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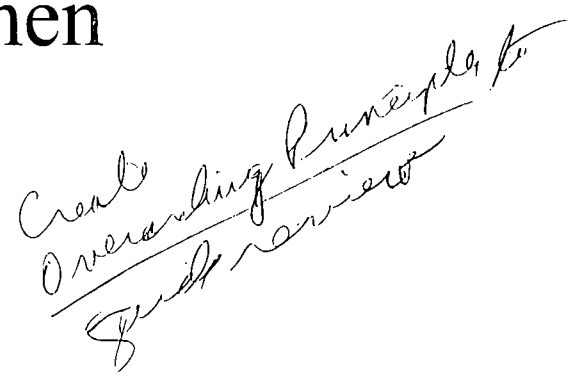

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Michael H. Cohen, Esq. is Director of Legal Programs at the Harvard Medical School Division for Research and Education in Complementary and Integrative Medical Therapies and the Center for Alternative Medicine Research and Education, Beth Israel Deaconess Medical Center. He is a Lecturer in Medicine in the Department of Medicine, Harvard Medical School. He is the author of *Complementary and Alternative Medicine: Legal Boundaries & Regulatory Perspectives* (Johns Hopkins University Press, 1998) and *Beyond Complementary Medicine: Legal and Ethical Perspectives on Health Care and Human Evolution* (Ann Arbor: University of Michigan Press, 2000).

He received his J.D. from Boalt Hall School of Law, University of California, Berkeley; his M.B.A. from Haas School of Management, University of California Berkeley; his M.F.A. from the Iowa Writers' Workshop, University of Iowa; and his B.A. from Columbia College, Columbia University. He served as a law clerk to the Honorable Thomas P. Griesa, in the United States District Court for the Southern District of New York, and as a corporate attorney in the law firm of Davis, Polk & Wardwell in New York.

References:

I would ask that my two books, referenced above, be incorporated by reference into this testimony and be made available to the Commissioners and staff, as appropriate, for scholarly references and more in-depth discussion of the above ideas.

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Written Testimony on Licensure and Credentialing

White House Commission on
Complementary and Alternative Medicine Policy

February 22, 2001

Introduction

Distinguished Commissioners:

I would like to present five key ideas concerning licensure in complementary and alternative medicine ("CAM") from my perspective as a legal scholar in the field:

1. The rationale for licensing CAM providers.

2. Models for licensure.

3. Creating national standards for licensure.

4. Scope of practice issues.

5. Related regulatory issues.

I will conclude with some thoughts on future directions for regulatory authority.

1. Rationale for Licensure.

Licensure refers to the legal authority granted by the state to practice a given health care modality.

During colonial times, licensure was neither afforded to health care providers nor required by the state. Anyone had a common law right to treat the sick with any desired modality.

Physician licensure originated in the 1760's as a means to prevent dangerous or unqualified practitioners from injuring the public, and to ensure greater education, training, and standards for practice. Thus, the original rationale for licensure of health care providers was twofold: fraud control and quality assurance.

By the 1850's, states enacted medical licensing laws, making it a crime to practice "medicine" without a license. These laws reflected attempts to monopolize professional health care. Subsequently states applied these laws against a variety of providers, including naturopaths, massage therapists, herbalists, iridologists, acupuncturists, and spiritual healers. By the beginning of the twentieth century, "Go to jail for chiropractic!" was a popular slogan for the profession.

Since then, four major groups of CAM providers have gained licensure: chiropractic, massage therapy, traditional oriental medicine and acupuncture, and naturopathy. In addition, M.D.-homeopaths are licensed in three states.

From the perspective of CAM providers, the rationale for licensure includes: (1) protecting such providers from prosecution for unlicensed practice of "medicine," and (2) providing legislative recognition of the profession, and thus a gateway to inclusion in hospital credentialing schemes, referrals from M.D.'s and other providers, and insurance reimbursement. These goals accord with public policy interest in respecting autonomous consumer choice, increasing consumer access to CAM therapies, and facilitating integration of conventional care with CAM.

2. **Models for Licensure**.

There are three models for licensure: mandatory licensure, title licensure, and registration. These are three distinct models, although legislatures sometimes use terms such as "licensure," "registration," and "certification" interchangeably (or to mean different things).

Mandatory licensure means that practicing the profession without a license is prohibited. For example: "The unauthorized practice of medicine without a license is prohibited." Anyone who practices medicine without a license to do so can be prosecuted.

Title licensure means that anyone can practice the profession, but one may not use the designated title without a license. For example: "No person may use the title 'massage therapist' without a license." Thus, anyone may offer massage, but any provider who uses the title "massage therapy" without a license may be prosecuted.

Registration means that to practice the profession, a provider must register his or her name, address, and training with a designated state agency. Typically registration imposes lower educational and training requirements than licensure. The state agency has the power to receive consumer complaints and revoke registration.

There are two additional avenues for regulating professional practice. The first is exemption from licensure. For example, religious healers typically are exempt from medical licensing statutes so long as they are practicing within the tenets of a recognized church (for example, praying for the patient and not recommending medication).

The second is the Minnesota model. A new Minnesota statute allows non-licensed CAM providers to practice, so long as they meet a number of requirements designated in the statute. For example, the CAM provider: (1) must not render a *medical* diagnosis; (2) must not recommend discontinuation of medically prescribed treatments; (3) must not engage in fraudulent advertising or deceptive conduct harmful to the public; and (4) must disclose his or her training and theory of practice. The model also establishes a state office to monitor complaints.

A significant body of scholarly literature argues that licensing boards generally do not effectively represent the public in maintaining fraud control and quality assurance. In accord with this critique, the Minnesota model presents a movement away from reliance on licensure as a mechanism of public protection, as well as increased reliance on informed patient choices, utilization of regulation to monitor practices, and a modified return to the common law system. Whether or not this model takes hold, it suggests that states may choose any of the five approaches, either singly or in combination, to regulate professional CAM practice in the future.

3. **Creating National Standards for Licensure**.

The Tenth Amendment to the United States Constitution reserves to the states the "police power," which includes the authority to determine *who* will be granted a professional health care license and *what* will be the requirements for licensure. In *Dent v. West Virginia* (1888), the United States Supreme Court affirmed that under the Tenth Amendment, the state has significant authority to determine who may or may not receive a license to practice professional health care.

State control makes licensure enormously complex. Each state has a different licensing scheme, with different statutory language, regulations, and judicial decisions interpreting these rules.

State legislatures often look to national professional groups to set standards of education and training as prerequisites to licensure, and to create accrediting bodies that can set standards and evaluative criteria for professional educational institutions. Members of CAM professions, however, themselves dispute how much training should be required for licensure in any given field; the extent to which such training should incorporate conventional medical models; and whether and how such education and training can incorporate intuitive and individualized expression of professional health care services.

From the CAM provider's perspective, licensure thus presents a tension between: (1) the desire to increase licensure of CAM providers and increase standardization of CAM education, training and practices across states, and (2) the desire to keep CAM practice flexible, non-standardized, and linked to subjective, interpersonal, and intuitive aspects of care.

This same tension can be seen from a public policy perspective. On one hand, increased licensure of a CAM profession (and increased standardization of licensure) across states may help facilitate research and ease referrals. Some argue that increased licensure also may enhance patient access, and increase consumer protection. Yet, increased licensure and standardization also may result in decreased individualization of services, increased fees, increased patient volume, decrease in time spent per patient, decrease of patient options, and a loss of the "heart and soul" of CAM practices.

In this way, licensure presents a possible "dark side" that often tempers calls for increased standardization and nationalization. This dark side creates conflicts about the desirability of licensure, even within CAM professions, and also tempers interest in more uniform practice guidelines.

