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Herbals and Other Dietary Supplements in the United States, Part III: A Historical and Contemporary Perspective

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LEARNING OBJECTIVES

1. Describe advantages and disadvantages of self-care practices, including herbal therapy, as they apply to early Americans.
2. Describe the 3 health care decision options available to consumers.
3. Identify factors that affect health beliefs and decisions.
4. Discuss the pros and cons of self-medicating with herbals.
5. Identify representative herbal/drug interactions.
6. Discuss the role of herbals in modern medicine.
7. Describe the role of the U.S. Food and Drug Administration (FDA) relative to herbals.
8. Summarize the responsibilities of health care professionals regarding herbals.

ABSTRACT: Herbals have been used for healing throughout human history. In the U.S., herbal products are regulated as nutritional products rather than drugs. Yet, it is clear that these products are promoted and used as drugs by consumers. As with any health care products, their value and validity depend upon appropriate use. Also, as other health care products, there are pros and cons associated with the use of herbals. These include considerations of efficacy, safety, product quality, and consumer and

professional education. Herbals will remain popular self-care products. Their appropriate use will depend upon the ability of both health professionals and consumers to accurately evaluate their health care needs and the products available to treat them. Both the pros and cons must be considered to ensure safety and efficacy.



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HERBALS AND OTHER DIETARY SUPPLEMENTS IN THE UNITED STATES, PART III: A HISTORICAL AND CONTEMPORARY PERSPECTIVE

Historical Considerations

Health care in America involves a dynamic and complex interplay between individual and cultural forces. Options regarding health care decisions have existed in various forms throughout human history. Each of these domains reflects efforts to balance individual and sociocultural influences (Table 1).

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TABLE 1. FACTORS THAT AFFECT HEALTH BELIEFS AND DECISIONS^{28, 61-65}

CULTURAL INFLUENCES

► Demographics

- Aging Population
- Birth Rates (e.g., increasing for lower socioeconomic groups; decreasing for middle and upper socioeconomic groups)
- Gender Differences (e.g., more women entering workforce)

► The Economy

- Health Care Costs
- Standards of Living

► Prevailing Cultural Beliefs and Orientations (e.g., health, therapy)

HEALTH CARE OPTIONS

► Availability of Alternatives

► Awareness of Alternatives

INDIVIDUALS

► Attitudes and Beliefs

- Acceptance of Available Options
- Emphasis on Health, Fitness, and Prevention
- Faith
- Frustrations with and Distrust of Professional Health Care
- Perceived Benefits, Barriers, and Costs for Taking a Given Course of Action
- Perceived Seriousness of the Problem to Treat
- Self-Responsibility for Health
- Values

► Education & Sophistication

- Availability of Health Information
- Awareness of Available Options
- Educational Level and Sophistication
- Media (e.g., advertising and promotional practices)
- Quality and Quantity of Information Available
- Understanding of Health and Health Problems

► Symptom Experience and Interpretation

- Accuracy of Self-diagnosis
- Impact of Assessment by Others (e.g., friends, family, coworkers)
- Denial
- Perceived Seriousness
- Competing Interpretations of Symptoms

► Disruptive Nature of Symptoms

- Disruption of Social Functioning (e.g., family, work, leisure activities)
- Frequency of Disruptions
- Persistence of Symptoms
- Tolerance of Symptoms

