Variations in Product Choices of Frequently Purchased Herbs

Caveat Emptor

Judith Garrard, PhD; Susan Harms, RPh, MPH, PhD; Lynn E. Eberly, PhD; Amy Matiak, PharmD

Background: Patients who report use of herbs to their physicians may not be able to accurately describe the ingredients or recommended dosage because the products for the same herb may differ. The purpose of this study was to describe variations in label information of products for each of the 10 most commonly purchased herbs.

Methods: Products for each of 10 herbs were surveyed in a convenience sample of 20 retail stores in a large metropolitan area. Herbs were those with the greatest sales dollars in 1998: echinacea, St John's wort, Ginkgo biloba, garlic, saw palmetto, ginseng, goldenseal, aloe, Siberian ginseng, and valerian.

Results: Each herb had a large range in label ingredients and recommended daily dose (RDD) across available products. Strengths were not directly comparable because of ingredient variability. Among 880 products, 43% were consistent with a benchmark in ingredients and RDD, 20% in ingredients only, and 37% were either not consistent or label information was insufficient. Price per RDD was a significant predictor of consistency with the benchmark, but store type was not.

Conclusions: Persons self-medicating with an herb may be ingesting ingredients substantially different from that recommended by a benchmark, both in quantity and content. Higher price per label RDD was the best predictor of consistency with a benchmark. This study demonstrates that health providers and consumers need to closely examine label ingredients of presumably the same or similar herbal products.

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O VER THE PAST 10 years, the use of botanicals and dietary supplements (BDS) by the American public has increased by an estimated 380%.¹ These products, including herbs, nutraceuticals,²³ complementary or alternative medications, phytomedicines or phytopharmaceuticals,⁴ and traditional medicines, are widely available in health food stores, pharmacies, grocery stores, discount stores, and other retail outlets, as well as on the Internet and through mail-order catalogs. This is a multimillion dollar industry in the United States, as illustrated by sales of over $600 million in 1998 for herbal products alone.⁵

Although the public has purchased these products in steadily increasing numbers over the past decade, relatively few patients disclose personal use of BDS products to their physician.¹⁶,¹⁷ Two population-based surveys conducted 7 years apart (1990 and 1997) reported comparable results about use of all alternative therapies, including BDS products: less than 40% of the therapies being used were discussed with the respondent’s physician.¹⁷

Despite the reluctance of most patients to admit BDS use with their health care providers, prescribers report an increase in patients’ questions about specific products. More than ever, health care professionals are expressing concern about the safety and effectiveness of BDS.⁸ Physicians have reported discomfort in responding to such issues owing to a lack of formal training in complementary and alternative medicine (CAM),⁹,¹⁰ as well as the absence of a conclusive body of research in this area. Although the number of CAM courses at the undergraduate and continuing education levels has grown in recent years,¹¹,¹² clinically applied BDS research remains inadequate.

There is widespread belief among the public that botanicals are harmless because they are natural products. Emerging research suggests, however, that there may be serious repercussions in interactions with prescription drugs, clinical conditions, or both.¹⁵,¹⁶ For example, in a recent study, Hypericum perforatum (ie, St John's wort) has been reported to have a negative, time-dependent interaction with digoxin,¹⁰ in addition to interactions with other prescription drugs such as indinavir,¹⁷ theophylline,¹⁸ and warfarin.¹⁹ Examples of other herb-drug interactions include valerian (which should

From the Divisions of Health Services Research & Policy (Drs Garrard and Harms) and Biostatistics (Dr Eberly), School of Public Health, and College of Pharmacy (Ms Matiak), University of Minnesota, Minneapolis. The authors have no relevant financial interest in this article.
not be used concomitantly with barbiturates because of the possibility of excessive sedation) or ginseng (which may affect blood glucose levels and should be avoided by patients with diabetes mellitus). Based on the results of a national survey in 1997, Eisenberg et al estimated that 1 in 5 Americans taking prescription drugs also use herbs, high-dose vitamins, or both, which suggests that 15 million adults may be at risk for adverse interactions due to combinations of medications.

