

PRESIDENTIAL ADDRESS

Herbalism in the Modern World

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INTRODUCTION

As the 19th century came to an end, modern orthodox medicine displaced traditional folk medicine in the United States. The advent of modern medicine, with its focus on the scientific method in elucidation of the causes of diseases and their treatments, has led to longer life-spans and generally better health in most of the industrialized world. It has also made medicine more remote from the general public. Furthermore, with the ever increasing use of technology, medicine has been perceived to have become the exclusive domain of corporate America.

During the past few decades, alternative medicinal practices including the use of natural herbal remedies, has begun to regain greater acceptance on our society. To many scientists, the desire to return to a "more natural" approach to health maintenance seems to be a repudiation of the progress made in medicine and the scientific methods responsible for the relative good health that we can expect as members of our affluent society. For many people, however, this shift is not so much a denial of the benefits of modern science, but a recognition that the benefits of modern medicine come at an extremely high financial cost. There is also a feeling that the dismissal of natural remedies by orthodox medicine and pharmaceutical companies may be based more on financial considerations than pure science.

As scientists, we might think that the public's doubts about the integrity of corporate medicine and their questioning of the motives of members of the scientific community are unjustified. However, when you examine the use of herbal medicines in the rest of the world (herbal extracts are prescribed throughout Europe and much of the developing world) and the fact that up to 75 % of prescription drugs in the U.S. are based upon natural plant products or directly derived from secondary plant products (Chevallier, 1996), these concerns may appear more reasonable.

My own interest in herbs and the commercial potential of native plants came about through a very circuitous path. Early in my career I was a student of plant systematics and was always fascinated by the ancient herbals, from both the historical and aesthetic perspectives of these great tomes. (Although access to the original work is almost impossible, high quality reproductions of

many of these texts are readily available. - e.g., Cruz, 1940, Dioscorodies, 1959, Gerard, 1931) Upon my arrival at South Dakota State University, I became involved in the ongoing research with *Echinacea* (Purple Coneflower) and have spent several years examining its basic botany, biochemistry and economic potential. This work and my more recent studies into the economic potential and unrealized medicinal value of secondary products of a broad array of native plant species has contributed to my interest in the resurgence of herbal medicine in general. Although there exists a great wealth of knowledge of plants on a world-wide basis, I will limit my discussion here to the history of herbs and herbals in western culture and personal experiences with modern herbalism, with which I am significantly more familiar.

THE PAST

The use of herbal remedies was a fundamental practice in all primitive societies and in Western culture provided the foundations of both botany and medicine. Careful observation and empirical data allowed early medical practitioners to utilize the cornucopia of biologically active secondary plant products found in nature. Although this knowledge was probably passed down orally for millennia, our first glimpse into this collective knowledge is an herbal by Theophrastis, considered the father of Botany, published around 300 B.C. (Chevallier, 1996). This text contained detailed descriptions of plants and their medicinal uses, but lacked illustrations.

During the first century A.D., Pedacius Dioscorides, a Greek army surgeon, produced one of the most important herbals in the history of western medicine. The text, translated into Latin as *De Materia Medica*, detailed more than 600 plant species and provided descriptions of their preparation for various maladies. Dioscorides' text was used virtually unaltered for 16 centuries, but many of the later versions or Codices were prepared with illustrations that did not accurately reflect his text. This practice at times had profound effects on the value of the empirically derived medical treatments. Although a multitude of different herbals were produced during the ensuing centuries, *De Materia Medica* provided the foundation for much of Western medicine during this period.

Galen, in the second century A.D., greatly affected medicine and the use of herbal remedies through the development of the Doctrine of Naturals (Chevallier, 1996). Based on Hippocrates humoral ideas (Good health was viewed as the result of the balance of four bodily humors or fluids: blood, black bile, yellow bile and phlegm.) and Pythagorean theory, all things, including plants, were determined to have natural characteristics (qualities such as dry, moist, hot cold etc.) that allowed their use to be determined in the light of "pure theory". Thus, the value of empirical observation and experience was diminished. This approach and subsequent theoretical considerations (i.e. Doctrine of Signatures where the appearance of a plant or plant part [God's signature] determined its proper use.) greatly reduced the value and efficacy of much of western medicine. This approach to medicine not only led to a diminished understanding of the power of herbal medicines, but contributed to the success of charlatans who preyed upon the desperately ill.

With the advent of modern orthodox medicine and the formation of medical associations such as the AMA in the late 19th and early 20th century, the ability to prescribe herbs became further removed from botanists, naturalists, and traditional practitioners of folk medicine. In an initial attempt to reduce the many abuses that unscrupulous hucksters were inflicting on the general public, practitioners of orthodox medicine moved to restrict the use of herbal medicine to licensed physicians. Later the use of herbs was greatly marginalized as the medical associations and pharmaceutical companies took control of medical practices in North America and, to a lesser extent, in Europe. Production of synthetic and patentable products hid the use of herbs in the laboratory where valuable biochemicals could be extracted, synthesized and packaged through registered pharmacists, under the control of licensed physicians.

