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White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

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WHCCAM Commissioner Briefing Book (3), May 14-16, 2001 [3]

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TESTIMONY BEFORE THE WHITE HOUSE SUBCOMMITTEE ON THE DELIVERY OF RELIABLE AND USEFUL INFORMATION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE

Good afternoon. My name is Diane Cole, and I am an education coordinator at the University of Virginia Cancer Center. I address you on behalf of health care providers and educators who are mandated to educate patients and their families at cancer centers across the country.

What we know is that 50% or more of all cancer patients are using some form of complementary or alternative therapy; we are trying to address the quality of that information, for the protection of the patient. Our patients are very vulnerable to being taken advantage of by companies and products whose bottom line is profit instead of cure or quality of life. Many of them trust their health professionals to provide excellent medical care, but they want to do more for themselves that help them feel in control.

These patients are making decisions about and are spending thousands of dollars on some therapies and products that have very inconsistent data to support their benefit. When they search the web, there is no standard on which to judge the credibility of the websites. Many patients will not tell their physicians what CAM therapies they are using, and many physicians do not feel comfortable advising their patients about what CAM therapies to use, if any.

Members of our network hear patients express their frustration and confusion about what they should be doing in terms of CAM every day. In response to this, we have developed a Guide to CAM Resources which is not exhaustive, but it gives patients a start. This Guide is provided in your packet of information.

Our network offers the following observations for your consideration, based on our experience with this patient population:

- **Students preparing to be health care professionals, as well as those already in the field, should be educated on complementary and alternative medicine practices and interventions. A better understanding of CAM services by all health care professionals is the best way to eliminate barriers and make CAM services more accessible.**

- **An oversight department in Health and Human Resources must be at the forefront of consumer safety issues, responsible for the labeling of herbal "natural" products and supplements. Consumers should be able to read a label and make good decisions about possible side effects and/or food/drug interactions.**

- **Medicare and third party reimbursement should be available to include modalities such as massage, acupuncture, and visits with other certified practitioners. Research in this area could prove that there is a real potential for tremendous cost savings to the burden of the present health care delivery system.**

- **Lastly, more research is needed in complementary and alternative medicine modalities. Research should encompass case studies and clinical trials that include the study of the placebo effect.**

Thank you for the time dedicated to this important topic of Complementary and Alternative Medicine that now occupies a prominent position in the delivery of health care services to our cancer patients.

Summary
White House Commission on Complementary and Alternative Therapy
May 16, 2001, Public Testimony
Presentation by Diane Cole, M.P.H.

Who we are:

A group of patient educators at NCI Designated Cancer Centers throughout the country. Included in our group are MD's, social workers, psychologists, chaplains, nurses, and health educators.

Who we serve:

Cancer patients and members of our communities

Within our network, we serve the needs of cancer patients (pediatrics and adults) throughout the spectrum of care – this includes diagnosis, treatment, rehabilitation, and end-of-life care. Many of us also serve our communities at large, providing education and awareness to people regarding health, lifestyle, and the early diagnosis of cancer.

Description of the Need:

- Fifty percent or more of all cancer patients are using some form of complementary or alternative therapy.
- Many patients trust their physicians to provide excellent medical care, but they want to do more for themselves that help them feel in control.
- Patients are making decisions about and are spending thousands of dollars on some therapies and products that have very inconsistent data to support their benefit.
- When patients search the web, there is no standard on which to judge the credibility of the websites.
- Many patients will not tell their physicians what CAM therapies they are using, and many physicians do not feel comfortable advising their patients about what CAM therapies to use, if any.
- The cancer patient population is very vulnerable to being taken advantage of by companies and products whose bottom line is profit instead of cure or quality of life.
- Education needs to be provided to let them know the importance of rigorous evaluation, and clinical trials are essential to knowing a therapy's risk and benefit. Patients are frustrated with the time clinical trials take to prove benefit to the cancer patient.

What We Have Done:

- Provided assistance in the past 2 years in developing parts of Dr. Jim Gordon's conference "Comprehensive Cancer Care: Integrating Complementary and Integrative Medicine."
- Developed a Guide to CAM Resources that we distribute throughout our network (attached).
- One member has contributed to a comprehensive guide to complementary and alternative therapies that can be found at http://www.canctr.mc.duke.edu/pated/CAM.asp
- Compiled a list of CAM fact sheets that have been written by and are provided at institutions across the country.
- We are currently in the process of developing FAQ sheets on CAM therapy.

Our recommendations to the White House Commission on Complementary and Alternative Therapy:

- Better education for all students preparing to be health professionals. This includes incentives for medical schools and nursing schools to include CAM information in their curriculum.
- More opportunities in continuing education for health professionals currently in the field. Continue the annual CAM conference and provide other affordable opportunities for education.
- Establish a department that regulates the labeling of herbal "natural" products and supplements. This department should also provide education to the public regarding reading labels, side effects, and food and/or drug interactions. Labeling should accommodate those of low literacy.
- Pass legislation that can expand third party reimbursement to cover more CAM therapies with certified practitioners (massage, acupuncture, meditation, etc.)
- Regulate the gathering of natural products from our world's rainforests.
- Increase funding for research that includes clinical trials on all aspects of CAM, including the placebo effect, pain management, and end-of-life care. Provide avenues where this research is then communicated to all health professionals and the public.
- Create a "seal" (like the Better Business Bureau has done) to indicate a standard of information provided on websites. This could be one indication for the consumer of reliable information.
- Provide better information to the consumer on how to evaluate studies, practitioners, and new products.
- Encourage collaboration among health organizations, such as what is being done within the patient education network, to work together not only on research but also on public education. Encourage collaboration especially between the mainstream/allopathic world and the CAM world.

Complementary and Alternative Medicine
A Guide to Resources

Articles/Books

Alternative Medicine Handbook by Barrie Cassileth. NY, NY: W.W. Norton, 1998. 340 pages. Available from W.W. Norton and Company, Inc. 500 Fifth Avenue, New York, NY 10110. 212-354-5500, FAX: 212-869-0856.

This book describes 53 major alternative and complementary medicine practices. It does not recommend treatments, but instead provides information about their backgrounds, goals, benefits, and risks to help the reader make informed choices. It is divided into seven sections addressing different categories of alternative and complementary treatments. Each section contains several chapters, each of which include a brief introduction, a description of the alternative or complementary therapy, and information about the claims of practitioners, theories or beliefs upon which the therapy is based, available research, potential benefits, and where to find additional information. This book contains a list of complementary therapies for common ailments, a glossary, a list of professional degrees and titles, and an index.

An Introduction to Complementary and Alternative Therapies by Georgia Decker, Ed. Pittsburgh , Oncology Nursing Press, Inc., 1999.

This book is a good resource for nurses and other health care professionals. It is a concise overview of many complementary and alternative therapies including bioelectric, manual healing, biologic therapies, herbal medicine, diet and nutrition, and lifestyle changes. The reference list in each section leads the reader to more detailed resources. This book is well organized and user friendly.

Choices in Healing: Integrating the Best of Conventional and Complementary Approaches to Cancer by Michael Lerner. Cambridge, MA: MIT Press, 1994. 667p.

This book presents an overview of conventional and alternative medicine cancer treatments and a thorough discussion of the impact of a cancer diagnosis on the individual. Includes a glossary, a resource listing, and a list of professional training programs in spiritual and psychological approaches to cancer treatments.

Comprehensive Cancer Care: Integrating Alternative, Complementary, and Conventional Therapies by James S. Gordon and Sharon Curtin. MA, Perseus Publishing, 2000.

Based on the findings of the annual conference co-sponsored by the Center for Mind-Body Medicine and the National Cancer Institute, this book is a guide to the integration of conventional, complementary, and alternative medicines for cancer care.

The book includes:

- *Reports on the most accepted and researched complementary and alternative practices, including assessments of their efficacy, side effects, cost effectiveness, and how they can best be integrated with conventional care*
- *Empowering advice for patients with clear action steps for speaking to doctors and evaluative guidelines for researching available treatment approaches*

- *Critical discussion of cutting-edge interventions such as nutrition, Chinese medicine, herbal therapies, mind-body approaches, and energy medicine that have undergone clinical trials and those which are now beginning to be employed.*

The Complete German Commission E Monographs: Therapeutic Guide to Herbal Medicines edited by Mark Blumenthal. TX, American Botanical Council,1998.

This reference provides information on 380 Commission E Monographs, which are based on clinical trials, field studies, case collections, scientific literature, unpublished proprietary data, and other carefully, reviewed information.

Both approved and unapproved herbs, component characteristics, and herbal combinations are addressed. Each monograph specifies composition, uses, contraindications, side effects, interactions, dosages, administration, pharmacological actions, warnings, precautions, and more.

Full Catastrophe Living by Jon Kabat-Zin. NY, NY, Dell Publishing, 1990.

This book is meant to serve as a practical guide for those readers, well or ill, who seek to transcend their limitations and move toward greater levels of health and well being. A practical guide to mindfulness, meditation and healing, the book is based on 10 years of clinical experience with more than 4000 people who participated in an eight week course, "The Stress Reduction and Relaxation Program", offered at the University of Massachusetts Medical Center in Worcester, MA.

Fundamentals of Complementary and Alternative Medicine by M. Micozzi, NY, Churchill Livingstone, 1996. 303 p. Available from Churchill Livingstone, division of Harcourt Publishing. Subscriptions, Foots Cray Highstreet, Sidcup, Kent, 877-784-6463, 877-784-6464

This book contains information about specific complementary and alternative medical therapy systems and approaches. The book presents medical, health, and science students, and interested readers with the foundations, tools, and historical context to understand the many fields of alternative medicine. It features chapters written by contributors on homeopathy, osteopathy, naturopathy, Ayurveda, Chinese medicine, Cuaranderismo, Western herbalism, and other systems. The book presents the contemporary complementary and alternative medical approaches that come from observations within, around and beyond the current Western, biomedical paradigm. The forward features an article by C. Everett Koop, the former U.S. Surgeon General. The list of contributors includes their professional affiliations. The book contains photographs and illustrations and is available on CD-ROM.

Herbal Medicine: Expanded Commission E Monograph edited by Mark Blumenthal and Alicia Goldberg. TX, American Botanical Council, 2000.

The original compendium, The Complete German Commission E Monographs-Therapeutic Guide to Herbal Medicines, developed by the American Botanical Council, set the benchmark as the leading government sanctioned authority on herbs. Now Herbal Medicine Expanded Commission E Monographs, selects the top 100 plus herbs and expands the depth of content, adding an extensive overview and supporting references to the literature. Full color photographs introduce each of over 100 herbs. Updated and expanded information enhances the value of the core Commission E material for quick referral and everyday use, including, extensive overviews and references, expanded sections on chemistry, pharmacology, contraindications, side effects, drug interactions, dosage and references, as well as name cross-

reference, safety, quality, and proper use during pregnancy and lactation. Herbal Medicine provides in-depth information from the best clinical evidence and research to describe each herb's botany, history, composition, safety, and therapeutic use. It presents the quality and efficacy of specific herbal formulations, provides supporting references to the literature and discusses drug interactions, toxicity, and dosage and administration issues.

Herbs Against Cancer by Ralph Moss. Brooklyn, NY, Equinox Press Inc., 1998.

This book traces the history and controversies surrounding the use of herbs to treat cancer. It focuses on only herbs from the western tradition, as well as some from the Native American tradition. Essiac Tea is covered in detail with other herbs such as Mistletoe, Grapes, Escharotics and Hemlock covered to a lesser extent. A discussion of paclitaxel (Taxol) from the Yew tree is also included.

Living Beyond Limits by David Spiegel, M.D. A Fawcett Columbine Book published by Ballantine Books, 1993.

Based on 15 years of research, Stanford University psychiatrist Dr David Spiegel outlines his proven program to help all people with chronic illnesses enhance the quality of their lives. The book delves into the essential healing connection between body and mind. It deals with important issues like strengthening family relationships, facing a shattering diagnosis head-on, facing the fear of dying, building and sustaining networks of support and improving communication with doctors.

Minding the Body, Mending the Mind by Joan Borysenko. NY, Bantam Books 1988.

In this highly readable layman's book, Dr Borysenko, co-founder and former director of the Mind/Body Clinic, New England Deaconess Hospital, uses personal stories to teach the reader how to use mental and physical exercises to transform one's life. The book teaches the reader how to use the "Relaxation Response" to boost the immune system, overcome chronic pain and alleviate symptoms of a host of stress related illnesses.

PDR Family Guide to Natural Medicines and Healing Therapies edited by David W. Sifton. NY, Three Rivers Press, 1999.

This consumer's guide addresses health care alternatives from age-old secrets of harmony, balance, and well being to the very latest nutritional discoveries.
Topics covered include:

- *Which widely available herbs, vitamins, and minerals act like potent prescription medications*
- *How certain natural remedies interact with conventional drugs*
- *Self-help techniques*
- *How to locate and choose a qualified practitioner*

This guide also addresses the latest findings on Acupuncture and Acupressure,, Aromatherapy, Ayurvedic Medicine, Biofeedback, Biological Therapies, Chiropractic Adjustment, Detoxification, Energy Medicine, Environmental Medicine, Homeopathy, Hypnosis, Light Therapy, Massage, Meditation, Mind/Body Medicine, Naturopathic Medicine, Orthomolecular Medicine, Tai Chi, Qigong, and Yoga.

PDR for Herbal Medicine. NJ, Medical Economics Company, Five Paragon Drive, Montvale, 1999. Second Edition.

This book is easy to use with a comprehensive section on medicine identification information. It consists of an alphabetical scientific and common name index, an indications index and therapeutic index. A drug/herb interactions guide, a color photograph herbal identification guide of more than 380 plants, an alphabetical compilation of approximately 600 herbal monographs and a glossary of common botanical terms is also included. It also contains a listing of poison control centers and drug information centers in the United States. The text is marketed primarily to health care professionals, but the general public will also find this reference easy to read. Information in the book is based primarily on European texts and sources, meaning that most of the references are from foreign sources. These would not be easily accessible if needed. Another drawback is that new information on herbal-drug interactions is constantly being discovered. The concern is that this book stays current, updating information regularly.

Spontaneous Healing by Andrew Weil. N.Y., Borzoi Book published by Alfred A. Knopf, Inc., 1995.

This book's theme is that the body can heal itself. The book is divided into three parts, including, part one which explains the existence of a healing system that interacts with the mind; part two which tells the reader how to optimize his or her healing system and part three which gives advise on managing illness, including an analysis of the strengths and weaknesses of conventional and alternative treatments.

Wherever You Go, There You Are by Jon Kabat-Zin. Source: Hyperion, 114 Fifth Ave., NY, NY 10011, 1994.

In this book, Jon Kabat-Zinn gives the reader a simple path for cultivating mindfulness in his or her life. It is a perfect book for those coming to meditation for the first time and to longtime practitioners. Just as a garden requires attending to cultivate flowers and eliminate weeds, mindfulness also requires regular cultivating. Cultivating the mind is to bring it to wakefulness meditation.

Videos

Affirmations for Getting Well Again (Carl Simonton, M.D.)
www.simontoncenter.com/Pages/fbooks.htm; 800-459-3424
Publisher: TouchStar Productions, Seattle (1996) Length 35:00

The purpose of this video is to unite mind, body and spirit for a personal wellness journey. The video is half affirmations and half guided imagery. O. Carl Simonton presents the introduction. Beautiful scenes, pleasant, relaxing music. The first half includes nature scenes with new age music and printed affirmations on the screen. The last half of the video, the screen is blank (eyes closed) for guided imagery for chemotherapy.

Affirmations for Living Beyond Cancer (Bernie Siegel, MD)
www.touchstarpro.com; 800-759-1294

A New Vision of Living & Dying (Sogyal Rinpoche)
www.store.yahoo.com/zamamerica; (800) 256-5262; (415) 392-2066

Complementery Therapies: Empowering the Cancer Patient (Xenejenex, 1999)
617-632-2931, available for $5.00 to any NCI affiliation or patient

Choice in Cancer (Michael Lerner, PhD)
Commonweal, 415.868.0970

Conversations at the Edge: Healing and the Spirit (Rachel Naomi Remen, M.D)
Commonweal, 415.868.0970

Focus on Healing Through Movement and Dance (Sherry Davis)

Gentle Yoga for the Physically Challenged (Margot Kitchen)
www.yogacalgary.org/pricelist.html

Healing and the Mind Series (Bill Moyers):
www.shopping.yahoo.com/video/

- Volume 1: The Mystery of Chi
- Volume 2: The Mind Body Connection
- Volume 3: Healing From Within
- Volume 4: The Art of Healing

Kids Tell Kids What It's Like... When a Family Member Has Cancer (Cancervive)
310-203-9232, 6500 Wilshire Blvd., Suite 500, Los Angeles CA 90048

Living with Cancer (S. F. Regional Cancer Foundation)
www.blockbuster.com

Look Good... Feel Better: Caring for Yourself Inside and Out (CTFA Foundation)
www.lookgoodfeelbetter.org; 800-395-LOOK

Mind & Body (David Spiegel)

On With Life: Practical Information On Living With Advanced Breast Cancer (NABCO)
www.nabcoinfo@aol.com; 888-80-NABCO

Prepare for Surgery, Heal Faster: A Guide of Mind-Body Techniques (Peggy Huddleston)
www.healfaster.com/private.html; orders@healfaster.com

One Move At a Time: Exercise For Women Recovering From Breast Cancer Surgery
(Christine Clifford); www.cancerclub.com

Relax, Refresh and Be Your Best (Naomi Judith Offner)
www.gentleyoga.com; naomi@gentleyoga.com; (760) 598-5224 or (800) 655-6668
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(Bernie Siegel, MD)
www.touchstarpro.com; 800-759-1294

Positive Imagery For People With Cancer
Healing Journey
(Emmet Miller)
www.cygnus.uwa.edu.au/~gaianet/nam/Miller-audios.html

Healing Imagery for People Facing Surgery (Patricia Palmer, EdD)
www.ecap-online.org; 800.759.1294
This tape includes imagery to help you feel calmer, decrease your need for pain medications and accelerate your recovery process. Use before, during and after surgery. 2 tapes

Healing Through Surgery - Subliminal - Prepare Your Body for Surgery
www.ecap-online.org; 800.759.1294
This tape is intended to be played before, during and after your operation.

