Withdrawal/Redaction Sheet
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001a. testimony	Huaihai Shan (partial) (1 page)	nd	b(6)
001b. resume	Huaihai Shan (partial) (1 page)	nd	b(6)
002. testimony	Tsao-Lin Moy (partial) (5 pages)	01/23/2001	b(6)
003. testimony	Kathleen Golden (partial) (1 page)	01/23/2001	b(6)
004a. testimony	Jennifer Daniels (partial) (1 page)	01/23/2001	b(6)
004b. letter	Jennifer Daniels (partial) (1 page)	nd	b(6)
004c. resume	Jennifer Daniels (partial) (1 page)	nd	b(6)
005. testimony	Tsao-Lin Moy (partial) (5 pages)	01/23/2001	b(6)
006a. testimony	Huaihai Shan (partial) (1 page)	nd	b(6)
006b. resume	Huaihai Shan (partial) (1 page)	nd	b(6)
007. letter	Jacob's Cure testimonial (partial) (2 pages)	nd	b(6)

COLLECTION:
Federal Records
White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

OA/Box Number: 43232

FOLDER TITLE:
WHCCAM Meeting Testimony, January 23, 2001 [4]

2011-0568-S
kc825

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001a. testimony	Huaihai Shan (partial) (1 page)	nd	b(6)

COLLECTION:
Federal Records
White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

OA/Box Number: 43232

FOLDER TITLE:
WHCCAM Meeting Testimony, January 23, 2001 [4]

2011-0568-S
kc825

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[001a]

The Application of Traditional Chinese Qigong in Psychiatry in the United States

Presenter: Huaihai Shan, M.D.

Associate Professor of Psychiatry
Shanghai XUHUI Mental Health Center, P. R. China
Shanghai University of Traditional Medicine, P. R. China
Shanghai Institute of Qigong Research P. R. China

Visiting Associate Professor
Department of Psychiatry
UMDNJ-Robert Wood Johnson Medical School
Robert Wood Johnson Medical School
671 Hoes Lane, UBHC, Room D-326
Piscataway, NJ 08854
Email: Shanhu@umdnj.edu
Tel: (732) 235-3360W, (b)(6)
Fax: (732) 235-4430

CAM approaches that have been applied to psychiatry include Qigong, biofeedback therapy, acupuncture, Chinese herbs, meditation, autonomic training, hypnosis, relaxation therapy and biotherapy. Although the clinical utility of Qigong has not yet been fully evaluated, a large number of practitioners and patients worldwide have accepted it. There is good anecdotal evidence supporting the use of Traditional Chinese Qigong in conventional medical settings for disorders including mild anxiety, depression and, most strikingly, psychosomatic disorders such as asthma. Unfortunately, there are relatively few adequate research studies on the use of Qigong in this field.

Following are some concerns about Qigong that should be considered in order to properly assess the application of Traditional Chinese Qigong in psychiatry.

1. Many Qigong masters do not have extensive knowledge to diagnose

properly medical problems that may be treated by Qigong.
2.The anecdotal evidence of efficacy is not acceptable by conventional medicine because it lacks placebo controls.
3. Qigong has been sometimes been misused in the community and conventional medical settings in China.

What is Qigong? Although Qigong is widely practiced in the world and there is growing number of people and patients who are interested in practice Qigong, there are still some different opinions about its definition. Qigong embodies two principles: Qi is the vital energy of the body and gong is the practice and training of the Qi. Traditional Chinese Qigong, a particular form of Qigong, is also known as medical Qigong.

Traditional Chinese Qigong is the ancient art of health maintenance and healing that originated several thousand years ago in China. Traditional Chinese Qigong has three elements: mind, breathing and movement. The ultimate goal of Qigong is to improve the functions of the Mind/Body in a balanced way. Traditional Chinese Qigong is also one of the psychological rehabilitation techniques. For thousands of years, millions of people have benefited from Qigong practices and believed that improving the function of Qi maintains health and heals disease. It is believed that regular practice of Qigong helps to cleanse the body of toxins, restore energy, reduce stress and anxiety, and help individuals maintain a healthy and active lifestyle.

I hope that psychiatrists and psychologists would consider evaluating Traditional Chinese Qigong as a method of behavioral therapy.

I suggest that NIH establish a focus for research of Traditional Chinese Qigong in NCCAM to evaluate the practice of Qigong including its indications and contradictions.

The practitioner should consider the safety limitations of Qigong in the treatment of medical problems because Qigong may induce some psycho-physiological responses that are not good for health if practiced incorrectly or inappropriately.

I would be pleased to offer some the training courses of Traditional Chinese Qigong in the United States. I hope NCAAM establish a system to license Qigong instructors in the future.

If this is done, the quality of the research in the application of the Traditional Chinese Qigong in psychiatry would be improved.

My colleagues and I are very interesting in the application of Traditional Chinese Qigong for psychosomatic disorders in psychiatry. In particular, we would like to compare Traditional Chinese Qigong with meditation and other relaxation therapies in a Methadone setting for treatment of drug abusers.

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001b. resume	Huaihai Shan (partial) (1 page)	nd	b(6)

COLLECTION:
Federal Records
White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

OA/Box Number: 43232

FOLDER TITLE:
WHCCAM Meeting Testimony, January 23, 2001 [4]

2011-0568-S
kc825

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[0016]

Huaihai Shan, M.D. Qigong Master

Associate Professor of psychiatry
Shanghai XUHUI Mental Health Center, P. R. China
Shanghai University of Traditional Medicine, P. R. China
Shanghai Institute of Qigong Research P. R. China

Visiting Associate Professor
University of Medicine and Dentistry of New Jersey
Robert Wood Johnson Medical School
671 Hoes Lane
Piscataway, NJ 08854
Email: Shanhu@umdnj.edu
Tel: (732) 235-3360W, (b)(6)
Fax: (732) 235-4430

I received M.D in Psychiatry from the Shanghai Mental Health Center of China in 1985. I have trained extensively in general psychiatry, medical psychology, Traditional Chinese Medicine including Qigong, acupuncture and other CAM therapeutic approaches. I had begun to study the research on the psychiatry, medical psychology and CAM in 1985 after I had completed residency program in psychiatry. I founded the several research grant in psychiatry from Chinese government since 1986. I am a principal investigator of Chinese Health Center grant for in Qigong and psychology. The Several articles have been published in Chinese journals on the Complementary and Alternative Medicine. I also have been training in psychiatry and complementary and alternative medicine in the United States since 1996.

I also received a certificate of medical Qigong instructor from Shanghai Traditional Chinese Medical University of China, School of Qigong in 1989. I have taught Qigong at Shanghai Mental Health Center, in Qigong clinic and the community. Over the past 10 years, I have successfully integrated complementary approaches into my clinical practice. I have completed the project of the application of Traditional Chinese Qigong-based stress reduction program in the treatment of Anxiety disorders that has been published.

My research interests are focused on the use of complementary and alternative medicine including Qigong therapy, acupuncture, Chinese herb medicine and mind/body medicine and relaxation therapy, to treat stress-related disorders. I have been dedicated to helping people heal themselves, increase vitality, cultivate spiritual growth by complementary and alternative medicine. I am currently working on the research of the comparing Traditional Chinese Qigong with Biofeedback therapy for psychosomatic disorders and other medical problems as postdoctoral fellow in psychophysiology lab at UMDNJ. I am also training the faculty and staffs learning Qigong practice in medical school and treat the patients by Qigong therapy. I believe that Traditional Chinese Qigong is one of the Complementary and Alternative Medicine that is very helpful for Americans in the future.

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002. testimony	Tsao-Lin Moy (partial) (5 pages)	01/23/2001	b(6)

COLLECTION:
Federal Records
White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

OA/Box Number: 43232

FOLDER TITLE:
WHCCAM Meeting Testimony, January 23, 2001 [4]

2011-0568-S
kc825

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[002]

Tsao-Lin E. Moy, LMT
(b)(6)
New York, NY 10038
(b)(6)
Email: tmoy@backessentials.com

Testimony to: The White House Commission on Complementary and Alternative Medicine Policy. January 23, 2000 – Commission Meeting on Training, Education, Certification, Licensure, and Accountability of Health Care Practitioners in Complementary and Alternative Medicine; Topic: Standards of education, training, licensure and certification in the field of Acupuncture and Oriental Medicine.

Good Afternoon Members of the Commission, thank you for your attention today. My name is Tsao-Lin E. Moy, I am a second year student at Tri-State College of Acupuncture, working towards a Master's Degree in Acupuncture and Oriental Medicine. I am also in the two year accredited Chinese Herb program. (this is a 450 hour program which prepares me to sit for the NCCAOM national exam in Chinese herbology and receive diplomat status)

I am a Licensed Massage Therapist since 1998 with a practice in NY and I assist in teaching at the Swedish Institute for Massage Therapy. In addition I have a BS in Int'l Trade and Marketing.

I will be offering the Commission testimony and insight on the standards of education in an accredited Acupuncture and Oriental Medicine program; the rigor of the program, the didactic hours, the hands on skills and supervision, observation/clinic hours, electives, human service skills and independent study.

I am passionate and committed to my education and training.
What has been most challenging for me as of student of Acupuncture and Oriental Medicine is learning to open my mind, to put aside my cultural biases and develop creative and abstract thinking.

An accredited Acupuncture and Oriental Medicine program is 3-4 years; approximately 2,200 hours of study and training.
More than 50% of those hours is devoted to hands on skills and supervision, observation and clinical experience. The remaining hours are for lectures, electives and independent studies.

[002]

Tsao-Lin E. Moy, LMT
(b)(6)
New York, NY 10038
(b)(6)
Email: tmoy@backessentials.com

The commitment to study, the hours of hands on skills, and clinical training provide an educational foundation for the theories of Acupuncture and Oriental Medicine.

I have outlined a description of coursework and hours.

First Year- 850 hours
170 hours of lecture:
Chinese philosophy provides the philosophical basis of Acupuncture and Oriental Medicine; The 5 diagnostic filters (Yin Yang, Qi/Blood/Fluids, Zang Fu, Five Elements and Meridian). Describing and distinguishing which filters a practitioner uses for arriving at an acupuncture diagnosis.

The fourteen major pathways of acupuncture energetics; including internal pathways, acupuncture points (locations and energetic functions), symptomatology and indications. The secondary vessels (tendino-muscular, divergent, luo) and the 8 Extraordinary Vessels.

Treatment planning and basic techniques and strategies; The Four Examinations, Nine Steps of Treatment Planning and Eight Principle Evaluations; pulse, tongue and Hara confirmation.

250 hours - Skills review and hands on contact: 80 hours includes palpation of meridians, point location, hara evaluation, tongue and pulse; in small supervised groups we practice basic techniques of needling, moxibustion; gua sha, cupping, auriculo-therapy and clean needle technique.
50 hours of body work training. A minimum of 20 hours of written independent patient documentation/project. 100 hours of direct patient interaction experience.

60 hours- Observation/Grand rounds, Clinical Hours: As part of our clinical experience we observe and learn from senior acupuncture practitioners treating actual patients.

[002]

Tsao-Lin E. Moy, LMT
(b)(6)
New York, NY 10038
(b)(6)
Email: tmoy@backessentials.com

At Tri-state we are exposed to a unique synthesis of various traditions of acupuncture such as: Japanese, TCM, Meridian, Vietnamese, Korean and French. These practitioners include: Dr. Mark Seem, Kiiko Matsumoto, Arya Nielsen, David Legge and Dr. Richard Tan.

These practitioners are long time leaders in the field of Acupuncture in the U.S. and have all published texts that help set the standard of education for the future Acupuncture and Oriental Medicine provider in the US.
The students in the Chinese Herb program are taught by Andrew Gamble, translator and editor of the Materia Medica Chinese Herbal Medicine.

70 hours – Human Service Skills:
Addressing communication and evaluation skills, client – centered training, patient / practitioner and professional training for clinical encounters.

90 hours – Independent Study Project:
Monthly workbooks, personal journals, and writing and research assignments.
170 hours – Anatomy & Physiology, Pathophysiology
40 hours – Electives

Second Year – 635 hours:
170 hours lecture:
We learn in depth the fundamentals of Chinese physiology and how that physiology may be used to trace the etiology of a disharmony. A much deeper understanding of the philosophical basis of Acupuncture and Oriental Medicine is applied to recognize signs and symptoms, and learn appropriate treatment strategies in each individual case rather than just memorizing a set of points for a text book pattern.

100 hours - Skills review and hands on contact:
In small supervised groups we learn and practice needling protocols through the meridian/zang fu, 5 elements and TCM diagnostic filters.

Tsao-Lin E. Moy, LMT
(b)(6)
New York, NY 10038
(b)(6)
Email: tmoy@backessentials.com

[002]

135 hours- Observation/Grand rounds, Clinical Hours: Clinical Observations and Grand rounds become core to our learning experience. Following and documenting the treatment strategies and protocols used by senior acupuncture practitioners, gives us further understanding and insight into clinical application of Acupuncture and Oriental Medicine.
70 hours – Human Service Skills
90 hours – Independent Study Project
40 hours – Electives
30 hours – Pathophysiology

Third Year – 720 hours
In the third year, the training, knowledge and experience in Acupuncture and Oriental Medicine comes to fruition. Students take the NCCA exams.
Influenced by various traditions in acupuncture, students are encouraged to develop their own style. A deeper understanding and clinical knowledge is applied in clinical rotations. Students plan treatment strategies and treat patients in Clinic under the supervision of senior acupuncture practitioners. Having access to senior practitioners for advice in clinic is an invaluable clinical experience.

120 hours Lecture
55 hours Field Seminars
100 hours Skills Review
85 hours Grand rounds/ Clincal hours
250 hours Clinical Practicum
90 hours Independent Study Project
20 hours Supervision.

The Tri-State Acupuncture and Oriental Medicine program is representative of the standard of education in an accredited program and the minimum requirement to practice as a competent provider of Acupuncture and Oriental Medicine.

[002]

Tsao-Lin E. Moy, LMT
(b)(6)
New York, NY 10038
(b)(6)
Email: tmoy@backessentials.com

Recommendations to the Commission:

1. I recommend that the Commission look to the existing creditialing bodies for guidance, and support the standards of education in Acupuncture and Oriental Medicine that have been established by the NCCAOM, ACCAOM and the State Education Dept of NY.

2. I recommend that the Commission not support abbreviated training programs, that these greatly diminish existing standards of competency and training; and ultimately diminish the quality of care available to the general public.

Thank you for your time today, I am available for follow up and assisting the Commission with further inquiry and documentation.

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003. testimony	Kathleen Golden (partial) (1 page)	01/23/2001	b(6)

COLLECTION:
Federal Records
White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

OA/Box Number: 43232

FOLDER TITLE:
WHCCAM Meeting Testimony, January 23, 2001 [4]

2011-0568-S
kc825

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[003]

KATHLEEN A. GOLDEN, L.Ac.
(b)(6)
New York, NY 10027
(b)(6)

January 23, 2001

Testimony to: The White House Commission on Complementary and Alternative Medicine Policy, Topic: Standards of Education in the Profession of Acupuncture and Oriental Medicine.

Good afternoon members of the Commission, thank you for your attention today. My name is Kathleen Golden; I am a licensed provider of acupuncture and Oriental medicine in New York State. I am here to represent the Acupuncture Society of New York (ASNY). ASNY is a professional organization representing the interests of practitioners and patients in New York. I maintain a private acupuncture and Oriental medicine practice in New York City. I am on the faculty of the Tri-State College of Acupuncture (NY), and have taught for other colleges of Acupuncture and Oriental medicine in New York. In addition to private practice and education, I have a background in public health. I have supervised acupuncture services in addiction rehabilitation programs and have worked as a provider of acupuncture and Chinese herbal medicine in an AIDS day treatment program for seven years.

For approximately thirty years, the acupuncture and Oriental medicine profession in this country has worked diligently to create high standards of education for the preparation of the practice of this more than two thousand year old form of medicine. There are three main national regulating bodies that create the foundation for educating the prospective professional. These organizations are: The Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM), The Council of Colleges of Acupuncture and Oriental Medicine (CCAOM) and the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM). These organizations have evolved the programs and national qualifying exams that are the basis for achieving entry-level status into the profession.

The national minimal standards for licensed acupuncture training require a three year master's level professional program of at least 1,725 hours, passage of the NCCAOM national exam in acupuncture or Chinese herbal medicine, demonstration of competency in point location and clean needle technique. In New York and many other states, schools exceed the 1,725 hours. In many cases the training will approach 3,000 hours. These accredited programs, draw on an international pool of the world's most experienced, talented acupuncturists and herbalists, educators and clinicians.

Once NCCAOM Diplomate status is achieved, a Diplomate is required to participate in 30 hours of continuing education with renewal of their national standing every four years.

The profession is proud of the level of education it provides for the practice of acupuncture and Oriental medicine in this country. The profession is constantly striving through internal discussion and dialogue to enhance the level of education available to the student of acupuncture and Oriental medicine. The profession is currently involved in creating the requirements for a clinical doctorate in acupuncture and Oriental medicine.

The Commission may hear testimony from other health care providers in this country that given a professional education in biomedicine, chiropractic, nursing, physical therapy or podiatry, and the many hours spent practicing the chosen medical art, that this is a basis for taking abbreviated training programs in acupuncture and incorporating it into an extant practice of medicine. This is simply not true. Acupuncture is not a single or simple 'technique or modality' that can be added to a healthcare practice with an abbreviated survey-like course. It is a healthcare system, with detail, complexity and subtlety, requiring long and serious study.

It is not appropriate for an allied healthcare provider to assume that they are capable of understanding the body and depth of work that students spend three years studying simply because they are already a healthcare provider. Acupuncturists do not assume that with a survey-like course of say 300 hours, which is the average for "acupuncture certification", that he/she could begin to make diagnosis of western medical conditions, chiropractic adjustments, or provide podiatric care. It is of constant amazement to my colleagues and myself that our profession is the only healthcare profession, we are aware of, that is in jeopardy of being pillaged by extant professions.

I find it professionally and culturally insensitive that abbreviated training programs publish these words in their brochures: "...By eliminating the multitude of superfluous, non-practical concepts surrounding myth and folklore which abounds in the usual acupuncture program..." The reference to myth and folklore is an implication that the medicine so generously shared by the Chinese and carefully cultivated over thousands of years has no basis in theory. This insults a complex form of medicine based on the Dao and the early observation of nature and the interrelatedness of all things on this earth.

One abbreviated 300 hour training program claims that it will "...give emphasis to the clinical, practical aspects of Asian healing arts to include acupuncture, Chinese/Japanese herbal medicine, Qi Gong, and Tui Na." It is difficult to believe a provider could be competent in these complex subjects with 300 hours of training. It takes most providers a lifetime to cultivate expertise in any of these single practices.

I have encouraged Ms. Tsao Moy to testify here today. Ms Moy presents a unique opportunity for the Commission to gain insight into the specifics of an education in acupuncture and Oriental medicine. Ms. Moy represents the current student body preparing for entrance into the profession of acupuncture and Oriental medicine. It is clear from the many hours of study Ms. Moy and her fellow students invest in their

education, that this is not an educational process that should be "abbreviated". To do so, insults the profession and destroys the integrity of the medicine. I believe it also inhibits the hope of the student to have a whole medicine to look forward to practicing with equal opportunity for an equitable livelihood.