Standards for ingredients and recommended daily doses (RDDs) of BDS have not been established by any regulatory arm of the US federal government. Although standardization may be the ideal, it may also be a practical impossibility. Plant products are composed of a number of chemical components, each of which may have varying levels of biological activity. In addition, components may differ depending on the plant part used, growing and harvesting conditions, and formulation (eg, capsule, extract, or tea). Thus, on a gram-per-gram basis, even products using the same plant parts may not be bioequivalent. For example, 2 products may contain the same plant (eg, St John’s wort) but differ in concentration of 1 or more of the therapeutically active ingredients (eg, Hypericum perforatum), thus rendering them phytochemically different. Given the lack of standardization and recent exponential growth in this industry, it is likely that products for the same herb will vary, perhaps substantially, in many ingredient characteristics. This study was an initial step in addressing that possibility.

The purpose of this study was to examine product variability based on label information for each of the 10 most commonly purchased herbs in the United States. Only the stated ingredients on the labels were compared; no attempt was made to assay the ingredients or otherwise determine whether the ingredients stated on the label matched the chemical(s) in the container. In lieu of federal standards, information from a recent textbook published about BDS by 2 clinical/pharmacists was used as a benchmark for ingredients and dosage levels for each herb. The specific questions examined in this study were the following:

- Variations Among Herbal Products. How did the products for each herb compare with one another in ingredients and RDDs printed on the label?
- Consistency Between Products and Benchmark. What proportion of the products for each herb were consistent with benchmark ingredients and RDDs? Was product consistency with the benchmark greater for some herbs than for others?
- Markers of Consistency. For each of the 10 herbs, could 1 or more markers, such as brand, type of store, or price, be used to identify products that were consistent with the benchmark?

METHODS

DESIGN

This was a cross-sectional, descriptive study of label ingredients and manufacturer’s dosage recommendations among herbal products available to the public for the 10 most commonly purchased herbs sold in 1998 in the United States. For many of these herbs, the same manufacturer provided 2 or more products under the same brand name that varied by ingredients, RDD, price, quantity, or information/instructions on the label. For this reason, the unit of analysis in this study was the product, rather than brand.

Data were gathered in January 2000, in a convenience sample of 20 retail outlets, with the following distribution:

- Grocery store (n=6; 2 nationally affiliated chain stores and 2 each of 2 local stores)
- Retail pharmacy (n=3; 1 each of 2 nationally affiliated chain stores and 1 local store)
- Discount store (n=6; 2 each of 3 nationally affiliated chain stores)
- Health food store (n=5; 1 each of 3 nationally affiliated chain stores and 2 local stores)

For each of the 10 herbs, all oral products available to the public on open shelves of the stores were included. Combination products (eg, echinacea with goldenseal) were excluded. Label information was collected on-site at each of the stores by a pharmacy student in the final year of the Doctor of Pharmacy program. A 2-step process was used to code product information and establish intercoder reliability: (1) once the data were collected, the pharmacy student coded all product information and (2) the study pharmacist independently recoded all of the product information without knowledge of the initial coding. There was 100% agreement between the 2 coders.

Only information available on the container of each product was recorded, with no additional questions to or input from personnel in the stores. Recorded data included name of manufacturer, all ingredients exactly as printed on the label (ie, plant species and plant parts), strength, label-specified RDD, quantity per container, and price per container.

In the absence of a set of federal standards for BDS ingredients or dosage recommendations, comparable information from a textbook, Professional’s Handbook of Complementary and Alternative Medicines (Professional’s Handbook), was used as a benchmark or point of reference. The Professional’s Handbook was one of few publications by academic or clinical pharmacists in the field not affiliated with a commercial manufacturer or distributor of any of the products included in this study.

The report of the German Commission E was not used as a working taxonomy for this study because we sought a more up-to-date reference and one that took advantage of the upswing in herb research that has taken place, particularly in the United States within the last 5 to 7 years. Moreover, selected information from the Commission E report was incorporated into the Professional’s Handbook.