Consumers choose to treat or ignore health problems (e.g., symptoms) that occur. Treatment can involve products or services selected from 3 basic domains. The *professional domain* consists of the culturally acknowledged and accepted health professionals most commonly associated with U.S. health care. These individuals complete standardized and usually rigorous training programs and must pass criteria (e.g., internships, state board exams) to be licensed or certified to practice. The *folk domain* characterizes health practitioners who often represent historically valid health practices (e.g., herbals), but are less culturally accepted and acknowledged compared with the professional domain. Training can vary significantly among these practitioners. Licensure or certification may or may not be required for practice depending upon the practice, public health considerations, and the state in which the individual practices. It should be emphasized that despite variations in training, there are many highly qualified practitioners in this domain who offer valid and beneficial health care services. Finally, the *popular domain* consists of self-care practices and products. It can include the use of prescription drugs previously obtained via the professional domain. The problem with this latter practice is that these prescription drugs are often used for a self-diagnosed health problem that may or may not be related to the purpose for which the medication was originally prescribed. Nearly 100% of all health problems are initially treated with some form of self-care. This represents a domain of remarkable, but vastly underused, potentials for the professional of pharmacy.

There were few formally trained physicians in colonial America. It would be another 200 years following the arrival of colonists before hospitals and medical schools would

become established, as they are known. Formally trained physicians were reluctant to leave European civilization for a country characterized by uncertainties and a lack of traditional medical supplies. As a result, Native American herbs were important to early colonists, especially during the winter months when few ships came from Europe. Native Americans not only sold herbs to the colonists, but were often involved in health care activities.¹

The family was the center of both social and economic life in early American society. Because of their role as mothers, women were caregivers for the entire family and often for other families, as well. In the fall, women collected and preserved medicinal herbs just as they did foods. Successful healing skills and recipes were valued and handed down from one generation to another.^{1,19} Home remedies and self-care were not merely conveniences for early Americans, but were essential for survival.¹ Most communities had at least one woman who was experienced with the use of herbals and other simple remedies. Even after doctors began to appear, self-care remained the most common form of health care. Doctors were sought only when the problem was considered to be too serious for self-care.³⁰

Because of the absence of traditional medicines and practitioners in colonial America, printed materials gained increasing popularity. Almanacs and newsprints became a resource of Old World recipes and medical information for the general public, although their distribution was limited. From the late 18th century on, domestic medical guides became increasingly available. The intent was to demystify medicine and to promote self-care practices.^{17,19}

One of the most well-known medical guides was written by a physician, William Buchan, and titled *Domestic Medicine—An Attempt to Render the Medical Art More Generally Useful by Showing People What is in Their Own Power Both with Respect to the Prevention and Cure of Diseases*. While he acknowledged the value of physicians, he also asserted that professional knowledge and training were unnecessary in treating most diseases.¹⁹

Samuel Thompson, a layman, achieved considerable success as a healer.^{1,19} His book, *Thompson's New Guide to Health*, was popular among botanical societies throughout New England and New York. These groups held conventions and published journals (e.g., much like AMWAY, Shaklee, and other groups today). John Wesley, the founder of Methodism, published a widely read book of medical advice in 1747 called *Primitive Physic*, which provided a listing of ancient cures and promoted individual autonomy in the care of illnesses.¹⁹

Such movements were not restricted to healing, but also reflected political and philosophical orientations that appealed to the laity both then and now. They promoted common sense, a faith in the simplicity and accessibility of valid knowledge, and a concern that educational aristocracy and a privileged order are hostile to ordinary people. They were opposed to the manner in which priests, lawyers, and doctors controlled their knowledge and kept it from common people.¹⁹

Movements such as the Thomsonians, Homeopaths, and Naturopaths were a cultural expression of political upheaval that continues today. The organized medical community has always insisted that regulations are necessary to protect the

public from quacks. Yet, American society is founded on principles of freedom. During the 18th and 19th centuries, there was much concern that licensure was more an expression of favor than of competence and that medical societies and boards created a type of monopoly.¹⁹

The demand for self-care is deeply rooted in American culture. Threats to cherished cultural values (e.g., freedom and independence) are deeply resented. Alternative health care practices (and especially self-care practices) have survived because they offer alternatives that are seemingly simple in concept and more harmonious with life, rather than antagonistic to it.¹⁰ Indeed, people prefer simple answers for complex problems. The concepts of modern medicine are often far too complex to be explained in simple terms. So, the seeming simplicity of things “natural” finds increasing appeal in a culture bewildered by advances in medical knowledge and increasing health care costs.