Healing Yourself: A Step by Step... Health Through Imagery (Martin Rossman, M.D.)
800-726-2070

Health Journey (Belleruth Naparstek):
- for People Experiencing Stress
- for People Undergoing Chemotherapy

www.healthjourneys.com; 1-800-800-8661

Mindfulness Meditation Practice Tapes (Jon Kabat-Zinn)
www.mindfulnesstapes.com; Stress Reduction Tapes, P.O. Box 547, Lexington MA 02420

Pain Control with EMDR (Mark Grant)
www.netstoreusa.com/abbooks/157/1572240741.shtml

Prepare for Surgery, Heal Faster (Peggy Huddleston)
www.healfaster.com/private.html; orders@healfaster.com

Preparing for Surgery (Henry Bennett, PhD)
800.213.3223; Patient Comfort Inc, 204 Park Avenue, Madison NJ 07940

Relax, Refresh and Be Your Best (Naomi Judith Offner)
www.gentleyoga.com; naomi@gentleyoga.com; (760) 598-5224 or (800) 655-6668
1176 Belmont Terrace, Vista CA 92084

Relaxation and Guided Imagery (Martin Rossman, M.D.)
800-726-2070

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510.527.3600 fax: 510.527.8404

East West Books
www.eastwest.com; 800.909.6161 fax: 650.988.9884

Explorations
800.720.2114; video tapes and many other yoga-related or cancer-related products are available.

Gaia Bookstore
www.darmer.com/gaia.htm; 510.548.4172 fax: 510.548.6134
1400 Shattuck Ave., Berkeley, CA 94709

Sounds True
www.soundstrue.com; 800.333.9185

TouchStar Productions of Meadville,PA (Barry Bittman, M.D.)
www.ecap-online.org; 800.759.1294

Yahoo Online Video Shopping
www.shopping.yahoo.com/video

Websites

Acupuncture.com
http://www.acupuncture.com/

AICR
http://www.aicr.org/aicr.htm

Alternative and Complementary Medicine Center-HealthWorld Online
http://www.healthy.net/clinic/therapy

The Alternative Medicine Homepage
http://www.pitt.edu/~cbw/altm.html

American Cancer Society
http://www.cancer.org/alt_therapy/index.html
This site provides general information on complementary medicine. This includes definitions, resources, articles, and other websites.

Ask NOAH about: CAM
http://www.noah.curry.edu/alternative/alternative.html

Center for Mind-Body Medicine
http://www.healthy.net/cmbm

Commonweal Home Page
http://www.commonweal.org/canproj.html
The Commonweal web page provides information on specific resources that include the credible Choices in Healing text by Michael Lerner, Herbal Therapies for Cancer, Recent Research Reports,etc.

Dr. Andrew Weil's Homepage
http://www.pathfinder.com/drweil

Health Journeys Website
http://www.healthjourneys.com

The National Cancer Institute CancerNet-Complementary and Alternative Medicine
http://cancernet.nci.nih.gov
Provides credible information on specific types of complementary and alternative therapies (for example: Shark Cartilage, Gerson Therapy, Laetrile, etc.)

National Center for Complementary and Alternative Medicine
http://nccam.nih.gov/
The NCCAM website provides information about this federal program and how it is organized. It includes news and events, research grant information, and educational resources.

NIH Office of Dietary Supplements Database
http://odp.od.nih.gov/ods/

Oncolink Specialty Site
http://oncolink.upenn.edu/specialty/complementary

Rosenthal Center for Alternative / Complementary Medicine – Columbia University
http://cpmcnet.columbia.edu/dept/rosenthal/

Steve Dunn's Cancer Guide
http://cancerguide.org/alternative.html

University of Texas Center for Alternative Medicine Research in Cancer
http://www.sph.uth.tmc.edu:8052/utcam/
This website includes information on the alternative medicine program at the University of Texas. It also includes links to other resources and a review of current therapies.

Diane Davis Cole, MPH
University of Virginia Cancer Center

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Comments of the American Dietetic Association #50
Before the White House Commission on Complementary and Alternative Medicine Policy
Washington, DC 20036
May 16, 2001

The American Dietetic Association represents 70,000 food and nutrition professionals who serve the public by promoting nutritional health and well being. Many ADA members are licensed, registered dietitians who provide medical nutrition therapy and preventive nutrition counseling to hundreds of thousands of Americans each year. To date, 43 states, the District of Columbia and Puerto Rico have laws that recognize the dietetic professional. ADA members base work on sound information drawn from peer-reviewed nutrition research and credible sources representing scientific consensus.

The members of ADA generally see nutrition-related CAM therapies as potential components of medical treatment and patient care in which qualified health care professionals work together to provide scientifically sound, safe or empirically proven therapies to better serve patient needs. ADA members welcome additional research that can support broader application of CAM practices. We believe patients who utilize nutrition-related CAM modalities should receive care from those who have appropriate knowledge, training and expertise. We also believe that dietetic professionals are valuable members of the extended team of CAM providers and play an important role in the integration of nutrition with other modalities of treatment.

Science supports the role of preventive nutrition and the role of medical nutrition therapy, or "MNT," in managing disease. However, continued research is needed to evaluate fully many CAM practices and to provide the substance for evidence-based medicine. ADA urges that any preventive or treatment strategy—conventional or CAM—be supported by sound science and evidence based practice before being integrated into a health care strategy.

ADA recognizes that nutrition interventions such as MNT or the use of dietary supplements, may reduce or eliminate the need for more costly medications or treatments. In the case of medical nutrition therapy, we have science to verify the role dietetics plays in medical care and outcomes research to demonstrate the effectiveness of MNT in treating diabetes, renal disease and cardiovascular conditions. A major research project is underway to evaluate health care utilization, costs and health outcomes of MNT on obese patients with Type-2 diabetes.

To help consumers make wise choices about food and dietary supplements, dietitians can provide nutrition counseling and education and can work with patients in developing a sound strategy to obtain nutritional health. Dietitians are the best resource for consumers who need or desire nutrition guidance and are most qualified to provide advice about whether to consume dietary supplements, which ones, and in what amounts.

For example, European studies support use of St. John's Wort for mild depression, which can be purchased for half the cost of a selective serotonin reuptake inhibitor. While this herb may be safe and efficacious for some, St. John's Wort has been shown to interfere with the efficacy of certain drugs such as Coumadin, cyclosporine, digoxin and protease inhibitors, and should not be consumed by patients who rely on those medications. There are many examples of food-drug or supplement-drug interactions, which makes evident the need for dietitians, especially as more Americans consider the use of dietary supplements.

ADA regularly monitors health care coverage for nutrition and nutrition-related services with the goal that all Americans have access to nutrition services supported by evidence-based medicine and provided by RDs.

Nutrition services are covered through reimbursement payments in some hospital, home health and post-acute care settings, but inconsistently among insurance plans and generally at levels inadequate to meet the needs of many Americans, particularly older Americans (IOM, 2000). The situation for the nation's elderly in likely to improve dramatically next year, as the Medicare Medical Nutrition Therapy Act goes into effect, providing MNT to Medicare patients with renal disease or diabetes. Congress also is considering legislation to expand the benefit to include cardiovascular disease.

Even with data showing that MNT coverage leads to fewer complications, fewer and shorter hospital stays and reduced costs for expensive treatments, overall reimbursement for nutrition services remains discouraging. Some managed care plans provide limited coverage and it appears the number of plans and the scope of coverage is increasing. The emergence of specialized insurance networks called "affinity networks" also is improving coverage. These networks offer CAM and many cover nutrition services provided by registered dietitians. However, in some cases CAM networks do not adequately screen providers and may offer nutrition services provided by less qualified individuals. We believe their emergence may help improve access to nutrition counseling for wellness or disease management provided these networks require nutrition providers to have the RD credential.

ADA is also encouraged that government and private-sector groups have begun to explore the prospect of public and private health care coverage for the treatment of obesity.

We hope work will progress rapidly to advance our understanding of the role of nutrition in preventing or delaying the onset of many chronic diseases, and to substantiate through evidence-based practice that coverage of nutrition services is a wise investment in public and private health care programs.

The American Dietetic Association urges the White House Commission to consider the following recommendations for its report to Congress and the President:

- Expand Medicare coverage of nutrition services to include all conditions where MNT is adequately supported by outcomes data (e.g., cardiovascular disease).
- Continue research to substantiate benefits and cost savings of nutrition interventions for cancer, osteoporosis and HIV/AIDS.
- Develop model obesity programs, compile outcomes data, and explore coverage of obesity treatment within Medicare and Medicaid programs.
- Encourage research that emphasizes and promotes wellness and "health" care beyond the current focus on disease management.
- Encourage research to identify effective strategies to assist consumers in appropriately selecting food, dietary supplements, fortified or functional foods, and nutrition-related complementary and alternative medicine therapies.
- Increase the number of randomized, controlled trials and reproduce results to determine whether individual dietary supplements can effectively treat or prevent diseases or other health conditions.
- Mandate quality and safety assurance measures for dietary supplements.

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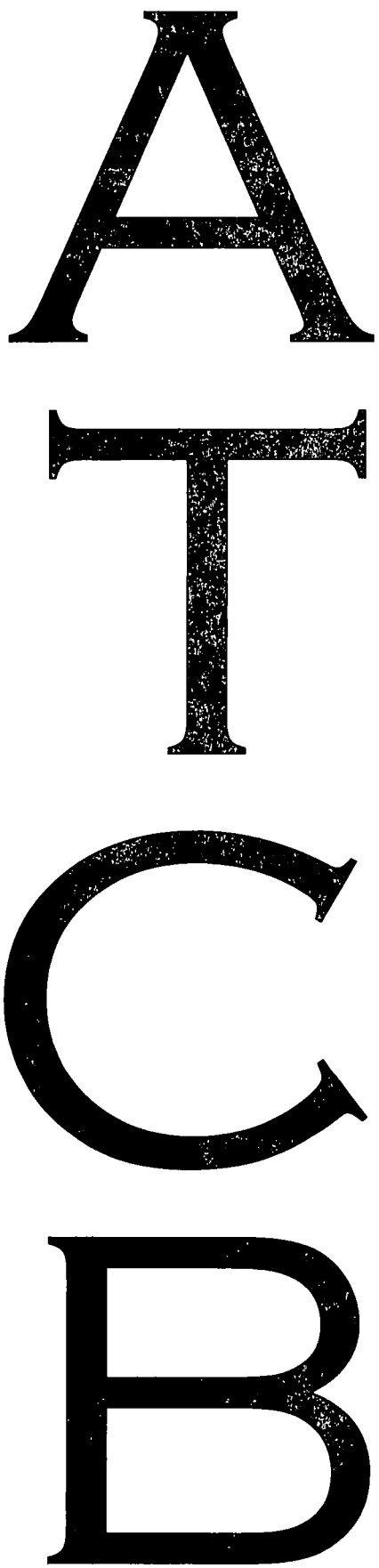

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3500 ATA Member

Credentialing Body

Registration of Art Therapists
Certification of Art Therapists
Recertification of Art Therapists
Oversees the Board Certification Examination

Mission

The mission of the ATCB is to promote, develop, and encourage the art, science, and practice of art therapy through standardized procedures for registration and certification.

Purpose and Goals

To protect and benefit the public through maintaining and developing standards of practice in the field of art therapy.

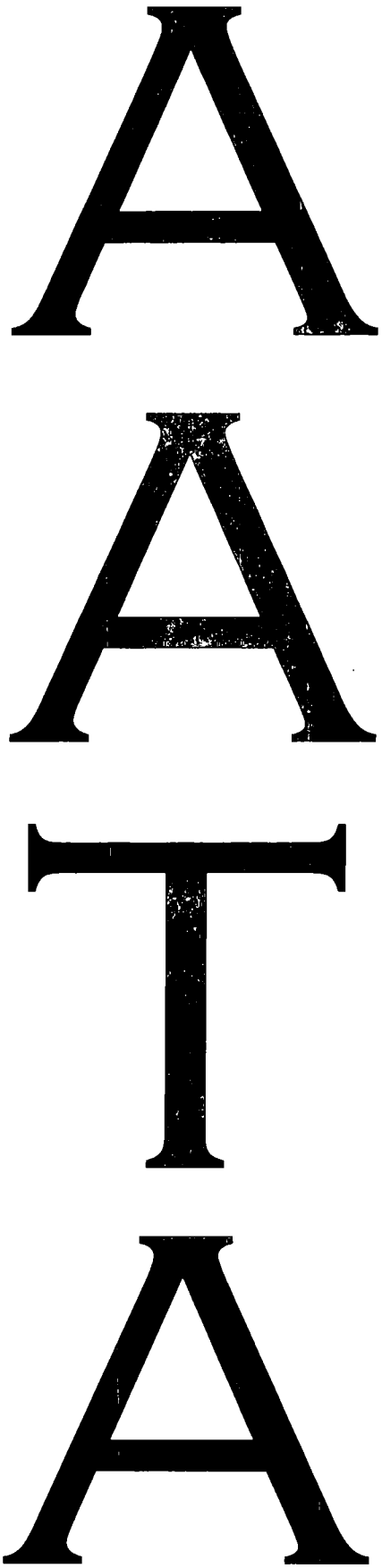
Registration

The designation "ATR" (Art Therapist Registered) is granted by the Art Therapy Credentials Board (ATCB) to individuals who have successfully completed the required educational and professional experience.

M.S. requirements

Board Certification

The designation "ATR-BC" (Board Certified Art Therapist) is granted by the ATCB to registered art therapists who have successfully passed the national certification examination. Recertification is provided every five years by documentation of continuing education, publication, presentation, exhibition, and other activities which demonstrate continuing professional competence.



American Art Therapy Association

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Membership Organization

Develops standards of excellence for Educational Programs and for Professional and Ethical Practice

Sponsors opportunities for continuing education through Regional and National Conferences

Mission

The American Art Therapy Association, Inc. is an organization of professionals dedicated to the belief that the creative process involved in the making of art is healing and life enhancing. Its mission is to serve its members and the general public by providing standards of professional competence, and developing and promoting knowledge in, and of, the field of art therapy.

Purpose and Goals

- Encourage the highest quality art therapy service to clients
- Facilitate communication among members and colleagues
- Support legislative efforts at the state and federal level
- Disseminate information to the general public
- Recognize excellence in clinical, professional, educational, and research activities

Publications

- Art Therapy: Journal of the American Art Therapy Association
- Quarterly Newsletter
- Annual Conference Proceedings
- A Guide to Conducting Art Therapy Research
- A History of Art Therapy in the United States

Audrey Di Maria MA, ATR-BC
Secretary of Art Therapy Credential Board

Report qualification standards of Art Therapists; report establishment of state licensure across US

Judy Simpson, MT-BC
American Music Therapy Association

Music therapy has a 50 year history of contributing to the treatment of individuals with a variety of disabilities and illnesses in the U.S. However, the lack of understanding by the federal government regarding music therapy applications, along with limited funding for research, direct services, and reimbursement, seriously restricts access to services. We would appreciate the Commission's assistance in accessing research funding and third party reimbursement for music therapy interventions.

(16)

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May 16, 2001

To: White House Commission on
Complementary and Alternative Medicine Policy

From: Judy Simpson, MT-BC
Government and Public Relations Associate
American Music Therapy Association

AMERICAN
MUSIC
THERAPY
ASSOCIATION

Music therapy is an established health profession in which music is used to address physical, emotional, cognitive, and social needs of individuals of all ages. We have a 50-year history of contributing to the treatment of individuals with a variety of disabilities and illnesses with more recent expansion of services to include prevention and wellness programs. Board certified music therapists use both instrumental and vocal music strategies to facilitate changes that are non-musical in nature. After assessment of the strengths and needs of each client, qualified music therapists provide indicated treatment and participate as members of the interdisciplinary team to support a vast continuum of outcomes.

To advance the awareness of music therapy, I have provided materials for the commission's review, including a CD-ROM containing 35 years of published, peer-reviewed research. This existing research not only addresses direct benefits dealing with specific illnesses but also demonstrates how music therapy can contribute to the amelioration of pain and distress that sometimes occurs with conventional treatments and invasive procedures. For example, the clinical application of music during chemotherapy treatments has been shown to reduce anxiety and nausea in oncology patients.

Intervention benefits have received attention outside of our association publications as well. In a recent Journal of the American Medical Association, music therapy research in a neonatal intensive care unit was featured. Data on the physiological benefits of music therapy included improved oxygen saturation levels, increased weight gain, and shortened length of stay. These positive outcomes, however, have not translated into more research opportunities or more access to services. If we know it can make a difference, what steps are necessary to provide and reimburse music therapy in every neonatal ICU? How do we progress from any positive research finding to increased access and coverage for effective music therapy interventions?

