</td>
<td>&lt;1</td>
<td>0</td>
<td>0.9</td>
<td></td>
</tr>
<tr>
<td>Any use</td>
<td></td>
<td>12</td>
<td>17</td>
<td>11</td>
<td>10</td>
<td>23</td>
<td>14</td>
<td>14</td>
<td></td>
</tr>
</tbody>
</table>

*Percentages weighted according to household size.
### Useful Herbal Products
(some evidence in support of uses)

- **Echinacea**  
  immune stimulant
- **Saw Palmetto**  
  BPH
- **Valerium**  
  sedative
- **Ginkgo**  
  circulation
- **Milk Thistle**  
  liver
- **Ginger**  
  nausea
- **Chamomile**  
  indigestion
- **Fever Few**  
  migraine
- **St. John’s Wort**  
  mild/mod depression
- **Hawthorn**  
  heart/circulation
- **Soy**  
  menopause symptoms
- **Kava**  
  anxiolytic
- **Black cohosh**  
  menopause symptoms
- **Green tea**  
  stimulant (antioxidant)

### Possibly Useful Herbal Products
(less evidence or conflicting evidence)

- **pycnogenol**  
  vision, antioxidant uses
- **ginseng**  
  adaptogen, tonic
- **grape seed**  
  vision, antioxidant uses
- **Evening primrose**  
  dysmenorrhea
- **Bilberry**  
  vision, antioxidant uses
- **Garlic**  
  hyperlipidemias, hypertension
- **yohimbe**  
  erectile dysfunction
Herbal Products Deemed Unsafe

- Aconite (Bushi)
- Aristolochia sp.
- Belladonna
- Blue Cohosh
- Borage
- Broom
- Calamus
- Chaparral
- Coltsfoot
- Comfrey
- Ephedra (Ma Huang)
- Germander
- Kombucha Tea
- Ma Huang (ephedra)
- Lobelia
- Pennyroyal Oil
- Poke Root
- Sassafras
- Scullcap
- Tansy Ragwort
- Wormwood

Complementary and Alternative Medicines “CAM”

- Fall under “Dietary Supplement” regulatory status (except homeopathic products)
- Dietary Supplements
  - vitamins, minerals, hormones
  - whole plant material, extracts of plants,
  - amino acids
  - miscellaneous “natural” products (e.g. glucosamine sulfate, melatonin)
Regulatory Issues

- Federal Food and Cosmetic Act of 1938 - safe
- Kefauver-Harris Act of 1962 - efficacy
- Vitamin and Mineral Amendments of 1972 - high dose OK
- Nutrition Labeling and Education Act of 1990 - food labels
- Dietary Health and Education Act of 1994 (DSHEA)

Dietary Health and Education Act of 1994 (DSHEA)

- not considered foods, food supplements or drugs
- no “therapeutic claims” unless approved by FDA
- no “health claims” unless approved by FDA
- limited “structure/function” claims allowed if there is some evidence to support them
  - examples of structure/function claims
- FDA must show product is unsafe
- Label must have a disclaimer “This statement has not been evaluated by the FDA”
- “third party” literature regs.
- Advertising regulated by FTC; all else by FDA
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Coricidin 'D'
COLD, FLU & SINUS
Antihistamine, Nasal Decongestant, Pain Reliever-Fever Reducer

Fast Relief of:
- Nasal & Sinus Congestion
- Aches & Pains, including headache
- Runny Nose and Sneezing
- Fever

NEW FORMULA
Dissolves Faster to Work Faster

24 TABLETS

Echinex
Standardized Echinacea Extract

Dietary supplement to support natural resistance against infection

supports your body's natural resistance
helps maintain health and well-being
all-natural herbal formula

30 tablets
Dietary Health and Education Act of 1994 (DSHEA)

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Each Capsule Supplies:
Ginkgo biloba extract (50:1) ... 40 mg
- Pure Ginkgo Extract
- European Formula
- 50:1 Concentrate
- 24% Flavoglycosides
- Look for the ☐ Assurance of Quality

Directions: As a dietary supplement, take 3 capsules daily, with or before meals.