While Americans may fail to exercise wisdom in their fads, their enthusiasm is never lacking. In the last quarter of the 20th century, the marvel and mystery of the plant has been rediscovered as if for the first time. Much of this trend can be traced to a growing dissatisfaction with modern medicine, or to the enticements of “natural” products. This “green revolution” has achieved incredible popularity, and there appears to be no limit to the number and variety of herbal products that will crowd retail shelves in the foreseeable future. The total number of herbals sold in mass-market outlets (grocery stores, pharmacies, mass merchandiser retail stores) is increasing, so that these products represent a significant and growing component of U.S. health care and economics.^{4,16,17}

Even though these products are not labeled as drugs, consumers use them for the treatment and cure of health problems, to prevent disease, and as proactive agents to maintain health and wellness. Additionally, they are often added to conventional therapies. Some health insurance companies cover herbals as “alternative therapies,” and herbal products are being considered for use by some managed care organizations.

Pros and Cons of Herbal Therapy

Herbals represent a unique entity among self-care products, since they are regulated as foods, rather than drugs. Yet, they are clearly promoted for self-care purposes. The relative pros and cons regarding the use of herbals paralleling self-care practices in general are summarized in Table 2.

TABLE 2. THE PROS AND CONS OF SELF-MEDICATING WITH HERBALS

	PROS	CONS
Safety	Many herbals are relatively safe when used appropriately.	Many herbals are toxic or can be hazardous if not used appropriately. Potential herbal/drug interactions
Effectiveness	Many herbals are beneficial for their promoted uses.	Many herbals offer no benefits for their promoted uses. Self-care may weaken consumer trust in health care professionals and decrease the demand for high-quality care.
Consumer Education	Consumers are more educated today regarding health.	Consumers often have misinformation and inaccurate beliefs regarding herbals. Consumers often lack the knowledge to make accurate clinical diagnoses and medical assessments or to select appropriate herbals for their actual needs. Misuse and abuse of herbals It can be difficult for people to think and act objectively in their own behalf or for significant others. Inappropriate use of medical references can lead to poor self-care decisions.

Cost	Self-care practices are less expensive than professional care (e.g., time and money).	Competition in an aggressive market can actually increase the costs of self-care products. Inappropriate self-care can result in increased health problems and costs. Ineffective self-care is not economical.
Convenience	Self-care is convenient and available.	Convenience and availability can discourage consumers from seeking professional care when it is truly needed.
Self-Responsibility	Self-care practices may reinforce responsibility for self and others. Self-care is perceived to be an inalienable right.	Overconfident and uninformed consumers are often willing to accept responsibility for self-care at times when it not advisable. Demands for self-care products and practices often involve unreasonable therapeutic expectations.
Self-Awareness	People are more aware of their bodies and how they feel than they can usually describe to a health care professional.	How people feel may not always correlate accurately to their actual health status.
Concerns & Emotions	Self-care practices allow people to avoid disappointments, anxieties, suspicions, concerns and embarrassments that may be associated with professional care.	Individuals may avoid professional health care at times when they truly need it.
Professional Manpower	Self-care practices reduce the demand for professional manpower.	
Medical Products	Herbal products do provide more therapeutic options for consumers.	More product options may provide greater quantity without an increase in quality.
Availability	Provides molecular/botanical modes upon which drug manufacturers can base new products	The current lack of quality control allows for questionable products to be marketed.

Safety and Efficacy

The pharmacologic activity and potential therapeutic benefits of many natural products have been documented throughout human history. It is clear that when used appropriately some of these products can expand the availability of viable and cost-effective health options. Some may eventually offer new and novel therapeutic approaches compared with previously available products. For example, glucosamine is being increasingly used as a treatment for certain forms of arthritis.⁴⁶⁻⁵⁸ Milk thistle is intriguing regarding its possible ability to reverse liver damage attributable to acetaminophen, alcohol, mushroom poisoning, and other hepatotoxins.³³⁻⁴⁵ Certainly, additional studies are needed to more clearly define the

appropriate uses and dosages, but the potentials of these agents should not be ignored.