The truth of the matter is that music therapy is not just a nice thing to provide to patients, it's a serious intervention supported by scientific evidence. Even with our long history, we don't have the necessary volume of research projects to make primary reimbursement easy. We have nowhere near what other related disciplines have when it comes to research funding. The lack of understanding and acceptance by the federal government, along with limited funding for research, direct services, and reimbursement, seriously restricts access to music

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therapy services. Without federal recognition and support, it's difficult to conduct the multi-site, large sample, longitudinal studies that we need to demonstrate the outcomes and cost effectiveness third party payers require. The current method leaves music therapists as freelance advocates with each provider and insurance case manager to prove music therapy is a valid treatment worthy of reimbursement.

We know music therapy can make a difference in healthcare, but we need help in getting that message to decision-makers. The American Music Therapy Association would appreciate the Commission's assistance in securing research funding and third party reimbursement for music therapy.

Thank you.

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Seasonal

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Presenter #53
Richard I. Goldberg, LCSW-C, BCD
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on behalf of Steven Vazquez, Ph.D.
May 16, 2001

White House Commission On Complementary and Alternative Medicine Policy

In the process of studying seasonal affective disorder, science has determined that serotonin is the intermediary through which light stimulation alters unwanted emotional states. A method called Emotional Transformation Therapy has profoundly extended this principal by combining specific colors with psychotherapy and a new type of eye movement. However, there are seven primary blockages in the healthcare research system that currently impede the systematic scientific study of this modality. These include scientific bias against novel ideas, human emotion, color, and the use of psychotherapy in the treatment of S.A.D. Other factors include private practice discovery versus university research, synergistic versus reductionistic process, and equal access to funding regardless of vested financial interest.

Scientific Bias Against Novel Ideas

Scientific research funding is awarded to projects that have already been supported by numerous other studies. When science has not had interest in a certain subject, the novel idea cannot be supported by previous studies enough to warrant real consideration for funding.

Recommendation: Provide an arena for novel ideas to be demonstrated. If the demonstrations prove efficacious, then open avenues for funding.

Scientific Bias Against Human Emotions

The scientific value system advocates logical thinking, intellectual reasoning and objectivity and, in the process, devalues human emotions. This narrow perspective leads to studies about moods as mechanical conceptions of human functioning that seek to block or remove "bad emotions". Emotional Transformation Therapy focuses on embracing, exploring, and working through emotions as the subject learns new autonomous functioning during the transformation.

Recommendation: Advocate a broader perspective when studying human emotions that is inclusive of the arts, psychotherapy, and spirituality.

Scientific Bias Against Color

Color has been seen as an element of the arts. Science has overlooked color stimulation as a possible means for serious healing in either medicine or psychology. Emotional Transformation Therapy is a breakthrough process that uses color as a major component for facilitating deep and rapid transformation of serious conditions.

Recommendation: Public awareness campaigns may help to reduce ignorance of the effects of light and color in healing.

Scientific Bias Against Psychotherapy For S.A.D. Treatment

The scientific study of seasonal affective disorder has demonstrated bias against psychotherapy. In over 600 research studies on S.A.D. since 1984 not one of the 600-plus S.A.D. studies has investigated the efficacy of psychotherapy as part of treatment. Before 1984, psychotherapy was accepted treatment for depression of all types.

Recommendation: Reward broader perspectives with opportunities to publish successful case interventions in a journal created for that purpose. Research grants could then be awarded to the most promising modalities

Private Practice Discovery Versus University Research

In private practice psychotherapists must innovate continuously because of the uniqueness of each client. University based scientists develop their research ideas and then apply them to actual people. Psychotherapists may often be in a better position to create new solutions, but do not often possess the resources or training to produce research.

Recommendation: Government support through technical scientific assistance may produce many exciting new solutions that would otherwise go uninvestigated.

Reductionistic Versus Synergistic Processes

The value placed on reductionistic research by scientists tends to omit synergistic or multilevel/multidimensional interventions that may often provide better treatment outcomes. The single cause "magic bullet" search effectively overlooks some potentially higher quality treatments such as Emotional Transformation Therapy.

Recommendation: Encourage outcome studies of synergistic processes like Emotional Transformation Therapy through more funding for this type of research.

Equal Funding Resources

Most research funding is related to financially vested interests. Emotional Transformation Therapy and other multidimensional modalities currently offer no financial incentives to investors. Therefore funding resources are limited.

In conclusion, wisdom dictates that equal opportunity for funding should not be denied for reasons of financial interest or philosophical bias. Policy should encourage research endeavors by virtue of their potential merit in the pursuit of human healing.

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A Research Imperative: Emotional Transformation Therapy

White House Commission on Complementary and Alternative Medicine Policy

By: Steven Vazquez, Ph.D.

I am speaking on behalf of a new and powerful method that combines light stimulation with psychotherapy, often combining with the use of a light-emitting machine.

Seasonal Affective Disorder (SAD) was identified in the professional research literature in 1984. There have now been hundreds of studies documenting that certain forms of light stimulation into the eyes have the ability to improve unwanted mood states. It was initially thought that the mechanism by which this takes place was via the alteration the brain's biological clock which affects our night/day cycles called circadian rhythms. As research progressed, it became accepted that light stimulation facilitated mood changes largely through the serotonin neurotransmitter system. In addition, research demonstrated that other moods, such as anger, anxiety, and depression in forms other than SAD, could be beneficially affected. Unfortunately, this research led exclusively to symptom-remedy methods through the use of various light devices without a facilitator which almost always provided only temporary relief. This meant that improvements needed repeated fixes, thus resulting in a dependency and no real learning, understanding, or new coping skills on the part of the person being treated. Essentially, light stimulation became another pill.

Scientific Bias Against Novel Ideas

Scientific research funding is awarded to studies that generally have already been supported by numerous other studies. It seems that an hypothesis must already have been "proven" in order to acquire research funding to demonstrate it further. In other words, there is little or no opportunity for an innovative idea to be adequately studied.

Recommendation: Alternative medicine practitioners should be allowed to demonstrate the efficacy of their approach in person. If a certain modality can be shown to produce positive results based on some set of agreed-upon criteria, government grants should become available for further research.

Private Practice Discovery Versus University Research

University researchers and therapists in private practice tend toward two different processes of discovering new ideas for eliminating human suffering. Therapists in private practice encounter psychological challenges on a daily basis. Regardless of the therapeutic orientation therapists must innovate continuously because each person is unique. The factors that necessitate creative adaptation on the part of the therapist in private practice are not present in the university setting. On the contrary, the university professor typically conceives of a new idea in the relative vacuum of theory, and then determines a research design that tests the validity of the hypothesis. This approach to research, while more standardized, fails to address the cumulative observations of therapists in private practice. The preponderance of research, however unfortunately constricted, takes place in the university setting, and is not inclusive of valid discoveries made by professionals in the field. This is comparable to eliminating from medical texts all of the hard won discoveries made during battlefield surgery. Finding a way to investigate and validate the observations of mental health professionals and alternative medicine practitioners is essential to maximizing our cultural progress towards a more complete understanding of healing. Private practitioners are not salaried, and thus unable to allot the amount of time necessary for a major research project. Therefore, the creative psychotherapist is rarely in a position to test what he or she already knows to be efficacious. By virtue of these limitations, the system inadvertently blocks research outlets for the psychotherapist who has an important perspective and creative solutions to contribute.

Recommendation: Provide technical scientific assistance to professionals outside the university research environment to capitalize on the discoveries in the private sector.

Synergistic Versus Reductionistic Processes

The hierarchical value system of scientific research holds reductionistic approaches as the most highly respected. In treatment, this usually means that scientists look for the "magic bullet" that is the single cause for a cure of a disease or a mental disorder. Consider the possibility that the better cures may be synergistic; so that two, three or four factors when combined in a certain manner result in a better outcome. This type of approach has a limited chance of being funded even if efficacious. It will be seen as soft research that is not cause-and effect-specific enough to be accepted in the larger scientific community.

In the field of SAD treatment, there are over 600 research studies. and in only one study was there an inquiry about what the subject was thinking and feeling during light stimulation. When scientists studied color, the reductionistic approach seldom accounted for the person's emotional state during the exposure. I discovered the ***radiant biosynthesis effect*** in which certain wavelengths of color are matched with specific emotional states that result in a profound transformation of the subject's thoughts, feelings, physiology, etc. However, the color exposure alone or the state of mind alone does not tend to transform the patient's state significantly.

Recommendation: Encourage outcome studies as much as basic research. Encourage outcome studies of synergistic procedures that show promise. More funding may assist in overcoming some scientists' reluctance to involve themselves in studies viewed as "soft" among their peers.

Scientific Bias Against Human Emotions

Logical thinking, intellectual reasoning and objectivity characterize the philosophy underlying the scientific approach. All of these types of thinking involve the avoidance of human emotion. This narrow perspective itself devalues emotions whereas the arts embrace and explore the range of human emotions. In acting, one must physically express emotions; in painting, one visually displays emotions, and in writing one transforms emotions into language.

These divergent philosophies strongly impact the way in which emotional issues are pursued in research. Scientific studies are replete with attempts to stop, block or eliminate emotions, which are seen as obfuscating the clarity with which an experiment is performed. In contrast to the standard scientific approach, the arts are informed by emotion. The arts explore emotions and utilize metaphor in service of deeper understanding. The scientific view leads to the use of surgery, drugs, electroshock and other methods that stop the "bad" feeling. On the other hand, the arts tend to demonstrate how working through emotions while negotiating various challenges cause a character to learn on the way to resolution of the "bad" feeling. Both approaches may end up with the initial emotional problem changed, but the artist's way is richer and the person has been empowered by drawing on his own potential for recovery. Emotional Transformation Therapy uses the artist's concept in psychotherapy.

Recommendation: Our perspective upon which these studies are based should be broadened to include the arts, social sciences and other views. This should be done for the purpose of seeking a more humane type of treatment that affirms the unique repertoire of emotions that sets humans apart from all other life.

Scientific Bias Against Psychotherapy For SAD Treatment

SAD scientific research is biased against psychotherapy. Since 1984, when SAD was first identified in the professional literature, there have been over 600 published studies. In all of these studies in the 1999 Canadian Guidelines For SAD Treatment, there are zero studies that assessed the effectiveness of psychotherapy for treatment.

Before the identification of seasonal affective disorder as a separate type of depression, psychotherapy was the most commonly utilized treatment modality. Success in treatment was commonplace then. However, once it was discovered that light could be used to treat SAD, scientific studies tended to focus on the use of light and ultimately, anti-depressants. While light is helpful, the new SAD approach changed the method to one of temporary relief that required daily use and created a dependency on new light devices. Essentially, no new learning took place in the individual during these processes and the length of time for treatment at least tripled to 3 or more years before the condition subsided. It is likely that this SAD approach represents a decline in the effectiveness of treatment from psychotherapy, but we do not know because it either never occurred to scientists to study the effectiveness of psychotherapy or no one was willing to fund such a study.

Recommendation: There have been massive funding grants provided by both private and governmental sources for this "trend" in treatment (over 600 research studies since 1984). Those responsible for allocating funds may not have understood the consequences of this shift in focus. A change in policy could readmit a synergistic psychotherapy approach to current research.

Scientific Bias Against Color

Color has been cherished by the arts for a long time. Architects use it for both beauty and profit. Theatre has used colored stage lighting to create moods and of course, the great painters have used it for their masterpieces. The Fortune 500 companies invest millions to employ artists because the choice of color in marketing is well known to affect consumer buying. However, scientists generally see color as primarily aesthetic and as having no real power in serious medicine or psychology. Our society has institutionalized scientific "truth" to be superior to artistic "truth".

Although there have been scientific studies on color, most of these studies address the ways in which color can be used to manipulate the consuming public. Few if any studies have been concerned with color's potential to heal the physical body or transform emotional states. Emotional Transformation Therapy is a breakthrough process that uses color to rapidly transform some of the troublesome human conditions.

Recommendation: This exists an issue of bias and preference. Policies could be altered to encourage awareness regarding these types of biases through public relations campaigns. Additionally, studies involving color and light in psychotherapy could be funded to produce data familiarizing the scientific community and the public at large with the power of light and color.

Equal Funding Sources

In most cases research is driven by the prospect of financial gain. For example, the pharmaceutical industry provides the vast majority of research funding for depression, which in turn creates more revenue for the drug companies. Financial success, while a valid motivational force, can distract grantors from their unbiased altruistic mission, which is the pursuit of the relief of human suffering. It appears that the system of research and healthcare is so huge that nobody is really guiding the ethical focus of "Does this research actually represent the best possible step toward optimal healing of human suffering?"

More efficient and consistent treatment modalities may allow a patient to attain desired results faster, however, the psychotherapist will experience a declin3e in income as a result. Paradoxically, in today's healthcare market, a patient's limited number of authorized visits may result in deeper and more permanent healing by the use of alternative treatment modalities. Interestingly enough, the research's pursuit of "quick fixes" in mental health, such as Emotional Transformation Therapy are in the best financial interest of all concerned especially the patients and the HMO's themselves.

Recommendation: Equal access to research funding should not be denied for reasons of financial interest, philosophical bias or precedent. Rather, all research endeavors should be evaluated based on their merit in the realm of human healing.

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Richard Ira Goldberg, M.S.W.
Private Practice

This oral commentary concerns the use of Emotional Transformation Therapy: light and color combined with specialized interactive guidance. We shall identify the scientific research with respect to light stimulation, identify obstacles to research and suggest remedies.

Nancy Kristine Haller, Guild Certified Feldenkrais Practitioner, LMP, BA
Feldenkrais Guild of North America

Nancy Haller
Feldenkrais Guild of North America

There is an enormous need in our country to have a statement defining "What is Health?" We are working to add to the burdened systems without an overall statement that gives some structure to light the end of the tunnel. When a public statement of health is made, the programs, people and products necessary to meet the statement to fulfill the outcomes are made available. Language will be vital to this process and needs to be inclusive and powerful. Looking into the future and understanding that it will take a century of generations to change the overall health of this nation, there is no better time than now to begin.

Once there is a statement for people to hear, see, think about, then gradually there will be action to meet the concepts and bring the reality to life. We all hear the statements contrary to health in our daily lives and we have followed them. Advertising has made catch phrases that we can recite and when we come to the place of making choices, they ring in our heads and influence our decisions. It is possible to use these same concepts to the advantage of people in relationship to their health.

Achieving health across the nation is a broad subject that requires allopathic, alternative, folk medicine, spirituality, environment, research, education and cooperation. There are models where all of these have a place, are deemed appropriate and necessary. Education and trust are paramount to begin this ongoing change in the whole structure. We need a campaign that begins in multiple directions coming from the stated mission for health in this country. The ultimate goal is survival.

This is the long-term project that needs to be addressed. Within the structure is a place for everything that is involved in creating a healthy society. It is understandable that there would be opposition to this concept. Many huge corporations have made billions supporting our unhealthy lifestyles.

Short term needs for health include creating the programs to fill the needs of people in prevention and care, education and accessibility to the programs by the people, trained professionals to work on many levels of care as the needs arise and options for payments that are affordable and will allow profits to the insurance companies. We are headed in a direction that is appropriate, yet it seems to be scatter shooting into the dark.

There is need for the empowerment of people to trust that they are the ultimate physician and we as practitioners are here to listen and aid in their health decisions, offer directions for appropriate services and recovery. As practitioners, we have the obligation to be educated, informed, cooperative, and able to hear the request to aid the client with their choices, suggest appropriate treatments or services and products. We have the need to have insurance coding that will accurately define the work or product that is provided. The insurance companies require that accurate billing is done and then they are responsible to insure that the practitioners have timely payments for services rendered. Acceptance by the public that they hold a portion of the payment responsibility, also

allows them to participate more fully in the ownership of their health and well being. Finding appropriate avenues for ease in acceptance of death will also be a portion of the work that is necessary for the future. The circle is possible.

Recommendations to the Commission are:

Make recommendations to the President that are large enough to encompass the growing needs of the public for generations to come. Create a Statement of Health for the country to develop and embody over the next century. Become leaders for the people with health and wellness programs that are tangible, affordable and responsible.

Build a nationwide education campaign to bring awareness to all people that health is possible and we are working together to achieve the goal. Educate the people about health from the prenatal to death. Include commitments to self-care, exercise and nutrition in the education process to begin to empower the public that the responsibility for their health begins with themselves.

Create and offer financial incentives to practitioners in training to work with people in areas that have the highest immediate needs. Develop respect for the diversity, education, and knowledge of the different practices and how to network and refer to the appropriate method of work for the best interest of the client and their needs at that time.

Offer incentives to corporations to fund and support the health of the nation. Build programs for mutual funding for research, insurance, tax incentives, and other programs to meet the ongoing needs of the growing population.

Require insurance companies to pay for services rendered within a specific time period to support the practitioner's decision to accept the added burden of billing and waiting for payments. Have appropriate codes for the services and products so that there is opportunity for accuracy in billing. Utilize a specific system of coding designed for reporting what type of service, products prescribed, length and number of visits to collect data for research.

Health, education and implementation are lifetime goals that will span many future generations. This is the opportunity for an evolutionary change in the attitude and intention of all people in relationship to their health and wellness.

#55 Julie Merrill, L.Ac., American Association of Oriental Medicine

Good Afternoon Commissioners. My name is Julie Merrill. I am an Oriental Medicine practitioner, a board member of the American Association of Oriental Medicine and the Vice-President of the Maryland Oriental Medicine Association. The AAOM is the oldest and largest national organization for acupuncture and Oriental Medicine professionals.

Let us return to the topic covered on Monday and Tuesday, CAM Coverage and Reimbursement. Do you see this (New York City Subway) token (hold up). Can you see the hole in the middle? Oriental Medicine practitioners' current reimbursement is just like this: a token with a hole in the middle of it. The hole in the middle of the token represents inadequate coverage. Proper coverage for services provided by properly trained practitioners can fill that hole by providing broader access to health care that actually has the potential to provide savings to the federal government. Federal programs and private insurance companies must reimburse for Oriental Medicine's full scope of practice: acupuncture, moxibustion, herbal therapy, manual therapy, nutritional counseling, etc. in conjunction with our diagnosis, evaluation, and treatment planning at each office visit. These treatments replace and reduce other more costly health care expenditures. This coverage should be mandated as a means to reduce the need for costlier interventions.