4. **Scope of Practice Issues**.

Once states decide to license a given class of providers, they must define the profession and set the *legally authorized scope of practice* for each provider. While medical doctors have authority to use medical education and training to diagnose and treat disease, other providers have a more limited and defined scope of practice.

Some statutes give a general definition of the licensed CAM profession, while others expressly state modalities the provider is or is not legislatively authorized to provide. The legally authorized scope of practice is set forth in these statutes and/or regulations promulgated by appropriate state regulatory boards, and these sets of rules subsequently are interpreted by judicial opinions.

The map of CAM licensure thus is complicated by the fact that some modalities—such as homeopathy or acupuncture —may be included within the scope of practice of several different professions (for example, depending on the state, naturopathy or chiropractic). In other words, quite frequently, no single profession has a state monopoly on the given modality.

Licensed CAM providers who exceed their scope of practice can be prosecuted for unlicensed medical practice. Typical boundary issues between professions include whether acupuncturists can recommend Western as well as Chinese herbs; whether chiropractors can give nutritional advice; whether nurses can offer therapeutic touch; and to what extent massage therapists can offer emotional counseling and support.

The potential for criminal liability creates fear and uncertainty in CAM practice, as it may be difficult to predict boundary violations. Licensed professionals inherently overlap in their scope of practice even in conventional health care. This overlap, and the corresponding conflict between practicing responsibly and managing liability, can become especially apparent when the philosophy underlying a health care profession is to treat the "whole person."

Many licensed CAM providers have a legal and ethical duty to refer the patient to a licensed medical doctor when the patient's clinical condition exceeds the provider's scope of competence. If the provider violates this duty to refer and the patient is injured, the patient may sue for malpractice. In addition, the provider who fails to refer where necessary may face professional discipline from the relevant regulatory board.

The duty to refer helps ensure that CAM providers remain within their scope of competence. This duty arises from the relationship between the provider and patient and depends on education and training, whereas the legally authorized scope of practice often is politically mediated, highly variable by state, and accompanied by the threat of criminal sanctions.

5. **Related Regulatory Authority; Future Directions**.

Licensure is one of several key legal issues in CAM regulation. Related, interlocking legal issues include informed consent, malpractice liability, and professional discipline. The few written judicial decisions (such as *Charell v. Gonzales* and *In re Guess*) suggest that licensed providers may find that merely integrating CAM into conventional care can result in malpractice liability as well as professional discipline.

The regulatory framework governing CAM emerged out of the sectarian rivalries of the late nineteenth century. Regulation in the twenty-first century requires wisdom and vision, or it well may recreate the destructive tendencies presented by history. Much scholarly work is required to guide the judicial, as well as the legislative and executive, branches of federal and state governments.

One potential contribution to regulatory authority, both state and federal, involves perspective. Just as Abraham Maslow proposed that human beings evolve along a hierarchy of personal needs (survival, safety, belongingness, esteem, and self-actualization), similarly, legal authority can be understood as evolving along a hierarchy of regulatory needs. These include fraud control, quality assurance, health care freedom, integration, and human transformation.

These needs are not exclusive, but they do represent different stages of thought about regulating CAM. For example, the values of fraud control and quality assurance represent important aspects of licensure and related regulatory structure, but they are neither the only, nor even the controlling, variables.

The value of health care freedom respects the flow of information such that consumers can make intelligent, voluntary, and autonomous decisions. Legal rules such as informed consent and assumption of risk partly reflect this value.

Integration reflects the value of learning ways in which different medical systems, across cultures and time, can teach our health care system.

Finally, transformation reflects the value of protecting the aspect of CAM that deals with personal and transpersonal, as well as social, wholeness. At its broadest level, transformation involves the maturation of humanity toward notions of individuation, fulfillment, happiness, and even enlightenment and planetary evolution.

A unified approach to regulation would take into account all five levels. This approach presents an opportunity to transcend the sectarian factionalism, competition, and professional monopolies of the late-nineteenth and twentieth centuries, and truly focus on compassion, healing, and the best interest of the patient. Such an approach to regulatory authority could begin to guide and support the next phase of evolution in global health care.

Conclusion

My purpose today is to present some ideas I have developed regarding licensure and regulation. I do not advocate either for or against licensure of any specific group of providers. I also do not present any specific recommendations. This is because I believe that my scholarly views must be tested in the political, social, and cultural give-and-take of the Commission, and of Congress, state legislatures, and associated administrative bodies.

If I can make one general recommendation, however, it is that the power to recommend is the power to create. Let us create the world we choose, and not the world we have inherited.

I look forward to your questions, and thank you for your kind attention.

Respectfully submitted,

Michael H. Cohen

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The Coalition for Natural Health

WRITTEN TESTIMONY

FOR

THE WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY

THURSDAY, FEBRUARY 22, 2001

Mr. Chairman and members of the Commission, my name is Boyd Landry and I am the executive director of the Coalition for Natural Health, a grassroots organization that represents over 2,500 natural healers nationwide. I appreciate the opportunity to address this distinguished panel, today, concerning a matter of utmost importance to my organization's constituency and to the public-at-large. The purpose of today's session is to discuss whether, how, and by whom national standards and/or certification procedures are established for CAM practitioners. I can save us all some time by first addressing the fundamental issue of "whether" national standards are needed. The answer to that question is a resounding no – thus eliminating the issues of "how" and "by whom."

The need for federal regulation in this area may be summarily disposed of for two reasons. One: there is no evidence that traditional natural health therapies pose any material risk to the consuming public so the primary prerequisite for regulation is

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absent. Two: industries that are *heavily* regulated by the government easily account for half of American fatalities (both directly and indirectly) each year – so why assert the supposition that government regulation would enhance consumer safety? And if the issue is not about consumer safety, then what is it really about?

Furthermore, as Jeffrey Goin, my organization's president, pointed out in his testimony to this Commission in the New York Town Hall Meeting, the issues of whether a health-related profession should be regulated and if so how, are within the sole province of the states. The local circumstances and needs that exist in one state are very different from those prevailing in other states. Only the lawmakers, consumers, and practitioners in each state can know what – *if any* – level of regulation is appropriate for their state.

The tenth amendment to the Constitution clearly states, "the powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the states respectively, or to the people." Therefore, we feel it inappropriate for a federal agency, department, or advisory board to insert itself for purposes of mandating, or even recommending processes or guidelines for regulation at the state level. If this Commission were to engage in this activity, it would be entirely unprecedented. The federal government does not set professional requirements and standards for doctors or lawyers, and it should not attempt to do so for natural health practitioners? Additionally, the Executive Order that established the White House Commission on Complementary and Alternative Medicine Policy contained no specific language that directed this Commission to concern itself with matters of regulation or licensing CAM modalities. Again, the establishment and

maintenance of professional standards and qualifications for natural healers as with all local professionals must be left to the states.

Now, back to the point that I made earlier about the real motivation for enacting licensure laws: Nobel Prize winning economist, Milton Friedman once stated, "The justification for licensure is always the same: to protect the consumer. However...observe who lobbies for imposition or strengthening of licensure. The lobbyists represent the occupation in question, not customers...I am myself persuaded that licensure has reduced the quantity and quality of medical practice...It has forced the public to pay more for less satisfactory medical service."

Echoing this point, Walter Gelhorn, renowned administrative law scholar and two-time winner of Harvard's triennial Henderson Prize – the country's highest award for administrative law scholarship once observed, "Only the credulous can conclude that licensure is in the main intended to protect the public rather than those who have been licensed, or perhaps in some instances, those who do the licensing."

