accessible via the Internet web sites of the various states as well as the ICA website http://www.chiropractic.org

While the practice of various health professions is established and regulated by the states, federal statutes and regulations have a powerful and growing impact on health care organization and delivery. The concept of the subluxation is clearly and emphatically recognized in federal statutes in a number of contexts. Indeed, no federal program recognizes chiropractic outside the context of the subluxation.

The federal statutes governing the Medicare program, where chiropractic services have been included since the early 1970's, defines chiropractic and reimbursable chiropractic services as:

> *A chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services), and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of subsections (s)(1) and (s)(2)(A) of this section and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation demonstrated by X-ray to exist) which he is legally authorized to perform by the State or jurisdiction in which such treatment is provided.* (42 USC Sec. 1395x (r)(5).

Medicare extends these concepts in the statute into the regulations governing the program with an express definition:

> *A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist.* (42 CFR 482 Subpart B Section 482.12 (7) (c)(1)(v).

Federal statutes establishing chiropractic participation in the Medicaid program employ the same terminology as in the general Medicare program. Federal Employee health Benefit Programs recognized chiropractic on terms negotiated between public employee representative committees and various insurance carriers but the federal workers compensation program identifies and defines chiropractic, once again, very specifically to include chiropractors and chiropractic services as follows:

> *The term "physician" includes chiropractors only to the extent that their reimbursable services are limited to treatment consisting of manual manipulation of the spine to correct a subluxation as demonstrated by x-ray to exist.*

THE CHIROPRACTIC ADJUSTMENT: THE CORE OF CHIROPRACTIC PRACTICE

Without question, the chiropractic adjustment of the spine and its adjacent structures to correct subluxation represents the essence of chiropractic patient care as established by state statute. No less than 38 state statutes specifically employ the term "adjustment" in reference to the procedures applied by the doctor of chiropractic. Most state statutes are very specific regarding the authority of the doctor of chiropractic to apply the adjustment and/or manipulation process to the area of the human spine and its articulations. State statutes recognize that chiropractic science is anatomically very specific to the spine but with broad body implications. No less than 18 state statutes include the concept of manipulation, and in almost every instance it is utilized in addition to the term "adjustment" Clearly, the terms are not meant to be synonymous.

> **Colorado**: *"Chiropractic"...includes ...the elimination of the abnormal functioning of the human nervous system by the adjustment or manipulation, by hand, of the articulations and adjacent tissue of the human body, particularly the spinal column.* (Colorado Revised Statutes Annotated, Title 12, Article 33, Part 1: 12-33-102 (1).
>
> **Connecticut**: *The practice of chiropractic means the practice of that branch of the healing arts consisting of the science of adjustment, manipulation and treatment of the human body in which vertebral subluxations and other malpositioned articulations and structures that may interfere with the normal generation, transmission and expression of nerve impulse between the brain, organs and tissue cells of the body...are adjusted.* (Connecticut General Statutes Annotated, Title 20, Chapter 372, 20-24 (1)

District of Columbia: *"Practice of **Chiropractic"** means the detecting and correcting of subluxations that cause vertebral, neuromuscular, or skeletal disorder, by adjustment of the spine.* (District of Columbia code 1981, Part I, Title 2, Chapter 33, s2-3301.2 (3)(A)

Georgia: *"Chiropractic" means the adjustment of the articulation of the human body, including ilium, sacrum, and coccyx...The adjustment referred to in this paragraph and subsection (b) of Code Section 43-9-16 may only be administered by a doctor of chiropractic authorized to do so by the provisions of this chapter.* (Code of Georgia, Title 43, Chapter 9; 43-9-1 (2)

Idaho: *"Adjustment" means the application of a precisely controlled force applied by hand or by mechanical device to a specific focal point on the anatomy for the express purpose of creating a desired angular movement in skeletal joint structures in order to eliminate or decrease interference with neural transmission and correct or attempt to correct subluxation complex; "chiropractic adjustment" utilizes, as appropriate, short lever force, high velocity force, short amplitude force, or specific line-of-correction force to achieve the desired angular movement, as well as low force neuromuscular, neurovascular, neuro-cranial, or neuro-lymphatic reflex technique procedures.* (Idaho Code, Title 54, Chapter 7: 540-704 (1)(a)

CHIROPRACTIC: A DRUGLESS SCIENCE

In the legislative process that established chiropractic and in the subsequent regulatory procedures that amplify and implement legislative directives, chiropractic is often defined by what is included within the professional scope of chiropractic practice as well as what is expressly prohibited. Among the prohibitions that characterize chiropractic is the absence of authority to prescribe or administer drugs. All fifty states expressly prohibit the prescription or administration of federally controlled substances by a doctor of chiropractic. No state authorizes the doctor of chiropractic to administer or prescribe anesthesia, vaccines or serums or radioactive substances for therapeutic purposes. State statutes tend to be quite specific in this area as is shown in the excerpts from state statutes presented below.

Alabama: *...but chiropractors are expressly prohibited from*

prescribing or administering to any person any drugs included in materia medica (Code of Alabama 1975 Title 34 Chapter 24 Article 4 Division 1, s 34-24-120 (c)

Arizona: *A doctor of chiropractic licensed under this chapter shall not prescribe or administer medicine or drugs...*(Arizona Revised Statutes Annotated Title 32 Chapter 8 Article 2, 32-925 (b)

Connecticut: *Practice chiropractic as defined in section 20-24, but shall not prescribe for or administer to any person any medicine or drug included in materia medica...*(Connecticut General Statutes Annotated Title 20 Chapter 372, 20-28 (b)(1).

District of Columbia: *"Practice of Chiropractic" does not include the use of drugs,...*(District of Columbia Code 1981 Part 1, Title 2 Chapter 33 Subchapter 1, Section 2-3301.2 (3)(A).

Georgia: *However, the term "chiropractic" shall not include the use of drugs...*(Code of Georgia, Title 43 Chapter 9, 43-9.1 (2).The status of the doctor of chiropractic, as established by statute, training and experience, includes the ability and authority to evaluate the general health status of an individual for certification purposes,

Louisiana: *The practice of chiropractic does not include the right to prescribe, dispense, or administer medicine or drugs...*(West's Louisiana Statutes Annotated Title 37, Chapter 36 Part 1 Section 2801 (3)(c)

New Jersey: *No licensed chiropractor shall use. . . or prescribe, administer, or dispense drugs or medicines for any purpose whatsoever...*(New Jersey Statutes Annotated Title 45 Subtitle 1, Chapter 9 Article 1 45:9-14.5)

New York: *A license to practice **chiropractic** shall not permit the holder thereof...to prescribe, administer, dispense or use in his practice drugs or medicines...(*Consolidated Laws of New York Chapter 16, Title VIII Article 132, 6551. Definition of practice of chiropractic (3).

Tennessee: *Nothing in this chapter shall be construed to authorize any of the following: Prescribing drugs...*(Tennessee Code Annotated Title 63, Chapter 4, 63-4-101 "Chiropractic" Defined-B Mandatory practices (d)(1).

The authorities established by law and the consensus that has evolved via such widely recognized bodies as the Council on Chiropractic Education and the Association of Chiropractic Colleges represent powerful elements that must be considered and understood in the development of any care delivery program initiative. Legal requirements represent absolutes. Consensus statements, definitions and positions adopted by diverse and widespread professional bodies within the chiropractic profession are part of the self-defining, self-governing process that any serious, mature profession should expect to see emerge. Along with more specific literature and clinical studies, these bodies of "evidence" can and should be an integral part of the body of data on which an objective and complete understanding of chiropractic is based.

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NOTE: Each quotation from state law in the body of this overview section is followed by the appropriate source information. Those references are not, therefore, included in this summary.

BASIC ESSENTIAL CHIROPRACTIC CARE

The doctor of chiropractic is a primary care, direct access, first professional degree level provider who serves as a portal-of-entry into the health care system. ICA understands the term primary care provider to be defined as: Any health care provider capable of providing first level contact and intake into the health delivery system, any health care provider licensed to receive patient contact in the absence of physician referral. All laws and regulations in the United States allow any citizen to seek the services of the doctor of chiropractic without referral from any other provider. Individuals are free to seek basic essential care on the same individual initiative basis that applies to other direct access providers.

Only the doctor of chiropractic is professionally competent to evaluate the chiropractic needs of a patient and to determine the level of service appropriate to meet those needs.

Chiropractic intervention is indicated in all instances where the objective and/or subjective presence of subluxation can be demonstrated and/or in a setting of routine checkups. Patient needs must be individually determined on the basis of recognized procedures, but the issue of clinical necessity of providing adjustive care shall be based on the presence of subluxation, and/or other structural mis-articulations, which may or may not have yet manifested subjective symptoms.

The International Chiropractors Association recognizes subluxation as an acceptable primary diagnosis, and includes the following official policy statement in their body of formally adopted position statements:

> *Subluxation is a responsible and credible diagnosis for the doctor of chiropractic and this condition should be recognized and reimbursed as a primary diagnosis by all third-party payment organizations, both public and private.*
>
> *The analytical/diagnostic determination of a subluxation indicates the need for chiropractic care.*

Chiropractic understands that illness, dysfunction (lack of wellness), etc., is the product of the body's inability to maintain itself or to successfully adapt to its environmental circumstances. While recognizing that illness has multiple origins, chiropractic science holds that under normal circumstances, the self-healing powers of the body will be sufficient to deal with illness or dysfunction. The doctor of chiropractic's duty is to assist the body in this process, and to remove as many barriers as possible to self-healing.

Chiropractic perceives the correction of subluxation at the earliest possible moment as the most basic, essential responsibility of the doctor of chiropractic. The adjustment of the subluxation(s) determined to be present is held by the chiropractic profession to be the unique, fundamental intervention chiropractic has to offer.

From the very beginning, the chiropractic model of health has had as its foundation the maxim that a human being is an ecologically and biologically unified organism. The relationship between a patient's internal and external environment must be understood. A major chiropractic premise is that the inherent recuperative power of the body aids restoration and maintenance of health. These assumptions comprise a wellness paradigm embraced by the great majority of the chiropractic profession.

THE OBJECTIVE DETERMINATION OF SUBLUXATION

The chiropractic literature specifically addresses the means of objectively identifying the presence of vertebral subluxation(s), apart from subjective patient complaints and/or symptoms. Such reproducible, reliable procedures are the cornerstone of chiropractic practice. It is essential to note that the existence of reliable objective indicators are the foundation for the clinical merit of basic essential chiropractic care.

Strong consensus as to acceptable objective procedures has emerged and such procedures have been incorporated into chiropractic education, authorizing legislation and routine chiropractic practice. Kent, Grostic, et al conducted a consensus study employing a variety of sound procedures that identified the following procedures as, "having progressed beyond the experimental stage, and are acceptable procedures for general clinical practice." Those procedures were:

a. Palpation (static and motion).
b. Postural analysis.
c. Orthopedic and neurological examination.
d. X-ray spinography.
e. Video fluoroscopy.
f. Computed tomography.
g. Magnetic resonance imaging.
h. Skin temperature differential analysis, including thermography.
i. Paraspinal EMG scanning.

Of the procedures identified by Kent and Grostic, six represent imaging or instrumentation procedures that are extensively addressed in the scientific literature.

Of the non-imaging and instrumentation procedures routinely employed by doctors of chiropractic, palpation is perhaps the primary procedure most universally applied. Indeed, Hass and Panzer state: *"The hands are the primary tools of the chiropractic and are of utmost importance in identifying subluxation."*

Faye and Wiles define palpation as:

> *"...the use of the tactile senses to determine variations in tissue consistence to recognize whether these variations are normal or abnormal. During palpation, the practitioner senses variations in temperature, shape and contour, textures, resistance, and motion. Palpation is usually conducted with a light, medium, or deep touch, using the pads of the fingertips...There are two basic classifications of manual palpation, static and dynamic."*

Palpation provides the doctor of chiropractic with unique information about the state of the patient and the relationship of the various spinal segments in the patient. Bryner and Bruin found that chiropractic colleges responding to their survey utilize palpation in basic diagnostic instruction, with an emphasis by those responding on motion palpation and "joint play assessment."

Palpation has been a key element in the chiropractic examination process from its very beginnings. D.D. Palmer and Dr. B.J. Palmer both wrote extensively on palpation and co-developed a variety of techniques, including nerve tracing, static and motion forms of palpation.

Akin to palpation, range of motion studies provide the doctor of chiropractic with important information about the state of a patient from individual testing and observation. Meeker writes, *"Assessing the range of limb and trunk motion is still considered to be one of the most objective ways to judge disability of the motor system and is a standard part of the chiropractor's diagnostic procedures."* Blunt, Gatterman and Bereznick offer a highly detailed discussion of mobility in the human spine and attempt to quantify ranges of normal for the various segments of the spine. In their anaylsis, *"the characteristics and analysis of normal dynamic regional and intersegmental motion are explored to understand a deviance from these patterns that characterizes the abnormal motion of a subluxation complex. A continuum of abnormal motion is described, from hypomobility to hypermobility and instability."* Blunt, et al note that, *"...the literature spawns a wide range of techniques used to evaluate and describe ranges of motion."* The utility and validity of all such procedures is related to the degree to which such procedures allow the patient's status to be quantified and measured, and the validity of the scales of normal and abnormal against which an individual patient's findings are compared. There is consensus, however, regarding the importance of range of motion studies in gathering subluxation related information and

such procedures continue to commend themselves to chiropractic practice because of the objective nature of findings.

Muscle testing is also routinely employed in chiropractic practice as a basis for gathering objective indications regarding the status of patients. Meeker writes, *"Assessment of muscle function for strength and quality of contraction is a standard test of the motor system. Manual muscle testing is popular and, indeed, forms the basis of several techniques used by chiropractors."* In the general healthcare literature (Mayer and Gatchel, 1988) muscle weakness is related to a number of complaints and dysfunctions. In recent years, the development of sophisticated muscle testing equipment, including computerized muscle testing equipment, has changed the status of these procedures somewhat from individual evaluations done by the DC to measures that fall into the category of instrumentation.