As for the analogy of the token, Oriental Medical professionals are concerned about the "tokenism" of various "discount" programs being fraudulently marketed by health plans to appear as a premium "benefit." Such token attempts can be replaced by broader-based healthcare industry mechanisms like the ABC insurance coding system developed by Alternative Link, discussed in yesterday morning's panel. While there are currently 2 CPT codes for acupuncture, a more complete coding system such as that developed by Alternative Link would not only aid in the equitable reimbursement of Oriental Medicine and CAM services, it would also improve tracking ability and further outcome research.

Other initiatives are also already underway. AAOM supports the Hinchey bill that would provide coverage of acupuncture to Medicare patients and federal employees. AAOM also supports continuation of the personal Medical Savings Account insurance option as a way to cover preventative healthcare services.

The hole in the center of the token also represents a gap in the logic that better trained practitioners are paid less than those who are less trained. A practitioner with a Masters or Doctorate in Oriental Medicine has the ability to make an individualized differential diagnosis to more specifically and effectively treat a patient than someone who has training in a completely different form of medicine who subsequently studied Oriental Medicine for 200 hours. To fill that hole, it is imperative that any licensed acupuncturist be able to bill for their full scope of practice, and that there be no multi-tiered billing for any service. There must be equal pay for equal services for licensed providers.

The federal government obviously wants to get on the moving train of quickly broadening healthcare options in this country, as evidenced by the formation of this Commission. To move forward, federal and private health care coverage systems should reimburse licensed Oriental Medical practitioners to carry out their full scope of practice, paralleling current billing procedures, so that the provision of healthcare services in the United States can branch onto a new track, with ancient wisdom propelling it.

Julie Merrill

~~Christina Herlihy~~, Ph.D.

National Certification Commission for Acupuncture and Oriental Medicine

Alice McCormick, Dipl. Ac. & C.H.
National Certification Commission for Acupuncture and Oriental Medicine

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Testimony (#56)

for the May 16, 2001 public hearing of

The White House Commission on Complementary and Alternative Medicine Policy.

Submitted by:
Su Liang Ku, President of
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Dear Honorable Members of the White House Commission on Complementary and Alternative Medicine Policy:

Thank you for the opportunity to testify in front of your Commission and to share my suggestions and input regarding the future Policy on Complementary and Alternative Medicine.

I would like to focus my testimony on Traditional Chinese Medicine / Oriental Medicine, hereinafter referred to as TCM.

Definition: For the purpose of this testimony, the term TCM refer to the form of health care practice (examination, diagnosis and treatment of patients), that is based on the general philosophy of Yin-Yang and Five element concept, all the basic and clinical theories of Traditional Chinese Medicine, with emphasis on the holistic and differentiation of syndromes of individual patients, and the treatment modalities including Acupuncture, Herbal medicine, Tuina massage and manipulation, diet and life style counselling, and the recommendation of therapeutic meditation and exercises.

1. Do you have ready access to CAM practices and interventions?

Currently there are many patients who do not have the access to TCM services and products because TCM practices and products are not covered by their health insurance. This has greatly diminished the patients' privilege of accessing TCM care and interventions to benefit their health. Especially for those poor and/ or senior citizens who have many chronic medical problems which can be effectively relieved by TCM but Medicare does not cover the TCM services.

In order to protect the health and well-being of our citizens, and to make this form of medicine more accessible, and at the same time to reduce overall health care expenses, additional Federal and State laws and policies need to be established to better recognize TCM in the following format:

A. TCM be recognized by Federal and State laws and policies as a form of standard medical practice.

B. TCM services and products be appropriately and adequately covered and reimbursed by all Federal and State programs and private health care coverage systems. This shall include:

Medicare.
Government employee health insurance policies.
Workman's compensation programs.
Any form of medical supplement programs.
Any form of rehabilitative programs.
All insurance companies licensed to do business in a State's jurisdiction.
Medicaid.
Others

C. All Federal and State funded health care programs and facilities be urged to provide quality TCM services and products to all patients who seek them.

Reasoning:

A. TCM is utilized by approximately 40% of Americans.

TCM is a well established, well documented, and complete medical system that has been practiced for thousands of years on billions of patients. Within its 30 short years (since 1972) of availability to the American citizen, TCM has been well received and is now utilized by approximately 40% of Americans as a primary health care service on a more frequent basis.

B. TCM is effective, safe and economical.

Americans are interested in having aTCM services for their health care because TCM is very effective, safe and yet very economical. The effectiveness can be revealed by the fact that 40% of Americans have turned themselves from knowing nothing about TCM in 1972 to becoming faithful patients of TCM with a majority of them paying out of their own pocket. The safety and economy of this practice can be easily revealed by the low malpractice insurance premium paid by TCM physicians: Average under $1,000.00 per year for a coverage of $ 500,000 per incident and $1,000,000 aggregate.

While it is to the best interest of the citizens / patients to be able to benefit from TCM services and products, it is also to the interest of the governmental and public programs, as well as private sectors, to cover TCM services because of the lower reimbursement expenses.

C. TCM is a well regulated professional practice.

TCM practice has been well regulated by the related State Departments or Board of Acupuncture, Currently over 40 States have established laws and/or rules / policies regulating the practice of TCM. Adequate examination and licensing procedures are in place and all TCM practitioners are duly licensed and / or registered. This should provide feasibility for adopting the above rules and policies, as well as assurances for the safe and effective practice.

2. How can access to safe and effective CAM practices and interventions be improved?

The access to safe and effective TCM practices and interventions may be improved by adopting clear policies defining the qualified provider by requiring one or more of the following:

A. National board certificate.

Certified as a Diplomat by the National Commission for the certification of Acupuncturist and Oriental Medicine (Dipl. NCCAOM))

B Licensed by State Board of Acupuncture.

C. Educational and training background.

Currently the Accreditation Commission of Acupuncture and Oriental Medicine (ACAOM) is accrediting TCM programs at a Masters degree level with a minimum 60 semester credit hour towards a Baccalaureate degree from an accredited college as prerequisite, plus a 4 academic year / 150 semester credit hour program of course work on TCM as the entry level to the practice. ACAOM has also adopted standards to accredit programs on a Doctoral level with a minimum requirement of 4000 clock hour or 222 semester credit hour course work in addition to the 60 semester credit hours as prerequisite . Foreign TCM graduates range from 4 to 6 years (4,000 to 6,000 clock hours) of medical schooling as entry level to TCM practice and an additional 3 to 6 years of schooling as an advanced training.

It is important to regocnize that TCM is a complete yet unique medical discipline with over 30,000 medical texts (not including journals) exist. This body of knowledge cannot be learned in a couple of hundred hours or by a non-residential training.

In the past 30 years of TCM practice in U.S., of the very few malpractice incidents of acupuncture or herbal medicine, most were caused by practitioners other than those who have received adequate training, or who were licensed by the State Board of Acupuncture or certified by the national board (NCCAOM). Therefore in order to ensure that patients have access to safe and effective TCM practice and intervention, the requirement of the above mentioned standards is essential.

In regards to the safety of certain herb; It is the interest of both the government and public that a professional service should be regulated while making that service available to the patients who seek or need it instead of being eliminated. This is similar to the utilization of certain drugs or surgical procedures, it should not be eliminated because it had problems caused by the utilization by unqualified practitioners. The use of those herbs shall be limited only by qualified practitioners such as licensed TCM physicians.

3. What type of CAM practice and interventions should be reimbursable through federal programs or other health care coverage system?

TCM practice and interventions performed by qualified practitioners as defined in # 2 above, should be reimbursable through federal programs or other health care coverage systems.

The following service items within the scope of TCM practice should be reimbursable:

1. *All the TCM examination, evaluation and diagnosis procedures.*
2. *All the standard TCM treatment modalities such as:*
   - A. *Acupuncture*
   - B. *Herbal medicine.*
   - C. *Tuina massage and manipulation.*
   - D. *Diet and life style counselling.*
   - E. *Recommendation of therapeutic meditation and exercise.*

The specific sub-categories and the adjunctive diagnostic and treatment methods of TCM practices and products that may be considered for reimbursement may be defined based on the scope of practice permitted by the State Licensing laws and rules, and / or by the training received by the provider.

Su Liang Ku, A.P., Professor
Florida Institute of Traditional Chinese Medicine

Will discuss third party reimbursement for CAM to include all types of health insurance including Medicare and Medicaid. Standardization of diagnostic and treatment procedures and coding. Assuring access to safe and effective CAM practices and treatment.

Sandra Chapp

Sharon Stevenson
National Center for Homeopathy

#57

American Institute *of* **Homeopathy** 801 N. Fairfax St., #306, Alexandria, VA 22314

Good afternoon. I am Dr. Sandra M. Chase, the immediate past President of the American Institute of Homeopathy, the nation's oldest national medical association, and a former President of the National Center for Homeopathy, the nation's largest public organization representing the interests of Classical Homeopathy. I am a family physician in the private practice of classical homeopathy in Fairfax, Virginia. I am here to share with you our concerns for reimbursement, in general, and via Medicare, in particular.

Homeopathy is unique in its regulatory status among CAM modalities in the US. Specifically, homeopathy is included in the 1965 Medicare Act [H.R. 6675, Part II, *Drugs and Biologicals* (t),(1)]. Additionally, the *Homœopathic Pharmacopœia of the United States* is recognized in the 1938 Food, Drug, and Cosmetic Act (21 U.S.C.§ 321 *et seq.*). This places homeopathic drug products under the ultimate regulatory authority of the FDA, which, in 1988, promulgated the Compliance Policy Guide 7132.15 for the regulation of their marketing.

Homeopathic physician visits, which range from a few minutes for a simple acute case up to 2 hours in length for a complicated chronic case, may be billed under current E&M codes, using the time component where more than 50% of the visit involves consultation, rather than physical examination. Codes for additional time may be added where the visit exceeds 60 minutes, or, alternatively, some physicians ask that the patient return for a second visit in order to complete the homeopathic case-taking process.

A keyword search for *homeopathy* on the website for Local Medical Review Policies (www.lmrp.net) referenced by Dr. John Whyte of HCFA earlier this week, reveals that only New York policy M-95-3 bans homeopathy, along with other alternative medicine, from Medicare coverage. This suggests that homeopathy is covered by Medicare everywhere else in the United States. (Incidentally, the language of the New York policy inaccurately describes homeopathy as including "therapies using such products as antioxidants, oxidizing agents, cellular and chelation therapies and hydrogen peroxide.")

Nonetheless, physicians employing homeopathy have been harrassed by HCFA in several states. The threat of that occurrence, along with the increasing complexity of E&M coding and the potential for severe punishments for mis-coding, have caused many homeopathic physicians to opt out of Medicare participation. The end result is limited access to homeopathic medical care among the elderly and the disabled, the very populations in which pharmaceutical costs are skyrocketing and the most potential cost savings could be achieved, as homeopathic medicines are only pennies a dose.

We recommend two actions:
First, the Medicare statute should be enforced as national policy, allowing physicians to practice homeopathy without fear of reprisal throughout the 50 states.
Second, when that is accomplished, we recommend the addition of a two-digit suffix to the E&M CPT code, indicating that homeopathy has been used. This simple mechanism would facilitate tracking of the utilization and cost-effectiveness of homeopathic medical care throughout the healthcare system.

Thank you.

1938 FD, Cosmetic Act

#57

Federal Food, Drug, and Cosmetic Act, as Amended, and Related Laws

FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED

CHAPTER I—SHORT TITLE

SEC. 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

CHAPTER II—DEFINITIONS

SEC. 201. [321] For the purposes of this Act—

(a) (1) The term "State", except as used in the last sentence of section 702(a), means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) [1] The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means the U.S. Department of Health and Human Services.

(d) The term "Secretary" means the Secretary of Health and Human Services.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) [*] The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any other such article.

(g) (1) The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the

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[1] Subsec. 201(a)(2) amended by sec. 4(a) of P.L. 90-639 and by Sec. 101 of P.L. 91-513.

NOTE—References in brackets [ ] are to title 21 U.S. Code.

[*] The following additional definitions for food are provided for in other acts:

Sec. 201a [321a]. Butter. The Act of March 4, 1923 (42 Stat. 1500), defines butter as "For the purposes of this chapter 'butter' shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for."

Sec. 201b [321b]. Package. The Act of July 24, 1919 (41 Stat. 271), declares "The word 'package' where it occurs in this chapter shall include and shall be construed to include wrapped meats enclosed in papers or other materials as prepared by the manufacturers thereof for sale."

Sec. 201c [321c]. Nonfat Dry Milk. The Act of July 2, 1956 (70 Stat. 486), defines nonfat dry milk as follows: "* * * for the purposes of the Federal Food, Drug, and Cosmetic Act of June 25 [sic, 1938 (ch. 675, sec. 1, 52 Stat. 1040). nonfat dry milk is the product resulting from the removal of fat and water from milk, and contains the lactose, milk proteins, and milk minerals in the same relative proportions as in the fresh milk from which made. It contains not over 5 per centum by weight of moisture. The fat content is not over 1½ per centum by weight unless otherwise indicated."

"The term 'milk', when used herein, means sweet milk of cows."

The definition of oleomargarine appears preceding sec. 407a.

diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C); but does not include devices or their components, parts, or accessories.

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(h) [1] The term "device" (except when used in paragraph (n) of this section and in sections 301 (i), 403 (f), 502 (c), and 602 (c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopeia, offical Homeopathic Pharmacopeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also

[1] Sec. 201(h) [illegible] by sec. 3(a)(1) of P.L. 94-295.

Federal Food, Drug, and Cosmetic Act, as Amended, and Related Laws

CHAPTER V – DRUGS AND DEVICES

SUBCHAPTER A – DRUGS AND DEVICES

ADULTERATED DRUGS AND DEVICES

SEC. 501. [351] A drug or device shall be deemed to be adulterated –

(a)[1] (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 706(a), or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 706(a); or (5) if it is a new animal drug which is unsafe within the meaning of section 512; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 512.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity

[1] Sec. 501(a) amended by sec. 101(a) of P.L. 90-399, and sec. 9(b) of P.L. 94-295.

from such standards is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia of the United States it shall be subject to the requirements of the United States Pharmacopeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopeia of the United States and not to those of the United States Pharmacopeia.

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

(e) [12] If it is, or purports to be or is represented as, a device which is subject to a performance standard established under section 514, unless such device is in all respects in conformity with such standard.

(f)(1) If it is a class III device—

(A)(i) which is required by a regulation promulgated under subsection (b) of section 515 to have an approval under such section of an application for premarket approval and which is not exempt from section 515 under section 520(g), and

(ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the Secretary within the ninety-day period beginning on the date of the promulgation of such regulation, or

(II) for which such an application was filed and approval of the application has been denied or withdrawn, or such a notice was filed and has been declared not completed or the approval of the device under the protocol has been withdrawn;

(B)(i) which was classified under section 513(f) into class III, which under section 515(a) is required to have in effect an approved application for premarket approval, and which is not exempt from section 515 under section 520(g), and

(ii) which does not have such an application in effect; or

(C) which was classified under section 520(1) into class III, which under such section is required to have in effect an approved application under section 515, and which does not have such an application in effect.

(2)(A) In the case of a device classified under section 513(f) into class III and intended solely for investigational use, paragraph (1)(B) shall not apply with respect to such device during the period ending on the ninetieth day after the date of the promulgation of the regulations prescribing the procedures and conditions required by section 520(g)(2).

[12] Secs. 501(e), (f), (g), (h), (i) added by sec. 3(d) of P.L. 94-295.

Federal Food, Drug, and Cosmetic Act, as Amended, and Related Laws

(B) In the case of a device subject to a regulation promulgated under subsection (b) of section 515, paragraph (1) shall not apply with respect to such device during the period ending—

(i) on the last day of the thirtieth calendar month beginning after the month in which the classification of the device in class III became effective under section 513, or

(ii) on the ninetieth day after the date of the promulgation of such regulation, whichever occurs later.

(g) If it is a banned device.

(h) If it is a device and the methods used in, or the facilities or controls used for its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 520(f)(1) or an applicable condition prescribed by an order under section 520(f)(2).

(i) If it is a device for which an exemption has been granted under section 520(g) for investigational use and the person who was granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by or under such section.

MISBRANDED DRUGS AND DEVICES

SEC. 502. [352] A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in a package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, or sulfonmethane; or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name, and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

(e)(1) If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (3)) of the drug, if such there be, and (ii) in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: *Provided*, That the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall apply only to prescription drugs; and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: and *Provided*, That to the extent that compliance with the requirements of clause (A)(ii) or clause (B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(2) [11] If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name (as defined in subparagraph (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(3) As used in paragraph (1) the term "established name," with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 508, or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient: *Provided further*, That where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homeopathic Pharmacopeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopeia shall apply.

[11] Subsec. 502(e)(2) amended by sec. 5(a) of P.L. 94-295.

(4) [14] As used in subparagraph (2), the term "established name" with respect to a device means (A) the applicable official name of the device designated pursuant to section 508, (B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then any common or usual name of such device.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: *Provided*, That the method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia of the United States, it shall be subject to the requirements of the United States Pharmacopeia with respect to packaging, and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopeia of the United States, and not to those of the United States Pharmacopeia: *Provided further*, That, in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

(h) If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i)(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

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[14] Subsec. 502(e)(4) amended by sec. 3(a)(4) of P.L. 94-295.