Acupuncture should not be subjected to a diluting process so that healthcare providers can tack on an additional charge to a medical bill. Because the American public pursues acupuncture and Oriental medicine as part of their healthcare, does not mean the profession should be adulterated for the convenience of providers. The American public deserves access to the finest the medicine has to offer, not what can pass for treatment. It is not a question of 'do no harm', it is that acupuncture and Oriental medicine has much to offer and should be offered as a whole, not piecemeal.

All medical professions excel at dealing with specific issues. I think individual professions should cultivate the finest that their particular profession offers. When one is in a car crash one wants a well-trained ER doctor, if one wants a spinal adjustment one wants a well-trained chiropractor. If one is looking for treatment by an acupuncturist, one wants the provider with the most education and clinical experience available, not the one who took a quick survey course. The differences in medical care available in this country should be applauded as freedom of choice, and should continue to be cultivated in their own right.

Recommendations to the Commission:

- Recognize the existing national education standards for the safe and effective practice of acupuncture and Oriental medicine that have been established in this country by the ACAOM, CCAOM and NCCAOM.

- ASNY encourages the Commission to support the profession in it's belief that anyone wishing to practice acupuncture and Oriental medicine be required to complete a training program that is closely modeled after the extant accredited programs that currently exist for competent entry level into the profession.

- That the Commission support the 'wholeness' of the medicine of acupuncture and Oriental medicine, and resist the political pressure that is applied in this country to 'piecemeal' the profession.

- That the Commission acknowledges the richness of this medicine and the generosity of the people of China to share this medicine with the people of the United States. That the Commission resist the use of continued cultural insensitivity that makes up a portion of the argument that allied healthcare providers use to substantiate their insistence that 'abbreviated' training programs are a valid form of education for providers in this country.

- That the Commission support the many students currently enrolled in Oriental medicine colleges in this country in having a 'whole 'medicine to practice when they graduate, and that they are fairly remunerated for their work.

Thank you for your time here today. As always, ASNY (914-923-0632) remains available as a resource for the Commission in pursuing its important work.

January 23, 2001

James S. Gordon, M.D.
Chairperson
White House Commission on Complementary and Alternative Medicine Policy
6701 Rockledge Drive
Suite 1010 MS-7707
Bethesda, Maryland 20817-7707

Dear Dr. Gordon,

As a physician and board member of the American Society of Acupuncture, I would like to comment on the education and training of health care practitioners in Complementary and Alternative Medicine.

As part of a physician's training, they complete of four years of graduate level medical training and four years of post-doctoral level training. This amounts to a minimum of 35,000 hours studying the human body and its processes, based on a conservative estimate of twelve hours a day over a period of eight years. Additional continuing medical education credits are also mandated by state and local agencies as minimum requirements for maintenance of good standing and licensure. Furthermore, physicians and dentists are required to complete 300 hours of training as a minimum for certification specifically in acupuncture alone, as well as recommendations by component societies for continuing education. It would be somewhat disingenuous to take the position that prior medical training is without significance with regard to the understanding and practice of C.A.M.

New York State was the first state to set standards regulating the practice of acupuncture for physicians and dentists. In 1972, the New York Society of Acupuncture was the first professional organization designed to provide comprehensive training in acupuncture, both didactic and clinical to physicians and dentists who wish to incorporate this modality into their practices.

Therefore, I feel that physicians who have completed designated training are more than qualified to provide not only safe but efficacious care in the area of C.A.M., and are better able to bridge the gap between eastern and western medical practices, which in concert provide the most comprehensive approach to medical care with the greatest benefit to society.

Sincerely,

Donald D'Angelo, M.D.
American Society of Acupuncture

TESTIMONY OF ARNOLD GORE, CONSUMERS HEALTH FREEDOM COALITION TEL.212-795-6460 EMAIL arnoldgore@mindspring.com

There are not enough doctors with an MD who practice Complementary and Alternative Medicine (CAM). Although New York State has a law providing that doctors should not risk losing their license just because they practice non conventional therapies or use treatments that are not the orthodox standard therapy. The office of Professional Medical Conduct (OPMC)has not observed this law, although the law has been on the books now for six years, and should be known to the entire staff of OPMC. As a result young doctors starting out are somewhat hesitant to risk their reputations and careers if it will cause professional and legal problems that could be avoided by wearing blinders and "keeping your head down". In order for CAM to gain wider acceptance there must be more physicians who are willing to recommend and use some of the more controversial treatments that directly compete with conventional treatments. Chelation therapy for Heart Disease has been shown conclusively to be safer and more effective than the conventional treatments such as Coronary Bypass Surgery and Angioplasty. The latter treatments remain a profit center in the economics of most hospitals.

Diet and Exercise have been shown to be effective in the treatment of Diabetes, but is not often used and New York State regulators are currently violating the Alternative Medical Practice Act by bringing a case against a doctor for using this medically and scientifically documented treatment even after they have been provided with this documentation.

The *Journal of the American Medical Association* of April 15.1998 published a study highlighting the dangers of prescription drugs. The researchers, analyzing published data reported that 2,216,000 patients suffered adverse drug reactions requiring hospitalization and 106,000 patients admitted to hospitals from these reactions died. These figures understate the problem in that it only covers those admitted to hospitals. Many did not go to hospitals after their adverse reactions.
There should be a source of information on natural vitamins,minerals and herbal substitutes for FDA approved prescription drugs, which are usually laden with dangerous side effects and are usually only marginally effective in alleviating the symptoms they were designed to fight. It is very rare for a prescription drug to actually reverse or cure the underlying cause of the symptoms.

The Health Insurance Industry and the Medicare program should be encouraged to make available materials showing patient-subscribers materials showing how safer more natural vitamins, minerals and herbs can be substituted for more dangerous and expensive prescription drugs. In order to avoid the appearance of only being interested in the cost savings, I would like to suggest that they refer patient-consumers to the websites of such respected Medical Doctors as Dr.Andrew Weil, www.drweil.com or Dr.Julian Whitaker, www.drwhitaker.com For research on herbal medicines they can look up www.herbweb.com or www.botanical.com or The American Herbal Pharmacopeia, www.herbal-ahp.org

The benefits can result in more appropriate health care with less complications of adverse drug reactions. The resultant savings to patients and third party payers could be significant and will in any case be far exceeded by the increase in health benefits realized by the people who substitute safer natural therapies for their prescription drugs.

If the Medicare System reimbursed patients for use of vitamins, minerals, herbs and other dietary supplements they would be even more widely used and would save on medical costs. European Countries reimburse for some herbal remedies that are widely accepted as treatments,particularly in Germany.

The most significant advancement in the treatment of Cancer has been made by Dr.Stanislaw Burzynski,MD of Houston,Texas. He has been in FDA clinical trials for over four years, and has reported fantastic results, but FDA has not seen fit to grant approval of his antineoplastons as a new drug which can be prescribed by all physicians. This fact is a disgrace to the integrity of the Drug Approval Process and undermines the patients' faith in the honesty and integrity of the Drug approval process. Something must be done to expedite this. Dr.Burzynski's most notable successes has been treating difficult brain cancers.

His antineoplastons are in FDA sanctioned clinical trials for varying cancers. Website www.cancermed.com you can link to a patient group that did well on the treatment and is willing to speak about its benefits at www.burzynskipatientgroup.org.
The detailed protocols for each of the clinical trials is on his website www.cancermed.com click on clinical trials for the 72 FDA supervised protocols .
The latest report of FDA supervised Phase 2 clinical Trials of Antineoplastons A10 and AS2-1 that I received in September 2000 included 35 evaluable patients diagnosed with glioblastoma multiforme(39% of patients),anaplastic glioma(36%),low grade glioma (14%),PNET(8%) and malignant meningioma (3%).
In the CAN-1 results of 35 evaluable patients of 43 results improved slightly some movement from partial response to complete response

Complete Response-CR	25.7%
Partial Response-PR	22.9
Stable Disease-SD	31.4
Objective ResponseCR+PR	48.6
Positive Resp CR+PR+SD	80
Progressive Disease	20

In Medullablastoma(PNET) in children under 12-2 protocols, The kind Thomas Navarro, a 5 year old, with national publicity to get FDA approval for antineoplaston treatment.

Objective Response CR+PR	33.3%
Stable Disease- SD	33.3
Progressive Disease	33.3

Other trials consistently show at least 60-70% positive response according to National Cancer Institute criteria. Other results are on the patient group website

CHARLES GANT MD PHD

I have been licensed to practice medicine in New York and have practiced orthomolecular medicine and CAM[1] for twenty years. Over three years ago, my drug-free, successful treatments of ADHD[2] were widely publicized. The New York State Office of Professional Conduct[3] subsequently launched an investigation[4] of my practice. Since then I have endured two interrogations, an office raid, charges of negligence, incompetence and fraud and eight months of hearings. My family and I have suffered enormous economic and emotional stress. Were it not for the prayers and support I have received, the gratifying effects of orthomolecular treatments in healing my grateful patients, good lawyers and expert witnesses who have generously allowed me to defer my economic debt and a spiritual basis for my life, I could not have survived this hell.

During the office raid, the OPMC seized nine charts from which charges were drawn up. Six of those nine patients eventually followed through with my CAM orthomolecular care and have had good outcomes. A patient's prostate cancer was reversed and arrested. A patient with disabling, severe fibromyalgia is relatively pain-free and has the energy to work again. A vegetative, severely autistic child has been educationally mainstreamed. A child with juvenile rheumatoid arthritis is medication free and mostly asymptomatic. A teenager with chronic sinusitis and migraines on nine medications is off medication and has fewer headaches. Another teenager with chronic, severe gastritis and colitis is well.

---

[1] **C**omplementary and **A**lternative **M**edicine
[2] Attention Deficit/Hyperactivity Disorder
[3] The Office of Professional Medical Conduct (OPMC) is a division of the NY State Public Health Department.

MEDICAL CENTER EAST • 5900 N. BURDICK ST., #205 • E.SYRACUSE, NY • 13057
PHONE: 315-656-7060 • FAX: 315-656-7736

The OPMC has broken New York State law[5] in many areas:

1) Education Law, Section 6527, subsection 4e[6] basically says that a physician can't be prosecuted for CAM care if it works. My CAM care worked but I was prosecuted for it anyway.
2) Section 230, subsection 6 of the Public Health Law[7] states that my jury "shall consist of two physicians and one lay member." The panel assigned to my case consists of two physicians and a physicians assistant[8]!
3) Public Health Law Section 230, subsection 10(a)(ii)[9] indicates that "medical experts (who practice CAM) shall be consulted" during investigations. Only conventional physicians, who have little understanding of CAM, were consulted during my investigation.
4) My charges concern the "care and **treatment**" of nine patients for indefinite periods of time. But when it became obvious CAM care "effectively **treats** human disease[10]" in six of the nine patients, the state has tried to block admission of this evidence and alters the charges as the case proceeds.

---

[4] Under the law in New York State, the origin or source of a complaint against a physician is deemed confidential, so one is never aware of, much less faced by, their accuser.

[5] The Alternative Medical Practices Act (Chapter 558 of the laws of 1994) made changes to both the Education Law (Section 6527) and the Public Health Law (Section 230).

[6] "This article shall not be considered to affect or prevent the following: (subsection e.) The physician's use of whatever medical care, conventional or non-conventional **which effectively treats human disease, pain, injury, deformity or physical condition**."

[7] "Any committee on professional conduct appointed pursuant to the provisions of this section shall consist of **two physicians and one lay person**.

[8] For all practical purposes, a physicians assistant functions as a physician, ordering diagnostic lab testing, performing physical exams, taking histories and prescribing drugs. A physicians assistant could never be considered to be a "lay person" as is mandated by this law.

[9] Public Health Law Section 230, subsection 10(a)(ii) states "if the investigation of cases referred to an investigation committee involves issues of clinical practice, **medical experts shall be consulted**. Experts may be made available by the State Medical Society of the State of New York, by county medical societies and specialty societies, and by **New York state medical associations dedicated to the advancement of non-conventional medical treatments**."

[10] Education Law, Section 6527, subsection 4e.

A recent article in the Journal of the American Medical Association[11] suggested that conventional medicine itself is the 3rd leading cause of death[12], resulting in one quarter of a million deaths per year[13] - deaths mostly from mistake-free, medical interventions conforming to accepted standards of care. CAM is conventional medicine's answer but what prevents conventional physicians from adopting CAM technologies? The chilling effect of prosecutions like mine is the primary deterrent to physicians. CAM will never be melded with conventional medicine until healthcare professionals are free to practice CAM without fear of unwarranted investigation and prosecution. And even if protective legislation is passed, there must be provisions dedicated to upholding existing law with clear punitive consequences for healthcare regulators who place themselves above the law.

---

[11] JAMA, July 26, 2000-Vol 284, No. 4, pp. 483-485.

[12] Behind cardiovascular disease (1st leading cause of death) and cancer (2nd leading cause of death).

[13] This calculates to approximately one death every 2 – 3 minutes in the US.

THE CORSELLO CENTERS
for
Preventive-Integrative Medicine

January 23, 2001

Dear Chairman and Honorable Members of the CAM Commission,

I am glad to have been given the opportunity to present to you my 15-year long struggle to keep my license to practice medicine. I am a 68-year-old physician – I came from Italy 39 years ago - and after the many steps to legally practice medicine in this country, I began my wonderful journey as a physician. I have been practicing medicine for about 40 years; yet have never harmed a patient.

In 1992 I was one of the twenty-five physicians *honored* to be asked by the National Institute of Health to set the structure of what is now called the Center For Alternative-Complementary Medicine.

Twenty years earlier, in 1972, I had made the conscious decision to use as little pharmaceutical products as possible, in favor of *non-toxic natural interventions*.

I then began to encounter the scorn of my colleagues, but nothing prepared me for what was soon to come. For the past 15 years, organized medicine has brought me in front of their notoriously biased tribunal several times. I have spent untold amounts of energy and money to protect my patients right to receive safe and effective treatments. I believed then, and still do, that synthetic chemicals are often toxic and dangerous.

This past May, the OPMC went for my jugular! My attorney informed me they wanted to take my license!

Since then, the OPMC has done nothing but defy the 1994 New York State Alternative Medical Practice Act.

200 WEST 57th STREET
NEW YORK, NY 10019
Tel: 212/399-0222 • Fax: 212/399-3817

175 EAST MAIN STREET
HUNTINGTON, NY 11743
Tel: 516/271-0222 • Fax: 516/271-5992

They *intentionally disobeyed* this New York State law by going after a number of New York alternative physicians, including myself.

They continued to defy the law, when they had a mainstream physician, *who admitted to not understanding any of the alternative treatments*, review my case! When I requested review by an alternative physician, *they flatly refused*!

Finally, a Supreme Court Judge, alarmed by the *lack of due process*, halted the OPMC trial with an injunction. The OPMC then tried to over-ride the Supreme Court Decision. The judge was shocked and out-raged by their disobedience and total disregard for the law, and reaffirmed the Stay Order.

It is extremely important for all of you to realize that *at stake*, is not only our licenses to practice non-toxic and effective medicine, but the *ability of the consumers to access the medicine of their choice*. A promise of access and choice is meaningless if it is thwarted by the State bureaucracy.

I believe the OPMC is a "runaway agency" that needs to be reformed to comply with the intent of the 1994 Health Law. Their purpose should be that of protecting the public against incompetent physicians, not to restrict the practice of medicine they do not yet understand!

Another compelling issue is that of the antipathy of the medical *insurance* industry against Alternative Medicine. I am told that they spearhead a good number of disciplinary actions. Their ***minimalist*** approach to testing is in stark contrast to our comprehensive and humanistic view of medicine for which Americans (much to the insurance company's chagrin) are willing to pay out-of-pocket.

I thank you very much for your kind attention.

Respectfully,

Serafina Corsello, M. D.

Serafina Corsello, M. D.

Barbara Sarah, C.S.W. White House Commission on Complementary Medicine
January 23, 2001

I address today you wearing three hats: one as the co-chair of the National Association of Oncology Social Workers Complementary/Alternative Medicine Special Interest Group, the second as the chair of the Complementary Medicine Committee and the Coordinator of the Oncology Support Program at Benedictine Hospital in Kingston, NY and third as an eight and a half year breast cancer survivor.

Wearing my first hat, I am in contact with professional oncology social workers from around the country who are being flooded with questions from patients about what CM treatments and procedures to pursue. This is especially true at that point in time when they have to make decisions about whether to conform to conventional treatments only or after conventional treatment is finished and they want to be able to do something to maintain good health.

In my second hat, I am working at a small upstate New York hospital where doctors and patients alike need more information to stay up-to-date with current research and practice. Our hospital wants to set up a CM center and we want to be able to offer our patients reliable services to help them stay healthy. Consistently, the most popular of my support group programs is our regular Complementary Medicine Discussion Group, where patients share information and practitioners come to make presentations. People are hungry for information yet I have to post disclaimers before our presenters speak, because I cannot necessarily endorse the information that is offered.

In my third hat as patient, I made a decision following my lumpectomy and axillary node dissection and after doing research and asking a lot of questions, not to do the conventional adjuvant treatments of chemotherapy and radiation that were recommended. I did do acupuncture and yoga, mistletoe and supplements. I began to meditate, got involved in an immune system study at a medical center. I altered my diet. I changed jobs and began working as an oncology social worker and became a passionate breast cancer advocate /activist. I became a personal example of the use of CM.

In all three roles I face daily a quagmire of information about Complementary Medicine: doctors, patients, other healthcare professionals and I, myself, have questions about the reliability of information flooding us from all sides. We need to have regular contact with a trustworthy, scientific national source that evaluates and promulgates this information and makes it available to us on a regular basis. We need doctors who are educated about the use of CM and who can spread the word to their colleagues. Patients are reluctant to tell their doctors about their use of complementary medicine because so many doctors have insufficient training on the subject. We need up-dates on CM through the Internet or hard-copy bulletins to other healthcare professionals such as social workers and nurses. They are the people who are in daily contact with patients who are desperate for information. We also need well-informed patient advocates who can pass information along to patient groups.

I propose that a Complementary Medicine Advocate Corps be established composed of designated educated and trained representatives from the above mentioned groups who would be regularly up-dated by the National Office on CAM on current research. These people could then disperse this information to their respective networks through existing publications, e-mail lists and gatherings of their special interest groups. Let's enlist those of us on the front lines to get that accurate information out to the public through a organized system of networking.

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
004a. testimony	Jennifer Daniels (partial) (1 page)	01/23/2001	b(6)

COLLECTION:
Federal Records
White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

OA/Box Number: 43232

FOLDER TITLE:
WHCCAM Meeting Testimony, January 23, 2001 [4]

2011-0568-S
kc825

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[004a]

Jennifer Daniels, MD/MBA
3100 South Salina St.
Syracuse, New York 13205

315-475-3393 office 315-475-2524fax (b)(6)

3 minute NIH speech.1/23/01

Thank you very much for inviting me to speak today.

I would like to share with you some suggestions for policy changes that, if made, would make it possible for me to do my work of helping people get well through complimentary and alternative medicine.

