

# THE PROGRESS OF CHINESE MEDICINE IN THE UNITED STATES

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## INTRODUCTION

In the United States, the progress of Chinese Medicine (CM) is an integral part of the growing field of complementary and alternative medicine (CAM). Although often used together or interchangeably, the term *complementary* refers to therapies used *in addition* to standard medical treatments while the term *alternative* describes medical practices used *instead* of the standard medicine. Also known under such headings as holistic, natural, mind-body or Oriental medicine, the field of CAM to a great extent incorporates and draws from the CM tradition. Elements and principles of four major disciplines of CM -- acupuncture, herbal medicine, massage and Tai-Chi/Qi-Gong exercises -- can be frequently found throughout the field of CAM. As a result, any comprehensive discussion of CM progress in America has to acknowledge progress of its elements within the context of other CAM techniques. Over the last three decades, the trend toward complementary and alternative medicine has become a significant area of exploration by the public, health care industry and the academia. Most of the interest has been driven by a growing consumer demand for “natural medicine,” forcing western practitioners to rethink their attitudes about alternative medicine.

## Key Events Influencing the Progress of CM in the U.S.

1972---President Nixon’s visit to China promoted interest in Chinese culture and opened new avenues of exchange. Traveling with Nixon, a *New York Times* columnist, J. Reston, reported benefits of an acupuncture treatment he received while in China. After an emergent appendectomy, Reston had acupuncture, which successfully relieved his post-operative gastrointestinal discomfort. His praising account of the experience and the featured TV shows about surgical operations with acupuncture anesthesia in China were widely publicized and prompted a great interest both among the public and the medical establishment.

1992---NIH (National Institute of Health) established the Office of Alternative Medicine (OAM). It greatly promoted the research and regulation of alternative medicine.

1993---Dr. David Eisenberg *et al.* at Harvard University conducted a study that was published in *The New England Journal of Medicine* (Eisenberg *et al.* 1993). The article showed that approximately one third of Americans used alternative medicine in 1990. The study sparked further interest and research activities.

1994---FDA (Food and Drug Administration) passed the Dietary Supplement and Health Education Act (DSHEA), (FDA 1995). DSHEA regulates herbs as dietary supplements. Like vitamins, herbs only need to meet the standards of dietary supplements to be sold on the market and are not subject to the rigorous regulations applied to standard drugs. This act greatly promoted the development of herbal medicine in the U.S..

1996---FDA reclassified acupuncture needles upgrading the supplies from Class III, experimental use, to Class II, general medical use (Moffet 1996a, Villaire 1998).

1997---NIH successfully sponsored an Acupuncture Consensus on Acupuncture Efficacy. The meeting confirmed the efficacy, application and safety of acupuncture (NIH 1998, Villaire 1998).

1998---In October, OAM was renamed as the National Center for Complementary and Alternative Medicine (NCCAM) with increased budget.

1998---In November, several major American medical journals (*Journal of the American Medical Association, Arch. Intern Med. et al.*) joined forces and published about 90 articles on alternative medicine. That event promoted alternative medicine to a new level of development and identified it as an area in need of further research. The journals acknowledged the significance of complementary medicine, described some of its potential uses, and called for further exploration. Attention was called to regulation and safety of complementary treatments.

1999---Government-sponsored Botanical/Dietary Supplements Research Centers are proposed (NIH 1999).

## **EVOLUTION OF THE CAM/CM FIELD**

### **Trends in CAM and the Status of CM in the U.S.**

In the past several years, numerous survey studies have examined the practice of CAM in the United States. Most often quoted is the pioneering study done by David Eisenberg *et al.* (1993, 1998) at Harvard University published in 1993 and updated in 1998. The comparative results from surveys taken in the U.S. in 1990 versus 1997 indicated a significant increase in the proportion of the population seeking alternative therapies. Specifically, the use of alternative therapies in the general population leaped from 33.8% in 1990 to 42.1% in 1997. The types of alternative medicine most used included relaxation exercise, herbal medicine, massage, chiropractic and acupuncture. In both the 1990 and 1997 surveys, alternative therapies were used most often for chronic medical problems such as pain related conditions (headaches, neck and back problems, arthritis); stress related conditions (depression, anxiety, and insomnia), fatigue, allergies, lung problems, digestive problems and high blood pressure. There were more alternative medicine users among women than men, and more among people aged 35-49 than other age groups. The studies found that the largest group of consumers consists of white, well-educated, comparatively affluent individuals who are more likely to live in the West than elsewhere in the United States. When accounting for the U.S. population growth, comparison of out-of-pocket expense for alternative medicine services between 1990 and 1997 suggests a substantial increase in total visits to alternative medicine practitioners, surpassing the number of total visits to all U.S. primary care physicians. The total estimated amount of \$27.0 billion spent on alternative medicine in 1997 represents an amount comparable to the projected 1997 out-of-pocket expenditures for all U.S. physician services (Figure 1).

Focusing on CM only, a study surveyed 575 Chinese medicine users in the United States from six clinics in five states (Cassidy 1998a, 1998b). The study demonstrated that demographics of the patients and conditions for which help was sought were similar to the CAM study by Eisenberg *et al.*. The majority of CM users reported 'disappearance' or 'improvement' of symptoms, improved quality of life, and reduced use of selected measures, including prescription drugs and surgery. Respondents reported utilizing a wide array of practices in addition to Chinese medicine, and expressed extremely high

satisfaction with Chinese medicine care. Ninety-nine percent of respondents had received acupuncture care, 59.7% had received moxibustion, and 35.5% had received Chinese herbs. No respondent reported experiencing important adverse events from acupuncture treatments.

## **ACUPUNCTURE**

Among alternative medicine practices in the U.S., acupuncture is the most recognized branch of CM -- one practiced by a large group of licensed acupuncturists, significant number of physicians and being the area of CM most commonly covered by medical insurance companies. It is estimated that 10 million treatments are performed each year to more than 1 million American patients. Currently, there are more than 10,000 non-physician acupuncturists and close to 3,000 physicians who incorporate acupuncture in their practice (Ulett *et al.* 1998). More than 53 acupuncture and oriental medicine schools have been founded in the U.S., about 36 states have established acupuncture committees or government agencies to control and regulate the practice of acupuncture, and several national acupuncture associations for acupuncturists and physicians have been organized nationwide (NIH 1997, 1998). Since most non-physician, licensed acupuncturists incorporate other CM techniques in their practice, the profession largely represents the general CM practitioners in the U.S..