CHOICE OF HERBS

The list of 10 most frequently purchased herbs, listed in Table 1 in descending order of sales, included echinacea, St John’s wort, Ginkgo biloba, garlic, saw palmetto, ginseng, goldenseal, aloe, Siberian ginseng, and valerian. The reported uses in Table 1 should not be interpreted as recommendations by us or those of Mar and Bent in their article. Table 1 also includes dose per day as described in the Professional’s Handbook. It is understood that dosage may differ according to the intended therapeutic use. For this study, benchmark dosages correspond to the most commonly reported use for each herb.

MEASURES

Consistency Between Products and Benchmark

Information from each product’s label was compared with the benchmark, including ingredients and RDD. Three nonover-
labels were often described as a range of dosages. Products were considered “consistent in dos- 
age” if any part of the label RDD fell within the benchmark range.

The categories were operationally defined as follows: If plant parts described on the product label matched those listed in the benchmark, then the product was coded as “consistent in ingredients.” If the product included not only plant parts specified in the benchmark but also other plant parts, the product was still coded as “consistent in ingredients.” If none of the plant parts matched those in the benchmark or if there was insufficient information to make a determination, the product was coded “not consistent in ingredients.”

In the absence of nationally accepted standards, both the herb RDD and the benchmark RDD were often described as a range of dosages. Products were considered “consistent in dosage” if any part of the label RDD fell within the benchmark range.

Markers of Consistency

Two dichotomous variables (yes/no) were created for each product: one for consistency in ingredients and the other for consistency in both ingredients and dosage. Four variables were defined as potential markers of consistency: brand name, type of store (grocery, retail pharmacy, discount, or health food), price per label RDD, and price per benchmark RDD.

STATISTICAL ANALYSES

All analyses were done separately for each herb. Descriptive statistics were used to summarize variations among herbal products and consistency between products and benchmark. Logistic regressions were used to examine markers of consistency, with “consistent with benchmark (yes/no)” as the dependent variable and each of the 4 markers (brand, store type, price per label RDD, and price per benchmark RDD) as separate factors.

RESULTS

VARIATIONS AMONG HERBAL PRODUCTS

Product Availability

Consumers had a choice of 880 products distributed among 241 different brands for these 10 herbs. Across all stores, the number of products ranged from 42 (among 15 brands) for goldenseal to 143 (among 33 brands) for garlic (Table 2). Most stores carried at least 1 brand for each herb, and most brands offered several products for the same herb.

Ingredient and Dosage Variability

Within each of the herbs, products varied widely in the ingredients listed (plant species and parts), RDD, and instructions for use. For some products, the label information was so vague that it was not possible to determine what the ingredients were. The range of strengths described on product labels varied by a factor of 5 for echinacea to 20 for goldenseal (Table 2). This lack of ingredient specificity on the label, the addition of plant parts not in the benchmark, and multiple products by the same manufacturer made comparisons difficult. For example, one manufacturer had 2 products for the same herb, one of which contained “Echinacea purpurea (aerial parts)” and the other, “Echinacea purpurea herb.” The latter is an example of insufficient plant part information to determine whether appropriate ingredients were used.
Because of the wide variability in ingredients and strengths offered, it was impossible to directly compare strengths across products. Thus, our comparisons focused on RDD, which varied by a factor of 6 for St John’s wort to 12 for garlic. Restricting the comparisons to products that presumably had the same plant parts (as specified on the label) did not reduce variations in range of daily doses.

### CONSISTENCY BETWEEN PRODUCTS AND THE BENCHMARK

**Consistency in Ingredients Only**

The percentage of products consistent with benchmark ingredients differed widely from herb to herb. Of the 880 products examined in this survey, 379 (43%) were consistent in both ingredients and dosage; 172 (20%) were consistent in ingredients but not dosage; and 329 (37%) were either not consistent in ingredients or label information was so vague that determination about ingredients was impossible (Table 2). In 4 of the 10 herbs (echinacea, St John’s wort, saw palmetto, and valerian), half or fewer of the products were consistent with benchmark ingredients. Among all 10 herbs, echinacea had the fewest number of products (30 [33%]) consistent in ingredients, while ginseng had the most (113 [100%]).

**Consistency in Ingredients and Dosage**

The herbs also differed in the proportion of products that were consistent with the benchmark in both ingredients and daily dose. They ranged from 2% of the 45 aloe products to 90% of the 51 Siberian ginseng products (Table 2). In 7 of the 10 herbs (garlic, ginseng, and Siberian ginseng), half or fewer of the products were consistent with the benchmark in both ingredients and dosage.

