

ACCP WHITE PAPER

White Paper on Herbal Products

American College of Clinical Pharmacy

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In 1990, an estimated 427 million visits were made to alternative medical practitioners in the United States, exceeding the estimated 388 million visits to primary care physicians during the same period.¹ The number of visits had risen to 629 million in 1997, with growth mainly due to an increase in new individuals seeking practitioners of alternative medicine.² An estimated \$27 billion was spent in 1997 on alternative medicine.²

Herbal and other natural products such as melatonin and megavitamins represent an area of great growth among alternative medical practices. Between 1990 and 1997, the use of herbal products increased 380% and megavitamin use increased 130%.² During this growth period, concerns have been raised about adequate research supporting efficacy claims and lack of uniform product standardization. The major issues surrounding the use of herbal products are discussed in this paper, and resources and recommendations for pharmacists to improve the informed use of these products by consumers are provided.

Overview of Complementary Medicine

“Complementary” medicine has been described

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by a variety of terms, including “integrative,” “naturopathic,” and “alternative.”¹ In addition to herbal and megavitamin therapies, alternative medicine includes a broad range of therapies and practices, which are defined in Appendix 1. Relaxation techniques, herbal products, massage, chiropractic, spiritual healing, megavitamins, and self-help groups were the alternative medical therapies most frequently used in 1997.²

In one study, individuals chose alternative medical care, not because of dissatisfaction with conventional medicine, but because alternative therapies were more congruent with their personal beliefs and values.³ Individuals using complementary therapies generally possess a high education and income level, although use crosses all socioeconomic categories.^{1,2} The most commonly reported conditions for which alternative medicines are used are musculoskeletal complaints, including back and neck problems; arthritis; sprains; and strains. Allergies, as well as central nervous system complaints of fatigue, insomnia, anxiety and depression, also have prompted the use of alternative sources of medical care.^{1,2} One report indicated that 60 million Americans over the age of 18 years have used herbs for general health maintenance and for colds, burns, headaches, allergies, rashes, insomnia and depression.⁴ Complementary therapies usually are used as a supplement to conventional medical care, with only 4.4% of individuals relying exclusively on alternative medical care.³ Patients have used complementary therapies to augment treatments for cancer and the acquired immunodeficiency syndrome. Also, a recent study of 101 caregivers found that over 55% tried at least one alternative

therapy to improve memory in patients with Alzheimer's disease, and 20% tried over three treatments.⁵

While the media have acknowledged the widespread use of complementary medicine for common ailments in the United States, less than 40% of individuals using these therapies inform their health care providers, as they anticipate disparaging remarks if they reveal their use of these agents.^{1, 2} Conversely, many health care providers are reluctant to ask patients about alternative medicine use, creating a situation that has been described as "don't ask, don't tell."² The reason for the reluctance among health care professionals may be due in part to their inadequate knowledge about complementary medicine, particularly herbal products. Furthermore, many therapies originated long before the 20th century and usually outside the traditions of Western medicine⁶ and thus lack evidence from the high-quality research methods that are the standard by which medical interventions are held. However, many herbal therapies do have unique pharmacologic actions that can benefit patients and spawn new research. The current paucity of evidence, particularly the absence of comprehensive knowledge on the constituents and activities of many herbal and natural products, raises concerns among health care providers as to whether some of these therapies pose an excessive public health care risk or result in delayed use of more effective therapies.

Introduction to Herbal Products

Over 20,000 herbal and other natural products are available in the United States.⁷ The most commonly purchased products include echinacea, feverfew, garlic, ginseng, ginkgo, goldenseal, kava, St. John's wort, saw palmetto and valerian. Some products are used for health maintenance or for benign, self-limited conditions. However, others are used to self-treat serious illnesses, such as hawthorn for congestive heart failure, milk thistle for liver disease, or St. John's wort for depression.

During their growth in popularity over the last several years, the promotion of these products has undergone fundamental changes. In the past, herbal products were promoted to consumers primarily by mail-order companies and health food stores. More recently, chain drug stores and grocery stores have advertised herbal products aggressively to consumers in a manner similar to

that for nonprescription drug products. The introduction of entire herbal product lines by traditional manufacturers, such as American Home Products, will likely increase this trend. For pharmacists and other health professionals confronted with inquiries from consumers about the health promotion claims of herbal products, it is important to acknowledge that some of these products have pharmacologically active chemical constituents, and, in essence, are drugs. Herbal products cannot be discounted as "natural" and hence, nontoxic entities, as many consumers believe. Although selected products may have therapeutically beneficial effects, many cause adverse effects⁸ and drug interactions similar to those experienced with conventional agents.⁹ In 1998, the American Association of Poison Control Centers received 6914 reports of adverse reactions from dietary supplements.¹⁰ Between January 1993 and October 1998, the Food and Drug Administration (FDA) received 2621 reports of serious problems involving these products, including 184 deaths.¹⁰ In contrast, in a study of 386 herb users, only 8% had experienced adverse effects.¹¹ Examples of adverse effects reported with some botanical products are shown in Table 1.¹²⁻²¹

The interaction potential of herbs with conventional drugs is a critical concern for drugs with narrow therapeutic indexes.⁹ For example, many herbal products, such as garlic, ginger, ginseng, ginkgo, and feverfew, possess antiplatelet properties that can be additive when used with drugs known to affect hemostasis such as warfarin or heparin, albeit through different mechanisms.²²⁻²⁶ Shankapulshpi, an Ayurvedic preparation used to treat epilepsy, increases the hepatic clearance and thereby decreases the serum concentrations and effectiveness of phenytoin when these agents are given concomitantly.²⁷ Recently, a significant interaction was identified in which St. John's wort reduced the area under the curve of the protease inhibitor indinavir by a mean of 57%, potentially leading to the development of indinavir drug resistance and treatment failure.²⁸ A comprehensive review of known and potential drug-herb interactions has been published recently.⁹