Still, the potential for adverse effects is inevitable whenever pharmacologically active substances are used naïvely or inappropriately. Much remains to be discovered about herbal products (e.g., drug interactions; impact of chronic use; use by specific patient groups, such as pregnant, lactating, elderly, or children; adverse effects). Because most herbals contain numerous components, it can be difficult to tailor products to specific symptoms or health problems.^{5,9}

Herbal products in America lack regulations to guarantee the safety and efficacy required

of other health care products. They may vary in their makeup or are adulterated with other substances. The relative concentration of ingredients can vary depending upon collection, cultivation, and preparation techniques. For example, some components may be present in greater concentrations if the herb is collected during one season of the year compared with other seasons.^{5,9} Quantitative and qualitative variations of this type could result in myriad problems. In short, there is no quality control.¹⁶ Increasingly, health officials are recommending regulation of the herbal industry.⁴

Problems with herbal use not only include the actions of the varied individual ingredients they contain, but also interactions with traditional drug products. Table 3 lists examples of the types of herbal and drug interactions that have appeared in various literature reports. Databases of this type are expanding rapidly as medical science continues to study and better understand these products. Interactions are

difficult to assess because the interaction depends heavily upon the product selected, the amount taken, and the amount of active ingredients contained in the product. Herbal products are not regulated as other nonprescription drug products. Herbal labels are often inaccurate regarding the actual contents. Even when the label is accurate, consumers are usually given inadequate instructions for use.

Finally, some herbals are harmless, but offer no therapeutic benefits. Consumers generally lack the informational base upon which to accurately discriminate between valid scientific discoveries and creative, but deceptive, health fraud promotions. The selection and use of products that lack efficacy can weaken public confidence in legitimate health care products. This can result in direct threats to the public's health if appropriate care is delayed and health problems become worse. The economic costs (e.g., health expenditures for worthless products and services) can be significant.

TABLE 3. EXAMPLES OF THE TYPES OF DRUG/HERB INTERACTIONS REPORTED WITH SOME POPULAR HERBALS ^{2-6,12,13,15-18,20}

DRUGS	HERBALS	INTERACTION
Anticoagulants	buchu chamomile clove echinacea feverfew garlic ginger ginko biloba ginseng green tea horse chestnut passionflower red clover	Potentiation of anticoagulants, including adverse effects

Anticonvulsants carbamazepine phenobarbital phenytoin	St. John's wort	Decreased drug effects via cytochrome P 450 induction by herb
Antidiabetics	garlic ginger ginseng	Hypoglycemic activity
Antihypertensives	ginger ginseng licorice ma huang yohimbe	Hypertensive activity
	garlic ginger ginseng St. John's wort	Hypotensive activity
Cardiac Drugs β-blockers cardiac glycosides diltiazem nifedipine β-blockers cardiac glycosides	guarana maté	Contains caffeine; increases heart rate and blood sugar
	St. John's wort	Decreased activity of drugs
		Metabolized by the cytochrome P450 pathway via enzyme induction by the herb
	licorice	Antagonism of β-blockers; increased heart rate and blood pressure
	ma huang	Disturbances of heart rhythm
CNS Depressants selective serotonin reuptake inhibitors sertraline	catnip chamomile hops kava kava passionflower St. John's wort valerian	CNS depression; potentiation of CNS activity of drugs, including adverse effects
	St. John's wort	Serotonin Syndrome (potentially serious); fever, sweating, dizziness
Monoamine Oxidase Inhibitors (MAOIs)	ginseng ma huang passionflower St. John's wort	Potentiation of MAOI activity and adverse effects; MAOI reaction, hypertensive crisis

