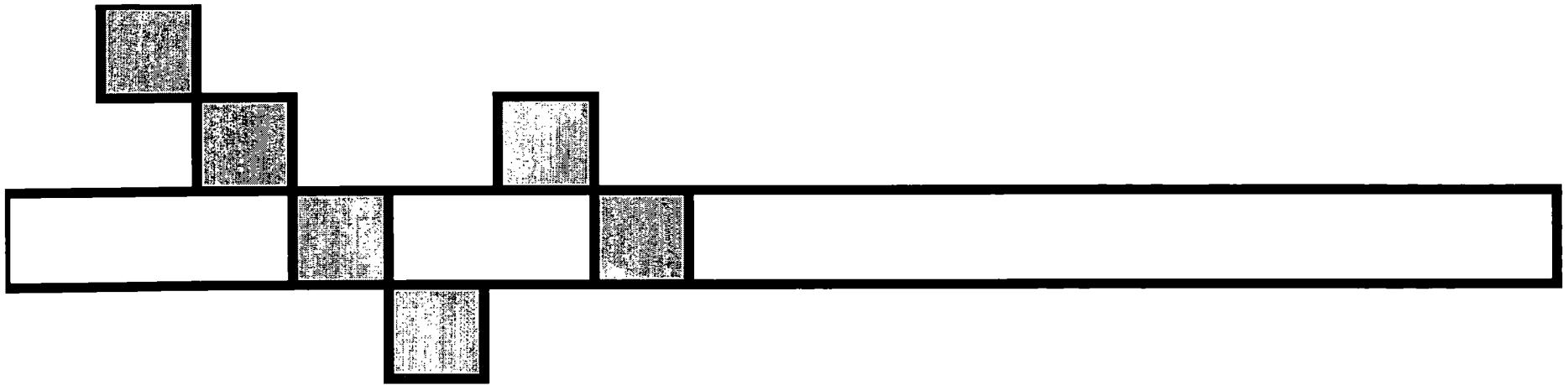
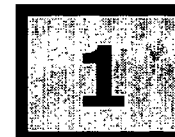




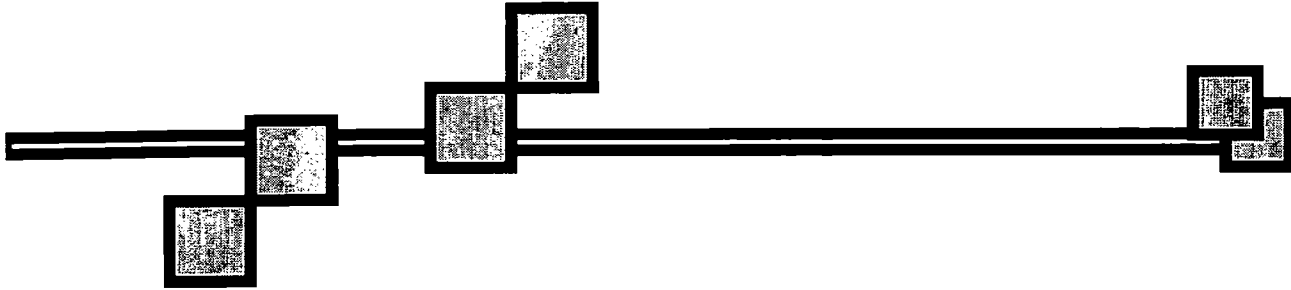
Collaboration in the Northwest



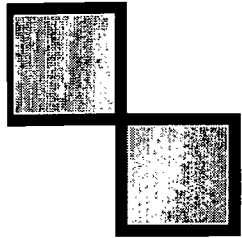
Dr. Joseph E. Pizzorno
President Emeritus, Bastyr University



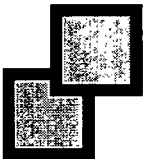
11/2/2000

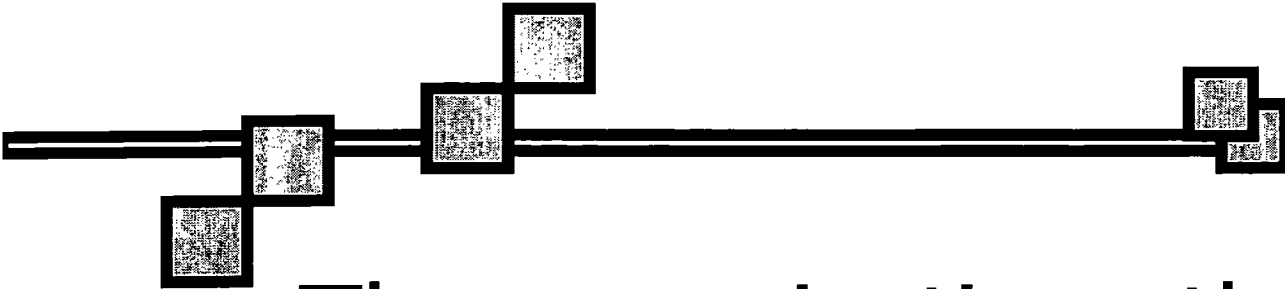


Welcome

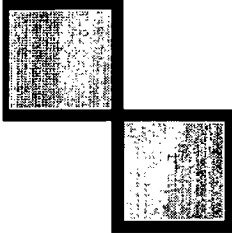


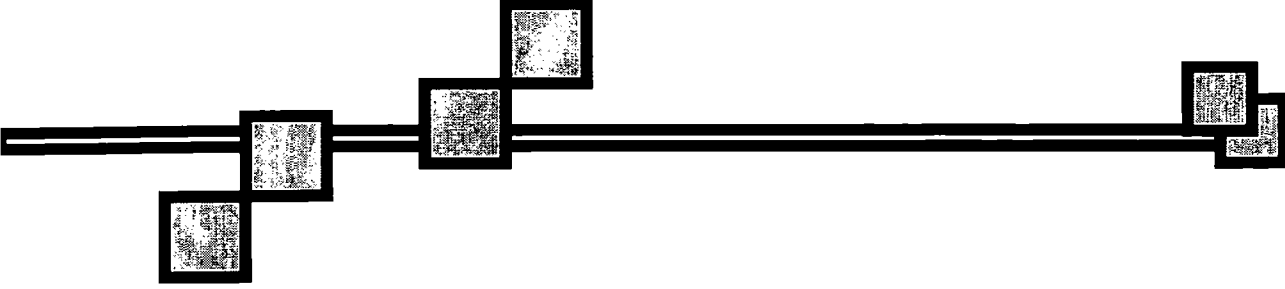
- We are honored and excited you are visiting us these two days
- Many organizations in the northwest have worked together the past two months to prepare what we hope will be a highly informative experience for you



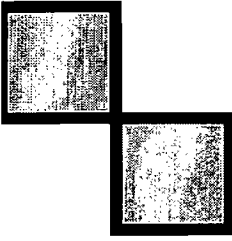


The organizations that provided the funding and personnel

- 
- King County 2010
 - King County Council
 - Region X Public Health
 - Bastyr University
 - American Massage Therapists Association
 - Washington State Chiropractic Association
 - Washington Association of Naturopathic Physicians
- 



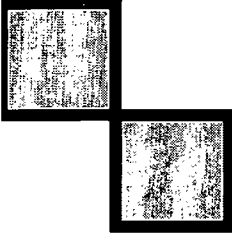
Themes

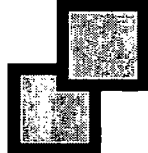


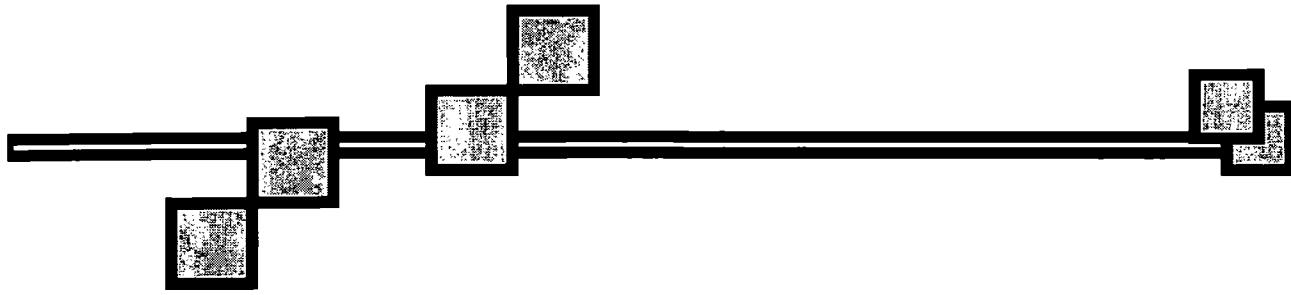
- We worked hard with the invited speakers to organize their presentations in the context of the four categories mandated by Congress
 - Through the information and recommendations provided, we hope you will hear 14 key themes, which I will present shortly
- 



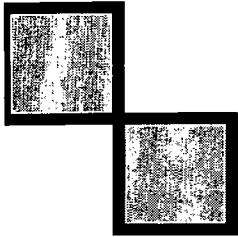
Successful Collaboration Requires Broad Commitment



- Local, state, and regional levels
 - Governmental bodies
 - Regulatory agencies
 - Academic institutions
 - Practitioners
 - Public Health officials and organizations
 - Payors
- 

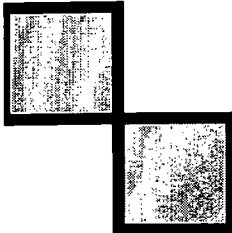


14 Themes



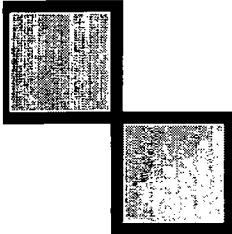


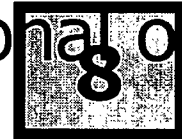
1. CAM is about systems of healing, not isolated therapies

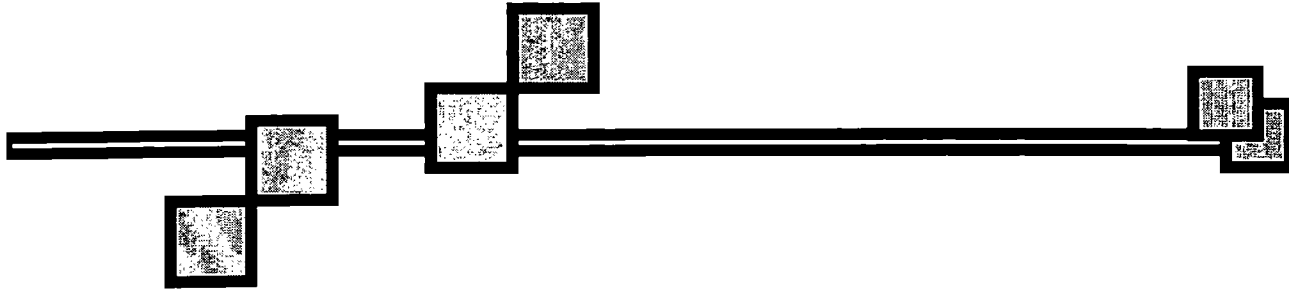
- 
- Natural (CAM) medicine is defined by philosophical system, not modalities, or the substitution of “green drugs” for synthetic drugs
 - These “systems” change the way we think about and provide health care
 - They even change the measures of success
- 



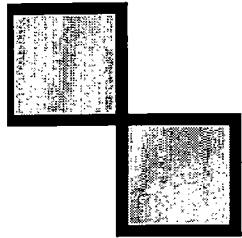
2. This “integration movement” in the Northwest is not only about integrating CAM

- 
- 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
 - Are we talking about grafting CAM onto conventional or conventional onto CAM?
- 

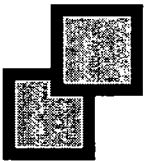


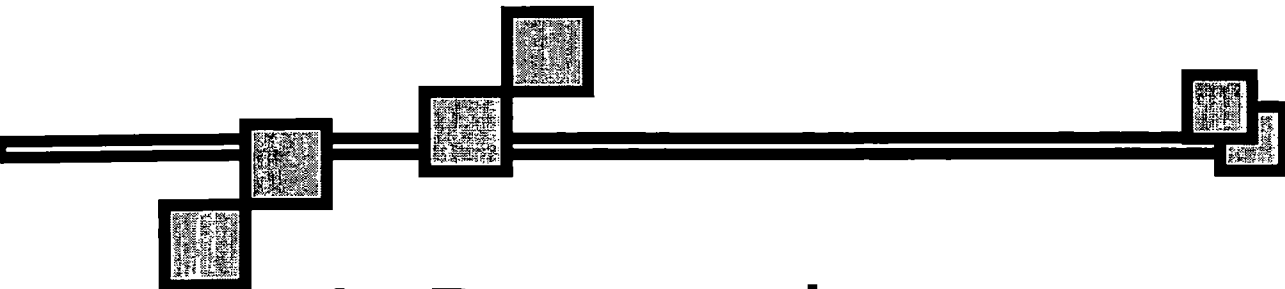


3. Facilitate collaboration

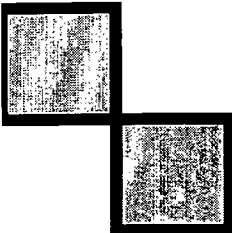


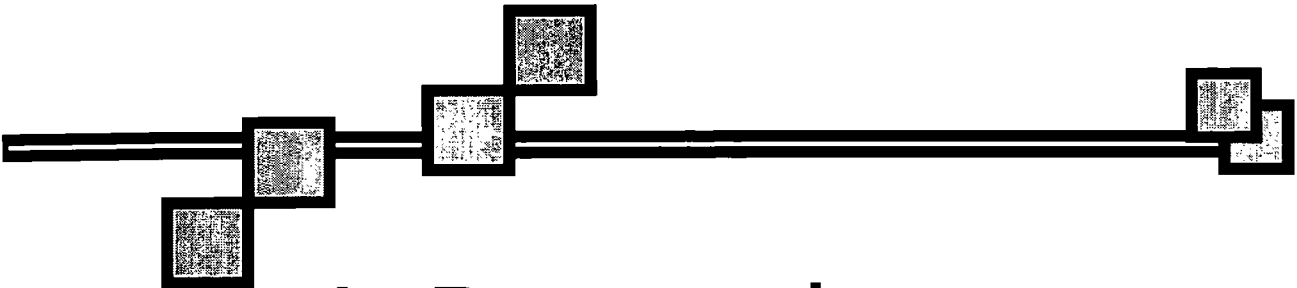
- Conventional practitioners
- CAM practitioners
- Public health
- Regulatory
- Payors
- Governmental





4. Research outcomes first, not isolated therapies

- 
- CAM is Multifactorial
 - Patient satisfaction and quality of life are critical measures
 - Just as we have reaped tremendous benefit by a huge investment in conventional medicine research, similar benefits will be found by investment in CAM
 - Develop consensus on research programs appropriate for CAM