Among the plethora of styles seen in the U.S. – including traditional Chinese acupuncture, French energetic acupuncture, auricular acupuncture, Korean and Japanese acupuncture, five element theory and myofascial or tender point-based acupuncture -- CM acupuncture is the classic form from which other styles originate and borrow from. Recognizing CM principles as the common ground for many styles, the point location used in the national acupuncture licensing exam is based on the CM tradition.

### **Regulation of Acupuncture**

The practice of acupuncture has been regulated on two basic levels: 1) acupuncture needles and 2) training and licensing requirements. Some of the regulations apply nationwide but many exist only at the state level contributing to wide discrepancies between the training required of the practitioners.

#### *Regulation of acupuncture needles*

When acupuncture was first becoming popular in 1972, after recommendations of an advisory committee, the FDA cautiously labeled acupuncture needles as “investigational devices”. By 1980, the FDA recognized the low risk use of acupuncture needles by qualified practitioners and modified its regulations to allow increased availability of acupuncture needles. In 1994, a petition by scientists, acupuncturists, and M.D.s practicing acupuncture urged NIH and FDA to review the investigational designation of acupuncture needles. Finally, in 1996 the FDA formally recognized acupuncture needles as a legitimate medical device and approved it for “general acupuncture use” by licensed, registered, or certified practitioners (Feely 1999, Lytle 1996, Moffet 1996a, Wu 1996).

Reclassification of the needles improved the image of acupuncture as a medically approved treatment, increased its accessibility, allowed medical insurance coverage, and expanded research funding for acupuncture.

#### *Regulation of the acupuncture practitioners*

In the U.S., those who want to treat patients with acupuncture needles has to have some kind of medical privilege (M.D., D.O., L.Ac., CA). The licensing and certification of acupuncturists and license standards has grown since the 1970's. Since the first laws were passed in California in 1972, 35 other states and the District of Columbia have approved the practice of acupuncture and identified licensing requirements. Although efforts are underway to standardize the field of acupuncture, regulations vary from stringent to nonexistent, and many states support a double standard: medical doctors, dentists, and osteopaths can practice the procedure without formal training, but acupuncturists must complete a specified number of training hours and pass a licensing examination (Mitchell 1995, 1996, 1997; Moffet 1996b; Acupuncture Committee 1997). A compendium of laws and practice requirements in every state, published by the National Acupuncture Foundation, may be obtained from the National Acupuncture and Oriental Medicine Alliance (Bailey and Leef, 1999).

#### **Non-Physician Acupuncture**

Over two-thirds of all acupuncture in the U.S. is done by non-physician graduates of acupuncture/Oriental medicine colleges, many of which were created in the last two decades. Several years after acupuncture practice started to take root in the U.S., a need for quality assurance was recognized. In 1981, three organizations -- ACAOM (Accreditation Commission for Acupuncture and Oriental Medicine), CCAOM (Council of Colleges of Acupuncture and Oriental Medicine) and NCCAOM (National Certification Commission for Acupuncture and Oriental Medicine) -- were established to set standards of practice and regulate the field of acupuncture (Bailey and Leef, 1999). The practice of acupuncture covers a wide range of modalities and tools and the title of acupuncturist is the starting point to practice other CM techniques such as herbal medicine, Oriental massage (Tui-Na), acupressure, breathing techniques, exercise, or nutrition. At this time there is no uniform licensing required to practice other CM techniques and the state-specific acupuncture regulations often determine the scope of the CM practice. In some states, acupuncturists can order medical tests and prescribe herbal treatments and nutritional supplements. In 24 states, acupuncturists can practice independently. In 10 other states, they must have patients referred to them before they can get paid from insurance or be supervised by a practicing physician, however, three of the ten states have introduced legislation to remove the restriction (Acupuncture.com 1999).

#### *Training standards*

Generally, the current standard for training is the master's degree level acupuncture program, with three to four academic years of professional study in an accredited acupuncture school. Students need to have a minimum of two years of undergraduate courses before attending a program. A clinical doctoral program in Oriental medicine is being proposed by ACAOM as the post-graduate degree; and if approved, it may eventually replace the master's degree as the entry level degree (ACAOM 1998).

### *CM and acupuncture schools*

According to the National Acupuncture and Oriental Medicine Alliance and the National Acupuncture Foundation, there are presently over fifty colleges in the U.S., with a total enrollment of over 6,500 students in 1999 (Bailey and Leef 1999). Most schools are private, each with its own history and philosophy. The majority of schools are members of the Council of Colleges of Acupuncture and Oriental Medicine (CCAOM) and, of those that are members of the council, most but not all are accredited by ACAOM. In addition to insuring quality of education and future competency of the practitioners, the accreditation of a college allows its students to obtain financial assistance from the Federal government and makes them eligible to take the national examination (Moffet 1996b).

According to *The Guide to Accredited and Candidate Colleges* published by the CCAOM, most of the acupuncture and Oriental medical schools tend to cluster around the east or west coast regions, with a few schools scattered in between. Reflecting general acceptance of acupuncture, many of the colleges on the east coast are located in New York, Massachusetts and Florida. On the west coast, colleges are prevalent in California, Washington and Oregon. The schools can vary widely in size, from ten or twenty students in smaller schools to over four hundred in larger ones. The student body is ethnically diverse, with Caucasians and Asian students being the predominant populations.

There are different traditions among the acupuncture/Oriental medicine schools, and their curriculums are far from uniform. While the CM tradition is the most prevalent one, other philosophies taught include Japanese, Five Element, and French Energetics acupuncture. Some schools may require that students acquire the knowledge of Chinese herbal medicine and take western medicine courses as a part of their training but other colleges may offer such courses only as an elective or not have them at all.