Consumer Education

Consumers are more enlightened today regarding health care than ever before. By

1980, it was estimated that there were more than 5,500 self-help books available. Unfortunately, the exuberance for

authorship often exceeds the credibility for authorship. Many individuals have written books with virtually no appropriate credentials or experience. Some authors have achieved notoriety and profited by providing the public with the information that it most desires. For example, one physicist wrote a successful health book with no health background whatsoever. In another, the author provided to the reader insights about pharmacists and pharmacies even though the author was not a pharmacist and had no real knowledge of “behind the scenes” pharmacy information. Another author argued that because he was not a health professional, he was best able to explain health concepts to fellow consumers. America currently has a \$100 billion health fraud industry (i.e., products and services promoted that have not been demonstrated to be safe or effective).^{59, 60}

Herbal information reflects thousands of years of popular and folk traditions, as well as recent scientific discoveries. Herbs with scientific validity for some purposes are often promoted for other purposes for which no validity exists. In fact, this is a common technique of disreputable promoters.

Consumers harbor a wealth of information of mixed validity. Exposure to both accurate and inaccurate information can confuse consumers and limit their ability to make correct health care decisions or to correctly distinguish between valid and invalid health concepts. The daunting number of health care products, including herbs, involves an overwhelming database of information. Even when accurate information is available, it can be difficult for people to think and act objectively in their own behalf. The most valid course of action is not necessarily the most desirable. One of the legitimate roles of health

professionals is to provide objectivity at a time when it may be difficult for individuals to do so for themselves. For example, the use of a less expensive herb may be attractive compared with more expensive professional care, even when professional care is truly needed.

A significant informational concern regarding herbs involves the designation of these products as “natural.” Many consumers believe that herbs are “nondrugs,” are devoid of adverse effects, and will not interact with other drug products. This is not true, but is congruent with the unethical and deceptive promotional practices designed to generate sales of these products.³²

Another source of confusion involves the many names that are associated with herbs. In early American publications, native plants were often described by their uses or by some obvious physical characteristic. In some cases, a given name can refer to several species of plants, which may have considerable variations in chemical and pharmacologic makeup (e.g., “Dye Weed” can refer to dozens of distinctly different plants used as a dye).¹ Even within the scientific community there is often a lack of agreement regarding the formal names of a given plant. As a result, an herb may be associated with numerous common and scientific names. The manufacturers and distributors of herb products will sometimes list a less common name in an effort to make their product appear to be unique.

Even though herb labels cannot promote their use as a drug, this does not prevent disreputable promoters and authors from making outrageous claims in the form of books, pamphlets, or other literature, which are often placed next to herb products in

retail settings.¹³ Because of their deceptive promotional practices, it has been relatively easy to dupe the public into believing that herbals represent a veritable smorgasbord of magical, mystical, but absolutely harmless, healing substances that have been ignored by traditional medicine because they pose a significant threat to professional profits.

Costs

Self-care practices typically involve lower costs than professional care, both in terms of time and money. The widespread availability of products in a competitive market environment minimizes the time required for locating products and making purchases. Competition tends to stabilize prices between outlets. Even so, the promotional costs associated with marketing, advertising, consumer research, creative packaging, and related costs can contribute significantly to product costs. Inappropriate self-care practices can result in significant health care costs in terms of both direct costs (e.g., medical expenses) and indirect costs (e.g., lost work time).

Convenience

Self-care practices are convenient and relatively available. Herbals, as other self-care products, are found at increasing numbers of outlets, including those that have not historically been associated with these products (e.g., gas stations, convenience stores).