Attorney and author, Michael Cohen, in his book, *Complementary & Alternative Medicine – Legal Boundaries and Regulatory Perspectives* (The Johns Hopkins University Press, 1998) states, "Licensure, creating specialization and professional monopoly, has always allowed licensees to fend off nonlicensed competitors." He further notes that medical licensure has proven ineffective in controlling incompetent or fraudulent practitioners. Mr. Cohen also astutely observes, "Since medical licensing boards are staffed by individuals drawn from, and committed to promoting, the licensing profession, medical licensing accentuates the protections of the interests of parties other than patients."

As this Commission well knows, more and more consumers are "voting with their feet" where access to natural health modalities is concerned. A frequently cited 1997 survey in the *Journal of the American Medical Association* (*JAMA*) reported that 42 percent of Americans used at least one of 16 alternative therapies during the previous year. Another intensive study on alternative medicine published in the November 1998 issue of *JAMA* stated that conservative estimates placed consumer spending on alternative therapies at $21.2 billion in 1997; this figure is up from $14.6 billion in 1990. The study further revealed that the majority of people who sought alternative therapy services paid all costs out-of-pocket. Most consumers apparently recognize that the prevention of disease and the maintenance of good health is always a more cost effective approach to healthcare than the necessity to cure a disease.

The Health Care Financing Administration estimates that national health expenditures will double by 2007 to exceed $2.13 trillion. As the dollar figures associated with biomedical delivery continue to skyrocket, it is no wonder that what has been termed the field of Complementary and Alternative Medicine (CAM) is rapidly attracting the attention of both biomedical practitioners and pharmaceutical companies, alike. Cost-effective and prevention oriented therapies present these industries with an opportunity to substantially offset their current costs of operation while simultaneously improving consumer satisfaction. It is eminently reasonably to conclude that money, rather than safety or efficacy, is the driving force behind this newfound attention and the efforts to justify the regulation of natural health care.

It is also interesting to note that until quite recently most natural health modalities were, by and large, ridiculed or shunned by parties to the allopathic medical model – to the degree that many patients were unwilling to admit to their own doctors that they were also clients of a natural health practitioner. However, the recent documentation of consumer interest and the tremendous dollar amount that it represents has transformed "charlatans and quacks" into prime targets for takeover or forced assimilation.

Another reason that exclusionary regulation of traditional natural health therapies is not advisable is because of the enormity, variety and history of the universe of natural healers. This universe includes without limitation generational healers, Central and South American curanderos and curanderas; French treaters; English herbalists; Native American tribal healers; other traditional naturopaths, and a wide variety of energy and other natural healers in this country, who use methods and remedies proven effective over thousands of years, and which have been handed down from generation to generation. We are in many instances speaking of therapies that have been consistently and successfully used for millennia. In other words, *if it ain't broke – don't fix it.*

The objective of the White House Commission should be to enable and expedite the flourishing of natural health in this country, not to restrict it. Growth and availability of these vital services will not come about by giving consumers fewer choices through restrictive licensing and other regulatory procedures that have already proven to be a dismal failure. This is evidenced by the legislatures of 18 states that have soundly rejected this type of restrictive legislation over the last four years. In this regard, if the Commission is to look to any developments at the state level, rather than pursuing a restrictive and exclusionary course

of action such as licensure, it would be more prudent to evaluate the feasibility of implementing innovative and progressive legislation like the "Complementary and Alternative Health Freedom of Access Act" (Statute 146A), which was signed into law in Minnesota on May 11, 2000. This Act listed 22 examples of complementary and alternative health care such as: naturopathy, homeopathy, and herbalism etc. that were exempted from the practice of medicine, thus enabling a variety of natural health practitioners to operate without fear of prosecution. The law mandates that all practitioners be required to present each client with a *Client Bill of Rights* before services are provided. The document must include 17 items of information prior to initiating the consultation.

In conclusion, I would like to reiterate the point that many natural health modalities have histories that predate conventional medicine and our government by thousands of years. And neither our government nor the biomedical community have any business involving themselves in the administration of something that they neither fully understand nor can improve upon – and this should certainly not be allowed to happen under the false pretence of protecting consumers. There is absolutely no evidence that these natural therapies pose any material risk to the consuming public, and the proof of their efficacy is found in the duration of their practice. If the services that these healers offer weren't effective, they wouldn't be flourishing as they are now. Simply stated, the most important litmus test for these service providers should be the one administered by consumers and the competition of the free market rather than unnecessary attempts at restrictive and exclusionary regulation.

Thank you for your time and attention.

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Hall

Divider Title: _____

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Sharon Hall	**Vice President, Risk Management**

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	YEAR	FIELD OF STUDY
Lincoln General School of Nursing, Lincoln, Nebraska	diploma	1975	Nursing
University of Nebraska, Lincoln, Nebraska	B.S.N.	1978	Nursing
University of South Florida, Tampa, Florida	M.P.H.	1989	Health Policy & Management

Employment

1978-1986	Held varying positions in clinical nursing practice, nursing education and management in hospitals, extended care facility, and university setting
1986-1989	Risk Management, Humana Hospital- Lucerne, Orlando, Florida
1989-present	Progressive levels of responsibility within the Risk Management Department to current position of Vice President, Washington Casualty Company, Bellevue, Washington

Licensure/Certification

- Associate in Risk Management (ARM) – Insurance Institute of America
- Professional Nurse Licensure in Washington State

Professional Affiliations

- Washington Healthcare Risk Management Society
- American Society for Healthcare Risk Management
- Risk and Insurance Management Society

HEARING OF THE WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY
February 22 – 23, 2001

Testimony of
Sharon L. Hall, Vice President Risk Management, Washington Casualty Company

Washington Casualty Company is a licensed medical malpractice insurance carrier in the Pacific Northwest. The company started providing liability insurance for complementary and alternative medicine (CAM) practitioners in 1995. The following testimony is based upon our experience in providing insurance and risk management services for naturopathic/homeopathic physicians and acupuncturists in the Northwest.

Washington Casualty Company requires completion of an application form and copies of the following documents, which are reviewed by our underwriters:

- current license or certification
- current curriculum vitae or resume
- informed consent form utilized
- consultation, emergency transfer & referral plan
- any advertisements, promotional or marketing materials utilized
- letterhead and billing statement
- declarations page of current malpractice insurance

Special attention is given to continuing medical education courses, nature of practice, claim history, and past disciplinary investigations or proceedings. For naturopathic physicians, inquiry is made into the practice of acupuncture and obstetrics.

Legislation in Washington state requiring health insurers to cover services by all licensed or certified healthcare providers in the state including CAM practitioners and licensure laws has led to the formalization of certain CAM practices. Examples of these are referral arrangements and informed consent documentation. Requirements imposed as a condition of reimbursement for services has also necessitated CAM practitioners to develop more guidelines to address standard operating practices.

Conventional medical practice has initiated the development of clinical practice and case management guidelines for various types of diagnosis and treatment. These are being utilized as a standard for care in many clinical settings. While certain procedural guidelines can be successfully developed and utilized to promote standards of care in CAM, additional research is needed to validate the safe and effective use of various modalities of treatment. If national practice guidelines are developed, CAM practitioners must utilize the guidelines in their practice or document in individual circumstances the rationale for guidelines not followed. In both cases, compliance with guidelines or the lack thereof, may be used in a malpractice case by either party to advance their position.