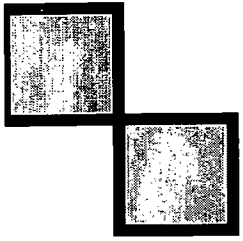


4. Research outcomes first, not isolated therapies (cont'd)

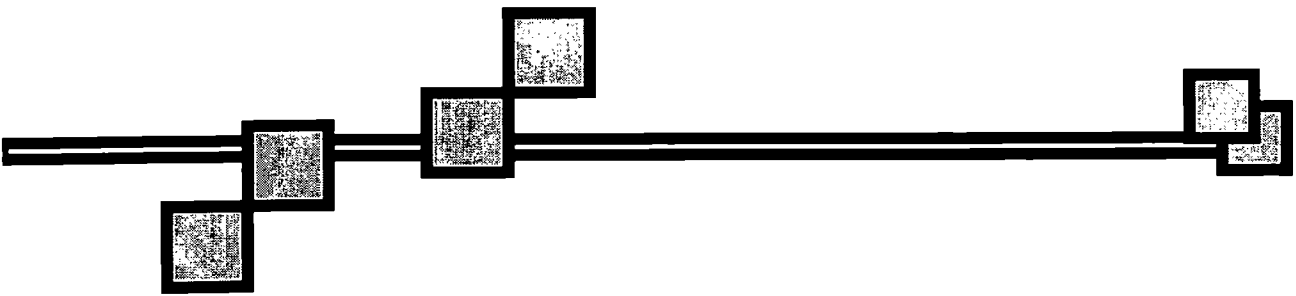
- 
- Fund research on payer databases to compare outcomes
 - Fund cost effectiveness studies
 - Host joint sessions for CAM and CM researchers and institutions to discuss and plan for collaborative research
 - Reorient the focus of CAM research from 90% bench and clinical trials to 90% outcomes, field research, and training of CAM clinicians to perform in-office research
- 
- 



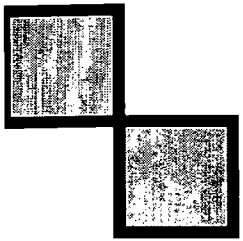
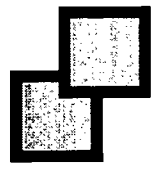
5. Level the playing field



- Disparities between CAM & CM (accredited & emerging) education, maturity and research is due to disparities in federal funding
 - CAM schools need support for education
 - Create and fund CAM-accredited Health Centers of Excellence
- 

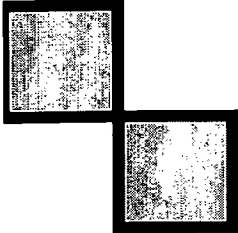


6. Strengthen accountability

- 
- Accountability and standards critical for public protection
 - Support activities that communicate and respect existing standards in emerging professions
 - Fund initiatives to improve and further develop standards
 - Accreditation
 - Practice guidelines
- 

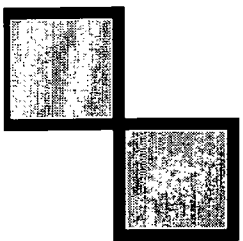
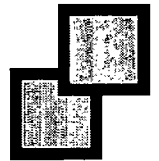


6. Strengthen accountability (cont'd)

- 
- Education
 - CAM practitioners
 - Conventional practitioners wanting to practice CAM systems or use CAM modalities
 - National certification boards with credible testing and credentialing processes
 - Practices
 - Modalities
- 

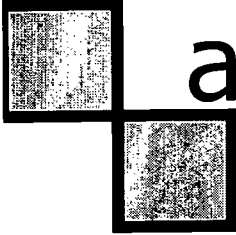


7. Critical need for appropriate nation-wide regulatory environment and standards

- 
- Uniform licensure, regulation for public safety
 - National board exams
 - Collect and disseminate information about state regulatory models that are working well to provide access and protect the public.
 - Encourage states to work together on the development of effective regulatory models
- 
- 



7. Critical need for appropriate nation-wide regulatory environment and standards (cont'd)

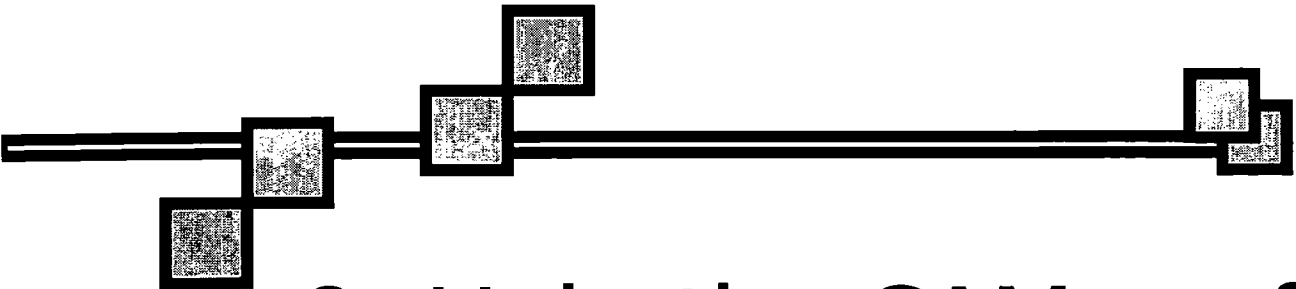


- Adapt federal guidelines to accommodate the natural life cycle of emerging professions
 - Encourage self-regulation of education and practice in a credible way
 - Develop national certification and/or credentialing standards based on the best available in each profession
- 

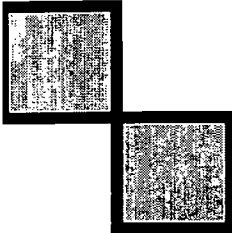
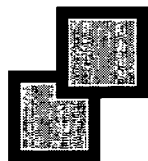


7. Critical need for appropriate nation-wide regulatory environment and standards (cont'd)

- 
- Encourage continuous improvement in those standards as educational institutions and examining boards improve
 - Constitutionally, health care regulation and licensing is a state prerogative, but feds can help with suggested standards, and financial incentives
- 

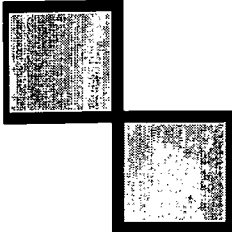


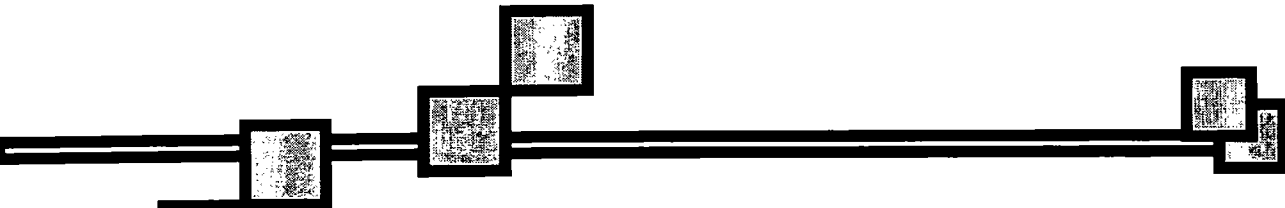
8. Help the CAM professions mature

- 
- Practice guidelines
 - Credentialing systems
 - Peer review (interdisciplinary and CAM)
 - Federal programs (Medicare, NHSC, etc.)
 - Infrastructure at CAM institutions
 - Fund research fellowships and training for CAM educators and providers
 - Provide NIH consultation to CAM schools that want to engage in research
- 

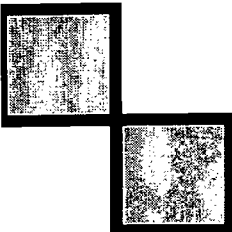


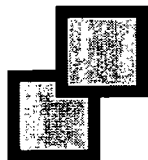
9. Deeply engage CAM professionals at all levels of evaluation and decision making

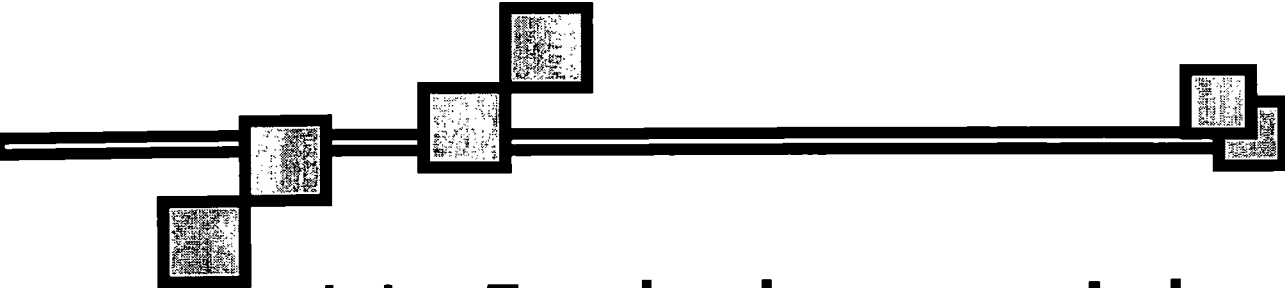
- 
- CAM professionals have considerable and sophisticated expertise
 - Health related committees and advisory bodies should require CAM educators and practitioners as expert advisers, consultants and/or researchers
- 



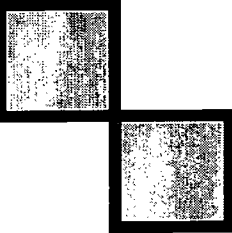
10. True integration & collaboration require joint training programs and clinical experiences



- Practitioners who train together, practice together
 - Not just CAM and Conventional 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
- 

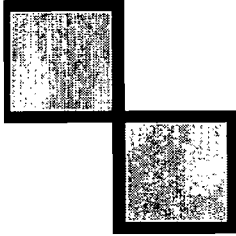


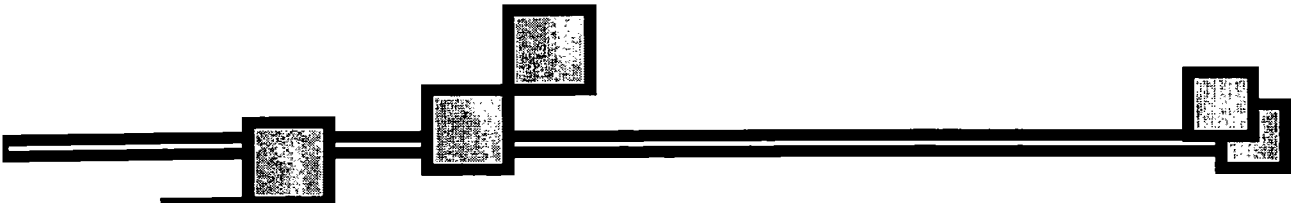
11. Include special-needs populations

- 
- Underserved (poor/uninsured)
 - Reduce health disparities
 - Special needs, e.g., HIV/AIDS, the elderly
- 

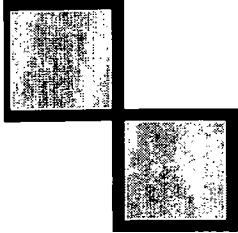


12. Reimbursement system needs careful reconsideration

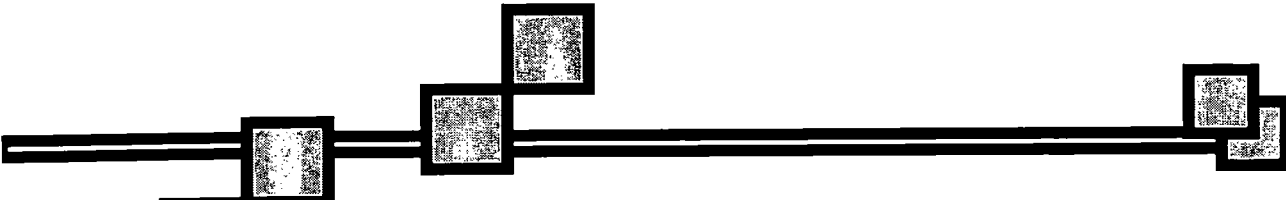
- 
- Health-promotion vs. disease-treatment coverage
 - Eliminate penalty for preventive services
 - Be sure to include payer perspective
- 



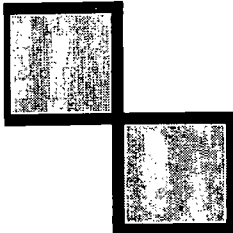
13. Critical need for accurate information for public and professionals



- Content databases: validate intervention efficacy & safety (Cochrane & others)
 - Adverse events, reporting, monitoring
 - Disseminate comprehensive information about education, scope of practice, and the impact of different regulatory models (and the lack of regulation) in the established and emerging CAM disciplines
- 

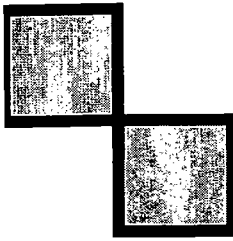


13. Critical need for accurate information for public and professionals (cont'd)

- 
- Provide education in, and a readily available database of, herb-drug-nutrient interactions
 - Provide information on CAM practitioner education and standards of practice
- 

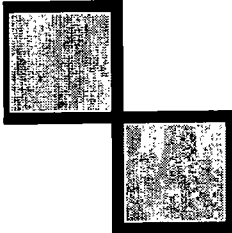


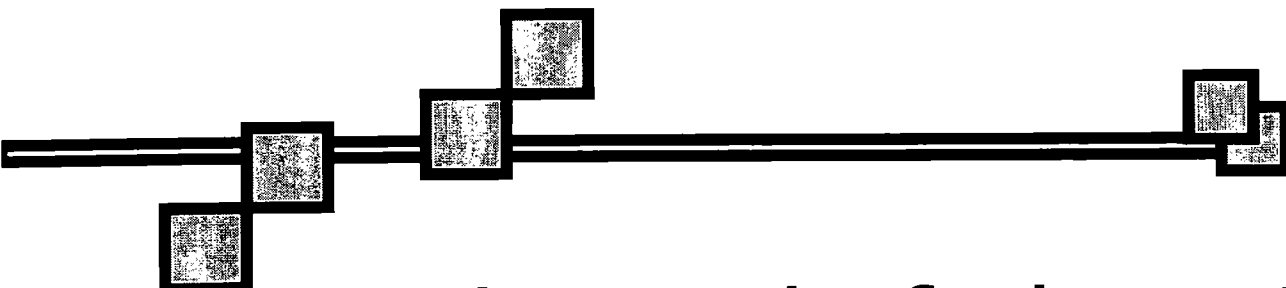
14. Critical need for natural product quality assurance, either private or public

- 
- Implement an effective program for ensuring product quality
 - Products should contain what the label indicates, and ONLY that
 - Appropriate standards for structure, function and health claims
- 

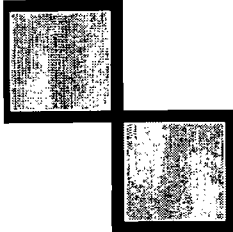
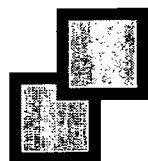


Ultimately, good health comes from personal decisions

- 
- This means public health critical for any real long term change
 - I believe the reason public health has been so receptive to CAM is the commonality of our philosophies:
 - Education
 - Prevention
 - Healthful living
 - Self-help
 - Personal responsibility for health
- 



At the End of These Two Days, I Think You Will:

- 
- See the value of collaboration
 - Recognize the importance of standards and accountability
 - That this remarkable phenomenon in the NW is not only about integration or leveling the playing field, it is about a shared vision to create a true healthcare system, not the limited disease-treatment system of today
- 

Collaboration in the Northwest

11/2/2000

Welcome

We are honored and excited you are visiting us these two days

Many organizations in the northwest have worked together the past two months to prepare what we hope will be a highly informative experience for you

The organizations that provided the funding and personnel

King County 2010

King County Council

Region X Public Health

Bastyr University

American Massage Therapists Association

Washington State Chiropractic
Association

Washington Association of Naturopathic
Physicians

Themes

We worked hard with the invited speakers to organize their presentations in the context of the four categories mandated by Congress

Through the information and recommendations provided, we hope you will hear 14 key themes, which I will present shortly



Successful Collaboration Requires Broad Commitment

Local, state, and regional levels

- Governmental bodies
- Regulatory agencies
- Academic institutions
- Practitioners
- Public Health officials and organizations
- Payors

14 Themes



11/2/2000

1. CAM is about systems of healing, not isolated therapies

Natural (CAM) medicine is defined by philosophical system, not modalities, or the substitution of "green drugs" for synthetic drugs

These "systems" change the way we think about and provide health care

They even change the measures of success



2. This “integration movement” in the Northwest 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

Are we talking about grafting CAM onto conventional or conventional onto CAM?