I am presently undergoing investigation in New York by the department of Professional Medical Conduct for getting a patient better. I advised a Vegan diet and exercise for a diabetic. His blood sugar fell from 465 to 138. He became noncompliant, his blood sugar became high and he sought care at an emergency room.

My office is presently closed as my defense requires too much of my time and it is too big a financial liability to expose myself to continued investigation as insurance only covers the first $25,000 of legal fees. This investigation has been 20 months and $35,000 so far and I still do not know what OPMC feels I did wrong.

I learned that OPMC is simply above the law. There exists no mechanism to determine if OPMC is following the law or to enforce public law where OPMC is concerned. OPMC is exempt from rules of evidence; can admit or exclude any information they please and reach conclusions that are not supported by the evidence that they have agreed to admit.

I.
OPMC SHOULD BE BOUND BY THE RULES OF EVIDENCE. This would make hearsay inadmissible and relevant facts admissible.

II.
DELIBERATIONS SHOULD NOT BE HELD IN SECRET. A shroud of secrecy merely permits the guilty to be exonerated and the innocent to be convicted. It does not ensure the safety of the public; Quite the opposite.

III.

A Physician under investigation by OPMC should be able to request review by a 3 MEMBER COMMITTE whenever it is felt that OPMC is violating a law. This committee should be COMPOSED OF A LAY PERSON , AN ATTORNEY with extensive malpractice experience and an ELECTED OFICIAL. It should not be under the control of the health Department . Public Law 230 is written on paper and believed to govern OPMC. After 20 months of litigation, I found that this whole body of law is disregarded and OPMC acts as it wishes. A few lawyers have enough experience with OPMC to know how they customarily proceed in certain situations. But , OPMC can and does change its patterns from time to time.

IV

The purpose of OPMC is to protect the public health by disciplining doctors. OPMCs JURISDICTION SHOULD BE LIMITED TO CASES OF PATIENT HARM.This provides an objective standard of when a matter is the jurisdiction of OPMC. It is inappropriate for OPMC to uphold the standard of care. This is the job of Specialty societies who issue Board certification based on examinations. Medical knowledge has a half life of 2 years. This means that in 10 years, 97% of the methods or drugs that we now use will no longer felt to be safe and effective according to the standard of care; 97% of today's rulings would not serve the long term benefit of patient health. In good conscience then, we have to acknowledge a more enduring standard; patient harm. Further, 75% of Iatrogenic deaths are caused by doctors who adhere to the Standard of Care; see attachment. Physicians and patients need the flexibility to deviate from the standard of care when such deviation causes no harm.

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
004b. letter	Jennifer Daniels (partial) (1 page)	nd	b(6)

COLLECTION:
Federal Records
White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

OA/Box Number: 43232

FOLDER TITLE:
WHCCAM Meeting Testimony, January 23, 2001 [4]

2011-0568-S
kc825

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[0046]

OPEN LETTER OF APPEAL ON BEHALF OF Dr. Jennifer Daniels.
An African– American Physician who offers Complementary and Alternative options to her patients

For 10 years, Dr. Jennifer Daniels had a thriving financially profitable practice in a medically underserved, poor, predominantly minority area of Syracuse 10 blocks from where she grew up. She and her 3 children live 2 blocks from her office.

Education
Dr. Daniels graduated Cum Laude from Harvard-Radcliffe in 1979, received her Medical Degree from The University of Pennsylvania, and concurrently received an MBA from The Wharton School in 1983.

She returned to Syracuse, purchased a city block and built her medical office.
She has been active in the community. Her efforts have resulted in streets paved, abandoned houses torn down, stopping a 30million dollar bond issue that would have raised property taxes and transferred money from the education budget to private developers, reduced drug trafficking and many other community benefits.

Dr. Daniels has an exemplary medical reputation. She has privileges at 2 area hospitals, no record of ever being sued for malpractice and is Board Certified in Family Practice.

20 months ago she came under investigation by the New York State Office of Professional Medical Conduct for recommending a Vegan diet and exercise to a diabetic .The patient got better under her treatment but became ill once he stopped the diet and exercise. He was treated at an area hospital He is alive and well.

$35,000 , 20 months later with a closed practice, she is now faced with an intractable agency and no adequate legal defense due to the unwillingness of the local legal establishment to take on the state of New York.

It is my hope that you can assist her in 2 areas that are immediately pressing; Referral to a trial lawyer willing to take on the state of New York and any contribution to her defense fund.

Her case is winnable. Thousands of New Yorkers do not receive alternative options from their Physicians due to fear of financial ruin, destruction of their practice, and a prolonged investigation such as Dr. Daniels is experiencing. If Dr. Daniels' case were sustained, access to alternative therapies would improve.

If you would like more information or wish to offer assistance of any kind, please contact Dr. Daniels at:

Jennifer Daniels MD/MBA - 3100 S. Salina Street - Syracuse, New York 13205

315-475-3393 Office 315-475-2524 FAX (b)(6)

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
004c. resume	Jennifer Daniels (partial) (1 page)	nd	b(6)

COLLECTION:
Federal Records
White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

OA/Box Number: 43232

FOLDER TITLE:
WHCCAM Meeting Testimony, January 23, 2001 [4]

2011-0568-S
kc825

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[004c]

JENNIFER DANIELS

Work:
F ily Medicine
3100 S. Salina St.
Syracuse, NY 13205
(315) 475-3393
Fax (315) 475-2524

Home:
(b)(6)
Syracuse, NY 13205
(b)(6)

EDUCATION

UNIVERSITY OF PENNSYLVANIA, SCHOOL OF MEDICINE, Philadelphia, PA 1983
Doctor of Medicine
Concentration in clinical medicine with emphasis on primary care. Clinical training included rehabilitation, mental retardation, alcoholism, pediatrics, and internal medicine.

Activities:
o Student member of Medical School Long Range Planning Finance Subcommittee
o Class Representative to Student Government

THE WHARTON SCHOOL, GRADUATE DIVISION, Philadelphia, PA 1983
University of Pennsylvania
Masters of Business Administration
Concentrating in Health Care Administration. Courses included health care financing, organization of health care, and legal aspects of health care.

Honors:
o McGraw Scholarship
o Henry Kaiser Family Foundation Prize

HARVARD-RADCLIFFE COLLEGE, Cambridge, MA 1979
A.B. Cum Laude, Biology Major

Honors:
o Radcliffe National Scholar
o National Merit Achievement Scholar
o Dean's List

PROFESSIONAL CERTIFICATIONS/MEMBERSHIPS

Medical - 1989 to present
Licensed to Practice Medicine and surgery in Pennsylvania, New York, Wisconsin
Advanced Cardiac Life Support (ACLS) Certification
Advanced Trauma Life Support (ATLS)
rican Medical Women's Association, Branch 18, Vice President
rican Medical Association
rican Association of Family Physicians
New York State Medical Society
Association of Clinicians of the Underserved
National Health Service Corps Alumni and Support Network
Southern Poverty Law Center
International Center of Syracuse
rican Medical Association Physician Recognition Award, 1991 to 1999
Board Certified, Family Medicine 1992-1999

EXPERIENCE

FAMILY MEDICINE, Syracuse, NY March 1991 - Present
Physician, Owner Solo practice providing general medical care for patients of all ages. Hospital privileges at Community General Hospital and Crouse Irving Memorial Hospital.

HILLBROOK DETENTION CENTER, Syracuse, NY April 1991 - Present
Physician. Responsible for routine physicals and general medical care for detainees.

HUTCHINGS PSYCHIATRIC CENTER, Syracuse, NY 9/90 - 12/93
Medical Specialist I. Responsible for general medical care of psychiatric patients in building #2. Supervise 2 nurse practitioners, Part - time

SYRACUSE CITY SCHOOL DISTRICT, Syracuse, NY 9/91 - 9/92
School Physician. Responsible for routine physicals for students at 6 elementary schools.

PHP, LAFAYETTE HEALTH CENTER, Lafayette, NY 8/89 - 1/91
Contract Physician. Provide general medical care for patients of all ages. Part - time

ST. JOSEPH'S FAMILY PRACTICE RESIDENCY, Syracuse, NY 4/88 - 7/90
Family Practice Resident. Clinical training in pediatrics, OB/GYN, and medicine to prepare for Board Eligibility in Family Practice

FORT TOTTEN INDIAN HEALTH SERVICE CLINIC, Ft. Totten, ND 1/87 - 3/88
Clinical Director and Physician. Provided general medical care for patients of all ages; supervised 2 physicians, 2 physician extenders, 3 nurses, 3 laboratory technicians, 2 pharmacists and 1 radiology technician.
- o devised plan to prevent UTI treatment failures
- o completed cost benefit analysis for H-Flu vaccine which prompted Health Service to provide vaccine
- o co-ordinates resolution of JCAH pre-survey deficiencies
- o implemented 24 hour coverage by telephone for patient problems

LAC COURTE OREILLES COMMUNITY HEALTH CENTER, Hayward, WI 3/85 - 12/86
Medical Director, provided general medical care for patients of all ages; supervised 2 nurses, 1 pharmacist, 1 receptionist, 1 lab/x-ray technician, 1 medical records clerk, and part-time physicians.
- o developed and implemented standards resulting in JCAH accreditation of health center
- o organized and operated diabetes clinic
- o increased patient volume from 10 patients per day to 35 patients per day

concurrent part-time employment ...EMERGENCY PHYSICIAN

SPECTRUM EMERGENCY, INC.
Hayward, WI

NATIONAL EMERGENCY SERVICES
Stanley and Woodruff, WI

ROLLING HILL HOSPITAL, Philadelphia, PA 7/84 - 3/85
House Physician. Responsible for patient evaluations and emergencies; discharge evaluations in same day surgery unit; employee clinic; codes; intensive care unit minor procedures; pre-employment, pre-admission, and annual physical exams; supervising physicians' assistants.

EXPERIENCE

ROLLING HILL HOSPITAL, Philadelphia, PA 7/84 - 3/85
Physician Reviewer. Member of Utilization Review Committee; Perform retrospective review of cases for which insurers wish to deny reimbursement; Perform concurrent review as part of internal quality assurance program; Assist attending physicians in documentation of medical necessity of patients' care.

CHESTNUT HILL HOSPITAL, Philadelphia, PA 6/83 - 6/84
Transitional Resident. One year residency program focusing on primary care with experience in ambulatory and in-patient management of pediatric, gynecological, adult and emergency medical problems.

THE GRADUATE HOSPITAL, Philadelphia, PA 5/82 - 11/82
Administrative Representative
o Resolved operational problems as they arose during weekends
o Submitted detailed incident reports which served as the basis for policy revisions

Administrative Resident
o Performed feasibility study to determine the Graduate Hospital's participation in State sponsored prepaid Medicaid reimbursement plan.
o As acting chairman of the Hospital Association of Pennsylvania (HAP) Subcommittee on Alternative Delivery Systems, led site visits to Boston, Pittsburgh, and Minneapolis/St. Paul. Evaluated Medicaid HMO's, hospital-based HMO's, Medicaid fiscal intermediary, self-insured business, and business coalitions. Submitted written reports which served as basis for formulating strategy to cope with lower funding levels in health care.

VETERANS ADMINISTRATION MEDICAL CENTER, Philadelphia, PA Spring 1982
Consultant. Analyzed reporting procedures in hospital laboratory system. Made recommendations to assure the timely processing of specimens and prompt communication of test results.

HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA, Philadelphia, PA Summer 1980
Student Researcher, Department of Gastroenterology, Developed experimental protocol,performed research, recorded data, analyzed data and composed abstract for publication. Title: Quantitative Morphometrics of Hepatomegaly in Mice With Hemolytic Anemia.

SOUTHWESTERN COMPANY, Nashville, TN 1976 - 77
Student Manager of Sales. Recruited salesmen to sell books door to door; conducted sales training sessions, advised, assisted and managed salesmen as they worked.

SELF-EMPLOYED Summer 1977
Door-to-Door Salesperson. Established business selling books door to door in Dayton, Ohio. Maintained inventory, sales delivery and cash flow records associated with $12,000 in retail sales.

HARVARD STUDENT AGENCIES, Cambridge, MA 1976
Assistant Manager, Catering Division. Interviewed, hired, trained, and coordinated personnel staff of ninety bartenders.

SELF-EMPLOYED Summer 1976
Established business selling books door-to-door in Scottsdale, AZ. Maintained inventory, sales, delivery and cash flow records associated with $5,600 in retail sales.

AWARDS RECOGNITIONS AND ACCOMPLISHMENTS

Medical

o Purchased vacant city block in medically underserved area of Syracuse, constructed a medical office building and started a solo family practice 1990.

o Abstract of research accepted for publication by the American Association for the Study of Liver Diseases (AASLD) 1980

o Represented published abstract at poster session of annual meeting of the AASLD in Chicago, IL 1980

Business - 1977 Southwestern Company, Nashville TN

o Gold Seal Award for selling books door-to-door for more than eighty hours each week

o Super Star Award for giving more than thirty presentations daily

o Growth Award for increasing personal sales by more than $6,000 in two consecutive summers

o Salesmanship Award for selling more than $2,000 of merchandise in one week.

Community Service Awards

o Community Impact Award, The Constitution (Newspaper), 1991

o Trailblazers in Community Medicine, Unsung Heroine Award, National Organization for Women, Central NY Chapter, 1991

o Health/Medical Award, American Muslim Community Center, Inc, Syracuse, NY 1991

o Outstanding Service to the Community, Dunbar American Legion Post #1642, 1991

o Certificate of Appreciation, Intelligent Young Minds, Youth Group at Southwest Community Center 1992

o Community Impact Award in Medicine, Syracuse Constitution (Newspaper) 1993

o Community Service Award, Daughters of Isis Aleppo Court #140, 1993

o Outstanding Contribution to the City of Syracuse, Mayor of Syracuse, 1993

o Honorary Woman of the Year, Syradaga Chapter, American Businesswomen's Assn 1993

o Recognition for participation as Active Teacher in Family Practice, American Academy of Family Physicians 1995

o Certificate of Appreciation, Lincoln Middle School 1990

o Louis H. Stark Memorial Award, Outstanding minority contribution to American Heart Association 1995-6

o Marjorie Dowdell Fortitude Award, Delta Sigma Theta 1996

o Post Standard Achievement Award, Syracuse Post Standard 1996

o Spirit of American Women Award, Girls Inc. of Central New York 1997

o Dedicated Service to the Syracuse Community, Mt. Carmel 7th Day Adventist Church

o Certificate of Recognition for Outstanding Service to the Chamber of Commerce, 1998

o Community Service Award, Southside Business Association 1998

o Volunteer Award, Elmwood Elementary School 1998

o Women of Distinction Award, Governor George Pataki, 1998

o Blue Cross Blue Shield Business of the Year Award, Partners for Education and Business 1999

o Certificate of Appreciation for Dedication and Commitment to the Syracuse Community, Peoples A.M.E. Zion Church, 2000

o Certificate of Appreciation for Contribution to Reforestation of Syracuse, Mayor Roy Bernardi, 2000

COMMUNITY SERVICE

Established and funded Annual $1,000 Scholarship for graduating High School Senior 1991 - Present
Keynote Speaker, Junior Achievement of Central NY - 1991
Volunteer, Syracuse Women's Commission 1990 - 1992
Volunteer, Clinic for the homeless 1991 - Present
Volunteer, Westside Clinic, 1993
Volunteer, City of Syracuse Board of Ethics, 1991 - Present
Commencement Speaker, McKinley Brighton Grade School 1991
Volunteer, Board Member, Syracuse Model Neighborhood Corporation 1991
Volunteer, Syracuse University Health Science Center Mentor program for Minority Medical Students
Volunteer Faculty, SUNY Health Science Center, Syracuse, NY 1991 - Present
Member, SUNY Health Science Center at Syracuse, Medical School Admissions Committee, 1997-

Investigations like these destroy physicians and make safe health care unavailable to the citizens of New York. There is no insurance that one can buy to cover the burden of these investigations. Malpractice insurance covers the first $25,000 of legal bills only.

MATHEMATICAL CALCULATIONS INDICATING THAT MEDICAL CARE IS THE LEADING CAUSE OF DEATH IN THE UNITES STATES IN 1997

Calculations are for the year of 1997 as more recent figures are not available all numbers are in thousands

Cause of Death	low	medium	high
Prescription drugs	98	108[1]	198
Over the Counter drugs	0.5	12	16[2]
Hospital acquired Infections	200	250[3]	680[3]
Doctor Error/ Negligence	44	98	120[4]
TOTAL	342.5	468	1,014

There were 2.3 million deaths in 1997.

To calculate percent of deaths caused by competent doctors, I divided 98 by 468 and subtracted from 1 = 79%

The total number of Iatrogenic deaths is 468 thousand. The total number of deaths was 2,300 thousands or 2.3 million. If one divides 468 (iatrogenic deaths) by 2,300 total deaths, one finds that Iatrogenic deaths is 20 % of all deaths in 1997. Therefore, 80% of all deaths were not Iatrogenic.

Iatrogenic death appears to be the number 3 cause of death. If one then limits the definition of Cardiovascular death to heart attack, the total deaths is 465.7 thousand from ischemic heart disease.

To determine the number of deaths in any category that were not iatrogenic. one need only multiply by 0.8.

Heart attack deaths 465.7 x 0.8 = 373 deaths due to hear attack

Cancer Deaths 537.4 x 0.8 = 430 deaths due to cancer

Iatrogenic deaths is the clear winner with a total that ranges from 468 thousand to 1.014 million depending on what sources and assumptions one uses.

As staggering as these numbers appear, they do not include outpatient prescription drug deaths, hospital falls or other injuries, complications of chemotherapy, or complications of radiation therapy.

So, the numbers in the realistic column are necessarily low.

I hope this is of help to you as you write policies to govern Alternative medicine. If patient harm is used as the criteria for discipline and patient benefit the criteria for endorsement. Availibility of alternative therapies will grow.

1. ABC.News.com 4/14 - two years given.

2. This # includes arthritis drugs which kill 16,000/yr - as provided by makers of Celebrex

3. Chest 1999 March; 115 (3 supp): 349 → 415 (ISSN: 0012-3692)
2 million nosocomial infections per year 12.5 to 36% mortality.

4. National Safety council 1998; Lucian Leape M.D.

January 23, 2001

Attached are comments to the White House Commission on Complementary and Alternative Medicine Policy. Care for the Homeless wishes to thank the Commission for their invitation to present our views at this town meeting.

J. Daniel Kanofsky

J. Daniel Kanofsky, M.D., M.P.H.

Psychiatric Consultant

White House Commission on Complementary and Alternative Medicine Policy

Dr. Daniel Kanofsky, M.D., M.P.H.
Psychiatric Consultant, Care for the Homeless

January 23, 2001

I represent Care for the Homeless, a non-profit organization that sponsors health teams that provide medical and social services to 24 outreach sites in New York City. We cover a wide spectrum of facilities, including family residences, single adult shelters, soup kitchens, and drop-in centers. In 1999 medical care was provided to approximately 10,000 clients of which over 3,000 were children. Fifty-five percent of our patients had no medical insurance coverage; 43% had Medicaid coverage; 1.3% had Medicare, and 0.5% had VA insurance. Clearly Medicaid is a major determinant of what kind of medical care our clients receive.

