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Subj: URGENT ~ Corrected version
Date: Thu, 30 Nov 2000 11:35:16 AM Eastern Standard Time
From: Paul Kurtz
To: whccamp@mail.nid.gov (Doris Kingsbury)
CC: Paul Kurtz, PKSKSH, SkeptInq

URGENT

Dear Ms. Kingsbury:

Please substitute the attached corrected copy for what I sent you yesterday. It was sent out without its being proofread. I very much hope you can include this.

Cordially,

Paul Kurtz

==========

Dear Ms. Kingsbury:

Please provide my response to the 4 questions to the Commissioners:

1) Should CAM be integrated with conventional medicine and why or why not?

I do not think that it should be integrated. I deplore the efforts to do so. The term "conventional medicine" is as a misnomer. What is labeled as "conventional" is modern scientific or evidence-based medicine. Many or most CAM therapies on the other hand are "conventional" and ancient, such as traditional Chinese medicine, Qigong, or spiritual importations from India.

Scientific medicine is a relatively recent development in human history, especially since the nineteenth century, when increased knowledge of physiology and human anatomy was refined. There have been a number of brilliant researchers who have contributed to our understanding, such as Claude Bernard, Louis Pasteur, Robert Koch, and Joseph Lister. Theories about the nature and transmission of infectious diseases, such as diphtheria, tuberculosis, malaria, typhoid, tetanus, polio, and the development of vaccines had important roles in immunization. Likewise important were the advances in epidemiology, public health, and sanitation. In the twentieth century endocrinology advanced--with the discovery of insulin, cortisone, and sex hormones. In the field of nutrition researchers discovered the role of vitamins. There have been significant new diagnostic tools, such as X-ray imagery, CT scans, mammography, and sonograms, to mention only a few. The great strides in surgery have been impressive, including cardiology, neurosurgery, and organ transplantation. The discovery of antibiotics has made enormous contributions to the cure of infectious disease. We should add to this the discoveries of DNA, biogenetic research, gene therapy, and other

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Reply

Reply All

Forward

innovations on the frontiers of research. All of these achievements have led to the reduction of infant mortality and the extension of life spans. As part of this process was the development, beginning in 1904, of rigorous standards of medical eduction in medical schools. Thus we see the remarkable effectiveness of modern scientific medicine--all for the benefit of humankind.
They key factor in evidence-based medicine is that any new diagnostic techniques and therapies be submitted to rigorous double-blind clinical tests. Unfortunately, CAM therapies, in our view, have not been adequately tested. Too often the claims of their validity have been anecdotal or highly subjective uncorroborated reports by practitioners and/or their patients, some of these based upon the placebo effect.

Surely, we cannot lump all CAM therapies together and make a blatant indictment. Each has to be examined objectively and impartially. Scientific medicine admits that fallibility and skepticism is part of its process of inquiry. On the other hand, we should insist that the public be safeguarded against unproven cures, untested therapies, quackery by practitioners and manufacturers out to make a profit.

2) Should there be access to and delivery of CAM products and practices? If so, why? If not, why not?

I do not think that there should be universal access and delivery of CAM products and nostrums. This will tend to weaken what is one of the finest health-care systems in the world based on scientific testing. CAM could undermine the line between genuine and pseudoscience. Each claim to validity must be tested by impartial neutral observers not simply their advocates. If a therapy proves to be effective, then it becomes part of scientific medicine. It is vital, in our view, that this Commission represent not simply proponents of CAM, but scientists and physicians who are skeptical of its claims.

3) If current CAM utilization trends continue, what consumer protection should be implemented?

CAM seems to be growing. I think the public should be protected. The government has an obligation to act against spurious or fraudulent claims. The free market--in selling adulterated goods and questionable services--needs to be monitored. The misuse of taxpayers funds needs to be safeguarded. The great issue is the health and welfare of the American public. Government sponsorship of questionable CAM therapies would be a disservice to the public interest.

4) What policy recommendations do you have for the Commission?

I would strongly urge as a first step the repeal of the 1994 Dietary Supplement Health and Education Act, which freed herbal medicines and dietary supplements from regulation by the FDA. Prescription drugs are required to be tested. There are no such safeguards for dietary supplements. There are now some 20,000 such supplements--including herbal and homeopathic remedies--on the market. Many of the manufacturers make false and misleading claims. Many have dangerous side effects. Some may have positive results. In any case, the packages should be properly labeled--there should be "truth in labeling." Those deemed to have possible noxious side effects by misuse should require a prescription.

Second, similar regulations should be enacted against other false claims--such as quack cancer cures, crash diets, Chelaton therapy, iridology, therapeutic touch, and magnetic therapy. This is particularly the case where

patients avoid scientific medicine and substitute alternative therapies, believing that since they are offered by the health-delivery system, they must be effective. There needs to be peer review, as in scientific medicine, but not simply by the practitioners in a field, but by other objective and neutral scientific reviewers.

Paul Kurtz, Chairman, Committee for the Scientific Investigation of Claim of the Paranormal; Publisher, The Scientific Reveiw of Alternative Medicine.

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1

IN DEFENSE OF SCIENTIFIC MEDICINE

Paul Kurtz

I

THE PUBLIC IS BEING INUNDATED BY NEW AGE SPIRITUALISTIC THERAPIES. Pseudoscientific health cures are highly popular in the media and among book and magazine publishers—visit any bookstore today and compare the shelf space devoted to science books with New Age, Occult, or Paranormal books.

As skeptics, we have encouraged research by the scientific community into these paranormal claims and we have published criticism of them. One question that is often asked by the media and the general public is this: Why should anyone bother to criticize clairvoyance, astrology, phrenology, or numerology? What harm do these do? Aren't they fun? In the past we would immediately respond by referring to blatant quackery in the health area—from faith heating by evangelical hucksters to Edgar Cayce's diagnosis of disease and his alleged cures. The uncritical public acceptance of health fads and diets can be dangerous to the public's health, especially if people substitute these nostrums for competent medical treatment. When we began our skeptical agenda, little did we imagine that alternative or complementary medicine would grow as rapidly as it has, especially in the past decade.

The National Institute of Health established an Office of Alternative

From Wallace Sampson, M.D., and Lewis Vaughn, eds., *Science Meets Alternative Medicine: What the Evidence Says about Unconventional Treatments* (Amherst, N.Y.: Prometheus Books, 2000).

Medicine in 1992 is funded with federal dollars, and there are many new alternative-medicine journals. Many of its leading doctor-gurus, such as Deepak Chopra, Andrew Wed, Bernie Siegal, and Larry Dossey, have published best-selling books that dominate the public's perception of medicine. Moreover, as Marcia Angell and Jerome P. Kassiter, editors of the *New England Journal of Medicine*, point out (September 17, 1998) the multibillion-dollar "dietary-supplement industry" is now exempt from Federal Food and Drug Administration (FDA) regulation; and the public isinundated with advertising claims. The Dietary-Supplement Health and Education Act, which was enacted in 1994, allows herbal remedies to be sold without requiring the manufacturer to prove their effectiveness and safety to the FDA. According to a recent story in the *New York Times* (February 1999), a federal judge ordered the FDA to lift its ban on cholestin, a powder made from a Chinese rice fermented with red yeast. The Agency had banned the import of this unapproved drug, which had been marketed as a dietary supplement. The powder contains a natural form of lovastatin, which is a key ingredient in Mevacor, a cholesterolreducing prescription drug.

Alternative medicine is growing also because many health-maintenance organizations and insurance companies now cover alternative medicine treatments. According to the *Wall Street Journal* (February 18, 1999), practitioners of the ancient art of healing known as Reiki won't need a license to practice their craft. The New York Massage Board voted to allow them to go unlicensed. Reiki masters allegedly heal with "spiritual energy" that flows through their hands without touching their patients. Ellen Kahne of New York City, according to the journal, claims that she was able to stop her cousin's asthma attack, even though hundreds of miles away! In response to the growth of public interest in alternative medicine, many medical schools are now teaching courses in it. We thus are suddenly faced with the extraordinary growth of alternative therapies, often in competition with scientific medicine.

With this problem in mind, many of us associated with the skeptics movement decided to organize a systematic response to alternative medicine. Thus we created in late 1997 an informal *ad hoc* "Council for Scientific Medicine," and we launched a new peer-reviewed journal, the *Scientific Review of Alternative Medicine*. In my view, the American Med-

ical Association should have organized such a group, but ever since the chiropractic profession successfully sued the AMA, that association has been reluctant to get into the fray. They are at times more concerned with their professional prerogatives than their social responsibilities. Because they have not entered into the fray, we have taken the initiative in organizing this effort.

The goal of the Council for Scientific Medicine is to defend the integrity and the importance of scientific medicine. Health has always been of primary concern to human beings—fearful of disease, pain, suffering, and death, they seek relief. Medical cures were based historically on folk medicine, cultural traditions, and religious superstitions. These remedies no doubt had some basis in experience, but cures were not grounded on rigorously tested knowledge and were often unreliable. A good illustration of a folk cure is as follows:

> My oldest brother had a toothache, and a man told us: You know them places that be on the inside of a mule's leg looks like it been sore or something. He told us to get a pocket knife and trim some of that off and put it in a pipe and let my brother smoke it. And we did that, and it stopped it.[1]

Everyone knows that grandmother's chicken soup is an excellent remedy for a cold, and that it will relieve symptoms in one week. Of course, without grandma's chicken soup it would take seven days. Folk medicine historically consisted basically of the use of vegetable products or herbs, or various forms of diet and exercise, some of these are no doubt effective, many of them based on the placebo effect. China and India and other Asian countries have a long history of traditional medicine. CSICOP had exchanged delegations with China, and we have visited institutes for Traditional Chinese Medicine in Beijing and Shanghai. One illustration of Chinese folk cures dramatically points to the problem. While in Beijing, James Alcock, a member of our first skeptics delegation to China in 1988, developed a bad cough and he went to a Chinese clinic, which offered to provide him with snake bile. The question we asked was, "Does it work or not?" Of course, the only way to tell is by rigorous testing. Alcock decided not to take it and managed to get some antibiotics.

II

In any case, scientific medicine is a relatively recent development in human history, especially in the nineteenth century, when increased knowledge of physiology and human anatomy was refined. There have been a number of brilliant researchers who have contributed to our understanding, such as Claude Bernard, the French scientist, who used experimental methods to clarify the role of the pancreas and of glycogen in the liver. There have been great breakthroughs in microbiology and bacteriology with the introduction of germ and bacteria theories by Louis Pasteur, Robert Koch, and others. The discovery of the importance of antiseptics was demonstrated by Joseph Lister. Theories about the nature and transmission of infectious disease, such as diphtheria, tuberculosis, yellow fever, malaria, typhoid, tetanus, polio, and the development of vaccines all had important roles in immunization. Likewise important were the great advances in epidemiology, public health, and sanitation. In the twentieth century endocrinology advanced—with the discovery of insulin, cortisone, and sex hormones. In the field of nutrition researchers discovered the important role of vitamins. There have been significant new diagnostic tools, such as X-ray imagery, CT scans, and mammography and sonograms. The great strides in surgery have been impressive, including cardiology, neurosurgery, and organ transplantation. The discovery of antibiotics has made enormous contributions to the cure of infectious disease. We should add to this the discoveries of DNA, biogenetic research, gene therapy, and other innovations on the frontiers of research. All of these achievements have led to the reduction of infant mortality and the extension of life spans—over three decades have been added to longevity rates in the twentieth century in affluent countries. As part of this process was the development, beginning in 1904, of rigorous standards of medical education in medical schools. Thus we see the remarkable effectiveness of modern scientific medicine—all for the benefit of humankind.

The question can be raised: How does scientific medicine relate to alternative medicine? Our response is that we should apply the same rigorous peer-review process to the claims of alternative medical proponents. What does this entail? First, that practitioners of alternative medi-

cine have a coherent, clearly defined explanatory theory that is internally consistent and falsifiable. We are concerned that acupuncture, chiropractic, chigong, and therapeutic touch, for example, lack such identifiable theories. Second, at the very least therapeutic practices and medications need to be rigorously tested. Here we are not talking about anecdotal information, hearsay, or self-proclaimed validations by their practitioners, but independent corroboration, double-blind, randomized, controlled clinical tests. We need statistical evidence of the reliability of such cures before we can accept them.

There is an ongoing battle between the advocates of scientific medicine and their critics. Many New Age alternative healers deny that science is applicable. They denigrate the medical establishment. They believe that skeptics dogmatically reject unconventional therapies. They think that there are hidden untapped powers of ancient natural remedies and therapies that need to be released.

Skeptics should not seek to defend the medical profession per se. Medical doctors are practical craftsmen, drawing on intuition and their own experience, and some perhaps are not sufficiently familiar with the methods of scientific research. The so-called medical establishment has in the past opposed novel theories and important pioneers, such as Pasteur and Simmelweis, who had to battle against received doctrines.

The medical profession has suffered two waves of criticism in the last thirty years. First, in the late 1960s and early 1970s the field of medical ethics developed. This sought to dethrone authoritarian doctors and to defend the rights of patients. The euthanasia movement is a dramatic illustration of this development; so is the demand for informed choice and the right of patients to resist treatment. After some controversy, medical ethics was accepted by those within the medical community, who, along with philosophers, ethicists, theologians, lawyers and the lay public, have developed new ethical guidelines for treatment. Second, alternative medicine now challenges the medical profession. It seems to me that the only adequate response is to be open to new claims of therapy, provided they are responsibly framed and testable. Thus we need to evaluate such claims and to seek to have them corroborated. We hope this will contribute, in a modest way, to the advancement of medical knowledge—and it should apply to orthodox as well as to alternative medicine.

III

The paradox that we face today is that this assault on scientific medicine is occurring in spite of the extraordinary advances that are being achieved. Why is this so? There are various explanations that I can only briefly suggest.

First, the traditional family doctor is being replaced by HMOs, clinics, and by teams of specialists. Many of these have lost the intimate personal relationship that medical practitioners of the past have had.

Second, hopeless patients in the terminal stages of cancer or other debilitating diseases often give up on orthodox scientific medicine and seek alternative cures. They are desperate to seek some help.

Third, many people swear by alternative medicine because they believe it is effective. This, I think, can be attributed to many factors: Many illnesses of the body, if left alone, will in time heat themselves. There are vague pains and maladies that are undiagnosed and which may in time also dissipate. The placebo effect can be powerful in regard to psychosomatic if not organic illnesses. Medical science is not infallible. There are many diseases we do not understand, nor are cures available. Moreover, the state of the art is constantly changing, and earlier methods subsequently may have to be abandoned or revised. Many patients do not understand the tentative fallible character of the process of scientific inquiry. We need to edify them and especially focus on preventative medicine.

Fourth, alternative medicine has become a highly profitable industry. Food additives, dietary supplements, herbs, and vitamins are being marketed to the public, often with few if any qualifications about their effectiveness. The media-oriented companies that dominate our society often focus on sensationalized reports of miracle therapies, and there has not been a national effort to provide adequate balanced information to the public.

Fifth, the growth of alternative medicine is related to other antiscientific attitudes in society. It is allied with a vague kind of regnant spirituality, especially in the writings of Deepak Chopra and Andrew Weil; and this has an affinity with New Age paradigms. It is also reinformed by postmodern attacks on objectivity in science. If knowledge is ultimately

validated subjectively, or by its relationship to a culture, then anecdotal reports and folk medicine would be admissible forms of "validation."

Skepticism has its work cut out for it. For human health is too precious to be squandered by premodern nostrums or postmodern fantasies. We need to submit the claims of health cures to careful evaluation. We need an open mind and should not prejudge the issue before inquiry. We also need to stimulate an appreciation in the public about the nature of scientific medicine and the need for caution about untested remedies.

NOTE

1. Quoted by Frank Reuter in "Folk Remedies and Human Belief-Systems: How Body and Mind Work Together to Make Folk Remedies Seem Successful," *Skeptical Inquirer* 11, no. 1 (fall 1986): 44.

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White House Commission on Complementary and Alternative Medicine Policy

December 4th and 5th, 2000

Hubert Humphrey Building

Room 800

200 Independence Ave. SW

Washington, DC

Session IV: Issues in Integrating CAM into Service Delivery

4:00 - 6:00 p.m. on Monday, December 4.