### *Licensure*

Licensure laws for non-physician acupuncturists vary from state to state, with differences in exam processes, titles, and scope of practice (Mitchell 1995, 1996, 1997). The acupuncture examination for non-physician acupuncturists accepted by most licensing agencies throughout the country is given either by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) or by state certification. Some states, such as California, only accept state certification examination and not the NCCAOM exam (Acupuncture Committee 1997). Most examinations include a written exam and a practical part, such as the Practical Examination of Point Locations Skills (PEPLS) and the Clean Needle Technique Examination (CNTE). Some states may have additional competency examinations, such as a practical portion on diagnosis and herb recognition (California). In order to be eligible for the NCCAOM or state acupuncture examinations, applicants must complete a three to four-year master's-level course. Additionally, those enrolled after July 1, 1999, must be graduates of accredited schools to be eligible for the national exam.

## **Physician Acupuncture**

While the public interest continues to grow, fueling creation of numerous CM and acupuncture schools in the last three decades, the medical establishment has been slow to warm up. For a long time, many physicians treated acupuncture as a curious but unproved technique and only a minority incorporated it into their practice. The establishment of the Office of Alternative Medicine (OAM) at National Institutes of Health (NIH) in 1992 significantly revitalized physician interest in acupuncture. It now appears that many mainstream physicians believe in the effectiveness of acupuncture and refer their patients for such treatments.

#### *Professional societies and academies*

- 1973---First physician and surgeon organization in the U.S. dedicated to acupuncture: The New York Society of Acupuncture for Physicians and Dentists.
- 1982---A Continuing Medical Education (CME) acupuncture course was established at UCLA, where many U.S. physicians continue to receive their training in principles of acupuncture.
- 1987---First *national* physician and surgeon organization dedicated to acupuncture: The American Academy of Medical Acupuncture.

Although it is not mandatory for physicians to be affiliated with or certified by external societies or academies in order to practice acupuncture, there are several that have set up guidelines to do so. For example, the American Academy of Medical Acupuncture has more than 1,200 members and is the sole professional acupuncture society for physicians in North America. The Academy publishes materials on acupuncture, sponsors continuing education programs and maintains a patient referral service for its practicing members. Its members provide consultation to physicians on how to incorporate acupuncture into their practices and apply for hospital privileges.

Certification by the American Academy of Medical Acupuncture (AAMA) requires an active M.D., dentist, or D.O. license; a minimum of 220 hours of university approved Category 1 Continuing Medical Education (CME) credits; completion of a one-year distance learning program of video training; and two years of experience practicing medical acupuncture (AAMA 1999). The members are also required to complete 50 additional hours of CME in courses on acupuncture or related topics every three years. Some states, such as New York, may require a total of 300 hours of Category 1 CME credits. In Hawaii and Montana, all health-care practitioners, including medical doctors, have the same three-year training requirements and must pass the same national examination as licensed acupuncturists. In contrast, other states do not have any requirement of training credit for M.D.s, dentists or D.O.s who can practice acupuncture without additional certification or a license.

#### **NIH Consensus Conference on Acupuncture**

In 1997, a landmark event demonstrated formal recognition of acupuncture by the biomedical establishment. The NIH sponsored a Consensus Meeting on Acupuncture during which high quality research data was reviewed by a panel of scientists and clinical investigators (NIH 1997, 1998). The NIH consensus listed several conditions for which

acupuncture can be clinically useful. The panel also acknowledged the need for further research to uncover additional areas where acupuncture can be applied.

Conditions for which efficacy of acupuncture is adequately established:

- post-operative and chemotherapy nausea and vomiting
- post-operative dental pain.

Conditions for which acupuncture was recommended as an adjunct treatment or an acceptable alternative:

- addiction
- stroke rehabilitation
- headaches
- pain syndromes such as menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome
- asthma

## **HERBAL MEDICINE**

### **Historical Background**

Throughout most of the twentieth century, the practice of botanical healing has been largely excluded in the development of modern medicine in America. This contrasts with European countries, especially Germany, where herbs were systematically incorporated into the general medical practice and are now prescribed and regulated in ways similar to standard drugs. In the U.S., this division between mainstream drugs and herbal therapies can be attributed to the following key historical factors: 1) low acceptance of herbal medicine by the medical establishment, 2) the development of pharmaceutical industry based on research and mass-production of purified chemicals, and 3) federal regulatory policies, mainly FDA divergent policies about standard drugs versus medicinal herbs.

### **Regulation of Herbs and Related Products**

Since its inception in 1906, the Food and Drug Administration has been involved in several legislative acts that affected herbal sales (O'Hara *et al.* 1998). The most important legislation -- one which has greatly contributed to the current boom in the herbal market -- is the 1994 Dietary Supplement Health and Education Act (DSHEA) (FDA 1995, Henney 1999). The act was passed with the goal of regulating the growing herbal industry without limiting the availability of herbal products. Specifically, the DSHEA classified herbal and other botanical products as dietary (i.e. food) supplements and allowed herbal products to be freely marketed. As dietary supplements, herbs and herbal products are thus excluded from the rigorous approval process required of the standard drugs. In order to take an herbal product off the market, FDA would have to demonstrate its potential health risks.

To protect consumers and provide regulation of the herbal industry, the 1994 DSHEA has: 1) set rules for the distribution of third party literature, 2) described the standards and

procedures for setting health claims concerning supplements, 3) specified the supplement ingredient and nutrition labeling information (Baker 1997, FDA 1999), and 4) authorized the FDA to describe mandatory conditions in which dietary supplements must be “prepared, packed or held” (so called good manufacturing practices, or GMP).

Effective March 1999, the FDA has a new regulation on the labeling of dietary supplements. All dietary supplements must bear a nutrition information label entitled “Supplement Facts” (Baker 1997, Friedman and Shalala 1998, Hubbard 1997, Kurtzweil 1999, Schultz 1997a, 1997b). The label must state the name and the quantity of each ingredient in the product, must identify the product as a “dietary supplement” and in the case of herbs, the part of the plant from which the product is derived must be stated. If known, the standard recommendation for daily consumption of each ingredient must be included.