Convenience may also be reflected in our perceptions of medical and health care products. Many medical concepts are relatively complicated. Consider, for example, the difficulties in explaining the pharmacologic relationships between antidepressants and neurotransmitters. Even though St. John's wort shares this property with other antidepressants, consumers readily relate to the simplistically

convenient, although inaccurate, interpretation of this herbal as "natural Prozac." With this in mind, it is both understandable and reasonable to recognize that convenience considerations are not restricted to the physical availability of products, but also intellectual convenience in the efforts of consumers to understand how drugs work.

Self-Responsibility

Professional health care has not always been available to human cultures. Survival has often been absolutely dependent upon the ability of individuals to provide care for self and others. In this way, self-care has not only existed as a component of self-responsible individuals, but is thought to promote self-responsibility among the members of societies, particularly in societies such as America where freedom is valued, self-care is viewed as an inalienable right. Unfortunately, misinformed consumers are often overconfident and willing to accept responsibility at a time when it is actually hazardous.

Self-Awareness

People are more aware of their bodies and how they feel than they can usually describe to others. Language is abstract. Words are used to represent concepts, ideas, and objects. Yet, efforts to describe symptoms and feelings are always fraught with difficulties. Messages that one sends can be easily misunderstood by the one who receives them. Self-care practices, if effective, not only avoid the misinterpretation difficulties of communication, but also involve a direct link between a health care intervention and an outcome. Unfortunately, individuals often misinterpret their own symptom experience. Thus, the seeming location of abdominal pain may be quite disconnected from the actual source of the pain. The

inability of individuals to accurately interpret their symptoms (or those of significant others) can result in ineffective or even hazardous self-care decisions.

Avoidance of Undesirable Concerns and Emotions

Professional care practices can be embarrassing. Personal examinations by members of the opposite sex, discussions of topics that are uncomfortable, explanations regarding the manner in which problems and symptoms developed, and myriad other issues may be difficult for individuals who are unaccustomed to such conversations. Self-care practices avoid these confrontational problems. Unfortunately, professional care may be avoided at a time when it is needed.

Professional Manpower

There are not enough health professionals in the U.S. to care for every health problem experienced by American consumers. Furthermore, the vast majority of common health symptoms and problems simply do not warrant the expertise of trained health professionals. Thus, self-care practices serve to limit professional care demands to scenarios for which it is more truly indicated.

Medical Product Availability

The availability of herbals has continuously served as a source of or inspiration for new medical products. Thus, the importance of the role of herbals in this regard cannot be ignored. Table 4 summarizes these roles in general terms. These are not roles that will abate in importance in years to come.

TABLE 4. ROLES OF HERBALS IN MODERN MEDICINE

Source of Difficult to Synthesize Drugs

Herbals offer a supply of drugs already manufactured by nature. Over the past several decades—and before the advances in medicinal chemistry—this was especially important. These herbals were once extremely important resources of a variety of useful medicines (e.g., some narcotics; ergots; cardiac glycosides, such as digitalis; many antibiotics; many serums and vaccines). Natural products are not necessarily better (and, in fact, are often less predictable and potentially more hazardous), but they do supply a source for needed drugs when no other ones are available. It is also worth noting that the synthetic manufacturing of drugs is almost always less expensive than extracting the same drug from natural sources.

Source of Substances that can be Modified to Make Improved Drugs

Once medical scientists identify the active ingredients in an herbal, they can modify the molecule to make it more safe and effective. This can include modification of substances that have little or no inherent activity (e.g., hydrocortisone and related steroids occurring in small amounts in nature can be produced in much larger quantities by the synthetic modification of stigmasterol, which occurs abundantly in soybean oil).

Chemical Models

Some herbals are not especially useful as they occur in nature. Medicinal chemists, however, can often use the herbal molecule as a chemical model upon which to develop new classes of drugs that are safe and effective.

HERBALS AND THE FDA

Many believe that U.S. herbal regulations should be as liberal as they are perceived to be in European countries. Yet, America is unique in the world in many regards. Our culture is characterized by the most aggressive retail competition in the world. So, the desire for herbal alternatives must be balanced with appropriate regulations to protect the public from disreputable manufacturers and promoters.