The essential point necessary to the discussion here is that a wide range of accepted, accurate means of determining the presence of subluxation have been developed and that strong consensus exists within the chiropractic profession as to what those means are and how and when they should be applied.

THE PROGRESSIVE NATURE OF SPINAL SUBLUXATION

Behavior such as physical and emotional stress, tension, chemical/environmental stressor repetitive motion, over-extension of spinal tissues and/or characteristics such as posture, weight, or even footwear can establish patterns of progressive subluxation that lead to the degeneration of spinal segments. Spinal degeneration and its reversibility has been the subject of considerable scientific debate. O.J. Ressell, based on a comprehensive review of 329 published references and a series of detailed case studies concluded that chiropractic intervention not only halted spinal osteoarthritis, but also reversed the deterioration process by measurable levels. Conversely individuals who exercise in a manner that puts the spine through a full range of motion on a periodic basis, develop the supporting muscles of the vertebrae and foster strong circulation, promote spinal health through such activities.

The incidence of spinal degenerative disease is well established. Tencer, et al, stated that osteoarthritis is detectable in 35 percent of the U.S. population by age 30 and Lawrence stated that ten percent of all individuals in the U.S. between the ages of 14 and 24 had roentgeno-graphically identifiable osteoarthritis. Numerous studies have also indicated that spinal degeneration plagues men and women equally and Anderson, Buerger, et al have indicated that osteoarthritis is not influenced by climatic, geographic or ethnic

considerations. Spinal degeneration is demonstrably a near-universal condition. The erosion of spinal tissues is seen by some as simply a natural and predictable manifestation of the aging process. Indeed, the nearly universal incidence of spinal degeneration is powerful evidence that this is a plausible assertion. The response of spinal tissues to the chiropractic adjustment, as demonstrated by Ressell, indicates that the process of spinal degeneration is not an unstoppable process and that chiropractic adjustments revivify the spinal tissues through the restoration of normal nerve function as well as stimulate biochemical changes that enhance the performance of spinal tissues.

The relationship between neurological deficit related spinal degeneration and the subluxation represent one of the most exciting research frontiers of human health. Likewise the health implications of the chiropractic adjustment, which works to eliminate such neurological deficits and conditions caused thereby, is already well established, but requires massive new research if the precise mechanisms of the healing process are to be fully understood.

Spinal degeneration associated with the subluxation complex has been well documented and much written about. Erhardt demonstrated in great detail the progression of the untreated subluxation via x-ray. Lantz, Harrison, Junghanns, and Eisenstein, likewise have shown the progressive nature of the subluxation. Such evidence indicates the high clinical utility of early chiropractic intervention, regardless of the presence of subjective symptoms.

PHASE DEFINITION OF SUBLUXATION

The degenerative nature of the subluxation has been widely described in terms of phases. Commonly, four phases of subluxation degeneration are recognized and have been widely described in the literature. As well, these four phases correspond to x-ray findings and can be demonstrated clearly via diagnostic imaging.

Near Normal: Prior to the emergence of any phase of subluxation degeneration, a patient who is in a state of basic effective functioning can be characterized as near normal. Such patients present with an absence of significant or outstanding clinical indicators and functions within normal limits.

PHASE I - SUBLUXATION

no radiographic degenerative changes
mild aberrant motion
mild muscle involvement
mild local tissue inflammation
mild biochemical changes/pathology
mild soft tissue degradation
mild neurological involvement

PHASE II - SUBLUXATION

mild to moderate radiographic degenerative changes
mild to moderate aberrant motion
mild to moderate muscle involvement
mild to moderate local tissue inflammation
mild to moderate biochemical changes/pathology
mild to moderate soft tissue degradation
mild to moderate neurological involvement

PHASE III B SUBLUXATION

Moderate radiographic degenerative changes
Moderate aberrant motion
Moderate muscle involvement
Moderate local tissue inflammation
Moderate biochemical changes/pathology
Moderate soft tissue degradation
Moderate neurological involvement

PHASE IV - SUBLUXATION

severe radiographic degenerative changes
severe aberrant motion
severe muscle involvement
severe local tissue inflammation
severe biochemical changes/pathology
severe soft tissue degradation
severe neurological involvement

EARLY DETECTION, EARLY INTERVENTION AND "WELLNESS"

Enhanced public awareness of environmental, psychosocial, and physiological issues through education and community action has forced early detection/early intervention into the public health agenda as a significant new priority. Smoking cessation, weight control, nutritional considerations, stress reductions, advice about exposure to environmental pollutants and education in respect to the potential dangers of over-the-counter drugs are examples of initiatives affecting the chiropractic patient population worldwide.

"A new awareness of the contribution of lifestyle, environment, and genetics infused medicine in the decade following. Sometimes called the 'wellness movement', this new orientation broadened the paradigm of traditional biomedicine. Since Dubos' essay on health, a body of research findings has accumulated that demonstrates the validity of a more comprehensive approach to health, one which recognizes the many antecedents and co-factors in the disease and healing process.

"Although not fully accepted by all physicians, the holistic concept of health is gaining stature. Dozens of studies by employers have begun to quantify the beneficial impact of health promotion programs in terms of reduced health care utilization and lower health care costs."

Long-term care concepts and considerations in chiropractic have been discussed by a number of authors. Jamison offers a comprehensive overview of the current trends in chiropractic, and worksheets for health care assessment. McDowell and Newell describe general health care indicators and instruments. Jamison reviews the improvement of basic health status by alteration of behavior, especially through health education.

Some recent surveys focus upon neuro-musculoskeletal chiropractic practice, but other current literature takes a firm stance on the importance of maintaining a focus on prevention and health promotion, through routine checkups.

A detailed analysis of a database collected during a three-year randomized study of senior citizens over 75 years of age revealed that patients who received chiropractic care reported better overall health, used fewer prescription drugs, and spent fewer days in hospitals and nursing homes than elderly non-chiropractic patients. The chiropractic patients were also more likely to exercise vigorously and more likely to be mobile in the community.

87 percent of the chiropractic patients described their health status as good to excellent, compared to only 67 percent of the non-chiropractic patients. Furthermore, the chiropractic patient spent 15 percent less time in nursing homes and 21 percent less time in hospitals than the non-chiropractic patients.

BASIC ESSENTIAL CARE

Subluxation is a progressive condition and it is therefore in the patients' essential interest to have subluxation addressed through the chiropractic adjustment at the earliest moment. Delay in receiving chiropractic care can result in increasingly severe subluxation dysfunction and require an extended period of chiropractic procedures to correct, proportionally prolonged according to duration of the period of neglect.

Such early detection and intervention to address emerging subluxation patterns is basic, essential patient care, and is addressed at the routine checkup and prevention visit. When the objective indicators of subluxation show the presence of a defined spinal lesion, the doctor of chiropractic is alerted to the specific anatomical and physiological basis for chiropractic intervention.

Subluxation(s) have been demonstrated to be present in persons of all ages, from the newborn infant to the most senior citizen. Likewise, authorizing laws and regulations

empower doctors of chiropractic to care for patients of all ages with no exceptions, and chiropractic education instructs professionals in training in the proper procedures and techniques necessary to address the spinal needs of all patients, including infants and the elderly. The Council on Chiropractic Education (CCE) the agency recognized by the United States Department of Education for the accreditation of chiropractic professional programs recognizes no exceptions or limitations on the appropriateness of chiropractic procedures because of age. The International Chiropractors Association recognizes the utility and appropriateness of chiropractic procedures for all persons regardless of age, and views efforts to restrict the access of any age group to chiropractic services as profoundly discriminatory, contrary to the laws of the several states and unsupported by the scientific literature.

Periodic chiropractic examinations to determine objectively the presence of subluxation(s) are in the patient's interest, and are called routine checkups and prevention visits. This is often referred to as maintenance or wellness care. The frequency of the need for such examinations must be determined on the basis of individual evaluation. Such periodic examinations are a vital component of quality basic health care. In the absence of subjective patient complaints of specific symptoms, the doctor of chiropractic must focus on objective measures and fully educate the patient on the status of their condition, and the measures to be taken to achieve optimal health.

Routine checkups provide both patient and doctor with the opportunity to examine environmental circumstances, behavioral factors and individual patient characteristics that may contribute to spinal problems. In addition to the adjustment of any subluxation(s) demonstrated to be present, if at all, in the course of routine checkups, the doctor of chiropractic may assist patients in altering conditions that might contribute to or set the state for on-going and/or progressively severe subluxation patterns. Such care efforts emphasize patient responsibility and may include exercise programs, weight loss, dietary counseling, life style modifications, education on body postures and mechanics, mental attitude, coordination training, safety habits, ergonomics, spinal hygiene, modification of life stressors, etc.

Health care policy makers, providers and consumers are becoming increasingly aware of the merits of early detection and early intervention in all human health concerns. From tooth decay to cancer, the progressive nature of human deterioration means that in both human and economic terms, early detection and early intervention are highly desirable goals.

CHIROPRACTIC PATIENT EVALUATION AND CARE PATHWAY

This decision tree regarding the pathways and evaluation process for a patient presenting at the chiropractic office is based on the doctor of chiropractic's competence to evaluate the general health status and needs of each patient and determine the appropriateness of chiropractic care and/or the need for referral to other provider(s) for urgent care, additional diagnostic evaluation in the context of another branch of the healing arts, concurrent care, or no care at all, etc. It also recognizes that the majority of patients making the decision to seek the services of any health care professional do so on the basis of some self-perceived symptom, problem or health concern, or at the behest of a patient or guardian.

1. Routine Checkup and Prevention/Wellness Care

2. Initial Presentation--Is Emergency Care Needed

Upon presentation of each new patient, the doctor of chiropractic determines whether there is any condition, element or crisis that requires the immediate referral for emergency life-saving care or urgent care.

The attending doctor of chiropractic is competent to determine, on the basis of immediate findings whether the patient is in immediate need of emergency intervention.

3. Initial Presentation--Is the Care of Another Provider Needed

In the course of this evaluation, the attending doctor determines whether there are findings that indicate the need for referral to another provider.

If indications for immediate referral are not present, the patient proceeds along the care pathway to the next level. If such a referral is necessary it does not preclude concurrent chiropractic care.

4. Determining Appropriate Chiropractic Care. Are There Potential Restrictions On Chiropractic Care

The elimination of imperatives to refer having been undertaken, the next step on the chiropractic care pathway centers on the development of an appropriate course of adjustive care, if needed. In that process, the patient's needs and circumstances are evaluated to determine whether there is a need, and if so whether there are any restrictions on the delivery of adjustive care. This evaluation process will direct the attending doctor to employ specific chiropractic techniques that are appropriate to the status of the patient.

5. Care Delivery

Having carefully worked through the evaluation process eliminating potential red flags to standard care and techniques, the doctor of chiropractic next outlines and delivers a

program of adjustive care according to the individual needs of the patient, based on the lifestyles and presenting factors, i.e. phase of subluxation.

6. Re-Evaluation for New Condition(s) and/or Re-Injury

On each encounter, the doctor of chiropractic will determine whether new conditions and/or injuries might require alterations in the care plan. If there are no such indications, the program of care previously devised will continue.

7. Progress Evaluation

After a reasonable period of care, each patient's progress will be evaluated to determine the effectiveness of the chosen course of care and to determine whether alterations in that program are indicated, ad determined by the clinician.

REFERRAL

Referral is a professional obligation that is present throughout all phases and aspects of the chiropractic practice. The primary obligation of Doctors of Chiropractic is to provide the highest quality of care to each patient within the confines of their education and their legal authority. It is the position of the International Chiropractors Association that this primary obligation includes recognizing when the limits of skill and authority are reached. At that point, it is the ICA's position that doctors in all fields of practice are ethically and morally bound to make patient referrals to practitioners in their own and/or other fields of healing when such referrals are necessary to provide the highest quality of patient care. This interchange of professional referrals includes, but should not be limited to, doctors of chiropractic, doctors of medicine, and osteopathy.

Doctors of Chiropractic are also obligated to receive referrals from other health care providers, applying to those patients the same considerations for quality and appropriateness of care as with any other patients. It is the position of the ICA that the professional obligation to the patient includes honest, full and straightforward communication with the referring provider on the issue of optimal patient care.

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A Summary of Studies on Benefits from CHIROPRACTIC CARE

Prepared by the International Chiropractors Association

Chiropractic health care has offered people the benefits of a conservative and natural method of healing without the use of drugs or surgery for over 100 years. It is the second largest health profession in America, with over 50,000 active practitioners, and is a licensed and recognized form of primary health care around the world.

Chiropractic care is directed toward the return to and maintenance of optimal health through spinal adjustment. Manual adjustment of the spine addresses the structural and functional problems that can develop from the effects of misalignment. The vertebral subluxation complex--a complex of disorders resulting from spinal misalignment--can include restriction or loss of movement (from altered muscular function and joint mechanics) as well as deficiencies in nerve transmission, ranging from interruptions in nerve communication functions to manifestations of altered sensations (such as tingling or pain) or loss of perception (such as numbness). Case-specific approaches to patient care, including supportive measures such as rehabilitative exercise, wellness lifestyle advice, and other non-invasive procedures as appropriate to individual case needs, may be included in some programs of chiropractic care.

Both laboratory research and clinical assessment studies through the years find chiropractic care to be both clinically effective and financially efficacious in meeting the needs of patients and in the resolution of numerous health concerns that can range from neck and lower back problems to individual body system functions. An expanding number of individual case studies point to beneficial effects of chiropractic care on many aspects of health and wellness.

Review of Chiropractic Efficiency

While there is a rapidly growing collection of clinical findings from scientifically conducted, randomized clinical trials showing the benefits of chiropractic care, only approximately 15 percent of all medical interventions appear to be supported by solid scientific evidence. Many independently conducted studies on an international scale highlight both the powerful clinical efficacy as well as the outstanding cost-effectiveness of chiropractic care for a wide range of health concerns. The findings range from older studies, from eras when chiropractic's exclusion by organizations such as the AMA made major research funding resources unavailable, to governmental level outcomes assessment projects and formalized scientific measurement by the medical establishment, and also both college-based research and individual practitioners collating clinical data in the field.