Recognizing the need for further exploration in the area of herbal and nutritional products, the DSHEA also created the Office of Dietary Supplements within the National Institutes of Health (NIH). The office’s function is to oversee research and to serve as a source of information about nutritional supplements to other federal agencies.

### **Dietary Supplement and Herbal Market**

Since the passage of DSHEA, the dietary supplements industry, including herbals, has blossomed. Most surveys show that more than half of the U.S. adult population uses dietary supplement products and spend approximately \$3.5 billion annually on herbs (O’Hara *et al.* 1998). In January 1999, National Public Radio, Kaiser Family Foundation and Harvard’s Kennedy School of Government surveyed 1,200 adults 18 years and older nationwide and found that 52% of all surveyed believed that dietary supplements were good for people’s health and well-being and 18 % identified themselves as regular users (NPR 1999). The results showed that regular users come from all demographic groups, including lower-income and less-educated Americans. There appeared to be no particular socio-demographic group largely over represented in regular users.

Currently, numerous herbal products are easily available in most mainstream stores such as pharmacies, grocery stores, health food stores, etc. These mainstream herbs are sold in consumer-appealing packaging with FDA regulated standard labeling. Many have brand names suggesting their therapeutic use such Mense-Ease™ (menstrual discomfort aid) or Dissolve™ (gall stone aid) and are priced higher than generic or wholesale products. The herbs chosen for marketing come from many traditions, mainly European, Asian, or Native American. Among all herbs, the few selected CM herbs are very popular; however, many other Chinese herbal preparations are still unfamiliar to the average herbal consumer. This situation will likely change in the future as the methods by which Chinese herbs are sold and used are transformed to fit the growing interest in botanicals. For example, before herbs became popular in today’s worldwide markets, most of CM herbs were displayed and sold in their original form as raw, dry plants. The original stores selling herbs were often located exclusively in Chinese-American shopping districts and most of the customers were of Asian descent. Regions with high Asian-American populations still have stores

where herbs are sold in a way reminiscent of ancient CM practice but most herbal products have been modernized. Many CM herbs are now processed to achieve powder or extract form which are then packed in the form of liquid, tablets, gel, and capsules (Antoniak 1994). Preparations can be made from a single herb or from a combination of herbs, vitamins, or minerals. An increasing number of herbal products is made by domestic companies, but many processed and raw herbs are imported from abroad (China, Taiwan, Japan, Korea, and Germany). In addition to the over-the-counter herbs, herbs can be purchased by health care practitioners directly from the suppliers or can be ordered by consumers individually via the Internet.

### *Herbal consumers*

Most consumers buy herbs on their own; they are either self-educated about the products they buy, follow someone else's advice, or an anecdotal account. Most of the available information about herbs come from advertisements, Internet, magazine articles, books on herbs, herb bottle labels, and store clerks. Typical buyers of herbs are characterized as generally healthy and taking the supplements usually for a single specific problem such as pain, constipation, insomnia, depression, low energy, aging, and memory impairment. If the herbs appear to help, most consumers will continue to use it. In the NPR study (1999), 72% of respondents stated that they would continue using a dietary supplement that works for them, even if a government agency said that the supplement is often ineffective. Most consumers are self-diagnosing and self-medicating. Some may consult with health care practitioners on their use of herbs while others may not.

### *Herbal sales*

A 1997 *Prevention* magazine poll by International Communications Research found that 33% of American adults spent an average \$54 a year on herbs for an estimated national herbal market of \$3.24 billion (MacDonald 1998). The ranking of top-selling herbs can vary geographically and depends on the herbal sellers surveyed. According to a recent report published in *HerbalGram* (Brevoort 1998), the top selling herbs in the U.S. are listed as follows:

Name of herbs	In US \$ - millions	% of growth in one year
Gingko	138	140
St. John's wort	121	2801
Ginseng	98	26
Garlic	84	27
Echinacea	33	151
Saw palmetto	27	138
Grapeseed	11	38
Kava	8	473
Evening primrose	8	104
Echinacea/Goldenseal	8	80
Cranberry	8	75
Valerian	8	35
All Others	31	
Total:	663.4	

## **Herbal Medicine Profession**

Although most users of herbal remedies are self-diagnosing and self-treating, many patients still seek advice from herbal medicine practitioners. In the U.S., patients can choose from a variety of professionals such as acupuncturists, naturopathic physicians, lay herbalists, chiropractors, nutritionists, as well as a subset of medical doctors, nurses and pharmacists interested in herbal medicine. Since herbs have been classified as dietary supplements, generally there is no licensing requirement for those who practice botanical medicine (Wicke 1995, Silverglade 1995). Texas is the first state establishing the Chinese herbology licensure separate from the acupuncture licensure (Bailey and Leef 1999). The profession of herbalists therefore varies greatly in the amount of training, scope of herbal knowledge and range of herbs used. Most formal training is given in acupuncture schools (CM herbal medicine) and naturopathic schools (Western herbal medicine predominately). Herbal courses are also slowly incorporated into medical school curricula and the number of botanical medicine seminars and articles for physicians is increasing. Other health care and lay herbal practitioners are self-taught or learn through an apprenticeship, through variable non-licensing training programs, or through family and community education (ethnic communities or families with strong multigenerational histories of herbal use). Many herbalists in the U.S. use combinations of herbs in their practice (Chinese herbs and herbs from other traditions). CM concepts of herbal medicine are not always utilized even when traditional Chinese herbs are used. Rather, most practitioners in the U.S. pay more attention to the knowledge of pharmacological effects and clinical application of herbs in terms of Western diagnoses than the CM paradigm (Jensen 1998, Winslow and Kroll 1998). Many alternative medicine practitioners in the U.S. use single herbs or standard herbal formulas rather than prescribing individualized herbal mixtures for each patient.