3. Facilitate collaboration

Conventional practitioners

CAM practitioners

Public health

Regulatory

Payors

Governmental



4. Research outcomes first, not isolated therapies

CAM is Multifactorial

Patient satisfaction and quality of life are
critical measures

Just as we have reaped tremendous benefit
by a huge investment in conventional
medicine research, similar benefits will be
found by investment in CAM

Develop consensus on research programs
appropriate for CAM

4. Research outcomes first, not isolated therapies (cont'd)

- Fund research on payer databases to compare outcomes

- Fund cost effectiveness studies

- Host joint sessions for CAM and CM researchers and institutions to discuss and plan for collaborative research

- Reorient the focus of CAM research from 90% bench and clinical trials to 90% outcomes, field research, and training of CAM clinicians to do field office research

11/2/2000

5. Level the playing field

Disparities between CAM & CM
(accredited & emerging) education,
maturity and research is due to
disparities in federal funding

CAM schools need support for education
Create and fund CAM-accredited Health
Centers of Excellence

6. Strengthen accountability

Accountability and standards critical for public protection

Support activities that communicate and respect existing standards in emerging professions

Fund initiatives to improve and further develop standards

Accreditation

Practice guidelines



6. Strengthen accountability (cont'd)

Education

- CAM practitioners
- Conventional practitioners wanting to practice CAM systems or use CAM modalities

National certification boards with credible testing and credentialing processes

- Practices
- Modalities

7. Critical need for appropriate nation-wide regulatory environment and standards

- Uniform licensure, regulation for public safety

- National board exams

- Collect and disseminate information about state regulatory models that are working well to provide access and protect the public.

- Encourage states to work together on the development of effective regulatory models

7. Critical need for appropriate nation-wide regulatory environment and standards (cont'd)

Adapt federal guidelines to accommodate the natural life cycle of emerging professions

Encourage self-regulation of education and practice in a credible way

Develop national certification and/or credentialing standards based on the best available in each profession

7. Critical need for appropriate nation-wide regulatory environment and standards (cont'd)

Encourage continuous improvement in those standards as educational institutions and examining boards improve

Constitutionally, health care regulation and licensing is a state prerogative, but feds can help with suggested standards, and financial incentives

8. Help the CAM professions mature

- Practice guidelines

- Credentialing systems

- Peer review (interdisciplinary and CAM)

- Federal programs (Medicare, NHSC, etc.)

- Infrastructure at CAM institutions

- Fund research fellowships and training for CAM educators and providers

- Provide NIH consultation to CAM schools that want to engage in research

9. Deeply engage CAM professionals at all levels of evaluation and decision making

CAM professionals have considerable and sophisticated expertise

Health related committees and advisory bodies should require CAM educators and practitioners as expert advisers, consultants and/or researchers

10. True integration & collaboration require joint training programs and clinical experiences

Practitioners who train together, practice together

Not just CAM and Conventional 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 special-needs populations

Underserved (poor/uninsured)

Reduce health disparities

Special needs, e.g., HIV/AIDS, the elderly

12. Reimbursement system needs careful reconsideration

Health-promotion vs. disease-
treatment coverage

Eliminate penalty for preventive
services

Be sure to include payer perspective

13. Critical need for accurate information for public and professionals

Content databases: validate intervention efficacy & safety (Cochrane & others)

Adverse events, reporting, monitoring

Disseminate comprehensive information about education, scope of practice, and the impact of different regulatory models (and the lack of regulation) in the established and emerging CAM disciplines

13. Critical need for accurate information for public and professionals (cont'd)

Provide education in, and a readily available database of, herb-drug-nutrient interactions

Provide information on CAM practitioner education and standards of practice

14. Critical need for natural product quality assurance, either private or public

Implement an effective program for ensuring product quality

Products should contain what the label indicates, and ONLY that

Appropriate standards for structure, function and health claims

Ultimately, good health comes from personal decisions

This means public health critical for any real long term change

I believe the reason public health has been so receptive to CAM is the commonality of our philosophies:

- Education
- Prevention
- Healthful living
- Self-help
- Personal responsibility for health

At the End of These Two Days, I Think You Will:

See the value of collaboration

Recognize the importance of standards and accountability

That this remarkable phenomenon in the NW is not only about integration or leveling the playing field, it is about a shared vision to create a true healthcare system, not the limited disease-treatment system of today

Kingsbury, Doris (NCCAM)

From: Todd L. Richards [toddr@u.washington.edu]
Sent: Tuesday, November 28, 2000 2:39 PM
To: Whccamp (NCCAM)
Subject: extended testimony from Todd Richards



neurofreeze.htm



Image1.gif



Image2.gif



Magnetic.doc

In our laboratory at the University

of Washington, we perform both "mainstream" medical research and "alternative" medical research. I feel that society can benefit greatly from the complementary and alternative medical practices, but I also feel that there is a lot of research that needs to be done to further develop and test the efficacy of these treatments. I think that some claims have been made without proper testing and validation. The medical community will be more prone to accept these new treatments if they have been tested in clinical trials that use outcome measures that have been proven in the past. An example of outcome measures that we have used and which are accepted by the multiple sclerosis research community are: 1) 25 foot walking test; 2) 9 hole peg test for manual dexterity; 3) mental performance test called the PASAT. In our laboratory, we are interested in the following areas of research

- 1) magnetic therapy;
- 2) mind over body medicine/effect of consciousness;
- 3) new diagnostic tests that use a detector of subtle energies of the body;
- 4) transfer of neural energy between humans.

In summary, the medical community has much to gain by combining proven treatments from:
both allopathic and alternative medicine,
both Eastern and Western practices,
both spiritual and physical methods, and
both energy (non-touch) and therapeutic touch.

Todd Richards, PhD
Professor of Radiology,
University of Washington
Seattle, Wa 98195
206-598-6725
toddr@u.washington.edu

Neurofeedback and bioelectric measurements in multiple sclerosis

Investigators:

Todd Richards, PhD, Juan Acosta-Urquidi, PhD, Department of Radiology, University of Washington,

This is a research activity (funded by "Higher Ground for Humanity"), to test the effects of neurofeedback and FreezeFrame (developed by the Heartmath Institute) on multiple sclerosis (MS). Neurobiofeedback is a proposed treatment to improve physical and mental performance and is based on self-regulation of brain electrical activity. FreezeFrame is a "mind over body" technique which involves training the subject to change their heart-rate variability and thus their autonomic nervous system. All subjects are monitored before and after neurofeedback training with tests designed to measure how well the brain is working (brain functional ability) and the subject's well-being.

Neurofeedback training procedure for research subjects:

Background

We are using a training technique that combines the Heartmath FreezeFrame method with neurofeedback. Researchers at the Heartmath Institute have developed a method to show people how to get their hearts to beat at a healthier and more loving rhythm.

See article in Natural Health magazine September-October 1997 edition, starting on page 98. The Freeze-Frame exercises have been scientifically shown to boost anti-aging hormones and immune system components such as immunoglobulin A (IgA). Dr. Richards attended a special training course in January 1998 hosted by the Heartmath Institute to learn how to use this technique for himself and also how to train others. As far as we know, this is the first study proposed to test the training in MS patients.

We have also purchased special heart zone music developed by Heartmath that aids the subject to achieve this higher state of consciousness.

During our specific training sessions we place EKG electrodes (or have the subject place them) on the chest and monitor heart-rate variability as described by Dr. Rollin McCraty

See American Journal of Cardiology vol 76, pages 1089-1093, 1995.

If the subject has truly achieved the desired state of consciousness, a very specific heart-rate variability wave will appear. We will show this wave to the subject in a biofeedback technique to let them train and optimize their mental/spiritual feelings to change the heart-rate variability. This technique is different from other biofeedback techniques for stress-reduction both in terms of what the subject is asked to think about and also the physiologic measures (the other biofeedback techniques usually don't measure

heart-rate variability). New software was developed to measure simultaneous physiological measurements of brain waves (electroencephalography), heart waves (electrocardiography, heart rate variability), respiration, and muscle waves (electromyography). We also measured physical and mental performance scores to correlate with physiological changes during the FreezeFrame and mind/body training. The mental/spiritual training was aimed at changing the emotional/consciousness state and also specific training was given to visualize healing, regeneration, reforming of nerve connections, and repair of the immune system.

Bioelectric Frequency Analyzer (BFA)

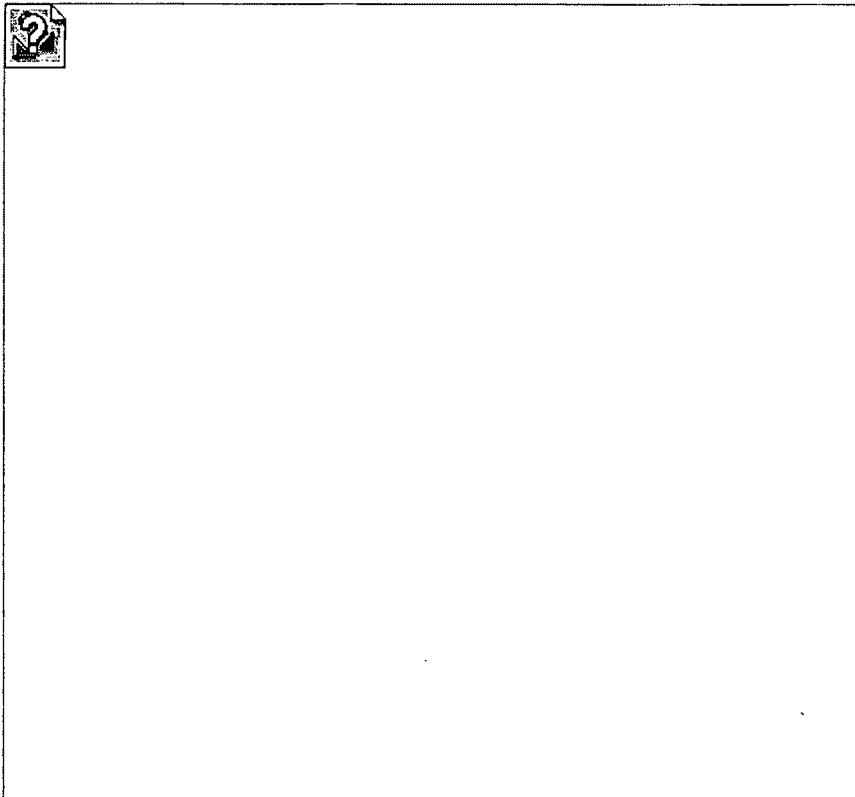
We are using the BFA detector to measure bioelectric field energy emitted by MS patients and by controls. The bioelectric frequency analyzer is a unique piece of equipment developed by a company called Energy Medicine Developments (North America), Inc.

Dr. Juan Acosta-Urquidi has obtained some amazing results with this detector in measuring controls during different states of consciousness.

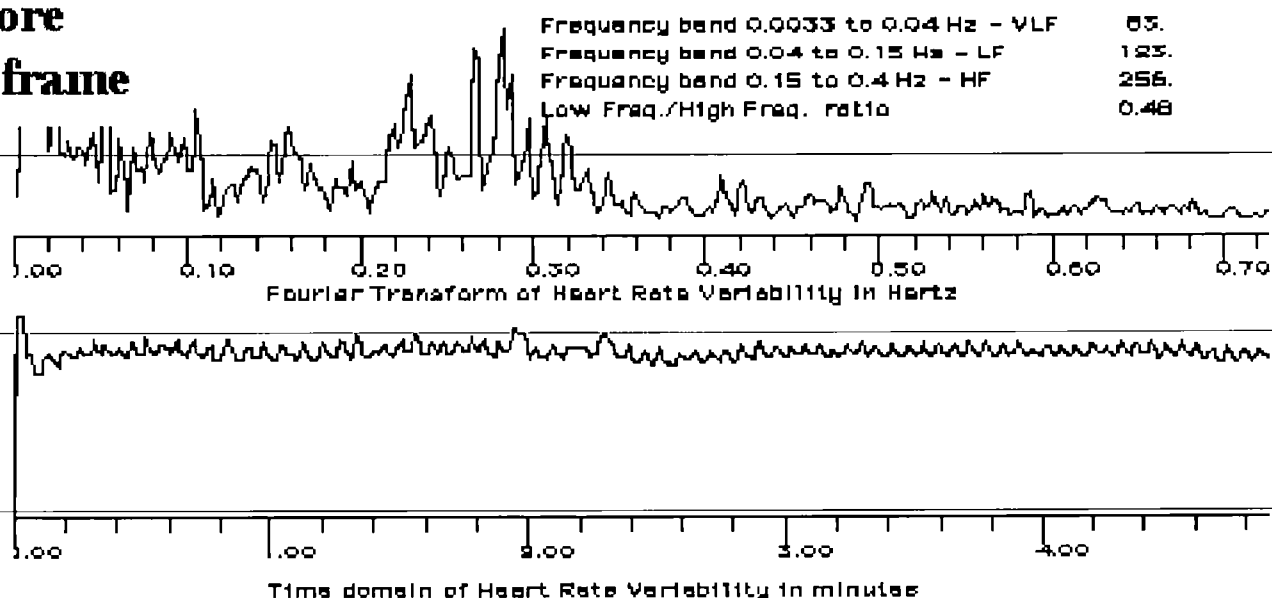
This electrodeless detector (called the bioelectric frequency analyzer, BFA) consists of a piezoelectric crystal mounted in a padded head frame (fitted with a photodiode and light source) which was connected to an amplifier and pc computer for analysis. The time-domain signal was Fourier transformed and displayed as a spectrum with a range of 1 -25 Hertz. This spectrum was used to determine possible energy peaks and deficits at specific frequencies. We have recorded new and robust signals from controls (BFA frequency resonances, range 3.8-22.8 Hz, mean 14.8+-7, N = 14), during different states of consciousness (or different mental states). In every case, the BFA signals did not correlate with the EEG signals (recorded from the same region of the head), in either peak frequency or magnitude/power. These results may imply that the BFA detector is measuring a different kind of energy than that measured with the standard EEG electrode.