Medicaid restraints often make providing alternative or complementary treatments a challenge. For instance, I recently evaluated a 40-year old woman from Puerto Rico who lives in a shelter with her four children. Leaving out the clinical details, this woman presents with a classical case of Seasonal Affective Disorder which is a pattern of regularly recurring episodes of winter depression seemingly caused by the dearth of sunshine in winter. Significantly, I believe this disorder led to the loss of her job, her husband and finally, her home. There is a very broad consensus among psychiatrists that the treatment of choice for Seasonal Affective Disorder is light therapy with a light box. However, New York State Medicaid will not pay the $200 needed to buy it. The only state Medicaid program which will pay for a light box is Maine. Medicaid did pay for the antidepressants, Effexor and Prozac, which gave some minimal relief and cost a little less than $200 per month. Thus, we have Medicaid spending almost $200 a month to provide an inferior treatment when this same $200 could provide an alternative treatment that is universally accepted as the preferred one and which could assist not just for one month but for many years.

Other examples of New York State Medicaid not reimbursing effective or promising alternative or complementary treatments involve the prescription policies for nutritional supplements.

Although Medicaid covers many supplements, such as vitamin C, folic acid and calcium, it will not pay for many others, such as vitamin E, omega-3 fatty acids and magnesium even though there is good evidence that these supplements can, respectively, be useful in slowing the progression of Alzheimer's Disease, stabilizing a manic-depressive disorder, and treating diabetes. Efforts to more favorably effect Medicaid coverage will permit much more of the homeless population access to alternative and complementary approaches.

Finally, more attention needs to be focused on the thousands of children living in homeless shelters, many of whom remain in the system for more than a year. These children may have nutritional deficiencies, learning problems, and psychosocial injuries that might be amenable to alternative or complementary techniques.

Healing the Patient and Healing the System: Integrating Public Health with Complementary and Alternative Medicine

Robert "Red" Schiller, MD

Chairman, Department of Family Medicine
Beth Israel Medical Center

Assistant Professor, Department of Family Medicine
Albert Einstein College of Medicine

Vice-President, Director of Manhattan Programs
Institute for Urban Family Health

16 East 16th Street
New York, New York 10003

212 206-5252
Fax 212 206-5251
rschiller@Institute2000.org

The recent expansion of Complementary and Alternative Medicine (CAM) into various medical settings has brought profound benefits to all sectors of the Health Care System. Physicians have become more humanized, less judgmental, and often using these techniques on themselves and their families, before they feel comfortable recommending them to their patients. Patients are more knowledgeable about choices in treatment and they are more confident in challenging their physicians. Insurance companies having recognized the value of certain therapies now reimburse for them. Many medical research and educational institutions include CAM as part of their inquiry or curriculum.

However, these achievements have benefited only a fraction of the population. People with inadequate health coverage have little or no access to these therapies. Not only do these people often receive marginal conventional medical care; they can not share in the benefits of the innovative approaches of CAM. Ensuring equal access to CAM for all citizens should be a high priority for health care reform. I believe there is a tremendous opportunity to bring the reform of public health policy together with the expansion of the practice of CAM in an effort to not only correct this inequity, but to address many of the problems of the health care system. As Complementary Medicine has re-introduced healing and the mind-body connection into conventional medicine, so can these practices bring public health back into the sphere of the medical mainstream. The key to bringing public health and medicine together exists in strengthening the system of primary care and enhancing these services with integration of Complementary Medicine.

I am a family physician in practice for over 15 years, most of it in lower Manhattan. Although I received training in acupuncture, I currently practice mostly homeopathy with some general family practice patients. In 1984, a group of us from Montefiore Medical Center, including Richard Grossman, Dr. Sonja Lopez, and Dr. Ellen Tattelman, established an acupuncture program, and offered Western herbs and some basic homeopathy at a primary care practice that served a lower income population in Yonkers, New York. This was my first experience with an Integrative Medicine Practice, and it helped me understand the crucial elements to a successful use of complementary medicine in a conventional primary care setting.

We learned that it is essential to build complementary therapies upon an existing, successful primary care practice. Primary care is the most efficient

way that people access the health system. A primary care team is a model of collaboration and integration of services, and complementary therapies can become part of the routine referral network of the practice. The primary care base provides a steady source of patients and income to the practice. Many Integrative Health Centers have failed because they do not have this primary care economic base to sustain the inclusion of CAM.

However, of all the primary care practitioners, family physicians are ideally suited to achieve this integration. We are trained to practice collaboratively and already use the bio-psycho-social model in clinical practice. Expanding this model to include CAM therapies fits readily with this model. The fact that family physicians appear to the largest group of physicians who currently express interest in CAM comes as no surprise.

In 1994, the Beth Israel Medical Center and the Institute for Urban Family Health established a residency in Family Practice, the first in Manhattan. Training these residents in Complementary Medicine is part of the Residency's mission. We established a successful family practice site and introduced CAM as the practice developed. Many of the faculty are trained in these skills that are used in the residency clinical programs. However, we made a significant change two years ago with the introduction of a one-month *required* experience in Complementary Medicine. I believe we are the only residency program that has made this experience a requirement. The goal of this month is to teach the residents some basic skills that can be easily incorporated into their practice. The skills include one week in each of the following: 20 basic Western Herbs, Mind-Body Techniques for relaxation and stress management, Osteopathic Manipulation, and review of 10 nutritional supplements. There are some additional presentations in Homeopathy and Chinese Medicine for introductory purposes. We have learned over the years that physicians are ready for more than broad introductory exposure to Complementary Medicine; they want to leave conferences with basic skills and a good plan for continued education. Many of our graduates report that they are using some of these therapies, and we plan to collect data for a thorough analysis of the value of this training.

Beth Israel Medical Center has made a significant commitment to CAM with the creation of the Center for Health and Healing, which the Commission has already seen. There is close collaboration between our Department and the Center.

From my early years as a resident until now, I have believed that beyond broadening the therapeutic options for the patient, the real potential for CAM is its ability to potentially radically transform the Health Care System. Many of us were drawn to learn about these methods because we knew of fatal flaws in our training and in the practices where we cared for our patients. We hoped, even expected that the widespread use of these therapies would promote a more caring system, one that was devoted to healing, and that encouraged the curious, critical use of new or ancient, unconventional therapies. The excitement, enthusiasm, and positive results CAM practitioners experienced in the exam room need to be extended to the surrounding community in the form of health education, health promotion, and health care reform for the community.

Some issues are ready for the transforming potential of complementary Medicine.

Racial and economic disparities in providing even adequate care has been highlighted as among the more important issues in the Health Care Crisis. Now is the time to correct these disparities in access to Complementary Therapies.

Drawing on my clinical and administrative experience I make the following recommendations to the Commission:

1) People without health insurance or inadequate coverage or with Medicaid and Medicare are entitled to equal access to CAM Therapies. HCFA and State Legislatures should provide a basic package of coverage of CAM therapies that are available to all patients, and should mandate that commercial health plans provide similar coverage.

2) These Basic CAM Clinical Services need to be defined, based upon principles that permit some local or regional variation reflecting the diversity of communities, and the availability of qualified practitioners. These services should be developed as an extension of a primary care practice model in order to benefit from the comprehensiveness and cost-effectiveness of primary care.

3) Training of Health Care Providers, both Physician and Non-Physician providers in these basic therapies are needed to meet the overwhelming demand for these services. Priority should be given to enhancing the skills of current primary care providers.

4) Financial Support for this initiative is the most challenging problem. With a fixed health care budget, other services and training may have to be reduced or eliminated. This is the crucial role for Public Health Care Policy. Supporting programs that provide the greatest health benefit to given communities will assist in these decisions. Research in CAM has identified some effective therapies. However, even without adequate research, we may have to rely on clinical anecdotes or "clinical common sense" in an effort to get to evidence that we need in a timely fashion until more comprehensive studies are concluded.

Although I have stressed the primary care setting as the optimal place for the successful integration of CAM, I enthusiastically support the efforts many practitioners have made in a variety of settings that treat specific populations or conditions such as Women's Health, Cardiovascular Disease, and Cancer. The current health care system already emphasizes specialty care and the transforming potential of CAM will be less impact if limited to these practice sites.

The current success in the spread of Complementary Medicine is bittersweet. Many Americans have benefited from these achievements, but it appears the Integration of Complementary Medicine has not yet transformed our current system. In many ways this integration has duplicated the best and the worst of how we provide health care.

This Commission can begin to set the transformation potential of Complementary and Alternative Medicine in motion by identifying opportunities to make constructive changes and direct those of us with the energy, enthusiasm, and commitment to implement them.

Recommendations to the White House Commission on Complementary and Alternative Medicine Policy
January 23, 2001

Provided by:
Ellen Tattelman, M.D.
Assistant Professor
Department of Family Medicine and Community Health
Albert Einstein College of Medicine/
Montefiore Medical Center
3544 Jerome Avenue
Bronx, NY 10467
(718) 920-5521
(718) 515-5416 fax
etattelma@montefiore.org

I appreciate the opportunity to present my recommendations to you. I am a family doctor, working at Montefiore Medical Center and a faculty member in the Department of Family Medicine and Community Health at Albert Einstein College of Medicine. For the last 15 years as a clinician, I have been integrating a number of different complementary medical approaches into the primary care of the medically underserved in the Bronx and lower Westchester. As a teacher, I have been presenting these modalities and their underlying philosophy to residents and medical students. Presently, I chair a group on CAM for the medical school's Department of Education where we have begun to integrate CAM education into all 4 years of the curriculum.

My experience has shown me that complementary and alternative medical education is critical to the education of health care professionals but we must acknowledge that education in CAM presents a significant challenge to our present medical and educational systems. Many schools now offer electives in CAM, but we need this training to be required and integrated into all areas of the curriculum. Often students hear an introduction to CAM, but they may hear this introductory talk many times without ever going deeper. We do need to teach some specific techniques to the students. Which area of CAM you choose to teach, whether it be mind/body approaches, the use of some Western herbs, or beginning bodywork techniques, is less crucial than approaching the techniques in a hands-on way, emphasizing self-care as crucial to health and healing. Use the best teachers you have available and let them teach from their expertise.

What is important is that we don't just substitute one of these techniques for a Western medical one. We don't just use an herb in place of a drug. We need to integrate conventional and unconventional medicine, but we also need to change the whole approach to patient care. We need to teach the deeper philosophical base of CAM. We need to teach about health and healing, about working with another person to help the body heal itself in order to reach harmony of mind, body, and spirit. When we bring CAM to medical education, we need to bring a change in the paradigm of conventional medicine. We have to move away from a focus of curing diseases to one of healing individuals within the context of their community and family networks. We should encourage research and evidence-based CAM practices, but we also need to endorse the connection between patient and provider that many people seek when they turn to CAM

practitioners. We need to emphasize, along with CAM techniques, the compassionate and loving embrace of each individual by the health care professional. This provides the basis for healing to occur.

In conclusion we must acknowledge that we need to change the paradigm of conventional Western medicine and CAM education needs to be a required, not elective, part of health care professionals' curriculum.

Ellen Tattelman, M.D.

Recommendations

A. CAM education requires a paradigm shift in medical education
   Emphasize listening, connection, and love between provider and patient
   Diseases may be cured, but people require healing–Janet Quinn, nurse educator (1)
   Work with a patient to allow their body to reach a healthier balance

B. CAM education must be a **required** part of health care professionals' education

C. CAM must be integrated into all aspects of medical education, pre-clinical and clinical
   For example, in the first year anatomy course, add a massage therapist, a chiropractor, or an osteopath to show how the knowledge of anatomy is used in these disciplines. Then you could use the stressful nature of anatomy lab to teach the students about stress reduction from the very start, using let's say, yoga, self-hypnosis, or meditation

D. Self-care is crucial to the health and healing of one's self and then others
   Teach in a hands-on way
   Pay attention to the stresses of medical education

1. Quinn JF. On healing, wholeness, and the Haelan Effect. Nursing and Health Care 1989;10:553-6.

The White House Commission on Complementary and Alternative Medicine Policy
Town Hall Meeting – Tuesday, January 23, 2001, New York, NY
Presentation by William Prensky

Commissioners of the White House Commission on Complementary and Alternative Medicine Policy, staff to the Commission, fellow panelists and presenters, and friends –

It is an honor to have been invited to address you today concerning the issues of integration in education for Acupuncture and Oriental Medicine and the barriers to integration in both education and in the practice of my profession. My name is William Prensky, and I am Director of the Graduate Program in Acupuncture and Oriental Medicine at Mercy College, in Dobbs Ferry, NY, and Chief of the Division of Acupuncture at Sound Shore Medical Center in New Rochelle, NY.

Mercy College is the first regionally accredited, Comprehensive Graduate Institution to introduce and integrate the study of Acupuncture and Oriental Medicine into the normative curriculum in professional Health Sciences. In 1996 Mercy College merged the study of Acupuncture and Oriental Medicine into a community of students and faculty working in all aspects of health care in a full array of graduate program in Allied Health, while maintaining the specific flavor and separateness of this field of study.

In a unique collaboration, Mercy College has joined with Sound Shore Medical Center of Westchester, an accredited teaching hospital with five accredited residency programs and three post-graduate specialty fellowships, to introduce the education and clinical training of Licensed Acupuncturists into the hospital inpatient setting. In addition, we have created at Sound Shore Medical Center the first fully implemented Division of Acupuncture staffed and led by Licensed Independent Providers of Acupuncture and Oriental Medicine which functions to bring Acupuncture services to all patients within the hospital.

As you are undoubtedly aware, the barriers to the integration of these practices, which have demonstrated a clear value to contemporary health care, remain in place long after the evidence of their value has been presented. Many things contribute to the reluctance of the system to accept new modalities and systems of thought, and chief among these barriers are inequities and insufficiencies in the education of professionals in all branches of medicine and health care.

We are faced with a number of questions, which surround the question of integration. Key among these are:

- What is the role that Acupuncture and Oriental Medicine can play in contemporary health care?

- What is the role for Acupuncture and Oriental Medicine in hospital based practice?

- What is the most cost effective way in which to deliver this medicine to patients?
- What is the most cost effective way in which to train and educate the professionals in AOM?
- What education is needed for contemporary medical students and physicians to allow them to integrate the knowledge about the availability of AOM for their patients?
- To what extent should AOM be considered a part of medicine?
- To what extent are AOM practitioners physician extenders?
- How do we prepare teachers for this medicine, and who teaches it in both AOM schools and in medical schools?
- From where will we get the future educators and researchers in this field?
- How can this practice be made more available to those patients for whom it is most beneficial?

We can address some of these questions by presenting you with a picture of what we have been doing and what we have learned over the past five years as we have integrated acupuncture and oriental medicine into hospital-based practice. It is important to note that until now acupuncture and oriental medicine, as practiced both by its own independent licensed providers and as practiced by physicians with no standardized training in the field, has been largely isolated from the mainstream of health care delivery. This isolation has resulted from a number of things, chief among which are failures of reimbursement schemes and resistance to integration by hospitals and clinics.

This isolation has been exacerbated by the isolation of AOM education. Taught until now only in stand-alone, small schools built upon the technical training model, there has been no strong academic infrastructure support, and, therefore, no buy-in by academic medicine or by academic allied health care.

But AOM offers us a unique opportunity to revisit both the nature of allied health care education and the relationship of allied health care to medicine, both in practice and in academics. Let me explain.

All students in the Mercy College graduate AOM program earn a masters degree in acupuncture and oriental medicine. To earn that degree these students must engage in two educational activities that are unique to the program.

1. They must engage in 5 semesters of in-hospital, inpatient training, during which time they rotate with a variety of medical teams in the hospital.
2. They must complete a formal research thesis, which generally consists of designing and implementing a clinical trial in the integration of AOM into contemporary therapeutics.

Indeed, four of the theses recently completed have pilot data so compelling that they are being used as the foundation for NIH research grant applications.

Why is this important? Because there must be two new intentions fulfilled by education in this field.

1. Evidence for the inclusion of acupuncture and oriental medicine must be a priority for our educational system.
2. Training for hospital based practice must be seen as a necessary step in developing pathways towards employment that will bring this medicine to the place where sickest patients are – that is, hospitals.

To accomplish this we are in the process of expanding our program and developing a new offering, the first post-graduate clinical and research specialty residency program for acupuncture and oriental medicine. Beginning in 2000, Mercy College funded 3 full-time post-graduate Teaching Fellows in AOM, who are engaged in developing with us an academic and clinical program which will prepare them to develop Acupuncture Services in hospitals around the country and to serve as the Chiefs of those services.

Our message, then, is clear. AOM must develop, and we are developing, the academic and clinical educational structures, knowledge, training and research to provide the information needed to integrate this practice into contemporary health care. This must, by its nature, be done not by marginally trained professionals in other fields, but by dedicated professionals in this field who wish to move the bar on academics to the highest level. The development of a true Ph.D. in the field of AOM is the necessary next step.

Given these goals, what policy changes need to be made to help implement them?

1. There must be enhanced federal support for AOM education at the highest academic levels. Certainly these supports must include participation in the Federal Stafford Loan Forgiveness Program, as well as enhanced outright grants for study for those groups under-represented in the field.
2. Federal funding support for hospital based residencies in AOM for AOM professionals needs to be developed.
3. We need increased federal support for AOM research, aimed at both providing evidence for the value of integration and, at the same time, for developing innovative means of asking questions. This support must be aimed at developing research competency within the field itself. And this research support needs to open funding availability to unconventional approaches to

research, exploring methodology which is not only linked to Randomized Clinical Trials based upon pharmacologic research but also is rooted in inquiry into the cultural context of medicine and the questions which pertain to each paradigm.

4. Training grants as well as research grants are needed, to develop the fundamentals of basic allied health education in this field and the nature of advanced academic research and education for the field.
5. The educational infrastructure of AOM has to be clearly identified and supported as separate from other disciplines, both in medicine and allied health. Respect for AOM as its own discipline and its own scholarly pursuit must be placed against the interest of medicine and other health sciences in the components of this discipline.
6. Federal policy which opens Medicare and Medicaid reimbursement for AOM is crucial if hospital based patient service is desirable, which it is.

Over the past five years our students have been a part of the hospital life at Sound Shore Medical Center, and the medical students and residents and house staff of Sound Shore Medical Center have rotated through the Acupuncture Center. As the two groups of dedicated students and providers have interacted, a number of lessons have been learned.

1. AOM students and faculty and medical students, faculty and residents can all learn to work together to enhance patient comfort. As the AOM Service has become a part of the tapestry and backdrop of normal everyday hospital life, patients and staff have come to expect it. Indeed, one of the most telling moments for us in these five years was the instance when a gerontologist was speaking with a patient in long-term rehabilitation and commented: "What more can we do for you – you have the anesthesiologist, the physical therapist and the acupuncturist who have all been seeing you every day. We are doing everything that we can." At that moment we knew that we had integrated and had become a part of the daily life of the unit.
2. The ways in which AOM can assist patients and hospital staff to attain better results are numerous – pilot projects we have conducted include the use of acupuncture in helping patients tolerate hemodialysis, in controlling peri-operative pain, in reducing dependence upon inhaled medications for acute and chronic respiratory disease, and in controlling intractable pain in terminally ill patients.
3. AOM students have not contributed significantly to our knowledge about the efficacy of integrated AOM because we have isolated them until now in separate schools and away from hospital based research. When they are integrated they contribute significantly.
4. The greatest barrier to integration is lack of understanding of the complexity of AOM and the nature of training in the field. As the medical and other staff at Sound Shore Medical Center came to understand the complex nature of the three-year, 141 credit program in which the Mercy College students were

enrolled at the masters level, they came to respect and rely upon the AOM faculty and students for daily service.