There are many prominent studies performed by distinguished institutions reporting on the important benefits of chiropractic care. The following series of summaries prepared by the International Chiropractors Association are a selection of landmark reports that have been published in recent history regarding the efficacy and cost-effectiveness of chiropractic health care.

Government-Related Reviews on Chiropractic Efficacy

The CHAMPUS Report

A comprehensive evaluation of the relevant professional literature collected between 1930 and 1981 examined 18 randomized clinical trials involving chiropractic care that all met the strict research specifications delineated by the Midwest Research Institute. This document noted that, clinically, there was "greater mobility following manipulation" and also "improved lateral flexion and rotation." In addition, this report found that "manual therapy was superior to placebos" and that "the duration of treatment was shorter for the manipulated groups."

This literature review also found that "numerous case studies throughout the literature report the satisfaction of chiropractic patients with the outcome of treatments." **(7)**

The Federal AHCPR Study

A landmark federal study, conducted by the Agency for Health Care Policy and Research of the U.S. Department of Health and Human Services, published their assessment and treatment guidelines in 1994 with the conclusion that chiropractic spinal adjustments are a recommended and effective form of treatment for acute low back problems in adults.

This study validates spinal adjustments as a highly effective form of care and concludes that conservative chiropractic care should be pursued prior to any surgical procedures or prescription drugs. In addition, the study conclusions specifically recommend against procedures such as surgery and prescription medication for acute low back problems. **(19)**

Ontario, Canada Ministry of Health: The Manga Report

A study on The Effectiveness and Cost-Effectiveness of Chiropractic Management of Low-Back Pain, conducted by a team of Canadian health economists commissioned and funded by the Ontario Ministry of Health, was based on an extensive review of international medical research literature. In summary, the report concludes that the best-conducted clinical studies show spinal adjustments by doctors of chiropractic are more effective, safer and more cost-effective than other treatments approaches.

This study finds, in summary, that "many medical therapies are of a questionable validity or are clearly inadequate" and that some are "unsafe" and even cause complications. The study determined that chiropractic care, in contrast, could save hundreds of millions of dollars a year for care of low-back pain alone. **(8)**

Ontario Health Insurance Plan: Manga Report II

This 1998 review of chiropractic cost effectiveness found "a clear need for greater coverage of chiropractic care under private and public insurance systems," and anticipated that this will "assure gains in both efficiency (producing health care services at the lowest costs) and effectiveness (getting the best health outcomes per dollar spent). "

The study reports "considerable empirical support for the cost-effectiveness and safety of chiropractic management of musculoskeletal disorders. This means that chiropractic care can bring about improved health outcomes at a lower cost." In addition, the report showed both an enormous amount of unnecessary direct and indirect cost plus worsening health of the patients from financial and procedural barriers to accessing chiropractic care. Over 80% of patients of chiropractors in the Ontario study had their back pain for more than six months, and had extensive medical and/or physiotherapy care up to the time they decided to see a chiropractor as their condition had not substantially improved under the medical model. The report finds this delayed utilization pattern produces deterioration in health in the patients and an enormous amount of both unnecessary direct and indirect health care costs. It supports increased insurance coverage provisions for chiropractic. **(9)**

Medical Reviews on Efficacy of Spinal Care

Annals of Internal Medicine Article

The article on "Spinal Manipulation for Low-Back Pain," published in 1992 in the third widest-read medical journal in America, reviewed the efficacy of spinal manipulation for low-back pain. The article reported that spinal manipulation was efficacious, and repeatedly found that spinal manipulation was very helpful to patients with acute low-back pain. It specifically called for more research to evaluate the beneficial effects of chiropractic. **(14)**

The 1990 British Medical Journal Study

One of the most thorough clinical trials performed to date in the field of back pain is a 1990 study reported in the acclaimed *British Medical Journal* that compared chiropractic and medical management of patients' low back pain. The comparison showed chiropractic is more effective than conventional hospital outpatient treatment for low-back pain, which included standard physical therapy. In addition, the benefits of chiropractic care persisted over time. In summary, the report indicated chiropractic "confers worthwhile, long-term benefit in comparison to hospital outpatient management." **(10)**

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Economic Reviews on Cost-Effectiveness of Chiropractic

The Richmond Study

A comparison of costs of chiropractors versus alternative medical practitioners conducted in 1992 summarized its extensive economic analysis with the finding that "chiropractic care is a lower cost option for several prominent back-related ailments." It concludes that if chiropractic care is insured to the same extent as other specialties, patients with certain conditions seeking chiropractic care as a first option could very well result in a decrease in overall treatment costs." **(1)**

The Virginia Study

This extensive study of mandated health insurance and chiropractic coverage concluded that while chiropractors may see their patients more frequently in certain clinical cases, their care has lower overall costs for many conditions. The study evaluated multiple parameters of cost and effectiveness that repeatedly demonstrated chiropractic care provides important therapeutic benefits at economical costs. These multiple benefits did not produce any notable increase in the costs of health insurance.

The report concludes that mandating chiropractic care into health insurance coverage provisions would not increase insurance costs but instead potentially reduce them. **(13)**

The MEDSTAT Data Base Review: The Journal of American Health Policy

The MEDSTAT Systems, Inc. Program has developed a database studying a wide range of acute and chronic neuro-musculo-skeletal conditions evaluating the records of 2 million inpatients and outpatients from all major health disciplines.

In summary, the MEDSTAT project has concluded that plans that have limited or no chiropractic coverage have the highest total costs per patient. It also reports that broader coverage of chiropractic services results in dramatically lower health care costs; for example, 35% lower hospital admission rates, 42% lower inpatient payments, and 23% lower total health care costs. **(12)**

Appropriateness of Forms of Chiropractic Case Management

The RAND Studies

The RAND Corporation, one of the largest on-university health sciences research programs in the country, prepared a comprehensive report in 1991 on The Appropriateness of Manipulation for Back Pain. The report discusses findings from a multi-disciplinary group of back pain experts evaluating spinal manipulation. Two RAND panels—one panel of only chiropractic experts and one panel using a mixed group of medical and chiropractic

experts--determined that spinal manipulation is an appropriate approach for many patients with low-back pain.

A second independent multidisciplinary report from RAND titled The Appropriateness of Manipulation and Mobilization of the Cervical Spine, published in 1996, supports the appropriateness of cervical manipulation. The report combined a discussion of literature reviews on effectiveness of manipulation and mobilization with a report on ratings by an expert panel on appropriateness of cervical manipulation for specific conditions. The panel found that cervical manipulation is far safer than "a number of medical treatments" given for analogous symptoms. The report also determined that manipulation is appropriate for many common categories of neck pain and headache. **(15, 16, 17)**

Comparison Studies on Chiropractic Care

The Dutch Study

A comparison study published in the *British Medical Journal* in 1992 evaluated the effectiveness of manipulation for the treatment of persistent back and neck complaints. The chiropractic group showed greater improvement in the primary complaint--as well as physical function--with fewer visits compared to physical therapy. It also demonstrated that manipulation and physical therapy are not interchangeable. This study concluded that manipulative therapy was better than "general practitioner and placebo treatment." The longitudinal benefits of chiropractic care were also demonstrated, with manipulative therapy showing better results than physiotherapy under study re-evaluations after 12 months. **(6)**

The British Medical Journal Study

An extended follow-up research study published in 1995 in the *British Medical Journal* found chiropractic care achieves superior results as compared with standard hospital clinic care for treatment of low back pain. This study randomly assigned 741 patients with low back pain to either standard outpatient care at the hospital or chiropractic care over a three-year period. The chiropractic patients consistently showed superior results and also reported a 29% overall improvement compared with standard hospital care. **(11)**

HMO Model Study

A retrospective study of patients seeking chiropractic care or other treatment at an independent physician HMO compared cost of care, surgical rates, use of diagnostic imaging, and patient satisfaction on claims made for acute low back or neck pain. Results of the study revealed the cost of care for both regions was substantially lower for DC patinets than non-DC patients, and found that use of prescription drugs and diagnostic imaging were significantly greater in the non-DC group. The study found that DC care outcomes and patient satisfaction were nearly identical to non-DC care but at substantially lower costs. In addition to appearing cost-effective as an approach to back and neck pain and being satisfactory to both patients and providers, the study highlighted how DC services can be well integrated in an HMO setting.

Industrial Studies on Chiropractic Efficacy

The Journal of Occupational Medicine Report
The 1991 Utah Study

A 1991 study of workers' compensation claims comparing medical care to chiropractic care and reported in *The Journal of Occupational Medicine* collated 3,062 separate injury cases for conditions with identical diagnostic codes. The sample studied 40.6% of the 7,551 estimated back injury claims from the 1986 Worker's Compensation Fund of Utah.

This study, like many others reviewing the shorter disability and lower costs for patients under chiropractic care for various health concerns, showed dramatic differences in chiropractic efficacy in comparison with medical management for the same condition. In fact, the number of workdays lost under medical care was nearly ten times higher than for those receiving chiropractic care.

This study also examined cost comparisons between medical and chiropractic providers for back-related injuries with identical diagnostic codes. It found compensation costs for work time lost were only $68.38 for patients who received chiropractic care compared to $668.39 for medically managed patients receiving standard, non-surgical medical treatment.

This comparison study also found that chiropractic patients return to work ten times sooner after an injury -- at ten times less cost. The researchers reported "for the total data set, cost for care was significantly more for medical claims and compensation costs were ten-fold less for chiropractic claims." **(4)**

The 1997 Utah Study

A 1997 study of injured workers in the Utah Worker Compensation Fund, published in the *Journal of Manipulative Physiological Therapy*, also favorably contrasted the cost of care by chiropractors in a managed care pre-authorization system with the comparatively escalated costs of treatment by medical physicians.

This retrospective review of 5,000 claims from 1986 and 1989 of injured workers found that costs of cases managed by chiropractors increased only 12% between 1986 and 1989, while the costs of treatment in cases managed by medical physicians increased 71%. In the same time period, compensation costs (wage replacement) only increased 21% for the chiropractic group, while there was a 114% increase for the medical group. **(5)**

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The Florida Worker's Compensation Study

This major 1988 study examined 10, 652 closed cases of patients with back-related injuries who were covered by Florida's workers' compensation law, comparing chiropractic case management with standard medical case management. The results indicated that the duration of temporary total disability was 58.8 percent lower for chiropractic care. In addition, 52.2 percent of all medical patient claimants were hospitalized compared to only 20.3 percent of chiropractic patients. **(20)**

Australian Journal

This retrospective study compared chiropractic and medical management of 1,996 cases of work-related mechanical low-back pain in 1992. The number of compensation days taken by claimants was significantly lower with an average of 6.26 days for chiropractic patients compared to 25.56 days for medical patients, and the average cost of compensation was four times greater for medical than chiropractic management. The comparison demonstrated that not only were fewer compensation days taken by claimants under chiropractic care, but that more patients under medical care failed to progress out of chronic status. The study recommends increasing participation by chiropractors and actually encouraging early referral by medical practitioners of patients with "mechanical low back pain" to maximize the financial and social savings inherent in chiropractic care. **(2)**

Chiropractic Efficacy With Other Health Concerns

There is a rapidly growing compendium of research indicating the potential benefits of chiropractic care with many categories of health concerns. Along with the many case reports of individual cases, there are increasing opportunities for longitudinal and large-population studies in process.

Chiropractic Care of Otitis Media Study

A landmark case study on the Role of the Chiropractic Adjustment in the Care and Treatment of 332 Children with Otitis Media, published in 1997 in the *Journal of Clinical Chiropractic Pediatrics,* tracks the clinical progress of children under care for otitis media through a battery of objective clinical measures. This study's results "indicate that there is a strong correlation between the chiropractic adjustments and the resolution of otitis media for the children in this study." Treatment outcomes measured by such objective measures as tympanographs and otoscopic evaluations indicated average numbers of adjustments for resolution of otitis media was 4.09 adjustments for acute OM, 5.00 adjustments for chronic. **(3)**

Chiropractic Care and Colic

A prospective study of 316 infants suffering from colic and selected according to well-defined criteria shows a satisfactory result of spinal manipulative therapy in 94% of the cases studied. The median age of the infants was 5.7 weeks of age at the beginning of care, conducted at 50 clinics by 73 chiropractors over a three-month period. The results were evaluated by combined review of assessment notes compiled by interview and continuous diary entries taken by the mother. Analysis of the data found that the results reported occurred within two weeks after an average of three office visits. **(1a)**

Chiropractic and Endocrine/Menstrual Function

This randomized clinical pilot study investigated the outcome measures before and after either a spinal manipulation treatment (SMT) or a sham manipulation. The primary objectives of this study were to compare the effects of spinal manipulation on a) circulating plasma levels of prostaglandin F2a metabolite, 15-keto-13, 14-dihydroprostaglandin (KDPGF2a), b) perceived abdominal and back pain and c) perceived menstrual distress in women with primary dysmenorrhea.

Forty-five women with a history of primary dysmenorrhea and age ranging between 20-49 (mean age = 30.3 years) were randomly assigned to either a group receiving spinal care (24) or a control ("sham adjustment") group. Abdominal and back pain was measured with a visual analog scale; menstrual distress was measured with the Menstrual Distress Questionnaire. Both were administered 15 min before and 60 min after care. Blood samples were collected by venipuncture for the determination of plasma levels of KDPGF2a at the same times. The plasma was then assayed for KDPGF2a by radioimmunoassay.

The perception of pain and the level of menstrual distress reported were significantly reduced by care, and the reduction was associated with a significant reduction in plasma levels of KDPGF2a in the SMT group. The study suggests that spinal care may be both an effective and safe nonpharmacological alternative for relieving the pain and distress of primary dysmenorrhea. **(2a)**

Internal Organ Disorders: Ulcers

A clinical trial conducted to evaluate the effectiveness of spinal care with an internal organ disorder compared 11 adult men and women having endoscopically confirmed diagnosis of ulcer disease with 24 cases of uncomplicated ulcerous disease treated by usual medical methods as a control. The experimental group received spinal manipulative therapy (SMT) over a period of 5-22 days with a range of 3-14 procedures, while the control group received traditional medical treatment (drug therapy) and the dietary regimen was standard for both groups. The effectiveness of care was evaluated using clinical parameters and performing weekly endoscopic examinations.