### *CM herbalists*

Majority of CM/acupuncture schools require courses in Chinese herbology and therefore acupuncturists are by far the major providers of CM herbal medicine. In 1994, of the 25 accredited schools of acupuncture in America, 15 have required training in Chinese herbology and 5 others offered elective courses on the subject. Hours of training varied among schools from 22 to 364. Starting in 1994, NCCA established a certification in Chinese herbology that can be acquired by interested candidates (NAF 1999). The certification bestows the title of “Diplomat of Chinese Herbology” on those who pass a national examination and provide a verification of experience. So far, herbal certification is the only -- yet not required -- proof of herbal competency and no nationwide licensing procedure is currently in place. Several states have specific legislation allowing acupuncturists to practice Chinese herbology, while other states tolerate acupuncturists’ herbal practice even though there is no legislation addressing the subject of botanical medicine. Only one state, Virginia, prohibits acupuncturists without proof of herbal training from using herbal medicine and the general leniency is attributed to the overall low incidence of herbal side effects and complaints.

Among the different regions in the U.S., the quality of CM herbal training is probably the highest and most consistent in the states of New York and California where the acupuncture/CM schools have the longest tradition. Historically, these two states have had

large populations of Chinese immigrants and many teachers of their acupuncture schools were originally trained in China.

### **Problematic Issues in Botanical Medicine**

As described earlier, the 1994 DSHEA classified herbs as dietary supplements and enabled a rapid expansion of all available herbal products. Although attempts to regulate the booming market are currently undertaken, assurance of safety, efficacy and quality control of herbal products continue to be sub-optimal. Reports of side effect, drug-herb interactions, inadequacy or contamination of herbal products have appeared and posed questions about the future of the botanical market (Angell and Kassirer 1998, Bachorik 1997, D'Arcy 1991, D'Arcy 1993, De Smet 1991, Koff 1995, Kupec 1998, Whitmore 1997, Yarnell and Meserole 1997).

#### *Example of Ephedra*

Ephedra (Ma Huang in Chinese) has long been used in CM to treat patient with asthma and upper respiratory discomfort. When monitored closely by an herbal medicine practitioner, a small dosage of Ephedra in combination with other herbs have been used safely and effectively. Out of the context of Chinese medicine and without medical monitoring, Ephedra-containing products may cause serious side effects as shown by the problems associated with its mainstream marketing. Having alpha and beta adrenergic receptor agonists as active ingredients, products derived from Ephedra are sold as weight loss pills, energy increasing (or pep pills), and body building supplements. Some of such products have contained high dosages of Ephedra in combination with caffeine and without proper labeling and warning. Consequently, over the period of 3 years (between 1994 and 1997) the FDA has received more than 800 reports of side effects caused by products made from Ephedra, including irregular heartbeat, sleeplessness, anxiety, tremors and headaches. Extreme reactions have included seizures, heart attacks, strokes and two deaths (Segal 1997). In June 1997, the FDA proposed a regulation to limit the amount of ephedrine, one of the active ingredients from Ephedra, in herbal products and to require proper informational and warning labels. Some experts fear such measure may not be enough and want Ephedra banned from the market.

#### *Contamination of herbs and related products*

Many CM herbs used in the U.S. consist of imported Asian patent medicines. Such medicines are mixtures of several different components including herbs, plants, animal parts, and minerals which are then formulated for sale into tablets, pills, or liquids. Being manufactured outside of the U.S., some of the Asian patent medicines have been identified to contain unauthorized or toxic ingredients, such as heavy metals, prescription drugs or other adulterants that may or may not be listed on the label. In fact, additives such as steroids, nonsteroidal anti-inflammatory agents, prescription antibiotics, sedatives, and narcotics have been found in some Asian patent medicines and domestic herbal preparations (Ko 1998).

#### *Manufacturing differences and mislabeling*

Unlike standard medicines, herbal preparations (either single herb or mixtures of herbs)

can vary between manufacturers and from batch to batch. The variability presents a quality and safety dilemma since an herb may be either toxic or therapeutic depending on its dose and/or the other components it is mixed with. The medicinal value of botanical preparations is affected by multiple factors, such as growing conditions, storage, handling, and preparation methods. In fact, potency of various products from the same plant can vary up to multifold. While some manufacturers may process a particular herb by simply grounding up the plant and putting it into pill form, other manufacturers may use pharmaceutical methods to extract and assay the desired compounds thus making tablets of consistent strength.

In 1995, *Consumer Reports* magazine looked at the composition of 10 different ginseng products available on the market (Herbal Roulette 1995). Although the amount of ginseng per tablet was listed on the labels, the amount of ginsenosides, thought to be the active component, was not always listed. The magazine found striking differences between different brands of ginseng products -- a fact that many herbal consumers may not be aware of.

Herbal labels may be incorrect and/or incomplete either accidentally or intentionally. The same common name may be applied to related plant species that may have different therapeutic effects and toxicity. Botanical products can be misidentified, the wrong part of the plant may be collected, or contamination by other herbs can occur. In two publicized cases, an outbreak of belladonna poisoning was attributed to an herbal tea in New York City, and a life-threatening heart arrhythmia in a young woman was traced to a digitalis-contaminated plantain extract (Winslow and Kroll 1998, Waxman 1996).

### **Resources of Herbal Medicine Information/Research**

Multiple pamphlets, books, advocacy publications (magazines, newsletters, etc.) and Internet sites attempt to disseminate herbal information as part of herbal marketing directed to consumers. The information in these sources are not subject to labeling guidelines and may claim anecdotal, untested or erroneous information. In order to promote safe use, several companies and organizations try to provide the public and health care professionals with unbiased, accurate information about botanical products. Examples include American Botanical Council (ABC), United States Pharmacopeia monographs on selected medicinal herbs, the 1999 Physicians Desk Reference (PDR) for Herbal Medicines, and Internet/web sites such as the FDA access to "MEDWATCH". Another valuable source describing the state of herbal market in the U.S. is *Botanical Medicine*. It is a comprehensive compendium of U.S. botanical trends, policies and issues of botanical research discussed during the 1994 historical "Symposium on Botanicals: A Role in U.S. Health Care?" organized by the Office of Alternative Medicine and the FDA.