Safety Issues

Standardization is the process by which one or more active ingredients of an herb are identified, and all batches of the herb produced by a single manufacturer contain the same amount of active

Table 1. Examples of Adverse Reactions Associated with Herbal Products^a

Organ System	Adverse Effect	Herbal Product
Immunologic	Allergic reactions	Royal jelly, ¹² yohimbine ¹³
Renal	Nephrotoxicity	<i>Radix aristolochia</i> ¹⁴
Musculoskeletal	Rhabdomyolysis	Wormwood oil ¹⁵
Hepatic	Hepatotoxicity	Chaparral, ^{16, 17} comfrey, ¹⁸ sassafras ¹⁹
Other	Mutagenicity	Frangula, ¹² rhubarb, senna, ²⁰ capsaicin ²¹

^aNot intended to be a comprehensive list.

ingredient.²⁹ Consumers expect the component ingredients of their nonprescription and prescription drug products to be standardized to ensure that each dose contains the requisite amount to elicit the desired effect. However, consumers either may not expect the same level of standardization for herbal products, or they assume they are standardized. One reason they may not expect the same level of product quality may be the commonly held perception by consumers that “natural is always good,” and precise quantification is unnecessary. Also, many herbal medicine advocates propose that the therapeutic benefit of herbal products stems from the synergistic action of the several natural components in the herb. They argue that some constituents that are thought to be inactive may play a role in the pharmacokinetics of the active component,³⁰ and that a standardized extract would diminish or eliminate the beneficial effects of the heterogeneous botanical product. No evidence currently is available to support or refute this argument.

One consequence of the lack of standardization is the variability in the quantity, or the complete absence, of the known or supposed active ingredient. Of 24 ginseng products assayed by a thin-layer chromatography spectrophotometric method, eight (33%) did not contain any detectable panaxosides, which are considered to be the active components.³¹ The total panaxosides' content in the remaining products ranged from 0.26–6.85 mg/250-mg sample.³¹ In a study of 44 feverfew products, 14 (32%) did not contain the minimum of 0.2% parthenolide content that is proposed, albeit disputed, as the necessary primary active ingredient and concentration. Another 10 products (22%) did not contain any detectable levels of parthenolide.³²

Good manufacturing practices (GMPs), which are required for foods and drugs, are not required for herbal products. Good manufacturing practices ensure that products meet specific quality standards, are not adulterated or

misbranded, and contain the correct ingredients and doses stated on the label.³³ Without GMPs, herbal products are at risk of adulteration and contamination.

The medical literature contains several examples of the adulteration of herbal and natural products with unlabelled ingredients and heavy metals. The FDA has received reports of bradycardia and heart block that were caused by ingesting plantain adulterated with digitalis.³⁴ This adulteration occurred when an inexperienced harvester mistook the digitalis-containing foxglove for the similar-appearing plantain. The product was sold for up to a year by several distributors before the problem was recognized.³⁴ Melatonin, in concentrations up to 7.11 µg/g, was found as an adulterant in feverfew, Huang-qin, and St. John's wort products.³⁵ A 41-year-old woman was reported to have an international normalized ratio of 11.5 after drinking hibiscus tea contaminated with warfarin.³⁶ A product known as “Sleeping Buddha,” promoted for insomnia, was found to contain estazolam, a prescription benzodiazepine.³⁷ Lead intoxication occurred in a 59-year-old woman who consumed a Chinese herbal remedy that had a lead content of 0.5 mg/tablet.³⁸ Her intake of 30 tablets/day amounted to 15 mg/day of elemental lead, resulting in a 24-hour urinary lead content of 1044 µg. These examples illustrate the significant risk to the public for serious adverse health consequences, which could be eliminated by product standardization and GMPs.

An important prerequisite for establishing standards is the identification and quantification of active components. The active ingredient or the quantity necessary for effectiveness has not been determined for several products. For example,^{39, 40} Some manufacturers standardize St. John's wort according to its hypericin content, which is only 1 of 10 identified active components in this herb.⁴¹

Some herbal manufacturers have set standards for their products. For the Centrum herbal

product line, PharmaPrint—a patented process that incorporates chemical and biological specifications—ensures manufacturing consistency. The company that developed the process has 11 herbal products in development and has applications for investigational new drugs filed with the FDA for saw palmetto and St. John's wort.⁴²

Deoxyribonucleic acid (DNA) fingerprinting is an analytical method using polymerase chain reactions to identify chemical components of herbal products. This methodology was recently made available by Univera Pharmaceuticals (Broomfield, CO) and can identify herbal and botanical ingredients based on their unique DNA characteristics.⁴³

While some manufacturers have developed standardized extracts for their herbal products, many have not.⁴⁴ The American Herbal Products Association (AHPA) has not taken a position on whether all herbals should be standardized.³⁰ Furthermore, no governmental agency has imposed regulations to ensure uniformity. A regulatory framework for herbal products is being developed in England.⁴⁴ If a similar model were adopted in the United States, some level of standardization could be developed and should help to protect public safety. Standardizing the content of one active component, while maintaining the relative content of all other constituents, may be a satisfactory preliminary approach to achieve acceptable consistency among products.

Regulatory Issues

From a regulatory perspective, herbal products are classified as dietary supplements. Before 1994, herbals were regulated as foods or drugs, depending on their intended use. When Congress passed the Dietary Supplement and Health Education Act (DSHEA) in 1994, a separate classification was created for dietary supplements. Under this categorization, herbals are not considered foods or food supplements. Unlike drugs, herbs do not need to be proven safe and effective to be marketed. Thus, herbal products are not required to undergo the lengthy, rigorous, and expensive approval process that is required for drugs. This lack of regulations concerns many health care professionals and poses a significant risk for consumers.