The experimental group experienced pain relief after 1-9 (avg. 3.8) days, and clinical remission an average of 10 days earlier than medical care. Chiropractic practice often

includes patients with gastrointestinal problems who report relief of their symptoms after treatment; the physiological basis for these results is under study. The normalization in segmental trophic innervation of the intestine's mucosal layer from adjustive correction, and positive reaction of the whole body's interactive systems under care, are considered as possible mechanisms. **(3a)**

Hyperactivity and Adjustive Correction

A single subject research design study using blinds between investigators evaluated the effectiveness of chiropractic care for reducing activity levels of hyperactive children. Data collection included independent evaluations of behavior using a wrist watch-like device to mechanically measure activity while the children completed simulated school-work tasks. Further evaluations included electrodermal tests to measure autonomic nervous system activity and chiropractic clinical evaluations to measure improvement in spinal biomechanics.

Improvement in the group as a whole was highly significant ($p = 0.009$) and agreement between each of the tests was also high in this study. In addition, five of seven children showed improvement in mean behavioral scores from placebo care to treatment and four of seven showed improvement in arousal levels. In addition to the indications of behavioral improvement in the results, the strong interest agreement provides impressive evidence that the majority of children in this study did, in fact, improve markedly under specific chiropractic care and indicates that this approach holds potential as an important non drug approach for hyperactive children. **(4a)**

Effects of Chiropractic Spinal Adjustments on Reducing Blood Pressure

This study examined the effects of chiropractic adjustments of the spine on blood pressure and state anxiety. A group of 21 patients with elevated blood pressure received chiropractic adjustments to the T1-T5 levels of the spine. Dependent measures obtained pre- and post-treatment included systolic and diastolic blood pressure readings and state anxiety assessment. Results indicate systolic and diastolic blood pressure decreased significantly in the active treatment condition, while no significant changes occurred in the placebo and control conditions. These findings mirror repeated chiropractic clinical experiences and support the hypothesis that blood pressure is reduced following chiropractic treatment, with potential long-term benefits of chiropractic care on blood pressure needing further study. **(5a)**

Improvement of Vision and Chiropractic Care

This research document reviews the literature regarding connections between the eye, the cervical spine, and spinal care in relation to clinical experiential data, theories for physiological mechanisms involved, and directions for future research in this area. The discussion addresses how visual improvement following spinal care is mentioned by patients more commonly than the appearance

of reports in the literature would suggest, and that the ocular effects of spinal care appearing in the literature include changes in visual acuity, oculomotor function, intraocular pressure, and pupillary size. **(6a)**

Chiropractic Care and Respiratory Function

Asthma and Children

A study of 81 children reported marked improvement in asthma related concerns after being under chiropractic care for 60 days. The children ranged from 1 to 17 years of age and the study showed improvement in 90.1%. The number of asthma "attacks" decreased by an average of 44.9%, and 30.9% decreased their use of medication. The authors concluded that "Chiropractic care, for correction of vertebral subluxation, is a safe, non-pharmaceutical health care approach which may also be associated with significant decreases in asthma related impairment as well as a decreased incidence of asthmatic 'attacks.'" **(7a)**

Chiropractic and Adults

A clinical study involving 55 adult patients, improved pulmonary function was reported in patients receiving spinal adjustments. The study noted significant functional and clinical effects following chiropractic care for the correction of upper cervical vertebral subluxation. **(8a)**

The International Chiropractors Association is the oldest national chiropractic organization in the world. Established in 1926 by B.J. Palmer (son of D.D. Palmer, the Founder of Chiropractic) the ICA represents thousands of practitioners, educators, students and lay persons dedicated to the chiropractic profession. The ICA has traditionally been and continues to be recognized as representing the moderate voice of the chiropractic profession. The ICA represents and promotes the interests of chiropractic, chiropractors and the patients they serve through advocacy, research and education.

Throughout its long history, the International Chiropractors Association has sought to educate and inform the public, other health care professions and health policy makers on the principles and definitions of chiropractic in order to foster a broader understanding and acceptance of the profession. The ICA has also established standards of ethical, technical and professional excellence as guideposts for the Doctor of Chiropractic. For copies of the ICA Policy Handbook & Code of Ethics including a description of the Practice of Chiropractic, contact the International Chiropractors Association.

For more information on chiropractic, call or contact:

International Chiropractors Association
1110 N. Glebe Road, Suite 1000 / Arlington, VA 22201-5722
(800) 423-4690 (703) 528-5000 FAX (703) 528-5023
E-mail: chiro@chiropractic.org **Internet:** http://www.chiropractic.org

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The International Chiropractors Association is the oldest national chiropractic organization in the world. Established in 1926 by B.J. Palmer (son of D.D. Palmer, the Founder of Chiropractic) the ICA represents thousands of practitioners, educators, students and lay persons dedicated to the chiropractic profession. The ICA has traditionally been and continues to be recognized as representing the moderate voice of the chiropractic profession. The ICA represents and promotes the interests of chiropractic, chiropractors and the patients they serve through advocacy, research and education.

Throughout its long history, the International Chiropractors Association has sought to educate and inform the public, other health care professions and health policy makers on the principles and definitions of chiropractic in order to foster a broader understanding and acceptance of the profession. The ICA has also established standards of ethical, technical and professional excellence as guideposts for the Doctor of Chiropractic. For copies of the ICA Policy Handbook & Code of Ethics including a description of the Practice of Chiropractic, contact the International Chiropractors Association.

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Tab 22

White House Commission on Complementary and Alternative Medicine Policy

6701 Rockledge Drive, Suite 1010, MS-7707, Bethesda, Maryland 20817 tel: 301-435-7592 fax: 301-480-1691
E-mail: whccamp@mail.nih.gov Website: www.whccamp.hhs.gov

January 31, 2001

Chris Hibbard, PhD and David Hibbard, MD
Co-Presidents
ISSSEEM Central Office
11005 Ralston Road-#100D
Arvada, CO 80004

Dear Drs. Hibbard:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy, established by the President in March of 2000. In carrying out its mandate, the Commission is addressing: (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at its Web site at <http://www.whccamp.hhs.gov>.

The Commission will meet on February 22-23 to discuss complementary and alternative medicine in terms of education and training of health care practitioners, quality of care, and accountability. To accomplish its goal, the Commission needs your organization's input before it begins its deliberations. Therefore, we would very much appreciate receiving your advice and comments on these issues by **February 13, 2001**, preferably by e-mail or otherwise by fax, so that the Commissioners have enough time to review them before the February 22-23 meeting.

The questions that follow were developed to guide the Commission's deliberations.

1. Are there national educational standards for ISSSEEM undergraduate, postgraduate, and continuing education? Should those national educational standards include exposure to conventional or western medicine as well as CAM other than subtle energies and energy medicine?
2. Should there be national standards or certification to provide CAM practices and products? If so, how and by whom should national standards or certification be established, to whom should they apply, and how should they be implemented?
3. Should the numerous energy healing organizations come together to form "a community?" If so, how and by whom should that "community" be formed?
4. Should there be condition-specific or modality-specific practice guidelines and why or why not? If so, how and by whom should these guidelines be developed, to whom should they apply, and how should they be implemented?

5. Are your members concerned about malpractice liability associated with providing CAM practices and products?
6. Are there any risks associated with CAM that may be of concern to your members? If so, can you suggest ways to minimize those risks?
7. Should there be a mechanism to address consumer concerns or grievances about the quality of CAM practices or products? If so, what should that mechanism be?
8. What information should a conventional health care provider communicate to a CAM practitioner? What information should a CAM practitioner communicate to a conventional provider either with a referral or without a referral as when a consumer self-refers?
9. What policy recommendations would you like to make to assure the quality of CAM practices and products whether they are provided by a practitioner or used as self-care?

Thank you for your invaluable assistance. Please send your written comments to Dr. Joseph M. Kaczmarczyk (e-mail: KaczmaJo@mail.nih.gov, fax: 301.480.1691, phone: 301.435.6197 or 7592), and contact him with any questions you may have.

The February meeting will be held in the Hubert H. Humphrey Building, 200 Independence Avenue, in Washington, DC. You are welcome to attend.

Sincerely,

Stephen C. Groft, Pharm. D.
Executive Director
White House Commission on
Complementary and Alternative
Medicine Policy

DISCUSSION GROUP IV
TAB 22 : ISSSEEM

INTERNATIONAL SOCIETY FOR THE STUDY OF SUBTLE ENERGIES AND ENERGY MEDICINE

February 16, 2001

Dr. Joseph M. Kaczmarczyk
The White House Commission on Complementary
and Alternative Medicine Policy
670 Rockledge Drive, Suite 1010, MS-7707
Bethesda, MD 20817

Dear Dr. Kaczmarcyk:

Thank you for contacting our organization concerning CAM policy. We hope that the following comments will be useful:

1. To the best of our knowledge there are no "national educational standards for ISSSEEM undergraduate, post-graduate, and continuing education [programs]."

   An excellent program, however, was recently put together by Bob and Ann Nunley and Norm Shealy in the Holos University Graduate Program, which is affiliated with Greenwich University.

   In addition, Obadiah Harris, Ph.D., President of the Philosophical Research Society (3910 Los Feliz Boulevard, Los Angeles, CA 90027, Ph. 323-663-2167, Fax 323-663-9443) has just received accreditation for CAM-related programs in the Philosophical Research University.

   One of the main features of these organizations, is that the client is accepted as a "partner" in what is done to handle both "cause and effect" in disease. Therefore, except for acute cases, self-reliance training, mental, emotional, and physical, is begun immediately.

   In regard to "national educational standards:" It seems to us that such standards should "include exposure to conventional or western medicine as well as CAM [methodologies] other than subtle energies and energy medicine."

2. Concerning "national standards of certification" for CAM practices and products: It seems that better than trying to implement "national standards or certification" *at this time* it would be more useful to require a degree, or certification, from a *peer-recognized* training program (such as the Brennan School of Healing, or the Wirkus Bioenergy Institute) or a degree from a *peer-recognized* holistic school, such as Holos, Greenwich, Philosophical Research University, or other University Medical School programs that offer CAM.

   Eventually individual states may become interested in certification of CAM practitioners, but we believe guidelines such as suggested in the immediately-above paragraph, would be more useful, *at this moment in time,* than an attempt to "regulate" a field whose boundaries are in a state of great flux.

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Email: isssеem@compuserve.com • **Website:** www.isssеem.org
Chief Executive Officer: C. Penny Hiemu • **2000-2001 Co-Presidents:** Christine Hibbard, Ph.D and David Hibbard, M.D.

4. Concerning "condition-specific or modality-specific practice guidelines," it would no doubt be an error, again at this moment in time, to attempt to set up guidelines. As yet, we do not have a sufficient intellectual grasp of what "energy healing" might imply, to set up guidelines. Eventually, as educational programs turn out graduate students, such an attempt may become practical.

5. There may exist ISSSEEM practitioners who are concerned "about malpractice liability associated with providing CAM practices and products," but we have not become aware of any such incidents.

6. The only risk that we can visualize "associated with CAM" is in not having a balanced therapeutic team *with a licensed medical doctor as both coordinator and final buck-stops-here leader.*

7. As we see it, mechanisms for addressing "consumer concerns or grievances about the quality of CAM practices or products" should be the same as for any therapeutic practice or product, medical, psychologic, psychiatric, or whatever.

8. Concerning "what information should a conventional health care provider communicate to a CAM practitioner?" To avoid confusing a relatively-unschooled prospective CAM therapist, it seems best to provide only the specific medical information which that particular practitioner might be able to make use of. In other words, this requirement would necessarily take into account the *level of knowledge* of the practitioner.

   For instance, a bio-psychologist using biofeedback-visualization training with clients could intelligently use a good deal more "conventional health-care data," than a "spiritual healer" of the Unity School of Prayer, even though the two practitioners might have essentially-equal levels of effectiveness with clients.

   This potentially-vexing concern would not arise, of course, in a therapeutic referral situation in which CAM procedures and products were handled by a CAM team headed by a board-certified physician. In such a case, the physician in charge would know from long experience what his or her individual team members would need to know, and this would maximize efficiency in use of team talents, intuitive diagnosis, therapeutic touch, massage, prayer, or homeopathy, etc., or a synthesis of modalities— including pharmaceuticals and surgery.

9. "What policy recommendations would you like to make to assure the quality of CAM practices and products?" In a nutshell, if we were sick, we'd rather work with a CAM team whose primary goal was to teach self-reliance, to whatever extent possible, and to aid in "recovery" in all other ways so we'd live another day to learn more about self-reliance and "self care."

Sincerely,

Christine Hibbard

Chris Hibbard, Ph.D., *ISSSEEM Co-President*

Elmer Green

Elmer Green, Ph.D., *ISSSEEM Founding President*

Tab 23

Information to be provided at the meeting

Tab 24

White House Commission on Complementary and Alternative Medicine Policy

6701 Rockledge Drive, Suite 1010, MS-7707, Bethesda, Maryland 20817 tel: 301-435-7592 fax: 301-480-1691
E-mail: whccamp@mail.nih.gov Website: www.whccamp.hhs.gov

February 3, 2001

Executive Director
National Association for Holistic Aromatherapy
P.O. Box 17622
Boulder, CO 80308

Dear Executive Director:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy, established by the President in March of 2000. In carrying out its mandate, the Commission is addressing: (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at its Web site at <http://www.whccamp.hhs.gov>.

The Commission will meet on February 22-23 to discuss complementary and alternative medicine in terms of education and training of health care practitioners, quality of care, and accountability. To accomplish its goal, the Commission needs your organization's input before it begins its deliberations. Therefore, we would very much appreciate receiving your advice and comments on these issues by **February 13, 2001**, preferably by e-mail or otherwise by fax, so that the Commissioners have enough time to review them before the February 22-23 meeting.