Let me leave you with one thought.

The future is not some place we are going to, but one we are creating.

The paths to it are not found, but made, and the activity of making them changes both maker and destination.

By creating a system which is built upon mutual respect we have arrived at an integration of service which has excited everyone in both institutions and involved educators and clinicians at every level in developing new integrative models. With your help we can develop models which can be applied for patient benefit throughout the country.

Thank you.

"MIND-BODY MEDICINE IN THE TRENCHES"

I am a pediatric psychologist working at the bedside of critically ill children. We provide treatment that is alternative and complementary to allopathic medical/surgical care in a large tertiary-care teaching hospital. We do so with full cooperation and close involvement of the medical surgical and nursing staff. For over twenty years, we have attended to children's quality-of-life needs. While our medical colleagues attend to pathogen and disease, we focus on their pain, their fears, and many of the unintended side effects of their medicine, surgery, and radiation. This includes pain, nausea, weight loss, fatigue, immune compromise not to mention loneliness and despair. The tools of our trade are, unlike the suture and scalpel, friendly to children. They involve harnessing the child's imagination and natural tendencies to joy and playfulness and using that to transform the meaning of the hospital stay from nightmare to feelings of mastery and understanding. Because we work elbow to elbow with medical and nursing staff and trainees, they too inevitably adopt an increasingly integrative, holistic approach to care. Our role in providing complementary care to sick children is hard-won. We are committed to put our treatment methods to rigorous testing and evaluation that you might expect of an intervention with a critically ill patient. That commitment has been instrumental in forging a working alliance with our medical colleagues. I would like to see academic medical institutions welcome practitioners who wish to integrate traditional, naturopathic and oriental approaches with our current technological focus. These approaches clearly offer a great deal to children. They have not been made available because:

1 Such approaches do not lend themselves well to empirical examination.
2 There are yet few satisfactory ways to establish qualifications and standards of practice in most modalities.
3 It is difficult but essential to question how a child can provide informed consent for alternative and complementary interventions.
4 We are reluctant to lay our hands on other people's children, even in the hospital, and even when they are healing hands, lest someone interprets it as a breach of medical ethics.

In conclusion, Pediatric Psychologists are uniquely suited to the task of bridging the gap between eastern medicine approaches and those of the average American physician. Key steps to take include establishment of qualifications for practitioners in whose hands parents must place their children's care and safety. Better educational information is needed for parents and pediatricians alike to render informed consent on behalf of their minor children as they expose them to traditional and complementary medicine. And finally, as a parent, I would wish know a great deal about any method or approached employed on behalf of my own children. Are their potential pitfalls or contraindications that I should know about? Are my child's doctors aware and supportive of non-Western approaches, even as they plug away at finding a medical cure? I thank the organizers of this commission for the opportunity to speak on this topic.

Kenneth S. Gorfinkle, Ph.D.
Assistant Clinical Professor of Psychology in Psychiatry
College of Physicians and Surgeons
Columbia University/New York Presbyterian Medical Center
622 West 168th St. Box 427 New York NY 10032 Phone 212-305-9985 Fax:
212-305-1249, e-mail: kg13@columbia.edu.

White House Commission
on Complementary & Alternative Medicine Policy
New York City January 23, 2001

Oral Testimony [#72]
Robb K. Burlage, Ph.D.
Director, Health Justice Ministries c/o National Council of Churches
Consultant, Health and Wellness Ministries,
The Riverside Church, New York City
Convener, Interfaith Health Seminar at Riverside Church
Founder and Editor, *The Health/PAC Bulletin*
475 Riverside Drive, Room 824, New York, N.Y. 10024
Phone 212-870-3560
* * * * *

"Our Communities' Right to Universal Holistic Health Care"

The National Council of Churches (NCC) and The Riverside Church, located adjacent in the Morningside Heights/West Harlem communities of Upper Manhattan, historically share a strong faith-based advocacy of universal health care as a human right and system efficiency. We also have been part of the quest for a truly holistic health care and an integrative medicine. We salute the mission of this White House Commission and your potential for making a significant new contribution to this quest.

Upon its 50th anniversary observance in November 1999, the National Council of Churches General Assembly affirmed co-initiation of a Faith Communities Universal Health Care Campaign just concluded across the Year 2000 elections (acronym "U2K"); as well as a role in supporting the ongoing Universal Health Care Justice Campaign. Former Congressperson, Rev. Dr. Robert Edgar, is NCC General Secretary. Also former Congressperson, NCC President Rev. Dr. Andrew Young, is a member of the Surgeon General's Steering Committee for the Campaign Against Racial-Ethnic Disparities in Health and Health Care. The moral disgrace, human suffering, and social costs of 45 million Americans and more without health care coverage and a hundred million more vulnerable and at-risk as seriously under-insured is an international scandal.

As representatives of NCC's international division, Church World Service and Witness, are constantly confronted throughout the world, we all should constantly consider the fact that the U.S. is the only industrialized nation in the world without such universal health care coverage. Even the Union of South Africa, with a heartbreakingly widespread epidemic of HIV/AIDS, a bitter history of Apartheid and severe resource shortages, has now made that commitment.

Our communities in Harlem and Northern Manhattan are composed predominantly of low and moderate-income, working families of minority African-American and Hispanic heritages; including almost one-third first generation immigrants. About 40% of our half-million people do not have basic health care insurance coverage and the racial-ethnic and socio-economic disparities of disease incidence, mortality, health risk, and ineffective care access. Ours are among America's most health at-risk populations.

The Health and Wellness Ministries of Riverside Church have been developing a unique program of congregation and communities-based health education and holistic health modalities, as well as clinical medicine support and referral. These programs have emanated particularly from volunteer activity in its environmentally distinctive Wellness Center, simultaneously towering over the Hudson River and the Harlem community. This includes courses, support groups, observances, retreats, and educational events such as the annual Health and Wellness Weekend.

The latter is highlighted by the guest sermon, this year on Sunday, March 25, to be delivered by Dr. James Gordon, Director of the Center for Mind-Body Medicine in Washington, D.C., author of *Manifesto for a New Medicine,* Chair of this Commission; in dialogue with Riverside's Senior Minister, the Rev. Dr. James Forbes, Jr. on the subject of the complementarities of medical and spiritual healing. (The previous pulpit guest on Health and Wellness Day a year ago was Surgeon General Dr. David Satcher.)

The Interfaith Health Seminar, co-sponsored monthly by Riverside Church and the NCC; has emphasized over the last five years topics regarding the politics of universal holistic health care. Our recurrent theme is "Our Communities' Right to Universal Holistic Health Care" -- in fact, it is the focus of our Wednesday, March 7 Seminar, 5 to 7 p.m. at Riverside.

The underlying quest is for community congregations-based action to improve public resource support and scientific development toward access for all to the emerging integrative medicine -- with an emphasis on holistic prevention, health education, and public health.

As a health care systems analyst with training in public health and urban planning, I believe that we need a major and expanding U.S. public resource commitment both to assuring universal access to holistic care and to scientific evaluation of the effectiveness of all health care modalities. Even more serious funding for the Center for Alternative and Complementary Medicine Research of the National Institutes of Health is required effectively to encompass all utilized and potentially useful modalities.

Yet, in fact, the major cost, danger, and unfulfilled benefit of health care today is the global monopoly of clinical, allopathic, prescription drugs research, production, marketing and pricing and the lack of effective coverage in the U.S. in particular for the tens of millions of our Medicare-eligible older adults and people with serious chronic illness and disabilities. Over 40% of the cost increase in health care overall in the U.S. last year was due to the price of prescription drugs.

Therefore, it should not be forgotten, in perspective – even for this distinguished Commission on Complementary and Alternative Medicine Policy -- that the major scientific health care evaluation gap, as well as socioeconomic coverage gap in the U.S. and internationally is regarding such essentially allopathic pharmaceuticals. As Professor Uwe E. Reinhardt wrote recently in an Op-Ed piece in the New York Times (1/3/01) with regard to "How to Lower The Cost of Drugs" -- as, he said, in particular because of the "morally troublesome impact on the millions of Americans -- many of them elderly (without) insurance coverage for such drugs":

"Private insurers and the government should agree to set aside just 1 percent of their collective yearly spending on prescription drugs and endow a $1 billion research institute. Such a private, nonprofit institute would be an authoritative, independent source of reputable research into whether new, improved drugs are, indeed, significantly new and improved." And, it should be added, whether they are significantly safe and efficacious."

Thus, in conclusion, let it be stated that the quest for our communities' right to universal holistic care -- particularly from across the 132,000 American faith congregations and communities, encompassing an overwhelming majority of Americans -- requires *comprehensively* vigilant action for better public policy and resource support. The mission of this White House Commission should make a significant contribution to our quest. We salute you and promise full partnership in implementation of your findings.

* * * * *

White House Commission on Complementary and Alternative Medicine Policy

Testimony Given by Kristen Georgi,
Traditional Chinese Medicine World Newspaper & Foundation
January 23, 2001

My name is Kristen Georgi. As editor of the Traditional Chinese Medicine World newspaper, the largest print media and website of its kind and one arm of the New York-based Traditional Chinese Medicine World Foundation, it is our goal to help build bridges of understanding between East and West, to sort through misunderstanding and misinformation and deliver what is authentic, beneficial, and sound through a variety of forums such as our newspaper, books, seminars and classes.

There is an ancient saying in Chinese medicine – "As long as you know the principles of Yin and Yang, you can be a good doctor." Chinese theory holds that the entire universe is composed of Yin and Yang, two complementary but distinct energies that are evident in all things.

We have come to a time in this nation's history when Eastern and Western medicine are merging to create a new complementary system for the health of the world. Because they are vastly different from each other in philosophy and practice, the key to the success of this merger is for each side to understand and accept its complement. There is no room for ignorance, suspicion, competition or fear.

It is our strong belief that education is the cornerstone needed to make this bridge structurally sound and enduring. We believe that it is the right of the American public to know that there are other options for healthcare available, options that fill the gaps left by conventional Western medicine. Our newspaper reaches the general public, 350 hospital-based centers of complementary medicine, and many of the 25,000 practitioners from novice to expert with articles about TCM theory, practice, policy, training, and research. With a circulation of 80,000 and more than 1.5 million visitors to our website, we have evidence that the consumer is hungy for this information.

In the World Health Organization's Report 2000, it is stated that the media can play an important role in healthcare stewardship by helping to set ethical standards for conduct, fostering balanced public information and serving as an effective interface between the public, healthcare providers and policy makers. Our paper's goal is to do exactly that by conveying thousands of years of Chinese experience-based knowledge to the modern, scientific, technological mindset of the West. It is our experience that the best way to achieve such a dialogue is to create a new dialect, one that weaves together the anecdotal evidence of 5,000 years with the science of today.

As an example, the cover article of our current issue is about a highly regarded researcher at Mt. Sinai School of Medicine who has just published the first paper in a prestigious Western medical journal concerning the use of a Chinese herbal formula for asthma. The meticulous research methodology is described, along with the TCM theory behind the efficacy of these herbs. The study concludes that the Chinese formula is as good as standard corticosteroids for the treatment of asthma, without the worrisome side effects. This work, which has been called courageous by reviewer Dr. Renata Engler of Walter Reed Army Medical Center, will bring new medicines to the West based on the

wisdom of the East. We ask you to support all such efforts that foster the most fundamental of human needs, the need to live in good health. You can do this by endorsing Chinese medicine's philosophy of healthcare, by providing platforms to meet the public's demand for information, and by funding additional research.

We believe it is essential for Western medical doctors to be further educated so that they can support their patients' choice of complementary care. Of all the complementary therapies, Chinese medicine is the most sophisticated and complete, employing herbal medicine, acupuncture, diet and specific kinds of energy exercise that have been used for centuries to prevent and cure diseases such as hepatitis, diabetes and cancer. Today in China both medical systems are taught and utilized side by side. It is common practice there to treat cancer with Western medical modalities such as radiation and chemotherapy in conjunction with Chinese herbs that strengthen the immune system and increase the T-cell count.

Unfortunately, that is not the case here in America. Many Western doctors discourage their patients from pursuing avenues of healing other than their own. This is especially alarming when a life-threatening diagnosis sends a patient in search of additional methods of care. In instances of chronic and acute disease, Western medicine's weak points are Chinese medicine's strengths. It is unconscionable that physicians undermine their patients' ability to access this valuable option because of their own fear and lack of knowledge. There is no need for competition. With education about the fundamentals of Chinese medicine, the consumer, the Chinese medicine practitioner and the conventional Western physician together can have the best of all worlds. The time has come to join in cooperation between Western and Eastern methods that use different approaches but share the same goal – the good health of the patient. We ask this commission to make a commitment of time, money, and people to provide the high quality resources needed to make this a reality.

Chinese medicine is not "new age" medicine. As long ago as 1979, the World Health Organization listed forty-one clinical indications for acupuncture and strongly supported it as a beneficial, cost-effective, preventive and therapeutic system for use worldwide. In her keynote speech at Beijing University in November 2000, Dr. Gro Brundtland, Director General of the World Health Organization, said, "China has made some of the most significant contributions to the advancement of medicine. Long before Europeans addressed medicine in a scientific manner, China had developed advanced techniques of diagnosis and treatment. Many of these traditional techniques are today applied around the world. Thousands of years of knowledge are there for the world community to tap and share."

Let us take a page from China's book by combining what is best in East and West. We ask you to provide support for education about the benefits of Chinese medicine for the American consumer. We ask you to end the atmosphere of suspicion and competition regarding Chinese medicine that is still pervasive in the Western medical community. We ask not for balance, but for harmony. Two things can be balanced. They can have equal weight on a scale but still be separate. Harmony means that they are not separate, but blended into a seamless whole. That is our wish for the healthcare of the future.

Thank you for allowing us to testify before this committee and we welcome the opportunity to continue this important work with new administration.

Dr. Ming Jin
(MD in China, Licensed Acupuncturist in NY & NJ)
990 6th Avenue, Suite 14L, New York, NY 10018
Tel.: (212) 868-1345 Fax: (212) 868-4091

Represent:
National Association of Chinese Medicine (NACM)
American Association of Traditional Chinese Medicine (AATCM)
American Association of Oriental Medicine (AAOM) Chinese Adversary Council.

To the Members of the Commission:

I am Dr. Ming Jin, a licensed acupuncturist and the medical director of the Ming Qi Natural Healthcare Center in Manhattan and Queens. During the past ten years, our center has treated more than 8,000 patients with a very high rate of success. In addition, I teach courses on acupuncture and Chinese herbal medicine at three colleges in the New York area.

I graduated from the Shanghai University of Traditional Chinese Medicine with a Ph.D. specializing in Obstetrics and Gynecology. My dissertation considered the efficacy of acupuncture and Chinese herbs in treating various OBGYN-related problems and diseases. In my Masters program, I studied the anti-aging effects of Chinese herbs.

I represent National Association of Chinese Medicine (NACM), American Association of Traditional Chinese Medicine (AATCM) and American Association of Oriental Medicine (AAOM) Chinese Adversary Council. I would like to highlight three points that are important in the development of policies and procedures with respect to Complementary and Alternative Medicine.

1. **Acupuncture and Chinese herbs are synergistic and complementary**. Today, acupuncture has been recognized and accepted by the government, most medical professionals and the general public. However, the lack of understanding of Chinese herbs - its uses, its effectiveness, and its complementary relationship to acupuncture - has significantly hampered the development of Chinese Medicine in the United States.

   Both methods of treatment should not be viewed in isolation. I recommend that the government account for the synergistic and complementary benefits of using both treatments in combination when formulating policies and procedures for Complementary and Alternative Medicine.

2. **Chinese herbs are not synonymous with health food or food supplements.** In addition to prevention and body toning, many Chinese herbal formulations can

effectively treat various medical conditions and diseases. In an address at the American Institute for Cancer Research's 10th Annual Research Conference in Washington DC, Dr. Jan Geliebter of New York Medical College reported that in both laboratory and clinical observations, a specific mixture of Chinese and American herbs shows promise as an effective treatment for prostate cancer. In my own clinics, I have used acupuncture and Chinese herbs to lower prostate specific antigen (PSA) levels and shrink ovarian cysts and fibroids with more than an 80% success rate.

Society would benefit greatly from the establishment of clear and reasonable guidelines by the United States government to assist manufacturers and practitioners of Chinese medicine to evaluate and utilize Chinese herbs. I urge the National Institutes of Health and other governmental agencies to prioritize research funding for Chinese herbs.

3. **Most adverse events related to Chinese herbs are caused by improper use of products**. Although the majority of Chinese herbs are safe to use, certain herbs do contain toxic compositions and /or cause side effects. For example, Ephedra (Mahuang) has been blamed for potentially life-threatening health problems, especially when taken with caffeine. However, Mahuang is a very valuable herb in treating asthma and other health conditions. Its toxicity has been well documented by the Chinese medical community, which has long recognized that Mahuang should always be used in conjunction with other herbs and preserved with honey to eliminate potential side effects. Unfortunately such knowledge is not widely known by current manufacturers, medical practitioners, and government agencies.

   Instead of banning effective herbs, such as Mahuang, due to a lack of understanding, I suggest that the FDA and NIH establish a panel of experts who truly understand both Chinese herbs and conventional medicine to provide valuable information to the medical professional as well as the public in dealing with such issues.

Thank you very much for your attention.

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
005. testimony	Tsao-Lin Moy (partial) (5 pages)	01/23/2001	b(6)

COLLECTION:
Federal Records
White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

OA/Box Number: 43232

FOLDER TITLE:
WHCCAM Meeting Testimony, January 23, 2001 [4]

2011-0568-S
kc825

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[005]

Tsao-Lin E. Moy, LMT
(b)(6)
New York, NY 10038
(b)(6)
Email: tmoy@backessentials.com

Testimony to: The White House Commission on Complementary and Alternative Medicine Policy. January 23, 2000 – Commission Meeting on Training, Education, Certification, Licensure, and Accountability of Health Care Practitioners in Complementary and Alternative Medicine; Topic: Standards of education, training, licensure and certification in the field of Acupuncture and Oriental Medicine.

Good Afternoon Members of the Commission, thank you for your attention today. My name is Tsao-Lin E. Moy, I am a second year student at Tri-State College of Acupuncture, working towards a Master's Degree in Acupuncture and Oriental Medicine. I am also in the two year accredited Chinese Herb program. (this is a 450 hour program which prepares me to sit for the NCCAOM national exam in Chinese herbology and receive diplomat status)

I am a Licensed Massage Therapist since 1998 with a practice in NY and I assist in teaching at the Swedish Institute for Massage Therapy. In addition I have a BS in Int'l Trade and Marketing.