The DSHEA of 1994 allows manufacturers of natural products to make claims regarding the ability of their products to alter structure or

function, but not regarding diagnosis, treatment, cure, or prevention of disease.⁴⁵ New rules, implemented by the FDA in early 2000, ban implied, as well as expressed, disease claims.⁴⁶ For example, any claims that the consumer could misinterpret easily as treating or preventing disease no longer are allowed. In addition, the definition of disease changed so that common, minor symptoms of life stages (e.g., premenstrual symptoms, hot flashes associated with menopause, wrinkles, acne) no longer are considered diseases. Product claims are now allowed for these ailments.

Under the new FDA rules, a product may bear health maintenance claims (e.g., "maintains a healthy prostate"), but not disease claims (e.g., "treats benign prostatic hyperplasia"). Products claiming to diagnose, treat, prevent, or cure a disease will be classified as drugs and thus require proof of safety and efficacy.⁴⁷ Manufacturers must be able to provide evidence that a claim is not false or misleading. When manufacturers state that their products affect body structures or functions, the label must include the following disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." In addition, companies must notify the FDA within 30 days after a product is on the market if it bears such a label.⁴⁵

The DSHEA allows herbal products to remain on the market as long as they have not been proven to be unsafe. Whereas a drug must establish its safety before it can be marketed, herbal products can be marketed unless, or until, proven to be unsafe.⁴⁸ The possibility exists that considerable morbidity or mortality may occur before an herbal product is identified as dangerous and removed from the market.

The dietary supplement Cholestin was reclassified as a drug. It is a red rice yeast product claimed by its manufacturer (Pharmanex, Provo, UT) to lower low-density lipoprotein cholesterol and raise high-density lipoprotein cholesterol. The product was found to contain mevinolin, which is indistinguishable from lovastatin. Because the claims classify Cholestin as a drug, the product was ordered off the market by the FDA unless the standards for drugs were met.^{47, 49} For now, the product remains on the market while the ruling is litigated.

In early 2000, the FDA published its Dietary Supplement Strategy (Ten Year Plan).⁵⁰ This plan

Table 2. General Description of Levels of Evidence

Level I	Randomized trials or meta-analyses in which lower limits of the confidence interval for the treatment exceed the minimal clinically important benefit
Level II	Randomized trials or meta-analyses in which lower limits of the confidence interval for the treatment overlap the minimal clinically important benefit
Level III	Nonrandomized concurrent cohort studies (studies with one group receiving the treatment and a concurrent group not receiving the treatment)
Level IV	Nonrandomized historic cohort studies (a study where outcomes from patients receiving a treatment are compared with a historic group with different treatment method)
Level V	Case series without controls

Adapted from reference 52.

sets forth the program goal, “By the year 2010, [the FDA will] have a science-based regulatory program that fully implements the Dietary Supplement Health and Education Act of 1994, thereby providing consumers with a high level of confidence in the safety, composition, and labeling of dietary supplement products.” This plan addresses safety, including adverse event reporting, follow-up of significant adverse event reports, and GMPs; labeling; boundaries, including clarification of the differences between dietary supplements and drugs and the use of health claims for dietary supplements; and enforcement activities. It also strengthens the FDA’s research and science capabilities for dietary supplement review and evaluation and provides a means for effective communication with stakeholders.

Postmarketing surveillance is an important component of monitoring the safety of herbal products. Reporting adverse events is facilitated through the FDA MedWatch system. In addition, the FDA developed the Special Nutritionals Adverse Event Monitoring System (SN/AEMS), which is a database of adverse events reported to the FDA that were associated with “use of a special nutritional product: dietary supplements, infant formulas, and medical foods.” The SN/AEMS database is accessed through the Internet and searched online to determine whether a specific dietary supplement is associated with adverse effects. The usefulness of this system depends on the extent of reporting of adverse events associated with dietary supplements, including herbal products, from health professionals and consumers.

These new FDA measures are important in the regulation of dietary supplements, including herbal products. As these measures are implemented, consumers can place increasingly more confidence in the safety, composition, and labeling of herbal products, and health care

professionals will be better able to counsel and monitor individuals who take such supplements.

Research Issues

Literature Retrieval

Research issues related to herbal therapy include considerations in retrieving the primary literature, using an evidence-based approach to evaluate studies, and in designing trials. The evaluation of any intervention, whether a surgical procedure, prescription drug, or herbal product, should begin with a thorough review of the literature. Because the National Library of Medicine does not consistently index articles on alternative medicine, the clinician using MEDLINE may not accomplish a satisfactory search. Still, a MEDLINE search is an important source of information. When necessary, MEDLINE searches may be supplemented by retrieving the references cited in the articles identified. EMBASE may index additional articles, and searching this database is strongly advised. Appendix 2 provides a bibliographic listing of reliable scientific sources of information on herbal products and alternative medicine.

Evidence-Based Evaluation

The current direction in medicine is practice based on evidence. While flaws and inferior science may have been accepted previously, treatment recommendations and decisions increasingly are expected to be determined by using evidence-based guidelines. The “test of time” or historical acceptance of alternative medicine, or of any element of medicine, is not a sufficient standard in today’s society. The evaluation of herbal and other natural products as a health care modality should use the evidence-based approach.