D.E. Kendall, O.M.D., Ph.D.

The National Guild of Acupuncture and Oriental Medicine (NGAOM) is grateful for the opportunity to share some of our views with the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) concerning issues on integrating complementary and alternative medicine (CAM) into service delivery. The NGAOM is a professional guild for practitioners of acupuncture and Oriental medicine organized under the auspices of the Office and Professional Employees International Union (OPEIU) of the AFL-CIO. Our goal is to provide a national focus that promotes health and well being through the utilization of acupuncture and Oriental medicine, and to advance, protect, and preserve the profession. To this end, the NGAOM recognizes the real-world physiological basis of acupuncture and Oriental medicine and promotes advancing the training of acupuncturists and Oriental medical physicians through education and advocacy. The NGAOM also champions evidenced-based modalities in order to obtain the highest possible clinical outcomes. Answers to the five questions received on integrating CAM into service delivery are provided following some introductory information on the NGAOM definition of Oriental medicine and its physiological basis, and a current status on acupuncture and Oriental medicine in the United States.

Definition: Oriental Medicine

Oriental Medicine is a physiologically based primary health care approach that historically (3000 or more years) has been a major part of world medicine. It utilizes a comprehensive medical model that is internally consistent with specific strategies for dealing with a wide extent of illnesses and health dysfunction. Tools utilized by an Oriental medical practitioner include a diverse range of clinical modalities. Most common are: herbal medicine; nutrition; heating therapy, including radiant heat and heat packs, some with and without herbs, and a technique of burning hairy fibers of common mugwort leaves know as moxibustion; manipulation, adjustment and articulation of body joints; specialized manual pressure and massage methods; other physical means, such as cupping and scraping; lifestyle counseling; exercise therapy and rehabilitation; movement and breathing exercises; preventative care; and a sophisticated needling therapy called "acupuncture" in the West. Acupuncture is used to treat ailments and conditions by stimulating certain critical locations on the human body in order to control and regulate the circulation of blood and vital substances, autonomic systems, and endogenous mechanisms, to restore physiological balance. This includes restoring somatic, visceral, immune function, and homeostasis, as well as promoting pain relief and tissue healing. The practice of acupuncture includes techniques of piercing the skin by inserting sterilized needles, and point stimulation by

use of pressure, electrical, mechanical, and thermal methods, to bring about desired therapeutic effects.

Promoting a Common Physiological Base

One critical goal of the NGAOM is to promote the best understanding of Oriental/Chinese physiology in order to establish a baseline for clinical practice and rational research, and to also provide a starting point from which more study can be continued. There can be a diversity in how clinical methods are applied, with different means applied to treat one disease, or a single treatment approach may be applied to treat different disorders. However, everyone has to have the same understanding of human physiology. Important to this task is to explain the Oriental/Chinese information using universally accepted anatomical and physiological terms. Fortunately, research in acupuncture and neurophysiology over the past two decades is providing sufficient insight to explain the Chinese theories in rational terms. This includes explaining how the logical insertion of fine needles can bring about medically useful restorative reactions in the human body to treat the ailments of humankind. (1, 2)

One of the most fundamental problems facing Oriental medicine and acupuncture concerns the Western confusion on what constitutes the physiological basis of this medical system. The ancient Chinese texts, especially the *Yellow Emperor's Internal Classic (Huangdi Neijing)* (600-300BC), provides details on postmortem and physiological studies. The Chinese discovered blood circulation some 2600 years before William Harvey's experiments in 1628. Ancient Chinese physicians: identified and named all the major blood vessels, correctly noting which were veins and arteries; provided the first rudimentary description of the body's defensive system and lymphatics; identified and correctly noted the function of the internal organs, including the critical function of the lungs in breathing in vital air needed to support metabolic processes, and provided weight and size measurements of the organs. Additionally they identified all the muscles in the body, including skeletal origins and insertions of the muscles; and, identified the brain, spinal cord, and critical neurovascular connections in the body, including to the optic nerves and to the heart. Although the ancient Chinese described features that are descriptions of brain and neural function, including propagated sensations provoked by needling, and sensory functions, they never described the peripheral nerves in any detail. (1)

Blood circulation of nutrients, defensive substances, other vital substances, and vital air now known to contain oxygen, to all superficial and internal regions of the body by the vascular system is considered one of the more critical features in health and disease. This idea is also true in Western medicine, but its importance has faded over the years. In supplying the superficial regions, major distribution (jing) vessels (mai) form collateral (luo) vessels (mai), which further branch into arterioles, capillaries, and venules (sun mai). These then connect to venous collaterals and finally distribution veins returning blood to the heart. At certain locations on the superficial body, collateral vessels supply critical neurovascular junctures now referred to as "acupoints" in the West. These critical junctures or acupoints are prime locations used in the practice of acupuncture. This physiologically rational concept suffered a tragic misfortune during the 1930s - 1950s when the blood vascular system described by the Chinese in terms of "jingluo" was mistranslated by the West as "meridians." Even the word "mai" which clearly means vessel, was translated as meridian. This resulted in the vascular system to be replaced by imaginary or invisible pathways. The problem was further complicated by mistranslating vital air (qi) as "energy" for lack of a better word. Nutrients, defensive substances, and other vital substances were also categorized as energy as well. The net result was a Western view of Oriental medicine that involves incomprehensible and physiological incorrect ideas. The idea of energy-meridians casts Oriental medicine in a metaphysical light and has been responsible for years of misdirected

research and education. It has also been responsible for much criticism of Oriental medicine with practitioners being accused of practicing metaphysical rituals (3) or participating in a religion (4). Some medical practitioners are so frustrated with the state-of-affairs they are reinventing acupuncture as medical acupuncture (5, 6).

The physiology of Oriental medicine is essentially the same as that of Western medicine except for some subtle differences in how it is viewed. This is especially true with respect to concepts of vitality (shen), how the body systems dynamically interact, and in how external and internal factors cause disease. Perhaps most important to the Oriental view is the highly integrated nature of the body involving neurovascular systems, the internal organs, and the external body which includes the musculoskeletal system. These major systems of the body give rise to viscerosomatic (internal organ to body), somatovisceral (body to internal organ), and somatosomato (body to body) relationships important in health, disease, and clinical practice. These relationships postulated by the ancient Chinese are essential to the application of needling therapy.

Current Status of Acupuncture and Oriental Medicine

Presently some 39 states and the District of Columbia recognize the practice of acupuncture and Oriental medicine by way licensure, certification, or registration. Twenty-three states allow practitioners to treat patients without a prior referral from another primary health care provider, i.e. MDs, chiropractors, or osteopaths. Two states require written authorization, two states require the practice of acupuncture to be supervised, and five states require a prior diagnoses. Eight states have licensing laws pending. Two states allow practice through a ruling by the Medical Board of Examiners. Thirteen states have independent boards, and in 16 states, acupuncture is regulated by a medical board of examiners, 10 of which have an advisory committee of licensed acupuncturists. In the remaining states acupuncturist are regulated by the department commerce, regulatory agencies, professional regulation or occupational licensing, or by a board such as the Board of Regents or the Board of Chiropractic. Three states require passage of their own state boards while the remainder of the states require passage of an exam given by the National Certification Commission for Acupuncture and Oriental Medicine. (7, 8)

The current range of practitioner responsibility includes supervised practice, treatment only after a medical doctor or chiropractic referral and prior diagnoses, and practitioners that are considered primary health care providers with the expectation to provide service that includes necessary referral for immediate Western medical care. These levels of responsibility are reflected in different educational requirements from state to state. The requirements are as low as 1000 hours to 2400 hours. Most school training programs meet this requirement with a three to four year master's degree ranging from 2175 hours to as high has 3300 hours. The primary health care practitioner level of responsibility clearly requires a higher level of education and ongoing training.

1.Should CAM be integrated with conventional medicine and why or why not?

With respect to CAM, the NGAOM feels strongly that Oriental medicine, including acupuncture, should be integrated into conventional care to improve clinical outcomes and improve the efficiency of service delivery. There is little question to the efficacy of the high technology emergency and heroic medical procedures responsible for saving many lives every year. However, many diseases, including the general malaise as result of our high stress society, dysfunction, pain problems, and obsessive behavior problems, affecting the bulk of the population, for what ever reason, do not always respond to convention care treatments. There is no single medical system that can cure all the people all the time. Hence, it is incumbent upon society to provide the best of all possible treatment schemes to better serve the public. Conventional care is a major part of world medicine but other systems, such as Oriental medicine, including acupuncture is also part of world medicine and has much to offer that would complement conventional care. When one medical system, with a very well focused theoretical approach, is allowed to dominate there is a risk that new ideas are shut out. This is especially true when different ideas are offered from foreign sources. By having a closed view on what constitutes medicine, there is a risk of getting out of touch with the patient population concerns for safety and efficacy, resulting in less than desired clinical outcomes. For example, the physiological model of Oriental medicine has some unique views in how the body works in health and disease, and provides new insight in treating disease and dysfunction. These ideas are consistent with Western physiology but have yet to be considered important to conventional care.

All practitioners of Oriental medicine and acupuncture can testify that most of their patients have been to many conventional care physicians before trying Oriental medicine. Conditions of these patients cover a full range of human disorders and pain problems. If Oriental medicine, including acupuncture was integrated into conventional care, a different opinion could be sought when a case was not responding without causing the patient to seek an independent Oriental medical provider. Consider the following case: a 55 year old male was dressing one morning after waking and while bending down to tie his shoes while seated on his bed, his whole body went into terrible spasms affecting his entire body. Fortunately, his neighbor heard him fall on the floor and called an ambulance. The man was taken to the nearest hospital where he was given pain medication, antispasm medication, was x-rayed, and examined by other diagnostic imaging techniques. After one week with no improvement the man was asked to leave the hospital because they needed the bed for someone that had a more serious condition. The man needed to call an ambulance to take his home since he was not able to walk and was still in incredible pain. On the way home in the ambulance the driver suggested that the man consider getting acupuncture and drove the man to a near by acupuncture clinic. The patient was wheeled into the clinic and after a 35 minute treatment he was able to stand up and walk out of the clinic on his own. After two more treatments the man's condition was totally resolved. Consider the poor utilization of hospital resources over a week period with no results. Had there been an Oriental medical provider or acupuncturists on the staff, it is possible this case could have been quickly resolved.

Potential cost savings along with improved outcomes is another reason for integrating Oriental medicine, including acupuncture, into conventional care. There are many studies that indicate that acupuncture can be utilized to reduce health care costs and improve treatment outcomes. A study of 29 patients with severe or osteoarthritis of the knee were randomized to receive the course of acupuncture treatments or to be placed on a waiting list to receive acupuncture treatments starting nine weeks later. Of the 29 patients, 7 were able to cancel the schedule surgeries. The cost savings were $9000 per patient (9). In another study, half of 78 stroke patients receiving standard rehabilitative care were randomly chosen to receive adjunct of acupuncture treatment. Patients given acupuncture recovered faster and improved to a greater extent, spending 88 days per patient in the hospital and nursing homes compared to 161 days per

patient for the standard care alone. Cost savings were estimated at $26,000 per patient (10). Fifty-six patients in a study at a worker's compensation clinic were randomized to receive either physical therapy, occupational therapy, exercise or the standard care plus acupuncture. Of the 29 treated with acupuncture, 18 returned to their original or equivalent jobs and 10 returned to lighter employment. Of the 27 patients who received only standard therapy, 4 returned to their original or equivalent jobs and 14 returned to lighter employment (11).

Utilization of Oriental medicine and acupuncture as safe modalities in the treatment of the elderly may have potential benefit. Some studies have noted that as much as 80 percent of older patients in care homes are not provided adequate pain management. Acupuncture and other Oriental medical procedures can be beneficial in increasing range of motion, address incontinence problems, and provide pain management strategies. Oriental medicine has a long history of applying techniques and approaches to assist with the problems of aging. This also represents an additional area in which outcome studies and further research is necessary. In one study sponsored by the National Institute on Aging and published in the May 3, 1995 issue of the *Journal of American Medical Association,* conventional exercise forms such as resistance flexibility training, walking, and platform balance were compared to the Chinese movement therapy known as "taijiquan." The taijiquan practitioners recorded a 25 percent decrease in injuries from falls.

2. What are the keys to successful integration of CAM with conventional medicine; how can they be translated into policy recommendations?

Better real-world education standards represent an important key to the integration of CAM with conventional care. These are discussed with respect to Oriental medicine and acupuncture under responses to question #4 below. More important, however, is to overcome the cultural biases and fear of economic consequences on the part of Western medical practitioners if Oriental medicine and acupuncture, practiced by professionals other than medical doctors, are integrated into conventional care. These pressures have contributed to or reduced the desire on the part of conventional medicine to communicate with their Oriental medical counterparts, even when these two groups may be treating the same patient. Conventional care is covered by Medicare and other Federally funded programs. These programs currently pay for medical doctors providing variant forms of acupuncture (needling therapy) such as neural therapy involving the injection of anesthetics into certain points of the body, trigger point therapy using either injections of anesthetics or dry needling, and other needling approaches described by terms other than "acupuncture." To cover professionally trained practitioners of Oriental medicine and acupuncture in the Federally funded programs is not an economic risk to conventional care providers. These unwarranted fears must be overcome in favor of improving clinical outcomes to better serve the general public.

Formal WHCCAMP policy recognition of Oriental medicine, including acupuncture, as a complete independent medical model that can work within the Western health-care system for the improved outcomes and cost-effective benefit of the health-care consumer would help reduce barriers to integration into conventional care. This recognition could be an important key to provide better education of other health-care practitioners in the area of utilization of acupuncture and Oriental medicine. It would also help improve inter-professional communication between Western practitioners, such as MD's DO's, RNs, and Oriental medical practitioners. This can lead to improved coordination of benefits and possibly reduce conflicting treatment or insufficient treatment, to better serve the patient's needs. Additionally, the nature of training for Oriental medical practitioners typically takes place outside of most Western medical settings.

This leaves the Oriental medical practitioner with little or no experience interacting with Western medical practitioners or being familiar with Western medical protocols, styles of communication, or culture. This adds a potential psychological barrier for the Oriental medical practitioner to initiate communication with Western medical practitioners. WHCCAMP recognition of Oriental medicine and acupuncture would also stimulate changes in training approaches to help improve inter-professional communication skills. WHCCAMP recognition would stimulate improved public education with regard to when and how to utilize acupuncture and Oriental medicine.

3. What other policy recommendations would you like to make to the Commission?

Other key areas where WHCCAMP policy could help the future integration of acupuncture and Oriental medicine into conventional care concerns areas controlled by the Federal government. This involves the possible future employment of Oriental medical and acupuncture practitioners at the National Institutes of Health (NIH), Veterans Administration (VA), and the Armed Forces. Another problem involves using conventional care to dictate the government's position on acupuncture and Oriental medicine. The WHCCAMP must recognize that acupuncture and Oriental medical theories have to be provided by Oriental medical and acupuncture experts. WHCCAMP policy should dictate that the NIH must have or utilize properly qualified Oriental medicine and acupuncture specialists to establishing government positions on this medical specialty.

Currently, all medical research, including that involving acupuncture and Oriental medicine is dominated by Western medicine. To date, most practitioners of acupuncture and Oriental medicine have been shut out of the research efforts. Even when they are included and responsible for developing the treatment protocols and actually treating the patients, they are not included in the published results. The major universities with or without teaching hospitals receive most of the research funds. The moneys are jealously guarded and there is a strict hierarchy that dictates who gets their name on the paper even though they might not have participated in the actual study. WHCCAMP policy should recommend an increase in research funding to conduct studies either done exclusively by specialists in Oriental medicine and acupuncture, or utilizes a team approach involving both Western and Oriental medical specialists. The critical importance of including qualified Oriental medical practitioners in designing research studies recently came to light where lack of an Oriental medical specialists led to a research mishap in Belgium where inclusion of a toxic herb caused kidney damage in many research subjects. Research is directed to clinical efficacy with emphasis on clinical outcomes, cost-effectiveness, and general theory of the Oriental medical model to help establish standards of care, a better understanding of optimal utilization, and possibly new therapies based upon the combined understanding of Western and Oriental medicine.