Our experience indicates that claims against CAM practitioners for negligent care are less frequent and generally associated with less severity of harm than claims against conventional health care providers. Our loss experience for homeopathic/naturopathic physicians are double that of acupuncturists. When a similar comparison is made between homeopathic/naturopathic physicians and insured family practitioners/internal medicine physicians, the CAM physician loss experience tends to be five times lower. This analysis is based upon open and closed claims reported to Washington Casualty Company from 1995 through 2000. Due to the fact that some claims have not been resolved, additional payments and expenses may be incurred. Also, some claims may not yet have been identified or reported. Differences in the loss experience between insured CAM practitioners and conventional physicians have not been formally studied in our organization, but may be attributed to a number of factors associated with CAM practice. Among these may include more active patient involvement in their own treatment regimen, more time spent with the patient, comprehensive medical/social history taking and a practice that involves less invasive procedures with less risk of complications.

Recommendations:

1. Educate conventional medical practitioners about CAM to promote collaboration in patient care and to avoid possible adverse effects related to the interaction of various treatment modalities.

2. Consider state licensure/certification of CAM practitioners to regulate and provide a common standard of practice.

3. Support evidence-based research to demonstrate the efficacy and relative safety of CAM therapies.

4. Promote confidential non-discoverable CAM quality improvement and peer review activities to enhance the quality of care.

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Olsen

Divider Title: _____

Steven Olsen
AMTA

WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY (WHCCAMP)

HEARING DATES: February 22-23, 2001

BIOGRAPHICAL SKETCH:
Steven C. Olson, BA
Massage Therapist,
Licensed in North Dakota
Nationally Certified in Therapeutic Massage and Bodywork (NCTMB)
President, American Massage Therapy Association (AMTA)

Steve Olson is President of the American Massage Therapy Association (AMTA), a professional membership association with more than 44,000 members. AMTA promotes and develops appropriate professional and educational standards; maintains a code of ethics; is active in the formulation of legitimate certification and accreditation processes; supports research via the AMTA Foundation; assists its chapters in state legislative efforts; and, acts as a resource on massage and massage therapy issues for the media, legislative bodies, consumers, and governmental agencies. Prior to serving as president of AMTA, Steve has been a Vice President and a regional representative to the Board of Directors of the association.

Mr. Olson has held the designation of NCTMB since 1993; has been licensed in North Dakota since 1985; and has been actively studying manual approaches to health care since 1975. His education includes a BA in biology and chemistry from Concordia College, and massage training in Washington State. To further his understanding of various types of massage, Steve has twice studied in China. His massage practice has been broad-based: massage therapist on staff for two nursing homes in Fargo, North Dakota and sixteen years in private practice serving individuals, the community and businesses. He has been a speaker and leader of workshops at approved continuing education events for the professions of massage therapy, nursing and social work.

WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY (WHCCAMP)

HEARING DATES: February 22-23, 2001

MEETING TOPIC: Training, Education, Credentialing, and Licensing
Specific questions (in the context of the future): massage licensure, recommendations for education and training standards to achieve licensure, and how the public benefits from regulation.

INTRODUCTION

Before entering into my comments centered on the topics specified for this hearing, I would like to make a few general comments regarding the collective history of massage, a snapshot of where we are today and a bit about the American Massage Therapy Association, or AMTA.

HISTORY

The practice of manual therapies extends into the distant past and can be said to have existed since humans first organized themselves into groups. They have been present in all cultures in all periods of history. As is the case for some other therapies, they predate the practice of allopathic medicine. In western traditions, the massage approach was systematized in the mid-1700s.

While we think that the current effort to consider whether massage therapy should be included in the practice of medicine is unique to this time, we have been here previously. In the 1930-40s, practitioners of soft tissue manipulation faced the very same issue. Many masseurs and masseuses were invited into the world of physical therapy. Of those who decided to continue outside of the allopathic medical model, a group gathered in 1943 and formed AMTA.

As a profession we owe a great debt to these individuals. In effect, they kept alive the body of knowledge that has emerged as the verifiably distinct profession and practice of massage therapy.

TODAY

The snapshot we are presented with today is very interesting:

- Massage therapy has been identified by numerous sources as the second most utilized approach in the world of CAM.

- According to consumer surveys commissioned by AMTA, the use of massage therapy among adult Americans has doubled since 1997.

- Our surveys also tell us that massage therapy is overwhelmingly perceived by the public as having therapeutic and/or medical benefits.

- 44% of American adults think massage therapy should be among the core benefits of their health plans.

- The consumer's voice is clear: they value what we do.

- From the practitioner side, AMTA members tell us approximately 15% of their practices are medical in nature, while the majority identify more closely with the description of working within the wellness and relaxation models.

- In the last five years, AMTA has almost doubled its membership. We are the primary voice in the profession and our profession is a major player in the world of CAM.

TRAINING AND EDUCATION

The topics of education and training have been addressed in our preliminary documentation. To summarize:

- The training of massage therapists is carried out by proprietary and undergraduate institutions;
- AMTA established the AMTA Council of Schools in 1982 for the purpose of establishing educational standards for massage therapy. There are currently 235 Council members, from a field of about 700 schools of various levels;
- In 1989, in conjunction with the Council of Schools, AMTA created a commission to approve and accredit massage schools;
- In November of 2000, the Commission on Massage Therapy Accreditation (COMTA) submitted its petition for recognition as an accrediting agency to the U.S. Department of Education;
- COMTA currently accredits 53 massage programs, which have demonstrated a required level of competence.
- At the request of other associations and schools, COMTA will be developing standards to accredit programs teaching Asian bodywork.

When COMTA receives its approval as an accrediting body, the profession of massage therapy will join the professions of acupuncture, chiropractic and naturopathy in having an accrediting body internal to the profession that addresses both institutional and programmatic accreditation. AMTA has made the promise to COMTA to provide financial support in perpetuity.

There are several other accrediting bodies that are serving massage therapy schools. However, none of them are currently able to thoroughly examine the programmatic side of massage programs. It is critical to the profession to have a valid accrediting body that can focus on the subject matter being taught to future massage therapists.

One of the major challenges in the training of massage therapists is to teach the manual skills needed to be successful. The profession must rely on training programs to provide these skills to students, as they are virtually impossible to measure with any validity when it comes to testing for licensure.

The length of educational programs is not uniform throughout the country. Where massage therapy is regulated, certain parameters are provided legislatively. In regulated states, the range of education requirements varies from 300 to 1000 in-class hours. In lesser jurisdictions (cities and counties), it's pretty complex and even weird. Some cities require as little as 80 hours (this is usually a tip that the "massage" that is occurring is really adult entertainment). Other municipalities, like Tucson, AZ, require a hefty 1000 in-class hours of training. So, when legal requirements for licensure of massage professionals are low, schools typically adopt that minimal number of training hours. Of course, there are programs that offer training that exceeds local and state minimum standards.

The current standard utilized by both COMTA and the AMTA Council of Schools is 500 hours. As an accrediting body, COMTA regularly assesses the profession in order to determine if a shift in the number of total training hours, or defined course of study is needed. AMTA is comfortable with standards developed by COMTA.

CREDENTIALING

AMTA has been focused on standards for most of its 58-year history. When there were few, if any, regulated jurisdictions, membership in AMTA was the lone standard that separated the legitimate practitioner from those doing the "other kind of massage". In unregulated areas, AMTA membership is often presented as if it were a credential; AMTA does not view membership as a credential.

AMTA has done the necessary and expensive work that identifies massage therapy as an independent and separate profession with its own unique body of knowledge. This led to the establishment of a credential that is statistically verifiable and approved by an external body that oversees credentialing processes, the National Commission of Certifying Agencies. In 1990, AMTA initiated the formation of the National Certification Board for Therapeutic Massage and Bodywork, a separate and independent organization to carry out this work. You will see this credential noted by the letters NCTMB – which stand for Nationally Certified in Therapeutic Massage and Bodywork.