I will be offering the Commission testimony and insight on the standards of education in an accredited Acupuncture and Oriental Medicine program; the rigor of the program, the didactic hours, the hands on skills and supervision, observation/clinic hours, electives, human service skills and independent study.

I am passionate and committed to my education and training.
What has been most challenging for me as of student of Acupuncture and Oriental Medicine is learning to open my mind, to put aside my cultural biases and develop creative and abstract thinking.

An accredited Acupuncture and Oriental Medicine program is 3-4 years; approximately 2,200 hours of study and training.
More than 50% of those hours is devoted to hands on skills and supervision, observation and clinical experience. The remaining hours are for lectures, electives and independent studies.

[005]

Tsao-Lin E. Moy. LMT
(b)(6)
New York, NY 10038
(b)(6)
Email: tmoy@backessentials.com

The commitment to study, the hours of hands on skills, and clinical training provide an educational foundation for the theories of Acupuncture and Oriental Medicine.

I have outlined a description of coursework and hours.

First Year- 850 hours
170 hours of lecture:
Chinese philosophy provides the philosophical basis of Acupuncture and Oriental Medicine; The 5 diagnostic filters (Yin Yang, Qi/Blood/Fluids, Zang Fu, Five Elements and Meridian). Describing and distinguishing which filters a practitioner uses for arriving at an acupuncture diagnosis.

The fourteen major pathways of acupuncture energetics; including internal pathways, acupuncture points (locations and energetic functions), symptomatology and indications. The secondary vessels (tendino-muscular, divergent, luo) and the 8 Extraordinary Vessels.

Treatment planning and basic techniques and strategies; The Four Examinations, Nine Steps of Treatment Planning and Eight Principle Evaluations; pulse, tongue and Hara confirmation.

250 hours - Skills review and hands on contact: 80 hours includes palpation of meridians, point location, hara evaluation, tongue and pulse; in small supervised groups we practice basic techniques of needling, moxibustion; gua sha, cupping, auriculo-therapy and clean needle technique.
50 hours of body work training. A minimum of 20 hours of written independent patient documentation/project. 100 hours of direct patient interaction experience.

60 hours- Observation/Grand rounds, Clinical Hours: As part of our clinical experience we observe and learn from senior acupuncture practitioners treating actual patients.

Tsao-Lin E. Moy, LMT
(b)(6)
New York, NY 10038
(b)(6)
Email: tmoy@backessentials.com

At Tri-state we are exposed to a unique synthesis of various traditions of acupuncture such as: Japanese, TCM, Meridian, Vietnamese, Korean and French. These practitioners include: Dr. Mark Seem, Kiiko Matsumoto, Arya Nielsen, David Legge and Dr. Richard Tan.

These practitioners are long time leaders in the field of Acupuncture in the U.S. and have all published texts that help set the standard of education for the future Acupuncture and Oriental Medicine provider in the US.
The students in the Chinese Herb program are taught by Andrew Gamble, translator and editor of the Materia Medica Chinese Herbal Medicine.

70 hours – Human Service Skills:
Addressing communication and evaluation skills, client – centered training, patient / practitioner and professional training for clinical encounters.

90 hours – Independent Study Project:
Monthly workbooks, personal journals, and writing and research assignments.
170 hours – Anatomy & Physiology, Pathophysiology
40 hours – Electives

Second Year – 635 hours:
170 hours lecture:
We learn in depth the fundamentals of Chinese physiology and how that physiology may be used to trace the etiology of a disharmony. A much deeper understanding of the philosophical basis of Acupuncture and Oriental Medicine is applied to recognize signs and symptoms, and learn appropriate treatment strategies in each individual case rather than just memorizing a set of points for a text book pattern.

100 hours - Skills review and hands on contact:
In small supervised groups we learn and practice needling protocols through the meridian/zang fu, 5 elements and TCM diagnostic filters.

Tsao-Lin E. Moy. LMT
(b)(6)
New York, NY 10038
(b)(6)
Email: tmoy@backessentials.com

135 hours- Observation/Grand rounds, Clinical Hours: Clinical Observations and Grand rounds become core to our learning experience. Following and documenting the treatment strategies and protocols used by senior acupuncture practitioners, gives us further understanding and insight into clinical application of Acupuncture and Oriental Medicine.
70 hours – Human Service Skills
90 hours – Independent Study Project
40 hours – Electives
30 hours – Pathophysiology

Third Year – 720 hours
In the third year, the training, knowledge and experience in Acupuncture and Oriental Medicine comes to fruition. Students take the NCCA exams.
Influenced by various traditions in acupuncture, students are encouraged to develop their own style. A deeper understanding and clinical knowledge is applied in clinical rotations. Students plan treatment strategies and treat patients in Clinic under the supervision of senior acupuncture practitioners. Having access to senior practitioners for advice in clinic is an invaluable clinical experience.

120 hours Lecture
55 hours Field Seminars
100 hours Skills Review
85 hours Grand rounds/ Clincal hours
250 hours Clinical Practicum
90 hours Independent Study Project
20 hours Supervision.

The Tri-State Acupuncture and Oriental Medicine program is representative of the standard of education in an accredited program and the minimum requirement to practice as a competent provider of Acupuncture and Oriental Medicine.

[005]

Tsao-Lin E. Moy, LMT
(b)(6)
New York, NY 10038
(b)(6)
Email: tmoy@backessentials.com

Recommendations to the Commission:

1. I recommend that the Commission look to the existing creditialing bodies for guidance, and support the standards of education in Acupuncture and Oriental Medicine that have been established by the NCCAOM, ACCAOM and the State Education Dept of NY.

2. I recommend that the Commission not support abbreviated training programs, that these greatly diminish existing standards of competency and training; and ultimately diminish the quality of care available to the general public.

Thank you for your time today, I am available for follow up and assisting the Commission with further inquiry and documentation.

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
006a. testimony	Huaihai Shan (partial) (1 page)	nd	b(6)

COLLECTION:
Federal Records
White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

OA/Box Number: 43232

FOLDER TITLE:
WHCCAM Meeting Testimony, January 23, 2001 [4]

2011-0568-S
kc825

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[0060]

The Application of Traditional Chinese Qigong in Psychiatry in the United States

Presenter: Huaihai Shan, M.D.

Associate Professor of Psychiatry
Shanghai XUHUI Mental Health Center, P. R. China
Shanghai University of Traditional Medicine, P. R. China
Shanghai Institute of Qigong Research P. R. China

Visiting Associate Professor
Department of Psychiatry
UMDNJ-Robert Wood Johnson Medical School
Robert Wood Johnson Medical School
671 Hoes Lane, UBHC, Room D-326
Piscataway, NJ 08854
Email: Shanhu@umdnj.edu
Tel: (732) 235-3360W, (b)(6)
Fax: (732) 235-4430

CAM approaches that have been applied to psychiatry include Qigong, biofeedback therapy, acupuncture, Chinese herbs, meditation, autonomic training, hypnosis, relaxation therapy and biotherapy. Although the clinical utility of Qigong has not yet been fully evaluated, a large number of practitioners and patients worldwide have accepted it. There is good anecdotal evidence supporting the use of Traditional Chinese Qigong in conventional medical settings for disorders including mild anxiety, depression and, most strikingly, psychosomatic disorders such as asthma. Unfortunately, there are relatively few adequate research studies on the use of Qigong in this field.

Following are some concerns about Qigong that should be considered in order to properly assess the application of Traditional Chinese Qigong in psychiatry.

1. Many Qigong masters do not have extensive knowledge to diagnose

properly medical problems that may be treated by Qigong.
2.The anecdotal evidence of efficacy is not acceptable by conventional medicine because it lacks placebo controls.
3. Qigong has been sometimes been misused in the community and conventional medical settings in China.

What is Qigong? Although Qigong is widely practiced in the world and there is growing number of people and patients who are interested in practice Qigong, there are still some different opinions about its definition. Qigong embodies two principles: Qi is the vital energy of the body and gong is the practice and training of the Qi. Traditional Chinese Qigong, a particular form of Qigong, is also known as medical Qigong.

Traditional Chinese Qigong is the ancient art of health maintenance and healing that originated several thousand years ago in China. Traditional Chinese Qigong has three elements: mind, breathing and movement. The ultimate goal of Qigong is to improve the functions of the Mind/Body in a balanced way. Traditional Chinese Qigong is also one of the psychological rehabilitation techniques. For thousands of years, millions of people have benefited from Qigong practices and believed that improving the function of Qi maintains health and heals disease. It is believed that regular practice of Qigong helps to cleanse the body of toxins, restore energy, reduce stress and anxiety, and help individuals maintain a healthy and active lifestyle.

I hope that psychiatrists and psychologists would consider evaluating Traditional Chinese Qigong as a method of behavioral therapy.

I suggest that NIH establish a focus for research of Traditional Chinese Qigong in NCCAM to evaluate the practice of Qigong including its indications and contradictions.

The practitioner should consider the safety limitations of Qigong in the treatment of medical problems because Qigong may induce some psycho-physiological responses that are not good for health if practiced incorrectly or inappropriately.

I would be pleased to offer some the training courses of Traditional Chinese Qigong in the United States. I hope NCAAM establish a system to license Qigong instructors in the future.

If this is done, the quality of the research in the application of the Traditional Chinese Qigong in psychiatry would be improved.

My colleagues and I are very interesting in the application of Traditional Chinese Qigong for psychosomatic disorders in psychiatry. In particular, we would like to compare Traditional Chinese Qigong with meditation and other relaxation therapies in a Methadone setting for treatment of drug abusers.

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
006b. resume	Huaihai Shan (partial) (1 page)	nd	b(6)

COLLECTION:
Federal Records
White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

OA/Box Number: 43232

FOLDER TITLE:
WHCCAM Meeting Testimony, January 23, 2001 [4]

2011-0568-S
kc825

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[0066]

Huaihai Shan, M.D. Qigong Master

Associate Professor of psychiatry
Shanghai XUHUI Mental Health Center, P. R. China
Shanghai University of Traditional Medicine, P. R. China
Shanghai Institute of Qigong Research P. R. China

Visiting Associate Professor
University of Medicine and Dentistry of New Jersey
Robert Wood Johnson Medical School
671 Hoes Lane
Piscataway, NJ 08854
Email: Shanhu@umdnj.edu
Tel: (732) 235-3360W, (b)(6)
Fax: (732) 235-4430

I received M.D in Psychiatry from the Shanghai Mental Health Center of China in 1985. I have trained extensively in general psychiatry, medical psychology, Traditional Chinese Medicine including Qigong, acupuncture and other CAM therapeutic approaches. I had begun to study the research on the psychiatry, medical psychology and CAM in 1985 after I had completed residency program in psychiatry. I founded the several research grant in psychiatry from Chinese government since 1986. I am a principal investigator of Chinese Health Center grant for in Qigong and psychology. The Several articles have been published in Chinese journals on the Complementary and Alternative Medicine. I also have been training in psychiatry and complementary and alternative medicine in the United States since 1996.

I also received a certificate of medical Qigong instructor from Shanghai Traditional Chinese Medical University of China, School of Qigong in 1989. I have taught Qigong at Shanghai Mental Health Center, in Qigong clinic and the community. Over the past 10 years, I have successfully integrated complementary approaches into my clinical practice. I have completed the project of the application of Traditional Chinese Qigong-based stress reduction program in the treatment of Anxiety disorders that has been published.

My research interests are focused on the use of complementary and alternative medicine including Qigong therapy, acupuncture, Chinese herb medicine and mind/body medicine and relaxation therapy, to treat stress-related disorders. I have been dedicated to helping people heal themselves, increase vitality, cultivate spiritual growth by complementary and alternative medicine. I am currently working on the research of the comparing Traditional Chinese Qigong with Biofeedback therapy for psychosomatic disorders and other medical problems as postdoctoral fellow in psychophysiology lab at UMDNJ. I am also training the faculty and staffs learning Qigong practice in medical school and treat the patients by Qigong therapy. I believe that Traditional Chinese Qigong is one of the Complementary and Alternative Medicine that is very helpful for Americans in the future.

Testimony of Christopher Kent, D.C.,
President, Council on Chiropractic Practice

The Council on Chiropractic Practice (CCP) is an apolitical, non-profit, 501 c (3) organization.

The mission of the CCP is "To develop evidence based guidelines, conduct research and perform other functions that will enhance the practice of chiropractic for the benefit of the consumer."

EVIDENCE-BASED PRACTICE

Evidence-based clinical practice is defined by Sackett as "Use of the current best evidence in making decisions about the care of individual patients...(it) is not restricted to randomized trials and metaanalyses. It involves tracking down the best external evidence with which to answer our clinical questions" (1)

This concept was embraced by the Association of Chiropractic Colleges in their first position paper. This paper stated:

> Chiropractic is concerned with the preservation and restoration of health, and focuses particular attention on the subluxation.
>
> A subluxation is a complex of functional and/or structural and/or pathological articular changes that compromise neural integrity and may influence organ system function and general health.
>
> A subluxation is evaluated, diagnosed, and managed through the use of chiropractic procedures based on the best available rational and empirical evidence. (2)

The CCP has developed a practice guideline for vertebral subluxation with the active participation of multidisciplinary experts in guideline development, research design, literature review, law, medicine, and clinical chiropractic.

GUIDELINE DEVELOPMENT PROCESS

The first step in guideline development was to analyze available scientific and clinical evidence.

Manual and computer literature searches were performed. This was followed

by a symposium for chiropractic technique developers, and an "open forum" where any interested person could present evidence. Those unable to attend were invited to submit written evidence.

After sorting and evaluating this evidence, the initial draft of the guideline was prepared and distributed to the panel for review and criticism.

International input from the field was obtained when the working draft document was submitted to 195 peer reviewers in 12 countries.

After incorporation of the suggestions of the reviewers, a final draft was presented to the panel for approval.

The finished document was printed and distributed free of charge to all known U.S. and Canadian chiropractors. Distribution to chiropractors in other countries is being undertaken.

Council on Chiropractic Practice Guideline No. 1, *Vertebral Subluxation in Chiropractic Practice* was accepted for inclusion in the National Guideline Clearinghouse after evaluation by ECRI, a collaborating agency of the World Health Organization.

As Sackett wrote, "External clinical evidence can inform, but can never replace, individual clinical expertise..." (1)

The most compelling reason for creating, disseminating, and utilizing clinical practice guidelines is to improve the quality of health care.

References

1. Sackett DL: Editorial: Evidence-based medicine. Spine 1998;23(10):1085.

2. Position Paper #1. Association of Chiropractic Colleges. July, 1996.

Contact Information

Christopher Kent, D.C.
195 N. Franklin Turnpike
Ramsey, NJ 07446

cbkent@ix.netcom.com

Phone 201-368-9600 FAX 201-828-9221

Resources

Clinical Practice Guideline No. 1, *Vertebral Subluxation in Chiropractic Practice*
Full text online at http://www.worldchiropracticalliance.org/ccp.htm

World Chiropractic Alliance website http://www.worldchiropracticalliance.org

Journal of Vertebral Subluxation Research http://www.jvsr.com

CINAHL database http://www.cinahl.com

MANTIS database http://www.healthindex.com

Patrick Gentempo, D.C., President, Chiropractic Leadership Alliance.
pg@subluxation.com. 800-892-6463
255 W. Spring Valley Avenue
Maywood, NJ 07607

Terry Rondberg, D.C., President, World Chiropractic Alliance
2950 N. Dobson Rd. #1
Chandler, AZ 85224
800-347-1011

Fabrizio Mancini, D.C., President, Parker College of Chiropractic
2500 Walnut Hill Lane
Dallas, TX 75229
president@parkercc.edu 214-352-7332 Ext. 7700

Brian J. McAulay, D.C., Ph.D., President, Sherman College of Straight Chiropractic
P.O. Box 1452
Spartanburg, SC 29304
800-849-8771

Lowell C. Fuller

60. **Kathleen Ann Golden,** Acupuncture Society of NY

✍

61. **Donald Dangelo,** American Society of Acupuncture

✍

62. **Tsao-Lin E. Moy,** Tri-State College of Acupuncture

I would like to offer testimony regarding the standards of education from the perspective of a student in an accredited Acupuncture program. The rigor of the program, and the amount of hours of study and hands on training and supervision a student experiences. I am a representation of this process.

✍

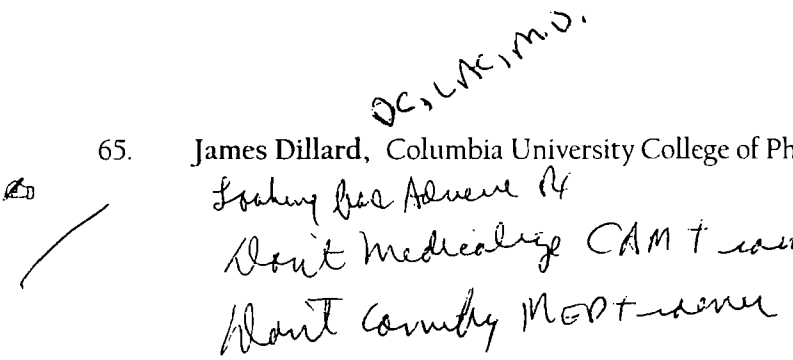
63. **Huaihai Shan,** University of Medicine & Dentistry of New Jersey

How to promote the Traditional Chinese Qigong in the United States: The Application of Traditional Chinese Qigong in psychiatry. Presenter: Huaihai Shan, M.D.; Associate Professor of Psychiatry; Shanghai XUHUI Mental Health Center, P.R.China; Shanghai University of Traditional Medicine, P.R.China; Shanghai Institute of Qigong Research, P.R.China; Visiting Associate Professor, Department of Psychiatry, UMDNJ,RWJMS.....CAM sssociated with psychiatry was included for Biofeedback therapy, Acupuncture, Chinese herbs, meditation, Autonomic training, hypnosis, relaxation therapy and Biotherapy that have been used in behavioral medicine. The patients seek to CAM for their health due to side effects of some drugs in neurotic disorders or other mental disorders. NIH and practitioners increasingly recognize Qigong as one of the CAM. Although the concept of Qigong has not yet been fully, practitioners and patients in the world have accepted it. There is good evidence supporting the use of Traditional Chinese Qigong. Traditional Chinese Qigong is increasingly practiced in conventional medical settings for mild anxiety, depression and other medical problems. The most medical problems were benefited from Qigong practice are psychosomatic disorders; for example, asthma and cancers, etc. These therapies have been done in the research and treatment for psychosomatic diseases and other medical problems in psychiatry. But there are few psychiatrists who are interested and study in this field in the world, especially in China. Currently, there are following some questions about Qigong that should be discussed in order to promote correctly the Traditional Chinese Qigong in the United States and the application of Traditional Chinese Qigong in psychiatry. 1. Many Qigong masters do not have extensive medical knowledge to diagnose properly for medical problems that will be treated by Qigong masters. 2. The evidence of efficacy cannot accept by conventional medicine because research is no placebo controls and lack of research skill among CAM practitioners. 3. Qigong is not scientific term according the conventional medicine and is not consistent with known medical science. Qigong has been misused in the community and conventional medical settings in China. There few results of research had scientific because many studies had no good design of research even though many studies have been done in China. What is Qigong? Although Qigong is widely practiced in the world and there is growing number of people and patients who are interested in the practice of Qigong, there are still some different opinions about the definition of Qigong at different fields in the world. Qigong embodies two principles: Qi is the vital energy of the body and gong is the practice and training of the Qi. What I am teaching now Qigong is one of the Traditional Chinese Qigong that is also called as medical Qigong. Qigong is well known in the world, but there are few people know what is real Qigong. Traditional Chinese Qigong is a different method from external Qigong and one of the self-practice as behavioral therapy. However, people practice Traditional Chinese Qigong could produce a serious psychophysiological reactions and reach far beyond our physical health. The many psychiatrists and psychologists were interested and involved in this field right now. But there is tendency the misleading the application of Traditional Chinese Qigong in psychiatry. Traditional Chinese Qigong is the ancient art of health maintenance and healing that originated several thousand years ago in China. Traditional Chinese Qigong has three elements: mind, breathing and movement. The ultimate goal on Qigong is to improve the functions of the Mind/Body in a balanced way. Traditional Chinese Qigong is also one of the psychological rehabilitation techniques. For thousands of years, millions of people have benefited from Qigong practices and believed that improving the function of Qi maintains health and heals disease. It is believed that regular practice of Qigong helps to cleanse the body of toxins, restore energy, reduce stress and anxiety, and help individuals maintain a healthy and active lifestyle. I hope that psychiatrists and psychologists would consider Traditional Chinese Qigong as behavioral therapy in psychiatry and the community because Traditional Chiniese Qigong is of the Mind/Body interventions. I suggest that NIH could build up a center for research of Traditional Chinese Qigong in NCCAM that would control and manage the practice of Qigong including what is