An integral part of the practice of Oriental medicine includes the use of Chinese herbs. The training and knowledge base of Oriental medicine in the area of herbal medicine is extensive, spanning thousands of years of development and, as such, represents the pre-eminent understanding of utilization, cautions, and future research potential in the area of Oriental herbal medicine. It is essential that the WHCCAMP include Oriental medical practitioners in all policy-making decisions with regard to regulation, research, and utilization of Oriental herbal medicines.

Oriental medicine and acupuncture, for the most part is a highly effective low technology approach in treating the ailments of humankind. Very little equipment is needed to support Oriental medical treatments. This makes Oriental medicine and acupuncture an ideal medical specialty suitable for treating military personnel, as has historically been done in China over the

centuries. Hence, possible positions could be created for primary care Oriental medical specialist to serve in the armed forces. This could improve medical coverage for the military and reduce costs. Oriental medical specialists should also be able to treat patients in the VA hospitals to help reduce cost in those facilities as well.

4. Given the significant (often conflicting) philosophical diversity among the multiplicity of schools or forms of acupuncture, how has OPEIU/the Guild contributed to the improved access to and delivery of not only acupuncture in particular, but also oriental medicine in general?

Oriental medicine involves a wide range of treatment modalities and has promoted a rich diversity in treating similar disorders with different methods, or applying a particular treatment approach to treating different disorders. The main problem that has plagued Oriental medicine is the introduction of physiologically incorrect ideas, invisible or imaginary anatomical concepts such as meridians, and beliefs involving circulation of energy that violate the laws of physics. These bogus ideas are the result of popularizing very poor Western translations since the 1930s by one particular individual who had no training in either medicine, physiology, or anatomy. Other translations that occurred before and after this period, however, show the reality of the Chinese medical theories (1). For some reason, most of the acupuncture and Oriental medicine schools, doggedly hold on to these fundamentally incorrect energy-meridian ideas and continue to teach these basic errors. In addition, they insist on using Chinese terms (such as qi, yin, yang, xu, shi, etc.) to explain their theories without adequate explanation or understanding of the terms. The net result is the lack of a realistic physiological model for Oriental medicine with many people just making up their own interpretations. This practice has created the idea that Oriental medicine is a belief system or is metaphysical in nature.

The NGAOM has sought out participating members that have invested much time and scholarship into understanding the basic Chinese theories and explaining these in modern biomedical terms. This has involved investigation of the real world aspect of Chinese medical theories, including a comprehensive biomedical explanation on how acupuncture works. Setting the record straight on the true physiological basis of Chinese/Oriental medicine is a major goal of the NGAOM. Any medical system must have a defensible understanding and application of the accepted basis of human physiology. Incorporating these ideas into practitioner training will lead to improved access and delivery of Oriental medicine, including acupuncture. It is our position that the public is best served by practitioners trained in Oriental medical theory and application that is consistent with the real world of physiology, and to render service as a primary health care providers. Training hours would need to be increased and through the process of attrition, those practitioners that have lower hours of training would be permitted to serve throughout their professional life. Eventually, over time, all practitioners would be educated at the primary health care provider level and be able to efficiently work within the conventional care environment, render a diagnoses that is consistent with Western biomedical understanding, have the ability to utilize Oriental medical modalities, knowledgeable as to when Western treatment is either necessary or more effective for the patient's condition, and the ability to communicate effectively with all other medical professionals. It does not include, nor does it need to include, the practice of modalities unique to Western medicine. The ability to formulate a diagnosis consistent with Western biomedical understanding is essential for patient safety, improved communication within the health care system, and development of future research, to improve overall service delivery.

Contrary to this opinion, some schools are promoting technician level training where certification can be obtained in either acupuncture, herbs, or Oriental medicine. These would not

be primary health care providers. However, on the other hand there are some acupuncture and Oriental medicine schools that have made inroads to working within Western medical and hospital facilities in the training of students. This process is encouraged by the NGAOM to facilitate better communication between practitioners of Western and Eastern medicine and improve the quality of training of Oriental medical practitioners. The wide range of capability represented by the schools show a need for national licensing standards. Also, standards of care are beginning to be developed but are not firmly established. There are few board specialties offered by the Oriental medical and acupuncture profession. The National Board of Acupuncture Orthopedics is but one example of a board specialty modeled after medical specialties.

5. What policy recommendations does OPEIU/the Guild have for the Commission to improve access to and delivery of acupuncture and the spectrum of oriental medicine for the populations such as the under-insured, uninsured, poor, and medically under served?

The NGAOM recognizes the seriousness of problem in providing medical coverage for the medically under served. The crowded county hospitals in Los Angeles county alone demonstrates the magnitude and urgency of the problem. The cost in maintaining these county hospitals is staggering where patients exclusively receive high-cost Western medical care. This same situation is common in other parts of the country. For the most part these individuals have to wait several hours in the lobby area of the hospital before receiving attention. Most are suffering from problems that could be suitably treated by use of acupuncture and Oriental medicine. These hospitals and their associated teaching universities (UCLA and USC for Los Angeles county) are funded by county and state taxes, and perhaps Federal grants as well. A WHCCAMP policy should require these hospitals to integrate acupuncture and Oriental medicine care into their programs. Well experienced practitioners could be hired on staff and arrangements could also be made with local acupuncture and Oriental medical schools to allow supervised interns to treat the medically under served.

WHCCAMP policy should also encourage Western medical teaching hospitals to participate with local acupuncture and Oriental medical schools in allowing supervised interns to treat the medically under served in the teaching hospital. This would provide a low cost solution in treating the medically under served and would also allow acupuncture and Oriental medical interns to be exposed to terminology, diagnosis, and protocols used in conventional care. WHCCAMP policy should also encourage acupuncture and Oriental medical schools to also develop programs where the medically under served can be treated by supervised interns in their own school clinics. These patients would be charged a lower fee, or charged no fee depending on their economic status.

Many of the indigent and homeless people that fit into the category of the medically under served have current and former alcohol and drug addiction problems. Alcohol and drug addiction is a difficult and costly social problem typically involving a multiple Western treatment approach. Oriental medicine has several highly effective and low cost treatment protocols involving the use of acupuncture or electroacupuncture that have demonstrated the capability of playing a significant role in recovery. WHCCAMP policy should also support treatment-on-demand and the inclusion of acupuncture and Oriental medical treatment within drug treatment programs, especially where Federally funded program exist.

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Clinton Presidential Records
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Divider Title: Campbell

Testimony Before the
White House Commission on Complementary and Alternative Medicine Policy
Washington, D.C.
December 4, 2000 4:00 – 6:00 PM
By Candace Campbell, Executive Director
American Preventive Medical Association

Session IV. Issues in Integrating CAM into Service Delivery

1. Should CAM be integrated with conventional medicine and why or why not?

We believe that full integration would best serve patients. Rather than the "us versus them" mentality which seems to pervade health care today, we would prefer to see a health care environment in which all types of practitioners work together for the benefit of the patient. Each practitioner brings unique background, training, experience and tools to the diagnosis and the treatment of a patient. If practitioners cooperate with colleagues from other disciplines; recognize the strengths and attributes of different treatments, systems and modalities; and focus on doing what is best for the patient, we would all be better served. Patients would also not be afraid of sharing information with their primary physician, which would lessen the opportunity for drug/herb/supplement interactions and would decrease the likelihood that one treatment could undermine or nullify the effectiveness of others.

2. Why should there be access to and delivery of CAM products and practices?

I propose framing the question a different way. Why *shouldn't* there be access to and delivery of CAM products and practices? By what contorted logic can we withhold safe and effective treatment from American consumers? Why should Americans be forced to a) travel to foreign countries for treatment; b) break the law in order to use some treatments; c) be limited by their education, financial resources, and personal determination to identify and locate safe and effective treatments; or d) suffer or die needlessly because policymakers and those with vested interests in competing treatments work vigorously to limit patient choice? Let's not forget that medicine is a business, and the nature of business is to stifle competition. In the United States, we have laws prohibiting monopolies, for good reason; unfortunately, they do not seem to adequately protect health care consumers. Access to CAM products and practices should be encouraged, promoted and protected no less than access to long distance phone service or computer operating systems. The present monopoly by one school of medicine and the tyranny that system brings to bear over patient care has convinced Americans that money, turf and ego are paramount to patient care.

3. What is the role of CAM products and practices in self-care?

Americans are taking increasing responsibility for their health and health care. This shift became quietly evident decades ago when running became popular. Now, as the baby boomer generation hits its stride, we see growing numbers of people making an effort to stay healthy, remain active and get fit. They are driving an anti-aging industry that did not exist twenty years ago. Part of

this shift is also reflected in the fact that people no longer turn themselves over to their medical doctor, do exactly what the doctor says, or believe that the doctor has all the answers. Instead, consumers are doing their own research, trying alternatives, pressing for answers, and taking back responsibility for their own health. CAM products and practices, as well as nutrition, exercise and lifestyle changes play a significant role in preventing and treating disease, and improving quality of life. In a sense, all health care short of emergency surgery could be considered self care; in most instances, practitioners guide us to safe and effective paths to recovery and health. In a much smaller percentage of cases, when necessary, they perform services such as surgery which must be provided by highly-trained practitioners. The chronic illness that plague so many people do not require that degree of invasiveness, and the top killers of Americans all respond dramatically to lifestyle changes.

4. From your perspective, what are the barriers to access to and delivery of CAM products and practices and how have (or how should) they be overcome?

The barriers run the gamut from individual efforts to protect turf to systemic resistance to change. From my perspective as Executive Director of an association of health care practitioners and consumers, they include the following:

1) Pharmaceutical companies, because of the perceived competition from CAM
   Solution: prohibit discrimination against CAM practices and providers in federal insurance programs and federal health care programs
   Solution: prohibit the U.S. Food and Drug Administration from discriminating against CAM products
   Solution: mandate that the FDA establish a system more appropriate for reviewing data on CAM products and establish appropriate standards (not pharmaceutical drug standards) for CAM products. The present system works only for patentable substances.
2) The Federation of State Medical Boards, because its members profess to believe that increased access will open the door to quackery, exposing vulnerable patients to unnecessary risks and even life-threatening therapies, or failure to use conventional treatments.
   Solution: Education
   Solution: Increased research
   Solution: Prohibit racketeering-like behavior among FSMB members bent on eliminating competing CAM therapies and practitioners under the guise of consumer protection.
3) The perception that CAM presents an economic threat to the allopathic medical industry
   Solution: Encourage cooperation and integration so that all benefit, rather than compete for consumer health care dollars
   Solution: Education regarding the benefits of CAM, especially in conventional medical schools, so that graduates know how and when to incorporate CAM or refer to CAM practitioners
4) Reluctance of third-party payers, policy makers and mainstream providers to accept new ideas
   Solution: Time
   Solution: Education. When payers, policy makers and providers realize that they are losing money and/or wasting tax payer dollars by failing to change, they will hopefully be able to overcome their reluctance and accept new ideas. If all else fails, a negative impact on their bottom line will drive more payers and providers to integrate.

5) Reluctance of the mainstream medical community to relinquish control/authority

Solution: Patient education. Once consumers realize that they have options, and once they are willing to accept responsibility for their own health, they demand greater access to a wider range of therapies and practitioners. In essence, they know what they are missing.

Solution: Patient revolt. The refusal of patients to acknowledge or acquiesce to that control/authority forces practitioners to change or be left behind. As in other competitive markets, patients can and will "vote with their feet."

6) Insurance coverage of CAM therapies and systems is generally lacking, which is creating a two-tiered system of limited access

Solution: Federal insurance should include coverage of CAM products and therapies

Solution: HCFA should recognize and utilize insurance codes developed by the private sector for CAM services

Solution: Federal insurance programs should eliminate discrimination against CAM providers by including coverage for products and services that are covered if provided by conventional practitioners, but not covered now if provided by a CAM practitioner.

Solution: Federal programs should encourage true disease prevention, as opposed to early detection, and federal insurance programs should cover prevention.

7) Lack of access to credentialing for CAM providers and lack of coverage by payers creates artificial barriers to what should be a comprehensive, patient-focused health care system

Solution: Practitioner organizations presently representing non-licensed or non-credentialed practitioners should establish educational and testing standards for their members, then work to have these credentials recognized in all 50 states.

Solution: State and federal legislators should refrain from engaging in turf warfare when deciding which practitioner types to recognize and reimburse; i.e.: if the Federal Government decides that Medicare should cover nutritional counseling for diabetics, it should not restrict such counseling to Registered Dietitians.

8) Lack of understanding of CAM among policy makers

Solution: Education (conferences, white papers, personal meetings, visits to clinics, etc.)

9) Reluctance to change the status quo, especially when we are told frequently and convincingly that we have the best health care in the world; changes in that system are perceived as a negative commentary on the medical community.

Solution: Perseverance. No one changes unless they have to. Typically, people change to avoid pain, embarrassment or loss of money. As the public increasingly turns to CAM products and providers, the conventional medical community will have to respond or risk becoming anachronistic, embarrassed, and under utilized.

10) Perception that the conventional medical community will take over CAM and marginalize CAM practitioners and practices.

Solution: Avoid integration efforts that establish the medical doctor as gatekeeper, or that treat CAM practitioners as somehow "lesser than" their M.D. colleagues.

Solution: Educate medical students about CAM so that they know what the various practitioners and modalities have to offer, and know when to refer and to whom.

Solution: Build trust and non-discrimination into integrated systems, including insurance coverage, so that practitioners and CAM products are treated equally and with respect.

So-called integrated systems that persist in treating CAM as the poor step child are destined for failure.

5. What are the keys to successful integration of CAM with conventional medicine; how can they be translated into policy recommendations?

The key to successful integration begins with improving the research base and ensuring the training and credentialing of CAM providers. In addition, conventional providers must expand their education to include at least a minimum understanding of what CAM has to offer and when to refer patients and to whom. Conventional providers must also resist the impulse to be all things to all people; ie: they should leave the acupuncture to acupuncturists, and nutrition counseling to nutritionists unless they are prepared to undertake the requisite education. Insurance reimbursement must follow to expand patients' access to CAM products and providers. The decision-making authority must be returned to the patient, and the sanctity of the physician-patient relationship must be reasserted.

Most importantly, state and federal policy makers and regulatory bodies must cease any efforts to eliminate and prohibit access to CAM products and practitioners. State medical boards must be prevented from harassing and censuring conventional practitioners who incorporate CAM products and therapies. The U.S. Food and Drug Administration must be prohibited from preventing consumer and practitioner access to CAM products and information about those products. The U.S. Federal Trade Commission must be prohibited from preventing the dissemination of truthful information about CAM products and therapies.

6. What other policy recommendations would you like to make to the Commission?

We strongly recommend that the Commission support the concepts outlined in the Access to Medical Treatment Act (HR 2635/S 1995 in the 106th Congress). A copy will be provided with my written testimony.
This legislation would create a federal statutory right for Americans to use products not approved by the FDA, so long as they and their practitioner follow the consumer protection guidelines in the bill. This would dramatically increase patient access to a wide range of safe and effective products and therapies; keep Americans in the United States and allow them to see authorized practitioners without fear of recrimination or arrest; prevent the creation of a black market in unapproved drugs; prevent the growth of a two-tiered health care system; decriminalize the actions of dedicated physicians and patients; and remove the inappropriate and dangerous decision-making authority federal bureaucrats now wield over patients.

I would also like to request that Commissioners review the *National Plan to Advance Integrated Health Care*, which was prepared at the request of Senators Daschle and Harkin. A copy will be provided with my written testimony. In consultation with numerous CAM experts and policy makers, we have addressed many of the issues the Commission is investigating and have identified actions steps and priorities in each major area. We are also planning a national summit in the Fall of 2001 to develop a CAM community consensus around the areas outlined in

this document. We hope that Commissioners will be able to participate in this important meeting.

The American Preventive Medical Association is a nonprofit advocacy organization dedicated to achieving health care freedom for all Americans. We work at the federal level to increase consumers' access to alternative therapies; to information about their health care options; and to practitioners who provide a nutritional and holistic approach to health care and disease prevention. We also promote legislation and regulation that protects the rights of practitioners to offer safe, non-conventional therapies. Our membership includes medical doctors, osteopaths, chiropractors, naturopaths, nutritionists, acupuncturists, doctors of Oriental medicine, massage therapists, consumers and others in 47 states and four foreign countries.