NCTMB is our field's only true credential; we call it the "big C".

One of the challenges of being in an emerging profession involves the use of the word certification. Practitioners use the term very loosely; most references to certification could be termed "certification with a little c", and can mean many things:

- A school training program may certify – you would need to know about the institution and its curriculum to know the value of the certification. Is it accredited and by what standards? What type of accreditation (institutional, programmatic)? Is the school operating legally in its jurisdiction?
- A political jurisdiction may certify a practitioner. But the question is what are the standards utilized?
- Individual educators or organizations may certify (I can certify you in the Steve Olson Method). This is even more difficult to understand in terms of validity.

So, NCTMB is our field's only true credential.

REGULATION

The laws governing massage therapy are not uniform. Currently there are 29 states and the District of Columbia that regulate massage. Some states regulate massage as a medically related profession, others as an occupation. Most provide title protection. At least one state has two levels for the profession: therapist and practitioner.

AMTA's efforts to identify the legitimate practice of massage therapy extend back to 1955. We created a draft legislative document called the Massage Registration Act. Amazingly, AMTA members succeeded in having this adopted in several states, including my home state of North Dakota in 1959. The legacies of these early efforts linger in many jurisdictions.

AMTA's current efforts regarding legislation are supported by our strategic plan; we encourage regulation at the state level. In states that do not regulate the profession, the city and county levels often adopt regulations. Unfortunately, many of these local laws focus on controlling "massage" in the context of adult entertainment, not the legitimate profession of massage therapy. It is strange, but by simply crossing a municipal or state boarder you can go from an area that treats massage therapy respectfully, to one that mandates that a practitioner have a felony check and an annual certification that they are free from sexually transmitted diseases.

AMTA is organized as a national membership association. Our members express their wishes at the state level via AMTA Chapters. While AMTA is supportive of state legislation, we rely on our Chapters to identify legislative goals. Therefore,

- We have a Government Relations Program that provides expertise to chapter leaders in establishing regulations favorable to the profession.
- We have established a legislative granting process to assist chapters with funding their legislative efforts.
- We regularly offer training for our members in how to enter the legislative arena.
- We monitor and track legislative bills that potentially affect the massage profession.
- We work cooperatively with other associations in legislative efforts and support coalitions between massage and bodywork groups.
- We provided a forum for the initial gathering of the Alliance of State Regulatory Boards of Massage Therapy.

One of the most difficult aspects of legislation rests in the area of scope of practice. We have worked diligently to develop language that provides massage therapists with the broadest definition possible. We have had to be careful to not "step on the toes" of other licensed professions and to take into consideration what legislatures are willing to accept. In all cases, we have accepted the political reality that our scope of practice must respect other professions that share all, or part, of our proposed definition of practice.
Consequently, there are often legislative exemptions provided for a myriad of professions to use the modality of massage, as they perform under their scopes of practice. A typical list includes chiropractors, medical doctors, physical therapists, nurses and cosmetologists/barbers.

The latest challenge to the development of scope of practice language revolves around allied practitioners who claim they do not practice massage therapy and wish to be exempted from

regulation. While this further complicates our desire for a clear definition of our scope of practice in the legislative world, we are making the necessary adjustments. The difficulties include trying to help legislators understand the practice parameters of "energetic" approaches, somatic practices and those stemming from the practice of modalities based on other medical theories, like traditional Chinese medicine. Based on AMTA's adoption of definitions of massage therapy, massage, therapy, and manual, we believe that our members can safely practice in many of the areas which other practitioners believe to be an infringement on their described scope of practice.

We will continue to work with allied associations to sort out these differences. We insist that they be a voice at the table in convincing legislatures that they should be granted an exemption from massage laws. We insist that they develop standards for the areas of what they believe are separate and distinct professions.

By being active legislatively, we are serving the best interests of the consumer and our profession. In licensed jurisdictions, consumers know that they have access to qualified professionals and recourse for complaints with a public governing board. Licensing may also assist the consumer obliquely by offering insurance companies a method of identifying qualified providers. AMTA works to remove local zoning laws that force massage therapists to operate in areas specified for adult entertainment businesses.

Our legislative and ordinance agendas can be summarized as follows: we wish to be regulated as a profession with appropriate standards in service to the consumer; we want the consumer to be guaranteed access to our services without a gatekeeper; we will cooperate with all legitimate practitioners who have established standards; and, we will work toward a clear scope of practice which includes permitting us to relieve muscular discomfort, focus on wellness and provide for stress reduction.

CLOSING

AMTA believes that massage therapy is a valuable part of wellness and health, that connects mind, body and spirit. There are some basic aspects of massage that consumers can learn for self-care, but massage therapy should be practiced by a person with sound training, knowledge and experience. Massage therapy is something that is and should be available to people at all levels of society and practiced in a caring, professional and ethical manner, in order to promote the health and welfare of humanity.

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Bezold

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Clement Bezold, Ph.D., president of the Institute for Alternative Futures and its for-profit subsidiary Alternative Futures Associates, received his Ph.D. in Political Science from the University of Florida. As a "futurist" he has applied scenarios and visioning techniques to help public and private organizations and international, state, and local governments more wisely choose and create the futures they prefer.

Dr. Bezold is a leading health futurist. He has developed concepts that have accurately described aspects of how the health care system and therapeutics will evolve. He has published widely on what might occur in health care and how we can choose the best possible outcomes.

He has led IAF's futures work with several government agencies (both health related agencies - VA, HHS, CDC, NIH, and other agencies GSA, DoD, DoJ). He has consulted with the World Health Organization in Geneva and its European Office (WHO/EURO) as well as the Pan American Health Organization (PAHO) on enhancing their ability to use health futures in their operations, particularly in support of WHO's vision of Health For All.

Dr. Bezold has coached many organizations, states and local communities in achieving their vision. These include futures projects for state legislatures, governors offices, courts in over 20 states and in communities across the US as well as for the American Cancer Society, the Disney Development Corporation and Celebration Health.

He is directly involved in AFA's private sector work; particularly doing scenario and vision coaching for global corporations.

Dr. Bezold has published books and reports on the future of government, the courts, and health care. His recent reports include, *The Future of Complementary and Alternative Approaches (CAAs) in US Health Care* and *The Future of Chiropractic: Optimizing Health Gains*. These reports provide the results of an 18-month study of major CAAs (chiropractic, Oriental medicine, and homeopathy) in the context of the key trends shaping health care. He has authored or edited several books on pharmaceuticals and biotechnology including *The Future of Pharmaceuticals*, *2020 Visions: Health Care Standards and Technologies* a USP book. His book (with Rick Carlson and Jonathan Peck) *The Future of Work and Health*, won American Health Magazine's Book Award. His articles have appeared in *The Futurist, Healthcare Forum Journal, Business and Health, Home Care,* and *Hospital & Health Service Administration*. He has taught at the University of Florida, Antioch University and American University.

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Statement
To
The White House Commission on
Complementary and Alternative Medicine Policy
By
Clement Bezold, Ph.D.
Institute for Alternative Futures
www.altfutures.com

Session on CAM Credentialing and Licensure:
Assuring Quality and Accountability in CAM Practice
February 22, 2001
Humphrey Building

Introduction

It is an honor to present my thoughts and recommendations to the White House Commission on Complementary and Alternative Medicine (CAM) Policy.

This area, driven largely by consumers, is the fastest growing component of U.S. health care.

The panel today is on CAM Credentialing and Licensure, Assuring Quality and Accountability in CAM Practice.