Preliminary Results

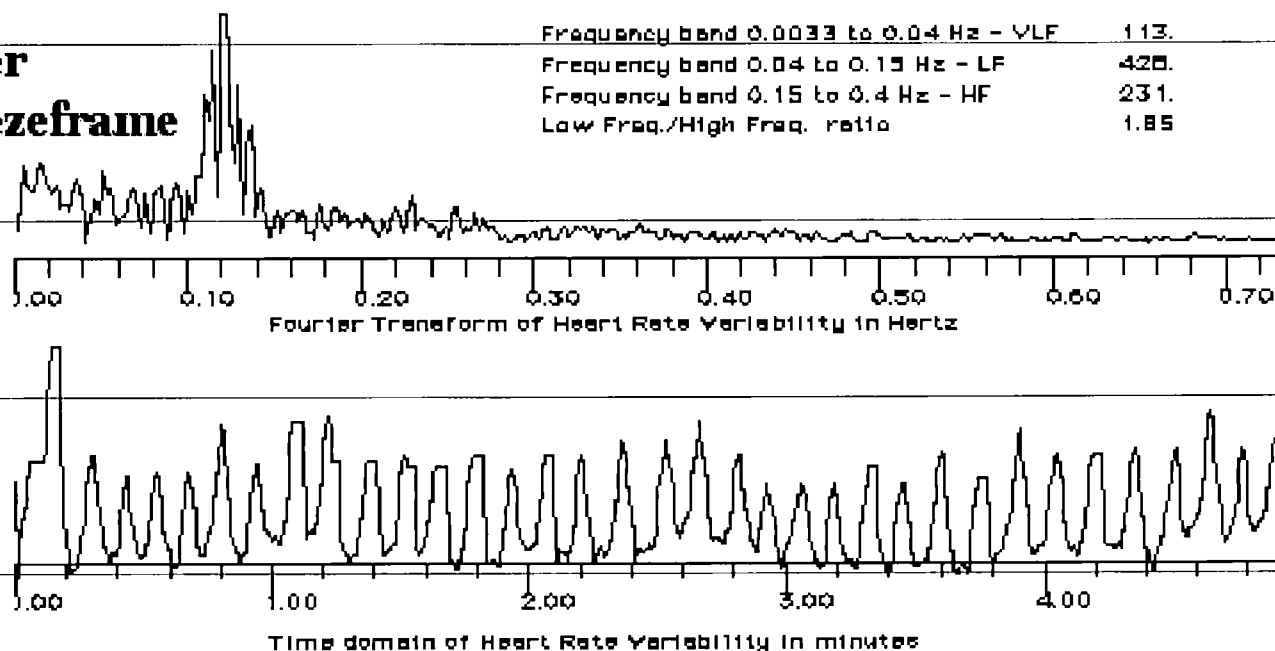
We have recently acquired new data from a patient with multiple sclerosis (approx. age 40, female, remitting-relapsing MS). Three ECG electrodes were placed on the chest and a physiologic monitoring system developed by J&J Engineering was used to measure heart-rate variability (HRV) and the spectral analysis of the time-domain heart rate wave. During the first 5 minute session, the subject was instructed to relax but not to meditate and the time domain and the spectral analysis are shown in part A of the Figure (shown below). The subject then received 20 minutes of FreezeFrame training while watching her HRV signal. The results of the last 5 minute session of FreezeFrame training is shown in part B of the Figure. As can be seen in the "low frequency band" (0.04 to 0.15 Hz) the value increased from 123 to 428 after the training. The low frequency/high frequency ratio increased from 0.48 to 1.85 after the training. The spectral analysis was performed using software written by the PI. Therefore, with FreezeFrame training, the subject was able to generate higher amplitudes in the beneficial heart rate variability frequency range.



A. Before FreezeFrame

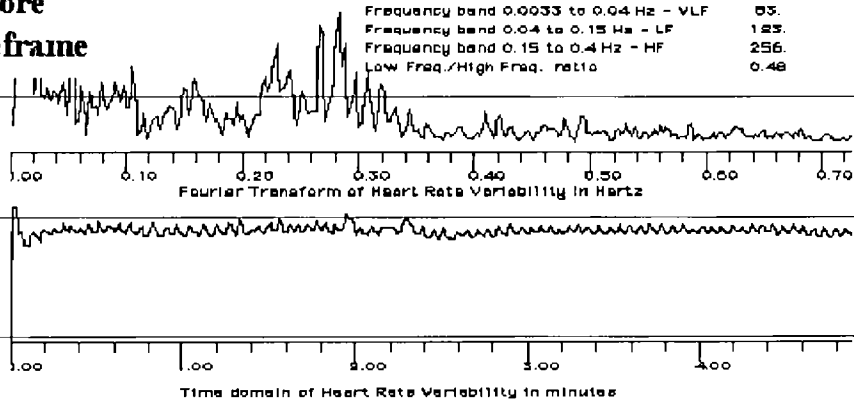


B. After FreezeFrame

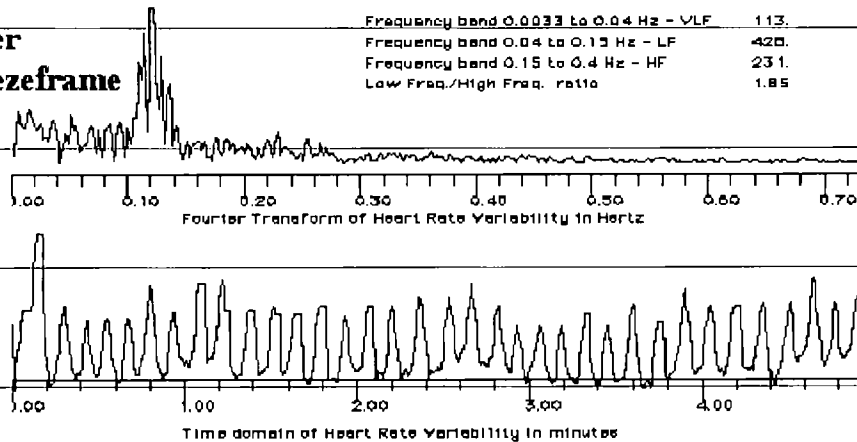


Effect of FreezeFrame on Spectral Analysis of Heart Rate Variability

A. Before FreezeFrame



B. After FreezeFrame



Effect of FreezeFrame on Spectral Analysis of Heart Rate Variability

Magnetic Therapy

Below is a list of our references and abstracts concerning magnetic therapy.

Phys Med Rehabil Clin N Am 1998 Aug;9(3):659-74

Bioelectromagnetic applications for multiple sclerosis.

Richards TL, Lappin MS, Lawrie FW, Stegbauer KC

Department of Radiology, University of Washington, Seattle, USA.

There are EM effects on biology that are potentially both harmful and beneficial. We have reviewed applications of EM fields that are relevant to MS. It is possible that EM fields could be developed into a reproducible therapy for both symptom management and long-term care for MS. The long-term care for MS would have to include beneficial changes in the immune system and in nerve regeneration.

Phys Med Rehabil Clin N Am 1999 Aug;10(3):729-54

Evolution of magnetic therapy from alternative to traditional medicine.

Vallbona C, Richards T

Department of Family and Community Medicine, Baylor College of Medicine, Houston, Texas, USA.

Static or electromagnetic fields have been used for centuries to control pain and other biologic problems, but scientific evidence of their effect had not been gathered until recently. This article explores the value of magnetic therapy in rehabilitation medicine in terms of static magnetic fields and time varying magnetic fields (electromagnetic). A historical review is given and the discussion covers the areas of scientific criteria, modalities of magnetic therapy, mechanisms of the biologic effects of magnetic fields, and perspectives on the future of magnetic therapy.

J Altern Complement Med 1997 Spring;3(1):21-9

Double-blind study of pulsing magnetic field effects on multiple sclerosis.

Richards TL, Lappin MS, Acosta-Urquidi J, Kraft GH, Heide AC, Lawrie FW, Merrill TE, Melton GB, Cunningham CA

Department of Radiology, University of Washington, Seattle, USA.

We performed a double-blind study to measure the clinical and subclinical effects of an alternative medicine magnetic device on disease activity in multiple sclerosis (MS). The MS patients were exposed to a magnetic pulsing device (Enermed) where the frequency of the magnetic pulse was in the 4-13 Hz range (50-100 milliGauss). A total of 30 MS patients wore the device on preselected sites between 10 and 24 hours a day for 2 months. Half of the patients (15) randomly received an Enermed device that was magnetically inactive and the other half received an active device. Each MS patient received a set of tests to evaluate MS disease status before and after wearing the Enermed device. The tests included (1) a clinical rating (Kurtzke, EDSS), (2) patient-reported performance scales, and (3) quantitative electroencephalography (QEEG) during a language task. Although there was no significant change between pretreatment and posttreatment in the EDSS scale, there was a significant improvement in the performance scale (PS) combined rating for bladder control, cognitive function, fatigue level, mobility, spasticity, and vision (active group -3.83 ± 1.08 , $p < 0.005$; placebo group -0.17 ± 1.07 , change in PS scale). There was also a significant change between pretreatment and posttreatment in alpha EEG magnitude during the language task recorded at various electrode sites on the left side. In this double-blind, placebo-controlled study, we have demonstrated a statistically significant effect of the Enermed magnetic pulsing device on patient performance scales and on alpha EEG magnitude during a language task.

,In Biologic Effects of Light 1998 Symposium, Eds Holick MF, Jung EG, Kluwer Academic Publishers: Boston, pg. 337-342, 1999

Pulsing magnetic field effects on brain electrical activity in multiple sclerosis

Richards TL, Acosta-Urquidi, J

Multiple sclerosis (MS) is a disease of the central nervous system. Clinical

symptoms include central fatigue, impaired bladder control, muscle weakness, sensory deficits, impaired cognition, and others. The cause of MS is unknown, but from histologic, immunologic, and radiologic studies, we know that there are demyelinated brain lesions (visible on magnetic resonance images) that contain immune cells such as macrophages and T-cells (visible on microscopic analysis of brain sections) Recently, a histologic study has also shown that widespread axonal damage occurs in MS along with demyelination. What is the possible connection between MS and bioelectromagnetic fields? We recently published a review entitled "Bioelectromagnetic applications for multiple sclerosis," which examined several scientific studies that demonstrated the effects of electromagnetic fields on nerve regeneration, brain electrical activity (electroencephalography), neurochemistry, and immune system components. All of these effects are important for disease pathology and clinical symptoms in multiple sclerosis (MS). EEG was measured in this study in order to test our hypothesis that the pulsing magnetic device affects the brain electrical activity, and that this may be a mechanism for the effect we have observed on patient-reported symptoms. The EEG data reported previously were measured only during resting and language conditions. The purpose of the current study was to measure the effect of the magnetic device on EEG activity during and after photic stimulation with flashing lights. After photic stimulation, there was a statistically significant increase in alpha EEG magnitude that was greater in the active group compared to the placebo group in electrode positions P3, T5, and O1 (analysis of variance $p < .001$, $F = 14$, $DF = 1, 16$). In the comparison between active versus placebo, changes measured from three electrode positions were statistically significantly even after multiple comparison correction.

—

EVALUATION OF A PULSED-MAGNETIC FIELD DEVICE ON MULTIPLE SCLEROSIS SYMPTOMS

**Poster presented at the Annual Meeting of the Consortium of Multiple
Sclerosis Centers, October 2-4, 1998, Cleveland, Ohio**

TL Richards, PhD, University of Washington, Radiology Department

MS Lappin, PhD, Energy Medicine Developments (North America) Inc.

ED Kramer, MD, Cooper Health System/ Robert Wood Johnson, Medical School

Camden, NJ

AD Alquist, University of Washington, Radiology Department

BE Floyd, University of Washington, Radiology Department

KC Stegbauer, , University of Washington, Radiology Department

FW Lawrie, Energy Medicine Developments (North America) Inc.

Introduction

The primary purpose of this research was to test the effects of a pulsing electromagnetic field on the symptoms and quality of life experienced by individuals suffering from multiple sclerosis (MS). This project used the Enermed device (Energy Medicine Developments (North America), Inc.) to expose patients to individually programmed pulsed electromagnetic fields. Previous results using this device have been reported for both multiple sclerosis (1) and migraine patients (2). We have recently published a review of bioelectromagnetic applications for multiple sclerosis (3) and this document contains background information on bioelectromagnetism and possible mechanisms for biological effects. Weak electromagnetic fields have been shown to affect nerve regeneration, brain electrical activity (electroencephalography), neurochemistry, and immune system components (see reference 3 and citations therein).

Methods

Study design

The effectiveness of the treatment was assessed in a 10 week, randomized, placebo-controlled, double-blind crossover study. Data were collected from three sites: University of Washington, Seattle, WA; Cooper Health System/Robert Wood Johnson Medical School, Camden, NJ; Neurology Center of Fairfax, Virginia. Subjects came on site for 4 visits for evaluation before and after exposure to both active (Enermed) and inactive (Placebo) devices. This study was reviewed and approved by the Institutional Review Board/ Human Subjects Committee at each site.

MS Subjects

MS patients were recruited from all three sites (125 total completed the study). To meet inclusion criteria subjects were: 1) diagnosed with clinically definite MS (Poser criteria); 2) between the ages of 18 to 60 inclusive; 3) medically stable -- no MS exacerbations for two months prior to the study; 4) medicinally stable - no changes in prescription for one month prior; 5) disabled in bladder control or muscle spasticity with a symptom rating of 2 or higher (0 = no symptoms, 5 = severe symptoms).

The Pulsing Magnetic Field Exposure

Subjects were exposed to a pulsing magnetic field produced by the Enermed device. This device is a watch-sized, programmable magnet powered by a 3 volt battery. It is designed to be worn

close to the body, and produces a 1 millisecond magnetic pulse in the 50 to 100 milliGauss range. A programmable chip allows the magnetic pulse trains to be sequentially produced for one to 16 frequencies (12.7 seconds duration for each frequency). In order to determine the most appropriate frequencies for treatment, each patient was scanned with a Bioelectric Frequency Analyzer (BFA) which measures weak electromagnetic fields produced by the body. The BFA consists of a quartz crystal detector embedded in a padded headset. The output signal is linked to an amplifier and a small computer for spectrum analysis. After subjects' devices were programmed they were shown how to tape or attach the device to a spot just below the collar bone on the chest. They were instructed to wear the device 6 hours the first day and then increase wearing time by 2 hours each day up to 24 hours a day.

Outcome Measures

The primary outcomes of this study were daily diary measures of bladder control and muscle spasticity. These included reports of daytime and nighttime urination frequency and ratings of the severity of any spasticity experienced during the day and night. Daily reports for the last three weeks of each treatment session (Enermed and Placebo) were averaged and compared. Secondary outcomes consisted of symptom ratings scales from the MS Quality of Life Inventory (MSQLI) developed by the Health Services Research Subcommittee of the Consortium of Multiple Sclerosis Centers (4). We used four of the abbreviated MSQLI scales (bladder control, fatigue, perceived deficits, and pain/sensory problems), plus a spasticity scale we created by modifying the pain effects scale. The surveys were administered prior to the first treatment session (baseline measure), and immediately following each four week treatment session. All five scales had excellent internal consistency reliabilities with Cronbach alphas averaging .80 or higher across the three time periods.

Results

Daily Diary Data

The daily diary measures were analyzed using repeated measures ANOVA, both with and without adjusting for covariates (age, sex, ability to walk 10 yards unassisted, and treatment sequence). Neither analysis showed significant treatment effects on frequency of urination or daily spasticity ratings.

Survey Data

Sample Selection. Before analyzing the survey data we dropped the 5 subjects who had physician diagnosed exacerbations during the course of the study and the 14 subjects who reported at baseline that they had no problems ("0") with spasticity and bladder control. This allowed us to examine the data for the subset of subjects (n=105) who might truly be candidates for the therapy, i.e., those experiencing relevant symptoms, without the error variance introduced by exacerbations and steroid treatments.

Spasticity and Bladder Control Problems. The means on the spasticity and bladder control scales favored the Enermed group, but were not statistically significant.