**Markers of Consistency**

For each of the herbs, is there a marker such as brand name, type of store, or price that consumers could use to identify products that were consistent in ingredients with the benchmark? A logistic regression of consistency, using all 880 products by brand name was not possible because the number of products per brand were insufficient and because products sold under the same brand name were often assigned to different categories of consistency with the benchmark.

An analysis between consistency and type of store (grocery, retail pharmacy, discount, or health food) was possible for most herbs; however, no statistically significant differences were found. In other words, consumers could not depend on type of store as a guide in selecting products consistent with benchmark ingredients.

Among products consistent in ingredients, the association between price and consistency with the benchmark in dosage was also examined. Results varied depending on whether a price based on label RDD or on benchmark RDD was used. Results showed that price per label RDD was positively associated with consistency with benchmark for 6 of the 10 herbs: echinacea, garlic, saw palmetto, ginseng, goldenseal, and Siberian ginseng (Table 3). The higher the price, the greater the likelihood of consistency with the benchmark. For example, every $0.25 increase in the label RDD price of a goldenseal product consistent in ingredients corresponded to a tripling of the odds of being consistent in dosage.

The opposite association between benchmark RDD and price was found for 4 herbs. Results showed that the lower the price (based on benchmark RDD), the greater the likelihood of consistency with the benchmark for St John’s wort, *Ginkgo biloba*, ginseng, and valerian.

On a practical basis, consumers are not likely to have a benchmark publication available as they stand in the aisles of a retail outlet making a purchase decision. However, the choice of the more expensive product (based on price per label RDD) for each of the 6 herbs, especially saw palmetto, goldenseal, and Siberian ginseng, might result in closer agreement with the benchmark.

An analysis was limited because of the exclusion of those products that were not consistent in ingredients. A decision rule based on these costs may therefore not apply when consumers are not aware of a product’s consistency.

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**Table 2. Variability in Number of Herbal Products, Brands, Strength, Label RDD, and Consistency With Benchmark**

<table>
<thead>
<tr>
<th>Herbal Product</th>
<th>No. of Products</th>
<th>No. of Brands</th>
<th>Range of Strengths Available</th>
<th>Range of Label RDD in No. of Tablets or Capsules</th>
<th>Consistent in Ingredients and Dosage, No. (%)</th>
<th>Not Consistent in Dosage, No. (%)</th>
<th>Not Consistent in Ingredients or Dosage, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Echinacea</td>
<td>92</td>
<td>27</td>
<td>100-500 mg</td>
<td>1 prn up to 10/d</td>
<td>12 (13)</td>
<td>18 (20)</td>
<td>62 (67)</td>
</tr>
<tr>
<td>St John’s wort</td>
<td>130</td>
<td>34</td>
<td>150-1000 mg</td>
<td>1-6/d</td>
<td>50 (38)</td>
<td>15 (12)</td>
<td>65 (50)</td>
</tr>
<tr>
<td>Ginseng</td>
<td>138</td>
<td>34</td>
<td>30-450 mg</td>
<td>1-6/d</td>
<td>54 (39)</td>
<td>9 (4)</td>
<td>79 (57)</td>
</tr>
<tr>
<td>Garlic</td>
<td>143</td>
<td>33</td>
<td>100-1800 mg</td>
<td>1 ap up to 12/d</td>
<td>71 (50)</td>
<td>40 (28)</td>
<td>32 (22)</td>
</tr>
<tr>
<td>Saw palmetto</td>
<td>77</td>
<td>25</td>
<td>80-1000 mg</td>
<td>1-9/d</td>
<td>33 (43)</td>
<td>1 (1)</td>
<td>43 (56)</td>
</tr>
<tr>
<td>Ginseng</td>
<td>113</td>
<td>30</td>
<td>100-560 mg</td>
<td>1-9/d</td>
<td>88 (68)</td>
<td>25 (32)</td>
<td>0</td>
</tr>
<tr>
<td>Goldenseal</td>
<td>42</td>
<td>15</td>
<td>50-1000 mg</td>
<td>1-9/d</td>
<td>16 (36)</td>
<td>17 (43)</td>
<td>9 (21)</td>
</tr>
<tr>
<td>Aloe</td>
<td>45</td>
<td>10</td>
<td>25-1100 mg</td>
<td>1-6/d</td>
<td>1 (2)</td>
<td>39 (87)</td>
<td>5 (11)</td>
</tr>
<tr>
<td>Siberian ginseng</td>
<td>51</td>
<td>18</td>
<td>200-1000 mg</td>
<td>1-9/d</td>
<td>46 (90)</td>
<td>3 (6)</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Valerian</td>
<td>49</td>
<td>15</td>
<td>100-1020 mg</td>
<td>1-9/d</td>
<td>8 (16)</td>
<td>9 (18)</td>
<td>32 (37)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>880</strong></td>
<td><strong>241</strong></td>
<td>...</td>
<td>...</td>
<td><strong>379 (43)</strong></td>
<td><strong>172 (20)</strong></td>
<td><strong>329 (37)</strong></td>
</tr>
</tbody>
</table>