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THE INTEGRATOR for the Business of Alternative Medicine

Shaping an Industry/Creating Health

Shaping Integration's Policy Context: *Two Reports Amidst the White House Commission*

In 1992, complementary and alternative medicine professionals from across the United States gathered in Virginia and created the *Chantilly Report*, a document that has helped shape the agenda for what was to become, in 1998, the National Institutes of Health National Center for Complementary and Alternative Medicine (NCCAM).

Today, the White House Commission for Complementary and Alternative Medicine Policy, is exploring broader complementary and alternative medicine (CAM) issues. (See July-August and September 2000.) On the table are questions of inclusiveness, fairness, standards, and definition—answers to which may undergird CAM integration activity in the decade to come. This issue of THE INTEGRATOR reviews two documents that identify new directions for the integration movement.

The *National Plan to Advance Integrated Health Care* was developed in the wake of the 1998 Congressional act that funded the Commission process as a multi-party collaborative effort at the request of U.S. Senator Minority Leader Thomas Daschle (D-SD).

Challenges and Collaborative Opportunities is a report on outcomes and recommendations of a recent meeting of a diverse group of 75 integrative medicine

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John Weeks

Crossing the Chasm

Individuals familiar with Geoffrey Moore's 1990 classic, *Crossing the Chasm*, will know that this book, about marketing high-tech products, has fruitful applications for those involved with the business of complementary and alternative medicine (CAM) integration.

The book presents a useful roadmap for integration's next steps—the focus of this issue. The perspectives on policy and collaboration, together with articles on CAM's controversial economic case, provide a good context for translating Moore's thesis into our environment. For those interested in substantive integration, Moore's argument represents a call to action.

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White House Commission Posts Tentative Schedule

The White House Commission on Complementary and Alternative Medicine Policy has announced its tentative schedule for meetings. The first regional Town Hall Meeting took place in September in San Francisco. At the regional meetings, the Commissioners will be soliciting testimony from individuals active in integration. Testimony can be in person or written. Contact information is:

- To register to present: 1.800.953.3298
- WHCCAMP Office Number: 301.435.7592
- On-line information: https://safe2.sba.com/whccamp/index.cfm;
- E-mail: whccamo@od.nih.gov
- Michele Chang, MPH, executive secretary: 301.435.6232.

Date	Site	Type of Meeting	Topic
Sept. 8, 2000	San Francisco, CA	TH	Region IX-West
Oct. 5-6, 2000	Washington, DC	WHC	Research, Part 1
Oct. 30-31, 2000	Seattle, WA	TH	Region X-NW
Dec. 4-5, 2000	Washington, DC	WHC	Access & Delivery, Part 1
Jan. 26, 2001	New York, NY	TH	Region II-North
Feb. 19-20, 2001	Washington, DC	WHC	Info Dissemination
Feb. 23, 2001	GA or FL	TH	Region IV-South
March 5-6, 2001	Washington, DC	WHC	Education/Training
March 12, 2001	Des Moines, IA	TH	Region VII-Midwest
March 16, 2001	TX or NM	TH	Region VI-SW
April 9-10, 2001	Washington, DC	WHC	Research, Part 2
May 14-15, 2001	Washington, DC	WHC	Access & Delivery, Part 2
July 5-6, 2001	Washington, DC	WHC	Review Draft Interim Report
Nov. 5-6, 2001	Washington, DC	WHC	Review Final Report
Dec. 6-7, 2001	Washington, DC	WHC	Final Full Meeting
March 2002	Washington, DC	WHC	Closing event

Key: WHC = Commission, TH = Town Hall

Two Reports

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industry leaders.

The findings, as well as information on how to see the full text of these documents, are offered to stimulate thinking and participation in both the emerging industry's collaborative directions and the White House Commission's policy processes. Steven Groft, PharmD, Commission executive director, recently affirmed that experience-based testimony of integration-active individuals who represent THE INTEGRATOR subscriber base is actively solicited. Details of the Commission's public hearing schedule are included above.

Report #1

NATIONAL PLAN TO ADVANCE INTEGRATED HEALTH CARE

Wayne Jonas, MD, past director of the NCCAM and member of the White House Commission calls the *National Plan to Advance Integrated Health Care* "the best written guidance we, as Commissioners, presently have in meeting our policy charge."

The detailed 20-page *National Plan* is viewed as an open, working document by its four authors: former Congressman Berkley Bedell (D-IA), Candace Campbell, executive director of the American Preventive Medical Association, Sheila Quinn, then executive director of the American Association of Naturopathic Physicians, and Pamela Snider, ND, public policy leader with Bastyr University. Table 1 outlines the document's structure.

While the Commission is constituted of roughly 50% newcomers to CAM, the co-authors of the *National Plan* each represent long-term involvement in the maturation and expansion of the CAM integration movement. Bedell, widely viewed as the godfather of U.S. Congressional activity on CAM, is joined by representatives of three organizations active in promoting CAM. APMA is comprised principally of medical doctors using CAM while the AANP and Bastyr each are involved with the distinctly licensed naturopath physicians. The document, influenced by a multi-disciplinary network of reviewers in a series of drafts during 1999, continues to be viewed as a work in progress by the authors.

Key Recommendation #1:
Promote Non-discrimination

Perhaps the most valuable focus of the document is on addressing historic inequities in current CAM activity between conventional academic medical centers and MD-based explorations and those of the distinctly licensed CAM professions. The core recommendation is bold: "Establish a non-discrimination policy affecting all funding at the federal level, requiring evenhanded treatment of all systems, disciplines, and modalities." Such a policy would have wide application.

Accredited CAM institutions would have greater access to funding for education, residencies, and research. To date, CAM schools operate largely without federal support. Even recent granting of funds from the NIH National Center ▶

for Complementary and Alternative Medicine has been almost exclusively to conventional academic centers. Licensed graduates of accredited programs in such fields as acupuncture, naturopathy, and chiropractic would be included in Medicare/Medicaid, public health, and loan repayment programs. Demonstration projects in integrative and co-managed care would be funded in the public health arena.

In fact, the plan recommends redressing the structural problems created by the lack of historic funding of CAM programs through investing in the rapid maturation of the distinctly licensed professions.

The Integrative MD as an Emerging Profession

The *National Plan* takes an "emerging professions" approach to evaluating and defining standards for CAM delivery. The internal standards established by the distinctly licensed professions are presented as guiding lights as the new profession of holistic and integrative medical doctor emerges. The document is blunt on present policy which, in most states, immediately grants medical doctors rights to practice a wide range of natural therapies regardless of their education: "Broad state practice acts for medial doctors are outdated in today's healthcare environment . . . High standards have been developed and sanctioned and are being used by public agencies for many CAM providers, but the standards are not applied to MDs and other conventionally trained providers."

At the same time, the authors promote efforts to stop "the unconstitutional, undemocratic behavior of (medical) licensing boards which continue to harass and censure practitioners for the use of CAM products and services."

Table 1: Foci of a Draft National Plan

Each section includes background information, identifies barriers, lists action steps, and recommends priorities.

- Research Issues and Goals
- Accountability and Education
- CAM Needs in Underserved and Special Needs Populations
- Regulation and Access to CAM products and Services
- Federal Benefits Discrimination against CAM
- Clinical Practice, Quality of Care and Delivery Systems.

Source: *National Plan to Advance Integrated Health Care*

Exploring Integrative Delivery

The *National Plan* recommends a practical agenda that explores broad outcomes on CAM inclusion. Sample recommendations include:

- Fund a General Accounting Office report on cost savings possible through incorporation of CAM products and services.
- Fund an Agency for Healthcare Research and Quality exploration of CAM practice guideline projects "involving the CAM professions."
- Support collaborative residency exchange programs and cross-disciplinary exchanges between the distinct CAM professions.
- Fund research in outcomes of practical explorations currently underway in payment and delivery.
- Empower gatherings to explore optimal models for incorporating CAM in public health, in co-management, and in integrative facilities.

While supporting expansion of research on individual natural agents, this draft National Plan repeatedly underscores a need for researching whole system outcomes of multi-factorial, whole person delivery models.

Key Recommendation #2:

High Level CAM Position in HHS

The draft *National Plan* is meant to encourage "deep thinking about the kinds of change we need if we are to create a context for optimal integration," the APMA's Campbell told The INTEGRATOR. Campbell, Snider, and others are considering the potential value in promoting a "National Policy Summit" through which a true consensus document might be created. States Campbell, "Honestly, if we feel that the Commission is responsive and will wrestle with changing this legacy of polarization and exclusion, the more we feel that the Commission may be doing the Summit's work. We like what we see so far and continue to watch closely."

On one overarching point the group is clear. Given the breadth of present and future federal agency involvement in CAM, the draft *National Plan* recommends that Congress establish an office at the assistant secretary level of the U.S. Health and Human Services and to expand, coordinate, and direct all federal activity.

The side-bar, page 5, tells how you can review the entire draft *Plan*.

Report #2

STRATEGIC DIRECTIONS FOR EMERGING INTEGRATIVE MEDICINE INDUSTRY

INTEGRATOR readers will know that a loosely defined "integrative medicine industry" is beginning to emerge in U.S. healthcare's evolution. The stakeholder parties are diverse—from employers to CAM professional organizations, academic medicine to CAM networks and venture capital interests.

But can these diverse interests legitimately be called an industry? If so, what are their common denominators? What are the recommendations of their leaders for their future?

Shaping the Future of U.S. Healthcare

To an increasing number of healthcare observers, the emerging industry of integrative care represents an important, shaping edge of U.S. healthcare's more retail-oriented, consumer-focused future. Yet little has been published about the emerging industry's stakeholders and their strategic direction in this consumer-oriented, integrative process.

Bridging this knowledge gap is a new report from IntegrativMedicine (OneMedicine.com) based on an interactive, invitation-only Summit held in May 2000. (See Table 2.) Seventy-five leaders of businesses representing integrative medicine's distinct stakeholders met to

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Lifestyle Advantage:
Ornish Group Links with Highmark for Rollout

The recent decision of Health Care Financing Administration to fund a demonstration project on the multi-factorial, mind-body program developed by **Dean Ornish, MD**, and promoted and managed through his Sausalito, California-based **Preventive Medicine Research Institute** (PMRI) begs significant questions: What if the results of the 1800 seniors show the Ornish program to be convincingly effective and cost-effective? While PMRI has more than a dozen institutional affiliates across the nation through which to create the population for the demonstration project (March 2000 INTEGRATOR), successful outcomes would push demand beyond PMRI's ability to deliver.

Into this breach stepped Pittsburgh-based **Highmark Blue Cross Blue Shield**. According to Highmark vice president **Anna Silberman**, the firm, which is the only insurer affiliate of PMRI, covers, delivers, and promotes the Ornish program in its service area. Highmark has found exceptional clinical success and a $16,000 cost savings per user (March 2000 INTEGRATOR).

Highmark's excitement with the program coupled with PMRI's needs, led the two firms to create a for-profit joint venture: **LifeStyle Advantage**. Silberman is the new firm's founding president. She told THE INTEGRATOR that LifeStyle Advantage's focus will be on supporting the national rollout by creating new delivery sites and payer partners. The new firm is presently in development and not yet officially announced.

Two Reports

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explore collaboration and define the projects that would optimize the business of integration. From that meeting, Summit convenor, **John Weeks**, publisher-editor of IntegrativMedicine's THE INTEGRATOR *for the Business of Alternative Medicine*, developed a seminal report on the state of the industry:
Challenges and Collaborative Opportunities: Strategic Leadership for Integrative Medicine Payment and Delivery. The Summit, from which the study was developed, included the following representation: hospitals/health systems (12); managed care/CAM networks (10); academic medical centers (9, 2 of them CAM schools); private integrative clinics (9); Internet e-health (9); national industry or professional association (8); information/content providers (5); employee benefits (3); public health (3); natural products (2); venture capital (2); and other/consultants (3). Sponsorship also reflected stakeholder diversity.

Ten Findings and 40 New Directions

The report documents exchanges as the Summit discussants and attendees explored the pros and cons of economic alignment with stakeholder partners. Solutions offered by participants demonstrate and publicize successful integration business models.

The report includes 10 findings that are coupled with recommendations offered by participants. (See table 3.) The goal at the Summit and in the report was to transform challenges and obstacles into solution-oriented projects. Roughly 40 projects are referred to as a "prescriptive roadmap" for efficiently enhancing the value of quality integrative care in U.S. payment and delivery. Sample projects include:

- Sponsor workshops involving CAM leaders and specific stakeholders—employers, health systems, managed care and public health—to collaboratively develop both optimal metrics and demonstration projects.
- Create white papers that concisely state the case, stakeholder by stakeholder, for embracing greater integration.
- Develop and manage an infrastructure for sharing between integrative clinics.
- Create a multi-stakeholder, national industry association as a vehicle for supporting integrative medicine initiatives in the national arena.

Survey Data Included

The report also includes full findings of two participant surveys. One is a 30-question pre-Summit survey developed to describe the character, mission, and beliefs of the emerging industry's leaders. The second, administered onsite at the end of the Summit, attempts to measure buy-in on six potential industry-wide initiatives. Two outcomes that topped the latter list are:

- Nearly unanimous desire to meet annually
- Interest in continuing to explore collaboration through Internet-based exploration between gatherings.

In response, IntegrativMedicine has created a specialized attendee only website set to launch in mid October and has set a date for Summit 2001. Details on purchasing the report, participating in the website, and potentially participating in Summit 2001 are presented in the sidebar on the next page (p 5).

Table 2: Integrative Medicine Summit Sponsors

Primary Sponsors
- THE INTEGRATOR *for the Business of Alternative Medicine*
- **IntegrativMedicine**

Supporting Sponsors
- American Hospital Association/Health Forum
- Inner Harmony Wellness Center
- Institute for Health and Productivity Management
- Triad Healthcare
- Health Business Partners
- Angela Mickelson (H, L & B)
- American Specialty Health
- Adams Harkness & Hill

Obtaining Reports and Participating in Industry Collaboration

IntegrativMedicine, publisher of THE INTEGRATOR, and primary sponsor of the *Integrative Medicine Industry Leadership Summit 2000*, has committed to a series of actions to stimulate additional collaboration between and among integrative medicine industry stakeholders. Jan Bruce, CEO of IntegrativMedicine, notes that in the Summit's spirit of collaboration, all the firm's income from the activities below will be used solely to underwrite Summit-related activity.

- *Challenges and Collaborative Opportunities: Strategic Leadership for Integrative Medicine Payment and Delivery* is available as a written report or to members of OneMedicine.com website. For additional information e-mail marcy.robinson@onemedicine. com.
- The Industry Leadership Summit attendee website at OneMedicine.com is a meeting place for ideas and exchanges that grew out of the Industry Leadership Summit. Members have ongoing access to interactive, state-of-the-industry discussions and resource identification as well as an electronic version of the report. The website will launch mid-October.
- *Summit 2001*, May 3-5, Scottsdale, Arizona. Attendance will be expanded from 75 to 110, with first choice for spots going to Summit 2000 participants. Those interested in participating should contact Marcy Robinson at marcy.robinson@onemedicine.com. INTEGRATOR publisher-editor Weeks will develop the Summit program.
- The draft *National Plan to Advance Integrated Health Care* will also be available to Summit attendees through IntegrativMedicine's Industry Leadership Summit attendee site at OneMedicine.com. The plan is also available by contacting the APMA (703) 759-0662) or Bastyr University (425-602-3143).

Table 3: Industry Leadership Summit Findings and Recommendations

Note: These findings, part of an *Executive Summary in the Challenges and Collaborative Opportunities* report, were not formal outcomes of the process but reflect themes that repeatedly surfaced during the course of the Integrative Medicine Industry Leadership Summit 2000.