Fatigue, Pain, and Cognitive Problems. Next we looked at the remaining three MSQLI scales: fatigue, pain/sensory effects, and perceived cognitive deficits. We were especially interested in

fatigue, as this symptom showed the greatest improvement within the Enermed group in our first study (1). Paired t-test results showed a significant treatment effect for fatigue ($t=-2.59$, $p<.01$), but not for the other two symptoms (Pain $t=-1.30$, $p<.20$; Cognitive $t=-.66$, $p<.51$). To rule out the possibility that the observed effects for fatigue were due to one or two extreme scores in the negative tail of the distribution, we also conducted a non-parametric test (Wilcoxon Signed Ranks test), based on ranks instead of means. This test also showed a significant treatment effect. In fact, ranks from the Wilcoxon test indicate that the ratio of subjects showing improvement on the Enermed relative to the placebo device was about 1.6 to 1.0 (56:36 with 12 ties). In other words, for every 10 subjects showing greater placebo effects, 16 subjects showed greater improvements on the Enermed device.

Subgroup Analyses. To see if certain subgroups responded differently to the Enermed we used repeated measures ANOVA to examine fatigue as a function of a) years with MS, b) ability to walk 10 yards, c) severity of symptoms at baseline, d) type of MS, e) sex, and f) research site. None of the interactions was significant, however, there were some trends worth noting. The Enermed appears to be most effective at alleviating fatigue for MS patients who can walk 10 yards unassisted and whose symptoms are neither very mild nor very extreme (see Figures 3 and 4). There were also unexpected significant main effects for research site - overall changes were greater at the Fairfax site than the New Jersey site, although the treatment effects appear proportional at the two sites (see Figure 5). Possible reasons for these differences need to be explored further.

Summary and Conclusion

Although the primary outcome measures (dairy reports) did not show significant treatment effects, the results of our secondary, survey-based analyses were encouraging. The MSQLI fatigue scale showed a significant treatment effect, and post-hoc analyses showed this result was replicated in one of the two single item measures of fatigue included in other instruments. These results clearly warrant additional research with a primary focus on fatigue. Fatigue is one of the most debilitating symptoms associated with MS, and any non-invasive, non-pharmacological therapy that might alleviate its effects would be a tremendous addition to the therapies currently available to MS patients.

References:

1. Richards TL, Lappin MS, Acosta-Urquidi J, Kraft GH, Heide AC, Lawrie FW, Merrill TE, Melton GB, Cunningham CA, Double-blind study of pulsing magnetic field effects on multiple sclerosis. *J Altern Complement Med* 3:21, 1997.
2. Lappin MS, Research on the utility of medigen device as a treatment for migraines. Research Report #1, April 1995. Vancouver, B. C.: Energy Medicine Developments (North America) Inc.
3. Richards TL, Lappin MS, Lawrie FW, Stegbauer KC, Bioelectromagnetic applications for multiple sclerosis, *Physical Medicine and Rehabilitation Clinics of North America*, 9, 659-674, 1998.
4. Ritvo PG, Fischer JS, Miller DM, Andrews H, Paty DW, LaRocca NG, *Multiple Sclerosis Quality of Life Inventory: A User's Manual*. New York: National Multiple Sclerosis Society,

1997.

Acknowledgements

We thank the Multiple Sclerosis Association of America for their generous financial support. We also thank Dr. Richard Kronmall and Statistics and Epidemiology Research Corporation for help with statistics and data analysis. We acknowledge the help of Catherine Cunningham for recruitment of subjects.

Figure 1 is a real Enermed Device. - placed next to methods

Figure 2 is a diagram of placement of Enermed Device on the body.

Figure 3 - placed below results section

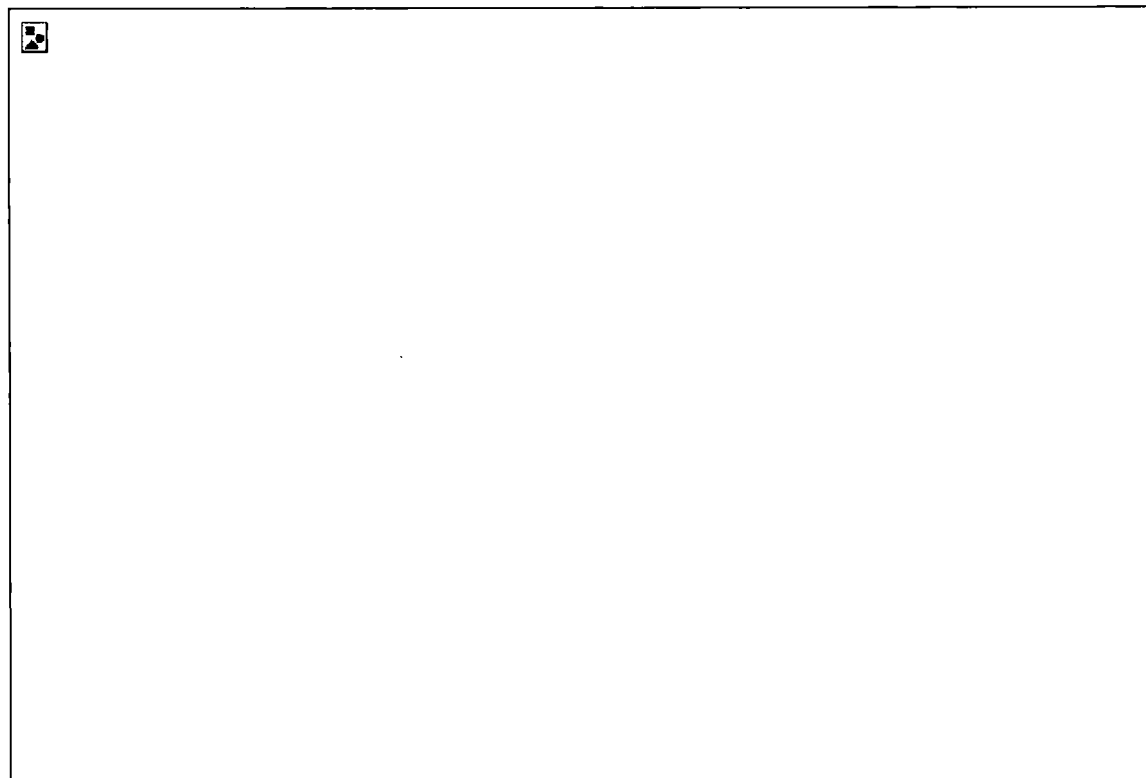


Figure 4

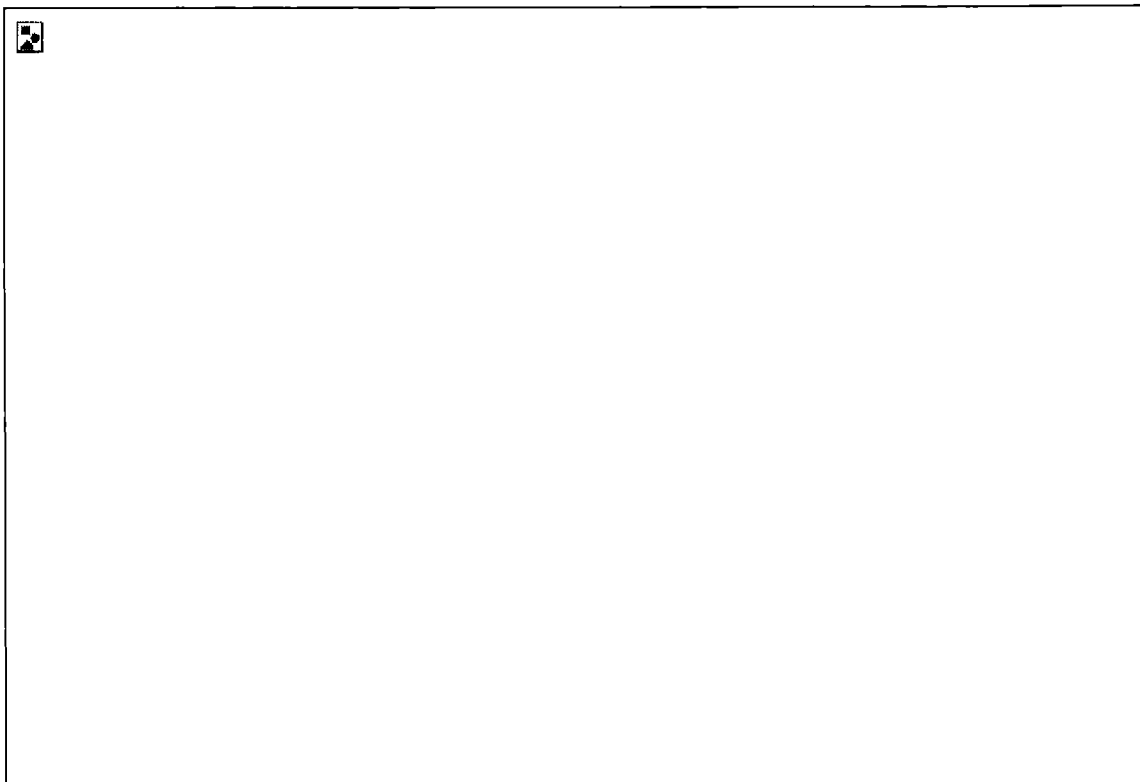
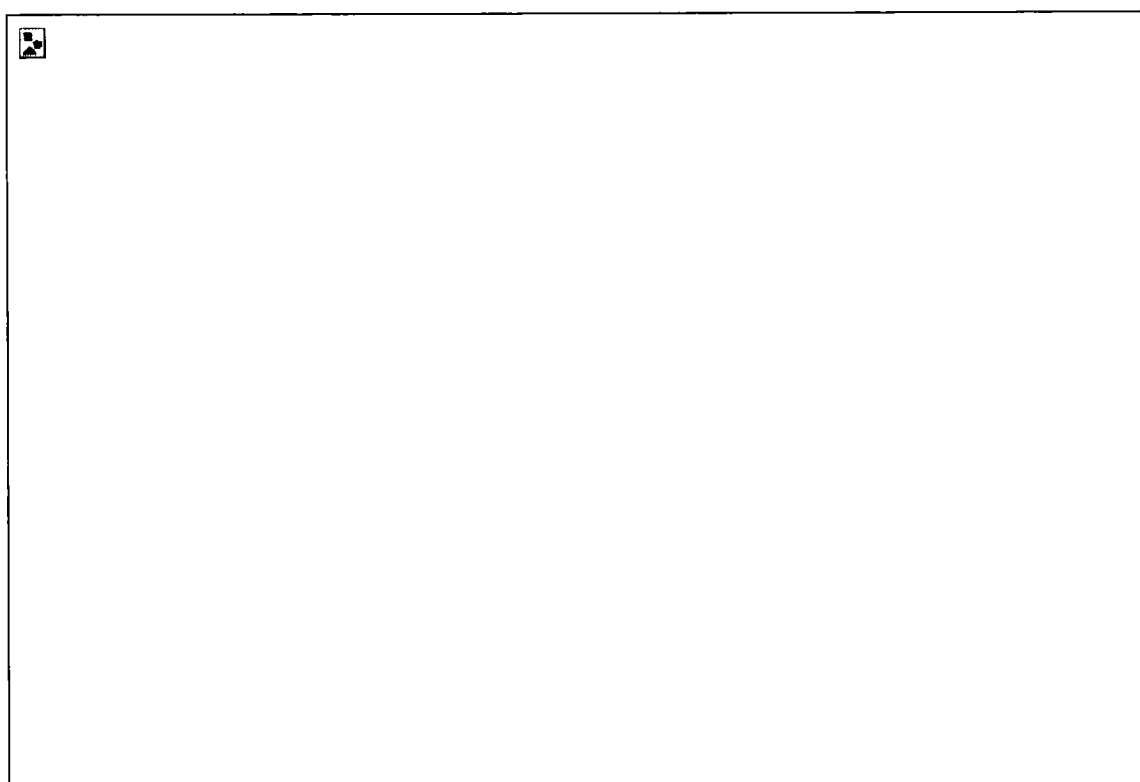


Figure 5



White House Commission on Complementary and Alternative Medicine
Seattle, Washington
October 30, 2000

Testimony: Washington State Health Professional Loan Repayment and Scholarship Program

Good afternoon, my name is Kathy McVay. I administer the Washington State Loan Repayment and Scholarship Program. Thank you for coming today and giving us this opportunity to showcase the excellent recruitment and retention programs we have in Washington State and the coordination that exists among all of the primary care professions. I would like to make three points today.

The Health Professional Loan Repayment and Scholarship Program is one of numerous legislative responses to health professional shortages in Washington State. Current data indicates an adequate number of health professionals are being trained, however there is a critical maldistribution affecting the rural and urban underserved areas of the state. The loan repayment and scholarship program has had a significant impact on placing health care providers in these areas. By linking financial aid in the form of scholarship and loan repayment to an obligation to practice in a rural or urban underserved area, the program enables communities to successfully recruit and retain health professionals.

I believe we are the only state in the nation that provides loan repayment and scholarship support for CAM professions. Their inclusion in the program is directly related to the work of the Health Personnel Resource Plan (HPRP). The HPRP was responsible for defining primary care providers. During that process, the HPRP concluded that naturopathic physicians are likely to locate in rural areas or have an interest in serving the urban underserved. Therefore, they were grouped with other primary care providers and gained eligibility for the program. Currently, our program includes naturopathic physicians and licensed midwives in addition to allopathic and osteopathic physicians, dentists, dental hygienists, nurses, pharmacists, and physician assistants. All are eligible to receive support from both scholarship and loan repayment. However, due to their lack of Medicaid/Medicare reimbursement, ND's are eligible for loan repayment only. Currently, two ND's are receiving loan repayment support in return for a three-year commitment in a community health center.

First point: Reimbursement - The decision to exclude ND's from scholarship was based solely on the lack of reimbursement to the profession for health care services. The loan repayment and scholarship program requires a recipient to provide primary care health care services to the rural and urban underserved communities of Washington State. Scholarship funds are intended to defray the educational expenses of a student in return for an obligation in a designated shortage area (not site specific) upon completion of the training program. In doing so, program recipients may not exclude clients who are eligible for Title XVIII or Title XIX of the Social Security Act, must accept assignment under the terms of that Act, must enter into an agreement with and accept payments from the state Medicaid agency, and must have an "open door" policy that is not based on ability to pay. Unless a program recipient can identify a specific health care system or practice willing to guarantee a salary for these services, their economic viability is questionable. After lengthy debate, the program's advisory committee agreed that committing a provider to service in one of these areas could not guarantee a viable

income and, further, the program could not accept the responsibility for putting the recipient in economic jeopardy.

On the other hand, loan repayment funds are intended to help repay debt that is incurred during the training program in return for a three-year obligation in a specific site. ND's are eligible for loan repayment because facilities are required to apply for site eligibility and program applicants must negotiate an appropriate employment contract with a priority site before applying for loan repayment funds. Therefore, the applicant for loan repayment has an income guarantee and their economic viability is not hindered by the program's requirements based on Titles XVIII and XIX.

Second point: Funding – As a result of the debate whether or not to include CAM professions in the program, Bastyr University has taken the lead in outreach and education to communities. A collaborative effort, led by Bastyr, resulted in writing and publishing the Integrated Care Options for Communities in Need slide show and narrative. Although this particular program features CAM professions, it is a model that can be used by other professions for community education and outreach. Ongoing funding is necessary to continue the work of collaborative projects such as this one. I support funding for the continuation and expansion of these activities in order to encourage collaboration among all primary care professions, which will, in turn, maximize loan repayment and scholarship program dollars by fully utilizing all program eligible professions.