The questions that follow were developed to guide the Commission's deliberations.

1. Are there national educational standards for aromatherapy undergraduate, postgraduate, and continuing education? Should those national educational standards include exposure to conventional or western medicine as well as CAM other than aromatherapy?

2. Should there be national standards or certification to provide CAM practices and products? If so, how and by whom should national standards or certification be established, to whom should they apply, and how should they be implemented?

3. Should the numerous aromatherapy organizations come together to form "a community?" If so, how and by whom should that "community" be formed?

4. Should there be condition-specific or modality-specific practice guidelines and why or why not? If so, how and by whom should these guidelines be developed, to whom should they apply, and how should they be implemented?

5. Are your members concerned about malpractice liability associated with providing CAM practices and products?
6. Are there any risks associated with CAM that may be of concern to your members? If so, can you suggest ways to minimize those risks?
7. Should there be a mechanism to address consumer concerns or grievances about the quality of CAM practices or products? If so, what should that mechanism be?
8. What information should a conventional health care provider communicate to a CAM practitioner? What information should a CAM practitioner communicate to a conventional provider either with a referral or without a referral as when a consumer self-refers?
9. What policy recommendations would you like to make to assure the quality of CAM practices and products whether they are provided by a practitioner or used as self-care?

Thank you for your invaluable assistance. Please send your written comments to Dr. Joseph M. Kaczmarczyk (e-mail: KaczmaJo@mail.nih.gov, fax: 301.480.1691, phone: 301.435.6197 or 7592), and contact him with any questions you may have.

The February meeting will be held in the Hubert H. Humphrey Building, 200 Independence Avenue, in Washington, DC. You are welcome to attend.

Sincerely,

Stephen Groft

Stephen C. Groft, Pharm. D.
Executive Director
White House Commission on
Complementary and Alternative
Medicine Policy

The National Association for Holistic Aromatherapy
2000 2nd Avenue, Suite 206
Seattle, WA 98121
206.256.0741

1. **Are there national education standards for aromatherapy undergraduate, postgraduate, and continuing education?**

Yes: NAHA has a committee called "The NAHA Council of Aromatherapy Schools and Educators" (CASE). This committee worked for five years to develop educational standards in the field of aromatherapy. The following includes these standards:

NAHA's Council for Aromatherapy Schools and Educators
In 1999, NAHA's Council for Aromatherapy Schools and Educators formally agreed on Guidelines for Professional Aromatherapy Training. These guidelines have been voluntarily adopted by several schools and independent educators throughout the United States and Canada. If you would like to register your school or name with NAHA please contact the National office at: 206-256-0741 and an education packet will be mailed to you.

NAHA's work in the field of higher education has focused on core curriculum requirements in aromatherapy. Below is an overview of the benefits of core curriculum.

Criteria for utilizing Core curriculum
It is necessary to make curriculum design work to have educators across a wide spectrum of the industry to participate. The needs of students and educators are acknowledged in the Curriculum design and incorporated based upon common ground.

Benefits of a core curriculum:
1. Provides an academic focus and encourages consistency in core material
2. Provides a common focus to share knowledge and expertise
3. Provides a strong foundation of knowledge for success in the field of aromatherapy
4. Provides a clear outline of what students can expect to learn in school
5. Provides the knowledge necessary for higher levels of learning and helps build confidence

Does Core curriculum mean that schools and educators can only teach what it covers?
Recognizing Aromatherapy educators and schools as creative, innovative and unique, it is essential to the vitality of the profession, that each education program be allowed to develop its own unique identity. Therefore each school and educator is able and encouraged to extend beyond the core curriculum.

The National Association for Holistic Aromatherapy is pleased to offer you this directory of aromatherapy schools and educators to help you in your search for aromatherapy education. NAHA highly recommends that you choose a school which fulfills your needs. For further information on the schools and educators listed in this directory please contact the individual schools and educators. NAHA does not endorse any one school nor do we take responsibility for your experience with any school. Complaints and comments regarding a school or educator may be submitted to NAHA's Ethics Committee at: 206-256-0741 or write to the National Office at: NAHA, 2000 2nd Avenue, Suite 206, Seattle, WA 98121.

Approved Standards for Professional Aromatherapy Education

Level Two: Professional Aromatherapy Certification

1. Required Standards of Education/Training

1.1 Schools and Educators wishing to comply with NAHA's Standards of Aromatherapy Training must provide a minimum of two hundred (200) hours of training and practical tuition in the fields of aromatherapy & essential oil studies and anatomy & physiology.

1.2 According to the standards approved and adopted by the Council, Aromatherapy and Essential oil studies should comprise of the following core curriculum requirements:

History and Modern Development
The basics of botany (specifically taxonomy)
Properties of essential oils within a holistic and clinical framework
Methods of extraction
Organic chemistry
Carrier oils
Blending techniques
Methods of application
Safety and Aromatherapy
Consultation and treatment program design
The basics of business development
Legal and ethical issues

1.3 According to the standards approved and adopted by the Council, Anatomy & Physiology training should include:

The following systems to be covered in depth: The Respiratory system and the Integumentary system, and the olfactory process.

Basic anatomy and physiology of the following systems: The Reproductive, Circulatory, Nervous, Endocrine, Lymphatic/Immune, Urinary, Musculoskeletal and Digestive.

Graduating students should be knowledgeable in the structure and function of all the major systems of the human body, together with the clinical science of at least five (5) common ailments of each.

Students entering an aromatherapy program with a degree in health related fields (e.g. Nurses, Massage therapists, Doctors) may test out or be exempt from the anatomy and physiology section only in relation to that part of the training which goes over the structure and function of each system. Pre-existing health professionals are still required to complete training in the application of essential oils to each system and the effect of essential oils on a variety of common ailments.

Any exemption of the anatomy and physiology portion of training should only be allowed when the request for exemption is fully supported by relevant documentation.

2. Required elements for student graduation based upon approved standards in aromatherapy education

2.1.1 Student must complete a 5-10 page research paper.
2.1.2 Student must complete a minimum of 10 case histories.
2.1.3 Student must sit and pass examination offered by school.

Aromatherapy Education
Standards of Training
Level One – Foundations Aromatherapy 30 hours
Curriculum:
Introduction to Aromahistory-focus on ancient cultures
Profiles of 10-20 essential oils
Production and Quality of Essential Oils
Basic Physiology-Methods of absorption, general overview of limbic system, lymphatic system, immune system, and skin.
How oils interact on physical and emotional levels.
Basic aromachemistry with contraindications of certain oils.
How to create a blend, carrier oils, and various methods of application.

ESSENTIAL OILS FOR LEVEL ONE
Cananga odorata
Chamaemelum nobile
Citrus limon
Citrus sinensis
Eucalyptus globulus
Lavandula angustifolia
Melaleuca alternifolia
Mentha x piperita
Pelargonium graveolens
Rosa damascena
Rosmarinus officinale
Salvia sclarea
In addition to the above 12 essential oils listed, 8 more can be chosen by the teacher.

Question 1b: Should those national educational standards include exposure to conventional or western medicine as well as CAM other than aromatherapy?

No, only as an elective. Aromatherapy is a holistic healthcare modality in and of itself. Along with anatomy and physiology and basic pathology one can practice holistic aromatherapy without exposure to conventional or western medicine or other CAM. Many individuals who study aromatherapy are already existing healthcare professionals such as RN's, MD's, Ph.D.'s, Herbalist and Massage Therapists.

Question 2: Should there be national standards or certification to provide CAM practices and products?

As given above, the National Association for Holistic Aromatherapy and CASE have established guidelines for aromatherapy education. Over the next year we plan on furthering our work in this area. There is also another organization called: "The Aromatherapy Registration Council" (ARC). This organization has set up with a

Professional Testing Corporation the first national exam for aromatherapy. You can contact the Professional Testing Corporation for further information about the exam at: 212-356-0660. or You can contact the Aromatherapy Registration Council (ARC) at: Info@aromatherapycouncil.org. With the guidance of the National Association for Competency Assurance based in Washington, DC the aromatherapy industry learned that there needed to be two organizations. One to form education criteria and standards and a separate organization to set up national certification through a national exam. This is what the aromatherapy industry has done between NAHA and ARC.

Based upon 11 years in the industry, I would say that aromatherapy education and national certification is still in its infancy. However, with leaders in the field we are furthering the profession every year by adding to our education programs as well as our awareness of aromatherapy being integrated into other CAM models.

Question 2b: If so, how and by whom should national standards or certification be established, to whom should they apply, and how should they be implemented?

National Standards in aromatherapy education and practice should be implemented and coordinated by the National Association for Holistic Aromatherapy (NAHA). NAHA has been established since 1990 and has valuable relations industry wide. NAHA has also already set standards in place which are being adopted by schools through the United States and Canada.

The Aromatherapy Registration Council (ARC) should be allowed to continue its work with the National Certification exam. As this can be used by employees and the public as a means to insuring they are in contact with a qualified and registered aromatherapist, both through NAHA and ARC.

Question 3: Should the numerous aromatherapy organizations come together to form a 'community'? If so, how and by whom should that 'community' be formed?

To my knowledge NAHA is the only educational nonprofit organization dedicated to enhancing public awareness of the benefits of true aromatherapy. NAHA has been actively involved with promoting and elevating academic standards in aromatherapy education and practice for the profession since 1990. If any community is to be formed than I would of course like to see it formed as a council for NAHA since NAHA has been involved with the industry since its early stages.

Question 4: Should there be condition-specific or modality-specific practice guidelines and why or why not? If so, how and by whom should these guidelines be developed, to whom should they apply, and how should they be implemented?

NAHA's Council for Aromatherapy Schools and Educators is currently addressing the issue of Scope of Practice as well as a clear Code of Ethics for practitioners. I believe that CASE and NAHA needs to put out a questionnaire to all practitioners of aromatherapy to learn more about their scope of practice and how they apply aromatherapy to healthcare needs. There is still much work which needs to be done to answer this question fully. Perhaps we shall be given another time to answer.

Question 5: Are your members concerned about malpractice liability associated with providing CAM practices and products?

Yes, NAHA members have requested liability insurance for their practice. We are currently providing liability to practitioners through the Associated Massage and Bodywork Practitioners Association. (AMBP) We are also looking into other insurance policies for practitioners and business owners. Currently many business owners including manufacturers are getting their liability insurance through the NNFA.

Question 6: Are there any risks associated with CAM that may be of concern to your members?

The main concern of our members is the large amount of individuals who may be practicing aromatherapy without any formal education in the field. Aromatherapy only presents a problem when misused by those without a proper education in the safe application of essential oils.

Question 7: Should there be a mechanism to address consumer concerns or grievances about the quality of CAM practices or products? If so, what should that mechanism be?

In regards to aromatherapy practice, NAHA has an Ethics Board which receives complaints and concerns from both our members and the general public. NAHA has also been issued a federally approved seal called: True Aromatherapy Products (TAP) which we hope will differentiate true aromatherapy products in the market place from synthetic products which call themselves aromatherapy. NAHA is currently creating a separate Trade Association to work with this seal.

Question 8: What information should a conventional health care provider communicate to a CAM practitioner? What information should a CAM practitioner communicate to a conventional provider either with a referral or without a referral as when a consumer self-refers?

A Conventional health care provider needs to communicate a health care history of the client along with any current medication the client is on. This should also include any concerns that the conventional health care provider has on the interaction of allopathic medicine with the CAM practitioner. CAM practitioners should provide conventional providers with details concerning their treatment approach with the client along with all supplements and essential oil applications to be utilized. A consumer should be allowed to choose their own method of health care.

Question 9: What policy recommendations would you like to make to assure the quality of CAM practices and products whether they are provided by a practitioner or used as selfcare?

I believe that CAM practices need to continue to allow individual modalities to regulated themselves from within. Having been involved with aromatherapy for over 12 years now in the United States, I believe that the aromatherapy industry (in reference to its practitioners) is still at a young stage. A stage, which many individuals throughout the United States are continuing to work diligently to advance. NAHA maintains its position within the aromatherapy industry by continually meeting the industries needs. NAHA's mission is to revive the knowledge of the medicinal use of aromatic plants and essential oils to its fullest extent and to restore aromatherapy to a truly holistic professional art and science. Aromatherapists don't want to be doctors, they are holistic practitioners and as such should be allowed to practice within an environment which respects its own limitations and always puts public safety and health before its own agenda. I believe the aromatherapy industry as a whole is capable of strong self regulation for the benefit of the public and the practice.

I thank you for contacting the National Association for Holistic Aromatherapy regarding CAM practices. Please feel free to contact us further should you have any questions. I look forward to hearing about the meeting to be held on February 22 & 23 in Washington DC.

Jade Shutes
NAHA President

Tab 25

White House Commission on Complementary and Alternative Medicine Policy

6701 Rockledge Drive, Suite 1010, MS-7707, Bethesda, Maryland 20817 tel: 301-435-7592 fax: 301-480-1691
E-mail: whccamp@mail.nih.gov Website: www.whccamp.hhs.gov

February 1, 2001

Executive Director
National Ayurvedic Medical Association
P.O. Box 3059
Santa Cruz, CA 95063-3059

Dear Executive Director:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy, established by the President in March of 2000. In carrying out its mandate, the Commission is addressing: (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at its Web site at <http://www.whccamp.hhs.gov>.

The Commission will meet on February 22-23 to discuss complementary and alternative medicine in terms of education and training of health care practitioners, quality of care, and accountability. To accomplish its goal, the Commission needs your organization's input before it begins its deliberations. Therefore, we would very much appreciate receiving your advice and comments on these issues by **February 13, 2001**, preferably by e-mail or otherwise by fax, so that the Commissioners have enough time to review them before the February 22-23 meeting.

The questions that follow were developed to guide the Commission's deliberations.

1. Are there national educational standards for undergraduate, postgraduate, and continuing ayurvedic medical education? Should those national educational standards include exposure to conventional or western medicine as well as CAM other than ayurvedic medicine?