#57

WYRTH POST BAKER, M.D., M.H.D., F.A.C.P.
4974 QUEBEC STREET, N.W.
WASHINGTON, D.C. 20016

202-362-8942

September 25, 1995.

Dear Mrs. Caffi:

The requested information is being faxed to-day

The original 6675, establishing the MEDICARE system omitted the Homeopathic Pharmacopoeia. During the extensive hearings I testified and was able to convince the committee that it should be included in the final amendment

REPORT

OF THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

TO ACCOMPANY

H.R. 6675

TO PROVIDE A HOSPITAL INSURANCE PROGRAM FOR THE AGED UNDER THE SOCIAL SECURITY ACT WITH A SUPPLEMENTARY HEALTH BENEFITS PROGRAM AND AN EXPANDED PROGRAM OF MEDICAL ASSISTANCE, TO INCREASE BENEFITS UNDER THE OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE SYSTEM, TO IMPROVE THE FEDERAL-STATE PUBLIC ASSISTANCE PROGRAMS, AND FOR OTHER PURPOSES

PART II

Drugs and Biologicals

(t) The term "drugs" and the term "biologicals", except for purposes of subsection (m)(5) of this section, include only (1) such drugs and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homoeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or (2) combinations of drugs or biologicals if the principal ingredient or ingredients of the combinations meet the conditions specified in clause (1), or (3) such drugs or biologicals as are approved, by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals, for use in such hospital.

Provider of Services

(u) The term "privider of services" means a hospital, extended care facility, or home health agency.

A copy of my testimony appears on page 781 of HEARINGS BEFORE THE COMMITTEE ON FINANCE OF THE U.S. SENATE ON H. R. 6675 Part 2

With my regards,

Wyrth Post Baker

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4974 QUEBEC STREET, N.W.
WASHINGTON, D.C. 20016

202-362-8942

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89TH CONGRESS } SENATE { REPT. 404
1st Session } { Part II

SOCIAL SECURITY AMENDMENTS OF 1965

REPORT

OF THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

TO ACCOMPANY

H.R. 6675

TO PROVIDE A HOSPITAL INSURANCE PROGRAM FOR THE AGED UNDER THE SOCIAL SECURITY ACT WITH A SUPPLEMENTARY HEALTH BENEFITS PROGRAM AND AN EXPANDED PROGRAM OF MEDICAL ASSISTANCE, TO INCREASE BENEFITS UNDER THE OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE SYSTEM, TO IMPROVE THE FEDERAL-STATE PUBLIC ASSISTANCE PROGRAMS, AND FOR OTHER PURPOSES

PART II

JUNE 30 (legislative day, JUNE 29), 1965.—Ordered to be printed

U.S. GOVERNMENT PRINTING OFFICE
49-648 O WASHINGTON : 1965

#57

Homoeopathic Pharmacopoeia Convention
of the
United States

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HPUS

THE LEGAL STATUS OF HOMEOPATHIC DRUG PRODUCTS SINCE 1897

The initials "HPUS" on the label of a drug product assure that legal standards of strength quality, purity, and packaging exist for the drug product within the package. The active ingredients are official Homeopathic Drug Products and are found in the current *Homœpathic Pharmacopœa of the United States.* The standards which must be met in order to append *HPUS* to a substance or a product are established by the Homœopathic Pharmacopœia Convention of the United States, a non-governmental, non-profit scientific organization composed of experts in the fields of medicine, arts, biology, botany, chemistry and pharmacy who have had appropriate training and experience and have demonstrated additional knowledge and interest in the principles of homœopathy. The Convention is an autonomous body which works closely with the Food and Drug Administration and homœopathic organizations notably the American Institute of Homœopathy and the American Association of Homeopathic Pharmacists. Guidelines are published for the prescription or over-the-counter status of homeopathic drug products.

The *HPUS* is declared a legal source of information on drug products (along with the USP/NF) in the Federal Food Drug and Cosmetic Act, 21 U.S.C § 301. Section 201(g)(1) of the Act. 21 U.S.C. § 321 defines the term "drug" as "articles recognized in the official *United States Pharmacopeia,* official *Homeopathic Pharmacopoeia of the United States,* or official *National Formulary* or any supplement to any of them.
Section 201(j) of the Act (221U.S.C. § 321) defines the term "official compendium" as the "official *United States Pharmacopeia,* official *Homeopathic Pharmacopeia of the United States,* official *National Formulary* or any supplement to them".

The *Homœopathic Pharmacopœia of the United States* is included in 42 U.S.C. § 801 the Medicaire-Medicaid statute and 21 U.S.C § 801 the Controlled substances Act. The FDA Compliance Policy Guide 7132.15 treats the subject of "Conditions Under Which Homeopathic Drugs May Be Marketed".

The Convention is responsible for the production and constant updating of the *HPUS.* The Board appoints a Monograph review Committee, a Pharmacopœia Revision Committee and a Council on Pharmacy to contribute to assist in the discharge of its ongoing responsibility. The Convention has a panel of experts which assists the Convention as required.

The *HPUS* is published as "Homoeopathic Pharmacopœia of the United States Revision Service" thus it can be kept current without delays implicit in a permanently bound form.

The HPUS has been in continuous publication since 1897, but was preceded by unofficial homoeopathic pharmacopoeiae since 1841, a total period of 150 years.

This information provided as a service by
The Homœopathic Pharmacopœa Convention of the United States

Similia Similibus Curentur

#57

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Instituted April 10, 1844

LEGAL STATUS OF HOMŒOPATHY IN THE USA

In regard to your questions about the recognition of homœopathy, I offer you the following information in that regard for the USA. It really involves two separate issues: pharmaceutical products and clinical practice.

Pharmaceutical products, whether conventional or homœopathic, are regulated by the federal government, specifically, by the US Food and Drug Administration(FDA). Homœopathic medicines were included in the 1938 Food, Drug, and Cosmetic Act which created the FDA, which was established to protect the public. Therefore, homœopathic medicines are officially recognized by the United States government. However, since homœopathic drugs predate the existence of the FDA, for many years they were considered over-the-counter drugs, meaning available without a prescription. The U.S. government recognizes two official pharmacopœiae in this country, the *United States Pharmacopœia* and the *Homœopathic Pharmacopœia of the United States*. In May,1988, the FDA published for the first time a written Compliance Policy Guideline as to how it would deal with homœopathic drugs. In recent years, some homœopathic drugs have now come under prescription, either because of their remedy source, such as *Opium*, or because of their clinical use, such as *Crataegus*.

Clinical practice, whether medical, osteopathic, etc., is regulated by each of the fifty states. Nevertheless, homœopathy was included in the 1965 Medicare Act which is a federal law that created the tax-funded healthcare system for the elderly and the disabled. In most of the states, homœopathic medical physicians are practicing under their conventional medical license. There are a few states, such as Arizona, Connecticut, and Nevada, in which there is a separate licensing board for homœopathic medical physicians. Additionally, there are a few states, such as Alaska and North Carolina, in which there are state laws which prohibit the revocation of a physician's license just because he or she practices an alternative form of medicine. Some other states are working towards a similar law.

As to your question about public use of homœopathic medicine, the sale of homœopathic drug products has grown geometrically in this country, which explains both the FDA's new keen interest in it and the dramatic increase in numbers of new homœopathic manufacturers, both domestic and foreign, here. Additionally, a sort of a bombshell, I think, went off within establishment medicine when, in Jan.,1993, the *New England Journal of Medicine* published an article by D.M. Eisenberg, M.D., et.al., of Harvard Medical School, which was a telephone survey of the public that revealed that a 34% of them were consulting alternative practitioners of various disciplines, even at their own out-of-pocket expense, since their insurance would not cover it, most often without telling their orthodox physicians. *Homœopathy in Europe* (7/94) contains a table on p.5 that shows in the USA 34% use non-conventional medicine, 3% using homœopathy (~7,500,000 people).

SANDRA M. CHASE, M.D., ..D.Ht. *22 April 1998*

White House Commission on Complementary and Alternative Medicine Policy

Meeting Topic II. Complementary and Alternative Medicine: Research Challenges

May 15-16, 2001

Testimony by Edward F. Owens, Jr. MS, DC
Director of Research
Sherman College of Straight Chiropractic

Thank you for allowing me to address you today. I am here to discuss some of the challenges we face in the chiropractic research community and reiterate what some of the other speakers for chiropractic have said. I am the research director at Sherman College of Straight Chiropractic in Spartanburg, SC and have been involved in chiropractic as an educator, researcher and practitioner for almost 20 years.

Sherman College Interim President, Dr. Brian McAulay, spoke to this body on February 23rd of this year. He raised three very important points that not only apply to chiropractic research, but to CAM in general.

- There is a huge disparity between the research funding to medical schools and that to alternative schools. The NIH alone granted some $6.5 billion dollars to the top 50 medical schools in 1999. The entire budget of the NCCAM, which funds most CAM research, is on the order of $70 million - about 1 percent of the NIH budget.

- We need to formally recognize the value and appropriateness of the meta-therapeutic health care paradigm that focuses on enhancing performance and function rather than treating disease. This would put more emphasis on the "complementary" in CAM, and recognize that there is a fundamental difference in the approaches between allopathic care and complementary care. Complementary care is more often aimed at improving the health of the whole person, rather than treating a particular symptom.

- More federal funding should be directed to research efforts in the wellness and preventive health paradigm that explores ways to help people avoid serious health problems and enjoy greater function and performance. This emphasis is a natural outgrowth of an increased awareness of the potential of meta-therapeutic methods to help forestall disease.

Two other chiropractic researchers spoke to this body on October 5th last year, Dr. Tony Rosner and Dr. Bill Meeker. Both of them had suggestions on how to accomplish some of the tasks Dr. McAulay suggested.

Dr. Rosner had a similar comment about the preventive aspect of chiropractic care, in particular the notion that regular chiropractic care over the long term can have benefit. At this point the evidence for his statement is largely anecdotal. There have been a few cross-sectional studies that showed how elderly patients under long-term chiropractic care tend to be more active, use fewer medical services and have better general health.

An emphasis on randomized clinical trials to test the efficacy of any therapy on a particular condition would not be effective in supporting or refuting the preventive benefits of long-term care. As Dr. Rosner pointed out, we need to relax the dependence on RCTs and open research funds to long-term descriptive studies, such as cohort designs and case series.

In our experience at Sherman College, federal funding for this kind of research is very difficult to obtain, even from the profession's own Consortial Center for Chiropractic Research. A suggestion from Dr. Rosner to provide properly balanced and enlightened study sections to review grant applications should help lower some of the barriers to the conduct of CAM research. We might also take this advice to heart in how we construct review sections in the CCCR.

In his presentation, Dr. Meeker went further to suggest that chiropractors and other CAM professionals be routinely appointed and otherwise included in research policymaking efforts (to include hiring chiropractors at the same level as other doctors in the Department of Health and Human Services as administrators and investigators). Certainly this initiative would provide a more knowledgeable and balanced staff, sensitive to the unique challenges of CAM research.

As an addendum to this presentation, I have enclosed a list of the research publications and presentations that Sherman College faculty members have produced in the past two years. The titles will give you an idea of the kinds of research we are interested in doing in chiropractic.

Thank you.

Peer Reviewed Publications by Sherman College Faculty, 1999

Owens E., Koch, D, & Moore, L (1999) Hypothesis Formulation for Scientific Investigation of Vertebral Subluxation. Journal of Vertebral Subluxation Research. 1999; 3(3).

Hoiriis K., Burd D., & Owens E.(1999) Changes in general health status during upper cervical chiropractic care: A practice-based research project update. Chiropractic Research Journal; 6(2):65-70.

Zhang J. (1999) The Correlation of Students' Entry-Level GPA, Academic Performance, and the National Board Examination in All Basic Science Subjects. Journal of Chiropractic Education; 13(2):91-99.

Owens E. (1999) Vertebral Subluxation-Centered Straight Chiropractic Research. Chiropractic Research Journal; 6(1);12-13.

Zeitz G., McAulay, B., & Mittal, V. (1999) Differentiating adoption from entrenchment: A Theoretical framework. Organizational Studies; 20(5); 742-776.

McAulay B. (1999) Negative push, positive pull: Differentiated work commitment in a turbulent career environment. Academy of Management annual conference in Chicago, August.

McAulay B., Zeitz, G., & Mittal, V. (1999) The Transition from Scientific Management to the New Management Model in Manufacturing: New Paradigm or Evolutionary Refinement? Association for Business History Conference, London, England, September.

Clusserath MT. Vertebral subluxation and a professional objective for chiropractic. Journal of Chiropractic Humanities 1999; 9(1):1-12.

Publications by Sherman College Faculty, 2000

Hart J & Boone WR. Pattern Analysis of Paraspinal Temperatures: A Descriptive Report. Journal of Vertebral Subluxation Research 2000; 3(4).

Owens EF. Theoretical Constructs of Vertebral Subluxation as Applied by Chiropractic Practitioners and Researchers. Topics in Clinical Chiropractic 2000; 7(1):74-79.

Owens EF, Stein T. Computer-aided Analysis of Paraspinal Thermographic Patterns: A Technical Report. Chiropractic Research Journal 2000; 8(2). In press

Owens EF, Pennacchio VA. Operational Definitions of Vertebral Subluxation: A Case Study. Topics in Clinical Chiropractic 2001; 8(1). In press

Senzon S. An Integral Approach to Unifying the Philosophy of Chiropractic: B.J. Palmer's Model of Consciousness. Journal of Integral Studies 2000 1(0). Online journal.

Owens EF. Philosophically driven scientific Investigation of Vertebral Subluxation. Proceedings Lisbon 2000 - ICA/FACTS conference.

McAulay B. Attitudes toward Chiropractic Philosophy: A Principle Components Analysis. Proceedings Lisbon 2000 - ICA/FACTS conference

McAulay B, Lemberger D, Owens EF. Success in chiropractic practice: a practitioner-based content analysis. Proceedings Lisbon 2000 - ICA/FACTS conference

Peer Reviewed Presentations and Posters by Sherman College Faculty, 1999

Zhang J. (1999) The effects of chiropractic care on short-term power spectrum analysis of heart rate variability. Association of Chiropractic Colleges Sixth Annual Conference. Orlando, FL, March.

Owens E, Donofrio J, & Guest T. (1999) Vertebral Subluxation Assessment in Clinical Research. Proceedings World Federation of Chiropractic, 5th Biennial Congress, Auckland, NZ, May.

Hoiriis K, Burd D, & Owens E. (1999) Changes in General Health Status During Upper Cervical Chiropractic Care. Proceedings World Federation of Chiropractic, 5th Biennial Congress, Auckland, NZ, May.

Owens E. (1999) Vertebral Subluxation Hypothesis Tree. Research Agenda Conference IV, Chicago, IL. July.

Hart J. (1999) Comparison of Upper Cervical X-Ray Listings to Upper Cervical Palpation Listings. National Subluxation Conference. Spartanburg, SC, October.

Donofrio J, Spano N, & Owens E. (1999) Reliability and Validity of Muscle Palpation as an indicator of Subluxation in the Upper Cervical Spine. National Subluxation Conference. Spartanburg, SC, October.

Owens E. (1999) Time-Series Analysis: A Research Method for Field Practitioners. National Subluxation Conference. Spartanburg, SC, October.

Owens E, Penrod M, & Stein T. (1999) Thermographic Pattern Analysis Using Objective Numeric Methods. Upper Cervical Conference, Marietta, GA November.

Hart J. (1999) Pattern Work in Chiropractic Practice. Upper Cervical Conference, Marietta, GA November.

Research Platform and Poster Presentations by Sherman College Faculty, 2000
Association of Chiropractic Colleges 2000 Educational Conference, March 15-18, San Antonio, TX (Presentations also published in the Journal of Chiropractic Education)

Owens EF, Hoiriis KT. The relationship between chronicity of complaints and changes in general health in a practice-based study.

McAulay B, Owens EF, Moore L, Hartley A. Clinical curriculum validation as a chiropractic college: a participant observation case study of an alternating bifocal model of work team effectiveness.

Brown S, Hinson R, Owens EF. Comparison of radiographic analysis and clinical outcome for two upper cervical specific techniques.

Owens EF. Thermographic pattern analysis using objective numeric methods.

Sherman College Lyceum, Spartanburg, SC.
Owens EF. Research in the Office Environment

Eighth Annual Vertebral Subluxation Research Conference, October 2000, Spartanburg, SC
(Presentations also published in the Journal of Vertebral Subluxation Research)

Owens EF. The Relationship Between Science, Philosophy, and Art in Chiropractic Research

Senzon SA. The Theory of Chiropractic Pattern Analysis Based on the New Biology

Hartley A, Charley L. Dissecting the Prone Leg Check

Clusserath M. Rationale for Multiple Common Indicators of Vertebral Subluxation

Hart J. Comparison of X-ray Listings and Palpation Listings of the Upper Cervical Spine

Clusserath M. The VSC Model and the Philosophy of Chiropractic

Chiropractic Philosophy Conference, October 2000, Spartanburg, SC
(Presentations also published in the Journal of Vertebral Subluxation Research)

Koch D. Force vs. Energy

McAulay B. Innate Intelligence and Universal Intelligence: Unnecessary Distractions in Chiropractic Philosophy?

Senzon S. Mental Impulse: Theoretical Construct or Scientific Reality?

Clusserath M. When is there Pain Associated with a Vertebral Subluxation?

Clusserath M. Philosophical Similarities between the Historically Opposed Groups in Chiropractic.