As a futurist, I will explore trends that over the next 5 to 10 years will affect health care, quality assurance and CAM. This view is important for the work of the Commission, as the changes that you recommend in 2001 and 2002 may take time to put in place and, once implemented, will be operating in a changing environment. In this context, the words of Wayne Gretsky, one of the highest scoring players in professional hockey, are relevant. When asked about the secrets of his success, Gretsky said that he skated to where the puck would be. Your recommendations need to anticipate where health care will be, in addition to where CAM practitioners will be.

Attached to this statement is the executive summary of the Institute for Alternative Future's 1998 Report on *The Future of Complementary and Alternative Approaches (CAAs) in US Health Care*. This report provides a more systematic review than I will have time to focus on today. In updating our

forecasts for this statement I sought input from several individuals and sources that were very helpful.[1]

As we explore the future of CAM, I urge you to consider your recommendations for the credentialing and licensure of CAM practitioners in the context of 1) our values for health care; 2) quality assurance of health systems, modalities, and products; and 3) forces shaping health care and the health professions.

1) Developing the health systems we want: what values

Quality assurance of CAM professionals should support achieving the larger values we have for our health systems, recognizing that there will at times be conflict among them, e.g. optimizing choice and optimizing cost effective care. The list below provides values that, while not agreed upon, are pursued by some sectors of health care.

Prime Values, Sometimes in Conflict

- Optimal health, optimal treatment for individuals
- Enhanced community health
- Consumer self care, self reliance
- Cost effective care
- Elimination of health disparities
- Protection against fraud and abuse
- Innovation in health
- Taking advantage of historical learning, wisdom of modalities
- Appropriate, cost effective training of health professionals
- Fair treatment for health care professionals
- Maintaining an appropriate health care professional workforce
- Consumer choice and consumer protection
- Intelligent choice and cost control

In considering credentialing, licensure and other means of quality assurance, it is essential for the Commission to consider what larger values the health system should achieve. It is important for your

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[1] I would like to acknowledge the following individuals for their insights as I prepared this statement: John Weeks, Pam Snider, Roy Swift, Jonathan Peck and Jennifer Kang.
Written materials include:
Institute for Alternative Futures, *The Future of Complementary and Alternative Approaches (CAAs) in US Health* Care. Alexandria, VA, 1998, copyright NCMIC Insurance Company. http://www.altfutures.com.
John Weeks, "Operational Issues in Incorporating Complementary and Alternative Therapies and Providers in Benefit Plans and Managed Care Organizations," 1996; and Weeks' invaluable newsletter which covers developments in this area – *The Integrator – for the Business of Alternative Medicine.*

recommendations to reinforce the values that you believe should characterize health care.

2) Credentialing and licensure of individual practitioners must be done in the context of quality assurance of health systems, modalities and products

The 20th Century saw the development and growth of self-regulation through credentialing and state regulation via licensure, especially for physicians. If you ask, did such systems lead to effective health care, many would say no. Licensure granted allopathic physicians the ability to prevent others from practicing, yet it did not hold physicians accountable for their outcomes or cost effectiveness. Some would argue that licensure has functioned more as guild protection rather than consumer protection.

The rationale for government regulation of the health professions is "market failure." The Flexner Report called for states to license physicians due to the prevalence of fraudulent modalities and practitioners, inadequate medical schools, and the inability of consumers to effectively judge quality. In the marketplace, consumers needed state protection.

The need for credentialing and some forms of licensure will still remain for some time, though in a moment, as a futurist, I'll review trends that are improving the ability of consumers to make more effective choices, including choices for self care.

Credentialing of individual practitioners must be done in the context of the health systems in which they practice. In addition, the modalities they use are in need of evaluation, as are some specific products.

Quality Assurance of
- Health Systems
- Modalities
- Individual Providers
- Specific Products

Credentialing and licensure systems often fail to identify, improve or remove ineffective or dangerous practitioners. These processes need to be assessed in detail and improved upon.

As individual practitioners work using particular products and within the context of health care delivery, financing systems, or other specific modalities, individual

practitioners must be held accountable. In addition, so must these other components that surround their practice.

In developing its recommendations, it is important for the Commission to recognize that quality assurance of individual CAM providers, through credentialing, licensing, and other means, must be done in the context of quality assurance for the health care system in which the individual is practicing; for the modalities they are using; as well as for the specific products they are using or recommending.

The discussion below on outcome measures, report cards and communications suggests that this will become easier over the next decade (not easy, but easier).

The Future: Potential Changes Affecting Quality Assurance, Accountability, Credentialing and Licensure

In the next five to ten years, and in some cases sooner, certain trends will have significant effects on quality assurance – both how we do it, and what we consider quality or how we define outcomes. The following is a list of some of the key trends the Commission must consider:

- Genomics & Customization
  - The mapping of the genome will lead to better understanding of gene-based differences in individuals. Definitions of disease, as well as related treatments, will be customized to individuals, or groups of individuals with certain genotypes or phenotypes (that is, physical or behavioral characteristics that are genetically related). For many pharmaceuticals, we are likely to know for whom they will work and who is likely to experience side effects. Given that there are an estimated 100,000 deaths a year from the side effects of pharmaceuticals, advances in this arena of genomics will be significant.
  - Likewise, CAM modalities will be challenged by advances in genomic knowledge.
  - The ability of genomics to give clues as to how and when to treat individuals or groups of individuals has been a long-term focus of certain CAM. In fact, some CAM have studied the diagnostic and therapeutic significance of phenotypic differences for thousands of years.
    - "Most leading complementary and alternative therapies have developed elaborate "phenotypic" approaches for differentiating among individuals. These represented evidence-based observations over long periods of time...Ayurvedic approaches...use the "dosha" system to characterize

individuals. Doshas can be thought of as beginning with body types... and adding layers of information about emotional tendencies, intellectual styles and spiritual inclinations. Likewise Oriental medicine and homeopathy have complex approaches to sub-grouping individuals phenotypically apart from their specific disease diagnosis. Homeopathy considers persons having similar syndromes, e.g. migraine headaches, not as having the same disease but as having similar symptoms pointing to deeper conditions that might be radically different. These deeper conditions usually cannot be treated by suppressing the symptoms according to homeopathy."[2]

- **It is important for the Commission to anticipate the challenges that phenotype and genotype customization will play by 2010. It is possible that the credentialing requirements of both conventional and alternative providers, as well as the expert systems that support them, will need to consider the integrated wisdom of these systems.**

- E-health
  - In this context, the definition of E-health encompasses both accessing health care information wherever it is needed as well as using expert systems to enhance the quality and usability of that information for individuals.
  - For health care professionals, e-health implies that, in systems where the diagnostic and treatment protocols can be put into algorithms, they can be shared more easily. For example, an allopathic physician, or a chiropractor, will be able to more reliably prescribe not only allopathic pharmaceuticals, but also homeopathic or Oriental medicines.
  - Consumers will have an equally enhanced ability to do self-care using these expert systems.

- Consistent Record Keeping and Electronic Medical Records
  - There are many unresolved issues regarding the consistency of medical record keeping in conventional medicine. Regardless, by 2010, there will most likely be consistent record keeping, mostly in electronic form, for both conventional health care and most CAM modalities.
    - **Privacy and discrimination protections are needed and the Commission should leverage a recommendation that privacy and discrimination protections anticipate any particular needs for CAM data (e.g. if those of a particular dosha are prone to a disabling disease).**

[2] The Institute for Alternative Futures, *The Future of Complementary and Alternative Approaches (CAAs) in US Health Care*, 1998, pp. 3-13, citing Dana Ullman, *The Consumer's Guide to Homeopathy*, New York, GP Putnam, 1995: page 8.