### **THERAPEUTIC MASSAGE**

Among alternative medical techniques, therapeutic massage has been very popular in the US and its profession has been growing exponentially. Eisenberg's study (1993) showed

that 7% of the U.S. population used massage in 1990 and identified massage therapy as the third most popular alternative therapy after chiropractic and relaxation therapies. A comparison of 1997 and 1998 surveys commissioned by the American Massage Therapy Association (AMTA) showed the number of Americans that used massage in one year increased from 8% to 13% between 1997 and 1998 (Opinion Research Corporation 1998). The study also showed that 30% of people surveyed stated they would see a massage therapist for a specific healthcare reason and 52% thought of massage as therapeutic. A look at trends in massage therapy shows that: consumers visit massage therapists about 75 million times annually; the therapy is equally popular among men and women and sought out by all age brackets; the therapy is especially popular among well-educated, well-off consumers (similar to demographics of other CAM therapies consumers) (AMTA 1999a). The therapy is also gaining acceptance among the medical establishment. Over two-thirds of patients who discussed massage with their medical doctor reported a favorable attitude by the physician (Opinion Research Corporation 1998). One national survey showed that more than half of primary care physicians would find massage therapy useful and of those, two-thirds would refer their patients for massage therapy (Grant *et al.* 1995).

### **Profession of Massage Therapy**

Examples of popular massage techniques available in this country are: Sweden's massage, Shiatsu, acupressure, the traditional Chinese massage of Tui-Na, rolfing, and reflexology. Massage is provided in many settings, such as therapeutic massage clinics, physical therapy facilities, acupuncture clinics, health and athletic clubs, spas, chiropractor's offices, and even the workplace. The number of massage therapists is estimated to be between 120,000 and 160,000, including students, and the number is expected to rise along with the mainstream acceptance of massage therapy (AMTA 1999b). In the last 10 years, the profession has undergone a transformation and massage therapy has been increasingly perceived as a type of medical treatment. In 1993, AMTA was founded to promote and upgrade the massage therapy profession by encouraging high educational and practice standards, funding research, and establishing national certification procedures (AMTA 1999c, Precht 1997). During the last decade, the membership of AMTA has tripled and the organization currently has over 35,000 members (AMTA 1999b). Since its first examination 6 years ago, the National Certification Board for Therapeutic Massage and Bodywork has certified over 33,000 practitioners (NCBTMB 1999). As of 1998, 25 states and the District of Columbia have laws requiring massage therapists to be licensed, registered, or certified, and 11 others are considering such legislation. Although licensing laws vary from state to state, most require completion of at least 500 hours of classroom instruction (including courses in anatomy, physiology, ethics, and massage and bodywork theory and application) and passing some type of proficiency exam (state or national) (AMTA 1999d). Much of the movement towards professionalism in massage therapy appears to be driven by medical insurance plans, some of which are interested in including massage therapy in their CAM benefits packages but want a proof of competency from massage therapists.

### **Traditional Oriental Massage**

The full medical potential of oriental massage is yet to be discovered by western physicians. With its focus on problem solving, oriental massage is well suited for integration to western practice. Well-designed research investigating oriental massage therapy is needed in order to alert health care professionals about the value of this type of massage, promote its integration into standard medical therapies, and encourage learning among physicians. Recent studies (AMTA 1999e) on massage therapy have shown benefits for a spectrum of conditions such as chronic pain syndromes, chronic fatigue syndrome (Field *et al* 1997a), asthma in children (Field *et al.* 1997b), fibromyalgia (Sunshine *et al.* 1996), PMS (Oleson and Flocco 1993), depression, anxiety (Field *et al.* 1992), post-mastectomy lymphedema treatment (Zanolla *et al.* 1984), and inflammatory bowel disease (Yoachim 1983). Hopefully, more research will appear in scientific publications, leading to a better overall acceptance of medical massage, further upgrading of its profession, and discovering the therapeutic value of oriental massage.

## **TAI-CHI AND QI-GONG**

In association with the rapid development of acupuncture and herbal medicine, the Chinese style of body-mind regulated technique, Tai-Chi and Qi-Gong, are also gradually accepted by many Americans. Tai-Chi and Qi-Gong exercises are offered by a variety of CM practitioners as well as the specialists, so-called Tai-Chi Masters. To teach Tai-Chi and Qi-Gong, no proof of knowledge such as a medical certificate or license is needed and many Tai-Chi and Qi-Gong exercise studios have been opened in areas where people seek CM. In California, almost every college or university has an extension of Tai-Chi and/or Qi-Gong class and there are daily morning TV programs with Tai-Chi exercises. Together with Yoga, Tai-Chi comprises the most popular non-conventional exercise techniques in America.

### **Tai-Chi**

Though this style of exercise is different from the traditional western fast, high impact exercise, Americans have been gradually recognizing the value of Tai-Chi. The slow movement of Tai-Chi helps relax, tones muscles, improves balance and regulates the flow of Qi. The technique promotes wellness, and alleviates stress and many chronic illnesses. Tai-Chi has been shown to be of benefit in the treatment of chronic illness and aging related conditions. In the U.S., the exercises have been especially advocated for older people who, due to age-related physical deterioration, are at risk of falling. A 1995 analysis of seven studies showed that, while any regular exercise lowers the risk of falling in people over the age of 60, Tai-Chi students had by far the best results. In comparison to regular conventional exercise, which lowered the risk by 13%, and to workouts including balance drills, which decreased the risk by 25%, Tai-Chi exercise provided an impressive 48% improvement (Atlanta FICSIT Group *et al.* 1997, Channer *et al.* 1996, Judge *et al.* 1993, Lai *et al.* 1993, Lan *et al.* 1996, Lan *et al.* 1998, Province *et al.* 1995, Schaller 1996, Wolf *et al.* 1996, Wolfson *et al.* 1996, Young *et al.* 1999).

### **Qi-Gong**

Associated with Tai-Chi, Qi-Gong is slowly being recognized in the U.S. Efforts are underway to promote scientific exploration of Qi-Gong and to spread the practice in the mainstream America (Reading 1997, Sancier 1996). In November 1997, the East West Academy of Healing Arts (EWAHA) sponsored the Second World Congress on Qi-Gong in San Francisco, California, which was attended by over 600 people from 15 countries (Stone 1998). The goal of the meeting was to increase awareness of Qi-Gong as a self-help method with documented beneficial health effects. Attendees ranged from medical researchers to those seeking medical knowledge for their own health; from experienced Qi-Gong masters to newcomers to the discipline.

