Tabs 1-12

Discussion Group IV

Discussion Group IV

Discussion on National Standards for Education + CAM

DISCUSSION GROUP IV

TAB

TAB

Tab 1

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 5, 2001

Martin L. Rossman, MD, Dipl.Ac.
Co-Director
Academy for Guided Imagery
P.O. Box 2070
Mill Valley, CA 94942

Dear Dr. Rossman:

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 education in guided imagery? Should those national educational standards include exposure to conventional or western medicine as well as CAM other than guided imagery?

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 guided imagery 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,

Steve Groft

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

Chang, Michele (NCCAM)

From: Kaczmarczyk, Joseph (NCCAM)
`ent: Tuesday, February 13, 2001 8:41 AM
o: Bill Fair (E-mail); Bill Fair (E-mail); Buford Rollin (E-mail); Conchita Paz (E-mail); Joan Matthews; Linnea Larson (E-mail); Tom Chappel (E-mail); Tracy Wiens (E-mail)
Cc: Chang, Michele (NCCAM)
Subject: Information from the Academy for Guided Imagery

Under separate cover, I have sent a copy of my remarks to the WHCCAM delivered at the New York Town meeting a few weeks ago. Along with that statement, I have appended the bibliography requested by Dr. Gordon which includes the scientific references that we believe support the conclusions we have reached.

In response to your query last week, I am submitting the following as an initial response on behalf of the Academy for Guided Imagery (AGI):

Q: Are there national educational standards for undergraduate, postgraduate and continuing education in guided imagery?

A: The only training program in guided imagery that provides evidence of competence is the Professional Certification Training program created and maintained by AGI. This program requires satisfactory completion of 150 hours of formal training, including 56 hours of small group supervision and direct personal evaluation by AGI faculty. The criteria we use for Certification are appended as Appendix A.

There is also an abbreviated certification training program for nurses called the Nurses Certification Program in Imagery, which was started by two of our nurse faculty members. They offer a 110 hour program for nurses and you can find their criteria for nursing certification through their website at: www.imageryrn.com

Q: Should national standards include exposure to conventional or western medicine as well as CAM other than guided imagery?

A: It is important to distinguish the uses of guided imagery in health and medical care from its uses in education, creativity training, learning, memory improvement, coaching, performance enhancement, design, and other non-medical fields. We believe that its uses in these areas are more educational than therapeutic, and that practitioners or teachers of this type of imagery generally do not need additional exposure to any type of medical training.

However, for guided imagery practitioners working in the health care field, national standards should be created to ensure that they are well educated and informed about general indications, contraindications, potential complications, and precautions when using imagery in most common medical situations.

While it would be difficult and unnecessary to teach everyone learning guided imagery everything known about all of its uses in either conventional or CAM-based medicine, practitioners should certainly be familiar with the potential medical aspects of the conditions they are treating.

For example, a practitioner using guided imagery to prepare patients for cardiac surgery and recovery would need to know a great deal about the medical and nursing aspects of the upcoming surgery, as well as the ongoing treatment of the underlying condition. A practitioner using imagery for smoking cessation would need to be familiar with the dynamics of nicotine addiction, but wouldn' t need to know about cardiac surgery.

Q: Should there be national standards or certification for guided imagery practices?

A: AGI believes strongly in national standards for guided imagery practitioners which is why we developed and instituted formal training and certification standards in 1989. We believe that demonstrating mastery of skills, sound clinical judgment, and the highest ethical standards is mandatory for any practitioner using guided imagery in a health-care setting, and that consumers have the right to full disclosure regarding the training and competence of their practitioners.

Q: How and by whom should national standards or certification be established, to whom should they apply, and how should they be implemented?

A: As discussed above, no national standards are needed for those working outside the health care arena. For health practitioners, existing models for setting professional standards are numerous and they should be studied and evaluated to determine the one that is most relevant to this application. Following a consensus conference (see below), a professional certifying board or agency should be created to determine standards of practice, requirements for certification, and criteria for maintenance of certification through continuing education.

Q: Should the numerous guided imagery organizations that exist come together to form a " community" ? If so, how and by whom should that community be formed?

A: We recommend that a Consensus Conference on Guided Imagery be held at NIH, modeled on the Consensus Conference on Acupuncture that was organized by Alan Trachtenberg in 1997. We believe that this conference should jointly be sponsored by NCCAM, NIMH, NCI, NINDS, NIDA, and other interested institutes. Invitees should include representatives from established guided imagery training and membership organizations, and other interested parties. During this conference, the published literature can be reviewed for scientific acceptability, the criteria for certification and a certifying agency can be established, and initial plans for establishing a " community" can be outlined.

Q: Are your members concerned with malpractice liability issues associated with

guided imagery?

A: In today' s litigious world, all health practitioners must be concerned with these issues, including AGI Certification graduates, which is why they have sought the most thorough training available and have passed the most stringent requirements for certification in our community. To our knowledge, there has never been a malpractice suit brought against a practitioner for using guided imagery, but this is likely to change unless national standards can be established.

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

A: As stated above, we believe that such guidelines should be developed for medical, surgical, nursing, mental health and CAM applications. Condition specific guidelines should be developed by experts in guided imagery who also have expertise in the application under consideration and in consultation with other experts in that field.

Guidelines must allow for the considerable creativity and individuality that characterizes the use of guided imagery while providing safeguards to insure that patients are being appropriately guided. Criteria for condition-specific certification can be established and monitored by whatever national certifying agency is created.

Q: Are there risks associated with guided imagery that are of concern to your members? If so, can you suggest ways to minimize those risks?

A: The major risks associated with guided imagery fall into two categories:

(1) The use of guided imagery instead of definitive medical or surgical therapies in certain life-threatening conditions; and

(2) The use of guided imagery for patients who also have severe or unstable psychological problems by practitioners who lack the proper training, knowledge or experience needed to use imagery safely.

Thorough training in recognizing and avoiding these risks are an integral part of AGI' s training program and should be part of whatever standards are ultimately set.

Q: Should there be a mechanism to address consumer concerns or grievances about the quality of guided imagery practices or products?

A: If there are national standards and criteria that define the practice of guided imagery, then there needs to be a mechanism established for grievances and complaints, as well as a method of investigating those complaints that is fair to both aggrieved and accused parties. These can be derived from models of similar

practices in other specialty areas.

Q: What information should a conventional health care provider communicate to a guided imagery practitioner? What information should the guided imagery practitioner communicate to a conventional provider either with or without a referral if the consumer self-refers?

A: Communication of information about a patient must always depend on the patient' s willingness to release that information. Provided that proper informed consent is obtained by the referring practitioner, the referral should include information about the patient' s diagnosis and basic medical condition, why the referral is being made, specific concerns for safety, any other information that can help the practitioner understand the issues that the patient is facing and what information the referring practitioner wants to hear back about the outcome of guided imagery therapy.

Q: What policy recommendations would you like to make to assure the quality of guided imagery practices and products whether they are provided by a practitioner or used as self-care.

A: As a minimum, we strongly recommend that all guided imagery health care providers, whatever their licensure, must complete a course of study equivalent to that provided in AGI Professional Certification Training. They should demonstrate satisfactory completion of this curriculum, and pass " boards" that test for knowledge acquisition and mastery of skills (including personal observation and evaluation).

This will assure patients, providers, third parties, and the public that the practitioner understands the background, history, theories and applications of guided imagery in the health professions, has demonstrated competence with the core skills required, has the ability to communicate well with others, conducts themselves professionally, accepts constructive feedback, and adheres to the highest code of ethical standards.

Martin L. Rossman, MD
President

Tab 2

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

Dort Bigg
Executive Director
Accreditation Commission for Acupuncture and Oriental Medicine
The Maryland Trade Center #3
7501 Greenway Center Drive-Suite 820
Greenbelt, MD 20770

Dear Mr. Bigg:

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

I am writing in response to your January 31, 2001 letter requesting that the Accreditation Commission for Acupuncture and Oriental Medicine ("ACAOM") submit written testimony addressing the nine questions in your letter. It is our understanding that our submission will be considered during the White House Commission's February 2001 meeting.

Background of Oriental Medicine

Throughout its long history, Oriental medicine has been a dynamic and evolving medical art and science. Oriental medicine is a comprehensive system of health care, which originated in China more than twenty-five centuries ago, with its own unique precepts, principles and techniques and is currently practiced in virtually all countries in the world. Oriental medicine techniques include acupuncture, moxibustion, Chinese herbology, therapeutic exercise, bodywork, Oriental physical therapy, and other treatment modalities such as cupping and gua sha. Combined with acupuncture techniques, these modalities provide a very effective treatment for many diseases and medical conditions. Further, Oriental medicine incorporates the body, mind and spiritual aspects of both patients and practitioners, and encourages personal responsibility for one's own health and well being.

Since the early 1970's, Oriental medicine has been rapidly adopted in the United States. US consumers have increasingly sought the benefits of Oriental medicine based on its effectiveness, safety and non-iatrogenic abilities and properties.

Oriental medicine practitioners, in most states, can legally treat illnesses affecting the human body using the techniques and traditions established in the medicine. Forty-one states, plus the District of Columbia have adopted specific laws and regulations regarding the practice of acupuncture and Oriental medicine. In addition to state regulation in the field, the Oriental medicine profession has responsibly developed certification and accreditation structures to ensure that the field of acupuncture and Oriental medicine is practiced safely and effectively.

The nationally-recognized certifying agency in the field, the National Certification Commission for Acupuncture and Oriental Medicine ("NCCAOM"), administers certification exams in acupuncture, bodywork and herbal therapy to ensure that practitioners have achieved the critical competencies necessary for the safe and effective practice of Oriental medicine. NCCAOM is accredited by the National Organization for Certifying Agencies, which represents the highest voluntary certification standards in the United States. The Accreditation Commission for Acupuncture and Oriental Medicine ("ACAOM") accredits acupuncture and Oriental medicine programs throughout the United States and Canada. ACAOM is recognized by the U.S. Department of Education as a reliable authority for quality education and training in the field and graduation from an ACAOM-accredited or candidate program is a requirement for state licensure in the vast majority of states with licensure laws and regulations. The field of Oriental medicine has a number of local, state and national professional associations and organizations which address professional, educational, licensure, public relations and other issues pertaining to the field.

ACAOM Testimony on the White House Commission 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?*

ACAOM accredits first professional Masters-level and Masters degree programs in acupuncture and Oriental medicine. ACAOM's accreditation standards are the nationally-recognized standards for acupuncture and Oriental medicine training in the United States. These standards are explicitly designed to prepare students to function as independent health care providers in acupuncture and Oriental medicine, including demonstration that they have achieved the critical competencies necessary for safe and effective practice upon graduation. Every state where acupuncture licensure exists, with the exception of Nevada, Louisiana and California, requires graduation from an ACAOM accredited or candidate program and/or passage of the national certification exam administered by the National Certification Commission for Acupuncture and Oriental Medicine ("NCCAOM") to become licensed as an acupuncturist or Oriental medicine practitioner. In addition, NCCAOM requires graduation from an ACAOM accredited or candidate school to be eligible for certification. ACAOM has worked hard to ensure that its curriculum standards keep pace with developments within the field. In 1985, ACAOM's standards in program length were 1350 hours for an acupuncture program. The Commission developed standards for a four academic year Oriental medicine program in 1990. Currently, ACAOM requires a minimum of 1725 hours over three academic years for an acupuncture program and 2175 hours for an Oriental medicine program. ACAOM recently held a retreat to again consider its program standards and has developed a proposal for further increasing the curriculum requirements based on the additional competencies expected of U.S. practitioners.

ACAOM's accreditation standards explicitly require didactic and clinical course work in the western biomedical clinical sciences. This includes training in 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 western laboratory and diagnostic tests and procedures as well as biomedical physical exam findings; infectious diseases, sterilization procedures, needling handling and disposal, and other issues relevant to bloodborne and surface pathogens; biomedical pharmacology including relevant aspects of potential medication, herb and nutritional supplement interactions, contraindications, side effects and how to access this information; the basis and need for referral to and/or consultation with allopathic medical providers; and the range of biomedical referral resources and the other modalities they employ. ACAOM's accreditation standards to not currently specify exposure to the modalities employed by other CAM providers. However, many programs include survey courses in other CAM fields to acquaint students with the other CAM disciplines.

In addition to ACAOM's standards for accrediting Masters degree and Masters level acupuncture and Oriental medicine programs, the Commission has recently adopted accreditation standards for clinical doctoral programs in Oriental medicine. The doctoral program is designed to provide advanced level training which builds upon the Masters level competencies. The curriculum for the program includes training to provide advanced level competencies in patient assessment and diagnosis, clinical intervention and treatment, consultative skills when interacting with allopathic health care providers, biomedical

assessment knowledge and narrative writing skills including but not limited to physical exams and related laboratory tests sufficient to facilitate patient care in collaboration with appropriate health care personnel, clinical supervision and management skills, and sufficient skills in clinical research to enable program graduates to be educated consumers of the scientific literature and research in the field. The Commission is just beginning to receive applications from colleges wishing to offer doctoral programs.

ACAOM does not accredit or approve Continuing Education programs or courses and its accreditation standards do not specify CE program content requirements. However, they do require that accredited or candidate programs offering CE possess an adequate administrative structure, competent faculty, a sound financial base, and appropriate facilities sufficient to offer quality CE programs without adversely impacting the quality of the ACAOM-accredited or candidate program(s). In the United States, continuing education requirements in the field of Oriental medicine are frequently regulated through state licensure laws and regulations which are enforced by state acupuncture or medical boards as a condition of continued licensure.