Third point: Inclusion in NHSC program – Currently, Washington State participates in the federal State Loan Repayment Program matching grant fund. However, we are not able to utilize those funds to support ND's or licensed midwives even though our state dollars are used to support those professions because those professions are not included in the federal program authorization. Including the CAM professions in the NHSC program, would allow Washington State to better utilize the funds we receive from the federal grant for states to match with local funds.

In summary, we have developed a successful, collaborative relationship among all health professions in Washington State. With more funding and fewer restrictions on reimbursements, that relationship will continue to grow and become even stronger.

Questions or additional information on this testimony may be requested from:

Kathy L. McVay, Program Administrator
Health Prof Loan Repayment/Scholarship Program
Office of Community and Rural Health
PO Box 47834
Olympia, WA 98504-7834
(360) 705-6665
kathy.mcvay@doh.wa.gov

Kingsbury, Doris (NCCAM)

From: Jennifer Jacobs [jjacobs@igc.org]
Sent: Sunday, November 19, 2000 5:10 PM
To: Whccamp (NCCAM)
Subject: Expanded Seattle Testimony



ExpandedWCCAM.doc

Attached are the expanded written comments to my testimony given on
October
31, 2000 at the Seattle Town Hall meeting.

Jennifer Jacobs, MD, MPH

Weiser M, Strosser W, Klein P. Homeopathic vs conventional treatment of vertigo: a randomized double-blind controlled clinical study. *Arch Otolaryngol Head Neck Surg.* 1998; 124:879-85.

References

- Bellavite P, *Homeopathy: A Frontier in Medical Science*. Berkeley, CA: North Atlantic Books; 1995.
- Chapman EH, Weintraub RJ, Milburn MA, Pirozzi TO, Woo E. Homeopathic treatment of mild traumatic brain injury: A randomized, double-blind, placebo-controlled trial. *J Head Trauma R* 1999; 521-42.
- Eisenberg DM, Kessler RC, Foster C, Norlock FE, Calkins DR, Delbanco TL. Unconventional medicine in the United States. Prevalence, costs, and patterns of use. *NE J Med*. 1993; 328:246-252.
- Eisenberg DM, Davis RB, Ettner SL, Appel S, Wilkey S, Van Rompay M, Kessler RC. Trends in alternative medicine use in the U.S., 1990-1997. Results of a follow-up national survey. *JAMA* 1998; 280:1569-1575.
- Ernst E, Kaptchuk, TJ. Homeopathy revisited. *Arch Int Med* 1996; 156:2162-4.
- Ferley JP, Smirou D, D'Adhemar D, Balducci F. A controlled evaluation of a homeopathic preparation in the treatment of influenza-like syndromes. *Br J Clin Pharmacol* 1989;27:329-35.
- Fisher P, Greenwood A, Huskisson EC, Turner P, Belon P. Effect of homeopathic treatment on fibrositis (primary fibromyalgia). *Br Med J* 1989;299:365-6.
- Healthcare Professionals in Private Practice in 1990*. Paris, France: National Office of Medical Insurance (CNAM); 1991. CNAM publication 61.
- Jacobs J, Chapman E, Crothers D. Patient characteristics and practice patterns of physicians using homeopathy. *Arch Fam Med*. 1998; 7:537-40.
- Jacobs J, Jimenez LM, Gloyd S, Gale J, Crothers D. Treatment of acute childhood diarrhea with homeopathic medicine: a randomized clinical trial in Nicaragua, *Pediatrics* 1994; 93: 719-25.
- Jacobs J, Jimenez LM, Malthouse S, et. al. Homeopathic treatment of acute childhood diarrhea: results from a clinical trial in Nepal. *J Altern Complem Med* 2000; 6:131-9.
- Jacobs, J, Springer DS, Crothers D. Homeopathic treatment of acute otitis media in children: a preliminary randomized controlled trial. *Pediatr Infect Dis J*, 2001 (In press).
- Jonas WB, Jacobs J. *Healing with Homeopathy. The Complete Guide*. NY: Warner Books, Inc., 1996.
- Kleijnen J, Knipschild P, ter Riet G. Clinical trials of homoeopathy. *Brit Med J* 1991;302:316-23
- Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients. *JAMA* 1998; 279: 1200-05.
- Linde, Clausius N, Ramirez G, et. al. Are the clinical effects of homeopathy placebo effects? A meta-analysis of placebo-controlled trials. *Lancet* 1997; 350:834-43
- Reilly D, Taylor MA, Beattie NGM, et al. Is evidence for homoeopathy reproducible? *Lancet* 1994;344: 1601-6.
- Reilly DT, Taylor MA, McSharry C, Aitchison T. Is homoeopathy a placebo response? Controlled trial of homoeopathic potency, with pollen in hayfever as model. *Lancet* 1986; ii:881-5.
- Swander, H. Homeopathy: medical enigma attracts renewed attention. *Am Acad of Fam Pract Rep*. 1994;XXI(6):1-2.
- Taylor, MA, Reilly D, Llewellyn-Jones RH, McSharry C, Aitchison TC. Randomised controlled trial of homoeopathy versus placebo in perennial allergic rhinitis with overview of four trial series. *BMJ* 2000; 321:471-6.
- Vithoulkas G. *The Science of Homeopathy*. NY: Grove Weidenfeld, 1980.

is thought to be due to enhancement of the immune response and other auto-regulatory systems of the body. (Bellavite, 1995)

Research opportunities for homeopathy in the US are few, due to the generic nature of the medicines, which cannot be patented. The NIH has funded several homeopathic studies and is now requesting new proposals for funding. Currently, I am heading up a study of homeopathy for hot flashes in breast cancer patients funded by the Department of Defense at Providence Medical Center in Seattle.

American Institute of Homeopathy Recommendations

The American Institute of Homeopathy (AIH) is the professional organization for medically trained homeopaths and sponsors educational programs, research, and interfaces with government agencies. The AIH recently sponsored a series of round-table discussions across the country of its members. These medical professionals were asked to answer the following question: "What needs to be done to enhance the practice and availability of homeopathy in the US?" The answers that came back were remarkably similar from all of the groups and covered many of the topic areas also being investigated by the WCCAM.

In the area of access and delivery, recommendations included improved licensure and standards of care, board certification of homeopathic professionals as well as improved insurance reimbursement, legislation to accept homeopathy as a legitimate standard of care, and legal support for homeopaths who are under fire by local medical groups. Recommendations in the area of education and training of health care practitioners included a program to implement primary care homeopathy courses for medical professionals, as well as regional meetings, study groups, and teaching clinics for physicians using homeopathy. Education about homeopathy to the general public, governmental agencies, managed care plans, the media, and politicians was also deemed important, through improved educational materials and our website. And finally, more research was recommended- into clinical efficacy and cost effectiveness of homeopathy as well as trying to understand the mechanism of action of homeopathy on a basic science level.

Specific Actions

Other specific actions that could improve access to homeopathy include:

- 1) Establish Departments of CAM in medical schools and residency programs where homeopathy can be taught
- 2) Cost effectiveness research to document the 15% cost savings of homeopathic physicians found in France (CNAM, 1991)
- 3) Reimbursement policies that allow adequate time for homeopathic consultations
- 4) Inclusion of homeopathy in low-income clinics
- 5) Hospital privileges for homeopathic physicians
- 6) Licensing of non-medically trained homeopaths, to work legally under the supervision of a physician, or other licensed health care provider

I would like to thank the Commission for inviting me to speak. Representatives from the American Institute of Homeopathy would be happy to provide more detailed testimony in your upcoming meetings about specific topic areas.

of health, including improvements in energy levels and sense of well-being. (Vithoulkas, 1980).

An extensive literature of homeopathic drug provings (experiments on healthy volunteers) carried out over the past 200 years has documented indications for more than 1000 medicinal substances used in homeopathic practice. Homeopathic medicines are prepared according to standardized methods as specified by the Homeopathic Pharmacopoeia of the United States (HPUS), which was mandated by Congress to regulate the manufacture of homeopathic medicines as part of the Food, Drug, and Cosmetics Act of 1939. Most homeopathic products are derived from plant, animal, or mineral sources and because of the highly dilute nature of the preparations, are without toxic side effects. (Jonas and Jacobs, 1996)

Prevalence and Practice of Homeopathy

Recently, there has been a resurgence of interest in homeopathy in the US. In 1990, it is estimated that there were almost 5 million visits to homeopathic providers. (Eisenberg, 1993) A later survey showed the use of homeopathy to have increased five-fold to 3.4% by the general population in 1997. (Eisenberg, 1998) Today homeopathy is used extensively throughout the world. In some European countries, as many as 30-40% of patients and physicians use homeopathy. (Ernst, 1996) It has been estimated that 2500 medical professionals in the U.S. currently use homeopathy to some extent in their practices. (Swander, 1994) Homeopathy is used mostly by upper-middle class patients for chronic health problems not helped by conventional medicine. (Jacobs, 1998) The cost of homeopathic medicines is extremely low, approximately \$5 for a bottle of 100 doses.

Except for three states, Connecticut, Nevada, and Arizona, there is no specific license for homeopathic physicians. Homeopathy is practiced by a wide variety of licensed providers including MD's and DO's, PA's and nurse practitioners, chiropractors, and naturopaths. There are a growing number of non-licensed homeopathic practitioners, whose legal status is undetermined. There are three certification boards for homeopathy, one for the medically licensed (American Board of Homeotherapeutics), one for naturopaths (Homeopathic Association of Naturopathic Physicians), and one that is open to all (Council for Homeopathic Certification). Some health insurance companies offer optional coverage for homeopathy, but most patients pay out of pocket. Homeopathy is not taught in any US medical schools, although it is often included in courses on CAM and it is taught in naturopathic schools. Most practitioners study homeopathy in postgraduate courses run by private institutions.

Homeopathic Research

I also conduct clinical research in homeopathy at UW where I am an assistant professor in Epidemiology and have published several homeopathic studies in conventional medical journals. There is a growing body of double-blind placebo controlled trials which suggest that homeopathy may be effective for a variety of clinical disorders. (Reilly, 1986, Fisher 1989, Ferley 1989, Kleijnen 1991, Jacobs 1994, 2000, Reilly 1994, Weiser 1998, Chapman 1999, Taylor 2000, Jacobs 2000) A recent meta-analysis of 89 blinded placebo-controlled homeopathic clinical trials found a combined odds ratio of 2.45 in favor of homeopathy when compared to placebo (95% CI 2.05 to 2.93). (Linde, 1997) The mechanism of action of homeopathy is not well understood, but

Expanded remarks to the testimony give to the White House Commission on
Complementary and Alternative Medicine, October 31, 2000, Seattle, WA

Jennifer Jacobs, MD, MPH

Clinical Assistant Professor, Department of Epidemiology, University of Washington
President, American Institute of Homeopathy

Introduction

I am a conventionally trained family physician who has been using homeopathy in my practice for nearly 25 years. I became interested in homeopathy after becoming disillusioned with the side effects of many of the conventional medicines I was using in my family practice residency. I have seen many patients helped by this practice, without the high cost and dangerous side effects of conventional medications, which were recently found to be the fourth leading cause of death in the US. (Lazarou, 1998)

The government has created commissions such as yours and centers such as NCCAM largely because of the huge public demand for alternatives to conventional medical care. Studies have shown that nearly half the US population uses alternative modalities. (Eisenberg, 1998) Why is the public seeking alternative medicine? The simple reason is that they know that they are not getting better with conventional medical care. I believe that the best way for homeopathy and other CAM modalities to be integrated into the health care system is to train physicians like myself and other health care professionals to use it in their medical practices.

Integration of CAM

I strongly disagree with other speakers who have suggested that the best way to integrate CAM into the health care system is to have alternative providers and conventional ones practicing side by side. The internist would refer a patient to the massage therapist or the acupuncturist for back pain, while continuing to manage the hypertension or arthritis with conventional treatments. Conventional medicine would remain the primary form of care, with CAM on the side for special situations- a dessert or side dish, if you will, to the main course of modern conventional medicine. This way of thinking appears to me very short sighted and contrary to the idea professed by many CAM practitioners- that of treating the whole person.

In order to integrate homeopathy and other CAM practices into the health care system in a meaningful way, it is essential that medically trained practitioners learn how to integrate it within their own individual medical practices. In this way patients can receive the best of both worlds- medically knowledgeable providers using alternative practices such as homeopathy or acupuncture to enhance their overall health.

Homeopathic principles

Homeopathy is a two hundred year-old system of medicine based on the principle of similars, which posits that a substance that can cause symptoms in a healthy person can cure similar symptoms in someone who is sick. Homeopathic treatment is individualized to each person, matching the specific signs and symptoms in that patient with those known to be associated with a particular homeopathic medicine. Individualized homeopathic treatment is thought to improve the mental, emotional, and physical levels

Kingsbury, Doris (NCCAM)

From: Jachinnock@aol.com
Sent: Sunday, November 19, 2000 1:59 PM
To: Whccamp (NCCAM)
Subject: WHC Testimony

Dear White House Commission,
Enclosed is my testimony from the Seattle Town Hall Meeting. Thank you very much.
Regards,
Julie Anne Chinnock

Good afternoon, my name is Julie Chinnock and I am currently a third year student in the Naturopathic Medicine Program at Bastyr University. I want to thank you for coming to Seattle and for this opportunity to provide you with this perspective and information.

The reason why I am here is to tell you that once I graduate as a fully trained Naturopathic primary care physician, it is my goal to practice in a healthcare shortage area. I am also speaking for up to 60% of my classmates. Currently, this option is not even minutely financially feasible to us in any other state but Washington. Under the Washington state Health Professional Loan Repayment and Scholarship Program, primary care health professionals, including naturopathic physicians, licensed midwives, and pharmacist doctors, are not only eligible, but encouraged, to work in those areas where there are health care service gaps.

But even then, there are limitations here when it comes to funding CAM providers. Speaking solely of Washington state, there are community public and private clinics that have expressed interest in hosting CAM providers for this program, yet lack of federal CAM health care reimbursement such as Medicare and Medicaid make it impossible for them to fund a salary for a CAM provider.

With the funding and reimbursement as it currently is, there is little chance we can practically serve in underserved areas without working for free and/or the risk of default on our student loans. So how is it possible for willing CAM providers to work in those areas which need health care the most?

#1 Funding

Through federal funding in all states, rural and underserved clinics should have the option for integration with licensed CAM providers, including acupuncturists, naturopathic physicians, and midwives. This includes grants and scholarships, subsidies for salaries, student loan reimbursement,

and
patient CAM health care coverage through existing federal and state
health
coverage programs. Fund training for clinics, rural hospitals, migrant
health
boards on CAM and CM emerging professions.

#2 Legislation

Changes should be made in federal legislation to include licensed
CAM
providers in all programs that currently cover and fund other primary
care
providers.

#3 Outreach and Integration

Once rural and underserved clinics are eligible and able to
participate
in these loan reimbursement programs, widespread outreach is necessary
to
inform them of current successful integration clinics (some of which
have
been referred to) and dissemination of valid information on CAM
providers to
staunch the myths which may be out there which currently discriminate
against
our abilities and professions.

Funding is suggested for collaborative training and experience at
the
student level. There are ongoing collaborations, but more support and
funding are needed for things such as a demo project between Bastyr
University and the University of Washington Medical School. Students
learning
together will increase their abilities to work together. Resources can
support organizations like SPARx and Physicians for Social
Responsibility
(Bastyr Chapter), as well as AHEC. Currently Bastyr students are
involved and
collaborating with each of these organizations in the interest of
providing
healthcare to rural and underserved communities.