In evidence-based medicine, treatment recommendations are determined by the level of

Table 3. Deficiencies and Problems Found Commonly in Studies of Herbal Products^a

- Treatment arm used herbal products having several ingredients
- Inability to identify active ingredient of the herbal product
- Lack of standardized extracts, formulations, and doses
- Potential for adulterated or misbranded products
- Comparison of herbal products to subtherapeutic dosages of conventional medicine
- Many studies published in foreign languages only
- Small sample size
- Poorly defined inclusion or exclusion criteria
- Insufficient description of patient diagnosis using established criteria
- Short study duration for long-term chronic conditions
- Few pharmacoeconomic or outcomes-based studies

^aThese problems are not exclusive to herbal products but also occur frequently in trials of traditional drugs.

evidence available from clinical studies, which are judged by the quality of their design and methodology. In developing consensus statements on antithrombotic therapy, the American College of Chest Physicians incorporated a grading system of recommendations based on the levels of evidence from the clinical trials used.^{51, 52} As summarized in Table 2, the levels of evidence range from level I (trials with the strongest design, such as randomized, controlled trials) to level V (case reports that provide useful information but no valid evidence for drug effectiveness).⁵² As with other grading systems, limitations exist with the levels-of-evidence system, especially in the complexity of combining study results and applying results to patients with differing baseline characteristics or underlying risk factors. Nonetheless, using such a system can provide an initial approach to objectively evaluate studies of herbal products for level of evidence and determine a grade of recommendation.

Whereas some studies involving herbal products can be graded as having level I evidence, many published trials have weaker levels of evidence and rank as level III, IV, or V. Generally, many studies of alternative medicine therapies have flaws in study design, lack evidence of using standardized products, or fail to account for biases. Because many products were introduced to the United States from other countries and cultures, their studies are not published in the English language, adding to the difficulty in their evaluation. Many of the deficiencies are common to studies of conventional medicine, such as poorly defined exclusion or inclusion criteria and short treatment duration. However, unique to alternative medicine are problems such as

product quality and standardization, as discussed previously. Other problems are listed in Table 3. Well-designed studies of some alternative therapies have been performed. Appendix 2 provides a comprehensive listing of information sources for these modalities. In particular, the Cochrane Library has a searchable collection of over 1500 randomized, controlled trials of alternative medicine interventions.

The Agency for Healthcare Research and Quality (formerly the Agency for Health Care Policy and Research) has issued a request for proposals for developing evidence-based reviews of various herbs. In response, the San Antonio Evidence-based Practice Center developed a team of national experts to review the literature addressing the use of garlic and milk thistle. Other teams have been assembled across the country to review other herbs. The results of this effort are anticipated to be published in the next few years.

Research with Herbal Products

Additional research is needed to satisfactorily determine the role of herbal products in health care. Well-designed, randomized, controlled clinical trials would best evaluate the efficacy, tolerability, and safety of herbal products, their comparative efficacy with conventional therapy, and potential drug interactions. Other areas needing research include assessing trends in usage, determining qualitative and quantitative standards for products, and evaluating long-term impacts on clinical outcomes, quality of life, and pharmacoeconomics. Because many individuals combine the use of herbal products with conventional medicine, as well as with other types of alternative medicine, research on these combined uses would be valuable.

The major barrier to research with herbal products and other types of alternative medicine is the relative lack of funding sources. Because most herbal and natural products cannot be patented, manufacturers have few incentives to fund large clinical trials. Increased regulations, as proposed by the FDA, as well as increased demands for clinical evidence by health care practitioners and educated consumers, may encourage manufacturers to conduct more clinical trials. In addition, many pharmaceutical manufacturers are planning to market herbal products and may be compelled to apply pharmaceutical testing and evaluation standards to herbal products. They may also be forced to fund studies evaluating the outcomes of combining alternative medicine with conventional therapies.

Both the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health (NIH) and the World Health Organization (WHO) have assisted or supported research in herbal products and other types of alternative medicine. Lobbying efforts by consumer groups and professional associations also can be an effective means to increase funding support for the scientific evaluation of all types of alternative medicine. Because the use of alternative medicines is a worldwide issue, large-scale global research efforts could be accomplished by collaboration, shared resources, and efficient use of the assets and expertise of each participating member. Private foundations that support medical research are another potential source of funding, and research objectives could be designed to meet foundation initiatives such as quality outcomes, cultural preferences for health care practices, use of health care resources, or self-care strategies with assessment of the need for referrals into health care systems.

The Role of Pharmacists

Millions of Americans take herbal products, and few inform their primary care providers. Many pharmacies sell herbal products, and pharmacists frequently are asked by both patients and other health care providers about the use of these products. The quality of the information on herbal products provided by pharmacists is unknown.

The basis for pharmacist involvement with herbal products is an extension of their established roles in pharmaceutical care, clinical

pharmacy practices, and collaborative health care teams. The pharmacist plays a key role in providing care to patients who are taking or contemplating taking herbal products. The variability in the degree of scientific evidence on efficacy and safety available to support the use of herbal products makes it even more imperative that pharmacists assume an active role in this area of practice.

Ideally, pharmacists should stock only those products that were manufactured with conformity to GMP guidelines. This information is not available from manufacturers, but should be. In addition, products containing only the part of the plant that was proven in clinical trials to be effective should be stocked. Herbal and natural products with questionable or unproven efficacy or those known to be harmful should not be inventoried, recommended, or sold. Pharmacists employed by large corporations may need to develop special strategies to maintain the quality of products offered for sale. Pharmacists are in an ideal position to be involved in the care of patients taking herbal products, to monitor for adverse events, and to ensure that appropriate outcomes are met.

Drug Histories

Because they are not classified as drugs and are not considered drugs by their users, herbal products frequently are not mentioned during drug interviews or listed voluntarily on drug lists. All drug histories should include questions about the use of herbal and other natural products. The “don’t ask, don’t tell” policy is not acceptable for pharmacists. Many consumers expect pharmacists and other health professionals to be skeptical, and even hostile, about the use of herbal products.¹ To encourage consumers to discuss their use, inquiries should be conducted in an open and nonjudgmental fashion similar to the manner of inquiring about other over-the-counter products.