	Findings	Recommendations
1	Consumers will continue to drive integration.	• Enhance the industry's ability to capitalize on, and expand, consumer demand.
2	Employers, next to consumers, are the industry's optimal stakeholder partners.	• Find CAM users in the employer community with whom to partner in demonstration projects. • Integrate CAM into wellness programs and disease management initiatives. • Consider onsite programs.
3	Success for the industry will require increased inclusion in mainstream payment and delivery.	• Foster creation of demonstration projects and data analysis to increase third-party payment and create shifts in physician referral patterns.
4	Present incentive structures in mainstream delivery cause significant resistance to integration.	• Health system budgeting is wise to assume slow adoption of integrative approaches by system physicians. • Good research without the trust of physicians in new approaches may be meaningless. Significant resources must target relationship development. • Increase provider comfort with CAM through experiential programs to "heal the healers." • Place CAM in health system benefits packages to promote personal use and understanding of CAM among the organization's providers and staff.
5	An employer move toward "defined contributions" would boost covered CAM services.	• Consider an industry-wide initiative in support of this shift as a means of enabling consumer choice.
6	Health services research will more rapidly create understanding of optimal integration than randomized controlled trials.	• Consider an industry-wide effort to create more federal or foundation support for the projects and questions identified by Summit participants.
7	Significant pools of useful data on the cost and utilization of CAM already exist.	• Identify and secure funding to support this research.
8	Demonstration projects present the optimal environment for measuring CAM's value	• Create partnerships between providers and interested stakeholders on limited projects with measures collaboratively defined with the stakeholder
9	Industry leaders view the ultimate success of their mission positively.	• Develop an infrastructure that will facilitate rapid sharing of best practices and successful models.
10	The integrative medicine movement's philosophic mission of health creation will only be successful if energized by a thriving industry of health creation.	• Create a visionary blueprint of optimal public policy, payment and delivery in an integrative medicine model. • Develop a national umbrella organization representing integrative medicine industry stakeholders, public health, and consumers, to be the voice and force for health creation.

Source: Weeks J. *Challenges and Collaborative Opportunities: Strategic Leadership for Integrative Medicine Payment and Delivery*. Newton, MA: IntegrativMedicine; 2000.

Two Studies Underscore Challenges Establishing CAM's Economic Value

Participants at the Integrative Medicine Industry Leadership Summit *and the authors of the draft* National Plan *spent a significant amount of time considering strategies for bridging the knowledge gap on the economics of complementary and alternative medicine (CAM). The two reports below, one a systematic review, another on conflicting reports to the U.S. Department of Defense about chiropractic, describe the potent context of scarcity and fervor over methodology and metrics that can emerge when analysis is undertaken.*

1.No Diving! Systematic Review Finds Shallow Pool of CAM Cost Studies

There is a kind of good news for CAM advocates in the recent *Economic analysis of complementary medicine: a systematic review*. The researchers, White and Ernst conclude, "There is a paucity of rigorous studies that could provide conclusive evidence of differences in costs and outcomes between other complementary therapies and orthodox medicine."

The good news comes from re-framing this finding:

A thorough review of English, French, and German language medical databases has found very little evidence to contradict assertions of CAM advocates that rapid integration of CAM services into mainstream payment and delivery will lead to significant cost savings.

Bottom line: Biases pro or con cost-offsets remain largely without an evidence base, according to this research team.

Just 35 Studies Found

The report, in Britain's *Complementary Therapies*, provides a foundational reference point for questions about CAM's cost-effectiveness. The searches "using the terms alternative medicine, cost benefit, cost effective or economic analysis" were performed on Medline (1969-1999), Embase (1985-1999), and AMED (through 1998). In addition, the researchers combined their own files and the "grey literature" of conference reports for less formal research. A total of just 35 studies met their criteria.

This report is an excellent backdrop for CAM clinicians and researchers. The authors begin with an overview of ▶

Cost Analysis of Demonstration Project Examining Integration of Chiropractors into DoD Facilities

Costs/Cost Offsets	Birch & Davis	Chiropractic Members/Muse & Associates	Comments
Estimated Costs			
One year, unconstrained open demand model	$70.9 million	$70.9 million	Both reports base economic assertions on this consumer-friendly model
Estimated Offsets			
Central range recovered days	-	$27.8 million	Both parties agreed on the number, a global, non medical measure of interest to employers. Yet M&A concluded that the DoD would have no way of realizing the cost savings so did not factor in these productivity savings.
Reductions in services	$6.7 million "hospital charges"	$18.0 million "total eliminated charges"	B&D represents a reduction in in-patient services only. M&A estimated additional cost savings including ER visits, and physician services, based on separate analysis of Medicare data.*
Saved charges from physical therapy substitution	$19 million	$50.1 million	M&A figures are based on extrapolations from Medicare data.*
Bottom Line	$45.2 million in annual net losses	$25.8 million in annual net savings	Differing assumptions produced an over $70 million differential between B&As predicted loss and M&A's savings

* M&A extrapolated from a study of Medicare patients which showed that individuals who use chiropractors tend to have lower utilization of conventional services across the board, even non-back conditions. The B&A study, on the other hand, limited offsets to savings associated with a diagnosis of lower back pain.

Source(s): Report on the Chiropractic Health Care Demonstration Program prepared by the Chiropractic Members in association with Muse & Associates. Final Report, form Birch & Associates. Contract No. DASW01-95-D-0026 Delivery Order 0116.

different types of cost studies: cost descriptions, cost-comparison, cost-effectiveness analysis, cost-utility analysis, and cost-benefit analysis. The writers also show sensitivity toward the types of information that may most appeal to different audiences: "It becomes important to decide whose perspective is being considered, whether that of the patients, the local health purchaser, or society as a whole." The researchers then walk through leading studies relative to CAM "as a treatment package," then individual modalities, including acupuncture, homeopathy and spinal manipulative therapy.

The top conclusion is simple and not surprising. "There is a need for high quality investigations of the costs and benefits of complementary medicine," the authors state. The question for integrative medicine activists is how to do something about the virtual silence in the literature. Until then, the collision between those assuming CAM is additive and those who assume significant cost-offsets cannot be arbitrated.

Source: White AR, Ernst E. Economic analysis of complementary medicine: a systematic review. *Complement Ther Med* 2000 Jun;8(2):111-118

2. Department of Defense: Experts Collide on Economics of Chiropractic

For individuals intrigued with the economics of CAM, examination of cost offsets, and modeling of cost comparison studies, the Department of Defense Chiropractic Health Care Demonstration Program has yielded two useful documents. One is the 100-page *Final Report* by the Birch & Davis Associates (B&D) consulting group. The other is a 50 plus-page minority report, prepared by the six chiropractic physician members of the Project's Oversight Advisory Committee in association with the Muse & Associates (M&A) consulting firm. This report was filed by the chiropractic members of the team after they felt that their input had not been appropriately included by Birch & Associates.

Contradictory outcomes underscore the complexity and politics of CAM cost analysis. Birch & Associates projects a $45 million annual loss from chiropractic inclusion, leading to a recommendation against the advisability of including chiropractic. The minority report, on the other hand, promotes advisability while concluding that the Department of Defense would realize $25 million in annual net savings. In fact, the authors suggest that if chiropractic utilization jumped from 10% to 20% of the military population, that savings would similarly increase. Table 1 describes areas of agreement and disagreement in the cost analysis of the demonstration project, which examined integration of chiropractors into DoD facilities.

Concurrent Findings: MD Perception and Patient Outcomes

While the two reports disagreed on the "advisability" of integrating chiropractic, both found integration feasible. Surveys of conventional providers found that respect of medical doctors for chiropractic services increased after integration. This report also affirmed chiropractic care's traditional strength versus conventional care: patient satisfaction and documented outcomes. Results on five measures were:

- 81% of DC patients and 55% of MD patients reported "excellent" in their satisfaction with their improvement after four weeks.
- 94% of DC patients and 77% of MD patients reported "excellent" in their satisfaction with the time their providers spent with them.
- Asked if they still felt restricted in their movement at four weeks, 49% of DC patients reported "not," 44.1% "somewhat," and 7.4% "very." For MD patients the findings were 32%, 50%, and 18%, respectively.
- Asked if they felt their problems limited their performance at four weeks, 73% of DC patients reported "no," 17% "somewhat," and 9.5% "yes." For MD patients the findings were 53%, 56%, and 21%, respectively.
- Asked if they agreed that they "had good results" after four weeks, 83% of DC patients reported "strongly agree," 13% "somewhat," and 5% "strongly disagree." For MD patients the findings were 50%, 25%, and 25%, respectively.

Following the dual reports, the policy decision on chiropractic inclusion moved from the realm of the technocrat back to the policy makers. The American Chiropractic Association and the Association of Chiropractic Colleges, armed with the minority report, are pushing a legislative solution in Congress.

Viewpoint

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Bell Curves and Manifest Destinies

Moore describes the bell curve of a new technology's acceptance. Out front are the "early adopters," the true believers.

In integration terms, these are the "CAM champions." Institutional involvement with a significant CAM venture requires a CAM-experienced leader to convince the organization to take a risk. Moore describes the early adopters as individuals for whom the new technology – in our case CAM – is not an end in itself but instead supports a broader mission. An example is Stephen Wiggins, then of Oxford Health Plans, pioneering a CAM benefit in 1997 in an effort to build a consumer-focused HMO. Another is Corrine Bayley, for whom CAM is an extension of an effort to shift her delivery system, St. Joseph Health System, toward more respect for spirituality and other non-biomedical factors in healthcare delivery.

The problem with the early adoption phase is that it's start-up and there isn't much money in it. Financial success requires movement into the next phase

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Viewpoint

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of the market. Moore draws the apparently smooth, upward line of the bell curve as new technology reaches toward the greener pastures of what he calls the "early majority." This rise, which looks on the graph to be as pristine and promising as a mountain road, is often felt as manifest destiny by CAM advocates. *We may be hurting in the present moment, with payers favoring the relatively empty promise of CAM discounts and integrative clinics struggling to find successful business models. But the future is ours!*

The Evidence Canyon

The smoothness of the bell curve's arc, however, is misleading, according to Moore. The point on the arc where early adoption swings upward may drop your front wheels, if not your whole vehicle, into Moore's chasm. Belief and mission and the best of impressionistic cases can't get you across and into the green. Why? Moore argues that purchasing decisions for the "early majority" on the other side of the chasm are made by managers not risk takers, by technocrats rather than visionaries. *Don't give me the pretty story of your consumer-powered vision. Show me the evidence. Show me the money.*

With hard evidence, the manager can champion the new technology. This is the health system executive who says, "*Yes, I know the consumer is using CAM. But you need to show me how to run an integrative clinic that makes money.*" The employer or managed care executive says, "*Sure, I'll go with a discount CAM product – no risk there — but you've got to show me cost-offsets before I'll cover alternative medicine.*"

As noted in this issue, just 35 quality studies on CAM economics were found by two leading British researchers in a recently published, wide-ranging search. Taken together, this motley mix of studies is more like a pile of discarded siding than a load of girders to erect a chasm-crossing bridge.

One Abutment Does Not Make a Bridge

An irony in integration activity is that, while accused of being "unscientific" by CAM detractors, most integration activists earnestly promote demonstration projects to develop the outcomes that will undergird substantial growth. Ever since a 1992 request for proposals from the NIH Office of Alternative Medicine drew more than 450 proposals for 30 exploratory grants of $30,000, CAM integrators have announced their desire for substantive analysis. Both of the reports reviewed in this INTEGRATOR are strewn with proposals for appropriate research and analysis. More than 90% of industry leaders said that, given just a $50,000 grant for a specific project, they could create useful, non-proprietary information for the integration business. The projects, the ideas, and the commitment represent a solid bridge abutment on one side of the chasm.

More than 90% of industry leaders said that, given just a $50,000 grant for a specific project, they could create useful, non-proprietary information for the integration business.

Meantime, most of the mainstream, purportedly "scientific" potential institutional partners that are the necessary abutment on the far side of the chasm continue to treat CAM as little more than a marketing ploy. One recent survey found an absolute zero of employer respondents exploring the critical question of whether CAM produces cost offsets. Ernst and White's literature review, described in this issue, found zero publications of managed care-based CAM economic offset research in United States.

The evidence suggests that, left to the "scientific" interests of the mainstream, the movement will not bridge across to the "early majority." And a majority of CAM industry leaders, when asked, believe their business success is linked to the substantive integration of shifted referral patterns and increased third-party coverage.

Engineering the Bridge: Policy Changes and Collaborative Action

How then will the chasm be crossed? The reports reviewed in this issue each provide clear guidance. A lack of commitment to experience analysis which characterizes activity of most mainstream partners, leads to simple conclusions. INTEGRATORS need to seek the exceptional CAM champions who will not only "early adopt" but also partner in incubating the data and business models. In addition, the federal government and philanthropy must each play major funding roles. Past issues of THE INTEGRATOR have documented the growing role of donated funds in start-up of health system-based integrative clinics.

One piece of this construction project may rest with you. Think about your own chasm-crossing evidence strategy. Take a look at the articles in this issue. Read the reports on which they are based. Then check out the schedule of meetings for the White House Commission and file your testimony, in person or through written submission.

The charge of the Commission may be read as bridge-engineering. Those active in practical, integrative medicine applications must make sure that bench researchers and individuals inexperienced in CAM don't control the bridge's design.

Your comments, as always, are welcome.

Business Developments

New Hampshire-Massachusetts-Washington
Highly regarded midwifery school opens East Coast branch
The Massachusetts Midwifery Alliance, an organization that supports the expansion of homebirth through well-trained, European-style direct entry midwives, has worked with the Seattle Midwifery School to establish an Eastern educational site. The new program links monthly three-day intensives at Springfield College, near Manchester, New Hampshire, with online education, plus the required practicum of hands-on training. Joanne Myers-Ciecko, MPH, executive director of the Seattle program, told The INTEGRATOR that the new program will also be offered at the Seattle site. Requirements for both observations and managements are higher for direct-entry midwives than for certified nurse midwives. In related news, the Midwifery Education and Accreditation Council, the accrediting organization for direct-entry midwifery education, will be up for approval by the U.S. Department of Education in December. For additional information, visit www.seattlemidwifery.org

Massachusetts
Community-wide CAM interests post clinic survey
Outcomes of a *Business Model Survey for Integrative/Complementary/Alternative Practices* are posted at www.alternativemedicinelaw.com. The survey, developed by attorney Michele Forzley, JD, and licensed psychologist Lynn Caesar, PhD, supported an unusual local association called the Integrated Medicine Network, a communication forum for diverse integrative medicine interests in the Boston/Cambridge area. The two authors provide an analysis of findings from the unnamed 12 facilities, many of which are sole-proprietor, non-affiliated operations. Roughly one-third report having broken even.

Massachusetts
Teachers, pharm school links to CAM clinic/network
The union-oriented marketing focus of Boston, Massachusetts-based Tapestry Group has secured a contract to deliver a discount access program for the Massachusetts Teachers Association. Tapestry (see Aug-September 1999 *Benchmarking* data) will manage the program for the 90,000 member organization, representing 200,000 covered lives, through its two clinics and a statewide network of CAM providers. Tapestry will be "wired into their website" according to Michael Shor, MPH, Tapestry's co-founder. The program is two-tiered with a premium card that gives members access to additional benefits. Tapestry is also presently a formal affiliate of the Massachusetts College of Pharmacy with which a Medication Reduction Program is under exploration. Co-directing that initiative are the pharmacy school's Lana Dvorkin, PharmD, and Tapestry clinical director Jerry Cantor, LAc. Tapestry's business model is unusual, particularly among clinics not directly owned by hospitals, in the push to bring a high percent of patients in through physician referrals. Presently 24% are physician referred. The model includes a medical doctor as medical director, but no MDs practice in the clinics. Visit www.tapestrycare.com for additional information.

New York
Upstate network chosen by major insurer
Lancaster, New York-based Prism Network, Inc., recently signed a contract to manage chiropractic care for the 700,000 members of Health Insurance Plan of New York. The management is direct access with a required pre-authorization. Prism's June-July newsletter, which announced the contract, also noted that the network's executives are involved in educating third-year medical students on chiropractic treatment at the University of Buffalo. In addition, researcher Paul Bluestein, DC, is leading a Prism team that is attempting to "establish standardized protocols for the treatment of specific diagnoses," which can be used as a tool to compare against individual provider practices. A sub-set of Prism providers is being used to develop the protocol strategy before rolling out the measuring project more broadly. Bluestein chairs the network's quality assurance committee. For additional information, call 716.681.1112.