There is a current and emerging qualified workforce of CAM providers
who
are in demand and lined up to work in those parts of our country that
are
lacking in healthcare coverage the most. With assistance from the
federal
government, assistance that is already granted to a portion of primary
care
physicians, we will be able to afford to provide this care, pay back our
educational debt, and Americans from all income levels will better
receive
the healthcare they want and need.

Kingsbury, Doris (NCCAM)

From: Williams, Autumn [Autumn_Williams@sba.com]
Sent: Thursday, November 16, 2000 12:23 PM
To: Kingsbury, Doris (NCCAM)
Subject: RE: Updating the registration website

Doris -

I do not find Greg Nickels in the database. Do you know if he pre-registered or registered on-site? I will keep looking, but if you can give me any ideas where to look that would help. Here are the other addresses:

Kent Pullen
516 3rd Avenue
Room 1200
Seattle WA 98104

Joseph Pizzorno
Expert Health Systems
4220 NE 135th
Seattle WA 98125

Maggie Fimia
516 3rd Avenue
Room 1200
Seattle WA 98104

Hope these help,

Autumn

-----Original Message-----

From: Kingsbury, Doris (NCCAM) [mailto:kingsbud@od31em1.od.nih.gov]
Sent: Thursday, November 16, 2000 10:55 AM
To: 'Williams, Autumn'
Subject: RE: Updating the registration website

Hi Autum can I get the addresses for these people:

Kent Pullen, Greg Nickels, Joe Pizzorno, Maggie Fimia.

They were registered for the Seattle meeting, I have to send letters to them today.

-----Original Message-----

From: Williams, Autumn [mailto:Autumn_Williams@sba.com]
Sent: Thursday, November 16, 2000 11:21 AM
To: Chang, Michele (NCCAM)
Cc: Kingsbury, Doris (NCCAM); Wiesenfeld, Susan
Subject: RE: Updating the registration website

Michele -

I have forwarded these (DC) revisions to our programmer.

Regarding the electroic file of participants with email address:

- 1) What format would you like? Excel or ascii would probably be the easiest to import, but if you prefer something else just let me know.
- 2) Do you want this file just for Seattle or for each future meeting?
- 3) Is this file in place of one of the other reports or in addition to?

Hope all is well with you,

Autumn

-----Original Message-----

From: Chang, Michele (NCCAM) [mailto:changm@mail.nih.gov]
Sent: Thursday, November 16, 2000 9:53 AM
To: Autumn Williams (E-mail); Susie Wiesenfeld (E-mail)
Cc: Kingsbury, Doris (NCCAM)
Subject: Updating the registration website

Could you kindly update the registration website as follows:

Remove Seattle registration site

Amend Washington site:

Dec 5 8:00 am -- 4:00 (not 8:30 a.m.)

Delete choice of either Dec 4 OR 5 for public comment: for this meeting it

is available ONLY on Dec 4

Revise text to delete "each day."

" Please note that the public comments session is scheduled for approximately 1:30pm-2:30pm [each day].

There is a time limit of 5 minutes for all oral comments - 3 minutes of testimony & 2 minutes of questions from commissioners."

DO NOT put up January site yet.

Thanks!

Also: We have decided not to send hardcopy thank you notes to participants, rather we will send an electronic thank you note. Therefore, can you provide me with an electronic report of each registered participant (alpha order) with their email address listed?

If Doris hasn't asked you, she does need full addresses for: Maggie Fimia, Kent Pullen, Greg Nickels, Joe Pizzorno.

Thanks.

Michele M. Chang, CMT, MPH
Executive Secretary
White House Commission on
Complementary and Alternative Medicine Policy
tel: 301-435-7592
fax: 301-480-1691

DEAR [Maggie Fimia, Kent Pullen, Joe Pizzorno, Pam Snider, Tom Shepherd, Shiela Quinn, Tom Trompeter, Lori Beilinski, Deborah Senn]

We would like to extend a special thank you for your tremendous assistance in making the White House Commission Town Hall Meeting in Seattle on October 30-31, 2000 such a success. The level of activity related to Complementary and Alternative Medicine (CAM) systems and interventions in the Northwest region of the country made the Seattle Town Hall meeting a pivotal event in the Commission's activities.

We were deeply gratified by the overwhelming number of participants and the quality of all the presentations. While this was not surprising based on the leadership of your region in CAM, we do appreciate the thought and effort that was clearly evident by how thoroughly all of the issues defined by the Commission were covered over the two days of hearings. We also greatly appreciated the hospitality and generosity of the King County Integrated Health Care 2010 Steering Committee. The reception and site visits were certainly among the highlights of our visit.

Please extend our grateful appreciation to your staff members, especially those who made such an effort to take care of the "small details." They provided an invaluable service by making our visit so pleasant and by supporting our staff on-site.

We will continue to solicit information from consumers, practitioners, researchers and others interested in the use of CAM in this country. We hope that you will remain in close contact with us, continuing to provide us with specific suggestions and participating in future activities. Your comments and suggestions are welcome throughout our process; please send them to us through our website, or e-mail them directly to us at whccamp@mail.nih.gov.

Thank you again for your hospitality and participation in our meeting to educate and inform the Commission of the diverse and multi-faceted issues involved in CAM services. We look forward to continued discussions on these important public health issues.

Signed by Steve and Michele

Kingsbury, Doris (NCCAM)

From: Libby Hogen [lhogen@crnusa.org]
Sent: Thursday, November 16, 2000 4:23 PM
To: Whccamp (NCCAM)
Subject: Copy of testimony for Coordinating CAM Research meeting



Statement, Oct
2000.doc

Dear Ms. Michele Chang:

Here is a copy of Dr. Annette Dickinson's testimony given at the CAM Research meeting on October 5 - 6, 2000.

If you need anything else please do not hesitate to contact me.

Thank you.

<<Statement, Oct 2000.doc>>

Libby Hogen
lhogen@crnusa.org
Council for Responsible Nutrition
1875 Eye Street, NW, Suite 400
Washington, DC 20006
Direct: 202-263-1024
Main: 202-872-1488
Fax: 202-872-9594

How can private sector CAM research be better coordinated with federally supported CAM research?

- Industry representatives need to participate on advisory councils, particularly at NIH. A visible representative can address the concerns of clinicians and government officials and serve as a bridge between the public and private sectors.
- A primer on funding mechanisms (for research and conferences) within government agencies that apply to industry should be compiled, to explain Cooperative Research and Development Agreements (CRADAs), small business grants, investigator-initiated (R01) grants, and contracts.
- Ongoing research and potential funding opportunities need to be more visible and private studies need to be added to government databases. For example, CRISP is an excellent tool to seek out information on federally funded studies. However, it needs to be updated more expeditiously and expanded to include clinical trials that are not federally funded. The ODS CARDS database will target dietary supplement research. The project should receive sufficient funding to include nongovernment funded research and be updated weekly. NCCAM serves as good model for its open visible process in determining future research projects. Concept ideas are discussed at its advisory council meetings, approved concepts are posted on the website and within a few months a request for applications (RFA) is issued and also posted on the website. A document explaining how each research agency determines its research agenda would be helpful.
- Consensus conferences should be held to highlight CAM therapies and remaining research gaps. For example, a conference on the safety and value of ephedra for weight loss could make a valuable contribution in this area of controversy. A conference on St. John's wort should be held after completion of the NCCAM-NIMH funded study centered at Duke University.

How can the private sector stimulate CAM research?

- Industry should be encouraged to submit its studies to peer-reviewed journals for publication.
- Industry should provide data from its unpublished studies to assist in selection of therapies for further study and contribute to the study design. For example, these data may help to narrow dosage range for phase I studies and alert investigators to potential side effects.
- Industry could provide vitamins, minerals, botanicals or other dietary supplement ingredients for clinical studies and assist in the formulation of appropriate placebos.
- Industry could co-sponsor symposia or conferences to provide networking opportunities between researchers and clinicians. CRN is currently planning one such conference for November 2001, in cooperation with the American Society for Pharmacognosy.

What are the obstacles/barriers and possible solutions to accomplish this goal, e.g., incentives?

- Convene meetings with journal editorial boards to solicit recommendations to increase acceptance of papers submitted by industry.
- Generate a clinical trials guidance document outlining the standard components and proper design of study protocols. CRN's Dr. John Cardellina is currently working on this type of document, and will be seeking partners to contribute to its content and enhance its value. Resources that will be used in preparing the guidance document include existing NIH guidelines and information being compiled by the International Conference on Harmonization (ICH).
- A mechanism is needed for industry to share study results that may involve proprietary information. The (soon to be launched) ODS CARDS database might serve as a repository for a listing of unpublished studies, identifying the lead investigator or contact person.
- Standardized products that are commercially available should be used in clinical trials, when possible. If special formulations are used that the consumer cannot buy off the shelf, then the study results don't translate directly to the general population.
- Industry needs to form partnerships with clinicians or academia (depending on the type of study). Various mechanisms are needed to bring together these disparate communities. CRN is in the process of establishing a Dietary Supplement Information Center, in cooperation with a major academic institution, and this Center could play a role. Also, a special website could be established to facilitate communications regarding ongoing research needs and opportunities.

**PRIVATE SECTOR ROLE IN STIMULATING RESEARCH
ON COMPLEMENTARY AND ALTERNATIVE MEDICINE:
PERSPECTIVES FROM THE DIETARY SUPPLEMENT INDUSTRY**

**Statement of Annette Dickinson, Ph.D.
Vice President, Scientific and Regulatory Affairs
Council for Responsible Nutrition
before the
White House Commission
on Complementary and Alternative Medicine Policy
October 5-6, 2000**

The Council for Responsible Nutrition (CRN) is a trade association representing more than 110 companies in the dietary supplement industry. Our membership includes companies that supply the bulk ingredients used in dietary supplements as well as the national brands and store brands of finished products available to consumers through all types of retail outlets including supermarkets, drug stores, discount chains, health food stores, direct sales, mail order, and the internet. Our member companies provide all types of dietary supplements defined in the Dietary Supplement Health and Education Act, including vitamins, minerals, amino acids, botanical products, and specialty supplements.

CRN was established in 1973 and prides itself on developing policies and programs for dietary supplements based on sound science. CRN's science staff currently includes four individuals with expertise in nutrition, toxicology, natural products chemistry, and genetics. We are in the process of creating a new executive position charged with the specific responsibility to identify opportunities for research partnerships with government and academia, and to help industry members take advantage of such opportunities to maximize their own contributions to the body of current scientific evidence. As part of this effort, we will also seek to be actively involved in the development of agency research agendas and the establishment of priorities based on optimizing impacts on public health. Dr. Cathy Fomous of our staff will be taking on these responsibilities.

We are pleased to be able to offer some suggestions on the role of the private sector in stimulating research into complementary and alternative medicine, from the perspective of the dietary supplement industry. Our responses will be tied to the specific questions posed in the letter of invitation to participate in this forum.

ADDENDUM TO WHCCAMP TESTIMONY

Charles A. Simpson, DC, DABCO
Chief Medical Officer
Complementary HealthCare Plans, Inc.
5319 SW Westgate Drive, Suite 130
Portland, OR 97221-2430

503-203-8333 ext 115
csimpson@chpnetworks.com

THE COST OF CAM: Add-on versus replacement?

THE PROBLEM

Inherent in the discussion of more complete integration of CAM into the mainstream of health care delivery is its potential impact on cost. Cost is certainly a determinant for business decision-makers in health plans and among purchasers. Cost should be a concern for public policy makers as well.

The fear expressed by many is that integrating CAM will drive costs up by adding services to the health care mix. Others argue that CAM services will actually lower the cost of health care by replacing more expensive medical technologies with less invasive and less expensive interventions from CAM practices.

Recent experience with integrating chiropractic into the US military highlights the difficulty in determining the add-on versus replacement (AVOR) cost of an alternative modality. Two separate analyses of a Department of Defense chiropractic pilot project arrived at opposite conclusions about AOVOR for chiropractic. One estimated significant cost increases (despite improved outcomes) while the other projected a net annual savings of \$25 million. Congress ultimately passed the F. Y. 2000 Defense Authorization Act (H. R. 4205) that includes a mandate for direct access to chiropractic physicians for all active-duty military personnel.

CAM advocates routinely cite anecdotes of patients saved from expensive medical procedures by CAM interventions. However, methodologically sound, population-based studies are lacking. Developing a reliable methodology is the focus of a research partnership between Complementary Healthcare Plans, Inc. (CHP) and the Kaiser Center for Health Research (CHR) in Portland, OR. This work is analyzing data retrieved from the management information systems (MIS) maintained by CHP and Kaiser-Permanente for clinical and administrative management purposes. CHP now has over 5-years' experience managing a direct-access chiropractic rider benefit in an HMO environment.

The current research efforts are aimed at this data field. CHP also manages naturopathic medicine, acupuncture/oriental medicine, and massage therapy. As significant data accumulate from these disciplines, economic evaluations of all these therapies will become feasible.

THE METHODOLOGY

Reliable and generalizable economic evaluations of CAM therapies are needed to help health insurers, purchasers, and public policymakers decide how to allocate resources. Currently available economic evaluations of chiropractic vary widely in structure and quality. No evaluations conform to national recommendations for cost-effectiveness analysis; studies that do refer to the “cost-effectiveness” of chiropractic have not estimated an incremental cost-effectiveness ratio of one intervention to another. Analyses of other CAM therapies and interventions are similarly unreliable, anecdotal, or non-existent.

Cost-effectiveness analyses that are generalizable across interventions and conditions require a common metric for health benefits such as quality-adjusted life years (QALYS), which simultaneously capture morbidity and mortality benefits of the subject intervention. Since most benefits of CAM, including chiropractic, are likely to improve the quality of life rather than extend life, appropriate quality adjustments are crucial to informative, unbiased, and reliable economic evaluations of these therapies. However, current methods of producing health state “utilities” for use in economic evaluation such as standard gamble, time trade-off, or visual analog scales usually focus only on direct health outcomes such as reduced pain or improved function. This may not matter much for evaluating interventions with significant direct health effects such as life-extending surgery. Interventions such as chiropractic, however, are not usually expected to produce greatly different direct health outcomes from their comparators. Yet, there is considerable non-economic literature that suggests that patients may prefer chiropractic or other forms of CAM to conventional care (or one form of CAM to another) based on characteristics of the process of care. These may involve attributes such as satisfaction, congruence with personal belief systems about health and well-being, an increased sense of autonomy, greater reassurance about their condition, or simply a sense of being listened to. If these attributes of care are considered to influence health in a positive way as some researchers suggest, it may be appropriate for the health care system to support their production. In any case, it is important to understand what benefits patients receive from CAM, and to incorporate them in economic evaluations of these therapies to the extent this can be done in a systematic and rigorous way.

Recognition of these sources of “process utility” has stimulated research into alternative survey methods of measuring health benefits of treatment such as willingness to pay (WTP) and conjoint analysis (CA). In CA, respondents are presented with hypothetical scenarios, preferences over which are elicited using ranking, rating, or discrete choice exercises. Regression analysis is then rigorously applied to the responses. The CA framework is conceptually flexible enough to establish the relative importance of different attributes in the provision of a good or service, to estimate marginal rates of substitution between different attributes, and to estimate the WTP for a particular attribute of care when cost itself is included in the analysis as an attribute. Perhaps of greatest relevance to economic evaluations of CAM, study results can also be used to generate “utility” estimates that are in theory, 1) applicable to cost-effectiveness analyses of CAM interventions, and 2) sensitive to important process attributes of CAM (as well

as conventional therapy). Although applied only recently to analysis of issues in the U.S. health care system, CA has been used for many years in market research as well as environmental and transport economics.