Senzon S. An Integral Approach to Unifying the Philosophy of Chiropractic: B.J. Palmer's Model of Consciousness

McAulay B. From 33 Principles to Coherent Concepts: Parsimony in Chiropractic Philosophy

Koch D. Chiropractic Philosophy: Where the Profession Needs to go to Advance.

World Federation of Chiropractic Conference on Education, November 2000, Ft. Lauderdale, FL

McAulay B, Naylor G. Philosophy Curricula in Chiropractic Colleges: A Content Analysis

International Chiropractors Association/Federation for the Advancement of Chiropractic Tenets Conference, November, 2000, Lisbon, Portugal

McAulay B, Lemberger D, Owens EF. Success in chiropractic practice: a practitioner-based content analysis.

Owens EF. Philosophically driven scientific investigation of vertebral subluxation.

McAulay B. Attitudes toward Chiropractic Philosophy: A Principle Components Analysis.

Edward Owens MS, DC #58

Barbara E. Moquin, Ph.D.(cand),R.N.,M.S.N.,CS-P NO
National Naval Medical Center
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Matt Ward Russell
National Integrative Medicine Council

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NIMC
National Integrative
Medicine Council

Statement of

Matt Russell
Executive Director
National Integrative Medicine Council

Before the

White House Commission on Complementary and Alternative Medicine Policy

May 16, 2001

5151 East Broadway, Suite 1095 • Tucson, AZ 85711 • 520-571-1110 Fax 520-571-1177 • www.nimc.org

Matt Russell
National Integrative Medicine Council

Chairman Gordon and members of the Commission, good afternoon. My name is Matt Russell and I am the Executive Director of the National Integrative Medicine Council (NIMC). The NIMC was created as a membership and advocacy organization to leverage the widespread demand for a new kind of medicine, one that appreciates the full range of resources to prevent disease and promote healing - from the best of allopathic medicine to the best of complementary and alternative medicine. However, the integrative approach does not simply add a handful of alternative therapies to the conventional physician's regimen, nor does it in any way deny the many strengths of allopathic medicine. Integrative medicine seeks to restore the focus of medicine on health and healing, emphasizing the centrality of the doctor-patient relationship and the human body's innate capacity for self healing and repair. It values lifestyle influences on health (such as diet, stress management, and exercise) and insists that physicians recognize their patients as more than just physical bodies.

Mr. Chairman, there are many important issues about which I could testify today. Just a little over a week ago, the Integrative Medicine Industry Leadership Summit convened in Arizona to address issues concerning reimbursement, clinics, employer strategies, CAM integration, and national policy. It was heartening to see such positive communications across stakeholder lines. While we honor all of the good work coming out of this summit, and expect to play an integral role in advancing issues of importance to the CAM professions, my testimony today focuses on specific public policy recommendations for physician education. This is an area where we believe an immediate opportunity exists.

Not surprisingly, the current structure of education and training of physicians in this country is inadequately preparing our physician workforce to meet the needs of patients. I believe it was Hippocrates who was often quoted as saying, "Cure sometimes, heal often, comfort always." Unfortunately, today's physicians are encouraged to cure always, heal if they have the time, and leave the comforting to someone else. Physicians are entering practice with frustrations about not being able to spend more than just a few minutes with their patients,

and are forced to rely too heavily on costly and impersonal technologies. Ironically, the shift toward high tech medicine over the past few decades is a dramatic departure from what our patients are saying loud and clear is important to them. Patients are looking for doctors who are sensitive about complementary and alternative therapies, and can knowledgeably guide their patients through the confusing maze of treatment options.

What, then, can be done to respond to this appeal for a healing-oriented health care system without neglecting the significant role that conventional medicine plays? There have been many, many solutions proposed. We have heard that our case needs to be made to the insurance industry, once issues of cost-effectiveness and quality can be ascertained. We have heard that the case needs to be made to employers, that if our nation's workforce unites behind this message, third-party payers will respond. We have heard that the solution lies in more appropriate research, moving away from the randomized controlled trial and towards clinical outcomes research. We have heard that consumers and health care providers alike need access to reliable information about choices in health care. These are all very important issues, each playing a significant role in this new system of care. However, if we do not have an appropriately educated physician workforce, no amount of research or reimbursement will ever find its way to our patients.

It is ambitious, if not unrealistic, to assume that we can realize the kinds of shift in medical education that we believe is important over the short-term. However, within only a few years, we can begin to see the initial effects of this model. The National Integrative Medicine Council is advocating for a small, federal demonstration project to gauge the effectiveness of building predoctoral medical education around the integrative model. The concept of providing grants to medical schools to evaluate new innovations in education is not new. Launched in 1997 under the Health Resources and Services Administration (HRSA), the federal UME-21 program has awarded grants to 18 medical schools, each of which has proposed certain curriculum innovations. We believe a similar system can be created for medical schools to build integrative curricula. Funding for medical schools for this purpose is critical, and we urge the Commission to recommend that HRSA set-aside specific funds for an integrative medicine education demonstration project. Another potential vehicle to create curricular innovations is through the reauthorization of the Public

Health Service Act, which Congress is soon expected to take up. The NIMC recommends an increase in appropriations for Title VII programs for the specific purpose of educating medical students in integrative medicine.

Mr. Chairman, we believe that many factors contribute to the development of this new system of care we collectively envision. It is about building stronger bridges between physicians and CAM providers. It is about an awareness that conventional medicine is in economic trouble. It is about providing access to reliable information. It is about empowering the consumer to make informed choices. And it is about building an infrastructure to bring the education of our nation's physicians back...to the future. This opportunity is before us today.

Thank you for the opportunity to share issues of importance to the NIMC. I would be glad to answer any questions.

PHARMAVITE

#60

DISSEMINATION OF RELIABLE INFORMATION ON CAM TO HEALTH CARE PROVIDERS AND THE GENERAL PUBLIC: A DIETARY SUPPLEMENT MANUFACTURER'S PERSPECTIVE

Statement of Carolyn Sabatini
Government and Regulatory Affairs Manager
Pharmavite Corporation
before the
White House Commission
on Complementary and Alternative Medicine Policy
May 14-16, 2001

Pharmavite manufactures dietary supplements and markets these products under the Nature Made and Nature's Resource brand names.

Since 1971, Pharmavite has been committed to providing consumers with quality dietary supplements that make a positive difference in people's lives.

We are pleased to offer suggestions on the dissemination of reliable information on CAM to health care providers and the general public.

Our response is tied to specific questions posed in the letter of invitation to participate in this forum.

How reliable information on CAM can be disseminated to health care providers and the general public:

I will share with the Commission some of Pharmavite's routine information-sharing practices. We encourage other dietary supplement manufacturers to continue or adopt similar communication approaches because information exchange benefits everyone.

Pharmavite regularly shares reliable information on its products with health care providers. We employ a team of registered dietitians who travel the country giving accredited, continuing education courses for pharmacists as well as science-based lectures on dietary supplements to other health care providers, professional associations and interested consumer groups.

Pharmavite Corporation • P.O. Box 9606 • Mission Hills, CA 91346-9606 • 818/221-6200 • 800/423-2405
Deliveries Only: 8510 Balboa Blvd., Northridge, CA 91325

We have developed a comprehensive, heavily-referenced product manual that outlines usage, recommended dosage, safety, side effects and adverse reactions, if any, with conventional medicines. We call it our Vitamin & Herb University and are pleased that the Purdue School of Pharmacy includes this manual as part of its curriculum. We also have distributed this manual to retail pharmacists, nutritionists and others nationwide.

Pharmavite also operates several toll-free information lines for trained professionals as well as the general public to address any questions about our products' safety, usage and stated benefits. We clearly note warnings on our product labels, if needed, and identify those groups of consumers -- such as pregnant women and those currently taking prescription medication -- who should consult with a health care provider before taking our products. In addition, our Web sites contain detailed product information, suggested dosage, drug-nutrient interactions and an information forum we call "Ask Our Nutritionist".

The second topic we'd like to address is:

Obstacles/barriers and possible solutions to accomplishing this goal:

One obstacle is the industry's inability to effectively communicate product quality to the public. While Pharmavite and other dietary supplement manufacturers follow strict quality assurance programs, the public and media perceive that we are not regulated. This misperception may in part exist because FDA has not fulfilled the Dietary Supplement Health and Education Act (DSHEA). Seven years ago, Congress passed DSHEA to give FDA the authority to among other things, set good manufacturing practices or GMPs for our industry that were "modeled after current GMPs for food".

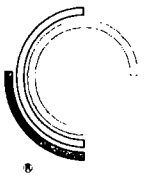
Working closely with the Council for Responsible Nutrition, an industry trade association, Pharmavite helped draft GMPs appropriate for dietary supplements that go beyond GMPs for food. The draft was submitted to FDA in November 1995 and published by the agency in February 1997 as an advance Notice of Proposed Rulemaking. After comments were received, FDA modified and finalized a GMP proposal, which was at the Office of Management and Budget awaiting review when the new administration took office in January 2001. The proposal was withdrawn in February 2001, along with numerous other pending regulations, to permit the new administration to review all actions.

Pharmavite has supported, endorsed and long awaited formal GMPs to complement our own efforts to build public confidence in the quality and safety of our products. We believe the Office of Management and Budget has an obligation to give FDA the ability to set the GMPs that we have been waiting for, for seven years. Our industry's ability to disseminate reliable information would be improved if people had a better understanding of how closely we are regulated.

Thank you.

Sen Barbara Bill Tony Cole - Payment of a Supplemental deduction Dietary Supplement Item

Statement of Carolyn Sabatini, Government & Regulatory Affairs Manager
Pharmavite Corporation, P.O. Box 9606 Mission Hills, CA 91346-9606



About PHARMAVITE

Nature Made and Nature's Resource brands are made by Northridge, Calif.-based PHARMAVITE. For more than 30 years, PHARMAVITE has offered high-quality vitamins, minerals, herbs and other nutritional supplements that promote wellness and help maintain good health. Pharmavite was also an instrumental force in developing the supplement industry's manufacturing standards recommended by the United States Pharmacopoeia (USP). For more information, call PHARMAVITE at 818-221-6200.

Pharmavite Corporation • P.O. Box 9606 • Mission Hills, CA 91346-9606 • 818/221-6200 • 800/423-2405
Deliveries Only: 8510 Balboa Blvd., Northridge, CA 91325

Carolyn Jones Sabatini, B.A., M.B.A.
Pharmavite Corp.

Pharmavite manufactures dietary supplements and markets these products under the Nature Made and Nature's Resource brand names.

Pharmavite shares reliable information on its products with health care providers in several ways. We employ registered dieticians who give accredited lectures on dietary supplements to health care providers nationwide.

We also distribute a comprehensive, heavily-referenced product manual to pharmacists which outlines usage, recommended dosage, safety, side effects and adverse reactions, if any, with conventional medicines. We call it our Vitamin & Herb University and are pleased that the Purdue School of Pharmacy includes this manual as part of its curriculum.

Pharmavite also operates several toll-free information lines for trained professionals and the public to address any questions about our products' safety, usage, and stated benefits. We clearly note warning labels on our products, if needed, and identify those groups of consumers who should
consult with a health care provider before taking our products.

What are the obstacles/barriers and possible solutions to accomplish this goal ?

One obstacle is the industry's inability to effectively communicate product quality to the public.

One solution is for this Commission to urge FDA approval of the Good Manufacturing Practices (GMPs) covering our industry that were first published as proposed rulings in 1997. Pharmavite has supported, endorsed and long awaited thse guidelines to complement our own efforts to build public confidence in the quality and safety of our products. GMPs will help us achieve that goal.

Christina Walker
The Shenk Human Energetic Institute

#61

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In this testimony I will present a case study and interweave recommendations concerning research.

A 19-year-old female victim of a car accident in a coma for 10 days experiences multiple fractures, hypovolemic shock, R pnemothorax and a near death experience. It takes one year to heal her physical symptoms. For the next 25 years she becomes a chronic pain patient. She goes from physician to physician who cannot find a reason physically for her pain. On her journey she comes into touch with alternative medicine. She starts with acupuncture and this starts to reduce the pain, but she is told she is unable to hold the treatments. She begins her studies in Healing Touch to study the chakra system for she knows her pain lies somewhere energetically. She begins to explore her consciousness to make sense of the many different frequency bands she experienced during her near death experience. Through the search of her consciousness she finds out she still disassociates and has not fully re-entered her physical body from the trauma she experienced so long ago. With this realizations she understands how could any energetic treatment give her the full results.

Recommendation: During research we need to get a sense of where is the person's energy body. For example the person may say I am beside myself, which means the energy body is next to the physical body. This may affect results if you mix population types because the treatment is different.

With this knowledge she has now acquired she enters a state of prayer to find someone that can teach her how to re-enter her physical body. This search leads her to Austria with the teacher Christine Schenk.

During the course of her studies with Christine Schenk she is taught and experiences that some parts of the energy system are closer to the physical body and others are farther away, so which space are we really researching. What levels of space are you studying in the energy body for each space has to be studied differently

Recommendations:. You need to know where you are according to the energy body anatomy

The patient learns to re-enter her body, make peace within herself and to start to feel the regeneration of her energy system with Christine Schenk's trainings. Now grounded and clear she finds out her entire energy system was smashed in the car accident which explains why she was disassociated, in chronic pain, and energetically unable to hold any form of alternative treatment. With this information she realized she needed to take a closer look at selection criteria.

Recommendations: Researchers need to understand the energy anatomy in a more comprehensive way. They need to see the big picture not just the small area they work in because that small area affects the entire energy system.

Research is based on science and the perception of the energy body is based on feelings, therefore our study designs need to be different. Sometimes we are chosen to walk the journey personally and experience research from that place which yields a different knowing. As long as we understand where we are and how we have our patients grouped we can accurately explore the world of energy.

The client I present to you today is me and I give more in-depth recommendations in the papers attached.

Thank-you so much for giving me the opportunity to share my journey for we are all in this journey together.

CHRIS®-Technique The Schenk Human Energetic Institute LLC
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Testimony on Research issues in Energy Medicine

1) **What can be done to expand the current research environment so that practices and interventions that lie outside conventional science are adequately and appropriately addressed?**

The following areas should be taken into consideration by the committee when address this first question.

a. **Educate about the differences between physical body research and energy body research.**
   i. **Include an understanding regarding the pitfalls and limitation of energy medicine when it comes to**
      1. **Selection criterion**
      2. **Randomization**
      3. **Control group: placebo or sham therapies in energy body medicine.**
      4. **Dosing of interventions and subgroup differences**
      5. **Better awareness of side effects of energy body medicine therapies.**

CAM therapies that affect the energy system need to be studied differently. To help understand this, we must first start with the awareness that we exist as two systems simultaneously. We have an energy body and a physical body. Many CAM therapies affect the energy body anatomy and physiology. Examples of these are Homeopathy, Acupuncture, and Hands on Healing. These approaches are commonly known as energy medicine therapies. Because these therapies are focusing on different systems and layers, the methods of studying need to also be uniquely different.

Western medicine focuses principally on the physical body. Therefore, these conventional research approaches are valid here. Some forms of CAM can be researched with this approach, since their principle focus is in the physical body space. Nutritional therapy, phytotherapy and aromatherapy are examples of these physical body focused CAM therapies.

When it comes to Energy medicine approaches however, these therapies need methods that are different due to the nature of this system. Outcomes of energy body research depend upon what area of the system is being studied. Our therapies can affect the energy body system on different levels or with in different organ systems. Error in interpretation can very easily occur if unique factors relating to the energy body system are not taken into consideration. We first need to understand how this energy body perceives, and functions to yield valid results.

The space being studied in the energy body network needs to also be well defined before initiating research. This allows us to formulate studies that hold together. We can however take the concept of western medicine rigor and structure and apply them to well-defined study groups.

SELECTION CRITERIA

One of the greatest difficulties in doing research in the Energy Medicine is population selection. We need a clear understanding if the presenting problem is physical or energetic before client selection can occur. A patient with gastritis or digestive problems can have the condition due to a purely physical disorder or due to an energetic disturbance that presents as physical system. Without a clear ability to distinguish which system is involved (and therefore which patients to group), the data will be confounded and unclear. These distinctions of symptoms in the history of the participants are critical in order to have a homogenous population to study.

Many other conditions to be studied with CAM approaches require an understanding of origin of the problem to yield the most accurate research outcome and avoid error. Within the energetic body, we need to have a clear understanding where in the system, the problem is originating. In the physical body, the problem can be heart related affecting kidney function rather than a direct kidney problem. So to, in the energetic body, one system can affect another. Knowing the origin of the energetic problem therefore will be important in doing successful and meaningful energy research. If we are not fully aware of a participant's energetic anatomy then errors can be made in participant selection.

Participants who have been involved with prior energy body therapies may affect outcome of results and need to be considered separately. This is because in most cases these therapies are medications to the energy body. Just as in western medicine research, selecting out these populations will minimize data alterations.

Examples of such patient populations with special situations are;

1) Pregnant women,
2) Mediators, and
3) People with interventions having long lasting effects on the energy body. Example of such interventions with possible long lasting effects include:
    a) Anesthesia
    b) Mind altering drug intake
    c) Breath work
    d) Psychotropic medication or
    e) Sedative medications of any kind.

Many of these groups should be studied in isolation to yield clear results.

THERAPUTIC DOSING ISSUES

Issues of dosing of energy therapies need to be quantified in order to standardized outcomes as well. Here we need to further be aware that an individual's metabolism for energy medicine therapies is different. Asian people energetic metabolism is differently that Europeans or African Americans. They may have different dosing needs and approaches. This needs to be taken into consideration when designing studies with CAM therapy to avoid outcome based errors and increased side effects.