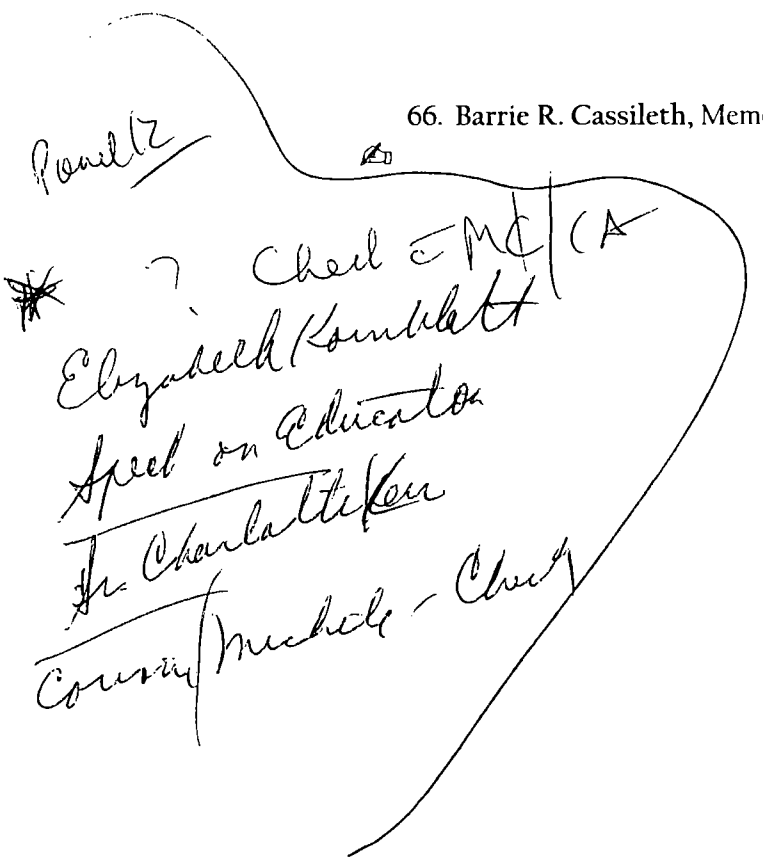
indication and contradiction of Qigong practice. The practitioner should consider the safety of Qigong in the treatment of medical problems because Qigong may induce some pyschological responses the are not good for their health if they were practiced in a wrong way or inapproriately. We would offer some the training courses of Traditional Chinese Qigong in the United States. I hope the NCCAM establish the system of license of Qigong instructors in the future. The quality of research in the application of the Traditional Chinese Qigong in psychiatry should be improved. We are very interested in the application of Traditional Chinese Qigong for psychosomatic disorders in psychiatry. Now, we would like to compare Traditional Chinese Qigong and Biofeedback Therapy in Methadone Setting for Drug Abusers and will evaluate the possible therapeutic effects of the Traditional Chinese Qigong and Biofeedback Therapy for drug abusers. How to promote the Traditional Chinese Qigong in the United States? I wish to increase the research funds in the application of Traditional Chinese Qigong in psychiatry. There few people know what is Traditional Chinese Qigong that is different from External Qigong and energy therapies in the western country. There is a tendency the misleading the application of Traditional Chinese Qigong in psychiatry even though Qigong has been widely used in the world, but Qigong has been misused in the community and conventional medicine. I wish psychiatrists and psychologists would be involved deeply in the application on Qigong in psychiatry.

64. **Christopher Kent**, Council on Chiropractic Practice

65. **James Dillard,** Columbia University College of Physicians and Surgeons



66. **Barrie R. Cassileth,** Memorial Sloan-Kettering Cancer Center



67. **Raymond Y. Chang,** Institute of East-West Medicine

To make CAM more accessible and transparent, we need to win the trust of the conventional medical community, which is still divided and occasionally hostile to CAM. It needs to be clear that although CAM practices maybe unconventional or at times its mode of action (eg aupuncture) even yet unaccountable by the current state of science, we need to ultimately judge it by outcome data. Unfortunately, the relative trickle of public and private funding available for formal trials will make such data unavailable for many CAM modalities and interventions for a long time to come. This has to do with patentability and profitability as well as other commercial and policy issues, and will need to be solved on a macro level over time. Meanwhile, although limited curricula for CAM has been included in most medical schools, serious CAM practice and training is lacking at the residency and fellowship level making most CAM practitioners by and large self-taught or self-professed. This quality of CAM practice can be enhanced with appropriate introduction of CAM into post-graduate training programs as well as most medical conferences as sponsored by the major medical societies. Education is less expensive to fund than research but will generate an awareness crucial for a future generation of practitioners to accept CAM modalities and practitioners.

68. **Janice Pingel,**

Mrs. Pingel used CAM successfully 10 years ago for a back problem. She's been combining conventional and CAM treatment for lung cancer that has metastasized to the liver. She was originally given 6 months to live, but her response to her current chemotherapy, which began at the same time she began using a specific Chinese tea, has her oncologist impressed. The oncologist believes her good scan results are likely due to the combination of treatments.

68. Joan Runfola

As both a cancer survivor and an oncology social worker who has counseled and guided people with cancer and their families for 23 years (with a special concentration on CAM), I feel it is not only important to get information out to the public on all aspects of CAM, but especially to give people seeking these treatments and approaches guidelines on questions to ask CAM practitioners in order to determine how safe and effective the approach is likely to be for them. I have developed a "Brief" on this topic which is used by Cancer Care social workers to help patients in this decision-making process (see our web site, www.cancercare.org). Medical consumers also need to be given what to look for in selecting specific CAM practitioners (licensing, qualifications, etc.) and list of national or local organizations who can refer them to practitioners with these qualifications. I have developed a list of some of those national organizations and can bring it to this meeting. Additionally, it has been shown that approximately 60-72% of medical consumers utilizing CAM treatments and approaches do so without discussing this with their physicians. The public needs to be educated about the importance of this and the deleterious results that can occur (e.g., negative drug/herb interactions, etc.) if they do not. They also need to encourage communication between the CAM practitioner and their physician. For this to occur, physicians need to be gaining more education about these approaches, with some requirements built in so thay learn these (either in medical schools, CEU's,etc.). If patients get negative responses from physicians who are totally closed to the idean of the patient using any form of CAM, the patient will go behind the physician's back to seek out these approaches, with no guidelines or oversight to ensure that it's done responsibly. Some form of listserv providing: (1) guidelines for decision-making (questions to be asked CAM practitioners); (2) lists of organizations which could describe necessary qualifications and refer to qualified CAM practitioners; and (3) scientically based, unbiased information about methodology, risks and benefits of CAM approaches could be put out by a reliable, unbiased organization (such as this commission or the Center for Complementary and Alternative Medicine out of NIH) to serve both physicians and the public to ensure at least a baseline level of dissemination of information.

70. **Barbara Sarah,** Oncology Support Program/Benedictine Hospital

I address you wearing three hats: one as the co-chair of the National Association of Oncology Social Workers Complementary/Alternative Medicine Special Interest Group, second as the chair of the Complementary Medicine Committee and the Coordinator of the Oncology Support Program at Benedictine Hospital in Kingston, NY and third as an 8 1/2 year breast cancer survivor. In all three roles I face daily a quagmire of information about CM: patients, other

JACOB'S CURE

A Fight Against Canavan Disease

My story begins in 1996 when my son Jacob was born, and then six months later diagnosed with Canavan disease, a fatal neurological genetic disorder. After being told Jacob would never hold up his head, sit, crawl, walk or say a single word, I was horrified to further learn that he would develop seizures, loose his ability to see, hear, swallow and would die within the first decade of his life. Even worse than the diagnosis, was the reality that there was no treatment to save my baby. I was told to take my baby home, make him comfortable and watch him die.

What I thought would be an endless journey, to search the world for any hope of a treatment, was not that at all. Within a month, I had located researchers from Yale University and the Auckland School of Medicine who had successfully treated two Canavan children with gene-therapy (in New Zealand) and were planning to treat 15 Canavan children in a US Phase I Clinical Safety Trial. Jacob was enrolled.

In January of 1998, after an extremely lengthy review process through the NIH, FDA and the Internal Review Boards at Yale, Jacob was finally treated and treated once more in September 1998. Jacob improved dramatically, but most impressive was his ability to generate new white matter in his brain.

As I sit before you today, Jacob again waits for the approval of yet another gene-therapy protocol that according to the researchers is safer, less toxic and technologically advanced. Where the prior therapy successfully reached a few areas of Jacob's brain, data indicates that the new procedure will deliver the gene, critical in saving Jacob, to all the areas of his brain.

With the excitement of this potential treatment comes the reality that Jacob deteriorates before your eyes as we wait for a review process that began back in May. While I am told by FDA officials that the review process is to ensure the safety of my child, I often respond by saying, "Why isn't the FDA equally concerned that Jacob could die because of lengthy reviews?" Equally concerning is that the FDA wants to ensure that patients and family members are fully informed, but yet we are kept at arms length from the review process.

Because of the orphan disease status of Canavan, there is zero federal funding that supports research in this horrific disorder. In addition to the emotional and physical toll taking care of my child has taken, I have also been given the responsibility of raising the funds necessary to support research with the potential of treating Canavan. Money is scarce, so I have become a very informed parent only able to support solid research. While I have been treated by officials at the FDA and NIH like a desperate mother willing to try any snake oil, the reality is that there simply is not enough money to support everything, so my choices must be made based on informed, concise information. And most importantly on evidence that the research I support has the potential of benefiting my son.

For an agency that prides itself on working hard to provide the public with safe, effective treatments, I am amazed at the snails pace and lack of regard the FDA has for terminally ill patients (and their families) who have no alternatives. They seem at rest with the fact that because they are taking an unethical amount of time to ensure safety, and patients may die while doing so, there is some sort of justification. I can assure you that there is never justification for a parent who must bury a child.

In my summation, Jacob's ethical right to receive a treatment that may stop the progression of Canavan, improve his quality of life and potentially treat or cure him is denied with each passing day he waits for an approval from the FDA. In addition, my right to choose what is best for my child is taken away as well. The same freedom this country prides itself on is the same freedom that has been taken away from Jacob and I.

It is my belief that protocols involving terminally ill patients must be reviewed more expeditiously and with different standards. Presently, the FDA must respond within 30 days of submission, but

P.O. Box 52
Rye, New York 10580

Ph: 914 673 2796

there is no limit for how many times they can ask for re-submissions, for which another 30-day response is allotted. I would propose the following:

1. For experimental research in preparation for clinical trials involving patients quickly deteriorating from terminal illness (with a small window of opportunity) there must be prior knowledge of the FDA's demands, a review process that begins prior to submission. Researchers and patients and patient representatives should be able to have open dialogue with the FDA to discuss protocol intensions, collection of data and risk/benefit ratios.

2. The FDA needs to have more interaction with the patients of the protocols they are reviewing to understand the magnitude and the necessity for treatment, the patients knowledge of the alternatives (in our case death) and the desire of the patients choice of treatments.

3. Upon submission, the FDA should be required to respond within two weeks. If there are further requests from the FDA that the researchers and patients seem unreasonable and would create an unnecessary delay, then the patients and/or family members should be able to waive the approval from the FDA and sign an informed consent to proceed with the treatment.

4. An oversight committee must be created to protect patients and oversee the FDA. There must be a balance. As stated by our local congresswoman, Nita Lowey, "If there is a level of comfort, parents or patients are informed and know the risks and there are no other options than we must move ahead and treat the patients."

I thank you for this opportunity to share with you my precious Jacob and the struggles we live though every day. I hope that our testimony will make a difference and most important save lives.

JACOB'S CURE

A Fight Against Canavan Disease

In September of 2000, I created Jacob's Cure, a non-profit foundation, because of my passion to save the life of my son, Jacob, who is afflicted with Canavan disease, a devastating genetic brain disorder. Because of an enzyme deficiency, Canavan demyelinates the brain. Without myelin or white matter, Jacob never reached his first milestone...lifting his head. He is essentially trapped in his body. Without intervention, Jacob will lose his sight, his ability to swallow, may be stricken with seizures, become too weak to fight off illness and die within the first decade of his life.

In 1998, my efforts resulted in Jacob's enrollment in a Phase 1 Gene-Therapy Clinical Safety Trial. Jacob, along with 14 other Canavan children exhibited positive results and miraculously, Jacob developed new myelin. There was now hope where none existed before.

With these exciting results, it is my goal and that of Jacob's Cure to continue to support the continuation and advancement of research in gene-therapy. Because Canavan is so rare, zero federal funding supports research in Canavan disease, so it is through the help of friends, family and a philanthropic community that Jacob and children like him may be cured.

As it is the goal of Jacob's Cure to help the children dying of Canavan today, an additional project supported by Jacob's Cure is Neural Stem Cell Transplantation at Boston Children's/Harvard, at the direction of Dr. Evan Snyder. This research has exhibited great hope in curing Canavan and most brain disorders because of the unique ability of stem cells to provide what the brain is lacking, while also repairing any damage that has occurred. Dr. Snyder and his team aim to treat Canavan children with stem cells by the end of 2001.

Currently, Jacob and 24 other children suffering from Canavan desperately wait for a second, more advanced gene-therapy procedure that is under review for approval at the FDA. The goal to begin this critical gene-therapy treatment is by February 2001.

- *Jordana Sontag, "Jacob's Mom"*
President

P.O. Box 52
Rye, New York 10580

Ph: 914 673 2796

The New York Times Magazine

DECEMBER 6, 1998 / SECTION 6

Their 19-month-old boy was deteriorating, and Richard and Jordana Sontag had come to Yale, desperate and angry. An experimental gene therapy was their only hope, but the scientists were not sure it was safe. The couple spotted Dr. Margretta Seashore in the lobby. 'Look at him,' Richard said, thrusting Jacob in her face. 'You tell him why this protocol is delayed while he's dying. ...You look at my son dying. Tell it to him.'

Keeping Jacob Alive

By Michael Winerip

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
007. letter	Jacob's Cure testimonial (partial) (2 pages)	nd	b(6)

COLLECTION:
Federal Records
White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

OA/Box Number: 43232

FOLDER TITLE:
WHCCAM Meeting Testimony, January 23, 2001 [4]

2011-0568-S
kc825

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

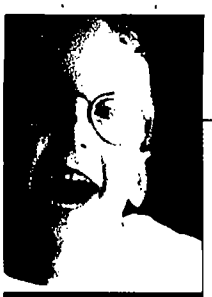
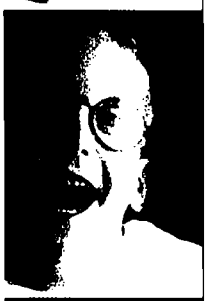
P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

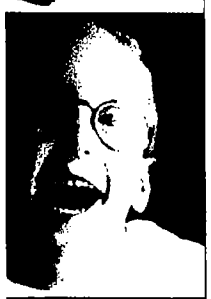
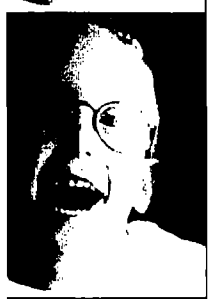
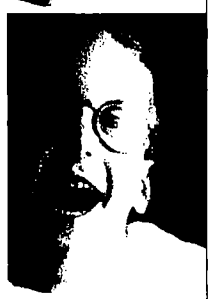
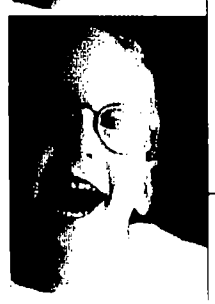
C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[007]

JACOB'S CURE

A Fight Against Canavan Disease

- A copy of a letter from (b)(6) *who suffers from Canavan disease. This letter documents the plea of a parent for help in ushering an approval for a treatment for her son.*

My name is (b)(6) Palatine, IL 60067. I have a 3 year old son, Max, who is dying of a rare and fatal brain disease.

Because Canavan disease (CD) is progressive, he is running out of time, and declining physically every day. Due to a lengthy and, in this case, too stringent review process by the FDA; medical treatment that Max has an ethical right to seek is being kept from him by a regulatory agency that is effectively protecting him to death.

I would like to explore the possibility of suing the FDA. To force them to allow my son, and fourteen other dying children to have access to a treatment that may slow down the progression of this devastating disease. These children are literally running out of time, and they deserve to get medical help even if it is only "experimental."

I realize that the FDA has been under a tremendous amount of pressure from Congress and the public to be extra cautious in approving gene therapy trials due to the unfortunate death of Jesse Gelsinger, he was enrolled in an unrelated clinical trial using gene therapy. Our children are now paying the price of this negative backlash. But, this has been going on for a year now, and I want my son to at least have a chance at a better quality of life.

Max received an injection of healthy genes by the same research team we are currently working with in a previous gene therapy Phase 1 Safety Trial in September of 1998, at Yale University. He did remarkably well. If that IND was being held to today's higher standards, and the negative view towards gene therapy, Max never would have been treated, or had the benefit of demonstrating such amazing improvements.

I only want the best for my child, and a chance at a better life, this is his only chance in the world. It is not as if there are other treatments that I am unwilling to try...this is our ONLY hope. It helped before and I want to try it again. I know the minimal risks and am willing to give full consent. I am not an uninformed parent.

Dr. Paola Leone at Thomas Jefferson Medical College has developed a better, safer, less toxic, and more effective means of delivering the corrected genes to our children's brains, and I want my son to have that treatment. All our tests show it is actually safer that the old method.