We believe that for all the CAM fields, it is critical that practice be licensed at the state level and that licensure be tied to graduation from a program which meets nationally-recognized accreditation standards for quality of education and training. There are some inferior training programs which are graduating students who, in our view, have not received adequate training for safe and effective practice. In California, for example, there are programs that are not accredited by ACAOM although their students are eligible for licensure. We believe that failure to base state licensure on graduation from an accredited or candidate program can place consumers at significant risks from being treated by inadequately trained professionals.

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?*

As noted above, the NCCAOM has established a nationally recognized certification exam and process for the field of Oriental medicine which is tied to state licensure in all states which license acupuncture and Oriental medicine practitioners with the exception of Nevada, Louisiana and California. It is our understanding that NCCAOM's NOCA-accredited certification exams and processes were designed based on recognized standards for certification exam development and psychometric evaluation including job survey analyses. In addition to administering certification exams for the field, NCCAOM's certification procedures include specific grounds for withdrawal of certification including chemical dependency, physical or mental incapacity, gross incompetence, felony charges, falsification on the certification application, examination fraud and violating NCCAOM's Code of Ethics. In this manner, NCCAOM enforces standards for practitioners to ensure that NCCAOM Diplomates are not engaging in activities which would be a threat to public safety. We believe that similar processes and standards should be required of all CAM fields. Without a certification process and appropriately enforced standards of conduct , there are no assurances that practitioners have attained the critical competencies and are conforming to necessary standards of conduct for safe and effective practice. We believe that such processes are a responsibility of each CAM field and profession. Self regulation is critical to protect the public and to maintain consumers confidence in any CAM profession.

With respect to CAM "products", herbal therapy is an ancient and integral part of Oriental medicine. ACAOM's accreditation standards explicitly require in depth training in the appropriate use of herbal products. This includes course work in materia medica (categories of herbs; functions and actions; dosages and contraindications for each herb; developments in herb research), herbal formulas (traditional formula categories, functions, actions and contraindications for each formula); developments in formula research; composition and proportion of herbs in each formula; patient education regarding administration, potential side effects, preparation and storage of formulas; etc); drug interactions with herbal medicines; and other relevant issues. In addition to didactic course work, extensive clinical training pertaining to herbal medicine is required of all students in an Oriental medicine program, including specific training regarding how and when to consult with and refer to allopathic health care providers regarding potential drug interactions with herbal therapy. Moreover, the NCCAOM administers a certification exam for the practice of Chinese herbology to ensure that NCCAOM Diplomates have achieved the necessary competencies in order to practice safely and effectively in prescribing herbal remedies. We believe that NCCAOM certification should be required for any practitioners who wish to prescribe Chinese herbs to their patients.

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?*

An acupuncture and Oriental medicine community already exists. The national organizations including ACAOM, NCCAOM, the Council of Colleges of Acupuncture and Oriental Medicine, the Acupuncture and Oriental Medicine Alliance and the American Association of Oriental Medicine have been holding regular 5-organization retreats on an annual basis to discuss issues impacting the field of acupuncture and Oriental medicine including those pertaining to licensure, certification, state laws and regulations, and many other matters. In addition, a number of state acupuncture boards have organized to form an organization for representatives of the various boards to discuss issues pertaining to state licensure standards. The national organizations for the field have also been coordinating their meetings so that they are all held during the same period and in the same venues. This has provided an opportunity for input and information exchange among the leadership for the entire field. ACAOM and NCCAOM also conduct public hearings to provide opportunities for the entire community to provide input on matters such as proposed accreditation standards, certification eligibility requirements and other relevant issues which could impact the field.

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?*

Modality-specific practice guidelines are already addressed in ACAOM's accreditation standards. For example, ACAOM's core curriculum and clinical standards for acupuncture require training in point location and the functions of each point, needling technique including needle insertion, depth, duration, manipulation and withdrawal, appropriate combinations of points, as well as specific requirements for other Oriental medicine modalities such as Oriental herbal therapy.

Acupuncture and Oriental medicine does not, however, readily lend itself to condition-specific practice guidelines or protocols. Effective treatment by Oriental medicine practitioners is based on tailoring individual treatments to a patient's particular constitution and presentation. Given the theoretical underpinnings of the medicine which is grounded in the energetic concept of Chi and energy flow which is unique to each individual, Oriental medicine should not be viewed as "cook book medicine" and treatments cannot not be "one size fits all" based on a particular medical condition. Thus, any practice guidelines developed for the field would have to be sufficiently flexible to accommodate the philosophy and theory of the medicine. There is an abundance of literature and an increasing body of research to support Oriental medicine treatment techniques for most western medical conditions. ACAOM's accreditation standards, however, do contain some general condition-specific practice guidelines. For example, ACAOM's core curriculum standards include requirements for herbal medicine training in such areas as herbal formulas and their functions, functions of individual herbs, etc.

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

Acupuncture and Oriental medicine has a remarkably good safety record when practiced by comprehensively trained practitioners, as demonstrated by the low incidents of legal claims and injuries. We attribute this excellent record to the fact that ACAOM's core curriculum requirements provide the necessary training to ensure safe practice, as well as the fact that Oriental medicine utilizes inherently safer medical modalities than many other health care professions. Because of its excellent safety record, malpractice insurance is widely available to licensed practitioners and insurance rates have been falling over time. Only three states, Colorado, Florida and Oregon have mandatory professional liability insurance requirements for practice. Our concerns with malpractice insurance relate to the practice of Oriental medicine by inadequately trained practitioners, which is why ACAOM strongly supports the adoption of national educational and certification standards as a requirement for licensure throughout the United States.

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?*

Possible risks associated with the practice of acupuncture and Oriental medicine, primarily by inadequately trained professionals, include neumothorax, bruising, fainting, bleeding and contracting infectious diseases (for acupuncture), burns (for moxibustion), and herb toxicity and drug interactions (for herbs). Consumers are most concerned with contracting infectious diseases. However, the vast majority
of practitioners and virtually all US trained practitioners use sterile disposable needles in their practices. ACAOM accredited programs are required to provide extensive training to minimize the risks of particular treatment modalities (e.g., clean needle technique and handling, OSHA compliance, herb/drug interactions and contraindications, etc.) and to properly manage acupuncture and Oriental medicine treatment injuries should they occur. In addition, NCCAOM's certification exam assesses the critical competencies in these areas. Notwithstanding these risks, the safety record for the field of acupuncture and Oriental medicine as practiced within the United States is superb. We believe that this can be directly attributed to the increasing number of states which are requiring that candidates for licensure

graduate from an ACAOM accredited or candidate program to ensure that they have received adequate training, and passage of the NCCAOM certification exams to ensure that candidates for licensure have attained the critical competencies necessary for safe and effective practice.

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?*

Virtually all state licensure boards have developed and enforce appropriate procedures for addressing consumer complaints against Oriental medicine practitioners. In addition, many state and national professional organizations as well as the NCCAOM have developed and enforce appropriate ethics codes for practice. We believe that these mechanisms are appropriate and effective.

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?*

ACAOM's accreditation standards require that programs provide explicit training in western biomedical clinical sciences and to recognize patient medical conditions that may require consultation with and/or referral to allopathic health care providers. Adequate communication between CAM and conventional providers can be critical to proper patient care. Just as acupuncturists and Oriental medicine practitioners receive this training, western trained physicians should receive sufficient basic training in Oriental medicine and in the other CAM fields to engage in meaningful interactions with CAM practitioners pertaining to patient care issues. CAM practitioners should have access to their patients' western diagnoses when their patients are being, or have been, treated by a conventional provider. This information can be obtained through patient questionnaires, through patient intake interviews, or by reviewing patient medical records prepared by other providers. As it pertains to the field of Oriental medicine, ACAOM's accreditation standards require programs to provide in depth training in history
taking and patient intake prior to Oriental medicine diagnosis and treatment, including seeking from the patient information on his or her medical history (e.g., medical conditions/diagnoses, medications, allergies, and other relevant information), recording vital signs, etc).

Just as a CAM provider should communicate patient information to a conventional healthcare provider to help facilitate proper patient care (particularly where a serious medical condition may be present), a conventional provider should similarly provide patient information to the CAM provider which may also facilitate proper patient care.

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?*

We believe that Oriental medicine providers should be licensed and available to consumers throughout the United States and that all the CAM fields should eventually develop the structures necessary to support licensing requirements. Licensure should be based on

graduation from an accredited or candidate training program which has met nationally-recognized accreditation standards for quality education and training and passage of a national certification exam. The adoption of state licensure standards which are at variance with national standards for training and certification should be strongly discouraged. Inconsistent state licensure standards can have the impact of making it more difficult for qualified practitioners to move from state to state, and can result in the licensure of inadequately trained individuals to the detriment of the consumers of CAM services. We also believe that there should be medical insurance reimbursement parity for licensed CAM providers in order to make these unique health care systems available to more consumers.

Dort S. Bigg
Executive Director

Tab 3

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 2, 2001

Douglas B. Kamerow, MD, MPH
Director, Center for Practice & Technology Assessment
Agency for Healthcare Research & Quality
6010 Executive Boulevard-Suite 300
Rockville, MD 20852

Dear Dr. Kamerow:

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. How and by whom should "quality" in terms of CAM be defined?
2. Should quality of CAM be measured? If so, how and by whom should it be measured?
3. What should consumers be told about CAM?
4. Should there be condition-specific or modality-specific practice guidelines and why? If so, how and by whom should these guidelines be developed and to whom should they apply?

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

1. How and by whom should "quality" in terms of CAM be defined?

Quality should be defined using the IOM definition. There would not seem to be a good reason to develop a new definition.

2. Should quality of CAM be measured? If so, how and by whom should it be measured?

CAM should be held to the same standards as Western Medicine and quality measurement must include a wide array of outcomes including ones that are patient-oriented. Quality of CAM should be measured just as we are measuring the quality of Western Medicine. It should be measured by those familiar with CAM, but who are also skilled in appropriate research methods. Effectiveness and cost-effectives should be measured. Patient outcomes that include physical and psychosocial functioning and quality of life should be included in the equation. The evidence base for CAM treatments should be developed. It should be noted that some of this work is now taking place as a result of NCCAM and AHRQ funding and also in the Cochrane Collabortion, but much more needs to be done.

3. What should consumers be told about CAM?

BUYER BEWARE! The truth as it is currently known: That the evidence base for CAM is lacking in many areas and very weak in others. That certain botannical products and dietary supplements may be harmful/dangerous for some people. Although a product may be natural, this does not ensure safety. Standards of quality related to purity and consistency need to be developed. That certain other types of treatments may be harmful as well. Finally, that many treatments may not be harmful or dangerous, but they may also not be efficacious or effective and may be costly.

4. Should there be condition-specific or modality-specific practice guidelines and why? If so, how and by whom should these guidelines be developed and to whom should they apply?

In general, clinical practice guidelines have been condition-specific. Standards of care have been developed that are modality-specific and should in many cases be developed for CAM practitioners. If CAM clinical practice, condition-specific, guidelines are developed, it should be done by a multi-disciplinary team. The model used by AHRQ's predecessor Agency is an excellent model, particularly as it did not rely primarily on practitioner consensus, but conducted systematic literature reviews and, where possible, performed meta-analyses to determine the evidence base for a treatment. The first strength of a guideline is its evidence base. Then, and only then, can a panel of experts be convened to "fill in the gaps" between the evidence and practice. The key for CAM guidelines, just as it is for all guidelines, is to *label* the strength of evidence behind all recommendations. It is ok to have recommendations based on expert consensus if there is not good evidence behind it; but it must be labelled as such.

Douglas B. Kamerow, M.D., M.P.H.
Assistant Surgeon General, U.S. Public Health Service, and
Director, Center for Practice and Technology Assessment
Agency for Healthcare Research and Quality (formerly AHCPR)
6010 Executive Blvd., Suite 300, Rockville, MD 20852
Voice: 301.594.4026; Fax: 301.594.4027; email: dkamerow@ahrq.gov

Tab 4

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 30, 2001

Marie Bianchi
Executive Director
American Association of Naturopathic Physicians
8201 Greensboro Drive, Suite 300
McLean, VA 22102

Dear Ms. Bianchi:

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 naturopathic medical undergraduate, postgraduate, and continuing education? Should those national educational standards include exposure to conventional or western medicine? What is the status of postgraduate training in naturopathic medicine? Should there be a required minimum level of postgraduate training for naturopathic physicians? If so, why or why not? How should this postgraduate training be created, structured, and funded?
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 various naturopathic 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

At your request, the American Association of Naturopathic Physicians (AANP) has prepared a response to the questions you have asked for the White House Commission on CAM Policy. Several individuals have contributed to this response:

Nan Dunne Boggs, ND - Co-Chair, Professional Affairs, AANP
Bob Lofft - Executive Director, Council on Naturopathic Education
Pamela Snider, ND - Bastyr University
Jennifer Booker, ND - Practice Guidelines Project, AANP
Paul Reilly, ND, LAc - Co-Chair, Scientific Affairs, AANP
Catherine Downey, ND - National College of Naturopathic Medicine, Dean, Graduate Medical Education
Christa Louise, PhD - Executive Director, North American Board of Naturopathic Examiners
Rick Liva, RPh, ND - Vital Nutrients, Inc.