New York
Fee schedule from an integrative cancer service
A useful, 45-page feature on medical massage for cancer in *Massage Therapy Journal*, Fall 2000, includes a profile of work as a massage therapist in the pro-

continued on next page

Table: Sample Fees Schedule—Memorial Sloan Kettering Integrative Services

Stakeholder	Fee
Inpatient	
Massage (45 min.)	$45
Reflexology	$45
Acupuncture, initial visit	$130
Acupuncture, follow-up	$110
Chemotherapy Suites	
Massage (60 min.)	$45
Massage, 10 sessions	$400
Relaxation	$45
Integrative Medicine Services	
Massage (60 min.)	$90
Relaxation	$80
Nutrition	$90
Music/Art therapy (individual)	$80
Music/Art therapy (group)	$15
Acupuncture	$130
Package (10 visits massage, relax, music, art)	$720
Chanting and toning, 10 classes	$120

Source: Memorial Sloan Kettering. *Massage Therapy Journal*. Fall 2000 (American Massage Therapy Association).

gram at Memorial Sloan Kettering Cancer Center. The services are offered in three locales: inpatient, chemotherapy suites and at a stand alone facility. The AMTA feature is available as a single issue price of $6.50. For additional information, call 800.525.2225.

Pennsylvania-New Jersey-Delaware
HMO affiliates add CAM discounts
The 2.6 million members of Philadelphia-based **Independence Blue Cross** will have access to a discount CAM affinity product through San Diego-based **American Specialty Health Networks.** IBC's president and CEO **G. Fred DiBona, Jr.**, explained the move this way in an early September release: "Independence Blue Cross has recognized its members' call for more choice and for access to care beyond traditional medicine." The program has a relatively steep 30% provider discount in the nine-county area of its largest membership. In a related statement, the 312,000 members of IBC affiliate that also serves New Jersey and Delaware, **AmeriHealth**, will offer members a similar benefit.

Colorado
Integrated pharmacy rollout includes practitioner rooms
The September 2000 issue of *Natural Business* includes a profile of a Boulder, Colorado start-up, **BoulderHealth Natural Pharmacy**, which is incubating a pharmacy model that will also have rooms for customers to privately consult with onsite pharmacists, nutritionists, herbalists, "and other holistic healthcare professionals." The initial site is a 3800 square foot facility. Founder and co-CEO **Barry Perzow** reportedly projects 100 stores nationally in 2-4 years through targeting the nation's 30,000 independent pharmacists. For additional information, call 303.442.0589.

Colorado
CAM clinic born out of hospital senior program approaches break even
The Integrator recently learned that Healthcare Center of Integrative Therapies at Longmont United Hospital is developing into an unusually successful financial model among hospital-based programs. The CAM program at the 135-bed, stand-alone hospital followed an organic growth model, initiated in 1994 when seniors asked gerontology nurse **Michelle Bowman, BSN, RN, C,** to add some CAM services. The original program featured massage, Tai chi, exercise, and yoga. The hospital, a **Planetree** member, invested in Bowman's CAM education, including an extended educational trip to China. On her return, Bowman began growing the program slowly. In 1998, the program became a formal hospital department that presently includes a 3000 square foot, five-patient room integrative clinic as well as management of CAM integration into other hospital services. Inpatient services with some CAM integration include oncology, birth, rehabilitation, and preoperative care. Providing services are seven part-time acupuncturists and 14 massage therapists who move between the clinic and inpatient needs in a seven-day-a-week program. Other practitioners include a medical herbalist, a practitioner of Alexander Technique, and nurses who provide touch therapy and Reiki treatments. The program is presently ahead of budget and within $8,000 of breakeven for the calendar year. Bowman attributes her relatively comfortable financial position to one important factor: "We don't have MDs on staff." She told The INTEGRATOR that the present shortfall is not viewed as problematic by the hospital. One reason is that since integrating CAM into obstetrics care, births have jumped from 80 per month to over 110. Bowman adds that her own compensation is "probably about half" of what would be paid to a medical doctor in her leadership position. The integrative clinic services, however, are not yet well integrated into physician practices, with "only about 2%" of the patient base due to physician referral. Based on her experience, Bowman has begun to speak and consult on CAM integration in rural and small hospitals, including four in Wyoming. Her work is to be featured in an upcoming text from **Aspen Publishing** text co-authored by **Frank Lawlis**. For additional information, call 303.485.8384.

Illinois
DC-PCP CAM business adds PPO line
Chicago-based **Alternative Medicine, Inc.**, developer of a unique CAM product that uses chiropractors as primary care providers (Integrator, January 2000), has rolled out a new preferred provider product. The product promises to fully integrate conventional and CAM services using the chiropractor as primary care provider with MD back-up and overall direction by a medical doctor. The benefit, which targets both self-funded plans and insurers, was quietly introduced last spring and has already been "embraced by" the **Chicago Transit Authority, Illinois Park Employees Health Plan,** and **Commonwealth Edison**, according to a mid-August release from the firm. For additional information, call 847.675.2580

New Mexico
National rehab firm explores integration
Jason Stein, DOM is heading up an informal CAM integration pilot in a **HealthSouth** facility in Albuquerque, New Mexico. The national rehabilitation firm has more than 100 hospitals and 1800 outpatient facilities nationwide Stein began offering acupuncture at the facility a year ago, through a partnership between the rehab firm and a local acupuncture school, the International Institute of Chinese Medicine. Stein's position is 25 hours per week and involves both inpatient and outpatient services. A massage therapist and tai chi instructors were more recently added to the services. Stein said credentialing "wasn't as difficult as (he) thought," recalling that the entrée was achieved through a marketing director who attended one of Stein seminars ▶

and championed the process. He reports that the firm is observing developments with the intent to consider expansion in other parts of the system. For more information, call 505.344.9478.

Washington-Wisconsin
HMO adds affinity product
Group Health Cooperative of Puget Sound is now offering its members a plan called *Complementary Choices* through which they can receive discounts of 20% on CAM services in 13 separate specialties. The offering is an expansion of a broad covered benefit, under the state's mandate, through American Whole Health Networks. For additional information, visit www.ghc.org.

Government Action

NCCAM Funding Expected to Jump

The CAM research economy is anticipated to have another huge boost in 2001. Funding for the NIH Center for Complementary and Alternative Medicine will jump by nearly 50%, from $70 million to $100 million. The boost is part of continuing expansion of medical research by Congress.

Federal Report Finds Shrinking Medicare Chiropractic

The Office of the Inspector General (OIG) for the U.S. Department of Health and Human Services released a report June 26 that found a "startlingly unexplainable reduction" in chiropractic services available to Medicare managed care beneficiaries. The reductions were particularly high when physician referral is required. (See Table.) The American Chiropractic Association believes this data will bolster its case in an ongoing lawsuit against HCFA for allowing plans to "illegally" limit services to chiropractors. The OIG report takes the position that medical doctors and osteopaths can also be the providers of manipulative services in the Medicare benefit. This issue is now before the federal court in ACA's litigation. The OIG report is entitled *Chiropractic Care: Comparison of Medicare Managed Care and Fee-For-Service* and is available through http://www.hhs.gov/oig.

Table: Chiropractic Usage Levels

Medicare (referral required)	
	1996 0.61%
	1997 0.96%
	1998 1.08%
Medicare Fee for Service (no referral required)	Approx. 4.25%
American Chiropractic Association, estimate of use in the public	6.5%

Study on Medicaid Reimbursement for CAM

A study from the University of Michigan Health System found that about a half a million Medicaid dollars per state is currently being spent on CAM. The researchers used a phone survey involving a Medicaid reimbursement specialist in each of 46 states which were reached. Chiropractic is covered in 34 states (74%), biofeedback in 10 (22%), acupuncture in seven (15%), hypnosis in 6 (13%), naturopathy in 5 (11%). In at least two states, alternative providers can serve as an individual's primary care provider. In five states, programs on early and periodic screening, diagnosis and treatment allow Medicaid patients access to alternative providers. (A special focus of the program was on CAM coverage of pediatric care.) Seven states expect expanded coverage in the next three years, with chiropractic, acupuncture, and naturopathy the most common services expected to find increasing inclusion. However, the average amount spent is under $500,000 per state per fiscal year. Only 5 states (11%) paid out more than this amount for CAM. The authors, led by Terrence Steyer, PhD, suggest that future research should assess both the amount of CAM used by Medicaid patients and their out-of-pocket CAM expenditures, and then look at the nature or the intervention and quality of care. Steyer presented results at a joint meeting last spring of the Pediatric Academic Societies and American Academy of Pediatrics. For additional information, call 734.764.2220.

Education and Conferences

Harvard Medical School is now offering a videoconference module for CME based on 14.75 lecture hours in the annual course developed by David Eisenberg, MD. $595. For additional information, call 617.432.1525.

October 11-13, 2000
Compassionate Medicine. Sponsored by Union Hospital in collaboration with the Association of Healing Health Care Projects will be held in Danvers, Massachusetts. Faculty includes Elliot Dacher, MD, health educator Georgianna Donadio, MSc, DC, and Leland Kaiser, PhD. $395. For additional information, call 781.477.3604

October 13-15
The 11th Northwest Regional Acupuncture Conference, Portland, OR Sponsored by Oregon College of Oriental Medicine, Oregon Acupuncture Association, and the National Sports Acupuncture Association. Programs will include research, insurance, and integrated care. $255. For additional information, call 503.253.3442, ext. 129

October 21-22, 2000
Annual Symposium. The Society for Acupuncture Research, Baltimore, MD. Co-sponsor is the University of Maryland. Among speakers are Christine Goertz, DC, PhD, from NIH NCCAM, and Brian Berman, MD. For additional information, call Howard Moffet, LAc, at 415-554-0154 or visit www.acupunctureresearch.org.

continued on next page

October 28-30
Medical Massage for the Cancer Patient. Sponsored by Memorial Sloan Kettering. Included in the multi-faceted course are legal-ethical issues, self-care strategies for the therapist, contraindications, demonstration as well as clinical indications. Cost: $350, plus $15 for an one-half day elective. For additional information, call 212.639.8629

October 28-31, 2000
The second Stanford-Harvard meeting on *Practical Applications and Evaluations.* Kauai, HI. Course directors are Eisenberg, **Ken Pelletier, PhD,** and **William Haskell, MD.** $695. For additional information, call 617.432.1525

October 29, 2000
"Integrative East-West Medicine: Blending Chinese and Western Medicine to Enhance Patient Care." One day course sponsored by **UCLA Center for East-West Medicine.** The focus this year, the fifth for the conference, will be on management of patients with chronic pain using integrative approaches, according to program organizer **Ka Kit Hui, MD.** The meeting is offered in collaboration with the **Asian Pacific American Medical Students Association.** For additional information, call 310.206.1876

November 9-11, 2000
Herbal Therapies and Other Dietary Supplements. Co-sponsored by Harvard and University of California, San Francisco. For additional information, call 415.476.5208

February 11-14, 2001
Implications for Clinical Practice led by David Eisenberg, MD. Sponsored by Harvard. For additional information, call 617.432.1525

May 17-19, 2001
Scientific Symposium on Integrative Medicine. Co-sponsored by UCSF and Harvard. For additional information, call 415.476.5208.

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Divider Title: Forzley

Licencing, Regulation and Access to Complementary and Alternative Medicine: An International and Comparative Approach and Related Research Projects

by Michele Forzley, J.D.

Prepared for presentation to the White House Commission on Complementary and Alternative Medicine Policy on December 4, 2000 in Washington, D.C.

CONTENTS

Licencing, Regulation and Access to Complementary and Alternative Medicine: An International and Comparative Approach and Related Research Projects

by Michele D. Forzley, J.D[1].

Introduction

In August 1999, I formed a committee on Complementary and Alternative Medicine (CAM) within the International Health Law (IHL) Committee of the American Bar Association(ABA). The leaders of the IHL elected to present a comprehensive program on the legal, regulatory and business issues related to CAM at the annual meeting of the ABA in August 2001. As a method of program content development, a study with three components was commenced. This method was selected to determine the interests of the potential audience composed of the legal and medical community. The components reviewed in this memorandum are the business model pilot study in Part II and the international research project on which this memo commences in Part I. A third component, the interview project is integral to this process, but is not reviewed here, purely due to time constraints.

The purpose of this memorandum is to introduce to the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) this study and some examples of preliminary research findings. Furthermore, its purpose is to suggest the value of these preliminary findings and that of further research along the lines of this study, to the successful completion of the function of WHCCAMP. Specifically, this memorandum is submitted on the issues of access and delivery of CAM and the education and training of health care practitioners of CAM as found in Sec.2(a) and (d) of Executive Order 13147, dated March 8, 2000.

PART I <u>International and Comparative Research</u>

Methodology

The main question underlying the international and comparative research is what legislative and administrative policy guidance can be gained from looking at how other countries, the European Economic Commission (EEC), international treaties and the World Health Organization (WHO) address the legal, regulatory and access issues related of CAM.? In light of the fact that so much CAM derives from sources foreign to the US, can the legal and regulatory environment of the countries of origin of various CAM modalities be of assistance? The international research project began with a preliminary comparison of the laws of UK, Spain and France, the European Economic Community, three international treaties and publications of the World Health Organization.

For each country, research was conducted to understand the definition of the scope of medicine, whether acupuncturists, homeopaths, chiropractors and osteopaths were regulated and if so how, and whether any other local rules of practice and/or common or civil law relating to health care was applicable. The inquiry also looked at whether the

same activities were regulated from country to country in the same manner, or at all, and what if any differences existed.

After reviewing only three countries it became abundantly clear that distinctions in treatment existed. Given that foreign local laws are rarely available translated in sufficient English, it was clear that no study could be accomplished in the absence of foreign local assistance from lawyers. Accordingly, a team of researchers needed to be assembled. To date, interim arrangements have been made with lawyers from the UK (Scotland, England, Ireland, and Wales), France, Germany, Italy, Spain, Switzerland, Holland, Belgium, Greece, Portugal, Romania, Russia and Lithuania, Turkey, Czech Republic, Poland, Hungary, Brazil, Canada, Japan, Republic of Korea, New Zealand, Poland, Norway, South Africa, Bulgaria, Romania, Cameroon, Suriname, Lesotho, Philippines, Ethiopia, Sierra Leone and Botswana, Mexico, Costa Rica, and Ukraine. This team was assembled at the 2000 summer session on private international law at the International Court of Justice at the Hague.

Regarding the EEC, WHO and international treaties, the working documents of international health and business transactions law and international public were surveyed for references to CAM and the issues of access and delivery. Many more documents are available for review and integration into a complete picture. The intent of the review is to merely establish the importance and relevance of these documents to the work of WHCCAMP.

Findings from preliminary research

France, Spain and the United Kingdom

A French national statute permit the practice of *specialites ancienne* described as, medicinal plants, whether indigenous or farmed, mixed or not. These may not be sold to the public, except from pharmacies or herb stores (herbortisteries). In France there is also national regulation of the profession of the "herboriste". The herboriste may be the same as a naturopath, but for this determination further research is needed. Another example of a sharp difference is the French view that the doctor patient relationship is one of contract not one of consent to treatment. This difference from our American common law view has interesting implications for negligence law and implications for the pay for services approach commonly used in CAM.

Looking at the practices of chiropractor and acupuncture, neither France nor Spain regulates these activities rather, they are "tolerated".. In the UK, acupuncturists and homeopaths have not yet been regulated at the national level while chiropractors and osteopaths have been under a regime very similar to the regulation of physicians. In contrast, acupuncturists and homeopaths must comply with local laws which render such practices unlawful if practiced without a premises permit obtained from a local council. If an acupuncturist wanted to set up in London for example, the London the Local Authorities Act of 1991 requires a health practitioner to establish that the particular practice specialty has an umbrella organization with a code of conduct, insurance requirements and disciplinary procedures in order to obtain the permit.

Within the interview project component of this study, the head of the one accredited school of aromatherapy was interviewed and she reported that this model of regulation was exported to Australia and has become national policy for aromatherapy practitioners.

Summaries of the rules are attached for the United Kingdom and France at Appendix A and for the European Economic Commission at Appendix B.