The popular view of naïve self-help books, uninformed consumers and legislators, as well as a great many self-serving health product promoters is that the U.S. drug approval process is slow, cumbersome, and pointless. It is even suggested that the FDA callously prevents availability of “valuable” and even “miracle” products. Yet, the FDA is a consumer protection agency. U.S. drug laws require that all drugs marketed in this country must be proven to be safe and effective for their promoted uses. Consider, for example, that in 1990 there were an estimated 600 to 700 plant species available in herbal products in the U.S. Yet, only 100 of these plants appear to have medical or economic merit.⁴

In the early 1970s, the FDA began an extensive review of nonprescription drug products. This review eliminated many unsafe or ineffective ingredients, allowed some prescription drugs to be sold without a prescription, and resulted in greater quality control of self-care products, and it continues today. This review initially regarded all over-the-counter (OTC) ingredients in use at the time as “old” drugs. As such, they were treated more leniently than “new” ingredients, which require extensive and expensive clinical trials to demonstrate safety and effectiveness. The FDA only considered U.S. ingredients to be eligible for old drug status. This excluded

most herbals, which were being used primarily in Europe. Herbals consumed primarily for their taste, aroma, or nutritional value may be sold as foods. If they are promoted for medicinal effects they are drugs and, therefore, must be tested as drugs. Without a mechanism for these products to be reviewed as “old” drugs, they would have to undergo the time-consuming and expensive clinical trials required of all new drugs.^{4,7}

The increasing popularity of herbals has not escaped the attention of U.S. officials. In fact, millions of Americans have expressed support of legislation to increase access to herbal products. This has resulted in the creation of the Dietary Supplement and Education Act of 1994 (DSHEA), which allows herbal product labels to communicate to consumers of potential safety problems, side effects, special warnings, and contraindications. DSHEA was discussed in greater detail in Herbals, Part I of this 3-part continuing pharmacy education (CPE) series—“Dietary Supplement Regulations: Impact on Pharmacy,” which was initially offered in 1999, but the CPE article and test expired and discontinued in 2002. According to the authors of Herbals, Part I, “Under DSHEA, dietary supplements are sold as ‘foods’ to be used to supplement the diet. They are not regulated as non-prescription drugs or as OTCs. Manufacturers do not need FDA approval for their safety and efficacy prior to marketing dietary supplements.”

Labels can also make statements about how the product can affect the structure and function of the human body (i.e., statements of nutritional support). Labeling cannot, however, make claims that the product is useful for the diagnosis, treatment, cure, or prevention of disease (i.e., labels cannot promote herbals for a “drug” purpose). The

Nutrition Labeling and Education Act of 1990 (NLEA) allows for statements on the labeling of food or nutrient products that describe the relationship between the nutrient(s) involved and specific diseases or health-related conditions. The NLEA guidelines, nevertheless, do not apply to herbal products.⁴ Thus, herbal products seem to be suspended between the domains of traditional food versus drug products.

Many of the arguments that favor widespread use of herbals in the U.S. reflect the acceptance and use of these products in Europe. In countries such as Germany, herbal use is widely accepted by both consumers and medical professionals. The majority of physicians prescribe herbals and government health insurance programs pay for some herbal therapy. In 1978, an expert committee was established to evaluate herbal remedies. This committee, which has come to be known as the "Commission E," consisted of health professionals (e.g., physicians, pharmacists, pharmacologists, toxicologists), representatives of the pharmaceutical industry, and lay persons. The data collected by the Commission included clinical trials, field studies, single case reports, scientific literature, standard reference works, and medical expertise. The review generated an assessment monograph for each herbal. More than 300 monographs had been completed by 1993. Of these, roughly two-thirds were found to be favorable (i.e., considered to be safe and effective), while one-third of the monographs was found to be unfavorable (i.e., unsafe, ineffective, or both). The Commission E did not require the safety and efficacy standards demanded of U.S. drug products, meaning they did not provide standards for the quality and purity of herbal products,⁴ and not surprisingly, universal agreement among health authorities (including German officials) was never

achieved. Even so, the approach was far less costly than the U.S. drug review process, and has been acknowledged as a possible model for other countries.^{4,20} It is clear that despite efforts to establish guidelines for safe and effective use of herbals, much remains to be learned about the use of these products as medicinal agents and, certainly, professional judgment is imperative.