2. Should there be national standards or certification to provide CAM practices and products? If so, how and by whom should national standards or certification be established, to whom should they apply, and how should they be implemented?

3. Should the numerous ayurvedic organizations come together to form "a community?" If so, how and by whom should that "community" be formed?

4. Should there be condition-specific or modality-specific practice guidelines and why or why not? If so, how and by whom should these guidelines be developed, to whom should they apply, and how should they be implemented?

5. Are your members concerned about malpractice liability associated with providing CAM practices and products?

6. Are there any risks associated with CAM that may be of concern to your members? If so, can you suggest ways to minimize those risks?
7. Should there be a mechanism to address consumer concerns or grievances about the quality of CAM practices or products? If so, what should that mechanism be?
8. What information should a conventional health care provider communicate to a CAM practitioner? What information should a CAM practitioner communicate to a conventional provider either with a referral or without a referral as when a consumer self-refers?
9. What policy recommendations would you like to make to assure the quality of CAM practices and products whether they are provided by a practitioner or used as self-care?

Thank you for your invaluable assistance. Please send your written comments to Dr. Joseph M. Kaczmarczyk (e-mail: KaczmaJo@mail.nih.gov, fax: 301.480.1691, phone: 301.435.6197 or 7592), and contact him with any questions you may have.

The February meeting will be held in the Hubert H. Humphrey Building, 200 Independence Avenue, in Washington, DC. You are welcome to attend.

Sincerely,

Stephen C. Groft, Pharm. D.
Executive Director
White House Commission on
Complementary and Alternative
Medicine Policy

Tab 26

White House Commission on Complementary and Alternative Medicine Policy

6701 Rockledge Drive, Suite 1010, MS-7707, Bethesda, Maryland 20817 tel: 301-435-7592 fax: 301-480-1691
E-mail: whccamp@mail.nih.gov Website: www.whccamp.hhs.gov

January 29, 2001

Ms. Sharon Steveson
Executive Director
National Center for Homeopathy
801 North Fairfax Street
Alexandria, VA 22314

Dear Ms. Steveson:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy, established by the President in March of 2000. In carrying out its mandate, the Commission is addressing: (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at its Web site at <http://www.whccamp.hhs.gov>.

The Commission will meet on February 22-23 to discuss complementary and alternative medicine in terms of education and training of health care practitioners, quality of care, and accountability. To accomplish its goal, the Commission needs your organization's input before it begins its deliberations. Therefore, we would very much appreciate receiving your advice and comments on these issues by **February 13, 2001**, preferably by e-mail or otherwise by fax, so that the Commissioners have enough time to review them before the February 22-23 meeting.

The questions that follow were developed to guide the Commission's deliberations.

1. Are there national educational standards for homeopathic undergraduate, postgraduate, and continuing education? Should those national educational standards include exposure to conventional or western medicine as well as non-homeopathic CAM?
2. Should there be national standards or certification to provide CAM practices and products? If so, how and by whom should national standards or certification be established, to whom should they apply, and how should they be implemented?
3. Should the numerous homeopathic organizations come together to form "a community?" If so, how and by whom should that "community" be formed?
4. Should there be condition-specific or modality-specific practice guidelines and why or why not? If so, how and by whom should these guidelines be developed, to whom should they apply, and how should they be implemented?

5. Are your members concerned about malpractice liability associated with providing CAM practices and products?
6. Are there any risks associated with CAM that may be of concern to your members? If so, can you suggest ways to minimize those risks?
7. Should there be a mechanism to address consumer concerns or grievances about the quality of CAM practices or products? If so, what should that mechanism be?
8. What information should a conventional health care provider communicate to a CAM practitioner? What information should a CAM practitioner communicate to a conventional provider either with a referral or without a referral as when a consumer self-refers?
9. What policy recommendations would you like to make to assure the quality of CAM practices and products whether they are provided by a practitioner or used as self-care?

Thank you for your invaluable assistance. Please send your written comments to Dr. Joseph M. Kaczmarczyk (e-mail: KaczmaJo@mail.nih.gov, fax: 301.480.1691, phone: 301.435.6197 or 7592), and contact him with any questions you may have.

The February meeting will be held in the Hubert H. Humphrey Building, 200 Independence Avenue, in Washington, DC. You are welcome to attend.

Sincerely,

Stephen C. Groft, Pharm. D.
Executive Director
White House Commission on
Complementary and Alternative
Medicine Policy

From: Todd Rowe [mailto:toddrowe@igc.org]
Sent: Monday, February 12, 2001 5:45 PM

Response of the National Center for Homeopathy to the White House Commission on Complementary and Alternative Medicine

Introduction

Responding to your questions regarding aspects of homeopathy as a CAM practice presents one special dilemma. Since the preamble to your questions focuses on practitioners and providers, the responses we give below will primarily address that aspect of homeopathy. However, it must be understood that in addition to the use of homeopathy by medically trained practitioners, there is a tradition of non professional use of homeopathy by the American public that stretches back over 200 years.

Pioneers crossing the Great Plains took with them their kits of homeopathic medicines. There are many people who assist their families, friends and others by recommending homeopathic medicines for self-limiting conditions. Most homeopathic remedies are available as over the counter (OTC) medicines. The National Center would not want to limit public access to homeopathic medicines, nor would it support limitations on the ability of individuals to
share their knowledge and experience in using homeopathic medicines.

As an outgrowth of public study and use of homeopathy, in the past 50 years many individuals who are not medically licensed have developed sufficient knowledge, training, and experience in using homeopathy to be able to offer their services to the public. As is the case with homeopathy generally (world-wide), they have demonstrated the excellent record of safety using homeopathy. We would not want to see these individuals prevented from assisting the public with the many health problems that are either self-limiting, resistant to conventional treatment, or for which no effective conventional treatment is available.

We strongly support the freedom of the public to make their own choices regarding their health and the freedom of homeopathic practitioners to serve the public. This includes broadening consumer awareness of the benefits of homeopathy and access to homeopathic treatment. Some people are very concerned that the establishment of standards could be used to limit practice, which would without justification limit citizen access to homeopathy and it myriad practitioners. Nevertheless, we support the principle that standards for professional education and certification developed by the homeopathic community as a whole are an important element of defining a homeopathic profession. These professional standards will assist the public in understanding how homeopathy can be used safely and effectively. It will also assist in improving understanding and communication between homeopaths, other CAM providers, and conventionally trained health care practitioners.

Question #1. Are there national educational standards for homeopathic, undergraduate,

postgraduate, and continuing education? Should those national standards or certification be established, to who should they apply and how should they be implemented.

The consensus from the homeopathic community is that there is a strong need for the formation of both educational standards and certification. The presence of homeopathic standards and certification helps the growth of homeopathy as a profession and lends legitimacy and consistency to what homeopaths do.

The homeopathic community already has in place a certification process. This consists of the Council for Homeopathic Certification (CHC) which certifies all individuals, irrespective of medical training. In addition, there is certification for separate specialties. The American Board of Homeotherapeutics (ABHt) certifies licensed medical and osteopathic physicians, the Homeopathic Association for Naturopathic Physicians (HANP) certifies licensed naturopathic physicians, the National Board of Homeopathic Examiners (NBHE) certifies primarily licensed chiropractic physicians, and the North American Society of Homeopaths (NASH) primarily certifies non medically licensed homeopathic practitioners. In addition, the Council for Homeopathic Education certifies homeopathic schools and educational programs throughout North America.

The current debate in homeopathic certification focuses on whether there should be a single certification board for everyone or separate homeopathic certification boards for each specialty. The National Center has remained neutral in this debate, although strongly supportive of the certification process for all professional homeopathic practitioners.

Descriptions of each of these entities are listed below.

A. Council for Homeopathic Certification

Description: This organization was founded in 1992, in response to a new vision for the future of homeopathy as a unified profession of highly trained and certified practitioners. To date, they have certified more practitioners than any other professional homeopathic organization. Their goals are to create a common standard to establish competence in classical homeopathy, define standards of homeopathic care and professional ethics, administer an exam process to certify homeopaths to this level of competence, assist the public to choose appropriately qualified homeopaths from all professional backgrounds with a national directory of certified practitioners, promote the inclusion of homeopathy within the recognized scope of practice of all health care professions and to cooperate with existing organizations to strengthen the homeopathic profession with an agreed credential and excellence in classical homeopathic training and practice.

Candidates for certification must fulfill educational and clinical experience prerequisites established by the CHC in order to undertake a challenging written exam. Those who pass the written exam subsequently take an oral examination. Successful candidates receive a certificate stating that they are "Certified in Classical

Homeopathy", and are entitled to use the credential 'CCH'. This certification is not a license to practice, but is an important step toward defining a national identity for the homeopathic profession.

Certification by CHC is a public statement of recognition by a practitioner's peers of training, knowledge, skill and competence in classical homeopathy. The certifying board includes homeopaths from major health care professions, as well as the growing group of professional homeopaths. This certification also assists the general public in choosing appropriately qualified homeopaths from all professional backgrounds.

Designation: CCH

Contact:

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Telephone: (408) 971-5915
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chcmail@homeopathy-council.org
http://www.homeopathy-council.org

B. American Board of Homeotherapeutics

Description: The ABHt was founded in 1959 and incorporated in 1960 (New York) for the purpose of promoting the science of homeopathy, and demonstrating its effectiveness to the medical profession, and insuring homeopathy's growth as a viable medical specialty in the U. S. The ABHt grants Diplomate (advanced specialty) status to those medical and osteopathic physicians applicants who meet the prerequisites and successfully pass a written and an oral examination. The ABHt in 1997 has also created a Homeopathic Primary Care Certification for the purpose of creating a minimum standard of competency in homeopathy. The ABHt grants Primary Care Certificate status to those licensed physicians, advanced practice nurses or physicians assistants who meet the primary care homeopathic education/training prerequisites and successfully pass the homeopathy primary certificate examination and who agree to practice within the bounds of their respective medical and homeopathic competence.

Designation: DHt

Contact:

801 N. Fairfax Street, Suite 306
Alexandria, VA 22314
#703-548-7790
Fax: 703-548-7792

C. Homeopathic Academy of Naturopathic Physicians

Description: The Homeopathic Academy of Naturopathic Physicians (HANP) is a specialty society within the profession of naturopathic medicine, and is affiliated with the American Association of Naturopathic Physicians.

The HANP's purpose is to further excellence and success in the practice of homeopathy by naturopathic physicians. It encourages the development and improvement of homeopathic curriculum at naturopathic colleges, sets educational

standards of practice in homeopathy through board certification and the education of naturopathic physicians, publishes the quarterly professional homeopathic journal Simillimum, hosts the HANP Annual case Conference, and offers board certification in classical homeopathy to qualifies naturopathic physicians.

Designation: DHANP

Contact:

Susan Wolfer, Executive Director
Homeopathic Academy of Naturopathic Physicians
12132 SE Foster Place
Portland, Oregon 97266
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D. North American Society of Homeopaths

Description: The North American Society of Homeopaths (NASH) is an organization of professional practitioners dedicated to developing and maintaining high standards of homeopath practice in North America. NASH was created in 1990 and was modeled after the Society of Homeopaths in the United Kingdom, the largest organization in the world of competent homeopaths without medical licenses.

The mission of NASH is to develop and support a qualified and certified homeopathic profession, distinct from, and in cooperation with other medical professionals, and to support the public in its right to receive high quality homeopathic care. To those ends, NASH certifies qualified homeopaths and maintains a directory of qualified homeopaths with the designation of R.S.Hom.(N.A.).

NASH certified homeopaths have met the educational standards and demonstrated their competency through examination and case presentations. NASH requires all applicants to pass the exam administered by the Council for Homeopathic Certification. Non-medically licensed as well as those homeopaths possessing non-primary care licenses are eligible for certification. Registered members are required to adhere to a stringent ethical code.

NASH also acts as a professional membership organization, working to negotiate malpractice insurance policies, working towards legal recognition of the profession of homeopathy throughout North America, presenting an annual conference, publishing an annual journal and a quarterly newsletter, and developing professional support programs for the professional homeopath.

Designation: RSHom

Contact:

1122 E. Pike Street, Suite 1122
Seattle, WA 98122
206-720-7000
Fax: 303-832-8993
www.homeopathy.org

E. National Board of Homeopathic Examiners

Description: The National Board of Homeopathic Examiners was incorporated in 1987. The Board evolved out of a vision of creating standardized interprofessional testing for the advancement of the homeopathic profession. The Board administers an examination every six months which certifies the basic level of proficiency of homeopathic practitioners who successfully pass the exam. Applicants must have previously earned a PhD, D.C., R. Ph., M.D., D. O, A.P., N.D., O.M.D. or equivalent degree and have received specialized training in a Board certified institution.

Designation: DNBHE

Contact:

PMB#832, P.O. Box 15749
Boise, Idaho 83715-5749
208-426-0847
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msassodc@aol.com
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F. Council on Homeopathic Education

Description: The Council on Homeopathic Education (CHE) was founded in 1982 as an independent and autonomous agency. Its goals are:

€ To establish, maintain, insure and improve the quality of education in the science and discipline of homeopathy in the United States and Canada.

€ To act as a resource center for questions regarding the content and presentation of lectures, seminars, academic programs and institutions dealing with the art and science of homeopathy.

€ To establish standards for the above presentations and to evaluate for approval, endorsement or otherwise certify such presentations or institutions.

The Council has been active in evaluating educational training in the United States since 1982. Participating organizations include: the American Institute of Homeopathy; the Homeopathic Academy of Naturopathic Physicians; the National Center for Homeopathy and the North American Society of Homeopaths. The board consists of representatives from member organizations, endorsed schools, and the public at large.

Beginning, advanced and clinical programs are evaluated at graduate and postgraduate levels. Episodic programs for continuing education units (CEU) are endorsed as well.

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212-560-7136

The homeopathic community is in the process of forming educational standards for the homeopathic profession. The National Center is strongly supportive of this process. A rough draft of these guidelines has been written and in the process of review by all organizations in the homeopathic community. These standards should be complete by mid summer of this year.