Abbreviations: ap, as personal preference; prn, as occasion requires; RDD, recommended daily dose.
The results of this study suggest that even when patients tell physicians about their use of an herb, neither may be fully aware of what has been ingested because of the wide variation in label information. Not only did product labels vary extensively in the quality and quantity of information provided, they also showed surprisingly wide variations in plant part ingredients and label RDDs. In some cases, descriptions on product labels were so vague about plant parts, or even the plant species, that experienced pharmacists on the study team were not able to discern ingredient information. If pharmacists trained to interpret pharmaceutical product descriptions are unable to understand the labels for some of these products, how can a layperson make sense of them, much less compare products with a benchmark or with one another or convey this information to their physician? Furthermore, how can a health care provider adequately advise a patient without an accurate and complete picture of what the patient is consuming?

Likewise, choosing a product composed of seemingly correct ingredients and plant parts will not guarantee that an appropriate dosage is consumed. Twenty percent of products with appropriate ingredients recommend an inappropriate dose. Of the remaining products with correct ingredients, most suggest a daily dose range. Consumers have to make their own judgments about where in the range a therapeutic dosage lies.

Results also showed that half or fewer of the products for 7 of the 10 herbs were not consistent with the benchmark in ingredients and RDD. Cost per label RDD was positively associated with consistency, but cost per benchmark RDD was negatively associated. This study was limited to the use of 1 benchmark, and the differences between label RDDs and benchmark RDDs were staggering. A more comprehensive approach would be to compare each product with information from multiple benchmarks based on other textbooks or guidelines; however, such a comparison was beyond the scope of this study. Also, this study did not address safety or effectiveness of any herb or herb product.

Federal legislation passed in 1994, the Dietary Supplement Health and Education Act (DSHEA), expanded the definition of dietary supplements to include botanicals, thereby placing BDS under the less stringent food industry guidelines rather than the much stricter drug product guidelines. Provided they were described as “dietary supplements” and no health claims were made about their effects, these products could be advertised and sold to the public on the basis of caveat emptor. Unlike prescription drugs, the burden of proof regarding safety of BDS is not placed on the manufacturers; rather, the Food and Drug Administration (FDA) must demonstrate that a BDS product is unsafe. Then in 1991, recognizing the need for further research and dissemination of information to clinicians, researchers, and consumers, the National Institutes of Health (NIH) created the Office of Dietary Supplements (http://dietary-supplements.info.nih.gov/) was established by Congress as part of the DSHEA legislation. The Office of Dietary Supplements has created and maintains the International Bibliographic Information on Dietary Supplements (IBIDS), a database that includes published international scientific literature on dietary supplements, vitamins, minerals, and botanicals, but not standards (http://ods.od.nih.gov/health.aspx).