Some information has been sent by members of this team directly to you. The remainder I have compiled here.

1. *Are there national educational standards for naturopathic medical undergraduate, postgraduate, and continuing education? Should those national educational standards include exposure to conventional or western medicine? What is the status of postgraduate training in naturopathic medicine? Should there be a required minimum level of postgraduate training for naturopathic physicians? If so, why or why not? How should this postgraduate training be created, structured, and funded?*

Naturopathic medical education in the United States and Canada is not undergraduate study, but rather a "professional program," leading to a professional degree. All entering student are required to have their undergraduate study completed (BS/BA) by the time of matriculation in a
naturopathic medical school.

National educational standards for naturopathic medical and postgraduate education have existed since the Council on Naturopathic Medical Education (CNME) was founded in 1978. CNME was recognized by the U.S. Secretary of Education in 1987 and maintained recognition until January 2001. The Secretary's decision on January 16, 2001 not to renew CNME's recognition does not affect CNME's role as a programmatic accrediting agency.

As stated on the Department of Education's Web site, which may be accessed from CNME Links Page <www.cnme.org>, lack of the Secretary's recognition by a programmatic agency does not indicate the accrediting agency is unreliable. The

Department of Education reported in its October 1999 staff analysis of CNME's petition for continued recognition that CNME is a reliable programmatic accrediting agency.

These national educational standards include comprehensive exposure to conventional medicine. Naturopathic medical education prepares NDs to be primary care providers "with the same breadth and depth that prepares an MD to be a primary care physician" (Oregon Office of Educational Policy and Planning).

Postgraduate training in naturopathic medicine exists at all of the colleges in their residency programs, and in remote site residencies as well. The National College of Naturopathic Medicine's Postgraduate Medical Education Program has been accredited by CNME.

Presently, the naturopathic colleges are creating, structuring, and funding the naturopathic postgraduate training programs in line with CNME's residency program certification standards. A limited number of residencies are available - 20 through NCNM, seven through Bastyr, and an unknown number (probably fewer than Bastyr) through SCNM. Almost all residencies are one year, with the emphasis on primary-care family practice. Naturopathic postgraduate education has been in existence since 1979 and continues to evolve. One state, Utah, requires for licensing the completion of a one-year postgraduate training program that is certified by CNME.

Regarding continuing education, each licensing jurisdiction has its own requirements.

There is general consensus in the naturopathic profession that requiring a minimum level of postgraduate training for naturopathic physicians is a desired goal. The limiting factors at this time are residency opportunities and the lack of federal funding for naturopathic residencies.

POLICY RECOMMENDATION: Include naturopathic postgraduate medical education (residencies) in the same federal funding source/s as for conventional postgraduate medical education.

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?*

National standards to practice naturopathic medicine have existed for 15 years, in the form of the Naturopathic Physicians Licensing Examination (NPLEX) which is used by all jurisdictions in North America as the standard for licensure. The North American Board of Naturopathic Examiners (NABNE) administers NPLEX and is currently

considering awarding certificates to those who successfully pass the exam, so that those naturopathic physicians who practice in states without a naturopathic practice act can provide evidence of their competency.

There are also specialty societies (Homeopathic Academy of Naturopathic Physicians and the American College of Naturopathic Obstetricians) which examine and certify those naturopathic physicians who specialize in certain modalities.

We believe that there should be national standards for CAM practices. These standards need to be developed with the input of a variety of perspectives including practitioners of Chinese medicine and acupuncture, naturopathic medicine, Ayurveda, Native American healing, botanical prescribing, homeopathy, massage and other bodywork modalities (e.g., Hellerwork). At least three levels of expertise would be distinguished: licensure, certification, and endorsement via apprenticeship. The standardfor each level would be set, for example using descriptors on what a practitioner at each level should be able to do (see below). Licensure would be the highest level and strict standards of education would be required. Certification might mean demonstration of competence, no matter how the knowledge was acquired. The third category would cover practitioners such as Native American healers. Implementation would require federal support for the standards, and could be carried out by national boards.

Supporting arguments follow:
First a distinction should be made between a CAM modality and a CAM system. A CAM modality may be defined as any single category of treatment, for example botanical substances, homeopathy, massage, acupuncture, etc.. A CAM system encompasses an underlying philosophy, having implications not only for which treatments are used, but also how they are used. CAM systems include naturopathic medicine, Chinese medicine, and Ayurvedic medicine.

In general, the demand for CAM is currently being addressed by three types of practitioner: Licensed and certified CAM practitioners, both those who treat within a system of medicine, and those who are certified in particular modalities. [Also,] unregulated practitioners; and the existing medical (allopathic) profession.

In regard to the first, licensed or certified practitioners are not universally accessible as not all states regulate these practices. In regard to the second, unregulated practitioners pose a potential threat to public safety. In regard to the third, not all CAM practices can simply be appended to existing allopathic systems because this assumes that the foundation of allopathic medicine is compatible with the underlying CAM philosophy. This is not always the case. CAM modalities can be used allopathically (for example, the use of St. John's wort as a substitute for Prozac). Or they can be used within a

system of treatment that is based on a different underlying philosophy. The CAM education that conventional providers receive is not always sufficient for safe and effective practice. Patient outcomes will vary depending on both the qualifications of the practitioner and the appropriateness of the modality within the larger treatment philosophy.

Because of this variability of practitioner philosophy and effectiveness, credentialing and licensing standards must be specific and consistent so consumers can evaluate the legitimacy of a practitioner who claims expertise in CAM practices. Just as supplements and other health care products need to be labeled according to federal standards so that consumers know the purity of, and indications for use of the product, practitioners must also be "labeled" (i.e., nationally credentialed) so a patient can clearly understand the qualifications of the practitioner and potential effectiveness of the therapy s/he is seeking.

Naturopathic medicine has an underlying systems-based philosophy with (Western conceptualization of) basic sciences at its foundation. It is not simply the use of a variety of natural (CAM) modalities. Naturopathic medical students attend a four-year in-residence program at an accredited naturopathic college where they study the basic sciences and receive didactic and hands-on clinical training involving extensive patient contact. Individuals who earn "degrees" via distance learning have no such training in basic medical sciences and have no patient contact. It has been suggested that the former be called naturopathic doctors and the latter be called simply "naturopaths". Individuals who wish to call themselves "naturopaths" use various natural (CAM) modalities with varying degrees of training in those modalities. However, they do not receive training in basic medical sciences nor do they understand the underlying principles of healing.

The suggestion that osteopathic doctors agree to allow unlicensable individuals to call themselves "osteopaths" would, undoubtedly, be met with considerable resistance. Why then should trained and licensable naturopathic physicians agree to a similar classification?

Beyond titles, a critical factor in public safety is the question of diagnosis. A healthcare practitioner must be able to diagnose (i.e., determine what the problem is) before s/he can appropriately treat. Diagnosis is the foundation of any healing system. How does an individual who has been trained via the internet learn to diagnose patient? Is s/he trained in how to perform a physical examination or is it simply the presenting symptoms that are treated? Treatment of those symptoms would be allopathic application of natural therapies: it treats a symptom as opposed to getting at the cause of the problem. Application of a therapy to counter a symptom requires little

understanding of the underlying cause.

Individuals who have obtained degrees via distance learning would have us believe that "naturopathy" refers simply to the safe use of natural remedies as have been handed down under the guise of "folk medicine". They imply that requiring more extensive education is tantamount to repudiating native American traditional medicine because it is not taught in schools. This is not the case. Learning via very lengthy apprenticeship is different from learning via the internet. Much is lost in the translation.

In the absence of CAM regulation, private network enterprises are already "credentialing" both licensable as well as unlicensable practitioners, demonstrating that these networks lack comprehensive information and guidance.

In an uneven regulatory environment there needs to be some means: For consumers to evaluate the qualifications of practitioners; For members of the health profession to feel confident referring to them; and For insurance companies to determine which practitioners they should reimburse.

Licensing laws regulating naturopathic medicine have been defeated in various states because people who call themselves "naturopaths", for fear of no longer being able to practice, have worked hard to oppose those laws. The way the laws have been written, individuals are not prevented from practicing natural CAM modalities; however they are prevented from calling themselves "naturopaths" because of the potential confusion with the qualifications of naturopathic physicians.

To become a licensed naturopathic physician, an individual must be qualified by four years of in-residence education at an accredited institution, and then pass the Naturopathic Physicians Licensing Examinations (NPLEX). NPLEX was established fourteen years ago to produce national board licensing examinations that qualified naturopathic physicians must pass in order to practice in any state that regulates the profession.

The North American Board of Naturopathic Examiners (NABNE) was formed because states were not consistent in applying credible criteria for qualifying applicants to take the NPLEX. NABNE ensures uniform standards of qualification and exam administration in order to protect public safety in the 11 states that license naturopathic physicians. In the other 39 states, the public has no reference against which to judge the qualifications of an individual who calls her/himself a naturopathic physician.

We recommend: Sponsorship of a national conference of CAM practitioners to explore options for levels of national credentialing standards. This conference would include

practitioners from: Chinese medicine and acupuncture; Naturopathic medicine and natural modalities; Ayurveda Native American healing; Botanical prescribing; Homeopathy; Massage and other bodywork modalities (e.g., Hellerwork). At least three levels of expertise would be distinguished: licensure, certification, and credentialing (endorsement?) via apprenticeship. The standard for each level would be set, for example using descriptors on what a practitioner at each level should be able to do.

One way to approach it would be to require that practitioners of systems of medicine be licensed while practitioners who use single modalities be certified in those modalities. The issue then becomes what criteria should be applied to each. A licensed entry-level practitioner should at least:

-Know how to take a patient history
-Be able to perform a physical examination (according to the philosophy as it is taught within that system);
-Be able to interpret findings of a physical examination
-Know what are normal values of physiological functions (lab tests)
-Know the signs and symptoms of common conditions
-Be able to diagnose common and dangerous conditions
-Know the relevant risk factors for a condition
-Know the complications and consequences of common conditions
-Be able to do a differential diagnosis
-Know common prognoses
-Know common accepted treatments
-Know possible side effects and interactions of treatments
-Understand and recognize contraindications
-Have knowledge of procedures
-Know when referral is appropriate
-Understand personal limitations
-Understand the psychosocial aspects of disease
-Develop treatment plans (both long-range and short-range)
-Know principles of Public Health reporting

An entry-level individual certified in a modality should at least:

-Know common accepted treatments for common conditions
-Know possible side effects and interactions of treatments
-Understand and recognize contraindications
-Know when referral is appropriate
-Understand personal limitations
-Know principles of Public Health reporting

Traditional healers could be endorsed based on apprenticeship within the cultural

group.

Federal support of national standards coming out of this conference would give consumers, insurers, and other health care professionals a criterion against which they could assess a CAM practitioner's qualifications.

Support for the development of credible structures (such as NABNE/NPLEX) for other CAM systems and modalities could include: Qualifying examinations (for licensure or certification) developed following the Standards for Educational and Psychological Testing. These examinations would be based on a blueprint developed from a practice analysis, with items written by trained item-writers who work in related fields, and would include appropriate analysis of items and exams.

Clear standards of educational qualifications to take the examinations. Unbiased and secure administration of examinations.

With regards to whether there should be national standards for CAM products: with the passage of the Dietary Supplement and Health Education Act (DSHEA) a few years ago, Congress gave power to the FDA to oversee the quality and safety of natural products that are in the market place. The FDA wrote specific guidelines for the production and manufacture of consistent high quality natural products. The guidelines are called Current Good Manufacturing Practices (cGMP's) for nutritional supplements and they are published in the Federal Register.

(Federal Register: February 6, 1997 (Volume 62, Number 25) Proposed Rules Page 5699-5709, From the Federal Register Online via GPO Access wais.access.gpo.gov Page 5699, Part IV, Department of Health and Human Services Food and Drug Administration, 21 CFR Ch. I, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements; Proposed Rule Page 5700 DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration 21 CFR Ch. I Docket No. 96N-0417 RIN 0910-AA59)

To date these proposed rules have not been officially adopted by the FDA. If and when they are, the FDA will put natural products manufacturers on notice that they have to comply with the rules within a specified time period. Dietary supplement manufacturers will have to register with the FDA. Then the FDA is supposed to inspect manufacturers to make sure they are complying with the FDA's cGMP's. Non-compliance brings warnings, fines, recalls or shutdowns. The absolute key here is giving the FDA the resources to carry out their role. Currently they do not have the manpower or financial resources to do so. Assuming the FDA carried out this charge we would have a national standard for consistent quality natural products as well as an

oversight body to assure compliance with those standards. Manufacturers should be given a grace period (12-18 months) to comply with the cGMP standards. Then FDA inspections will begin to assure compliance.

The dietary supplement industry for the past several decades has operated with no oversight whatsoever. The FDA stepped in only when there was an overwhelming safety issue or a company was making blatant drug claims for a dietary supplement. The industry was free to cut corners, shirk quality control and do just about whatever they wanted and get away with it. This climate mostly continues to exist today. Without a clear set of standards and an effective oversight body to hold manufacturers accountable to those standards the free-for-all environment will persist.