This document will be available from the Council for Homeopathic Education (see above). The introduction to the document is quoted below.

[3]The Council for Homeopathic Education (CHE), with the support of the Homeopathic Community Council (HCC), held a Summit Meeting of invited representatives of key homeopathic organizations on January 28-30, 2000. The intention of this Summit was to achieve consensus on the homeopathic and medical competencies and standards necessary for the practice of homeopathy in North America. Discussions have continued since that time.

The Council for Homeopathic Education was founded in 1982 with the mission to accredit homeopathic schools and educational programs. In 1999, the CHE identified the establishment of consensus on standards and competencies as a priority necessary to achieve its mission. Accreditation of educational institutions is a function vital to the development and recognition of homeopathy as a health-care profession.

Homeopathy is currently utilized by a wide variety of health-care practitioners in the United States and Canada. The political-legal environment in which homeopathy is practiced is in a state of evolution. These complexities make the job of the CHE in identifying the competencies and standards to which schools must prepare students a complicated task. It is a task that must be undertaken with sensitivity to many perspectives and an awareness that health care in the North America is heading rapidly toward new potentials.

While the Summit group has outlined homeopathic and medical standards and competencies, we emphasize that the means of acquiring these competencies may vary from formal instruction to self-study to clinical supervision. Ideally, the training process will include all three of these elements. The important thing is that the instruction be based on definable standards and that homeopaths must be capable of demonstrating these competencies and proficiencies by the standardized measurements utilized by certification boards.

This document is a draft developed by the representatives of homeopathic organizations who were invited to the Summit and who chose to send one or more representatives. The CHE understands that the statement of standards outlined here is a first step. To become a statement of the will and intention of North American homeopaths, this document must be debated and refined by the larger homeopathic community. One of the positive outcomes of the Summit process was the high degree of consensus among participants from diverse segments of the homeopathic community, including practitioners with and without medical licenses. We believe this heartening outcome is a good omen for the future, and for harmony within the homeopathic profession. Unless otherwise indicated, statements in these documents represent consensus. For those points on which we were unable to agree, we have set forth the arguments for and against so that the larger homeopathic community can make its decision. In fact there were only two such points.

One area where opinions diverged was on whether or not it was necessary to outline potential models under which homeopaths would practice. While some felt it contributed context and substance to the discussion of standards, others felt it unnecessary and ill advised at this time. Also, there was debate about the models themselves. The reasoning on both sides of these questions is given in the Discussion of Models for Homeopathic Practice section so that the community at large can reflect on these issues. We realize that many practitioners have a strong preference for either the word ³client² or the word ³patient² In drafting this document, we had to choose one, for the sake of simplicity. We have used ³client² in most contexts, but we mean it as a neutral word to refer to anyone who seeks homeopathic care.

The Summit process was assisted immeasurably by the monumental efforts of our professional colleagues, national and international, who have spent many hours considering, deliberating and publishing their thoughts on these issues. The documents to which we referred regularly are listed in the Selected Bibliography.

Consensus on standards for classical homeopathic practice will have important implications and benefits for the interdependent components of the homeopathic community -- schools, accreditation organizations, certification boards and professional organizations. Indeed, these standards can lay the groundwork for the recognition of an independent profession of classical homeopathy in the United States.

Summit participants felt that formalizing the homeopathic and medical requirements for the professional practice of homeopathy will lead to greater unity in the profession. This has already proved to be the case within the diverse Summit group, who were able to agree not only on homeopathic competencies, but on medical competencies as well. While this unity may help propel homeopathy into the mainstream, it can only happen if homeopathic principles are honored.

We submit these documents to the North American homeopathic community in the hope that they will be debated and further refined and can become a powerful tool in the strengthening of the homeopathic profession.[2]

Question #2: Should there be national standards or certification to provide CAM practices and products? If so, how and by whom should national standards or certification be established, to whom should they apply and how should they be implemented?

The National Center for Homeopathy is a strong supporter of national standards and the certification process for homeopathic practice. It is crucial however that the various forms of CAM not be lumped together or overseen by a single board. The standards and certification necessary for the practice of homeopathy are quite separate and distinct that the needs of other forms of CAM. It is our feeling that each CAM practice should establish their own set of national standards and their own certification board(s). Each CAM practice should come together as a community to facilitate this process.

With respect to national standards for homeopathic medicines, this is provided by the

Homeopathic Pharmacopeia of the United States (HPUS) as part of the Food and Drug Act. Homeopathic medicines are included only after having met certain scientific standard of proof of indication, and they are manufactured according to FDA guidelines. From time to time, marketers of new products attempt to label them as homeopathic simply because they are dilute, when they do not meet homeopathic standards for administration or inclusion in the HPUS. Any regulatory assistance in prohibiting this practice would benefit the practice of classical homeopathy as well as protecting the public against these untested substances.

Any regulatory assistance in prohibiting this practice would benefit the practice of classical homeopathy as well as protecting the public against these untested substances

Question #3: Should the numerous homeopathic organizations come together to form a community. If so, how and by whom should that community be formed?

The task of coming together to form a community is the central task facing the homeopathic profession in America today. A community is a group of people who get together to share a common interest. That interest, such as homeopathy, is larger than the individual. The ability for various factions in homeopathy to come together will be greatly facilitated by the legitimization of homeopathic practice and the definition of what kinds of patients can be treated by what kinds of homeopathic practitioners. The economic and legal concerns that endanger individual practitioners could then take a back seat to the larger community issues. By coming together as a group, a homeopathic community can be established through which this larger interest can flower and grow. The community can provide the structure that will allow the spirit of homeopathy expression. It keeps the creative spark that is homeopathy alive. Without the existence of a strong homeopathic community, homeopathy cannot grow as a profession.

A strong community can only be grown from within. It cannot be imposed from without, such as by an outside agency. There must be a perceived need and a common bond that unites the community.

Homeopaths have a long tradition of being fiercely independent, rugged individualists. This has made it difficult to form a single all encompassing homeopathic community. However multiple efforts have been made to facilitate the growth of the homeopathic community, which are briefly discussed below.

The National Center for Homeopathy is the largest homeopathic organization in the United States. It is a non profit membership organization and its mission in part, is to grow homeopathy by the establishment of a strong homeopathic community. Its board consists of an eclectic group of practitioners, pharmacists, educators and administrators dedicated to homeopathy. The National Center has increasingly been turning its attention to the growth of the homeopathic community in recent years. It stands ready to assist in the process of community growth.

The Homeopathic Community Council (703-548-7790) is an organization that consists of leaders from the various homeopathic organizations through out the United States. This organization is dedicated to forming dialog and building bridges between the various homeopathic groups, subgroups and factions. Most recently, this organization has not been very active, although it recently helped to fund and sponsor the formation of national homeopathic standards of practice.

Homeopaths Without Borders (970-927-0570 fax) helps to homeopathically treat and educate individuals in under served areas throughout the world. This also includes areas of need in the United States. Through this process, homeopathic practitioners learn to work together, forming strong bonds of homeopathic community. Most of their work takes place outside of the borders of the United States.

There also has been increasing recent discussion of forming a single homeopathic professional organization where all practitioners come together in community. Currently, this is still in the discussion phase, but may be occurring as soon as fall of this year.

Question #4: Should there be condition-specific or modality-specific practice guidelines and why or why not? If so, how and by whom should these guidelines be developed. To whom should they apply, and how should they be implemented?

The National Center would be opposed to the establishment of practice guidelines within the homeopathic profession. Homeopathy does not treat conditions. It treats individuals. An individual seeing a homeopath for treatment of migraine headaches, could need any of 1000 different homeopathic medicines. Condition specific guidelines would simply not be possible in homeopathy.

Modality specific guidelines are equally problematic. One of the most important aspects of homeopathy is the process of individualization. Each patient must be approached individually. For each person at any point in time, the individualized remedy must be found that fits their specific personal characteristics and life circumstances and considers the entirety of their health imbalances and history. Similarly, the methods utilized by homeopaths are also individualized. There are many possible approaches to a given case that may all be effective. To choose only one (modality specific guidelines) would be to destroy the very flexibility of the individualization process that makes homeopathy effective.

However, there is an underlying need for each person's health condition to be appropriately assessed with respect to the nature of their pathology and prognosis. The National Center does support standards of medical competency for homeopathic practitioners.

Perhaps more important than condition specific or modality specific guidelines are the creation of ethical practice guidelines. This should include issues such as providing accurate and detailed professional disclosure of each practitioners training and

background and informed consent, to list just a few.

Question #5: Are your members concerned about malpractice liability associated with providing CAM practices and products?

Homeopathy has an excellent record for safety. The incidence of malpractice cases concerning homeopathy is low. However, for homeopaths licensed in a particular profession, having malpractice coverage may be highly desirable. Recently, insurance companies have broadened their effort to cover the practice of homeopathy.

Most MD[1]s and DO[1]s practicing homeopathy carry some form of malpractice insurance, according to the requirements of the state in which they practice. This is much harder to obtain for homeopathic practitioners who are licensed as acupuncturists or chiropractors. The majority of these individuals work without malpractice insurance. Naturopathic physicians can obtain insurance that covers all aspects of their practice, including homeopathy. Recently, the North American society of Homeopaths has been able to assist some of it registered member in getting malpractice coverage.

Equally important with this issue is finding way to induce insurance companies to help cover the cost of homeopathic treatment. Although medicare and blue cross reimburse for homeopathic treatment, most HMO[1]s still do not include CAM or reimburse inadequately for homeopathic services. Patients often must pay out of their own pocket and this limits the scope and depth of treatment. Given homeopathy[1]s record of safety, efficacy and cost effectiveness, the national cost of health care could be significantly reduced if homeopathy were covered as an alternative to more expensive conventional treatments.

Question #6: Are there any risks associated with CAM that may be of concern to your members? If so, can you suggest ways to minimize those risks?

Generally, homeopathy is a safe form of CAM and the risks associated with practice are few. One concern is the missing of important medical conditions on the part of unlicensed practitioners. The solution to this problem is the setting of standards and national certification that include medical competencies.

Another issue is the inappropriate usage of Over the Counter (OTC) homeopathic preparations, which is complicated by standard FDA labeling requirements that do not fit the homeopathic paradigm. The most important way to reduce the risk is to educate the public as to the nature of homeopathy, how it can be used most appropriately and the importance of seeking well qualified homeopathic practitioners for conditions that are not self limiting or that by their nature or severity require the supervision of a practitioner experience in managing that condition.

Question #7: Should there be a mechanism to address consumer concerns or grievances about the quality of CAM practices or products? If so, what should that mechanism be?

Traditionally, concerns about professional practices have been addressed to the professional organization of which the practitioner is a member.

Traditionally, concerns about professional practices have been addressed to the professional organization of which the practitioner is a member. The National Center feels that each CAM practice should address the concerns and grievances of its own practice and products. Each CAM practice is too distinct and separate to effectively create one organization to over see them all. This is especially true of homeopathy whose central philosophy is quite distinct from that of many other forms of CAM. For example, most forms of CAM utilize a symptom oriented treatment approach, whereas homeopathy focuses on treating the whole individual.

Concerns about homeopathic practices should be addressed through certification (see above, question #1). In homeopathy, there is still controversy about who should best administer the certification process. Concerns and grievances about the quality of homeopathic practice should also be focused on a state level and not federal. Two states exempt homeopathy and other CAM practices from medical practice acts. Currently three states in the country have homeopathic licensure for MD[1]s and DO[1]s. Thirteen states in the country have licensure for ND[1]s. Several states include homeopathy within the scope of practice of acupuncture or chiropractic licensure.

The Federal Drug Administration is the vehicle to address concerns and grievances related to homeopathic products. There is also an organization that helps to oversee the homeopathic pharmaceutical industry, the American Association of Homeopathic Pharmacists (AAHP: 800-478-0421).

Question #8: What information should a conventional health care provider communicate to a CAM practitioner? What information should a CAM practitioner communicate to a conventional provider either within a referral or without a referral as when a consumer self-refers?

This is difficult. Ideally, every practitioner who is participating in treatment of a given patient should communicate and work together in the patient[1]s care. In practice, many conventional health care providers are either openly antagonistic or not interested in their patients CAM treatment.

Even for conventional health care providers that are open to CAM, there are obstacles. One of the central difficulties is language. It is often difficult for conventional health care providers and CAM practitioners to communicate in a language that both can understand. To attempt to reduce CAM practice to the language and diagnostic codes of conventional medicine, is to destroy the very nature of what they do. Rather than reducing CAM to conventional health care, both fields of practice need to find a common ground.

In practice what often works best is a summary of treatment in non technical language, including treatment goals and plans. All referrals should also include

reasons for the referral. Conventional health care providers and CAM practitioners should communicate not only at the outset of treatment but periodically as treatment progresses.

Question #9: What policy recommendations would you like to make to assure the quality of CAM practices and products whether they are provided by a practitioner or used as self-care?

Most importantly, the National Center would be a strong advocate of self determination and health care freedom. Each person should have the freedom to choose whatever practitioner they wish. Each health care practitioner should have the freedom to practice as they wish as long as they obey the central tenet: [3]first do no harm[2]. Homeopathy should be available at all levels of health care.

The National Center is a strong supporter of certification and the creation of standards of practice. It also strongly supports education of the public in regards to homeopathy and homeopathic treatment. For this to be accomplished, there is a strong need for the continued growth and development of the homeopathic community.

Board of Directors
National Center for Homeopathy

Tab 27

White House Commission on Complementary and Alternative Medicine Policy

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January 30, 2001

Christina Herlihy, PhD, Chief Executive Officer
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Acupuncture & Oriental Medicine
11 Canal Center Plaza-Suite 300
Alexandria, VA 22314

Dear Dr. Herlihy:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy, established by the President in March of 2000. In carrying out its mandate, the Commission is addressing: (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at its Web site at <http://www.whccamp.hhs.gov>.