- **Likewise the Commission should recommend that CAM, and conventional health care practitioners using CAM approaches, must generate appropriate practice records to generate outcome data, as a precondition for recertification and continued licensure. This information is important so that 1) patients can monitor the success of their care 2) data can be aggregated for appropriate research and public health purposes and 3) report cards or other accountability measures can be developed for each practitioner.**
- The requirements of the Health Insurance Portability and Accountability Act (HIPAA) give the presumption of control over medical records to the individual who must grant permission for use of their personal medical data for purposes beyond treatment. This presumption will be applied to CAM practices. Simultaneously, there will be trusted intermediary groups such as patient/disease groups that will be allowed, by their members, to aggregate medical records. These intermediary groups will thus emerge as the sources of report cards on systems, modalities, practitioners and products that result.
- **The Commission should support the assumption of patient control of access to records and ensure that any issues unique to CAM modalities are considered.**

- Biomonitoring
  - By 2010 biomonitoring will be low cost and relatively common; for example wristwatch type devices will be used to collect key data and integrate it into the individual's medical record. The data will also include input from the individual assessing their condition.
  - By 2010 video monitoring will be common for a wide range of uses beyond health care. Within health care it is likely to become part of the electronic medical record, for things such as examinations of the mouth surface. In addition to the practitioner reading the condition of the mouth surface, expert systems will supplement their assessment through the surface images captured by video camera.

- Widespread Use of Outcome Measures, Report Cards
  - By 2010 outcome measures will be developed and "report cards" available for individual health care providers, both conventional and CAM (by 2010 much of what is now called complementary and alternative will be integrated into conventional prevention and care).
  - **The Commission needs to consider and recommend ways to ensure that appropriate outcome measures and report cards are developed for CAM modalities.**
    - These measures are important for both organized payers and individuals in choosing what therapies are appropriate.

        - These measures need to address treatment, but also prevention, wellness and function enhancement.
            - For example, currently an estimated 35% of visits to chiropractors is for wellness or maintenance. The individuals comprising this group have decided that the outcome is worth the continued expenditure in time and funds. By 2010, outcome measures and report cards should and are likely to assess the outcomes of these wellness or maintenance treatments.

- Broader Approaches to Quality
    - The measures that consumers and society in general are using to assess quality are becoming broader, including the following areas of quality:
        - Inherent quality – usually for physical products, e.g., is the identity of the product what it is on the label. In this area, the US Pharmocopeia (USP) is moving to develop inherent quality standards for herbal products.
        - Functional quality – does the product or procedure work, how well, and at what relative cost? Outcome measures are clearly targeted at this type of functional quality, often presuming inherent quality is already assured.
        - Contextual quality – are there larger values that the use of this product or service entails. The focus of the ISO 14000 standards on environmental protection is an example of this. The contextual standards for products and services are parallel to the social screening done by the socially responsible investment community (in 1999, one out of every eight professionally managed dollars invested in the US had some type of social screen attached to it). More advanced environmental concerns, particularly sustainability, as well as social concerns such as equity, are likely to be among the values that will be included in quality assurance systems such as ISO standards.
        - CAM practitioners generally pride themselves that their practices are more environmentally benign and sustainable. By 2010 credentialing and licensure are likely to have to confront measures of these "softer" variables.

- Broader Definitions of Health and Health Outcomes
    - Paralleling the expansion of our notion of quality is the expansion of definition of health. In the US, the Healthy People 2010 Objectives have established two overarching goals that reflect our expansion of the definition of health: 1) longer years of healthy life and 2) the elimination of health disparities. Disparities are those differences that are avoidable and unfair. Globally, this broader sense of health to include eliminating disparities is paralleled in WHO's "health for all"

vision. WHO argues that health will not be achieved until certain values are achieved. These values are equity, solidarity, sustainability, ethics, gender and human rights.

- By 2010 the report cards developed to provide accountability for health systems, modalities, health care professionals, and products, are likely to include some forms of these higher standards.
- **The Commission should recognize the Healthy People 2010 overarching goal of eliminating health disparities and consider how CAM professionals can be held accountable for contributing to the achievement of this broader definition of health.**

- Smarter Markets – The rationale for licensure (providing a state sanctioned monopoly to certain qualified providers to work exclusively within a scope of practice) is market failure. Consumers are not effectively equipped to make their own judgments, particularly where the procedure or its outcomes are extremely technical and have significant health consequences. By 2010 there will still be instances where markets fail enough to require licensure, but those instances will be fewer than today. Given the ability to report the outcomes often by genotype and phenotype, consumers will have a better sense of which systems, modalities, practitioners and products work for them.
  - Consumers currently use a variety of personal criteria in their choice of health care providers. This will continue.
  - Some groups of consumers will also shop for providers and services using broader value screens and will be further aided by groups providing this information. For example, women's breast cancer groups, or the American Cancer Society, will be developing report cards that reflect the broader interests of their constituencies, not only for effective cancer care, but for cancer prevention and for reducing disparities in cancer.
  - Consumers shopping for cancer services will use these information resources.
  - **The Commission should encourage health professional schools and training organizations to enable practitioners to deal with these broader and also, more subtle comparisons that go beyond simply evaluating the effectiveness of treatment.**

- E-learning, E-testing and Credentialing
  - Credentialing and licensure are based on various types of testing. By 2010 E-learning (learning focused on the individual learner's knowledge level, interest level, and learning style) will have the capacity to accelerate how quickly health care providers can be trained initially or with additional new skills. Virtual reality tools, akin to the flight simulator for pilots, will also accelerate skill development.

- Testing will become more automated. In some fields, private testing companies are competing against professional associations to administer the certifying test for practitioners.
- As we evolve systems that capture outcomes in practice, it will be possible to recertify practitioners on the basis of their outcomes.
- We will have the capabilities to compare outcome differences among practitioners with differing levels of training and other attributes, e.g. How does a chiropractor's outcomes compare to those of a physician doing manipulation after a short or a long training course?

Conclusion

In review, once again, the context for credentialing and licensure includes

- The values we want our health systems to promote
- The interacting levels of accountability: health care systems, modalities, practitioners, specific products
- The forces shaping health care more broadly over the next decade

The Commission should anticipate these factors as you develop recommendations related to quality assurance, certification and licensure:

- Reinforce consumers' ability to know and to do self care and healing
- Ensure that health care practitioners have the appropriate training, but not more than they need to receive
- That the credentialing and licensure systems serve consumers and practitioners

Finally, as the Commission considers its recommendations, it is important to remember:

- The larger values that the health system should achieve. It is important for your recommendations to reinforce the values that you believe should characterize health care.
- Quality assurance of individual CAM providers, through credentialing, licensing, and other means, must be done in the context of quality assurance for the health care system in which the individual is practicing; for the modalities they are using; as well as for the specific products they are using or recommending.
- The challenges that phenotype and genotype customization will play by 2010. It is possible that the credentialing requirements of both conventional and alternative providers, as well as the expert systems that support them, will need to consider the integrated wisdom of these systems.
- Privacy and discrimination protections are needed. In addition, there may be particular needs for CAM (e.g. if those of a particular dosha are prone to a disabling disease).