CONTROL GROUP: PLACEBO OR SHAM THERAPIES IN ENERGY BODY MEDICINE
BLINDED STUDIES IN CAM THERAPY

Traditional research in western medicine depends as much as possible on randomizing the participants and blinding them to protocols to prevent the introduction of bias. This model has shortcomings when it comes to research in energy medicine. You cannot placebo an energy body. Energy body blinding is not possible because we have specific sensory perceptions that are present with this system. The perceptions of telepathy, clairvoyance and clairsentience, all makes it impossible to truly blind the participant if the practitioner is aware that the placebo is being applied. In this scenario an energy body will simply perceive the researcher as not truthful and possibly avoid trusting or participation. Whatever the reaction, the end result will no longer be neutral and will affect the data. That is why studies that support single blinding as a technique in this population are not effective models.

Double blind approaches are ideal but difficult and can only apply to some CAM therapies. An example of this can be homeopathy studies. Routinely the practitioner cannot be blinded to what they are doing if they are administering the therapy on the patient. They can be blinded to the outcomes in some cases, but they sense and feel what is taking place and adjust their therapies accordingly. In short, a true double-blinded format is difficult to achieve with energy work, but can occur when there is a substance that is prescribed and taken by the participant at a later time. A study where the practitioner must do an intervention with or to a client is not possible to bind. We must study these approaches as we would when we study surgery research since the surgeons cannot be blinded in their process as well.

SIDE EFFECT AWARENESS

Any therapy that works would also mean that it must have side effects. It would be counter intuitive to believe other wise. To expand the current research environment we need to develop a clearer awareness of the side effects of our treatment modalities so that studies can be better formulated. Commonly observed side effects of energy therapy can be:

Sleeping disturbances	Constant Fatigue	Backache	Constipation
Lack of concentration	Shaking Chills	depression	Dizzy spells
Circulatory problems	Changes in eating habits		Hot Flashes
Suicidal tendencies	Headaches		

STANDARDIZATIION REQUIREMENTS FOR ENERGY RESEARCH

a. Establish a standard in terminology regarding energy body medicine.
Other confounding factors that make energy body research different than conventional research are that different subcultures and different backgrounds confabulate our understand regarding naming conventions in energy medicine. Words like energy filters, flows, and prana have different meanings in different settings. We also perceive the energy body world differently based on culture, schooling, methods, and our own individuality. This further confounds the data, and requires that we be clear on what exactly we are doing. The bottom line is that test results are not comparable unless we speak the same language using the same words and meanings, as a conventionally trained medical doctor would discuss the finds of a broken leg that needs intervention. In order to effectively proceed with research of the caliber of western physical body medicine, this terminology issues needs to be addressed.

b. Establish a clearer definition regarding energy body anatomy and physiology so that tighter population grouping is possible for future studies.
As mentioned previously, we need to have a clear definition of the population being studied. If the condition is energetic in nature, we need to be clear of the anatomy and physiology of the energy body in order to know where the condition originates and appropriately select patients with the same disorder for study.

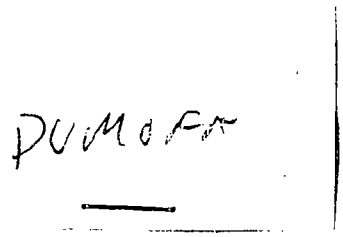
c. Establish a clear understanding of what space each energy body modality is operating in within this terminology set.

Without knowing the space we are studying we can never really ask the correct question to appropriately design energy body studies. Each therapy needs to be understood as to what level in the energy system it is effecting. Each type of energy body practice group needs to be able to explain or formulate a theoretical position on what part of the energy body system its practices is affecting. This is critical because in the system of the energy body, space is a clear factor for successful navigation.

At this time the most successful models for studying Energy body approaches will be in an outcome based model in comparison to conventional approach. Outcome based is suggested since we do not have tools to directly measure energy changes. The issue of appropriate patient selection is still present and is directly appropriate to level of training and clear understanding of what effects

the therapy is thought to have on the system. In summery then, to expand the current research environment to adequately address the space of energy body medicine, the following need to be satisfied:

a. **Educate about the differences between physical body research and energy body research.**
    i. **Include an understanding regarding the pitfalls and limitation of energy medicine when it comes to**
        1. **Selection criterion**
        2. **Randomization**
        3. **Control group: placebo or sham therapies in energy body medicine**
        4. **Focus on questions of dosing of interventions and subgroup differences**
        5. **Encourage better awareness of side effects of energy body medicine therapies.**
b. **Establish a standard in terminology regarding energy body medicine.**
c. **Establish a clearer definition regarding energy body anatomy and physiology so that tighter population grouping is possible for future studies.**
d. **Establish a clear understanding of what space each energy body modality is operating in within this terminology guideline.**


PUMOFF

Alan Dumoff
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AMERICAN ASSOCIATION OF NATUROPATHIC MEDICAL COLLEGES

AND

AMERICAN ASSOCIATION OF NATUROPATHIC PHYSICIANS

TESTIMONY TO WHITE HOUSE COMMISSION ON CAM POLICY

WASHINGTON, D.C.

MAY 16, 2001

Dear Commissioners and Staff:

Thank you for the opportunity to appear before you today. While we have provided information at previous WHCCAMP meetings, we would like to make the following points:

THE HEALTH OF THE AMERICAN PEOPLE IS AT RISK

- reimbursement for CAM services and products, and coordination of CAM research, is in the American public's interest
- access to CAM services is needed by the elderly, the poor, the uninsured, and in rural areas

PLURALISM IN AMERICAN MEDICINE

- diversity, with separate but equal systems of healing
- professions in parallel, collaborative integration
- maintain the "gene pool" of ideas
- enhance creativity, critical thinking, competition of ideas, economic competition, and market forces
- each system of healing has its strengths and weaknesses; combining systems results in losses for each

"To many observers, modern medical control over the terms and process of integration has resulted in the loss of important aspects of traditional theory and practice, issues seemingly unimportant to modern medicine. [For example] Fewer

acupuncture points are taught than in the classic system and aspects of the theory of traditional Chinese medicine have been de-emphasized. The effect of "modernization" resulting in a lesser system has also occurred with traditional medical education in India." (British Medical Journal, Vol. 322, 20 Jan 2000, p.165)

- assimilation impacts public safety

  Adverse events are far more common in less-trained medical acupuncturists (tends to be MDs with less than one year of training) than in better-trained acupuncturists (36 to 43.6 months training. The adverse event rate has been reported as 2:1. (Towards a Safer Choice: The Practice of Traditional Chinese Medicine by Bensoussan and Myers, 1996, Australia)

- the various CAM professions and traditions, their history, their standards, their bodies of knowledge, represent a national resource

  - naturopathic physicians represent a separate and distinct medical system

    - distinct standards, licensing, credentials, accreditation

    - distinct body of knowledge, scope of practice

    - recognized as physician providers in eleven states

      Naturopathic medical college prepare(s) NDs "with a biological and biomedical education of the same breadth and depth that prepares an MD to be a primary care physician. Naturopathic medicine...diverges from other forms of primary medical care at that point where professionals in common possession of scientific facts conscientiously disagree on how best to use their shared knowledge in treating patients." (Oregon Office of Educational Policy and Planning Administrator David Young, April 18, 1989)

  - CAM providers are sought by the public, not for certain modalities, but for the clinical philosophy or culture or paradigm in which they are applied

  - in a pluralistic system, there should be equal access to and equal regulatory and financial support for the various systems

REIMBURSEMENT FOR CAM PRACTICES AND PRODUCTS

- public choice requires equal access to physician providers of various schools of medicine

  - one example: Connecticut requires any insurance company which covers the services of a physician to not discriminate among MDs, DOs, or NDs

- however, Connecticut's policy does not apply to federal employees and Medicare beneficiaries

- such "illusionary access" should be prohibited by federal policy by eliminating conflicting policies, regulations and laws

- public safety for providers who diagnose and treat, and are primary care or primary contact, requires access to credentialed, licensable professionals with educational standards, clinical training, board examinations, and peer review

  - credentialing is required in order to receive reimbursement for CAM services

  - to be credentialed, one must be licensed, and trained in an accredited program to a recognized scope of practice

  - licensure, credentialing, and education are linked through the reimbursement system for public safety

  - the licensed CAM professionals must be integrated throughout the health care system for safe and effective access

  - Data on access, delivery, and reimbursement for naturopathic care are available from several states (Washington, Connecticut, Montana)

    Price-per-member per month for users of CAM services (acupuncture, massage and naturopathic medicine) has been found in one study to be approximately $0.20. A large majority perceived these services to be helpful. 61% reported that the CAM treatments had resulted in diminished use of their pain medication, and 55% reported a decrease in the use of their "conventional medical team." (Utilization, Patient Satisfaction and Cost Implications of Acupuncture, Massage and Naturopathic Medicine Offered as Covered Health Benefits. Darrell Stewart, MHA, John Weeks, Stephen Bent, MD)

COORDINATION OF CAM RESEARCH

- the coordination of CAM research has been addressed by our profession's representatives in previous Commission meetings (see testimony from Traub at San Francisco Town Hall Meeting, Standish and Pizzorno at Seattle Town Hall Meeting, Kail at Dec.4-5 meeting,)

- NCCAM is coordinating CAM basic science and clinical research, and facilitating the development of infrastructure at CAM research institutions

• the proposed Office of CAM at HHS should coordinate other types of research not included in the NCCAM mandate, such as research in health services, cost effectiveness, policy, education, and practice guidelines. This Office could also collaborate with NCCAM in holding a conference on the challenges of CAM research and CAM research methodologies

• appropriations are necessary for demonstrating efficacy and cost-effectiveness of CAM services and products. The burden of funding this research should be fair and equitable compared to that which is provided for conventional care pathways and interventions.

SPECIFIC POLICY RECOMMENDATIONS

1. **Commit to medical pluralism**

• embrace the fullness of diverse health care systems

Conventional, traditional, indigenous, complementary and alternative models of care, and their bodies of knowledge, have contributions to make to the healthcare which is culturally most appropriate and effective for individuals and communities. Best practices are discovered through exploring diverse structures for integration, including parallel, collaborative, and assimilative models.

• encourage licensing all CAM providers consistent with educational standards

• require inclusion of licensed CAM providers in CAM policy making and as researchers and advisors in all federally-funded CAM studies

• establish CAM offices at and appoint naturopathic physicians and other licensed CAM professionals to the staffs of federal health care agencies, including NCCAM, NIH, DHHS, CDCP, Agency for Health Care Policy and Research, Bureau of Indian Affairs, Public Health Service, National Health Service Corps, VA, and HRSA

•appropriate funds to layer a premium on any grant at NCCAM for including a CAM research institution instead of only a conventional one, and, for naturopathic institutions, it be a Council on Naturopathic Medical Education-approved naturopathic medical school that conducts research

• use the term "every category of provider" in federal law

•has withstood challenges through both Democratic and Republican legislature majorities, has generated the most controversy, and is the most popular, as well as having been upheld by the US Supreme Court

• specific criteria must be met: the CAM profession must be regulated by the state Department of Health with licensure or certification; the scope of practice must allow the provider to treat the condition that the patient presents; the provider must be contracted to be eligible for reimbursement; the patient must have benefits covering a condition that is within the scope of practice of the chosen provider

• this is not the same as "any willing provider", nor is it a mandated benefit; it allows consumers access to a choice of the provider who will treat the condition in which they are seeking care

• insurers have the right to credential providers as long as the standards are consistent with those established by the Department of Health

• fund residency programs for naturopathic physicians so that they may provide care and conduct research along side MD/DO residents at federally-funded health clinics and hospitals

• authorize HCFA and provide appropriations to reimburse for licensed CAM services to Medicare recipients, the poor, uninsured and underserved

2. **Mandate a non-discrimination policy for reimbursement for licensed CAM providers in all federal health care programs and agencies**

• remove exclusionary language from existing federal laws and regulations

• examples of agencies with exclusionary language or no mandates (for naturopathic physicians and other licensed CAM providers):

Indian Health Service policy-restrictive

National Health Service Corps - exclusionary

Field and Public Health Research - Centers for Disease Control - no mandate or appropriation for funding

Outcomes Assessment and Cost Effectiveness - Health Care Financing Authority/Medicare-exclusionary

NIH Institutes for Cancer, Heart, Lung, Blood research need mandates for CAM "offices" for research.

Graduate Medical Education - exclusionary

• as a first step, fund residency programs for naturopathic physicians in rural health settings, and include student loan forgiveness programs and Medicare reimbursement

• improve reimbursement for both conventional and licensed CAM providers under federal programs for behavioral change (affects greater than 50% of major diseases and their costs)

• fund a HRSA or DHHS National Credentialing Roundtable

• investigate and integrate licensed CAM systems and modalities and training standards as credentialing requirements for provision of CAM services by all health care providers

• endorse inclusion of naturopathic physicians and other licensed CAM providers at HCFA's CPT "table"

• prohibit any "separate but equal" costly, segregational, and disintegrational CPT scheme for any physician level provider, especially naturopathic physicians, as it does not result from any profession-wide consensus

• use the model of the Washington State Insurance Commissioner's Work Group on a federal level

3. Fund research on utilization of naturopathic medicine and CAM providers

• harvest existing information

• evaluate beyond clinical outcomes to global measures

• include patient satisfaction, lost time/productivity, functionality, quality of life, use of conventional services and medications, emergency department visits, hospitalization

• mandate a GAO report on the cost savings possible through the incorporation of licensed CAM services and CAM products

We once again appreciate the opportunity to bring our concerns before you. Please contact us if you would like any further information or clarification.

Sincerely,

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Evan Pugh Professor of the Solid State Emeritus • Professor of Geochemistry, Emeritus • Professor of Science, Technology and Society, Emeritus
Visiting Professor of Medicine, University of Arizona • Distinguished Professor of Materials, Arizona State University

May 1, 2001

Dr. Gerry Pollen
White House Commission on CAM
6701 Rockledge Drive
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Bethesda, MD 20817-7707

Dear Dr. Pollen,

I enclose my comments to be included in the packet for the Commission for the May 15-16th meeting. I hope you can get me on the public comment list on the 15th.

Sincerely,

Rustum Roy

WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE

Comments for "Research" Session
May 16, 2001

by

Prof. Rustum Roy

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Research to Support CAM

A New Strategy for Funding Research: Modeled on DOD and Corporate Research

The questions of what, how, and when in research on what is called CAM are critical in designing what will no doubt be a very large research program – possibly a billion dollars per year – in the next several years.

By far the biggest danger the Commission faces is the temptation to equate all approaches to "research" with current NIH practices. Speaking as a research physical scientist with 50 years experience and very generous funding from public and private sources, I believe this would be an egregious error with very serious consequences. The research paradigm used by NIH is the so-called linear theory of R&D, namely that *science* leads to *applied science* which leads to *technology* which favorably impacts *society*. CAM research should turn much more to the reliable models used in the hard science and technology fields. While the linear paradigm has been under attack by historians and science policy experts for some 20 years (1,2), it has been completely demolished in the 1990s. The corporate culture (which does 60 percent of the R&D in the United States) of the *world* has universally switched philosophically to (what was done in practice anyway) *applications-driven basic research* as its basic R&D theory. There are no more corporate blue sky "basic research" labs anymore. In the U.S., by a seriously erroneous misreading of Vannevar Bush, NSF and NIH (1) created an enormously complex, hugely wasteful of human resources, system to perform the relatively simple task of disbursing money to competent scientists. The Department of Defense, and most of the major corporations, provide us with a model much more suited to CAM.

Hence, WHCCAM needs to be able to assert that it is on this very firm ground when it opts for the DOD and corporate model of *application (or outcomes)–driven research*, including very basic research (instead of the NSF-NIH model). In this model, all research keeps the "end" or purpose in view, even while working on esoteric detail. In this model, success is measured by real impacts on socio-technical realities. In this model, knowledgeable managers in touch with the field they supervise make the hard

decisions, and explain them to their superiors as needed. These are the real peers of the proposers: with direct accountability. In contrast, anonymous, undefined peers who may have virtually no knowledge of the person or the field make the decision in the linear system, with zero responsibility. In this model, nearly 30 percent of the investigators time is saved in the proposal process.

By far, the most potent argument for using this style of research management is the very existence of CAM. CAM is alive and well because of its success with the consumer and her/his direct judgment on success or failure. CAM is an applications-driven field, surely its research should not abandon its own *raison d'etre*. All CAM research should work backwards from the whole-person to the clinical cell and then to the molecular level. Derek Price of Yale, America's dean of science historians, asked us all to keep in mind that, "Thermodynamics owes more to the steam engine than vice versa," and, "The arrow of causality historically is largely from the technology to the science." Indeed, that science is applied technology. Exactly the opposite theory exists in most research funded by NIH. Observations of healing and clinical and epidemiological outcomes are the leads to basic science. The very best empirical outcomes-based science for thousands of years (traditional healing practices) has identified for the world many highly successful or suggestive healing modalities. These form the basis of a dozen major global healing systems. They are the golden nuggets to be followed upstream by the most modern methods.

Recommendation #1

Use applications-driven DOD (6.1 and 6.2) and corporate models for selecting research to be funded which emphasizes the track record or performance or the purpose, not the traditional so-called paper peer-reviewed NSF-NIH model, which relies on the promises of the proposer.

Certainly a major part of the CAM research should be to seek some level of understanding – not for itself alone – but in order to expand or improve its availability – of a successful CAM practice.

A Model from Modern Successful Physical Science/Engineering Research

The empirical fact is that in these fields, every scientist is on the lookout for observations of new properties, new phenomena, which are way "out of the box," far above all earlier reports, etc. It is those key observations of extraordinary properties (recall the High T_c superconductor) which trigger an avalanche of interest. In medicine, it has been the opposite so far: such observations have been ignored or scorned so far. The opportunity is enormous.