ORIGINAL STANDARDIZED GINKGO BILOBA EXTRACT

Ginkobo
MENTAL ALERTNESS DIETARY SUPPLEMENT

- Improves Memory & Concentration
- Enhances Mental Focus
- All Natural Herbal Extract

36 TABLETS
40 mg Each

U.S. Patent No. 5,399,348

$1.50 Cash Rebate Inside

Bartell Drugs
134-4225
G7 DKT

13.99 *
New DSHEA Labeling Requirements

- implied claims banned also
- health maintenance claims OK
- definition of “disease” narrowed so that “life stage” symptoms (acne, hot flashes, wrinkles etc) are not considered diseases
- “science-based” regulatory program for dietary supplements will be in place at the FDA by 2010
- voluntary adverse event reporting started (thro MedWatch and Special Nutritionals Adverse Event Monitoring System)
“When I started on GroBust I measured myself. After two weeks on GroBust I could feel a difference, so I measured myself again. Sure enough I had already grown a full 1/2 inch! I have been on the product for 3 1/2 months now and I am 4 inches larger! Thank you for this wonderful natural alternative to surgery!” — J.S., St. George, Utah

Just listen to what Herbal V has done for the sex lives of people like you!

“On a scale of 1 to 10, it’s a 15. Electrifying. It’s like a wonder pill!”
— Bill B., Ballwin, Missouri

“I haven't had sexual relations in 11 years. Then with Herbal V it was... wow! It works again!”
— Brian Q., Sunrise, Florida
Problems with Existing Regulations

• requirements to make therapeutic claims are unrealistic
  – herbals are not patentable
  – no consideration for long safe use
  – less consideration for non USA studies
• dietary supplement label is inappropriate
• meaningful package insert lacking
• innovator companies have no protection
  – example: Saccharomyces boulardii*
• limited “official” monographs for herbals in USA (USP)

Problems with Existing Regulations

• No GMPs for herbals (proposal by FDA)
• Huge problems in quality control
• Unethical and criminal elements in industry
  – example: adulteration
Hypericin and Hyperforin in Eight Brands of St. John’s Wort

<table>
<thead>
<tr>
<th>Product</th>
<th>Hypericin (%)</th>
<th>Hyperforin (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperfin</td>
<td>0.29</td>
<td>1.89</td>
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<tr>
<td>PNC</td>
<td>0.12</td>
<td>0.20</td>
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<tr>
<td>Brite-Life</td>
<td>0.22</td>
<td>1.16</td>
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<td>ShopKo</td>
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<tr>
<td>Shurfine</td>
<td>0.17</td>
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<tr>
<td>YourLife</td>
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<tr>
<td>Nature’s Balance</td>
<td>0.03</td>
<td>0.01</td>
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<tr>
<td>Natrol</td>
<td>0.25</td>
<td>0.48</td>
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</table>

Variation in the Amounts of Active Ginsenosides (Panax Species) and Eleutherosides (*Eleutherococcus senticosus*) in Ginseng Products in Relation to the Amounts Indicated on Their Labels. Adapted from Harkey et al. (Am J Clin Nutr 2001;73:1101-6), with the permission of the publisher.
Estimated Daily Lead, Mercury, and Arsenic Ingestion for Heavy Metal-Containing HMPs Recommended for Adults and Children


Internet Marketing of Herbal Products Study
Morris and Avorn JAMA 2003;290:1505-1509

Methods: Searched using 5 search engines the first page hits for 8 popular herbals

Findings: 273 of 338 (81%) made 1 or more health claim
only 12% provided references to back claim
only 39% of kava sites mentioned hepatotoxicity
Examples of Internet Health Claims (JAMA 2003;290:1505-1509)

Ginkgo Biloba  “Its effects in improving circulation also contribute to its use for impotency and peripheral vascular insufficiency …. Ginkgo treats depression, headaches, memory loss and ringing in the ears (tinnitus). It is also recommended for Alzheimer's, asthma, eczema, heart and kidney disorders.”