Inquiries should address the specific health care purpose for which the patient is using, or is considering using, an herbal product. Common reasons for use include health promotion; disease prevention; poor outcomes and limited treatment options for a serious illness; exhaustion of conventional therapies; dissatisfaction with, or lack of efficacy of, conventional therapies; significant side effects or risks associated with conventional medicine; belief that herbal and natural products are better or safer; preference

for personal involvement in the decision-making process; and cultural or spiritual preference.³

Pharmacists, other health professionals, and consumers must be vigilant in detecting and reporting suspected serious adverse events from prescription drugs, over-the-counter agents, and natural products to the FDA's MedWatch program. The SN/AEMS is a valuable way to detect emerging serious problems resulting from the use of natural products, but only if professionals and consumers are proactive in reporting problems.

Patient Education

Pharmacists should maintain accurate information about herbal products and use this expertise when advising consumers.⁵³ Pharmacists should strive to provide unbiased evaluations and to correct any misconceptions about the benefits and toxicities of these products in a manner similar to that done for over-the-counter and prescription agents.⁵⁴ Suitable resources, such as those listed in Appendix 2, can assist pharmacists in this role.

For the consumer using herbal products, the pharmacist should determine if the patient's herbal therapy is appropriate or if other therapies, conventional or otherwise, would provide better alternatives. The pharmacist should review the patient's drug regimen (including prescription, over-the-counter, and herbal and natural products) and disease states for potential or actual drug-related problems. Assisting the patient in streamlining a regimen of herbal and conventional therapies may result in eliminating products with similar effects or those that have not provided a benefit following a therapeutic trial. For example, it may be more economical to use saw palmetto in place of finasteride if a standardized, reputable saw palmetto product is available. Combinations of certain herbal products and conventional drugs may cause synergy of similar adverse events or may result in significant drug interactions.

For the consumer who is contemplating the use of herbal products, pharmacists should provide advice about the risks, as previously highlighted. In addition to efficacy and safety, factors such as cost and adherence should be considered, especially if the patient is taking other drugs. Care should be exercised if the patient is pregnant. Allergies should be reviewed carefully, with special caution for those who have plant and pollen allergies. Caution should be

taken when little is known about the short-term or long-term effects of any product. Without the pharmacist working with the patient who plans to take herbal products, the patient may do so independently, with potentially adverse outcomes.

A major challenge is the patient who chooses to use herbal products as a substitute for conventional therapy without the knowledge and approval of the primary care provider. In this situation, the pharmacist can play a key role in educating the patient about the potential for delaying the initiation of proven therapy, or not allowing adequate time for a therapeutic trial.⁵⁵ Pharmacists need to establish rapport with their patients, maintain regular contact and follow-up, and, most important, encourage the use and continuation of therapies that have been effective.

With Medicare and many states requiring patient counseling and education, pharmacists must be able to recognize potential interactions, including those involving herbal products.⁵⁶ Liability issues involving alternative medicine are yet to be fully determined. However, by documenting that objective information on both risks and benefits was presented and that an informed decision was made by the patient, pharmacists should be able to demonstrate actions that were in the best interest of their patients. If high-quality studies of a particular herbal product are not available, the process for making therapy recommendations is the same as that for conventional medicine. Pharmacists play a critical role in educating patients and health care providers about the evidence available regarding efficacy and potential adverse effects, and in making recommendations consistent with that evidence.

To assure comprehensive care is maintained, the patient should inform, or permit the pharmacist to inform, the primary care provider that the patient is, or will be, taking alternative medicines.⁵⁶ Pharmacists who sell herbal products must avoid conflicts of interest when advising patients about these products. As with other nonprescription products, recommendations must be made in an unbiased manner based on the potential for benefit to the patient.

Pharmacist Participation in the Health Care Team

By keeping fully informed about herbal products, the pharmacist can be a valuable source of information for conventional and alternative

medical providers. The pharmacist should provide updates to the health care team on commonly used herbal products and serve as a resource for questions from the team members. Working closely with each patient's primary care providers, the pharmacist can provide expertise to identify and distinguish between side effects induced by conventional agents and plant-derived products. The management of side effects caused by these products and recommendations for treatment options are additional aspects of the pharmacist's role.

The pharmacist also should collaborate with the health care team in conducting research on the use of botanical agents. Pharmacists should encourage and share the responsibility for publishing these research results.

Pharmacists no longer can ignore the significance of herbal products and other types of alternative medicine in their daily practices. Staying informed and educating others should be an integral part of all pharmacists' responsibilities in providing complete pharmaceutical care to patients.

Pharmacy Education

Since the late 1970s, the formal education of pharmacy students about herbal and natural products has declined steadily. Courses in pharmacognosy, formerly required for all pharmacy students, were deleted during periods of curricular changes and as pharmacognosy faculty retired. A survey of 77 colleges of pharmacy conducted in 1997 revealed that 74% of the schools offered one pharmacognosy course averaging almost 3 credit hours, with one-third of the time devoted to herbal products.⁵⁷ However, in two-thirds of the schools, the course was an elective offering, hence limiting student exposure. A survey addressing the broader topic of alternative medicine recently reported similar findings.⁵⁸

Although the new accreditation standards of the American Council on Pharmaceutical Education require instruction on self-care topics, herbal products and the broader topic of alternative medicine are not mentioned specifically.⁵⁹ The best approach to teaching herbal and natural products is unknown, but integrating core information across the curriculum into courses such as medicinal chemistry, pharmaceuticals, and therapeutics is recommended. Discussions of herbal and natural products in therapeutics courses should

emphasize the findings and limitations of current research in the medical literature and the levels of evidence supporting or refuting their use, just as they do for conventional treatments. Discussions of drug-induced diseases such as nephrotoxicity and hepatotoxicity should include herbal and other natural product causes. Courses would be enhanced by the participation of faculty with clinical expertise in the area of herbal medicine.