POLICY RECOMMENDATION: Support federal funding of a national conference of CAM practitioners to explore options for national credentialing standards, with the ultimate result of establishing such standards.

POLICY RECOMMENDATION: Direct the FDA to officially adopt the proposed rules for cGMPs for dietary supplements.

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

A rich, effective professional community of naturopathic medicine's individual physicians and supporting institutions already exists. The various naturopathic medicine organizations have a well-developed "community" that is an outgrowth of common, shared experience in naturopathic medical school, the fellowship that is felt at our annual national conventions, and the fact that many of our leaders hold multiple positions in the various naturopathic medical organizations. The naturopathic community consists of those individuals who have for the past 3 decades devoted their intellectual and creative capital to the establishment of an accountable, licensable profession. Individuals united in the effort to bring the valuable tools of vis medicatrix naturae into the 21st century toiled originally in the face of the prevailing conventions of the mid-century medico-scientistic mindset. Having preserved, enhanced and consistently demonstrated the efficacy of naturopathic practice to a point where the value of this and other CAM tools are recognized by the conventional health care system and clamored for by the public, the naturopathic community now faces a disruptive force in the form of the anti-regulatory forces which has a stated intention to reverse the institutional achievements of the past 30 years. Licensable naturopathic physicians have bent their efforts to developing credible institutions of higher learning (National College of Naturopathic Medicine, Bastyr University, Southwest College of

Natural Medicine and Health Sciences, Canadian College of Naturopathic Medicine); to establishing state and provincial licensing with accompanying regulatory agencies (12 states/territories and 3 provinces); and to creating nationally and internationally cooperative authorities for testing and regulatory standards (the North American Board of Naturopathic Examiners, the Naturopathic Physicians Licensing Exam, the Federation of Naturopathic Physicians Licensing Authorities).

This has been an internal, self supported effort, manifested without the customary subsidization and support of the governmental or other professional institutions that have been engaged for the development of especially conventional medicine. At this juncture, as the naturopathic community's institutions and impact is raising a silhouette discernable on the national radar screen, there has been an upwelling of effort from individuals eager to profit from the value of the medicine and the integrity of the professional community's effort, without a commensurate commitment to the historical and current educational or practice standards inherent to naturopathic medicine.

The American Naturopathic Medical Association (ANMA) is a disorganized group with dubious "credentials" (obtained through distance learning) whose leaders use tactics of obfuscation and divisiveness, while falsely claiming to be true "naturopaths" and wishing to "unite" the profession. Attempts to negotiate with and include this element in our community have proven difficult if not impossible, as the ANMA is opposed to licensure of naturopathic medicine and has filed numerous lawsuits and engaged in malicious prosecution against the AANP.

This contingent seems to require some retrogression, significant anti-regulatory efforts and attempts to promulgate markedly diminished educational standards. These forces have profited from the professional naturopathic community's distaste for employing similar tactics of historical re-writing and obfuscation. All efforts at customary dialogue extended by the professional naturopathic community have been rebuffed. Our lack of success at engaging the anti-regulatory forces in a meaningful exchange has enabled this element to create a false impression of in-fighting and disunity within a single entity. In fact, there is documentable historical and contemporary data to illuminate what exactly the naturopathic community has always been, what naturopathic medicine is, and how the community of entrepreneurs and coat-tailing profiteers is a different element altogether: an element with a destructive agenda that unfortunately does seem to be in a position to potentially obscure core issues and reverse real progress.

There can be created a sufficient opportunity, a proper forum, to effectively communicate and exchange the necessary information to clarify finally the question "What is the naturopathic community"? There have been tools developed that provide

criteria and methodology for evaluating naturopathic medicine as well as other CAM practice communities in order to determine a practitioner groups' positioning on a continuum of definitions, that is, those definitions commonly accepted as describing a public service health care profession. We encourage the Commission to examine these evaluative models and to support the application of the most appropriate model to CAM practitioner communities under scrutiny. (See Dr. Pamela Snider's "taxonomy on emerging professional and communities of practice" an d Dr. Clyde Jensen's "Rainbow Continuum")

POLICY RECOMMENDATION: Conduct a study, with federal funds, of the naturopathic profession which applies an appropriate evaluative model.

POLICY RECOMMENDATION: Prohibit distance learning programs from awarding doctoral degrees in naturopathy and naturopathic medicine.

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?

Condition specific guidelines are essential for clear delineation of the application of the philosophy and principles of CAM practices. These guidelines are needed for the education of non-CAM providers, health care facilities that wish to include CAM services that presently do not, third party payers, state and national public health care systems, and institutions providing health care education for future providers who will need an understanding of CAM practices. Health care consumers can make better informed choices in healthcare decision making when practice guidelines are available in layperson terminology which include both CAM and conventional care guidelines.

To date practice guidelines receiving the highest scores for reliability are those generated through a profession generated algorithm or decision tree, with multi-disciplinary committees, graded review of research and research funding provided by multiple sources. A CAM example may be a naturopathic medicine algorithm for otitis media which includes pediatricians, otolaryngologists, family practitioners and allergists on review committees. Existing research supporting typical naturopathic interventions would be assessed utilizing already existing practice guideline methodology of grading research by strength.

Leadership of such a project by a CAM provider would be essential for quality and authenticity of such a guideline. Using the example above, naturopathic medicine is based on a set of principles and practices which emphasize early diagnosis, early intervention, prevention and patient responsibility for self care and self care choices

through education. Treatment of otitis media is based on the principles of using the least amount of force or lowest effective level of intervention, utilizing any or all of the following; diet, herbal medicine, nutritional medicine, homeopathic medicine, hydrotherapy and lifestyle counseling. Prevention through patient education is emphasized. Utilization of other health care disciplines on consensus panels and panels of experts would serve to strengthen and broaden the guideline, as well as develop important relationships between CAM and non-CAM health care providers.

Implementation of the guidelines would be throughout the naturopathic profession and the educational system for naturopathic medicine. Implementation of such a guideline by non CAM trained providers would not be possible until education to minimal levels of competency had been accomplished and appropriately certified.

POLICY RECOMMENDATION: Establish CAM practice guidelines committees which are federally funded.

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

The licensable naturopathic community is highly concerned about malpractice liability from the perspective that the availability and provision of such represents one element of essential professional standards for practitioner accountability and protection of public safety. There are a number of malpractice insurance companies that provide coverage to licensed NDs. We look forward to increasing numbers of opportunities for ND's to purchase coverage, as licensing is achieved uniformly across all states and the insurance industry follows suit to offer services. The credentialing systems for this industry require the standards of education, testing and licensing developed by the naturopathic profession, and which is available to CAM professions in general as a model for development.

The malpractice industry provides ratings, derived from relative costs and risk to the consumer, to the healthcare system of providers, based on their practice safety records. Washington Health Casualty Company, (14100 SE 36th Street, Suite 100 Bellevue, WA 98006) has evaluated it's company history, which in the form of these ratings shows the following relationships:

Professional Standards: Effects On Safety, Insurance Rating Scale for Malpractice

- NDIs .7
- Dermatologists .7
- ND Midwives 1.0
- MD Family Practice 1.0 1.5

OB[1]s 8.0
Neurologists 12.0

To the degree that the ND practices covered by Washington Casualty are representative of the licensable community, this data reflects an appropriately low level of injury risk when the population examined are licensed professionals.

Some corroborating evidence based on the historical relationship of licensed NDs in the northwestern US to the malpractice industry can be found in Professional Standards: Effects on Safety, Jury Verdicts Northwest -- "Jury Verdicts Northwest has conducted two reviews for the Washington Association of Naturopathic Physicians. No malpractice judgements have been found against a naturopathic physician since 1983".

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?*

Yes, there are risks. And the solution in a word is licensing. There exists a pervasive, (and indeed deadly) mythology regarding the presumed safety of natural therapies. An anecdotal example is as follows - a gentleman was stopped by the highway patrol in Florida a few years ago because of suspicious driving behavior. The officers expected to find a drunk driver. The man was not under the influence of alcohol. Rather, he was experimenting with an over-the-counter form of the generally benign herbal remedy Kava Kava, which has a mild relaxant and anti-anxiety effect. The typical dose is 2 capsules every four to six hours. This man had, with typical American gusto, figured more was better, and proceeded to ingest 67 capsules all at once. He was not drunk, but he was altered, and dangerous behind the wheel of his car.

Unfortunately while it is certainly difficult to hurt oneself or anyone else by using natural therapies and products, especially as available in the retail marketplace, it is not impossible, as remarkable human behaviors amply exhibit. Herbal medicines and nutritional supplements in concentrated forms, can be abused, either deliberately or in untutored combination with conventional drug therapy. There is as yet not an optimal system for required reporting of untoward incidents. Where NDs are licensed, they are subject to the federally mandated National Practitioner Data Bank and the Healthcare Integrity and Protection Databank, as are all regulated practitioners. Where practitioners are licensed, they are required by law to maintain current knowledge of the burgeoning research on combinations of natural and conventional pharmaceutical remedies. As degreed professionals, they are active initiators of and participants in investigatory clinical trials of the modalities in use.

Abraham Lincoln once said: "The legitimate object for government is to do for the

people what needs to be done, but which they can not, by individual effort, do at all, or do as well, for themselves." It is the primary duty of state professional licensing boards to protect the public. In the 12 jurisdictions in the US where naturopathic medicine is already licensed, this is accomplished by mandated standards for appropriate education, psychometrically valid testing, and an application process which documents the candidate's moral character and academic, examination and legal history. Public safety is further protected by licensing agencies with policies and procedures which provide for ongoing updating of the qualified applicants' practice history and personal legal history, as well as a complaints and investigation process. Such process and an accompanying disciplinary procedure, backed by the jurisdictional power of the state, assures both the public and the practitioner of due process and appropriate suspension or revocation of practice privileges.

The willingness of the graduates of 4 year naturopathic medical colleges to be examined, to subject themselves to regulation, to make their practice accountable to law and other professional sanction, is a measure of this group of practitioners' devotion to quality of service in the public good. The integrity of the intent to be transparently available to scrutiny in the name of public safety should be a defining characteristic of a healthcare provider. In healthcare, where negligence, mistakes and wrong-roads taken have potentially devastating impact on consumers, the integrity of licensure is essential.

Virtually every licensing act regulating the practice of naturopathic medicine in the United States and Canada are explicitly title protection acts. There is a national standard which considers issues of public safety to be guarded by the titled licensees having documented for the state that they have met specific higher education and psychometrically valid testing standards. Without even entering the debate about the meaning or Œownership" of the title naturopath, it is not hard to imagine, or for that matter to document, the harm that becomes real when the public is confused about the meaning of a title, especially the title "doctor". That licensing is not a guarantee of safety is a specious argument. In fact, although we would like to believe the public is fully capable of exercising appropriate attention to practitioner credentials, that everyone always makes informed choices, actually many people are regularly seduced by messaging that obscures the truth of it¹s content. Poorly trained, unregulated practitioners misdiagnose, delay or prevent appropriate treatment, can not participate effectively in an optimal referral system for the benefit of the patient, and there by cause harm. Without regulation there is little incentive to participate in either a reporting system or effective continuing education.

A recent tragic example provides a painful illustration of the consequences to safety in an unregulated jurisdiction. In October of 1999 an 8 year old girl named Helena Rose Kolitwezew, who was an insulin dependent diabetic, died because her mother was

convinced by a charlatan that he was providing safe and effective care for her daughter. This man, who displayed a diploma from a correspondence school selling so-called doctoral degrees in naturopathy, was apparently not well enough educated to understand that an insulin dependent child can not be taken off her insulin and treated with herbs. The mother trusted, the child died and the man is charged with manslaughter. His trial begins in the next few weeks. This miserable event took place in Asheville, N.C., where there is as yet no licensing for naturopathic medicine. If Helena's death lends weight to the demand for regulation of practitioner claims there may be derived some scant meaning for the nightmare of her unnecessary death. I encourage the Commission to take the opportunity to ensure no similar disaster overtakes any other American family, by lending every assistance to the promulgation of appropriate, uniform professional standards, including regulation by licensure, to the CAM community.

POLICY RECOMMENDATION: Minimize the inherent risks of CAM practice by a federal policy which encourages and supports state licensing of CAM providers.

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?

Mechanisms to address consumer concerns or grievances about the quality of CAM practices or products are highly desirable. Please see #6 for commentary regarding licensing as an essential tool for protecting public safety, and providing complaint mechanisms, with teeth, for consumer grievance. Our society has yet to come up with a more effective way to guarantee consumer protection than the regulatory mechanisms that work to prohibit non-compliant, non-standard practices. The degree to which a practitioner group subjects itself to an organized, internally generated system of surveillance, to discipline by governmental agencies on the outside as well as its own professional associations and other self-regulated agencies, provides a clear statement of the practitioner groups' sense of responsibility to public health, safety and professional accountability.

As regards product safety -- the effectiveness of a practitioner's treatment depends on the reliable potency, the dependable quality of the product tools available. A regulatory watch dog that functioned to guarantee standards of purity as well as quality of products would be welcomed in naturopathic practice as a boon to both doctor and patient. Both would be saved mostly a great deal of waste-- of time for the doctor who must educate the patient about how s/he determines product quality, and especially of money for the patient, who has typically invested heavily in ineffective self-treatment to some significant degree of loss, before turning to the CAM professional for efficient guidance to effective therapy.