The European Economic Commission

The European Economic Community has also grappled with CAM issues and has produced several noteworthy directives and resolutions. Perhaps the most interesting is the Council's 1995 call[2] for a report to study policy on generic medicinal products in the EEC member states, and OECD countries including the US, Canada and Japan. The Council wanted to collate existing member state laws relating to plant preparations, technical requirements for assessment, registration, marketing authorization, and they wanted to assess the impact on the public health of the price differentials on generic medicinal products as compared with patented products. They also wanted to collate legislation applicable to international trade. Unfortunately further research within the EEC[3] has not uncovered in this report to date.

However, the Commission resolved and reported to the European Parliament in 1996[4] on a number of points are relevant to the mandate of WHCCAMP. The resolution is quite extensive and covers such diverse subjects as the environment, marketing, animal testing, genetic experimentation, biotechnology, mergers in the pharmaceutical industry and more topics related to medicinals. In reviewing the diversity of directions the Commission took in this resolution, it is helpful to recall the origins of the EEC which were trade related and that to large extent it still does not issue laws of a federal nature, but rather it sets law making standards for member states which ultimately enact their own version of the law within the limits set in Directives. Nonetheless, the breadth of the resolution is wide and far reaching and broaches the same direction established by the World Health Organization in its current strategic agenda[5], one of which is to look at the links between health and improved economic performance.

Here are some highlights from the resolution:

-a reaffirmation of EEC health policy to include responsible self-medication,

-an expression of an interest to explore a commitment on biotechnological development and human rights,

-an acknowledgment that citizen's attitudes towards health care have shifted to gentler forms of healing, and

-that alternative medicines have significant employment opportunities for small and medium sized enterprises.

They also charged themselves with the preparation of the setting up of a Traditional Medicines Evaluation Agency

-to assess the worth of phytomedicines,

-to develop a responsible policy on exports of medicinals,

-to draft a code of conduct for producers of medicinals for export to the third world,

-to expend effort towards achieving harmonization of pharmaceutical registration under the framework of international conferences on harmonization (such as the Hague Conference, UNIDROIT, the UN), and

-that current intellectual property safeguards be maintained in line with TRIPS[6].

The Council also issued directives in specific areas. In 1992, it issued its rules on the advertising of medicinal products for human use, on homeopathic medicinal products and on homeopathic veterinary medicinal products and rules on general product safety which apply if a product is not covered in the rules on medicinals. Only the rules on homeopathic medicinals will be examined here briefly.

Directive 92/73 provides the rules on homeopathic preparations. The stated objectives of the Directive are

-to reduce differences between the provisions of member states that may hinder trade between states of homeopathic preparation and those that lead to discrimination and distortion of competition between manufacturers of such products,

-to protect public health,

-to reaffirm a public health policy objective that patients should be allowed access to the medicinal products of their choice, provided all precautions are taken to ensure the quality and safety of the products, and

- to harmonize the rules on the manufacture, control and inspection of member states so as to allow the circulation of products which are safe and of good quality.

The Directive establishes a simplified registration procedure for homeopathic preparations. In so doing, EEC took into consideration the very low level of active principles homeopathic preparations contain and the difficulty of applying to them the conventional statistical methods relating to clinical trials. The following conditions, if met, were sufficient to qualify a homeopathic preparation under this system:

-it is administered orally or externally,

-no specific therapeutic indication appears on the labeling or in any information relating thereto, and

-there is a sufficient degree of dilution to guarantee the safety a the medicinal product; in particular the product may not contain either more than in one part per 10,000 of the mother tincture or more than 1/100th of the smallest does used in allopathy with regard to active principles whose presence in allopathic medicinal products results in the obligation to submit a doctor's prescription,

-other labeling requirements are met, and

- required documentation is submitted.

On the issue of education and training, the EEC has established rules for the recognition of diplomas and professional qualifications when the activity in question is not restricted to a physician[7]. Thus, a CAM practitioner can seek the acceptance of his or her credentials in another state of the EEC based on a set of European wide set of rules for

recognition of educational background. This is a standard to which the US should aim.

World Health Organization

The World Health Organization (WHO) through the office of Traditional Medicine is undergoing a study of all member states to answer the questions that follow on the use of traditional medicine. Traditional medicine is defined by the WHO, as the ways of protecting and restoring health that existed before modern medicine, using approaches that belong to the cultural traditions of each country. The term can include acupuncture, traditional birth attendants, mental healers and herbal medicine. The questions included in the WHO country study are;

-What is the extent of complementary medicine?
-What education and training is available?
-What does the licence to practice medicine include?
-What complementary medicines are covered under insurance both public and private?

Regrettably, the report is not yet available, however, this author was able to obtain a sample for the country of Belgium, a copy of which is at Appendix C. Assuming the data collected for all countries is of similar quality, then the report will be extremely useful to advance the international and comparative research project and for analysis and organization for its value to the issues of access and delivery. A collaboration with the WHO Office of Traditional Medicine may prevent duplication of effort, provide ready data to support the work of WHCCAMP.

International treaties

International treaties are part of the international research project because of the role they play in shaping American law and the law of the countries that ratify any treaty. They also influence American policy, even if a treaty is not ratified by the United States. This is so, because any treaty with enough signatories to put it into force, will rise to the level of customary international law, or what is considered a basic standard of behavior at an international level. Therefore, before any US legislative or administrative policy recommendation is made, it should be measured against US obligations under treaty and customary international law.

Treaties exist for many activities. In the field of health, there are essentially no treaties directly on the subject of health. Rather health is treated within a number of other treaties with substantive import on such diverse topics as intellectual property law, the environment, human rights and biological diversity. Reviewing fully any treaty is far beyond the scope of this memorandum. A few will be highlighted to make the point that a full review of all relevant international documents is urged in order to incorporate existing laws and standards into the work of WHCCAMP, avoid conflicts with US international obligations and prevent duplication of effort.

The treaties selected for comment are the TRIPS agreement[8], the United Nations 1992 Convention on Biodiversity and the International Covenant on Economic, Social and

Cultural Rights (ICESCR).

ICESCR: Most recently, the United Nations Committee on Economic, Social and Political Rights reaffirmed[9] pursuant to Article 12(1) of the ICESCR that every human being is entitled to the highest attainable standard of health conducive to living a life in dignity, rather than the absence of disease or infirmity. In this light, the Committee commented that *availability, accessibility, acceptability* and *quality* were the essential terms to achieve health. Regarding *accessibility*, the Committee noted the following sub-elements: non-discrimination, physical accessibility or services within safe physical reach of all parts of the population, and economic accessibility or afford-ability with payment to be based on the principle of equity and information accessibility with its corresponding components of privacy and confidentiality.

TRIPS: The TRIPS agreement is concerned with international intellectual property rights. It provides an international framework and standard for the protection of patents, copyrights and trademark with which the laws of all World Trade Organization member states must comply. The United States is a member. It contains elements related

- to exclusions from patent-ability for diagnostic, therapeutic and surgical methods of treatment,

-prohibitions against patenting chemical compounds as opposed to the process for production of compounds which can be patented,

-it is the focal point for the debate on AIDS drugs in the developing world, which is a debate over the relative importance of patent holder rights and health care delivery, which debate will strike CAM with regard to botanical and indigenous medicines,

-it is the main source of international law for the process called compulsory licencing,

-it is the source of the sui generis form of protection for plant variety, also found in the 1961 Convention for the Protection of New Varieties of Plants (UPOV)[10].

Along a similar line is the Convention on Biodiversity which seeks to achieve a fair and equitable sharing of the benefits derived from the utilization of genetic resources. To the extent that the WHCCAMP will comment at all on intellectual property protection related to herbals, botanical and indigenous medicines, TRIPS and other treaties must be considered.

Telemedicine, CAM, Globalization and the Future of Healthcare Access and Delivery

One of the challenges of health care today is its delivery across state and national boundaries. The draft International Telemedicine Treaty, presented to the WHO, aimed to harmonize conflicting and end duplicated licencing rules for health care professionals in a similar manner to the way the EEC established principles for the recognition of diplomas and professional education. An international system for harmonizing licencing requirements is one necessary element to meet this challenge. This is the delivery side of the equation of health care.

On the access side of the equation, another obstacle needs to be surmounted. That is that

health care consumers cannot purchase health care anywhere they are with the same ease that they can access their bank account information and funds with a ATM card. How is CAM connected to this dilemma?

In the view of this author widespread CAM use is a by-product of several forces, including globalization, expansion of international trade, the seven minute doctor visit, the greater population diversity in every country on earth, rising consumer choice and consciousness of choices, and the democratization of information as the result of the internet and CNN. As between these forces, one can only guess at which one has had a greater influence on the broad scale worldwide usage of CAM. Whichever, the fascinating question is to where is CAM leading us?

Certainly, CAM is leading to more choice in the kind of healthcare we receive. It is also one of the necessary bridges to electronic health care cards, which will contain our health files, our insurance records and billing and payment mechanisms, and help maintain our privacy. When health care cards are fully operational internationally, then the access side of the equation will be fulfilled. Why is this true? Consider the US retiree who chooses to live in Mexico or the traveling business person who becomes ill in another country, or the family who moves from state to state for employment, or the growing use of Telemedicine and malls for more than shopping. How do any of these people get a prescription refilled in another state, let alone another country or obtain medical care? What if a patient wanted to receive an certain operation in another state of country? Is it not an embarrassment to us that we can barely go beyond our the geography of our zip code for routine care?

To remove these impediments to access, and serve the needs of those who travel and relocate and those in geographical areas with less electronic infrastructure, we will need ways to carry all our health care information with us. Even information as basic as what vitamins we consume each day should be in this card, never mind what herbals we self prescribe nor what surgeries or other interventions we may have experienced.

This information must be in a language that everyone can understand. To do this, we will need a common language or lingua franca of health care. CAM offers us the opportunity to develop that language because its roots are international and cultural and because no language coding standard currently has been established. With this language, greater progress can be made towards the modernization of not only the US health care system, but that of most of the rest of the world

This international research project is devoted to this language development as the larger horizon, for which CAM is a bridge.

PART I Recommendations

- ☐ Correspond and cooperate with the EEC and their efforts to regulate CAM.
- ☐ Correspond and cooperate with the WHO Office of Traditional Medicine.
- ☐ Analyze worldwide licencing, regulatory and access practices.
- ☐ Check all policy recommendations in light of applicable international treaties to prevent conflict.
- ☐ Recommend US participation at the international level on harmonization efforts.
- ☐ Join the multi disciplinary discussion between trade, health and economic factions.
- ☐ Widen the horizon on CAM. to an international language of health care.

PART II

Summary of the Results of the Business Model Pilot Survey for Integrative/Complementary/Alternative Practices

Origin and Objective of the Study

The impetus for this survey arose during the April 2000 meeting of the Integrated Medicine Network (IMN). The IMN is a collegial organization of complementary and alternative medicine (CAM) providers and related organizations located in or around the Boston/Cambridge, MA area. The group meets monthly to discuss issues of concern to an open membership. During the April 2000 meeting, a discussion queried whether or not CAM programs are financially viable. Two members of IMN, Michele Forzley, JD and Lynn Caesar, Ph.D., volunteered to develop and conduct the survey to further investigate this question.

The results were presented in June 2000 to the IMN membership and all respondents were invited. Results were subsequently presented to various audiences nationally and reported in the Integrator, the IMA Newsletter and are still privately presented.

Methodology

The authors developed questions for the survey based, partially, upon categories described in the book, Third Opinion: an International Directory to Alternative Therapy Centers for the Treatment and Prevention of Cancer and other Degenerative diseases (by John Fink, 1997, Avery Publishing Group, Garden City Park, New York). Additional questions were generated by the authors.

The survey was distributed through e-mail, regular mail or fax to a sampling of CAM programs or practices. Part of the sample was derived from a list of CAM activities and resources in the Greater Boston Area List compiled by Beth Israel Center for Alternative Medicine. Thirteen (13) surveys were sent to locations from this list. The remaining sample (3) consisted of CAM centers or practitioners listed in the book, Third Opinion, as well as CAM programs listed on the internet (2) and CAM programs in the Massachusetts-New Hampshire area known to the authors (2). Three (3) additional surveys were sent to three practitioners affiliated with the American Herbalists Guild. An announcement of the project along with a copy of the survey was e-mailed to 42 members of the IMN membership list, and 146 members of the Integrated Medicine

Alliance (IMA) membership. A total of 211 surveys were sent through these sources. Follow-up phone calls were made to named recipients to ask if each would complete the survey. Of the 23 surveys sent to specific CAM facilities, eight (8) were completed and returned. Of the eight respondents, two worked for the same agency so this number was collapsed to yield seven (7) respondents (30% response rate). Five additional surveys were completed by members of IMN and IMA who received e-mail announcing the study. A total of 13 respondents completed the survey.

Policy on confidentiality: The survey gave all recipients the opportunity to remain anonymous. If we did not have permission from a respondent, the information gathered will remain anonymous. Most respondents failed to answer the question on permission to use their name. Under the circumstances, the authors have chosen to exclude all contact information of respondents from this report.

Observations and Conclusions:
As this was a pilot survey with a small sampling, we conclude with some observations that appear reasonable based upon responses and discussions at presentations. The authors believe that a larger sampling that offer a statistically significant sample would confirm preliminary observations and conclusions. Such a study is in the future we hope.

One: Available Services
The most frequently cited CAM services offered are (in order of frequency) acupuncture, therapeutic massage, chiropractic, yoga and Chinese herbal medicine, Mind/Body Medicine, and Nutritional Counseling.

Two: Choosing a Healing Model is Critical to Success
In addition to length of time in operation, the second most significant factor related to financial success is the healing model selected. Clearly there are differences in financial outcome experience depending on the healing model used, with the most successful so far to be those offering a disease or population specific program. The author surmises that no healing model is better than another, only that an organization must select one that is appropriate to the population it seeks to serve. Respondents reported having selected one of the following options; disease specific treatments such as AIDS, or population specific treatment such as women's health, wellness care, or maternal care, or an integrative approach (offering both allopathic and complementary and alternative services within an integrative model) or a holistic healing center within a larger institution or a stand alone clinic. Other options included a traditional modality such as psychotherapy mixed with complementary and alternative treatments in contrast to centers that offer only CAM.

Three: Credentialing and Licencing is Chaotic and Erratic- Harmonize
Credentialing is all over the board, no standards are available and great secrecy attached to how it is being done. Everyone is recreating the wheel and spending inordinate time on trying to figure out how to credential. There is frequent reliance on the medical model of credentialing and the umbrella of the nursing scope of practice to offer energy based

modalities. No consistency is available from state to state on licencing standards as they are not harmonized in any way.

Four: Identify Other Sources of Funding
CAM centers that serve AIDS patients report break-even as recipients of public funding that enables them to serve low income and disadvantaged populations. AIDS centers have been in existence longer and have access to sources of funding as yet untapped by CAM centers.

Five: Length of Time in Business
Length of time in business is generally an indicator of greater financial success. As a general rule, it takes about three years before a business achieves break even. Only the AIDS clinics have been in business over five years. Significantly, the next earliest commencement date of a respondent was 1997. Two fell on this date, one of which one reported passing break-even and the other had not yet done so. Three respondents began in 1999.

Six: Implement Economies of Scale
Centers that are part of a hospital system are funded in part by budgets that serve the entire hospital. These centers are able to take advantage of economies of scale in certain aspects of business operation and thus reduce start-up and operational expenses. Some centers reported careful planning to avoid cost overruns and a strategic decision to operate only those programs that pay for themselves to avoid losses.

Seven: Rely on Self-Pay for Now
The majority of respondents rely on self-paying clients. Many centers that offer CAM and allopathic services do generate 100% of fees for CAM from self-pay visits. The fees only represent a small portion of the overall income of the center as reported.

Eight: Gain Basic Business Skills and Knowledge
With the exception of healing centers in hospital systems, the 501c3 and LLC forms, many offer services as a sole proprietor, a form of doing business with the least amount of legal protection. This would not be a recommended form of business.

Questions and Responses
The Questions used in the study and a summary of responses is at Appendix D. This section summarizes the salient aspects of the answers for each question. Some quotes have been added to add the flavor of what respondents offered as comments.