In addition to integration across the curriculum, specific courses might be designed to attain higher skill levels. For example, courses might emphasize the psychological aspects of self-care and factors that motivate patients to use herbal and natural products. In professional practice laboratory courses, students should be taught communication techniques that encourage consumers to talk about their use of these products and that develop nonjudgmental, supportive approaches to promote open and honest communication. Students must be made aware of their professional responsibility to public health by discouraging the use of dangerous products, whether herbal or nonherbal in origin.

For practicing pharmacists to fulfill their roles as educators on the use of herbal and natural products and contribute to the well-being of public health, continuing education and skills should focus on four core areas: (1) Pharmacists should have a thorough knowledge of common herbal and natural products in terms of their derivation, safety and efficacy, and drug interactions; (2) All pharmacists should have the ability to triage individuals in an ambulatory environment to determine those conditions for which self-care might be appropriate or, at a minimum, not detrimental; (3) The pharmacist must have effective oral communication skills that incorporate an appreciation for the health beliefs of culturally and ethnically diverse populations; and (4) Pharmacists must possess the technologic and critical appraisal skills for retrieving and evaluating relevant lay information and scientific literature on herbal topics.

Summary

Individuals increasingly are taking a more active role in their health care, and herbal products have emerged as a common choice among self-care therapies. Pharmacists are active participants in the care of patients who are taking herbal products. Currently, most pharmacists are not educated adequately about herbal products

and other types of alternative medicine. Furthermore, good information about many of these products is not available. These combined factors present a challenge for pharmacists as they seek to provide optimal care and counseling to patients who use herbs or supplements. We recommend the following actions to place pharmacists in better positions as effective agents protecting public safety:

- Regulations should be implemented at a federal level to require basic levels of standardization and quality control in the manufacture of herbal products.
- Indexing terms in medical bibliographic systems should be expanded to target herbal products.
- Funding should be increased for scientific research evaluating herbal products.
- Pharmacy schools should include a competency statement in their curricula regarding herbal medicines.
- Continuing education in herbal products should be available and encouraged for all pharmacists.

Pharmacists should approach the use of all therapeutic interventions with scientific rigor, whether they are traditional or complementary in nature. Patients will benefit as more information is known and widely disseminated. By actively embracing the responsibility for counseling individuals on the appropriate use of herbal products, pharmacists will become a recognized source of expert information in this rapidly growing area, yielding important improvements in the quality of care.

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Appendix 1. Glossary and Short Descriptions of Other Alternative Medicine Practices

- Acupuncture: practice of piercing specific areas of the body with needles to relieve discomfort associated with painful disorders, to induce surgical anesthesia, or for therapeutic purposes. This procedure originally was introduced and practiced in China.⁶⁰
- Alexander therapy: therapy designed to increase awareness and voluntary inhibition of personal habitual patterns of rigid musculoskeletal constrictions.⁶¹
- Aromatherapy: use of fragrances and essences from plants to affect or alter a person's mood or behavior and to facilitate physical, mental, and emotional well-being. The essential oils in plants contain chemicals, many of which have therapeutic properties and have been used historically in Africa, Asia, and India.⁶⁰
- Ayurvedic medicine: traditional Hindu system of medicine that is based on customs, beliefs, and practices of the Hindu culture. Ayurveda means "the science of life."⁶⁰
- Balneotherapy: therapy by hot or warm baths in natural mineral waters or spas. It includes not only bathing in, but also drinking, the waters. It does not include whirlpool baths.⁶⁰
- Biofeedback: use of instrumentation to give immediate and continuing signals of change in bodily function of which a person is usually unaware.⁶⁰
- Chiropractic: system that is said to use the recuperative powers of the body and the relationship between musculoskeletal structures and functions of the body, particularly of the spinal column and the nervous system, in the restoration and maintenance of health.⁶⁰
- Curanderismo: Latin-American, community-based folk system of medicine that consists of two components. The first, humor model, classifies activity, food, drugs, and illness as having characteristics of hot or cold, and dry or moist. Good health is maintained by achieving a balance between these characteristics. The second component involves the treatment of folk illnesses.⁶²
- Hydrotherapy: external application of water for therapeutic purposes. It is differentiated from balneotherapy by emphasizing the use of plain water, whereas balneotherapy emphasizes the use of mineral water.⁶⁰
- Hypnosis: state of increased receptivity to suggestion and direction, induced by the influence of another person.⁶⁰
- Massage: systematic application of petrissage, effleurage, friction, percussion, stroking, static pressure, vibration, or other manual manipulations to the soft tissues (muscles, ligaments, tendons, fascia) of the body. These techniques include, but are not limited to, Rolfing, Trager, Bidegewebsmassage, Neuromuscular Therapy Hellerwork, acupressure, myofascial release, strain-counterstrain, positional release, shiatsu, and the manual stimulation of trigger points.⁶³
- Meditation relaxation techniques: mental exercises such as concentration or visualization, postural modifications, and breathing exercises designed to reduce mental and/or physical arousal. These techniques include meditation, Jacobsen exercises, the Mitchell method, autogenic training, visualization and imagery.⁶¹
- Osteopathy: a system of therapy and medicine based on the theory that the normal body is a vital mechanical organism whose structural and functional states are of equal importance and is capable of making its own remedies against infections and toxic conditions when there are favorable environmental circumstances and adequate nutrition.⁶⁰
- Qigong (pronounced "chee gong"): in Chinese, "qi" means energy and "gong" means a skill or practice. Together they translate as "a skill or practice of cultivating energy." Qigong is a Chinese practice of self-care that involves the combination of specific regulation of body movement and posture through physical exercise with meditation involving careful regulation of breath and deep relaxation states. It is done to enhance the mind-body connection and thus promote health.^{64, 65}
- Reflexology: manual stimulation of points on the foot thought to correspond to the organs and structures of the body.⁶¹
- Therapeutic touch: a method developed in the 1970's by Dora Kunz and Dolores Krieger (from the New York University Nursing School), wherein the healer's hands are placed, in a systematic way, on or near the patient to facilitate palliative relief or cure.⁶³
- Tai chi: an ancient Chinese system of exercise or an "art for life." The practice stimulates the nervous system, increases blood circulation and glandular activity, strengthens muscles, and exercises the joints. The movements are circular and gentle, done in an even, slow tempo, synchronized with the breath.⁶⁶
- Vegan diet: diet that excludes all animal products such as flesh foods, milk, cheese, eggs, butter, and honey.⁶⁶
- Vegetarian diet: diet that excludes flesh foods such as meat, fish, fowl and their derivatives. It is sometimes called lacto-ovo vegetarian because it includes milk and eggs.⁶⁶
- Yoga: orthodox system of Hindu philosophy, which includes exercise for attaining bodily or mental control and well-being.⁶⁰
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Appendix 2. Sources of Information on Herbal Medicines and Alternative Therapies