Currently licensable NDs have the science-based education that makes them critical consumers of the natural product industry. Efforts redundantly performed by individual doctors, as well as by each college's training program, would be assisted by the development of and FDA-like entity for natural products.

Under the current system the consumer has no idea when they are buying a good quality product or not, unless it harms them or they experience an adverse event. In the absence of harm, a poor quality product largely goes unnoticed. If the standards are adopted and enforced as stated above in the response to question #2, the issue of quality becomes moot in most cases.

In the case of adverse events or harm the same mechanism should be set up and followed for reporting of adverse events as it currently exists in the pharmaceutical industry.

POLICY RECOMMENDATION: Establish a mechanism for the reporting of adverse events of CAM products comparable to that of the pharmaceutical industry.

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?

In terms of adequate patient care and the standards of good medicine the information provided by either a CAM provider to a conventional provider or vice versa would be similar to that provided between any two referring conventional doctors. In brief the referral or report should include the following:
a. adequate identifying information such as name, age, date of birth
b. chief or presenting complaint, or problem list
c. history of presenting complaint and previous treatment
d. summary of patient's medical history including current medications, prior surgery/hospitalizations, pertinent family history, review of systems, social history
e. details of evaluation of presenting complaint done at providers office, physical exam and lab test findings
f. assessment of above including a presumptive diagnosis, rule outs, confirmatory tests run or suggested
g. treatment plan including lifestyle, diet, medications and supplements as well as an evaluation of response to therapy and prognosis.

The above format, with minor variations, is commonly accepted in medicine and has been developed in order to provide as much information as possible in a concise

manner. Such a format is appropriate for all medical practices whether conventional or complementary. When sending letters to another discipline it is helpful to keep in mind the level of familiarity with discipline-specific terminology. For example an acupuncturist might explain how "liver qi stagnation" might relate to premenstrual symptomatology.

In the interest of enhancing interdisciplinary communication between providers, it is useful when time permits to give brief explanations of intended actions of treatments in terminology the other provider might understand. This is especially helpful when dealing with skeptical conventional care providers. An example might be " The patient was advised to take fractionated pectin powder, 1 teaspoon twice daily. This compound can reduce the potential for metastasis by blocking galectan 3 receptors on tumor cells."

In general, it is appropriate to provide regular updates to referring providers and to other practitioners who are concurrently treating the same patient. This can help to prevent duplication of effort as well as help prevent improper combinations of medications. For example, if a conventional provider reported that she/he were prescribing coumadin, other providers would understand not to administer vitamin K. They might also determine that other treatments to reduce risk of clotting, such as fish oils, might be appropriate.

It is only by maintaining such open channels of communication that we can begin to build bridges of understanding and trust between diverse professions. As providers see the benefit to patients of various disciplines they can better determine when and how to utilize those services for other patients.

POLICY RECOMMENDATION: Direct the appropriate federal agency to publish guidelines which set forth proper referral protocol.

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?

By and large the quality of pharmaceuticals manufactured in the US are very high and the public trusts companies to provide consistent quality. This came about because Congress gave the FDA the responsibility and resources to make sure the industry produced products that were safe, efficacious and of consistent quality. Pharmaceutical cGMP[1]s were established, companies had to register with the FDA and to assure compliance inspections were conducted every so many years. Many government bodies are involved in this process and it has become a part of our medical culture. The same thing has to happen to assure quality, safety and efficacy of natural products. Congress has to allot the financial resources, the FDA has to officially adopt the

guidelines and standards, and the necessary governmental agencies have to work together to assure compliance with the standards.

Additional policy recommendations representing our views regarding CAM practices are being sent to you by Pamela Snider, ND. Thank you again for your invitation for us to contribute to the Commission's work. Please let us know if we can be of any further assistance.

Michael Traub, ND, DHANP, CCH
Vice-President, American Association of
Naturopathic Physicians

The AANP has received a request for information from the White House Commission on Conventional and Alternative Medicine (CAM) Policy, to help the Commissioners prepare for their upcoming meeting in Washington D.C. on February 22-23. I have been asked by Dr. Traub to respond to some of these questions. Appendices are being sent tomorrow by Federal Express. Please copy and distribute what the Commissioners would find useful.

1. ***Are there national educational standards for naturopathic medical undergraduate, postgraduate, and continuing education?***

Please refer to answers from my colleagues, Dr. Michael Traub (American Association of Naturopathic Medicine, Vice-President), Dr. Catherine Downey (National College of Naturopathic Medicine) and Bob Loft (Council on Naturopathic Medical Education-CNME). I understand that Mr. Loft is sending the CNME guidelines and Dr. Downey has sent NCNM's Residency Program Manual. I would like to add the following to their input.

- *Naturopathic medical undergraduate training refers to bachelor's level pre-medical training required for entry into naturopathic physician training programs.*
  Naturopathic medical undergraduate training: a minimum of three years pre-medical bachelors level courses are required for entry into all colleges accredited by the CNME and whose graduates are eligible to become licensed naturopathic physicians in all licensed states. Mr. Loft has forwarded the CNME guidelines to you. All United States and Canadian colleges training naturopathic physicians for licensure require this minimum of three years pre-medical training for entry into their four-year ND programs. Most qualified applicants for entry into these programs have exceeded these requirements. The majority of qualified applicants accepted into the programs have obtained their bachelor degrees while completing pre-medical course requirements.

- *Graduate training refers the four year 4100-4500 hour professional training program delivering the Naturopathic Doctorate degree.*
  Graduate training: The standard naturopathic medicine program requires 4100 hours of basic sciences, clinical sciences, modality, case management, theory and supervised clinical training. Naturopathic programs range from 4100-4500 hours. This standard is nationally recognized and is clearly stipulated in the CNME guidelines. All states licensing naturopathic physicians require this standard of training for graduates to be eligible to take the Naturopathic Physician Licensing Exam (NPLEX). Satisfactory scores on NPLEX in both basic and clinical sciences are required in licensed states to become a licensed naturopathic physician.

  Our four-year training programs for NDs are similar in terms of credit load to a five-year program of conventional medical training. For example, conventional medical programs require 18-23 credits per quarter over a four-year period to attain the MD degree. ND programs require 26-28 credits per quarter during a four-year period. Many ND students

maintain this credit load by either enrolling for some of these credits continuously every summer or by extending their program to five-year tracks.

Challenges faced by naturopathic colleges are student loan caps which force students into a more intensive four-year track for financial reasons – naturopathic colleges are 90% funded by student tuition and do not currently receive the same level of access to student loans and federal funding enjoyed by conventional medical and nursing schools.

- *Postgraduate training refers to both residency and specialty training.*
  Postgraduate training: Postgraduate training includes residencies as well as specialty training recognized by the naturopathic profession. Postgraduate residencies are available at all of the naturopathic colleges in their residency programs. All CNME recognized naturopathic colleges have established departments for Graduate Medical Education during the last five years. However, while the number of available residencies has expanded, there are not yet enough residencies for all graduates. There is general consensus that requiring a minimal level of postgraduate training for naturopathic physicians is a desired goal. The CNME has established national accreditation guidelines for postgraduate residency programs.

  One state currently requires NDs to have one year of residency training (Utah). There is also general consensus in the profession that we favor the establishment of a residency requirement in licensed states.

- *Continuing education will refer to annual training required to maintain ND state licensure.*
  Continuing Education: 15-20 hours of continuing education is required by most licensed states to maintain licensure yearly. Professional consensus is that this standard should become uniform. Increases are being considered in several states.

Postgraduate training is an interesting "beta site" for taking a look at an emerging standard in an emerging profession. While there is consensus that postgraduate residency training of 1-3 years (including specialty training opportunities) is desired and should be required, the profession must receive federal and state funding to establish an adequate number of residency sites. Until funding for graduate medical education is available through the appropriate federal agencies and legislation (HCFA, BPHC, HRSA, GME), it is not appropriate to require this level of training for all naturopathic physicians.

Current required standards today are producing well-trained, competent and safe naturopathic physicians. (*ND and dermatologists malpractice insurance rating scales are 0.7, MD family practice is 1.0-1.5, OBs are 8.0 and neurologists are 12.0. Washington Casualty Company 14100 SE 36th Street, Suite 100, Bellevue WA 98006.*

In terms of malpractice judgements, Jury Verdicts NW conducted 2 reviews for the Washington Association of Naturopathic Physicians. No malpractice judgements have been found against a licensed naturopathic physician since 1983 as of 1999.)

a) Should those national educational standards include exposure to conventional or western medicine?

Yes, these national education standards should and do include exposure to conventional and western medicine.

Basic Sciences

Naturopathic medical education requires two years of basic medical sciences training. These basic sciences are equivalent to basic sciences training in conventional medical schools require the same textbooks and are taught by PhD faculty who are often also teaching in medical schools

(Appendix 1: Letter from the Office of Educational Policy and Planning; Salem, Oregon; April 18, 1989, by David A. Young, Administrator, Academic Degrees and Program Review to the National Council Against Health Fraud.)

(Appendix 2: Excerpted curricula summaries from naturopathic college catalogs.)

Naturopathic colleges and basic sciences faculty are also involved in "The Integration Project." The project goal is "the systematic, intensified integration of naturopathic theory, principles of practice, and paradigm throughout naturopathic medical college curricula."

This integration is being built on the physician level science based educational structure and mission already in existence in naturopathic medical colleges. PhD faculty in naturopathic colleges are being trained with regard to underlying naturopathic philosophy and principles. A process of ongoing systematic dialogue and inquiry is fostered between our academicians, clinicians, and researchers concerning the underlying theory of naturopathic medicine. Faculty and researchers are bringing the fruits of this endeavor into the classroom, both in terms of scientific research and empirical observation.

(Appendix 3: "The Integration Project: Principles, Theory and Paradigm of Naturopathic Medicine in Curriculum Development;" Association of Naturopathic Medical Colleges, 1996-2000)

Clinical Sciences

Naturopathic training includes two years of clinical sciences training. Supervised clinical training (approximately 1200 hours) is provided in outpatient primary care clinics (see Appendix 2). Didactic conventional clinical sciences are part of this two years; for example, gynecology, cardiology, pediatrics, oncology, geriatrics, rheumatology, gastroenterology. Training is similar to that of a conventional family medicine provider in terms of pathophysiology, conventional diagnosis of pathology, lab diagnosis, physical exam skills, basic pharmacology, public health and minor office procedures. Distinctly naturopathic

diagnosis, treatment, and prevention strategies and modalities skills are a significant part of clinical training. Further evidence of exposure to conventional clinical sciences is available by reviewing the syllabi and textbooks required in these courses, many of which will be very familiar to a family physician. A list of these textbooks can be provided upon request.

b) What is the status of postgraduate training in naturopathic medicine?

Residency training was addressed in part (a).

Naturopathic physicians receive specialty training through several pathways. NDs may specialize in modalities (nutrition, botanical medicine, etc.), populations (geriatrics, pediatrics, women's health) or clinical specialties (cardiology, dermatology, etc.). Postgraduate specialty training is another example of the "front line" of emerging standards for our profession. There is overall consensus that the general care/primary care model is our foundation, and specialties can be developed subsequent to primary care training. Ethically, there is consensus that in order to describe oneself as a specialist in any area of naturopathic medicine, one must obtain additional training. Training pathways now include:

- Postgraduate specialty boards within the naturopathic profession (Homeopathic Academy of Naturopathic Physicians-HANP, Botanical Medicine Academy-BMA, American College of Naturopathic Obstetricians-ACNO) which have developed or are developing standards for postgraduate specialty training, testing and certification (documentation available upon request)
- Dual degree, licensure or certification (ND/LAc; ND/DC; MD/ND; ND/Masters of Science in Nutrition; ND/PhD; ND/MPH; Spirituality, Health and Medicine, etc.)
- Continuing education training conferences for state approved continuing education credits in other areas of clinical practice

Policy Recommendations

Postgraduate specialty training is continuing to develop throughout naturopathic colleges. This area of professional development is ripe for federal funding and for exchange programs in collaboration with conventional medical schools.

Exchange programs should be developed between conventional and naturopathic medical schools. These programs could be funded by the Bureau of Primary Health Care (BPHC), Health Resources and Services Administration (HRSA), and developed and facilitated by the AAMC and the Association of Naturopathic Medical Colleges.
(Appendix 4: The Future of Naturopathic Medical Education, 1996: Southwest College of Naturopathic Medicine Anthology, Vol.1 by Pamela Snider, ND)

c) Should there be a required minimum level of postgraduate training for naturopathic physicians? If so, why or why not? How should this postgraduate training be created, structured, and funded?

Some of this has been addressed in part (a).

Standards for residency training have already been developed by the CNME and are in use by our college GME departments. Standards and requirements for naturopathic postgraduate training must continue to be developed and approved by the CNME. However, new postgraduate training opportunities could be created by a consortium including all conventional and CAM accredited colleges and universities consulting and working together to develop pathways and opportunities for exchange programs between existing regionally or nationally accredited conventional and CAM educational institutions.

Policy Recommendations

It is my experience and recommendation that postgraduate naturopathic training should include at least one year of purely naturopathic residency training. The development of in-patient natural medical "healing retreat" centers as training sites is a critical priority (*see Appendix 4*). Additional naturopathic specialty training (homeopathic medicine, nutrition, botanical medicine, spirituality, health and medicine, physical medicine, natural hygiene, etc.) and/or exchange programs with conventional medical schools could then be pursued by ND graduates (for example in rural health care, community and public health, geriatrics, pediatrics, and other areas of general or primary care practice).