During the meeting, the research on the effect of Qi-Gong practice on asthma, diabetes and the effect of emitted Qi on cancer cells were presented. Other sessions dealt with explorations of connections between Qi-Gong and related disciplines such as acupuncture, cranio-sacral therapy, naturopathy, and homeopathy. It is further encouraging that articles exploring effects of Qi-Gong in areas such as hypertension, brain activity, kidney function, enzyme and immune function and sex hormone levels started to appear in the American literature (Sancier 1996).

## **ADVERSE EFFECTS OF CAM**

With increased use of CAM in the U.S., it is expected that some of the services will be of substandard quality, misused, done inadequately, or produce side effects alone or in combination with other standard medical treatments. In addition to adverse effects of herbal products (as discussed earlier in the chapter), reports of problems due to acupuncture, massage, and chiropractic treatment have been found.

David Studdert *et al.* (1998) has a publication on medical malpractice implications of alternative medicine. The data collected from malpractice insurers was used to analyze the claims experience of chiropractors, massage therapists, and acupuncturists for 1990 through 1996. Analysis of malpractice suits against massage therapist shows that most complaints relate to minor injuries (61%), although a significant proportion (14%) relate to sexual misconduct. Top three claims against chiropractors include disk problems, fracture, and failure to diagnose. Side effects associated with acupuncture are rather minor, such as failure to remove needles (usually no injury post removal), infections, and minor tissue trauma; however, more serious, often isolated cases have been described: irreversible nerve damage, burns, pneumothorax, and hepatitis B infection. In general, the study shows that claims against alternative medicine practitioners occurred much less frequently and typically involved injury that was less severe than claims against physicians during the same period.

## **MEDICAL INSURANCE**

Unlike most of the other developed countries, United States has no universal medical

coverage and instead has established a complex medical insurance industry. In the U.S. system, numerous medical insurance companies offer medical benefits plans that specify which medical services the insurance will pay for (often labeled “the standard medical care”). Any services outside these specifications have to be paid for by the patient. Ignored, even ridiculed by the mainstream physician, alternative medicine (by definition, not a part of the *standard* care) had to suffer such status of ‘an outsider’ for a long time. Medical coverage for CM or other CAM treatments was non-existent and any interested patients had to pay out-of-pocket for alternative medical care. Such extra expense can present a barrier for those with limited resources and selects for either well-off patients able to afford the cost or those who turn to alternative medicine as a treatment of last resort.

This bleak situation has been changing in the last few years, mainly as a response to continuous patient interest in alternative care. Series of surveys demonstrating wide consumer demand for CAM therapies have sparked the interest of the medical insurance industry. One survey done by an insurance company (a managed care company) Oxford Health Plans, Norwalk, CN shows that 33% of its 1.5 million members have sought alternative treatment in the last 2 years (Chowka 1998a, 1998b). Responding to the growing market for CAM, a number of health care insurers decided to start offering medical coverage on complementary medical procedures. The interest of medical insurance companies has been instrumental in the regulation of the CAM field since to be included in a package of benefits, an alternative medicine practitioner must present proof of proficiency such as a professional license.

Most of the major private insurance companies in the U.S. have developed insurance programs to provide benefits for alternative medicine (mainly chiropractic, acupuncture, and therapeutic massage). For the government-sponsored medical insurance, legislation addressing CAM benefits is also being developed. In fact, insurance coverage of chiropractic treatment is mandated by law in at least 42 states, acupuncture -- in 7 states, and naturopathy -- in 2 states (Studdert *et al.* 1998). As a mark of the growing legal acceptance of CAM, a bill passed in 1997 in California included acupuncturists as treating physicians in the workers’ compensation system (CAAOM 1998).

American Specialty Health Plan (ASHP) -- a quickly expanding managed care insurance company in the western part of the U.S. for chiropractors and acupuncturists -- has a benefit package which includes acupuncture and traditional Chinese herbal medicine. As of 1998, patients are allowed 20-40 annual visits to network acupuncture providers and \$500 per year is allotted for the traditional Chinese herbal supplement benefit.

## **CM AND CONVENTIONAL MEDICINE**

After a long period of getting the cold shoulder from mainstream physicians, CAM therapies are starting to be acknowledged by the American medical establishment. The interphase between conventional and alternative medicine is created in several areas which include 1) research, 2) medical education, and 3) clinical practice.

### **Research**

In response to the high prevalence of alternative therapies in the U.S., the American Congress initiated the creation of a central agency coordinating and sponsoring research into complementary and alternative medicine. In 1992, the Office of Alternative Medicine or OAM was founded within the National Institutes of Health in Bethesda, Maryland, with the goal to 1) facilitate the evaluation of alternative medical treatment modalities, 2) gather and disseminate information about CAM, and 3) promote the integration of effective therapies into the mainstream medical practice. Initially awarded a modest \$2 million budget, the Office has since undergone an exponential growth reflecting the extent of government investment into studying CAM practices. In October of 1998, the OAM was expanded and renamed as the National Center for Complementary and Alternative Medicine (NCCAM) with an increased budget of \$20 million in 1998 and \$50 million in the 1999 fiscal year.

The OAM and NCCAM Fiscal Year Budget

1992	1993	1994	1995	1996	1997	1998	1999
\$2M	\$3.5M	\$3.5M	\$5.4M	\$7.4M	\$12M	\$20M	\$50M

Since its conception, the OAM and now the NCCAM, have been instrumental in promoting research in the field of alternative and complementary medicine. The office has established research links with multiple institutes within NIH, the U.S. Food and Drug Administration (FDA), the Agency for Health Care Policy and Research (AHCPR), and other federal agencies. It has launched several large clinical trials, provided “seed grants” for the development of novel projects, and by 1999 appointed thirteen CAM Research Centers. The Research Centers are expected to act as long-standing sources of high-quality CAM research and serve as the research training and career development sites. In 1998, an intramural training program was begun which currently supports four research fellows. The investigations sponsored by the NCCAM focus mostly on common chronic illnesses, women’s health, and addictions (see list below). Grant proposals for other conditions that may benefit from CAM are encouraged and reviewed by the NCCAM.