Journals

These journals specifically or regularly address alternative therapies and include original research. The reader is referred to Ulrich's International Periodicals Directory, 38th edition (New Providence, NJ: RR Bowker, 2000) for more detailed information. All journals listed are active. The year refers to year of first publication.

English Language, Peer-Reviewed

- Alternative Medicine Review, 1996 (academic/scholarly publication)
- Alternative Therapies in Clinical Practice, 1994 (academic/scholarly publication)
- Alternative Therapies in Health and Medicine, 1995 (academic/scholarly publication)
- American Journal of Chinese Medicine, 1973 (abstracting and indexing service, academic/scholarly publication)
- Australian Journal of Medical Herbalism, 1989 (academic/scholarly publication)
- Australian Traditional Medicine Society Journal, 1998 (academic/scholarly publication)
- British Journal of Phytotherapy, 1990 (academic/scholarly publication)
- European Journal of Herbal Medicine, 1994 (academic/scholarly publication)
- Focus on Alternative and Complementary Therapies, 1996 (academic/scholarly publication)
- Forschende Komplementaermedizin/Research in Complementary Medicine, 1994 (online edition, academic/scholarly publication)
- HealthInform, 1995 (newsletter, abstracting and indexing service, academic/scholarly publication)
- Journal of Alternative and Complementary Medicine: Research on Paradigm, Practice and Policy, 1993 (academic/scholarly publication)
- Journal of Herbal Pharmacotherapy, first issue slated for fall, 2000 (academic/scholarly publication)
- Journal of Interprofessional Care, 1984 (academic/scholarly publication)
- Planta Medica, 1935 (academic/scholarly publication)

Non-English Language, Peer-Reviewed

- Hebei Zhongyi/Hebei Traditional Medicine, 1979 (Chinese, academic/scholarly publication)
- Tijdschrift Voor Integrale Geneeskunde, 1984 (Dutch, academic/scholarly publication)
- Zhongguo Yaoxue Wenzhai/Chinese Pharmaceutical Abstracts, 1982 (text in Chinese, index in English, abstracting/indexing, academic/scholarly publication)

Non-Peer-Reviewed or Peer Review Status Unknown

- Alternative and Complementary Therapies, 1994
- Complementary Therapies in Medicine, 1993 (academic/scholarly publication)
- Complementary Therapies in Nursing and Midwifery, 1995 (academic/scholarly publication)
- HerbalGram, 1979
- Phytomedicine, 1994 (academic/scholarly publication)

Databases

The Research Council for Complementary Medicine (RCCM) home page has more details on most of the following. The RCCM's Internet address is provided in Web site section below.

AMED (Alternative and Allied Medicine Database). Produced and updated monthly by the British Library's Medical Information Centre, this database contains 65,000 references from 400 journals on alternative and complementary medicine. Online searches are available through Datastar or MIC-KIBIC. The database is also available on floppy disk and in printed format as the Complementary Medicine Index from the British Library Medical Information Service, Boston Spa, United Kingdom. More details are available from the British Library (01937 546 039).

CISCOM (Centralised Information Service for Complementary Medicine). This RCCM database of research references and abstracts combines data from MEDLINE, AMED, other specialized European databases and in-house citation tracking. There is no direct access to the database, but mediated searches can be arranged by calling the RCCM (+44 0207 833 8897). Fees for use of the service start at £15 (UK) and depend on the scale and complexity of the request. Data are provided in printed or electronic format. A special feature of the CISCOM database is a large collection of randomized, controlled trials, including the full registry of the Cochrane Complementary Medicine Field.

The Cochrane Library. This database provides rapid access to regularly updated systematic reviews of the effects of health care (Cochrane Database of Systematic Reviews [CDSR]), structured abstracts of quality-assessed, previously published reviews (Database of Abstracts of Reviews of Effectiveness [DARE]), references to controlled trials (Cochrane Controlled Trials Register [CCTR]), and references to articles on the science of reviewing research and sources of further information (Cochrane Review Methodology Database [CRMD]). This evidence-based medicine database is developed and maintained by Collaborative Review Groups and is more likely to provide useful information on alternative therapies, including herbs, than is MEDLINE. Subscription information is provided on the Cochrane Library Web site listed in the Web site section below.