Recommendation #2

Especially in the early stages, identify the CAM procedures and practices from all over the world which are most extraordinary, which have the highest signal/noise ratio, and do research on them. Again from the DOD (and corporate) world, this is the only justification for its basic (6.1-6.2) money to be spent. This has a dual payback. We can identify the really new phenomena and causes, but it also presents the most weighty intellectual challenge to established physical science models of the 19th and 20th centuries.

Support research on the truly extraordinary observed in healing events.

References

1. Deborah Shapley and Rustum Roy. "Lost at the Frontier." ISI Press, Philadelphia (1985).
2. Derek de Solla Price. Sarton Lecture, AAAS, Washington, DC (1983).

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White House Commission on Complementary and Alternative Medicine Policy

Proposed Meeting Schedule*

DATE	SITE	TYPE	TOPIC
February 22-23, 2001	Washington, D.C.	WHC (4)	EDUCATION/TRAINING
March 16, 2001	Minneapolis, MN	Townhall (4)	
March 26-27, 2001	Washington, D.C.	WHC (5)	INFO DISSEMINATION and WELLNESS
May 14-15-16, 2001	Washington, D.C.	WHC (7)	RESEARCH II and REIMBURSEMENT
July 2-3, 2001	Washington, D.C.	WHC (8)	REVIEW INTERIM REPORT DRAFT
October 4-5, 2001	Washington, D.C.	WHC (9)	PROGRESS ON FINAL REPORT
December 6-7, 2001	Washington, D.C.	WHC (10)	REVIEW FINAL REPORT
March 2002	Washington, D.C.	WHC (11)	CLOSING EVENT

*This information, including dates and locations, may change based on recommendations from the Commission. Updates are posted on our website: http://whccamp.hhs.gov as soon as they become available.

White House Commission on Complementary and Alternative Medicine Policy

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White House Commission on Complementary And Alternative Medicine Policy

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Commissioners' Biographical Sketches

Dr. James S. Gordon, of Washington, DC, who will serve as Chair of the Commission, is currently the Director of the Center for Mind-Body Medicine. Previously, he chaired the Program Advisory Council at the Office of Alternative Medicine of the National Institutes of Health. In addition to maintaining a private practice in Psychiatry and Medicine, Dr. Gordon has been a Clinical Professor at the Georgetown University School of Medicine in the Departments of Psychiatry and Family Medicine since 1980. He is a member of the National Institute of Health's Cancer Advisory Panel and was the Director of a Special Study of Alternative Services for the President's Commission on Mental Health. He has written extensively on the subjects of psychiatry and alternative and holistic care, and serves on the Editorial Boards of Alternative andComplementary Therapies and Alternative Therapies in Health and Medicine. He received his A.B. from Harvard College and his M.D. from Harvard Medical School.

Dr. George M. Bernier, Jr., of Galveston, TX, is a hematologist/oncologist and is currently the Vice President for Education at the University of Texas Medical Branch. Previously, he was Vice President for Academic Affairs, Dean of Medicine, and a Professor of Medicine at the University of Texas. Dr. Bernier has held academic appointments at the University of Pittsburgh, Dartmouth-Hitchcock Medical Center in Hanover, New Hampshire, and at Case Western Reserve University in Cleveland, Ohio. He has published numerous articles and abstracts, and several books. He received a B.A. degree from Boston College and a M.D. degree from Harvard University.

Dr. David E. Bresler, of Los Angeles, California, is one of the first contemporary American scientists to study and research acupuncture, guided imagery, and other mind/body approaches. As a professor in the UCLA Departments of Anesthesiology, Gnathology/Occlusion and Psychology, he applied his findings to treating clinical problems that did not respond well to conventional care, beginning with chronic pain. As the Founder and Executive Director of the UCLA Pain Control Unit, he and his team created the first multi-disciplinary, university-based chronic pain program in America. Dr. Bresler has authored or co-authored numerous publications, as well as twenty books and workbooks. Currently, Dr. Bresler serves as Associate Clinical Professor of Anesthesiology at the UCLA School of Medicine, Executive Director of the Bresler Center, Clinical Consultant to the UCLA Pain Medicine Center, Dean of Mind/Body/Spirit of the University of Integrated Studies, and Co-Director of the Academy for Guided Imagery. Dr. Bresler received his B.A. from Brandeis University, his M.A. from Bryn Mawr College, and his Ph.D. from UCLA. He received his Certificate in Acupuncture from the Institute for Taoist Studies.

Mr. Thomas Chappell, of Kennebunk, ME, is the co-founder and CEO of Tom's of Maine, which he co-founded with his wife Kate in 1970. It is a company that produces innovative, natural personal products and natural wellness products in a caring and creative work environment. Mr. Chappell is founder and CEO of the Saltwater Institute, a learning institute of leaders seeking to integrate their value into their personal and professional lives. He is active in many philanthropic organizations, among them an Advisory Council member for the Center for Study of Values in Public Life at Harvard Divinity School, Harvard Divinity School Dean's Council, and a Board Member of the Nature Conservancy of Maine. He has written two books, The Soul of a Business and Managing Upside Down. Mr. Chappell received his B.A. from Trinity College and his Master's in Theology from the Harvard Divinity School.

Dr. Effie Poy Yew Chow, of San Francisco, CA, is the founder of the East West Academy of Healing Arts in 1973 and, more recently, The EWAHA Qigong Institute, the American Qigong Association, and the World Qigong Federation. She is the recipient of over twenty awards including "The Humanitarian of the Year 1999" and the "Visionary of the Decade 2000" awards. She has been the only Qigong Grandmaster and acupuncturist involved in the development of national health policies within DHHS. She was also involved in the first Ad Hoc Advisory Panel of the Office of Alternative Medicine at NIH. She has made over two hundred and fifty media appearances and interviews in the area of complementary and alternative medicine. Dr. Chow received her training in Traditional Chinese Medicine and Qigong in China, Hong Kong, Taiwan, Canada, and the United States. She is a registered public health and psychiatric nurse and has received a Master's degree and a Ph.D.

Mr. George Thomas DeVries, III, of Rancho Santa Fe, CA, is Chairman, President, CEO and co-founder of American Specialty Health, Inc. and its subsidiaries, American Specialty Health Plans, American Specialty Health Networks, American Specialty Health Systems, and Healthyroads.com. In his position, he manages complementary and alternative health care benefits, networks and services for over 100 health plans covering over 40 million Americans. American Specialty Health Plans is a licensed specialty health plan covering over 4 million Californians for chiropractic and acupuncture. American Specialty Health Systems is a health services intermediary in over 20 states serving over 1.7 million members. American Specialty Health Networks is a national health services organization serving over 35 million Americans and offering a national provider network of over 19,000 chiropractors, acupuncturists, massage therapists, dieticians, naturopaths, and fitness clubs. Healthyroads.com is a complementary healthcare consumer products company offering e-commerce and mail order. Mr. DeVries was the National Entrepreneur of the Year for Health Sciences in 2000. Mr. DeVries has published a number of articles and has lectured on alternative health care in managed care and third-party reimbursement. He received a B.A. from the University of California at San Diego.

Dr. William R. Fair, M.D., of Longboat Key, FL, was, until recently, the Florence and Theodore Baumritter/Enid Ancell Chair of Urology, and was Chief of the Urology Service at Memorial Sloan-Kettering Cancer Center in New York City. Currently, he is Emeritus Professor of Urology at the Joan and Sanford I. Weill Medical College of Cornell University and Member Emeritus at Memorial Sloan-Kettering. Dr. Fair serves on the Cancer Advisory Panel for the National Center for Complementary and Alternative Medicine. He is the Editor-in-Chief of Molecular Urology and the Associate Editor of Alternative Therapies in Health and Medicine, and on the editorial boards of other highly respected journals. He has published extensively in the areas of urology and oncology. He chairs the Committee on Complementary and Alternative Medicine of the American Urological Association, and is Chairman of the Clinical Advisory Board of Haelth, LLC. Dr. Fair received his B.S. from the Philadelphia College of Pharmacy and Science and his M.D. from Jefferson Medical College.

Dr. Joseph J. Fins, of New York, NY, is an internist and Director of Medical Ethics at New York Weill Cornell Medical Center of New York - Presbyterian Hospital, Associate Professor of Medicine and Medicine in Psychiatry at the Joan and Sanford I. Weill Medical College of Cornell University, Associate Professor in the Program in Clinical Epidemiology and Health Services Research at Weill Cornell Graduate School of Medical Sciences, and Associate for Medicine at The Hastings Center. He lectures extensively and has written widely in the field of Medical Ethics. Dr. Fins received his B.A. from Wesleyan University and his M.D. from Cornell University Medical College.

Dr. Veronica Gutierrez, of Lake Stevens, Washington, practices with Gutierrez Family Chiropractic. She is a professional member of the World Chiropractic Alliance, serving on the Board of Directors. She serves as Chair of the Council on Women's Health and Director of Programs in Public Policy. Dr. Gutierrez has been very active in the chiropractic community, serving on many boards and commissions. She has received numerous awards in her profession, including awards from the Chiropractic Society of Washington, the Straight Chiropractic Academic Standards Association, and the International Chiropractic Association. Dr. Gutierrez received her Doctor of Chiropractic from Palmer College of Chiropractic and did post-graduate work at Cleveland College of Chiropractic.

Dr. Wayne B. Jonas, of Alexandria, VA, is currently a member of the Department of Family Medicine of the Uniformed Services University of the Health Sciences F. Edward Hebert School of Medicine. Previously, Dr. Jonas served as the Director of the Office of Alternative Medicine for the National Center for Complementary and Alternative Medicine at the National Institutes of Health. Prior to that, he served as the Director of the World Health Organization Collaborating Center for Traditional Medicine. He has authored and co-authored numerous publications on alternative and homeopathic treatment and care. Some of his current research includes projects in environmental toxicology, neurotoxicology, stroke, and biofield healing. Dr. Jonas received a B.A. from Davidson College and a M.D. from Bowman Gray School of Medicine.

Sister Charlotte Rose Kerr, R.S.M., of Baltimore, MD, is a Registered Nurse, a Practitioner of Traditional Acupuncture and, since 1977 a Senior Faculty Member at the Traditional Acupuncture Institute. Previously, she was an Assistant Professor of Nursing at the University of Maryland School of Nursing. Sister Kerr has been a member of the Advisory Council of the National Institutes of Health (NIH) Alternative Medicine Program. She has spent several summers in Europe, studying such subjects as Theology and Healing. In her work, Sister Kerr emphasizes the integration of Western traditional medicine and complementary healing methods. Sister Kerr received her B.S.N. from the University of Maryland School of Nursing. She received her Master's Degree in Public Health from the University of North Carolina and another Master's Degree in acupuncture from the College of Traditional Chinese Medicine, U.K.

Ms. Linnea Larson, of Oak Park, Illinois, is Associate Director of West Suburban Health Care (WSHC), Center for Integrative Medicine in Oak Park. Previously, she was the Behavioral Science Coordinator at WSHC Family Practice Residency Program. She was a clinical social worker at St. John's Hospital in Springfield, Illinois, where she provided inpatient and home hospice services and was also associated with the St. John's Center for Mind-Body Medicine. She also has worked as a family therapist and as a lecturer at the University of Illinois at Springfield. Ms. Larson received a B.A. from Knox College and a M.S.W. from the University of Illinois at Urbana-Champaign.

Dr. Tieraona Low Dog, of Corrales, New Mexico, currently serves as the Medical Director for the Tree House Center of Integrative Medicine in Albuquerque. With more than twenty years in the field of botanical medicine, she was recently elected to serve as Chairperson for the Dietary Supplements and Botanicals Expert Panel for the United States Pharmacopoeia. Dr. Low Dog received her medical degree from the University of New Mexico School of Medicine. She is part of the core faculty for Columbia University's Botanical Medicine Course for Physicians. Dr. Low Dog is currently working with Beth Israel on the development of a continuing medical education program on herbal medicine for physicians. She frequently lectures on the subject of herbal medicine. In 1998, she received the International Martina de la Cruz award for her work with indigenous remedies.

Dr. Dean Ornish, of Sausalito, CA, is one of the founders, and the president and director of the non-profit Preventive Medicine Research Institute. He is Clinical Professor of Medicine at the University of California, San Francisco, and a founder of the Osher Center for Integrative Medicine there. He was the first to prove that heart disease is reversible by changing diet and lifestyle. He has published many books and academic papers and has received numerous awards in recognition of his work. Dr. Ornish received a B.A. from the University of Texas and completed his medical training at the Baylor College of Medicine in Houston, Harvard Medical School, and the Massachusetts General hospital. He was a clinical fellow in medicine at the Harvard Medical School. Dr. Ornish was recognized by Life magazine as "one of the 50 most influential members of his generation."

Dr. Conchita M. Paz, of Las Cruces, NM, has maintained a private practice, in which she specializes in family medicine, for ten years. Currently, she serves as a part-time faculty member at the University of New Mexico School of Medicine and at the Southern New Mexico Family Practice Residency Program. She was Chairperson of the Family Practice Department and serves on a number of committees at Memorial Medical Center. Dr. Paz received her B.S. and M.D. degrees from the University of New Mexico

Joseph E. Pizzorno, Jr., N.D., of Seattle is one of the world's leading authorities on science-based natural medicine. A physician, educator, researcher, and expert spokesperson, Dr. Pizzorno is co-founder and founding president of Bastyr University, the first fully accreditated, multidisciplinary university of natural medicine in the United States. Dr. Pizzorno is the author of Total Wellness and co-author of the Textbook of Natural Medicine and the Encyclopedia of Natural Medicine. In 1996, he was appointed to the Seattle/King County Board of Health, the first natural medicine practitioner in the country to receive such appointment. In 1999, Dr. Pizzorno was elected Chair of the American Public Health Association Special Primary Interest Group on Complementary and Alternative Medicine. He has been licensed as a naturopathic physician in Washington State since 1975. Dr. Pizzorno is now President Emeritus and Senior Advisor to the President of Bastyr University. In September 2000, the Cancer Treatment Centers of America recognized Dr. Pizzorno as Humanitarian of the Year. He currently travels worldwide, lecturing and promoting science-based natural medicine and integrative healthcare. He also co-founded a company to bring natural medicine concepts to corporate health promotion programs.

Mr. Buford L. Rolin, of Atmore, AL, has been the Health Administrator for the Poarch Band of Creek Indians since 1984. He is a member of the State of Alabama Public Health Advisory Board and a member of the Board of Directors of the Creek Indian Heritage Memorial Association. Mr. Rolin is currently the Chairman of the Creek Indian Arts Council. He is the former Chairman of the National Indian Health Board, and he still serves as a member of the Executive Committee and as a Member-At-Large. He has received several awards from the National Indian Health Board, and he has also received a Lifetime Achievement Award from the Poarch Band of Creek Indians. Mr. Rolin attended the Health Services Administrators Development Program at the School of Community and Allied Health of the University of Alabama and Pensacola Junior College.

Ms. Julia Scott, of Washington, DC, is Past President of the National Black Women's Health Project (NBWHP), a national membership organization that focuses on wellness, self-help, and health advocacy. Previously, she was Director of the Public Policy and Education Office of NBWHP. Ms. Scott was Special Assistant to the President and Coordinator of the Adolescent Pregnancy Child Watch at the Children's Defense Fund. She has directed and administered to several foundations and community health agencies and has written numerous articles on African American Women's health. Ms. Scott was educated in nursing at the Waterbury Hospital School of Nursing.

Dr. Xiao Ming Tian, of Bethesda, Maryland, is Director of the Academy of Acupuncture and Chinese Medicine and Wildwood Acupuncture Center. Dr. Tian is currently conducting a National Institute of Health (NIH) supported clinical trial with Georgetown University Medical School to treat fibromyalgia patients using acupuncture. He has completed many research projects on the use of Chinese herbal medicine and dietary supplements to treat and prevent arthritis, sports injuries, and fibromyalgia, in collaboration with NIH and the U.S. Department of Agriculture Nutrition Center. In 1991, Dr. Tian was the first person to be appointed a Clinical Consultant of Acupuncture to the NIH medical staff. He is an Adjunct Assistant Professor of Preventive Medicine at the United States Uniformed Health Service. Dr. Tian is the President of the American Association of Chinese Medicine. He is also the Honorary Director of the China Association of Traditional Chinese Medicine and Vice President of The International Academy of Medical Qigong, both in Beijing, China. He currently serves as an advisor to World Health Organization and Pan-American Health Organization on traditional medicine. Dr. Tian received his Medical Degree from Beijing Medical University and was a Ph.D. Research Fellow at NIH.

Dr. Donald W. Warren, of Clinton, Arkansas, currently practices general dentistry, which includes dental cranial osteopathy, an alternative and complementary approach to health; temporomandibular joint dysfunction treatment, an alternative treatment for head, neck and facial pain and orthodontics/orthopedics. Since 1989, Dr. Warren has presented seminars on dental cranial osteopathy, temporomandibular joint dysfunction treatment, contact reflex analysis and designed clinical nutrition, and correct dental occlusion. Since 1999, these seminars have been accredited by the Academy of General Dentistry. He also instructed a hands-on clinic at the Texas College of Osteopathic Medicine, hosted by the Sutherland Cranial Teaching Foundation. Dr. Warren has taught in the United States, the United Kingdom, and Australia. Dr. Warren received a B.A. from Hendrix College and a D.D.S. from the University of Tennessee College of Dentistry. Since then, he has continued to study in his fields of expertise and is a diplomat of the American Board of Head, Neck and Facial Pain.

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