This study relied on the dosage recommendations of the Professional’s Handbook. Because few comprehensive clinical trials have been conducted for most herbs, the dosages given in the handbook were derived from available references and research, studies often con-

### Table 3. Association Between Consistency in Dosage and Prices per Label RDD and Benchmark RDD Among Products Consistent in Ingredients

<table>
<thead>
<tr>
<th>Herb</th>
<th>No. of Products (N = 550)</th>
<th>Price per Label RDD</th>
<th>Price per Benchmark RDD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Echinacea</td>
<td>29‡</td>
<td>8.87</td>
<td>2.45</td>
</tr>
<tr>
<td>St John’s wort</td>
<td>65</td>
<td>1.28</td>
<td>0.54</td>
</tr>
<tr>
<td>Ginseng</td>
<td>59</td>
<td>0.08</td>
<td>0.88</td>
</tr>
<tr>
<td>Garlic</td>
<td>111</td>
<td>22.69</td>
<td>6.07</td>
</tr>
<tr>
<td>Saw palmetto</td>
<td>34</td>
<td>4.70</td>
<td>36.19</td>
</tr>
<tr>
<td>Ginseng</td>
<td>113</td>
<td>4.11</td>
<td>1.34</td>
</tr>
<tr>
<td>Goldenseal</td>
<td>33</td>
<td>22.76</td>
<td>2.93</td>
</tr>
<tr>
<td>Aloe</td>
<td>40</td>
<td>1.02</td>
<td>0.54</td>
</tr>
<tr>
<td>Siberian ginseng</td>
<td>49</td>
<td>10.05</td>
<td>361.40</td>
</tr>
<tr>
<td>Valerian</td>
<td>17</td>
<td>3.47</td>
<td>2.66</td>
</tr>
</tbody>
</table>

Abbreviation: RDD, recommended daily dose.

*Information in boldface indicates a statistically significant association.
†Odds ratio given for a $0.25 higher consumer price.
‡One echinacea product was excluded because the label RDD was based on “per need.”
§Insufficient data to calculate, since there was no benchmark dosage for aloe juice products.
ducted without randomization, without a standardized product, and with a small sample size. Thus, the authors reported to us that they frequently had difficulty in finding significant agreement on dosage between studies. Confounding the predicament further is the question of dosage equivalence across plant species. For instance, in evaluating echinacea research, Fetrow and Avila found studies on 9 different Echinacea species. The state of the science is not sufficiently advanced to make a determination as to whether dosage remains constant across species.

Even with a clear definition of species and plant parts, neither the physician nor the consumer can be certain that the product described on the label accurately describes the contents of the container without a laboratory analysis. Such an analysis was not part of the present study. ConsumerLab.com LLC (White Plains, NY), an independent commercial testing company, evaluates the validity of the contents of selected BDS products and posts the results on the Web at http://www.consumerlab.com. In the research literature, the issue of product integrity has been addressed in several publications, 2 for the consumer and 1 in a peer-reviewed journal.

The results of this field study illustrate some of the difficulties in choosing among myriad products of commonly used herbs. Because of the paucity of clinical trials and outcome studies, health care practitioners face an even more daunting task in advising patients about the responsible use of herbal preparations and other dietary supplements. Although the results of this study are not generalizable to a national setting or to other BDS because of its limited scope, the wide variations in ingredients and dosage ranges in just this sample of 880 products of 10 herbs in 1 metropolitan area should alert health providers to additional kinds of issues to raise with patients. Knowing that a patient is taking a specific herb or other BDS is not sufficient without further details about ingredients and dosage as described on the label. Patient adherence to label instructions is another topic that clinicians need to discuss with patients.

While labeling has remained largely within the purview of the FDA, most advertising falls under the jurisdiction of the Federal Trade Commission. In limiting the regulatory role of the FDA, the intent of the US Congress may have been to enable consumers to have unrestricted access to BDS products, but the public has been poorly served. Without adequate and timely information, the consumer is at the mercy of an increasingly entrepreneurial industry, as described in a recent article in the New York Times. Physicians and their patients alike need comprehensive and up-to-date information that can provide one way to “level the playing field” and heed the admonition, caveat emptor.

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Corresponding author and reprints: Judith Garrard, PhD, Division of Health Services Research & Policy, School of Public Health, MMC #729, University of Minnesota, 420 Delaware St SE, Minneapolis, MN 55455 (e-mail: jgarrard@umn.edu).

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