The specific aims of the proposed pilot study are to:

1. Evaluate the feasibility of implementing a conjoint analysis of low back pain treatment within a population of HMO patients who are between 21 and 70, diagnosed with low back pain, and who have used either chiropractic or conventional treatment. In this pilot study, we will focus on assessments of validity and reliability, including respondent burden and internal consistency.
2. Produce preliminary data on 1) the identification of relevant process attributes of low back pain treatment among an HMO-based population of low back pain patients, and 2) the magnitudes of their relative importance.
3. Produce preliminary estimates of both health state utilities of, and WTP for, the treatment of low back pain that incorporate both attributes of the process of care and its direct health outcomes. These estimates would inform the future development of more reliable and valid utility and WTP estimates for eventual use in formal economic evaluations of CAM and conventional therapies.

In theory, CA can be applied to the vast majority of CAM therapies and interventions where the treatment plans are individual-specific. Cost-effectiveness studies of conventional medicine are usually dependent on comparing a new procedure (such as a drug) with a “gold standard” mode of care. This reductionist approach is well suited to conventional therapies, but fails to account for much (if not most) of what goes on between a CAM practitioner and the CAM patient. CA may be a method of developing the metrics of benefit measurement that can in turn be used to compare CAM on an “apples-to-apples” basis with other therapies.

THE PARTNERSHIP

The Northwest Region of Kaiser Permanente (KPNW) contracts with Complementary Healthcare Plans, Inc. (CHP) to provide chiropractic services for its members. This relationship offers a unique opportunity to explore the feasibility of CA as a method of assessing the benefits of chiropractic and conventional treatment of low back pain within an HMO population, and in a systematic way that is conceptually suitable for use in formal economic evaluations. As the KPNW relationship with CHP matures and other CAM disciplines are added to KPNW, opportunities to look at other CAM interventions and therapies will arise.

This current study will use CA to elicit preferences of a sample of KPNW patients for chiropractic visits that vary by attributes of process and health outcomes. It will generate important initial data that inform the development of utility instruments that are sensitive to both process and outcome. We expect that lessons from this study will readily generalize to future economic evaluations of other CAM (and conventional) therapies and interventions, especially those conducted in the managed care context.

To: White House Commission on Complementary and Alternative
Medicine Policy

From: Cindy Breed ND

Re: Written Testimony from the Seattle Town Hall Meeting

I am a naturopathic doctor practicing in the integrated setting of the King County Natural Medicine Clinic at the Kent Community Health Center.

In this setting, I along with the other CAM disciplines of acupuncture and massage practice side by side with conventional medical providers providing health care services to the medically underserved. Earlier in the day you heard from Tom Trumpeter and Dr. Judy Featherstone about this clinic

This integrated care setting gives us the opportunity to improve the quality of care that we offer to the patients that we serve, and the chance to broaden our knowledge of medicine by learning from each other.

Our clinic works because we were able to incorporate CAM providers into an already existing Community Health Center. Initially this idea brought many challenges including acceptance by the existing conventional medicine providers, and how to make the services available to the people that we serve.

Because we have licensing laws in Washington State for CAM providers, we were able to address concerns about standards of training and scope of practice.

Through daily contact and cooperation as well as regular meetings we continue to build growing knowledge and trust among providers.

Making natural medicine services available to our managed care patients and the sliding fee scale offered to those without insurance make the services accessible. For our patients with Medicare and fee for service Medicaid which does not cover natural medicine services, we offer the sliding fee scale. This lack of coverage does limit access for some.

Providing natural medicines like herbs and nutritional supplements to patients on a sliding fee basis is another important piece to providing access.

In order to further expand integrated care settings, I believe attention must be focussed on these areas.

First-non-discrimination in all government health programs for CAM provider participation and reimbursement.

- Many clinics have shown an enthusiastic interest in providing similar services in their communities.
- The major stumbling blocks seem to be:
 - Lack of credentialing standards for CAM providers in some states.
 - Lack of licensing laws for CAM providers.
 - Lack of access to medicare and medicaid reimbursement for services.

To further expand integrated care settings I recommend attention to:

- Licensing laws in all states.
- Credentialing standards consistent with the best available in each profession or discipline.
- Access to Medicare and Medicaid reimbursement.
- Access to all government health programs including student loan repayment programs.
- Integration of other Community Health Centers.

- Replicating models of already existing integrated clinics like the Kent Community Health Center and the other clinics that you will hear about soon.

Research Institute
14500 Juanita Drive N.E.
Kenmore, Washington 98028-4966
(425) 602-3165
FAX (425) 602-3079
<http://www.bastyr.edu>

White House Commission on CAM Policy

Seattle WHC Remarks: Monday October 30, 2000

Leanna J. Standish, ND, PhD, LAc

Director of Research, Bastyr University

Welcome to Seattle. Today you will learn about some of the progressive strides forward that Washington State, and King County in particular, have made in establishing CAM research programs, CAM academic training, and CAM clinical programs. You will hear about the progressive Washington State insurance laws that mandate third party coverage of services provided by licensed CAM providers. You will see first hand the value of including NDs as primary care physicians. You will hear about the integrated health care programs for which King County is now famous:

- The King County Natural Health Clinic –the first publicly funded integrated primary care clinic in the U.S.
- Evergreen Hospital's integrated medicine clinic
- The integrated Seattle Cancer Treatment and Wellness Center where MDs and NDs work together to care for cancer patients.
- Bastyr's HIV/AIDS Integrated Care Clinic
- The HIV/AIDS Madison Clinic at Harborview Hospital.
- The Seattle Healing Arts primary care clinic where CAM and conventional professionals provide integrated care.
- The Dean Ornish program at Swedish Hospital for the treatment of cardiovascular disease.
- The collaboration between CAM professionals and Regional public health initiatives such as the Building Bridges program.

All of these progressive clinical programs are excellent opportunities for research: practice-based outcomes research, clinical epidemiology research, and even RCTS. You will hear about the rich databases created by Washington State medical insurance companies and HMOs, as well as state tumor registries, that provide a rich source of data that allows us to investigate not only the demographics of CAM use but also health outcomes associated with their use.

When I last spoke before you in Washington, DC I said that there are three obstacles to CAM research. I want to state them again.

1. Lack of appropriate, efficient FDA policies and procedures for CAM therapies.
2. Lack of understanding and sensitivity to CAM concepts among IRBs at non-CAM institutions that are making go, no-go decisions about clinical studies in CAM.
3. Lack of research infrastructure and training at CAM institutions that have true CAM expertise.

It is this last problem that is the most challenging to solve. Between 1992 and 1999 only seven CAM institutions received funding from OAM or NCCAM compared to 76 conventional universities. This means that only 9% of CAM research grants have gone to CAM researchers who teach and do research at clinics and colleges that specialize in CAM and have for decades, not just this year because now there are dollars for research at the NIH in what is a new area for many applicants.

The reasons for this discrepancy include the fact that many CAM academic and clinical centers do not have the research expertise and infrastructure to produce high quality NIH grants. Faculty at CAM institutions have little time for research. They are overloaded with teaching responsibilities because most CAM academic centers are dependent on tuition for their revenue.

There is a potential serious risk of CAM experts not being actively involved in researching their own field. The risk is the potential and likely loss of the best ideas, the most significant concepts, and most important CAM therapies. If we are not careful as we move towards mainstreaming and integration we may lose the very best of the fringe ideas. The price of mainstreaming may be high: commodification, and dilution of the whole systems CAM practice, and a new green pharmacy that does little to improve either health care or change the basic assumptions of science or medicine.

NCCAM's exciting current funding initiative on Frontier Medicine is a laudable attempt to prevent this potential loss. However, we need to do more to support CAM scientists and clinicians that have developed and are using effective therapies in order to bring these therapies into the light of science. If we continue to put most of our research dollars into the conventional universities we may end up with a bland science that misses the most important challenges to the basic tenets of the biological sciences. If even a few of the claims made by some fields of CAM are correct it will change our very basic concepts about what biological systems are and how they work. Some of the most exciting work in CAM cancer treatment, for example, is not being discussed by the NIH or evaluated by grants funded by the NIH. The best CAM cancer clinicians have not been at the table. Some don't even know that there may be a place at the table for them.

A potential solution is to request NCCAM to develop funding mechanisms for planning grants to CAM academic centers to develop their own research agendas and clinical trial consortiums. The best research programs are likely to come from minds trained in natural, holistic medicine and CAM. We need each of the main CAM medical communities to develop their own research programs. The chiropractic community has already made strides forward in this area. We need all the CAM professional communities to do the same; Chinese medicine, naturopathic medicine, massage therapists, homeopaths, the bioelectromagnetic research community, the CAM cancer treatment community, to name just a few. Who better knows what the most important research questions are than those who have true expertise in CAM?

CAM institutions need a funding mechanism to help them develop research infrastructure. They need labs, equipment, training in research and grantsmanship for their faculty and clinicians, funds for release time from heavy teaching loads, small grants to help them collect pilot data without which they don't stand a chance of getting an NIH grant. Maybe we really do need an affirmative action plan for CAM institutions. If we don't provide this kind of leg up, a leveling of the playing field, we risk losing the very best ideas and concepts in alternative medicine.

At the conference on science and spirituality sponsored by the Institute of Noetic Sciences, Duke University and the Rockefeller Family Foundation that just ended yesterday one clear conclusion emerged. Small pilot clinical studies, with small samples, even when placebo controlled and randomized are statistically likely to generate negative data. Power of small studies is low. NCCAM's R21 as well as the Frontier Medicine program focuses on small exploratory studies with caps on funding for each study that almost by definition are under powered. We may risk missing small or even moderate effects of CAM therapies by this strategy. Some of the most interesting CAM therapies deal with subtle phenomena that require well-powered studies to detect. By capping funding levels for exploratory studies in CAM we may have inadvertently generated a whole research endeavor biased towards Type II error.

I would like to make a number of specific recommendations to this Commission.

1. In order to increase sample size and power of exploratory CAM clinical studies NCCAM R21 exploratory research grants that now fund most CAM research *not* have a \$125,000 per year cap. Remove the cap and ask PIs to develop budgets based on the scientific needs of the research question.
2. I recommend that NCCAM fund planning grants to CAM academic centers in order to develop research agendas, clinical trials consortiums, and strategic plans for implementation. CAM research should be designed and executed by CAM experts with the help of experts from the conventional medicine community. Thus far the emphasis has been placed in the other direction (research designed and executed by conventional universities with CAM consultation) and because of this bias we risk losing the best science.
3. Please request of NCCAM that an RFA specifically for CAM institutions to help them develop research infrastructure and a cadre of CAM experts who are also trained in research methods.
4. We should request the FDA to establish a CAM task force to develop policies and procedures for investigational use of CAM therapies, including homeopathic and ultrahigh dilutional biologics and pharmacologies.
5. Allocate funds and authority to NCCAM or other appropriate federal regulatory agencies to provide education to IRBs at conventional medical schools regarding CAM concepts and principles of practice so that they can provide more informed ethical oversight of CAM clinical research.
6. Request a federally funded RFP process to fund research on insurance company CAM databases that tell us about demographic and patterns of use, but more importantly the health outcomes associated with that use. We must have an answer to the question of whether CAM use has additive or substitutive costs to

the U.S. health care system and whether the inclusion of CAM provider coverage has had a positive, negative or neutral effect on public health.

7. Request the NCI to provide funding to CAM cancer clinicians to do the difficult administrative and clinical work of producing a Best Case Series.
8. Fund programs to support prospective practice-based outcomes research using a case series and wait-list control method. In 18 months we at Bastyr hope to have results from our new initiative in the area of Hepatitis C. Our new hepatitis C clinic will provide comprehensive science-based natural medical treatment at the same time that we collect data for a prospective case series study. This is a collaborative research effort with hepatologists at the University of Washington. If this model succeeds it will provide an example of how to provide expert CAM treatment that is largely covered by third party payers at the same time that we collect data on outcomes.

—

#54

—

White House Commission on Complementary and Alternative Medicine
Testimony
October 30, 2000
Seattle, Washington

Presented by
Leah Kliger
Director, Integrative Medicine, Evergreen Healthcare,
Kirkland, Washington

425 899 2644 LKliger@echc.org

- Good afternoon, my name is Leah Kliger, Director of Integrative Medicine at Evergreen Hospital and Healthcare in Kirkland, Washington. I want to talk with you today about how you, through educational grants and economic incentives, can provide access to education and training at the local, community levels. This can help our health care system our physicians and nurses, and other community hospitals, forge better alignment between the majority of our medical staff who are not vocal supporters of CAM integration and hundreds of local CAM practitioners. We need new and different language that encourages participation, not words and actions that raise hackles. We need to help our physicians and nurses regain their sense of themselves as healers, not only disease managers, so they can better communicate across the entire health care spectrum.

In 1997 we discovered that 69% of our physicians felt they did not have the knowledge to communicate and confidently talk with their patients about alternative medicine, nor to appropriately refer patients to CAM practitioners. 88% of our physicians indicated they desired information and access to credible scientifically based information. Based on these needs, Evergreen has an integrative medicine task force, publishes an alternative medicine newsletter and has underwritten a variety of continuing medical education sessions, case conferences, and workshops for care givers and the entire community.

Just two weeks ago on a Friday morning some 40 physicians on our medical staff participated in a workshop led by Dr. Rachel Remen—But it is rare that our physicians and nurses can take time to attend educational sessions since it means giving up both patient care and the income that goes along with running an office or a nursing unit. Typically they can only grab a few hours a year—not nearly enough to change practice patterns nor be the competent guide to CAM services that our patients ask them to be.

Through education, we want to:

- Make it easy for physicians, nurses and other clinicians to have access to reliable and credible sources of scientific data.

- Develop financially self-sufficient models for initiating clinical and educational programs and services.

We need your Help:

1. Make a combination of educational grants, tax credits, and vouchers available to community hospitals, to our medical staff, and to local CAM practitioners. These would pay not only for continuing education sessions and workshops but would also provide economic incentives to the physicians, nurses, and community CAM providers who attend them. For example, we want to develop two way training programs whereby conventionally trained doctors, nurses and CAM practitioners teach each other about specific conditions and approaches and learn new language and philosophy. In a time of scarce resources, we currently have no monetary incentives to offer busy professionals develop curriculum, teach, or even to attend. However, grants, tax credits to physicians and CAM practitioners in private practice, and other incentives would make it financially feasible for learning to occur.
2. We ask you to fully fund CAM research studies that make it easy for community hospitals and physicians to participate. For example, our pediatricians have indicated an interest in participating in CAM research studies about pediatric asthma.. Community hospitals and physicians

have patients—at the local community hospital level, but we don't have the money or resources that make it viable for us to participate in a meaningful way.

3. Develop a no cost or low cost way to have simple, electronic links to credible CAM sites that can be easily linked to physician and hospital websites.
4. Quickly establish an evidenced based national formulary for botanical medicines.

On behalf of our entire community, 650 physicians, our board, our community advisors, our nurses and other caregivers, I want to thank you for traveling to the Puget Sound area and carefully listening to our needs. We want our physicians, nurses and care givers to be better able to talk with their patients about CAM, to make appropriate referrals to CAM practitioners, to have more knowledge, and access to resources. I look forward to answering any questions, working with you, and advocating for changes to the current system.