- CAM, and conventional health care practitioners using CAM approaches, must generate appropriate practice records to generate outcome data, as a precondition for recertification and continued licensure. This information is important so that 1) patients can monitor the success of their care 2) data can be aggregated for appropriate research and public health purposes and 3) report cards or other accountability measures can be developed for each practitioner.
- The importance of supporting the assumption of patient control of access to records and ensuring that any issues unique to CAM modalities are considered.
- The need for appropriate outcome measures and report cards specifically developed for CAM modalities.
- The Healthy People 2010 overarching goal of eliminating health disparities. CAM professionals can contribute much and be held accountable for the achievement of this broader definition of health.
- The need for health professional schools and training organizations to enable practitioners to deal with these broader and also, more subtle comparisons that go beyond simply evaluating the effectiveness of treatment.

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THE FUTURE OF COMPLEMENTARY AND ALTERNATIVE APPROACHES (CAAs) IN US HEALTH CARE

Executive Summary

INSTITUTE FOR ALTERNATIVE FUTURES

JULY 1998

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Winn

Divider Title: _____

James R. Winn, MD
Executive Vice President
Federation of State Medical Boards of the United States, Inc.

Dr. James Winn is the Executive Vice President of the Federation of State Medical Boards of the United States, Inc., a national organization whose membership includes medical licensing and disciplinary boards in the United States, District of Columbia, Guam, Puerto Rico and the Virgin Islands. Since 1989, Dr. Winn has worked diligently as the Federation's leader and primary spokesperson representing the Federation to the leadership of other organizations on the state, national and international levels. Under his direction, the Federation has prospered rapidly and has had significant recognition as the premier organization concerned with medical licensure and discipline.

Dr. Winn is a Charter Fellow of the American Academy of Family Physicians and a former Diplomat of the American Board of Family Practice. He received his medical degree from the University of Texas Medical Branch at Galveston in 1967 and interned at Breckenridge Hospital in Austin. He completed additional postgraduate training at the University of Texas Medical Branch at Galveston. Since completing his medical training, Dr. Winn has been actively involved with countless organizations and committees concerned with the promotion of quality medical care and protection of the public. He is a former member of the Texas State Board of Medical Examiners and was the Secretary of the Board, Chairman of the Board's Committee on Reciprocity, and a member of the Board's Legislative Committee and Foreign Medical Graduates Committee. He is a former member of the State Quality Assurance Executive Committee of the Texas Medical Foundation, a former member of numerous committees of the Texas Medical Association (TMA) as well as the AMA Delegation and currently serves as a consultant for TMA's Council on Medical Education. Additionally, he served as President of the Texas Academy of Family Physicians and is currently a member of the Board of Directors of the Tarrant County Medical Society located in Fort Worth. On the national level, Dr. Winn is a member of the National Board of Medical Examiners and currently sits on the Executive Committee of the National Practitioner Data Bank, as well as the Composite Committee and the Budget Committee of the United States Medical Licensing Examination. He is also a member of the National Advisory Committee for a grant on "Pain Management and State Regulatory Policy" awarded by the Robert Wood Johnson Foundation to the University of Wisconsin Comprehensive Cancer Center's Pain and Policy Studies Group.

Dr. Winn's involvement in international affairs is especially noteworthy. Under his direction, the Federation has been the catalyst for organizing an International Association of Medical Licensing Authorities for the purpose of facilitating the ongoing exchange of medical regulatory information, promoting high standards for physician licensure, registration and practice, and supporting licensing authorities in protecting the public interest in the field of health care. With his support on the Interim Governance Committee, the Federation will act as the initial Secretariat for the Association. Additionally, Dr. Winn frequently participates as an invited speaker at conferences abroad or of a global nature to ensure the Federation's international recognition as a leader in providing support for medical licensure and discipline around the world.

Testimony for the White House Commission on Complementary and Alternative Medicine Policy

Meeting: **Plenary Session III: *CAM Credentialing and Licensure: Assuring Quality and Accountability in CAM Practice***
Date: **Thursday, February 22, 2001**
Presenter: **James R. Winn, MD**
Executive Vice President
Federation of State Medical Boards

State medical boards are required by law to protect the public's health, safety and welfare. They do this by assuring only qualified individuals render services to the public; developing rules and standards for medical practice; and by taking appropriate action against a licensee to protect the public from the unprofessional, incompetent and unlawful practice of medicine.

Included among the many responsibilities of medical boards for ensuring effective regulation is the protection of the public against questionable and/or deceptive medical practices. The proliferation of complementary and alternative medical practices (CAM) and promotions in the United States has caused the Federation and its member boards concern because some of these medical practices are questionable in that they lack scientific research and clinical validation. Some others are worthless and likely to deceive the public. In short, some CAM therapies may pose a risk to the public's health, safety and welfare.

National and state legislative initiatives have been a cause for further concern because of their potential for restricting state medical boards' ability to provide appropriate regulation which will allow consumers access to efficacious CAM therapies while protecting them from unsafe practices.

There are varying degrees of potential harm that can impact patients who undergo questionable and deceptive forms of health care. There is (1) economic harm, which results in monetary loss but presents no health hazard; (2) indirect harm, which results in a delay of appropriate treatment; and (3) direct harm, which results in adverse patient outcome.

The Federation's Special Committee on Questionable and Deceptive Health Care Practices was established in 1995 to research, review and evaluate the status of questionable health care treatments, procedures, and/or promotions, and to develop strategies for recommendation to state medical boards for the regulation and discipline of physicians who engage in unsafe and/or deceptive practices.

The Committee's final report, adopted in 1997, strongly supports the concept that the prevailing standard of care used in evaluating health care practices be consistent, whether such treatment is regarded as conventional or unconventional. Such standards

include: appropriate documentation; informed consent; appropriate monitoring, and follow-up; rationale for treatment; and periodic review of efficacy of treatment.

The criteria used to evaluate health care practices and whether or not a licensed physician is practicing medicine in an acceptable manner includes the following:

- Has an adequate patient assessment been conducted to determine that the patient has the condition for which the treatment is being prescribed?
- Is the methodology promoted for diagnosis as reliable as other available methods of diagnosis?
- Is the risk/benefit ratio greater or less than that for other treatments for the same condition?
- Is the treatment based upon competent and reliable scientific evidence, including properly conducted clinical trials, and/or is it supported by a scientific rationale?
- Are the practitioner's promotional claims supported by competent and reliable scientific evidence?
- Is there a logical and reasonable expectation that the treatment offered will result in a favorable patient outcome?
- Is the practitioner excessively compensated for the service provided?
- Is the benefit achieved greater than that which can be expected by placebo alone?
- Has the patient's informed consent been adequately documented in the medical record?

In order to effectively process a complaint or report involving questionable or deceptive health care practices, state medical boards must determine whether or not the practice in question is (1) indicated, (2) appropriate, and (3) reasonably safe as compared to established treatment models. Research indicates that only four (4) medical boards have adopted CAM policies to assist them in determining whether or not specific medical practices constitute a violation of the state's Medical Practice Act – the Illinois Department of Professional Regulation, the Kentucky Board of Medical Licensure, the Nevada State Board of Medical Examiners and the Texas State Board of Medical Examiners. The remaining states have no formal policies or guidelines in place and, instead, deal with complaints involving CAM issues on a case-by-case basis. Therefore, medical boards would benefit from guidelines to help them assure that the provision of CAM services is based on appropriate and competent standards of medical practice. Accordingly, the Federation is developing model guidelines to assist its member boards in communicating their expectations to physicians who are (1) engaged in a practice environment offering both conventional and alternative forms of treatment; and (2) engaged in cooperative therapeutic relationships for their patients with non-physician licensed alternative healthcare providers.

Standards to be established in these guidelines will include, but will not be limited to, the need for: adequate patient assessment; scientific evidence supporting the treatment; a favorable risk/benefit ratio; informed consent, including documentation that the risks and benefits have been disclosed to the patient; and periodic review.