THE PRESENT

During the past 30 years there has been a renewed interest in the use of herbal medicines in western cultures and in the United States in particular. In China the barefoot doctor program of the 60's led to increased use of herbs and other folk medicines and to a general recognition of their potential benefits, especially in regions where orthodox medicine was unavailable. Adoption of a similar strategy by the World Health Organization in several developing nations and the recognition of the continued use of herbs in orthodox medicine in Europe further stimulated interest in use of traditional medicines and a holistic approach to health in the U.S., especially among members of the baby boomer generation.

Since the 1960's, a growing segment of the American population rejects orthodox medicine or at least feels that a holistic approach, in conjunction with orthodox medicine, offers an affordable and practical alternative to the corporate medicine practiced in the US. This movement has created a \$12 billion herbal market in this country this year, with an estimated growth potential of >10% each year in the foreseeable future.

The initial restrictions on the sale of herbs as medicines during most of this century and the dismissal of their value by orthodox medicine, which continued to prescribe pharmaceuticals comprised of >75% plant products, created considerable skepticism among the populace. This skepticism was documented recently in an NPR / Kaiser Family Foundation / Kennedy School of Government Survey on Americans and Dietary Supplements where 69% of respondents stated that dietary supplements, other than vitamins and minerals, are important to their personal health. More tellingly, when asked "If a government agency said that the dietary supplement you use most often is ineffective, do you think you would stop using it, or you would you continue using it because it works for you?" (Based on those who use supplements regularly/sometimes; n=412) 72% said they would continue using it.

In 1994, this vocal segment of society successfully lobbied the US Congress to remove the restrictions on the sale of herbs by creating the Dietary Supplement Law. This law virtually removed the FDA's ability to oversee the sale and marketing of herbs. Unfortunately, it not only allowed sincere and educated

practitioners of herbal medicine to ply their trade, but opened the door for charlatans to advertise and sell products without any knowledge of their traditional use, efficacy, toxicity, or requirement for quality control. Changes in the Dietary Supplement Law have also induced many large companies to enter in to and exploit the herb market by removing the need for any substantive research or evaluation of their products. In fact, almost any product may be sold as a dietary supplement with little or no oversight as long as the manufacturer does not make any overt health claims. This aspect of the law creates quite a paradox in that most of the compounds are sold based upon their supposed medicinal qualities, but are officially advertised as dietary aids that have no medicinal value. Manufacturers rely on word of mouth advertising and the numerous Internet and popular press sites that tout their efficacy. If herbal medicines are ever going to be fully utilized by the majority of the US population and fulfill their theoretical potential, efforts to ensure quality control and efficacy are essential.

In an ongoing study in my laboratory, we have examined the variation in quality and content of several commercially available *Echinacea angustifolia* preparations. Using ethanol extractions and HPLC separation of more than 100 *Echinacea* plants collected from throughout the Midwest as a base line, we found that the capsules and tinctures tested contained < 25% (some <5%) of the ethanol extractable components that would be expected if the products contained the advertised amounts of properly dried root materials (the traditionally used portion of *E. angustifolia*). Furthermore, individual capsules within a lot number and capsules from different lot numbers showed significant variation in ethanol-extractable compounds. Although these are only preliminary findings, they suggest that there is little chance of discovering the potential of herbal medicines with the present lack of regulation.

The demonstration of efficacy, another major weakness of the current system of utilization of herbal medicines, is an even more daunting problem. There is a paucity of data as to the proper dosage and proper method of administration for most herbs. These data are essential before we can measure efficacy. The method of administration and proper dosage of an herb must initially be based upon traditional usage. For herbs used in European or Asian traditions these data are readily available. However, many of the currently "hot" herbs are native to the Americas, where much of the knowledge of the traditional use of these plants has not been recorded or made available to the population in general. Although we know of many plants used by Native Americans, relatively little of the specific methods of preparation and use are available. Their knowledge has been ignored or dismissed, due in part to the nature of the interactions between the early European settlers and the Native peoples. In addition, American Indians hold much of this information sacred - not to be discussed except when specifically directed by their deities. (This is an area that may be addressed in the future through efforts by Native American Land Grant Colleges, as they document the large body of knowledge that is part of the Native American oral tradition.)

Even when there is a basis for their use, efficacy of herbal medicines is the most difficult of the issue to address. Even with the current mandate to explore

alternative medicine, NIH-funded studies of herbal preparations are unlikely, except where specific claims of disease cures and clinical trials can be made. Because many herbal preparations are thought to act in an holistic fashion resulting from synergistic effects of their chemical constituents, and act to improve overall health and prevent diseases, studies of efficacy require large populations studied over years to determine whether use of an herbal preparation significantly decreases the occurrence of disease. These types of studies demand participation by large pharmaceutical companies or other private sources. However, because plant extracts and other plant preparations are not easily patented, pharmaceutical companies will not be interested.