Federal Graduate Medical Education (GME) financing systems must pass legislation and or rules authorizing GME funding for licensed naturopathic physician residency training and coverage of ND resident services. The Bureau of Primary Health Care, the Bureau of Health Professions and the Health Resources Services Administration should provide grants to each of the accredited naturopathic medical schools to rapidly expand purely naturopathic residency, specialty and postgraduate training programs and sites as well as exchange opportunities with conventional and other accredited CAM schools.

The Health Care Financing Administration (HCFA) must incorporate legislative language and promulgate rules to cover services from ND licensed providers in all licensed states. The Medicare Act must be amended to provide for these changes. The distinctly licensed CAM professions must be appointed to the HCFA Joint CPT Committee to address coding, evaluation, and management documentation. Two examples before Congress are the Medicare Medical Wellness Act and the Medicare Medical Nutrition Act providing the sole right to have nutrition services reimbursed to registered dieticians. While we support registered dietitians receiving this coverage for services, we recommend expanding the legislation to include all CAM regulated professions whose training scope of practice provides regulated nutrition services.

The Council on Graduate Medical Education draft report, "*Financing Graduate Medical Education in a Changing Health Care Environment,*" recommended "reform of the entire GME financing structure" (Washington Highlights, Vol.1,No. 35, September 22, 2000). I recommend an addendum to the report concerning licensed CAM professions and GME

financing. GME reforms relevant to both CM and licensed CAM provider services should both be addressed before attempting any major reform to GME systems.

The Balanced Budget Refinement Act of 2000 (HR 3077) would improve services for Medicare recipients. This bill allows GME payments for psychologists. We recommend incorporating GME payments for licensed naturopathic physicians in this legislation or similar legislation. Authorizing language for ND residency funding in all GME funding streams should be written into this legislation (and rules) including authorizing Medicare direct and indirect GME, Children's Hospital GME, and Title VII grants from HRSA for licensed naturopathic physicians.

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?***

Re: Practices

This very important question should be answered from a consumer and payor system perspective. Accountability is the complex issue driving this question. No single activity or process guarantees accountability. National standards, processes and guidelines tend to provide the accountability consumers need for safe and effective health care while we all wait for the research data to emerge.

"We know when accountability is present in health care practices when the consumer or patient has confidence in

- the safety, efficacy and cost effectiveness of the treatment
- the competence and accessibility of the provider
- recourse/opportunity for redress if something goes wrong

The most common pieces of a comprehensive model for professional accountability include many professional standards, processes and guidelines, data and research as well as government and regulatory oversight and peer review."
(Appendix 5: Quinn, Sheila. "Accountability A Complex Issue." Moderator. "Beyond Data: Standards as Integration Models." International Conference on Integrative Medicine. April 1999. Seattle, Washington.)

National standards have already been developed for the distinctly licensed CAM professions and by traditional and indigenous systems throughout the world. It is important that we not "recreate the wheel". Conventional medical education should integrate CAM on a strong and tested foundation. The standards already developed by these systems and modalities of health care are rich national resources for mainstream health care delivery systems and conventional medicine in the search for answers about the safe and effective integration of CAM into medical school training and retraining the conventional medical workforce. There are

standards in these professions which are still emerging such as practice guidelines and postgraduate training, Federal funding for completion projects is recommended.

Key questions are: how can we collect and centralize the existing data on these standards? How can we use that data to inform federal and state policy, and the integration of these standards into mainstream healthcare education and service areas? Existing national standards or certification for providing CAM practices and products which have already been developed and are reflected in federal legislation, state legislation, licensing acts, regulations, or through national, regional and profession accreditation bodies must be understood. These standards should then be uniformly recognized by the federal government in regulations, legislation and benefits programs. The highest existing standards in the distinctly licensed CAM professions and modalities.

Policy Recommendations

Funded completion of these standards by the distinctly regulated CAM systems *(Appendix 6: OIC Table)* should be supported. A funded initiative with CM and CAM leadership on usability of these standards should be developed at HRSA. To answer this question completely, the Commission might consider recommending that the following steps be funded by an appropriate federal agency such as HRSA, BPHC or DHHS.

1. ***Research:*** What are the national standards, processes, and guidelines that are currently recognized by states licensing CAM providers? What education is required? What scope of practice does this education lead to? What are the adverse events and safety records for each of those professions and modalities? What other processes, standards, and guidelines have been developed by each of the CAM curriculum systems or modalities within those systems, which have been vetted by states and incorporated as safe guidelines and standards for CAM practice?
2. ***Compare***: How much of this training already exists in conventional medical education? What are the gaps?
3. ***Identify***: What kind of training are conventional providers seeking in CAM or Integrative Medicine (IM)? What kind of conventional training are CAM providers seeking?
4. ***Develop Consensus***: Establish a national "Blue Ribbon Credentialling and Standards Round Table" to produce a white paper with consensus recommendations on integration of the highest existing CAM standards for CAM practice of therapies, modalities, disciplines and systems into mainstream education, regulation, clinical services and the market place. Mandate equal and expert representation by all CAM and conventional disciplines, modalities and systems in developing these recommendations. Include public health,emerging professions, communities of practice and traditional and indigenous healers in this process. Recommendations should also include opportunities to link accredited CAM, CM, IM training sites and systems.

Products

Policy Recommendations

In answer to the question about the provision of CAM products, I strongly recommend that the U.S. federal government study and replicate both the process and the model used by the Health Protection Branch (HPB), Ottawa, Ontario for natural products regulation. The federal government in Canada has established an Office of Natural Health Products (ONHP) at the HPB with an excellent interdisciplinary advisory board. The ONHP has authority at the same level as the HPB: Drugs Directorate – Canada's FDA.

The charge of the ONHP is to regulate natural health products (botanical, nutritional, homeopathic and others). The advisory board is working to promulgate guidelines for the appropriate and safe regulation of natural health products. The Ministry of Health in Ottawa led the process which established this ground breaking model for safe and effective natural health products regulation. Paul Saunders, ND, PhD, is a member of the ONHP Advisory Board and is Associate Dean at the Canadian College of Naturopathic Medicine. His testimony was provided to the Commission during the Seattle Town Hall Meeting, October 30-31, 2000.

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

There is a strong naturopathic community in the United States. The term naturopathy was applied historically since 1905 to physician level (i.e. 3-4 year training) which was comparable to the era appropriate conventional medical training at that time. There are two different groups of providers using the term 'naturopathic doctor' to describe themselves. One group is the licensed or licensable naturopathic physician trained by nationally recognized standards which are required and recognized by state law in order to be licensed. The other group does not have physician level training, clinical training or any particular standard of training. Rather, training appears to range from none to a variety of continuing education and correspondence classes. This division in the naturopathic community has developed much the same way as the division in the established conventional health care professions developed prior to the Flexner Report. As conventional medicine developed high standards for education and public accountability and these standards became mandatory for state licensure and practice, conventional medical diploma mills and substandard conventional medical training was eliminated after the Report in favor of higher, uniform standards of training. (See Ludmerer, Kenneth M. 1999. *Time To Heal.* Oxford University Press: New York, NY).

In a regulatory vacuum, a lower standard will develop and its proponents may try to eliminate the emergence of the higher standard into state law. The lower standard may develop because there are those people who wish to be titled as the higher standard, but do not wish to undertake the training. This is an obvious public protection issue. Alternatively, for very positive and useful reasons, a less fully trained provider standard can be developed with uniform national training and certification standards and oversight, and clearly title and market their subgroup so as to be

distinct from the fully trained, physician level (higher) standard. A good example of this is homeopathic medicine, where there are 3 primary groups:

- Physicians trained in homeopathic medicine: ND's, DC's, MD's, DO's
- Professional homeopathic physicians: a non-physician 2 and 3 year educational standard. Professional homeopaths function as consultants or specialists and refer to primary care as needed. Standards for training and certification and scope of practice are internationally recognized.
- Lay homeopaths: This is a community of practice with no specific training standards.

The critical issue for the public in this discussion is the recognizable, uniform training of providers to specific skills and competence, directly relevant to their scope of practice: "training to competency to scope." It is my experience as a member of an emerging profession and many interdisciplinary government, reimbursement, public health, education, and research groups, that a key need for all stakeholders in dealing with new health care groups and professions is specificity. Specifically, what are the professions qualifications to practice their purported scope of practice safety? How will the public recognize that? What is the status of national consensus on standards, safety, efficacy and the processes and guidelines established by that profession? Specific recognition of each training model or standard by regulatory bodies is critical for their decision making.

We face two problems as professions emerge:

1. Typically, professions assemble this kind of information and self-report without any uniform template indicating specific continua for these standards, benchmarks and criteria to evaluate themselves against. It would help all stakeholders to forge a model template with specificity (re: each standard) in consensus with emerging and established CAM and conventional professions.
2. Communities of practice in emerging professions are rich seedbeds for innovation but suffer during their emergence into professions from a lack of unifying standards of accountability entitling them to the public recognition and access.

Policy Recommendations

It would be an excellent contribution to health care reform to establish an Office For Emerging Professions. This Office would provide guidance, funding opportunities, support, and accreditation guidelines to assist professions and communities of practice in improving their practice and accountability to the public without losing important and necessary innovations for health care. This process could be a means to actually accredit a profession and track its status clearly as it emerges and develops. This Office could be established through DHHS or the Bureau of Health Professions.

Emerging professions waste a tremendous amount of resources on political turf battles. These resources would be better spent for the public good if emerging professions could engage in a fostered process of developing and refining and accrediting their professions and practices with

the goal of safe and effective public access, and innovations to improve community and individual health.
(Appendix 7: Snider, Pamela. Three Continua for Evaluating Emerging Professions: Benchmarks and Criteria For Emergence. See also Clyde Jensen's model sent to Dr. Kaczmarczyk recently as an example. Both models have been submitted to the Center for Health Professions for their study on emerging professions).
(Appendix 8: Snider, Pamela. Draft 12/12/00. Draft Definitions and taxonomies: A Model to Evaluate Emerging Health Professions (p3, 4, 5, 6, 7). Submitted to the Center for Health Professions).

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?***

The following guidelines for CAM policy integration were developed by King County Integrated Health Care 2010 (now Northwest Integrated Health Care 2010, NIHC 2010) working group in September 2000, and presented at the Seattle WHC Town Hall meeting.
(*Appendix 9: Pizzorno, Joe. "Collaboration in the Northwest". October 30-31, 2000.*)

Principles for CAM Integration and Policy Development

1. ***CAM is about systems of healin, not isolated therapies.*** Natural (CAM) medicine is defined by philosophical systems, not modalities, or the substitution of "green drugs" for synthetic drugs. These "systems" change the way we think about and provide health care, they change the measures of success, effectiveness and cost effectiveness.

2. ***This "integration movement" is not only about integrating CAM.*** It is about mutual collaboration to create a true health care system, not the limited disease-treatment system that today dominates thinking and resource allocation. Mainstream medicine must shift its mission/focus to health creation.

3. ***Facilitate collaboration: mandate the" deeply round" table for government advisory, staffing and decision making positions, agencies and processes.***

4. ***Research outcomes first, not isolated therapies***: Reorient the focus of CAM research from 90% bench and clinical trials to 90% outcomes, field research, and training of CAM clinicians to perform in-office research.

5. ***Level the playing field.*** Disparities between CAM & CM (accredited & emerging) education, maturity and research is due to disparities in federal funding. The federal government needs to create and fund CAM-accredited Academic Health Centers of Excellence.

6. **Strengthen accountability** and standards critical for public protection by supporting activities that communicate and respect existing standards in emerging professions. Fund

initiatives to improve and further develop CAM standards.

7. ***There is a critical need for appropriate nation-wide regulatory environment and standards,*** uniform licensure, regulation for public safety, and national board exams. Collect and disseminate information about state regulatory models that are working well to provide access and protect the public. Adapt federal guidelines to accommodate the natural life cycle of emerging professions. Develop national certification and/or credentialing standards based on the best available in each profession. Constitutionally, health care regulation and licensing is a state prerogative, but the federal government can help with suggested standards, and financial incentives.

8. ***Help the CAM professions mature*** (see #6 and others).

9. ***Deeply engage CAM professionals at all levels of evaluation and decision making***. Health related committees and advisory bodies should require CAM educators and practitioners as expert advisers, consultants and/or researchers.

10. ***True integration & collaboration requires joint training programs and clinical experiences. Practitioners who train together, practice together.*** Include not just CAM and CM but public health as well. Support strategies for expanding integrated care settings in which conventional, CAM and public health providers practice side-by-side, learning from each other and being jointly committed to improved quality of care.

11. ***Include underserved and special-needs populations.***. Develop policies in support of Healthy People 2010.

12. ***Reimbursement system needs careful reconsideration.*** Replicate the Office of Insurance Commissioner, Washington State Clinician Workgroup on the Integration of CAM at a national level, to continue progress.

13. ***There is a critical need for accurate information for public and professionals***.