*CAM research center grants*

- Stroke and Neurological Conditions (Kessler Institute for rehabilitation, West Orange, NJ; The University of Medicine & HIV/Aids (Bastyr University, Seattle, WA)
- General Medicine Condition (Beth Israel Hospital, Harvard Medical School, Boston, MA)
- Women’s Health Issues (Columbia University College of Physicians and Surgeons, New York, NY) Dentistry, Newark, NJ)
- Addictions (Hannemin County Medical Center/ University of Minnesota Medical School, Minneapolis, MN)
- Aging (Stanford University, Palo Alto, CA)
- Asthma, Allergy, and Immunology (University of California at Davis, Davis, CA)
- Pain (University of Maryland School of Medicine, Baltimore, MD)
- Cancer (University of Texas Health Science Center, Houston, TX)
- Pain (University of Virginia School of Nursing, Charlottesville, VA)
- Pediatrics (University of Arizona, Tucson, AZ)
- Cardiovascular Diseases (University of Michigan at Ann Arbor, MI)
- Chiropractic (Palmer Center for Chiropractic Research, Davenport, IA)

Apart from research funding, the NCCAM is expected to continue the OAM's function in providing technical support in the form of grant-writing workshops, clinical research workshops and consultations on clinical investigations. Since their creation, the OAM and now the NCCAM have organized a number of conferences for medical professionals on CAM-related topics such as wellness, acupuncture, cancer treatment, botanicals, research methodology, and insurance reimbursement. In addition to educating health professionals, the NCCAM also serves the public by disseminating reliable information about CAM medicine.

### **Medical Education**

In the last few years, several studies confirmed increasing tendency to teach CAM courses at U.S. medical schools. A study in 1995 by the Alternative Medicine Interest Group of the Society of Teachers of Family Medicine showed that about one-third of the family medicine departments at medical schools and one-third of family practice residency programs offered CAM teaching (Carlston 1998). Only 3 years later, a study by Wetzel *et al.* demonstrated that almost two-thirds of all U.S. medical schools offered courses in complementary or alternative medicine (Wetzel *et al.* 1998). Of the 123 courses reported, 68% were stand-alone electives, 31% were part of required courses, and 1% were part of an elective. Departments most active in teaching such courses were family practice and internal medicine; however, most courses did not have a single department responsible for its teaching. Some courses were offered in affiliation with outside CAM institutes or centers, some were initiated by an individual school's office of medical education, others were interdepartmental. The format and content of instruction varied greatly between institutions, from short electives to month long clerkships; from lectures only (majority) to diverse, hands on experience (selected few schools). In general the CAM education at medical schools is widely supported by such organizations as the OAM and the AMA and many schools are now establishing separate departments of complementary and alternative medicine. Much of the investment in teaching CAM is student driven and multiple student interest groups have extended their exposure to CAM beyond what their medical school offer (organizing "brown bag" lunches with different CAM practitioners or visiting CAM practice sites) (Daly 1996, Milan *et al.* 1998, Shaw 1999).

### **Clinical Practice**

Prompted by the high demand for CAM and its promise of business or academic opportunity, many conventional medicine practices and universities have attempted to establish integrative treatment sites. After the initial excitement wore off, such task has proven to be a challenging endeavor requiring in-depth knowledge of western as well as eastern medicine (Astin *et al.* 1998, Berman *et al.* 1998). Some clinics have experienced difficulties since their establishments (few had to close down), some are successfully thriving, others are being formed. Many western medicine health systems are opening the so called "center of complementary medicine" in response to patients' interest. Among examples of clinics/programs that aim to integrate conventional and CAM medicine are: the UCLA Center for East-West Medicine, the Center for Spirituality and Healing at the University of Minnesota School of Medicine, the Center for Integrative Medicine at Jefferson Medical College, and the California Pacific Medical Center's (CPMC) Health

and Healing Clinic (Shaw 1999).

#### *UCLA Center for East-West Medicine*

A clinical, educational and research center, UCLA Center for East-West Medicine was formally established in 1993 and is devoted to full integration of western and traditional Chinese medicine. The center has a successful East-West medicine clinic run by experienced western medical doctors familiar with CM and licensed acupuncturists trained in western medicine and modern sciences. These clinicians work in unison throughout the diagnostic and therapeutic process. An individualized management plan is designed for each patient using western medical drugs, therapeutic massage, acupuncture, education on dietary and herbal supplements, physical therapy, and Tai-Chi/Qi-Gong exercise.

As a part of a major university in the U.S., the center also serves as an active educational and research base. Since 1996, the Center sponsored several international conferences on integrative East-West medicine for physicians and other health care professionals. The meetings covered broad range of topics from chronic pain management to successful aging. The center also has selective courses on integrative medicine for first year, fourth year medical students and medical residents. The center explores effective ways of integrating eastern and western medicine in medical practice and uses creative ways in teaching integrative medicine to students (for example, use more clinical cases and hands-on experience in teaching). The clinic also serves as an innovative laboratory where the efficacy of various CM techniques is evaluated.

## **CONCLUSION**

The field of alternative medicine in the U.S. has undergone a tremendous growth in the last decade. Individual branches of CM have entered the mainstream at different rates with acupuncture leading the progress. Despite making some strides, the field continues to be in a state of flux. The merger of CAM and conventional biomedicine is ongoing in diverse ways and in different settings. New data about popularity and efficacy of alternative therapies compete with reports of side effects, failed expectations and warnings of quackery. As such, the field of alternative medicine is seen by some as an area of great promise and opportunity and by others as untested waters, murky and deceiving. Despite contradictory information, those believing in the great potential of CAM hope that this transitory state will lead to a better, more integrated medicine and an overall improvement in people's health with the principles of the CM paradigm providing the guiding framework.

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