THE ROLE OF HEALTH PROFESSIONALS

The health care professions seek to provide safe, effective, appropriate, and necessary care for the sick.¹⁷ Even so, cultural changes, increasing health costs, and advances in medical technology during the 20th century have caused many Americans to seek alternatives to traditional medicine.^{17,28}

As the public increases its use of herbals, it is important for health care professionals to better understand these products by revisiting their studies of botany, chemistry, and pharmacology and by expanding their knowledge of popular self-care practices.¹³ Not all herbals are safe and effective—herbals, as all medicinals, must be used in proper doses, in appropriate formulations, and for appropriate lengths of time for their benefits to occur. It is important to know what conditions can be treated with self-care practices and which ones need professional medical care. For example, herbals are rarely effective for use in emergencies or acute-care situations.^{17,20} Consumers need advice about the rational use of all health care products.¹²

Professional responsibilities regarding herbals (Table 5) extend beyond merely understanding what is now known about natural products. Additional research is absolutely essential to better understand these products and their legitimate role in

contemporary health care and to identify new drug products. Finally, regulations are needed to ensure that herbal products are

prepared in accordance with safe manufacturing practices, and that labeling and product information is accurate.

TABLE 5. HEALTH PROFESSIONALS' RESPONSIBILITIES REGARDING HERBALS

- ◇ **Increase Knowledge of Herbals**
 - Administration
 - Adverse effects
 - Contraindications
 - Dosage
 - Duration of therapy
 - Efficacy
 - Interactions with drugs and foods
 - Risks, warnings, and precautions
 - Safety
- ◇ **Prevent Destruction of Natural Resources**
- ◇ **Promote Quality Assurance Practices and Regulations**
- ◇ **Promote Research**

THE FUTURE OF HERBALS

The contribution of plants to human well-being and medicine is beyond question. Unfortunately, the tendency of humans to “soil their own nest” by the selfish and greedy exploitation of natural resources is also beyond question. Rain forests, whose natural resources are largely undiscovered, are being destroyed at an alarming rate. Finding possible new drugs there has become a race against time. It is clear that Americans will opt for these alternatives more and more as problems with traditional medicine and third-party payers continue to plague our culture. So, these products merit appropriate investigation to avoid therapeutic misadventures and economic fraud, but also because many may offer valid therapeutic alternatives.

CONCLUSIONS

Herbals are here to stay, as they have been for centuries. Ironically, they are actually far more traditional as medications than the

processed tablets and capsules to which we commonly refer as “traditional.” In coming years, their use will inevitably increase. The accountability demanded of the manufacturers and promoters of these products should be no different from what is demanded of the manufacturers and promoters of other medical products. And, health professionals should commit themselves to an understanding of these products, just as they do of other health care products and practices. It is tempting to broadly classify herbals either as “miraculous” or “worthless.” Yet, in reality, they are neither. Their merit, as with all health care products, is absolutely dependent upon rational use. For health care professionals, this demands an objective exploration of their merits and limitations.

The psychologist and philosopher, Abraham Maslow, once said, “When the only tool you have is a hammer . . . you tend to treat everything as if it were a nail.” To refuse to

better understand these products or ignore their potential merits deprives the culture of potential medical “tools.” At the very least, a continued avoidance of these products

only serves to further alienate health care providers from a public that is increasingly committed to their use.

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