Appendix 2. Sources of Information on Herbal Medicines and Alternative Therapies (continued)

Databases (continued)

Cochrane Complementary Medicine Field. This section of the Cochrane Library was established to meet the growing need for evidence-based research in alternative medical practices. The primary aim of the database is to compile randomized, controlled trials of alternative medicine interventions, particularly from journals that specialize in this area. The full registry of this database is included in CISCOM (listed above). However, a fee is required for a mediated search of CISCOM. Sometime in the near future, this database will be added to the CCTR of the Cochrane Library. This database is only available to subscribers of the Cochrane Library.

EXTRACT. This database contains annotated and codified information about the chemistry, pharmacology, and therapeutics of medicinal plants. More information is available from the Simon Mills Centre for Complementary Health Studies, University of Exeter, Streatham Court, Rennes Drive, Exeter EX4 4PU, United Kingdom (+44 01392 264498 weekdays).

NAPRALERT (Natural Products Alert). This database contains 125,000 entries on natural products used worldwide, including chemical, pharmacologic, and ethnomedical information, and is updated monthly by Scientific and Technical Information Network. Summary information can be found at <http://info.cas.org/ONLINE/DBSS/napralertss.html>.

Natural Medicines Comprehensive Database. This extensive database, maintained by the editors of the *Pharmacist's Letter/Prescriber's Letter*, contains information on over 1000 herbs and dietary supplements with an index containing over 7000 brand names. Each herb/supplement listing includes 15 categories of information that address the most common questions faced by practitioners. The database is well referenced and is available as an electronic version (<http://www.NaturalDatabase.com/>) and print version (refer to the books section of this appendix). The Web version is continuously updated and allows more sophisticated searching than does the print version. It also contains a more extensive brand name index.

Web Sites

Research Council for Complementary Medicine (RCCM): <http://www.rccm.org.uk/>. The home page contains a comprehensive listing and descriptions of bibliographic databases, indexes, and journals related to alternative medicine. The RCCM is a resource for health care professionals only; they do not serve the lay public. CISCOM is the RCCM's database. Unfortunately, on the completion of existing commitments, the RCCM will cease to operate. At the time of this writing, the home page was still accessible.

American Botanical Council (ABC): www.herbalgram.org. The home page provides access to information on ordering HerbalGram (see journals), The Complete German Commission E Monographs (see books), and an herb book catalog.

NIH's National Center for Complementary and Alternative Medicine (NCCAM): <http://nccam.nih.gov/>. The NCCAM facilitates research and evaluation of alternative medical practices and disseminates this information to both health professionals and the public. From their home page one can access general information on alternative medicine, a listing of program areas, calendar of events, and the CAM Citation Index. The CAM Citation Index consists of more than 180,000 bibliographic citations from 1963–1998 extracted from the National Library of Medicine MEDLINE database. This database allows one to search or browse the database, which is organized by CAM system, disease, or method. This database is limited by using MEDLINE, which has only 23 subject headings for alternative medicine and is not as extensive as CISCOM or the Cochrane Library.

The Cochrane Library: www.cochrane.co.uk. This Web site contains information about the Cochrane Library and how to access it. Only abstracts are available free from the Internet. A subscription is required for the other services.

Center for Food Safety and Applied Nutrition: <http://vm.cfsan.fda.gov/>. This Web site has a section on dietary supplements, including information on the Dietary Supplement Health and Education Act (DSHEA) and the Special Nutritionals Adverse Event Monitoring System.

International Bibliographic Information on Dietary Supplements (IBIDS): <http://dietary-supplements.info.nih.gov/databases/ibids.html>. IBIDS is a database of published, international, scientific literature on dietary supplements, including vitamins, minerals, and selected herbal and botanical supplements. It is produced by two government agencies, NIH's Office of Dietary Supplements and the U.S. Department of Agriculture's Food and Nutrition Information Center, and currently contains 328,000 citations and abstracts.

Micromedex Internet Healthcare Series: <http://micromedex/mdxdocs/mdxhome.html>. Micromedex is developing a reliable, comprehensive source of information for alternative medicine at this Web site. The AltMedDex System was introduced in February 1999 and will contain more than 50 evidence-based monographs on herbal, vitamin, and other dietary supplements. The clinically focused, scientific information also will contain guidelines and recommendations to assist clinicians in making appropriate therapy choices and decisions.

Books

PDR for Herbal Medicines, 2nd ed. Montvale, NJ: Medical Economics, 2000.

PDR for Nonprescription Drugs and Dietary Supplements, 20th ed. Montvale, NJ: Medical Economics, 1999.

Bisset NG. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis. Washington, DC: MedPharm Scientific Publishers, 1994.

Blumenthal M, Busse WR, Goldberg A, et al, eds. The Complete German Commission E Monographs: Therapeutic Guide to Herbal Medicine. Austin, TX: American Botanical Council, 1998.

Bratman S, Kroll D. Clinical Evaluation of Medicinal Herbs and Other Therapeutic Natural Products. Rockland, CA: Prima Health Publishing, 2000 (updated quarterly).

Appendix 2. Sources of Information on Herbal Medicines and Alternative Therapies (continued)

Books

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Miscellaneous

The following article in the library science literature may be helpful in conducting a literature search in alternative medicine. It provides a detailed discussion on conducting electronic database searches, including specific examples of terms and strategies to use when searching MEDLINE, EMBASE, BIOSIS Previews, and SciSearch. In addition, the article discusses AMED, International Pharmaceutical Abstracts (IPA), NAPRALERT, and The Cumulative Index to Nursing and Allied Health (CINAHL).

Snow B. *Alternative Medicine Information Sources. Database 1998 (June/July);21:18-29.*

Inclusion in this list does not represent endorsement by the authors.