14. There is a critical need for natural product quality assurance, either private or public.

Policy Recommendations

OVERALL PRIORITIES

- Establish an Office on CAM and Integrated Health Care at the assistant secretary level at the U.S. Department of Health and Human Services with the authority to: oversee, coordinate

and direct all federal CAM activities through this office; and direct and oversee incorporation of CAM in all federal benefits program. Develop, open, structured and ongoing communication pathways among legislators, regulators, public health, the research community CM, CAM and IM providers, researchers, educators and organizational representatives; increase and coordinate federally-funded research in all research agencies.

- Establish "Blue Ribbon" Panels to direct the now Office and Congress (see above) on CAM and IHC policy and legislative requirements and to increase communication and education and collaboration among legislators, regulators, federal agency personnel, third party payers; CAM educators, licensed CAM providers, researchers and practitioners; and conventionally trained Integrated Health Care proponents. It is essential that the make-up of all such panels be cross disciplinary. Fund joint conferencing in key areas of mutual interest.

- Ensure that licensed CAM providers from all CAM fields, and credentialed IHC proponents, are represented on Advisory Boards and Scientific Review Panels at CDCP, AHCQR, NIH-NCCAM and other agencies as appropriate, including the new Office on CAM and IHC at HHS.

- Research legislation and rules which control CDCP, AHCQR, IOM, NIGMS, HRSA, BPHC, DHHS, DOD and other agencies. Follow the example of NIHCCAM. Propose amendments and rule changes as necessary to mandate inclusion of CAM regulated professions and IM..

Examples of agencies with exclusionary language or no mandates:

Services - Indian Health Service policy-restrictive
Services – National Health Service Corps – exclusionary
Field and Public Health Research – Centers for Disease Control – No mandate or appropriation for funding.
Outcomes Assessment and Cost Effectiveness – Health Care Financing Authority/Medicare-exclusionary
NIH Institutes for Cancer, Heart, Lung, Blood research need mandates for CAM "offices" for research.
Graduate Medical Education exclusionary – CM professions only

- Establish legislation and federal policy that mandates inclusion and funding (appropriation) of IM and CAM regulated professions in all appropriate federal programs. Patients must have equal access to all licensed or accredited provider types, and licensed providers must have equal opportunity to participate in all federal programs. To accomplish this, hold joint interagency meetings with NIH, FDA, HHS. HRSA Bureau of Health Professions and Bureau of Primary Care: Approve accredited CAM colleges and licensed CAM professionals and professions for grant eligibility, eligibility federal funding in all federal programs. Example: incorporate authorizing language to include all licensed CAM providers in the National Health Service Corps.

- Fund "National Credentialling and Standards Roundtable". Include national conferences, with a Blue Ribbon task force representing accredited colleges of conventional healthcare and licensed alternative health professions, national associations for licensed CAM and CM professions, and emerging professions. Include organizations and task forces involved with standard setting in CAM and CM education from within conventional medical education.

- Establish an Office on CAM and Integrated Health Care in each DHHS, USPHS Region. Begin with offices in Region X and other regions with most extensive CAM and IM activity. Authorize an interdisciplinary work group for decisions, assessment and implementation of CAM integration. Work in co-ordination under the National Office to achieve goals of Healthy People 2010. These "deeply round tables" foster trust and respect for quality, credibility, competence and shared mission – and build a solid foundation for innovation and reform focused on improving community health

- CAM policy integration in general should focus on the goals of Healthy People 2010, and include an emphasis on public and community health and service to the underserved. Health disparities and partnerships for health improvement are also key areas where CAM can help us a lot.

Research

- Fund Basic sciences clinical trials outcomes health services and academic research centers at CAM institutions to help support the necessary development of a research and academic infrastructure.

- AHCRQ: Establish a competitive bid process to support and research one dozen clinics in US in various sectors, selection to be made with IHC and CAM accredited institutions. Produce data and reports, including longitudinal data. Needs 5 years funding minimum.

- Fund National CAM and IM research methodologies consensus conference. Recommend AHCRQ sponsor this Summit. Invite IOM.

- Develop CAM Offices at the National Institutes of Health with interdisciplinary advisory boards composed similarly to NIHCCAM's board.

Education/Accountability

- Fund demonstration project via HRSA on CAM and CM education and cross-disciplinary training. Mandate and fund true partnership between accredited conventional and CAM schools as demonstration sites.

- Fund collaborative CAM/conventional residency exchange programs and residential

programs in CAM institutions

- Involve CAM colleges and conventional medical schools in projects to increase CAM access for minority and under served populations. Publish outcomes of these education pilot programs.

- Identify CAM standards gaps, and fund consensus projects to foster improvements (practice guidelines, residencies, research) through AHCQR, GME, Medicare, HCFA, CDC.

- Fund National Congress for CAM and IM leadership to define consensus recommendations for credentialing standards in White Paper for federal and state guidance. Research and report on emerging and established accountability standards in health care professions; summarize and compare standards in CAM and non-CAM fields. Identify pathways and provide funding for the inclusion of existing CAM standards into established health care systems.

- Establish CAM accredited College Academic Health Centers of Excellence to collaborate with IM/CM Colleges. Approve professionally accredited CAM colleges and providers as eligible for federal grants and programs.

Underserved/Special Needs Populations

1. Include licensed CAM professions in Medicare/Medicaid regulations. Revise authorization language and propose appropriations to provide access to National Health Service Corps Program for licensed CAM providers. Allow access to licensed CAM professions in other federal health care programs.

2. Include licensed CAM professionals and IHC experts in Public Health jobs, boards and facilities, State and County Health Boards and clinics.

- Health Resources and Services Administration:
  - Bureau of Primary Health Care Services: fund a demonstration project for under served and minority populations receiving CAM services; assess access and outcomes-publish results.
  - Bureau of Health Professions Fund CAM Residency Training Programs in underserved/special needs populations

- Fund pilot projects to facilitate the development of integrated services in regional and local Community Health Centers. Facilitate the integration of co-management teams into state and county health department clinics (with training) using successful models such as the King County Natural Medicine Clinic, Kent, Washington. Fund these workforce re-training programs to provide opportunities for increasing levels of competence from introductory, to

modality, to full system training in CAM disciplines for health care providers in these clinics and systems.

- Fund National Conference on methods for utilizing CAM health care in under served or special needs population. Allow HMOs and provider networks which accept risk on capitated Medicare or Medicaid clients to utilize CAM providers and therapies and to implement integrated health services. Fund research to assess cost effectiveness.

- Create dialog and fund pilot project bringing CAM providers and traditional healers (Native American, Hawaiian, etc.) and schools to a common strategy for their populations.

- Northwest Indian College (NWIC) is now an academic health center for USPHS Region X.. Two hundred and fifty out of 500 US Native American tribes reside in Region X.. NWIC and Bastyr University are currently collaborating on building public health career ladders between institutions. Fund implementation of results of DHHS Appreciative Inquiry between NWIC and BU as a pilot site.

Regulation/Access to Services

- Improve reimbursement for behavioral change (affects greater than 50% of major diseases and cost) by both CAM and conventional providers.

- Adopt the Office of Natural Health Products Model: HPB-Ottawa, Ontario, by using this model to develop appropriate procedures, regulations and guidelines for safe access to national health products.

- Support, as a matter of national policy, the standards of practice inherent in state licensing laws, as credentialling guidelines for State Departments of Health, NCQA and JAHCO.

- Support funding by AHCRQ for CAM practice guideline projects involving the CAM professions; establish both baseline CAM system specific guidelines as a foundation. Then develop integration/integrative practice guidelines.

- Promote insurance equality for CAM providers and therapies. We believe that the next steps should include strong commitment to research. Not just research of clinical efficacy but research of true utilization of CMA services in conjunction with, or replacement of, normally covered conventional care. Case management considerations should be addressed and education of all entities is the most important by-product of such an effort. Finally, a national forum of this caliber, or multiple forums in several locations, can break down barriers in people or groups that are operating in a non-educated environment.

Programs – CAM Inclusion

- See Priorities

- Pass legislation to mandate inclusion of all licensed CAM providers, services and accredited CAM colleges in all relevant federal health programs.

- Request a GAO report and mandate research on the cost savings possible through the incorporation of CAM systems, products and services. Educate policy makers about the safety, efficacy and cost savings possible through CAM products and therapies.

Clinical Practice, Quality, Delivery

- The National Commission for Quality Assurance (NCQA), must be encouraged to work appropriately with licensed CAM and emerging CAM professions to establish credentialing procedures, educational requirements, and supportable standards of practice. It will need to work closely with experienced professionals in each field to identify or develop quality measures for CAM. NCQA should be brought into the loop as soon as possible.

- A nationwide study should be funded to examine the impact of licensure on costs, health care practices, consumer protection, standards and credentials.

- The licensing boards, HMO boards, hospital boards -- all of the enforcement bodies now in place to regulate the practice of medicine -- will need to be restructured to allow for the incorporation of CAM.

- Licensed CAM or emerging CAM professions will have to report on or set standards of education, scope of practice guidelines, and continuing education requirements, as well as monitor compliance. Resources are needed to help these processes develop and mature, such as a National Adverse Events reporting System for CAM services and products.

- Identify and describe practice integration models now in use; disseminate this information. Three such models are integration within single provider (i.e., naturopathic physicians); co-management team; cross-referral and cooperation between institutions and networks.

- Establish an Interdisciplinary Immunization/CAM Taskforce in Region X.

- Fund and conduct Regional Consensus Conferences on Integrated CAM and Conventional Best Practices to reduce preventable disease, such as adult onset Diabetes Type II Implement recommendations.

- Provide federal funding through NIHCCAM, HRSA, BPHC, and CDC for local community demonstration projects and strategic planning to integrate CAM and CM health services. The

King County 2010 and Northwest Indian College regional Memorandum of Understanding with DHHS are excellent pilot sites. Establish priorities, assess outcomes.

Thank you for the opportunity to provide this information to you and to the Commissioners, and for your dedication to the White House Commission's work. We wish you well at the next White House Commission meeting. Please feel free to contact me if you have any further questions.

Sincerely,

Pamela Snider, ND
Associate Dean, Naturopathic Medicine Program

Enclosures Appendices 1 - 12

Appendices

Appendix 1: Young, David A. Letter from the Office of Educational Policy and Planning in Salem, Oregon sent to the National Council Against Health Fraud. April 18, 1989.

Appendix 2: Excerpted curricula summaries from accredited naturopathic college catalogs: National College of Naturopathic Medicine, Bastyr University, Southwest Colelge of Naturopathic Medicine.

Appendix 3: "The Integration Project: Principles, Theory and Paradigm of Naturopathic Medicine in Curriculum Development;" Association of Naturopathic Medical Colleges, 1996-2000.

Appendix 4: Snider, Pamela. The Future of Naturopathic Medical Education, 1996: Southwest College of Naturopathic Medicine Anthology, Vol.1.

Appendix 5: Quinn, Sheila.. "Accountability A Complex Issue." Moderator. "Beyond Data: Standards as Integration Models." International Conference on Integrative Medicine. April 1999. Seattle, Washington.

Appendix 6: Office of Insurance Commissioner, WA State. "Issues in Coverage for Complementary and Alternative Medicine Services: Report of the Clinician Workgroup on the Integration of Complementary and Alternative Medicine," January 2000. 1998 Table-Status of Standard Setting in CAM Professions.

Appendix 7: Snider, Pamela. "Draft: Three Continua for Evaluating Emerging Professions: Benchmarks and Criteria For Emergence." (See also Clyde Jensen's model sent to Dr. Kaczmarczyk recently). Both models have been submitted to the Center for Health Professions for their study on emerging professions.

Appendix 8: Snider, Pamela. Draft 12/12/00. A Model to Evaluate Emerging Health Professions (p3, 4, 5, 6, 7). "Draft Taxonomies and Definitions For Emerging Professions", Submitted to the Center for Health Professions for their study on emerging professions.

Appendix 9: Pizzorno, Joe. "Collaboration in the Northwest" presented to the White House Commission on the Integration of CAM. Seattle Town Hall meeting. October 30-31, 2000.

Appendix 10: Twenty-one Competencies for the Twenty-First Century (Chapter IV). In Recreating Health Professional Practice for a New Century. December 1998. Center for the Health Professions, UCSF.

Appendix 11: Naturopathic Medicine: Integration Models. Overview: Educational handout 1999.

Appendix 12: Naturopathic Medicine Professional Standard, Guidelines and Processes. Affiliated Organizations: educational handout 1999.

Tab 5

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

Mr. David E. Molony
Executive Director
American Association of Oriental Medicine
433 Front Street
Catasauqua, PA 18032

Dear Mr. Molony:

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 oriental medicine undergraduate, postgraduate, and continuing education? Should those national educational standards include exposure to conventional or western medicine as well as "non-oriental medicine" 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 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

Tab 6

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

Garrett F. Cuneo
Executive Vice President
American Chiropractic Association
1701 Claredon Boulevard
Arlington, VA 22209

Mr. Cuneo:

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 chiropractic undergraduate, postgraduate, and continuing education? Should those national educational standards include exposure to conventional or western medicine as well as 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 chiropractic 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 memebers 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

February 12, 2001

Joseph M. Kaczmarczyk, MD
White House Commission on Complementary
And Alternative Medicine Policy
6701 Rockledge Drive
Suite 1010
MS-7707
Bethesda, Maryland 20817

VIA E-mail KaczmaJo@mail.nih.gov

Dear Dr. Kaczmarczyk:

The American Chiropractic Association (ACA) appreciates the opportunity to respond to the questions posed in a letter sent on January 29, 2001 by Stephen Groft, Chairman of the White House Commission on Complementary and Alternative Medicine Policy. Representing nearly 20,000 members, the ACA is the largest chiropractic professional organization in the United States. In this capacity, we welcome and encourage an on-going dialog with the Commission as it develops its formal policy recommendations. In addition, if this commission develops chiropractic-specific policy recommendations, we would respectfully request the opportunity to review them prior to their submission to Congress.