The Commission will meet on February 22-23 to discuss complementary and alternative medicine in terms of education and training of health care practitioners, quality of care, and accountability. To accomplish its goal, the Commission needs your organization's input before it begins its deliberations. Therefore, we would very much appreciate receiving your advice and comments on these issues by **February 13, 2001**, preferably by e-mail or otherwise by fax, so that the Commissioners have enough time to review them before the February 22-23 meeting.

The questions that follow were developed to guide the Commission's deliberations.

1. Are there national educational standards for acupuncture and oriental medicine undergraduate, postgraduate, and continuing education? Should those national educational standards include exposure to conventional or western medicine as well as CAM other than acupuncture and oriental medicine?
2. Should there be national standards or certification to provide CAM practices and products? If so, how and by whom should national standards or certification be established, to whom should they apply, and how should they be implemented?
3. Should the numerous acupuncture and oriental medicine organizations come together to form "a community?" If so, how and by whom should that "community" be formed?
4. Should there be condition-specific or modality-specific practice guidelines and why or why not? If so, how and by whom should these guidelines be developed, to whom should they apply, and how should they be implemented?

5. Are your members concerned about malpractice liability associated with providing CAM practices and products?
6. Are there any risks associated with CAM that may be of concern to your members? If so, can you suggest ways to minimize those risks?
7. Should there be a mechanism to address consumer concerns or grievances about the quality of CAM practices or products? If so, what should that mechanism be?
8. What information should a conventional health care provider communicate to a CAM practitioner? What information should a CAM practitioner communicate to a conventional provider either with a referral or without a referral as when a consumer self-refers?
9. What policy recommendations would you like to make to assure the quality of CAM practices and products whether they are provided by a practitioner or used as self-care?

Thank you for your invaluable assistance. Please send your written comments to Dr. Joseph M. Kaczmarczyk (e-mail: KaczmaJo@mail.nih.gov, fax: 301.480.1691, phone: 301.435.6197 or 7592), and contact him with any questions you may have.

The February meeting will be held in the Hubert H. Humphrey Building, 200 Independence Avenue, in Washington, DC. You are welcome to attend.

Sincerely,

Stephen C. Groft, Pharm. D.
Executive Director
White House Commission on
Complementary and Alternative
Medicine Policy

On behalf of the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM), I wish to thank you for giving us the opportunity to submit comments to the White House Commission on Complementary and Alternative Medicine Policy.

We offer the following responses to the Commission's nine questions.

1. Are there national educational standards for acupuncture and oriental medicine undergraduate, postgraduate, and continuing education? Should those national educational standards include exposure to conventional or western medicine as well as CAM other than acupuncture and oriental medicine?

National education standards for acupuncture and Oriental medicine currently exist at the postgraduate level and are set by the Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM). ACAOM, a private, non-governmental agency that was formed by the Oriental Medicine (OM) educational institutions, "grants public recognition to an institution or program that meets certain established and nationally accepted criteria of quality" (ACAOM Accreditation Handbook, 2000).

Following the same review protocols associated with other systems of institutional and programmatic accreditation, ACAOM requires institutions to complete a comprehensive self-study, which is then submitted for peer review. Site visits and public hearings are always conducted in conjunction with a school's application for accreditation. Programs that earn ACAOM accreditation have been judged to satisfy rigorous criteria under the following categories: clarity and attainment of purpose, legal organization, governance, administration, records, admissions, evaluation, program of study, faculty, student services, library and learning resources, physical facilities, equipment, and financial resources.

ACAOM is the sole accrediting agency recognized by the U.S. Department of Education and the Council on Higher Education Accreditation to accredit professional programs in acupuncture and Oriental medicine. It currently lists 46 programs as accredited or in candidacy status. The majority of U.S. states with practice acts governing acupuncture specify graduation from an accredited institution. The National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) currently specifies graduation from an ACAOM accredited institution or an institution judged to be its equivalent (reviews conducted by independent foreign credential review organizations) as a requirement for national certification.

National accreditation standards for acupuncture and Oriental medicine, as specified by ACAOM, require exposure to conventional or western medicine. ACAOM's core curriculum for education under this category specifies, but is not limited to, the following components: biomedical diagnostic skills, treatment planning that includes making appropriate referrals, and biomedical clinical sciences. Curricula in accredited schools must also include biomedical and clinical concepts and terms; human anatomy and physiology; pathology and the biomedical disease model; the nature of the biomedical clinical process, including history taking, diagnosis, treatment and follow-up; the clinical relevance of laboratory and diagnostic tests and procedures, as well as biomedical physical examination findings; infectious diseases, sterilization procedures, needle handling and disposal, and other issues relevant to blood borne and surface pathogens; biomedical pharmacology, including relevant aspects of potential medication, herb and nutritional supplement interactions, contraindications and side effects and methods of accessing

this information; the basis and need for referral and/or consultation; and the range of biomedical referral resources and the modalities they employ.

The NCCAOM is unable to comment on the efforts by accredited schools to expose students to other CAM specialties. At this time, a national review program similar to that offered by the Accreditation Council for Continuing Medical Education (ACCME) does not exist for the review of continuing education programming in acupuncture and Oriental medicine. The NCCAOM supports and encourages the development of such a program, and until one becomes available, the NCCAOM relies in part on its own continuing education review system, referred to as the "Professional Development Activity (PDA) Provider Review Program." This program reviews professional development coursework, voluntarily submitted by providers, against NCCAOM's own recertification requirements for continuing professional development. The following elements are considered during the review process: outline of the program; summary of the information being presented including a statement as to how it relates to the acupuncture and Oriental medicine fields; qualification of instructor(s); and method of attendance verification.

It is the NCCAOM's understanding that a number of state licensing boards have internal systems for the review of continuing education programs as well. It is also our understanding that ACAOM Accredition Standards require that accredited schools offering continuing education programming must demonstrate adequate resources and administrative structures to support such activities.

Currently, the NCCAOM will accept professional development coursework submitted by candidates seeking recertification that are either taught by an ACAOM accredited school, approved by a state licensing board, or which have been reviewed by the NCCAOM itself.

The NCCAOM encourages the future development of a national continuing education review program for CAM similar to that of the Accreditation Council for Continuing Medical Education (ACCME).

2. Should there be national standards or certification to provide CAM practices and products? If so, how and by whom should national standards or certification be established, to whom should they apply, and how should they be implemented?

The NCCAOM supports the establishment of national certification programs for all CAM practitioners. The NCCAOM is a non-profit organization that awards certification in acupuncture, Chinese herbology, and Asian bodywork therapy based on nationally recognized standards of safe and competent entry-level practice. NCCAOM's voluntary certification programs were established at the request of the Oriental medicine community. Those that have earned the title "Diplomate" of the NCCAOM have satisfied rigorous training and education standards and have been evaluated to have the necessary knowledge, skills, and abilities defined by the profession as necessary for safe and effective practice. Additionally, all Diplomates are required to attest to the fact that they are mentally and physically able to practice, and that they are free from disciplinary action and drug or alcohol dependency. All are required to abide by a 16-item Code of Ethics.

The following outline details the standards of eligibility and examination that must be satisfied by an applicant seeking NCCAOM's certification in acupuncture.

Applicants for acupuncture certification must:

- graduate from a formal, full-time school or college acupuncture program that meets NCCAOM's accreditation requirements (ACAOM Accreditation is the current accepted standard) that can document *at least a three-year curriculum providing a minimum of 1725 hours of entry-level acupuncture education.* The program *must include a minimum of 1000 didactic hours and 500 clinical hours.* The remaining 225 hours may be either didactic or clinical. The program must consist of no less than 27 months of attendance. Correspondence programs do not qualify. One year of school is defined as 450 clock hours in no less then nine months;

or

- complete an apprenticeship (on-going work with a tutor or preceptor who assumes responsibility for the theoretical and practical education and training of the apprentice) *of at least 4,000 contact hours in no less than three (3) years* and no more than six (6) years. To qualify as a preceptor, an individual must either be a state approved instructor in acupuncture or must document five years of experience with a minimum of 500 acupuncture patient visits per year with no less than 100 different patients prior to becoming a preceptor;

- complete a course in Clean Needle Technique to address safety concerns that exist in the area of disease transmission. The CNT course is currently offered by the Council of Colleges of Acupuncture and Oriental Medicine (CCAOM);

- attest to the fact that they are free from alcohol or drug dependency, free from disciplinary action, and are mentally and physically able to practice;

- successfully complete NCCAOM examination requirements, which include a five-hour Comprehensive Written Examination and a separate one-hour examination of Point Location Skills.

The NCCAOM is a member of the National Organization for Competency Assurance (NOCA) and since 1991, has been accredited by the National Commission for Certifying Agencies (NCCA), which sets the highest voluntary certification standard in the United States. Organizations that earn NCCA accreditation are required to demonstrate, through a rigorous system of self-study and peer review, that their programs meet or exceed numerous standards that are organized under the following nine categories:

1) Purpose
2) Structure
3) Resources
4) Candidate Testing Mechanisms
5) Public Information About Programs
6) Responsibilities to Applicants for Certification and Recertification
7) Responsibilities to the Public and to Employers of Certified Practitioners
8) Recertification Programs
9) Criteria for Maintaining Accreditation

Each of NCCAOM's certification programs has been implemented in a manner consistent with the standards of the NCCA.

Currently, 40 states and jurisdictions have laws regulating the practice of acupuncture. Of those, 37 require NCCAOM acupuncture certification to fulfill all or part of their licensure requirements, thus establishing the NCCAOM as the national certification standard in Oriental medicine. Furthermore, 3 states have laws that regulate the practice of Chinese herbology, and of these, all require NCCAOM Chinese herbology certification.

The NCCAOM believes that the profession itself best determines the establishment and evaluation of criteria for safe and effective practice. It, therefore, endorses the idea of self-regulation by all CAM professions with respect to the implementation of national certification programs. The NCCAOM also believes that when public welfare is the highest priority, the accreditation standards of the National Commission for Certifying Agencies (NCCA) serve as the best guide for program implementation. Other CAM programs will be well served by following the national standards of NCCA. Having itself satisfied these standards, the NCCAOM feels that it serves as a sound model for the establishment of national certification programs in other CAM areas.

NCCAOM certification does not include standards relating to products. At this point, however, it is important to note that our Chinese herbology certification exam does require candidates for certification to demonstrate competency in the following areas: methods of preparation and administration of herbal formulas, including dosage, timing, frequency, duration, and form; selection, modification and development of appropriate formulas; indications and functions of representative herbal formulas; internal structures and dynamics of herbal formulas; properties of individual herbs; principles governing the combination of herbs; precautions; and when to make appropriate referrals to other healthcare professionals.

The NCCAOM believes that the profession has acted responsibly in protecting the public welfare, and that certified practitioners of Chinese herbal medicine are qualified to administer Chinese herbal preparations. In that it is our primary mission to protect the public welfare, we would encourage federal support for the following activities: the establishment of an Office of Herbal Products within the FDA; limitations placed on the accessibility of herbal preparations that are currently available for over-the counter consumption by moving certain categories of herbs to a "professional-use only" category, whereby such preparations would only be available through certified/licensed professionals. In a country where categories of shampoo can only be purchased through licensed cosmetologists, placing herbal preparations in a category of "professional use only" seems obvious and prudent.

3. Should the numerous acupuncture and oriental medicine organizations come together to form a "community?" If so, how and by whom should that "community" be formed?

There are many national acupuncture and Oriental medicine organizations in existence, each serving a specific and necessary function. The organizations in the Oriental medicine arena already meet on a regular basis to share information relevant to the profession and to work in a collaborative fashion. While this collaboration is worthwhile and productive, OM organizations are always mindful of the limitations that may be imposed by an individual organization's mission or existing policies. In addition, OM organizations respect that legal barriers imposed

by antitrust laws limit the extent of collaboration on economic issues. With respect to its interactions with other organizations in the profession, the NCCAOM is very careful to observe antitrust laws and all accreditation requirements imposed by its accreditor.

4. Should there be condition-specific or modality-specific practice guidelines and why or why not? If so, how and by whom should these guidelines be developed, to whom should they apply, and how should they be implemented?

The NCCAOM supports the development of condition- and modality-specific practice guidelines in CAM and believes that the profession itself should develop these guidelines. Once developed, implementation could be accomplished through such avenues as accredited education and continuing education programming.

Because acupuncture and Oriental medicine are relatively young professions in the United States, the issues that have been placed high on the priority list are such things as raising public awareness and acceptance; the application of uniform, national standards for education; the application of consistent regulation across states with respect to standards of competency; and equitable reimbursement for practitioners. It will thus be some time before the profession can focus on and funnel the necessary resources to the development of condition/modality-specific practice guidelines. Only with substantial federal funding, similar to that provided to the allopathic medicine profession, will the development of condition/modality-specific practice guidelines happen sooner.

5. Are your members concerned about malpractice liability associated with providing CAM practices and products?

Members of the acupuncture and Oriental medicine profession are as concerned about malpractice liability issues as members of any other healthcare profession.

It is important to note that to date, the acupuncture and Oriental medicine professions enjoy an excellent safety record. The same appears to be true for other CAM specialties. An unpublished study conducted by Beth Israel Deaconess Medical Center's Center for Alternative Medicine Research in collaboration with David Studdert, JD, and Troy Brennan, MD, JD, (www.bidmc.harvard.edu/medicine/camr) reviewed malpractice claims filed from 1990 through 1996 provided by principal chiropractic, acupuncture, and massage therapy insurance carriers. The review indicated that the rates and severity of claims against licensed providers of alternative medicine are lower than those made against medical doctors. Furthermore, survey data provided to the National Acupuncture Foundation by the California Acupuncture Board (www.acuall.org) revealed that from July 1992 to May 1999 an average of 25 complaints (representing 0.5% of licensed acupuncture practitioners) per year were filed. This record is in contrast to the 10,751 complaints (representing 10.1% of licensed allopathic practitioners) filed against physicians as reported in the 1998-1999 Annual Report of the Medical Board of California.

6. Are there any risks associated with CAM that may be of concern to your members? If so, can you suggest ways to minimize those risks?