PART II Recommendations

- ☐ Conduct the study with a statistically significant sample. Add new questions.
- ☐ Establish education and training programs on business basics, including marketing, pricing, and strategic planning.
- ☐ Identify and create a directory of funding sources within the United States government.
- ☐ Identify and create a directory of non-governmental funding sources.
- ☐ Develop national licencing and credentialing standards, model language and a system of mutual recognition and harmonization between states for both.
- ☐ Harmonize national licencing and credentialing standards with the international community.
- ☐ Develop a common language within the CAM community.
- ☐ Conduct cost and outcome studies.

CONCLUSION AND RESTATEMENT OF RECOMMENDATIONS

I wish to thank the White House Commission on CAM Policy for the opportunity to present my views. For convenience, Parts I and II Recommendations are restated below. In closing, this author would like to draw the attention of the reader to the following.

Part I looked at what is happening internationally and Part II, the US domestic view. At both levels there is concern and attention to the questions and problems of licencing, insurance coverage and the relationship between trade (or business as we call it) and health. The Europeans are looking at their OECD friends to see what they are doing as they grapple with these CAM questions and the WHO is looking at all its members to discern the same. If anything, the wisdom of the methodology of this study, the international and comparative approach to licencing, regulation and access to CAM has been confirmed. This method is hereby recommended to the White House Commission on CAM Policy as an integral means to fulfill its mandates.

Michele D. Forzley, J.D.
November 29, 2000

PART I Recommendations

- ☐ Correspond and cooperate with the EEC and their efforts to regulate CAM.
- ☐ Correspond and cooperate with the WHO Office of Traditional Medicine.
- ☐ Analyze worldwide licencing, regulatory and access practices.
- ☐ Check all policy recommendations in light of applicable international treaties to prevent conflict.
- ☐ Recommend US participation at the international level on harmonization efforts.
- ☐ Join the multi disciplinary discussion between trade, health and economic factions.
- ☐ Widen the horizon on CAM. to create an international language of health care.

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- ☐ Develop a common language within the CAM community.
- ☐ Conduct cost and outcome studies.

APPENDIX A

France

Scope of Medicine	Medical doctors are nationally regulated
Sage-Femme	Mid-wives are statutorily regulated at national level
Acupuncturist	none
Homeopathy	none
Naturopathy/Herbalist	national regulation of la profession d'herboriste
"Ancient Specialties"	national statute permitting authorization of the practice of *spécialités ancienne*, described as medicinal plants whether indigenous or farmed, mixed or not. May not be sold to the public except from pharmacies or herboristeries (herb stores). Art. L. 659, Code de la Santé Publique.
Chiropractors	none
Homeopaths	none
Osteopaths	none
Practice/Local rules	not available
Common law	French view that doctor-patient relationship is one of contract not one of consent to treatment, any failure is an action for breach of contract rather than negligence based liability.

United Kingdom

Scope of medicine	Medicine Act of 1983
Acupuncturists	No regulation at national level see local practice
Chiropractors	Chiropractor Act of 1994 virtually identical to Osteopath Act.
Homeopathy	No regulation at national level see local Regulations of the products - see Medicines Act of 1968

Naturopathy/Herbalists	No regulation of the person Regulation of the products - see Medicines Act of 1968. Yet herbal remedies are exempt from licencing
Osteopaths	Osteopath Act of 1993 modeled on Medical Act of 1983. Earliest complementary modality to be licenced and most widely used in UK. Elements copies into Chiropractor Act of 1994. Include: registrar of chiropractors, educational committee, standards of proficiency, code of practice, disciplinary procedures, appeals process, indemnity insurance requirements, provisions that comply with EU rules, such as anti-competition, data protection and access to personal health information.
Practice/Local rules	e.g. London Local Authorities Act of 1991, unlawful to use a premises without a permit from borough council, exceptions for medical practitioners or members of a body of health practitioners where the body has codes of conduct, insurance requirements and disciplinary procedures. Applies to acupuncturists, massage therapists, other healers.
Common law	various requirements- for standard of care, disclosure, consent, causation, vicarious liability, fraudulent representations, etc.

APPENDIX B

European Economic Community

Medicinal Plant Preparations

Council resolution identifies issues to be considered include: collating existing provisions relating to plant preparations, also called generic medicinal products, technical requirements for assessment, registration, marketing authorization, and assess impact on public health of price differentials on generic medicinal products as compared with patented products, and collation of legislation applicable to international trade.

***Council also calls for a report to study policy on generic medicinal products in the Member states of the EU, other OECD countries including the US, Canada and Japan.

Homeopathic Medicinal Products

September 1992, EEC Directive was enacted to address homeopathic medicinal products as follows:

1. recognizes that the proprietary medical product rules are not always appropriate for homeopathic preparations,
2. in some states they are recognized and not in others, but are *tolerated*,
3. recognizing the low level of active principles and the difficulty of applying them to conventional statistical methods relating to clinical trials, a simplified registration procedure is established,
4. some states have a homeopathic tradition,
5. a homeopathic medicinal product shall mean any medicinal product made from homeopathic stocks in accordance with homeopathic manufacturing procedure described in the European Pharmacopeia,
6. Ten articles follow with detailed specifics on application for simplified registration, labeling, manufacture, control, inspection, sanctions, quality control, homogenization of state law differences, which types of homeopathic preparations qualify for registration, e.g. Only oral preparations qualify, etc.

Proprietary Medicinal Products	The directives are the equivalent of US FDA rules on drug testing and approvals. Chapter 13.30.15 (PMP)
Advertising of Medicinal Products for Human Use	Directives apply only to products regulated under proprietary medicinal product rules
General Product Safety	Apply only if no other rules apply, so these rules do not apply to drugs regulated by PMP.

APPENDIX C

Belgium [1]

The extent of complementary medicines [2]

According to a 1998 poll, almost 40% of the population has used complementary medicines at least one time. The study indicated also that women use complementary medicines more often than men do and that 77% of users are satisfied with these treatments.[3] The most widely used complementary medicines in Belgium are homeopathy (81% of users), acupuncture (38%), osteopathy (27%), phytotherapy (25%), chiropractic (21%), along with a moderate use of other therapies.[3] The same study showed that most complementary medicine treatments are carried out by doctors and physiotherapists.[4] The most used medicines are homeopathy (59% of doctors using complementary medicines), acupuncture (40%) and phytotherapy (28%).

The categories of medical practitioners who use acupuncture are not clearly defined (physicians or physiotherapists). The use of manipulative treatments is divided between physiotherapists (33%) and non-allopathic practitioners (34%). Regarding organizations linked with homeopathy, there are three physicians and pharmacists associations and two for patients.

*Education and training*7

Complementary medicines are not taught in Belgian medical schools, neither in the basic curriculum, nor in post-graduate training. However, the Belgian Medical Faculty of Homeopathy organizes courses for physicians, surgeons, dentists, pharmacists and veterinarians, following the standards of the European Committee for Homeopathy. Furthermore, there are two associations of acupuncturists holding training courses in the evening and during weekends. The program lasts for three years.[5]

The licensing to practice[6]

In Belgium, the legislature chose a monopolistic approach for licensing medical doctors. In this country, the practice of medicine, which includes diagnosis, treatment,

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[1] See Maddalena S., The legal status of complementary medicines in Europe – A comparative analysis, Stämpfli, Bern 1999, chap. 2.4.

[2] See Maddalena S., *op. cit.*, chap. 2.4.1.

[3] One physician out of four wants reimbursement for such therapies while 59% of users and 36% of non-users expressed that they were ready to pay higher premiums to cover such reimbursements.

[4] One physician out of four uses complementary medicines. In general, they are general physicians.

[5] It has to be said that practitioners using acupuncture are generally trained in East Asia or in France.

[6] See Maddalena S., *op. cit.*, chap. 2.4.2.

prescriptions, surgery and preventive medicine, is exclusively reserved for doctors.[7] The performance of medical acts without a legal qualification is an offence. There is no specific regulation on complementary medicines in Belgium yet and no legal text mentions complementary medicines. However, there is a draft of law on the subject and a law should be set up. Non-allopathic practitioners are sometimes prosecuted for illegal practice of medicine.[8] The enforcement of this law was reported to be strict in Belgium. However, today, public prosecutor offices prosecute only charlatans who knowingly deceive and financially exploit the public, and non-allopathic practitioners having prescribed "treatments" which led to an accident (sometimes lethal).The misuse of the title of physician is also punishable. Doctors are, in principle, legally able to practice in any branch of medicine and may practice in any of its sub-specialities.[9] Therefore, doctors may use complementary medicines. However, doing that they may find themselves in conflict with their professional organization. Indeed, although physicians are in principle free to use complementary medicines the Order of Physicians set limitations on therapeutic freedom by promulgating a Code of Professional Ethics which practically forbids their use. Furthermore, when doctors using non-allopathic treatments are subject to a complaint because the patient suffered damages and was not cured, the disciplinary Courts generally consider they have violated these articles because they did not use a treatment in accordance with the allopathic medicine.[10]

Concerning the situation of paramedics, they may provide alternative techniques (e.g. osteopathy by physiotherapists) when working under the supervision of a physician. Regarding the practice of acupuncture by physiotherapists, it is illegal but tolerated when the treatment is requested by a physician. One should note that the National Council of the Order of physicians considers acupuncture as an experimental medical technique and that vertebral manipulations are considered as medical acts by the Ministry of Public Health. Regarding more specifically chiropractic and homeopathy, their practitioners are currently trying to obtain official recognition. They want to obtain the same status as dentists have.

Regarding the future, the Belgian government approved in February 1998 a proposition with regard to the exercise of medical professions in order to register "*non-*

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[7] Access to medical practice is regulated by the Practice of Medicine Act of 1967 which introduced a monopoly in this field.

[8] The three conditions of illegal practice of medicine are: 1 the practice of a medical activity; 2 by an unauthorized person; 3 in an unusual way.

12 In order to be able to fully practice medicine, the holding of an academic degree in medicine is necessary. The registration on the List of the Order of Physicians is also mandatory. In order to obtain this registration, a certificate of good character and repute is requested. Furthermore, doctors have to submit their diploma for inspection to the Medical Commission (Article 7 paragraph 1 Practice of Medicine Act 1967).

13 In comparison, they never apply these articles when a patient suffered physical injuries following an allopathic treatment.

conventional" practices.[11] Concerning the content of the draft, there are rules on the registration of some therapies and the minimal requirements with regard to the training and the safeguard of quality standards.

The coverage of complementary medicines[12]

In Belgium, there is both public and private coverage for some complementary medicines. Regarding public coverage, the Social Security System officially does not reimburse complementary medicines, because the nomenclature does not contain dispositions about them. It does not matter whether they are provided by physicians or by non-allopathic practitioners. However, practically speaking, doctors using complementary medicines may guarantee their patients that part of their fees will be reimbursed.[13] In order to obtain reimbursement for osteopathic treatments, physiotherapists have to prescribe treatments under a classic designation. A mutual insurance company[14] was the first to decide, in March 1997, to partially reimburse specific complementary treatments. The insurance reimburses 25% of homeopathic remedies up to a maximum cost of 6000 BF per year and per beneficiary. Regarding osteopathy, the insurance reimburses 400 BF for each treatment with a maximum of six treatments, but only if they have been provided by physicians, nurses and physiotherapists. The list of homeopathic remedies which are reimbursed is inspired by the EU Directive on homeopathic products. Insurance companies consider extending the reimbursement to other techniques, such as acupuncture, phytotherapy, etc. There are private insurance companies which reimburse chiropractic. Acupuncture is also partially reimbursed.

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[14] The project will soon be examined by the Belgian Parliament.

[12] See Maddalena S., *op. cit.*, chap. 2.4.3.

[13] Currently, because of the difficult financial situation of the social security, complementary medicines will not be reimbursed in the near future.

[14] The socialist mutual insurance of Tournai-Ath.

APPENDIX D

Questions and Responses

This section summarizes the salient aspects of the answers for each question. Some quotes have been added to add the flavor of what respondents offered as comments.

1.a. What complementary/alternative health care services do you offer?

Oriental medicine including acupuncture (7), tuina and moxibustion (2) and Chinese herbal medicine (3).

Chiropractic (4)
Therapeutic Massage (shiatsu, acupressure, deep tissue, Swedish) (5)
Yoga (3)
Nutrition (3)
Mind/Body workshop (2)
Women's holistic health (1)

1.b. What illnesses do you treat? Are you disease specific?

Primary Care (4)
Chronic Illnesses (4)
Populations Specific (3)
HIV (2).

2. Are you a stand alone clinic or part of another organization? If part of another organization, please indicate the type. For example, teaching hospital, school, spa. Also, please indicate which department if any sponsors you.

stand alone (8)
part of a hospital system (4)
association of practitioners (1)

3. What is your legal structure? For example, corporation, division, unit.

501c3 (4)
Sole proprietor (4)
LLC/C-corporation (3)
division (2)

4. Describe your staffing.

Responses mixed and not reported here.

5. How are you funded? Fees, angels, venture capital, loans, benefactors.

Fees (9)
Fund raising, and foundations (3)
Public Funding (3)
Managed Care/ Insurance (2)
Loans (1)

6. a. What per cent of your revenues are from self payers? 50-100% (6) 0-50% (5)
from insurance ? 50-100% (5) 0-50 (1)

b. What per cent of your revenues are from conventional treatments?
0% (8)

60-98% (4)

7. a. What is your fee structure. (Include a copy)
Respondents refused to offer this information.
b. Do you offer a sliding scale?

8. Have you achieved break even? Yes (5) No (7)
If not, when do you expect to do so? Six months to two years
What impediments do you foresee to breaking even? None
How do you cover your shortfall now?
E. " Right now our effort is interdisciplinary and woven into the fabric of hospital rehabilitation and education operations. As such it is difficult to answer this question. Our rehabilitation departments are under pressure from declining reimbursement and we see the growth of this effort as a way forward for these departments. We are always in danger of losing a particular service that does not break even. We plan to articulate a business plan that will support further growth. A critical need is physician interest, involvement and referral"
F. investment funds

9. What population do you work with?
Not reported here.

10. What per cent of your services are gratuitous?
Respondents had difficulty with this question and did not answer it.

11. How have you credentialed non-medical personnel? Would you attach your credentialing guidelines to your response please?
Elements of credentialing process as reported:
-Required number of years of direct patient care experience.
-Certification from accredited school. E.g. Massage
-Certification from an approved program e.g. yoga.
-All employees- reference and background checks, physicals and two-tier TB test
-Internal medical staff credentialing process (credentialed as Allied Staff member)

-Use of nursing license scope of practice to incorporate other modalities.
-Proprietary- refuse to disclose
-Insurance for practice.
-No non-medical clinicians.

12. Any comments you wish to make? Please add them here. And thank you for your support for this project.
Comments not reported here.

13. Are you interested in a national umbrella organization of all the associations related to complementary/alternative medicine? If so, what would you like its role to be?

Yes, to assist with issues such as credentialing, training clinicians, doctors, nurses, etc in this area, research, sharing of resources, business management and reimbursement, finances, how to conveniently manage the information that is out there about who is doing what, lobbying, public education, APMA is probably the closest to fitting the bill, lobbying for greater inclusion of CAM in managed care contracts.

14. Name and contact information and starting date.

1990-(2) 1997-(2)
91-(1) 99-(3)

ENDNOTES

1.A biography of Michele Forzley is appended at page 25 of this memorandum.

2.Council Resolution of 20 December 1995 on Medicinal Plant Preparations, 95/C 350/05.

3.The Office of the Delegation of the European Economic Commission to the United Nations in New York assisted in this query.

4.Resolution on the communication to the Council and the European Parliament on the outlines of an industrial policy for the pharmaceutical sector in the European Community (COM(93)0718- c3-0121/94) Official Journal C 141, 13/05/1996 p. 0063.

5.World Health Organization Strategic Agenda Statement at the 105th Session of the Executive Board which launched the Commission on Macroeconomics and Health under Dr. Jeffrey Sachs.

6.Trade Related Aspects of Intellectual Property Agreement (TRIPS), one of the agreements of the General Agreement on Tariffs and Trade.

7. Written Question E-2932/98, Directive 89/48EEC and 92/51/EEC.

8. Id at note 3.

9.22nd session, April 25-May 12, 2000.

10.The US has the Plant Variety Protection Act.