In response to the Commissions specific questions, the ACA respectfully submits the following responses:

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

   In the United States an individual pursuing a doctorate in chiropractic must meet educational and training requirements including a minimum of six years full-time university-level education followed by national and state licensing-board exams. Of those six years, two years must include university credits in qualifying subjects and then a four-year undergraduate program at a chiropractic college.

   To apply to a chiropractic college, a student is required to have at a minimum two years of pre-professional college education with a curriculum concentrated in the basic and biological sciences. Some chiropractic colleges are now requiring a bachelors degree. The purpose of the basic science component of the chiropractic curriculum is to give the student a thorough understanding of the structure and function of the human body in health and disease. With this foundation, students progress through the clinical sciences, where they begin to develop the knowledge and skill necessary for examination, diagnosis, and treatment.

A chiropractic college curriculum consists of a minimum of four academic years of professional education averaging a total of 4,822 hours. There are five curricular areas that are emphasized in chiropractic education: adjustive techniques/spinal analysis, averaging 555 hours of clinical program, principles/practice of chiropractic, averaging 245 hours; and biomechanics, averaging 65 hours. The clinical courses offered in chiropractic colleges dealing with diagnosis and chiropractic principles are allocated the most time, followed by orthopedics, physiologic therapeutics and nutrition. Three areas - adjustive techniques/spinal analysis, physical clinical laboratory diagnosis, and diagnostic imaging - account for an average of 52 percent of the education in clinical sciences. In addition, during internship, two years of hands-on clinical experience is focused on manipulation as the primary treatment procedure thus the emphasis in chiropractic clinical sciences is clearly on diagnosis and manipulative therapy.
Postgraduate specialties include, but are not limited to, chiropractic sciences, neurology, nutrition, orthopedics, radiology, and rehabilitation and sports chiropractic. The Council on Chiropractic Education (CCE) is the accrediting agency for chiropractic education programs in the United States. It was recognized by the U.S. Department of Education in 1974.

The CCE and its Commission on Accreditation is an autonomous national organization recognized by the secretary of the United State Department of Education as the authority on the quality of training offered by chiropractic colleges. Certain requirements must be met before accreditation status can be initially received or renewed. The CCE Standards for Chiropractic Programs and Institutions includes criteria for assessment and planning, governance and administration, facilities, services and policies, instructional program objectives and content, faculty qualifications, admissions requirements, outcomes assessment, clinical competency and research. The CCE is a member of the Council on Higher Education Accreditation and the Association of Specialized and Professional Accredators.

Post Graduate Standards
Virtually all states have a mandatory continuing education requirement for doctors of chiropractic to maintain or renew their license to practice. Most prevalent is at least 12 hours per year in topics such as diagnostic skills, chiropractic techniques, risk management, public health, and professional boundary issues.

Recognizing that doctors of chiropractic must keep abreast with new data and advanced procedures in health care, the chiropractic profession has supported continuing education as a yearly requirement for licensing. Each accredited chiropractic college maintains a postgraduate (continuing) education division to provide postgraduate education to better assist the doctor of chiropractic in the care of the public. Each postgraduate division or department produces programs, courses, and seminars that are designed to upgrade the competence, knowledge and ability of graduate doctors of chiropractic.

All CAM providers who have direct access to patients should possess the ability to differentially diagnose and to refer and/or co-manage their patients' treatment if the condition is beyond their scope of expertise.

There is a significant amount of exposure in chiropractic education to conventional or western medicine, since the typical chiropractic curriculum utilizes the same text and scientific information provided in medical schools. This is especially significant in the realm of the basic sciences and diagnostics (e.g. clinical exam, laboratory, imaging, clinical testing). Some chiropractic colleges include courses in materia medica to better train their practitioners in the medical options available. Chiropractic colleges also provide courses in alternative forms of CAM.

One issue of significance is the limited ability for the chiropractic student to observe and manage a broad spectrum of conditions and or diseases as typically seen in a teaching hospital. While some chiropractic colleges and medical teaching institutions have had occasional collaborative activities, typically there is a lack of cooperation from the medical institution side. This is particularly egregious given that most of these institutions are supported by state and federal taxes. These public institutions should provide any accredited institution, traditional medicine or CAM, the opportunity to broaden the student practitioners' knowledge and clinical expertise.

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

In the United States, the practice of chiropractic is recognized by statute in all 50 states. Most common among all state laws is the ability of a patient to directly seek care from a doctor of chiropractic (primary care) and the duty and right of a doctor of chiropractic to perform an examination and provide a diagnosis.

Under the auspices of all chiropractic colleges, students are required to pass a practical examination on their manipulation skills and a clinical competency exam prior to internship. In addition, the chiropractic profession is held to rigorous skill testing for licensure. The principle testing agency for the chiropractic profession in the National Board of Chiropractic Examiners (NBCE). Established in 1963, the NBCE develops and administers a standardized national exam. In the development of the test, the NBCE utilizes no particular philosophy but formulates its test plans according to information provided collectively by chiropractic colleges, state licensing agencies, field practitioners, and subject specialists. Among the top goals in administrating standardized exams are the promote of high standards of competence and assisting state licensing agencies in assessing competence.

In its role as an international testing agency, the NBCE conducts the following examinations: Part I Basic Science subject exams – General anatomy, spinal anatomy, physiology, chemistry, pathology, microbiology and public health; Part II Clinical subjects exams – General diagnosis, neuromusculosketal diagnostic imaging, principles of chiropractic, chiropractic practice, and associated clinical sciences; and Part III Written Clinical Competency Examination Case - history, physical examination, neuromusculosketal examination, diagnostic imaging, clinical laboratory and special studies, diagnosis or clinical impression, chiropractic technique, supportive techniques and case management.

In addition, all states require a practical examination prior to licensure. This state licensure skill testing includes at a minimum, diagnostic imaging, differential diagnosis, chiropractic technique and case management.

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

There already exist chiropractic "communities" that bring together the various chiropractic organizations in the promotion of research, education and practice. Among these organizations are:

The World Federation of Chiropractic, which is made up of national associations from over 60 countries. The WFC represents these groups as well as the chiropractic profession in the international community. The WFC has ties to the World Health Organization and is a member of the Council of International Organizations of Medical Sciences. The goals of the WFC are to work with the national and international organizations to provide information on chiropractic, and to promote high standards in education, research and practice. Every two years, the WFC holds a meeting to review scientific research and continuing education information.

The Congress of Chiropractic State Associations was formed in the late 1960s and is a non-profit organization consisting of state chiropractic associations. The mission of the Congress is to provide an apolitical forum for the promotion and advancement of the chiropractic profession through service to member state associations. The purpose of the Congress as stated in its Rules and Regulations is: to form a coalition of official chiropractic state organizations, serve as a forum or clearing house to help solve mutual state programs on a non-partisan basis, cooperate with other organizations in the advancement of natural health and chiropractic, assure that chiropractic attains its rightful place in the healing arts and to initiate, encourage and support programs and projects for the advancement of the chiropractic profession.
The ACA has also encouraged member participation in the American Public Health Association. Within the APHA is a Chiropractic Health Care Section. The section serves as a vehicle for chiropractic participation in mainstream public health activities and works to enhance chiropractic communications, education

and credibility on public health matters. Additionally, the ACA would certainly consider other national interdisciplinary health care organizations that would be based on parity of the professions and are dedicated to improve health for everyone.

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.**

   Any guidelines, whether condition or modality specific, must be developed through consensus by the chiropractic profession and reflect mainstream chiropractic practices. It is important to note that guidelines are dynamic, changeable and revisable as the profession, research and practice of chiropractic grows in knowledge and develops in the future.

   The practice of chiropractic may include a variety of responses to a particular clinical program and that adherence to any particular guidelines is voluntary. Except as provided otherwise, all practice guidelines should not be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of a specific procedure must be made by the practitioner in light of the individual circumstances presented by the patient.

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

   Every profession has procedures that have risks associated with them. The fact is that virtually all interventions by medical doctors have complication rates higher than most commonly used chiropractic interventions. While there is no reliable method to determine which patient may be prone to adverse reactions, some patterns have emerged – and doctors of chiropractic are educated in the screening of high-risk patients. Thus, through initial examination, doctors of chiropractic are able to help avoid adverse incidents by making the effort to recognize those patients who could be at risk from treatment. The goal of the profession is to reduce those risks to zero and to help educate the medical profession about the dangers of the untrained application of spinal manipulation.

   Chiropractic is one of the safest forms of treatment available today. According to a study by the RAND Corporation, a serious adverse reaction from cervical manipulation occurs once in 1 million manipulations. The complication rates for manipulation of the lumbar region of the spine are even lower. The same study showed that on the rare occasion of an adverse reaction it is often the result of improperly trained health care providers performing the manipulation procedure.

   When compared to the number of illnesses and death that will occur this year from the appropriate use of prescription and over-the-counter drugs, the number

of serious complications from chiropractic treatment is extremely low. A 1999 Institute of Medicine report concluded that medical errors kill anywhere from 44,000 to 98,000 hospitalized Americans each year. In addition, a study published in the April 15, 1998 issue of the *Journal of the American Medical Association* found that more than 2 million Americans become seriously ill every year from reactions to correctly prescribed drugs and 106,000 die from those side effects.

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?**

In a study addressing the safety of chiropractic spinal manipulation/adjustment, it is cited that improper adjusting technique is a major risk factor. Since "the greatest contraindication to manipulation is lack of training and skill, full-time practice is essential." (S.R. Geiringer, "Manipulation Appropriate Low Back Pain Treatment? Questions and Answers," *Journal of Musculoskeletal Medicine* 7 (1990) 13-14.) More recent authors have supported this particular position as well.

Duly licensed chiropractors utilize spinal manipulation/adjustment in treatment regimens nearly 100% of the time and are rigorously skill tested spine examination, and diagnosis in this treatment technique (spinal manipulation). Therefore, they are equipped to recognize and avoid clinical contraindications.

Several states, including Tennessee and West Virginia have taken statutory steps to limit the risks of improperly trained health care providers performing spinal manipulation by mandating a minimum number of classroom and clinical hours a provider must master prior to performing chiropractic spinal manipulation.

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?

State licensing boards are by statute empowered to protect the public health safety and welfare. A chiropractic license is considered a privilege that may be suspended or revoked if a chiropractor is found in violation of established laws and regulations.

State statutes require a licensing board to regulate each licensed profession. Their responsibilities are to investigate consumer complaints, oversee the general application of health care laws, help update and develop regulations that better define appropriate conduct, continually review required credentialing for doctors to practice safely and effectively, and apply appropriate disciplinary action,

In addition to state-specific chiropractic licensing boards, there is also the Federation of Chiropractic Licensing Boards (FCLB), which was founded in 1926 to maintain higher, uniform standards in areas related to chiropractic licensure, regulation, discipline, and education. As part of its mission, the FCLB conducts

an annual conference for the unified adoption of resolutions protecting the professions examining regulatory standards and the consumer.

All health care professionals, including CAM providers that market their services to the general public, should be under the auspices of a licensing board to ensure proper credentialing and safety to the public.

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?

Doctors of chiropractic are trained and licensed to perform examination and diagnostic procedures. Accordingly they, like any other health care provider, should provide any pertinent historical information, examination findings or treatment outcomes to any other licensed health care provider that would assist that provider in treating the patient. This process should be reciprocal among all licensed health care providers.

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?

All CAM providers should be held to equivalent criteria as other licensed health care providers in the areas of education, licensure, oversight from licensing boards and public opinion. Care must be taken that the principles of each CAM practice be maintained and not supplanted by allopathic philosophy. As an example, prevention and wellness are a principle of the chiropractic profession and should be utilized as the cost effective mechanism they have been shown to be, not discouraged in managed care programs as a quick fix for cost controls. Rather than make CAM fit the medical model, for the well-being of all consumers, guidelines must be in place for responsible, interdisciplinary collaborative work between allopathic and CAM providers.

The ACA appreciates the opportunity to work with the Commission on the development of CAM policies. If you have any questions regarding our response, or require additional information, please contact Ingrida Lusis, Director of Government Relations, at 703/276-8800 or by email ilusis@amerchiro.org.

Sincerely,

Garrett F. Cuneo
Executive Vice President
American Chiropractic Association

Tab 7

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 30, 2001

Aviva Romm, CPM, AHG
Executive Director
American Herbalist Guild
1931 Gaddis Road
Canton, GA 30115

Dear Ms. Romm:

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 herbal and botanical undergraduate, postgraduate, and continuing education? Should those national educational standards include exposure to conventional or western medicine as well as CAM other than herbs and botanicals? What is the current status of your certification? Why, how, and by whom was the certification process and examination developed and administered? Who is eligible to participate in your certification? How much does it cost? Is the certification life-long or time-limited? What does your certification mean for patients and for practitioners/providers? How does your certification relate to the assuring the public access to safe, effective CAM practices and products? What lessons did you learn as a result of embarking on the certification process?
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 herbal and botanical 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