At present, the prospects for regulation of this market and the elucidation of the true potential of many of these herbal medicines is bleak. Although there is an effort by the FDA to create over-the-counter regulation of herbal medicines using the European model, where traditional use and preparation of the products is the basis for sale, the economic potential of the market is likely to stifle any real efforts toward meaningful evaluation of herbs. The potential of a virtually unregulated, multi-billion dollar market has attracted many of the world's largest pharmaceutical companies (e.g. Bayer, Centrum) and many other new herb marketers. The probability that these companies and the myriad of other entrepreneurs entering the market will press for, or allow, stronger regulation of marketing and demand costly research that might limit sales is negligible.

Concurrent with the entry of many of these large companies, has been an effort to lower the standards for defining products "organic". Most traditional herbalists and practitioners of holistic medicine insist on all natural products in their treatment regimes. Changes in these regulations would allow large-scale production of plants that could make the claim of being organic without meeting the current rigid standards. For large scale production, this would allow more mechanized and less labor-intensive means of producing these high-value products.

THE FUTURE

It takes little foresight to know that for the near future, there will be an increased use of plants in both orthodox and herbal medicine in the USA. Plants and plant products still make up the majority of pharmaceuticals used in this country, and there is an active search of the tropics for new plants to fill the needs of the pharmaceutical industry. The need for new antibiotics and compounds to treat a host of human and animal diseases has stimulated interest in the herbal traditions of Europe and Asia. There is even beginning to be a recognition by the pharmaceutical industry that the indigenous peoples of the Americas have a vast body of knowledge of native plants and their uses. The knowledge of these peoples was for the large part ignored by the European settlers, but now there is a developing appreciation of the possibility that there may be undiscovered valuable plants growing in our own backyards. Additionally, as discussed above, the market for herbal medicines as replacements for or supplement to orthodox medicine will continue to grow, because they

are seen as cost effective and believed by many to be as effective as standard pharmaceuticals over the long run.

There can be little doubt as to the potential benefit of the vast number of still-to-be-discovered secondary plant products and their medicinal potential. This potential will continue to drive the marketing and use of herbal preparations. Perhaps even more important for the herbal drug market is the change in public opinion of the value of herbal remedies and tonics. Natural herb preparations are more commonly seen as inexpensive alternatives to costly pharmaceuticals and the putative preventive-medicinal value of many of the herbal products has great appeal to many as life expectancies increase and the population becomes more health-conscious.

As was true in the past and is currently common place, the herbal market will be driven by a wide range of people and interests. There are a large number of traditional herbalists (e.g. Christopher Hobbs) and members of the established scientific community (e.g. Varro Tyler - former Dean of Pharmacy at Purdue University, and David Duke - USDA) who believe in and promote the use of herbs based on an empirical and scientifically-grounded approach. There are also many well-meaning, but poorly informed practitioners that will prescribe herbal remedies based upon quasi-religious beliefs and/or scientifically unfounded theories (e.g. the Doctrine of Signatures). In addition, the industry will continue to be plagued by charlatans and unscrupulous entrepreneurs whose only motivation is profit.

This mix of players, the lack of support by a large portion of the medical research infrastructure, and almost no real funding for clinical evaluation of herbal medicines makes the probability of great strides in the use of herbal medicines, except as the basis for production of standard pharmaceuticals, seem very limited. In this way, for at least the near future, we seem destined to repeat the past, with much of the true potential and limitations of herbal therapies remaining in the realm of anecdotal data and statements of belief. Although the market will expand, lack of data will prevent meaningful evaluation of the products.

Although an immediate upswing in our understanding of efficacy of herbal products is not likely, the future of herbal medicinal research is not without some glimmer of hope. The public's general interest in their use, and the entry of the big pharmaceutical companies into the market, with the accompanying participation of local pharmacists through whom the products are marketed, has led to the recognition and prescription of these products by many General and Family Practitioners (e.g., Dr. Gott's syndicated column in many of the region's newspapers and the SD Public Radio monthly medical call in program).

The recognition by the general public that there is a need for regulation and study also has the potential to eventually force a closer examination and generate the funding support for the needed research. In the NPR Poll discussed above, a majority of the same people who said they would continue to use a dietary supplement even if a government agency said if it was ineffective, recognized that there is a need for more governmental regulation to ensure the purity, ensure truthfulness in the industry's claims and to protect

them from harm. If these desires are conveyed to Congress, especially in light of the ever increasing numbers of people using herbal products, there may be a change in the overall picture. In fact, this process has already started with the development of an NIH funded program for alternative medicine. Congress pushed NIH to fund research in alternative medicine when they passed the Dietary Supplement Law, however, little money provided for research has actually gone toward clinical trials or even examination of traditional uses of plants, instead the money was used to fund development of research centers. Perhaps in the future, this will change in response to the concerns of society at large, and at least for the most widely used herbs, a true understanding of their potential can be reached.

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