St John's Wort_  “St John's wort is effective in the treatment of mild to moderate depression … recent studies have shown that it could have a potent anti-viral effect against enveloped viruses.”

Echinacea_  “Because it has natural antibiotic actions, Echinacea is considered an excellent herb for infections of all kinds. In addition, it works to boost lymphatic cleansing of the blood, enhances the immune system and has cortisone like properties which contribute to its anti-inflammatory action. It is recommended for stubborn viral infections, yeast infections and for arthritic conditions.”

Saw Palmetto_  “The lipophilic extract of the saw palmetto (ser repens) berries is the most widely used herbal preventive and therapeutic agent for benign prostatic hyperplasia (BPH).”

Solutions: Presidents Commission on Dietary Supplement Labels recommendations and suggestions to FDA ('97)

• * set up system to review botanicals for OTC status

• urge to study regulatory systems in other countries

• call for surveillance of adverse effects

• set up system for “traditional use claims” or the like for products that may not meet OTC data requirements

• call for use of outside experts in product reviews
FDA Warnings

• FDA posts warnings of contaminated or harmful supplements
  • tiratricol or TRIAC (triiodothyroacetic acid)
  • aristolochic acid (renal toxicity)
  • ephedra alkaloids
  • Comfrey
  • Kava and hepatotoxicity
• FDA recall of PC-SPES (contamination with warfarin and maybe DES)
• To get email postings see www.fda.gov

Solutions

• New compendial monographs on herbals underway

  – USP monographs (USP24-NF14) and label logo

  – Micromedex and other objective “use monographs”

  – WHO Monographs on Selected Medicinal Plants

• GMPs for Dietary Supplements are immenent
• United States Pharmacopoeia/National Formulary
• Non profit corporation that sets standards for drugs and biologics
• Is in the process of creating standards for dietary supplements
  • Limits on heavy metals, pesticides
  • Limits on microbial contamination
  • Quality control specs for marker compounds
USP Dietary Supplement Verification Program

• Manufacturer must agree to meet standards set by USP and their monographs
• Must agree to inspections and random analyses of products
• USP analyzes the product and inspects the manufacturing facility
• Pharmavite is the first manufacturer to seek USP verification (Nature Made, Nature’s Resource) for their line of herbals and dietary supplements. The “USP” will appear on the labels.

www.usp.org

Consumerlab.com

• A private company testing and certifying dietary supplements
• Membership is $24/yr and includes access to The Natural Pharmacist database
• Manufacturers whose products “pass” are listed on consumerlab’s website (www.consumerlab.com)
• Manufacturers who do not pass are also listed
• A manufacturer whose product “passes” can (for a fee) include the consumerlab seal on their label
Product Selection Issues

- Select “name brands” recognized for quality

- select “standardized” products that give potency per unit of the product of an important marker compound

- select products used in the positive clinical trials

- select “standardized extracts” where appropriate

- select products that have batch numbers, expiry dates, and have the new label elements

- avoid complex herbal mixtures
Some “Name Brand” Botanicals

Warner Lambert
  Quanterra Mental® (ginkgo)
  Quanterra Prostate® (saw palmetto)
Whitehall-Robins Healthcare
  Centrum® botanicals line
Pharmaton (Boehringer Ingelheim)
  Ginsana ® (ginseng)
  Ginkoba ® (ginkgo)
  Venastat ® (horse chestnut)
  Movana ® (St. John’s wort)
SK-Beecham
  Alluna ® (valerian and hops)
Pharmavite
  Nature Made ®
  Nature’s Resource ®
Phyto-Phamica
  Nature’s Way

What can we do?

• Dialog with NDs and other prescribers

• ask patients about herbals they may be taking

• offer the best products

• press for regulatory reform

• stay informed
Choosing Herbals - Advice for patients

• Be sure you have an accurate diagnosis.
• Select a “name brand”, quality product;
• If the advertising says “cure” “breakthrough” “detoxify”, etc – forget it!
• Tell your doctor and pharmacist what you are taking to avoid interactions with Rx or other OTC medications.
• Use one supplement (single ingredient) at a time.
• Keep the container with labels in case of future adverse reactions.