It is my understanding that the FDA, as a regulatory agency, still must answer to the law. My son has a right to seek medical treatment. He is suffering from a 100% fatal and PROGRESSIVE disease, and this is his only option for treatment. Is there anything I can do, legally, to force the FDA

P.O. Box 52
Rye, New York 10580

Ph: 914 673 2796

to release the "clinical hold" they have placed on our IND? We can't wait any longer.

Several Senators and Congressman are already working on this matter, but they are getting nowhere. The Principle Investigator for the protocol, Dr. Leone, has explained to me that she has done all she can do on our behalf. The FDA is "acting conveniently too conservative" How can they use stall tactics when my child is trapped in a body that is deteriorating more and more everyday? Once he is placed on a feeding tube and becomes completely paralyzed... it will then be too late for treatment!

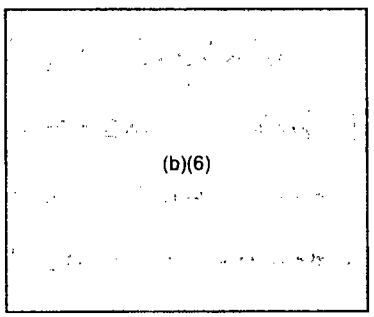
If you think we have a case, I will of course be able to furnish you with any and all information regarding the specifics of our situation, and the IND (proposed protocol). I am sure Dr. Leone would be willing to speak with you as well.

This case is precedent setting because we can prove that when Government is too big their protection can potentially kill people waiting for medical treatment. People, who otherwise have no hope, and no other option. Regulatory agencies do not have absolute authority, especially when they are under pressure to look good, and are overworked. In this scenario people like Max are slipping through the cracks. This is when the law needs to step forward and force the FDA's lengthy review process to be reassessed.

I run a public charity dedicated to funding medical research to cure Canavan disease, I can sue either on behalf of the foundation, or as a parent (there are also 14 other families involved in this struggle).

For more information about Canavan disease please visit our website at http://www.canavanresearch.org/ Thank you for your time and consideration of this important matter.

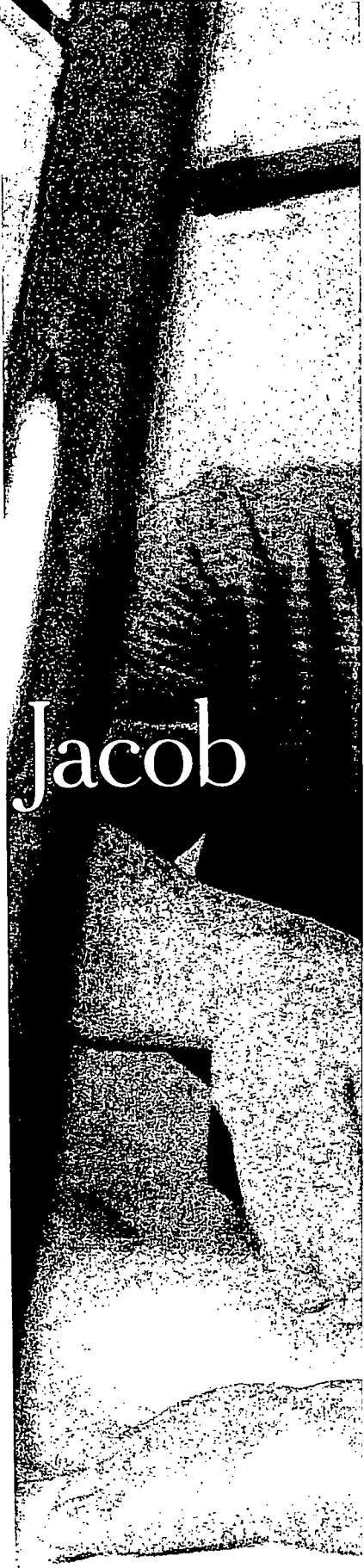
Cordially,



Until recently, there was no hope for a child with Canavan disease. But when the Sontags learned that their only child was born with it, they were prepared to sacrifice anything to get him the experimental treatment he needed. They didn't know that might include their marriage.

Fighting for Jacob

By Michael Winerip



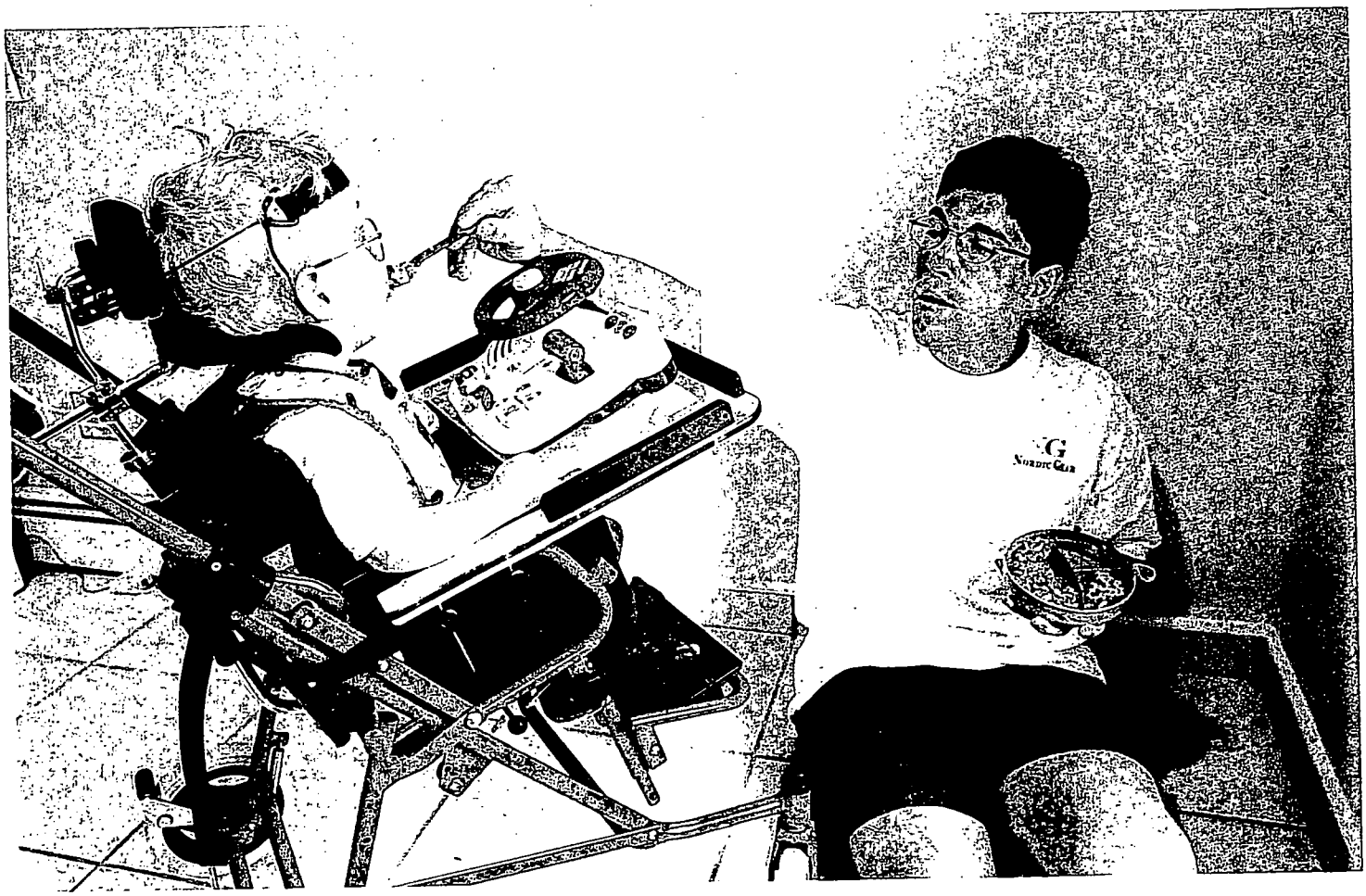
Jordana and Richard Sontag were speeding toward Yale University, angry, desperate, ready to unleash their secret weapon, which they had carefully loaded into the back of their Grand Cherokee. For a year, they had done everything in their power to save their dying baby boy, Jacob. The well-to-do young couple and relatives had donated more than $200,000 to Yale to underwrite experimental gene-therapy research aimed at curing the rare genetic disease that plagued Jacob. They had helped pay to bring two leading researchers from the other side of the world to Yale and to transport from a lab in Germany the precious concoction of healthy genes that might save their son and a dozen other dying children with Canavan disease. They had hired lawyers and enlisted United States Senators to lobby the medical oversight committees for approval of the experimental procedure.

And then they waited. Week after week, Yale officials assured them that the medical school's review committees and the governmental agencies would soon take action. But spring had given way to summer, and summer to fall, and still nothing. Jacob's adorable blond head had grown too heavy for him to hold up, and he had little control of his limbs, which hung at his sides, making him floppy like a rag doll.

In hopes of speeding the review, Jordana had assembled two notebooks full of records documenting the complete medical history of 1½-year-old Jacob Ross Sontag, starting with the first sonogram. The names of all those committees and agencies that had to approve the experimental treatment made her head throb and at night turned her dreams dark and anxious: the Human Investigation Committee and Biological Safety Committee at Yale; the Recombinant DNA Advisory Committee at the National Institutes of Health; a staff review at the Food and Drug Administration. All had to say "yes" before the children could be treated. But as the

Richard and Jordana with Jacob, after he was hospitalized with a 103-degree fever.

Photographs by James Estrin



Above: Richard and Jacob at mealtime. Right: Jordana in a moment of quiet anguish.

Sontags knew, H.I.C. wouldn't act until B.S.C. did; B.S.C. preferred R.A.C. to give an expedited approval first; and R.A.C. was waiting until H.I.C. ruled. And how did the Sontags explain that to friends who asked, "How's it going?"

"We plan to see anyone who will see us," said Richard on the drive to Yale. "We'll look into offices, the cafeteria — we'll find them!" That fall day in 1997, as they hurried through the lobby of Yale-New Haven Hospital wheeling the secret weapon, they couldn't believe their luck. There was Dr. Margretta Seashore! The enemy! To the Sontags, Dr. Seashore epitomized all the bureaucratic delays that were killing them. She is an internationally known genetics professor, appointed by Yale to shepherd the experimental procedure through the review process. At 59, Seashore is careful, thorough, academic — precisely the type of person who was driving the Sontags crazy. Seashore was a generation older than the bold team of junior Yale researchers who had actually developed the new gene therapy, tested it on 300 rats, 4 monkeys and 2 children in New Zealand and pronounced it ready to go for its first trial in the United States.

As far as the Sontags were concerned, Seashore represented the establishment, when they needed a firebrand to shake up Yale.

Seashore was waiting in the lobby to meet a group of medical students for a tutorial and was surprised to see the Sontags. She tried to make small talk, but they would not be distracted. "I'm sorry I can't sympathize," said Jordana. "We're living with a dying child the past 18 months."

Richard unfastened the secret weapon and began yelling. "You look at him!" he screamed, lifting Jacob out of the stroller and pushing him at Seashore. "You tell him why this protocol is delayed while he's dying!" The father was speaking so loud, people in the lobby were staring. Seashore noticed that her four medical students had arrived and appeared to be in shock.

"How could you prevent our child from treatment?" Richard yelled. By then, Richard was crying, Jordana was crying, Jacob was howling and Seashore looked ready to burst into tears.

"I do understand your desperation," Seashore said. "You have to understand, the biosafety committee is trying to be safe." She suggested that they consult the medical-school dean about the delays. "I'm under tremendous pressure the past months, overseeing this protocol."

"That's a luxury compared to being parents of a terminally ill child," said Jordana.

Seashore's hands were trembling. She warned she'd take herself off the protocol if this pressure continued: "If I do, this trial is dead."

"You look at my son dying," Richard screamed. "Tell it to him!"

Seashore would later call that Sept. 24, 1997, showdown a watershed. "I was shocked at their behavior in public," she said. "What that said was: We have desperate people here; they're going to blow the place up; we have to make a deci-

Michael Winerip is a staff writer for the magazine.

PHOTOGRAPHS BY JAMES ESTRIN/THE NEW YORK TIMES

thought Yale's biosafety committee was stalling. ... were putting foreign DNA into the brains of ... people," she said.

sion." After the Sontags' visit, the assistant to the medical-school dean spoke to members of the Yale biosafety committee and told them that it was time to decide — yes or no— but soon. The next week, the committee approved the therapy, and in the following months the other committees did, too. The Sontags' desperate plan had worked. On Jan. 2, 1998, Jacob Sontag was scheduled for surgery at Yale, the first time doctors in this country planned to treat a genetic disease by shooting a syringe full of healthy genes directly into the brain.

The four medical students who witnessed that confrontation have told Seashore it's the best clinical lesson they've had at Yale, and indeed, many of the forces shaping medical practice and research converged that day in the lobby to detonate the nasty explosion. For the Sontags, the experimental therapy was the sole hope they had to reverse the degeneration of their only child, precious Jacob, suffering from a rare disease that eventually leads to paralysis, blindness, severe retardation and death, typically between ages 5 and 10. To the Sontags, gene therapy — introducing healthy genetic material into malfunctioning cells so that they can produce a missing enzyme Jacob's body needs — was brilliant, and they knew from news articles that the approach was being used in hundreds of trials on cancer, cystic fibrosis and heart disease.

In the Sontags' corner were two junior Yale researchers, Dr. Matthew During, 41, and Paola Leone, 34, a neurobiologist. Since 1995, when parents of another dying child had begged During and Leone to apply their skills to Canavan, the two had moved at a breakneck pace. The Sontags understood these researchers had their own reasons — there will be great rewards for the scientist who figures out how to deliver large amounts of healthy genetic material to the right cells. For During and Leone, Canavan could be the template for other genetic therapies, revolutionizing medicine; the dying children promised to be the perfect human subjects. As for the parents, they just thanked God that anyone would take on such a rare "orphan" disease.

On the other side were Seashore and three dozen colleagues on Yale's oversight committees, many of them fearful that in this era of deregulation safety standards are being lowered, allowing treatments like the fen-phen diet drugs to reach the public without adequate testing. "The heart of the question," Seashore said, "is when is it time for something in a scientific lab to be made available to people?" Seashore had seen the career of one of her colleagues, the geneticist Dr. Reuben Matalon, upended by moving too quickly from the test tube to humans. In the early 1990's, Matalon thought he had developed a pregnancy screening test for Canavan. And then, to his horror, four pregnant women who had tested negative gave birth to babies with the disease. "I wasn't going to let anything like that happen to me," Seashore said.

I first met Jordana and Richard Sontag in May 1997. Richard's sister, Deborah Sontag, is a friend and colleague (the Jerusalem bureau chief of The Times) and had told me of her younger brother's quest. She was skeptical, but also in awe of how determined her brother and sister-in-law were to find a cure and how open they were about Jacob. A few months before, in Feb-

Richard comforting Jacob as Dr. Charles Duncan, center, and his assistant, Dr. Sung Lee, inject the new genes.

ruary 1997, to celebrate Jacob's first birthday, Richard and Jordana had rented a restaurant banquet room, hired a Musical Munchkin and invited 50 friends and relatives to the party.

Until recently, there was no hope for a child with Canavan, which is most prevalent among Ashkenazi Jews like the Sontags — affecting 1 in 6,000 Jewish infants. Both parents must be carriers for the disease to manifest in the offspring. Children have a defective gene that can't produce a key enzyme needed to break down an acid in the brain known as NAA. Scientists hypothesize that a surplus of NAA develops, which in turn interferes with the formation of myelin, the white coating that covers nerve cells. Without myelin, the brain's nerve cells can't relay messages to the body, eroding motor control to the point of paralysis. Autopsies reveal spongy brains full of tiny holes.

At birth, the baby appears normal. But by 3 months, parents notice a lack of responsiveness. Misdiagnosis is common. Jacob was first thought to have developmental and vision problems. At 4 months, he was fitted for glasses. At 5 months, a specialist said it was Leigh's disease. By the time Canavan was identified, Jacob was 7 months old.

Most families had only bleak things to tell the Sontags. They met parents who medicated their children around the clock, who felt any physical therapy was a waste. A mother from Philadelphia said: "Don't get him glasses. It won't matter to him, and you don't want people staring." There were parents who confided that they quietly let the children die instead of rushing them to a hospital during a seizure. "The best thing you can do," they said, "is have another child who is healthy." To Jordana and Richard, this was Canavan's defeated old guard speaking.

The couple was not used to failure. In 1992, when Richard was 30, he bought out a two-man firm that produced battery-heated socks and in five years built it into Nordic Gear, a multimillion-dollar outdoor accessory company with three factories and 350 employees. At an age when many are still deciding what to be, Richard was flying to the Orient first class on business and arranging meetings with his bankers. For her part, Jordana was a creative public-relations executive, savvy enough to get one of Richard's items featured on an Oprah Winfrey pre-Christmas show highlighting great gift ideas.

In the spring of 1997, in the midst of their quest for treatment, they bought a seven-bedroom, seven-bathroom home with a pool on 1.75 acres in a wealthy Westchester County suburb. That enormous house made Jordana uneasy, but Richard saw it as a testament to his business success.

They were determined to treat their son as normally as possible. When I first met Jacob, at 15 months, if his head fell onto his chest, Richard would say: "Pull up your head Jacob. Come on Boo." And slowly, Jacob did. "Say hi," Richard coached, and light came into Jacob's eyes, a smile appeared, his mouth opened and a tiny "Hi" came out. Then Richard would kiss him all over, turn him upside down and make gassy noises against his neck while Jacob beamed.

"Other Canavan families are amazed by Jacob," said Jordana. "They've never seen a Canavan child so advanced." The Sontags made sure Jacob had extensive weekly therapy — physical, speech, occupational — all publicly financed as part of a Federal early-intervention program for disabled preschoolers. They constantly read to him. On a trip to Philadelphia, Jordana sat in the back seat and read and sang the entire two hours while Jacob was mum, staring through his blue-rimmed glasses: "Is Clifford in his doghouse? Is that where Clifford is? Little Man, how come you're so smart?"

They were delighted he was already 25 pounds, while a 7-year-old Canavan girl they'd met, Morgan Gelblum, weighed *Continued on page 61*

PHOTOGRAPHS BY JAMES ESTRIN/THE NEW YORK TIMES

The genes they had been waiting so long for, the genes that could change their son's life, had arrived, in an ice bucket that looked surprisingly like a cooler.

just 30. Instead of giving him a mushy diet — he had limited chewing control — they fed him Cheerios, waffles, chicken soup with matzoh balls. Canavan children tend to have trouble sleeping — imagine not being able to shift your body for 10 or 12 hours — and most parents sedate them. "They put them to sleep with one pill and wake them with uppers," said Richard. If Jacob cried, they checked on him, but let him cry himself to sleep.

Strangers saw Jacob's stylish glasses and his polo shirts and commented on how much he looked like the boy, Ray, in the film "Jerry Maguire." "People don't realize he's handicapped," said Jordana. But the Sontags were no fools. Jordana was constantly downloading articles, and one described how much of the brain's development is completed by age 2. "Every month he doesn't have the surgery, he's losing," she said. "At 6 months, he wasn't far behind other children. Now at 15 months, he should be walking, and the distance from where he should be and where he is gets larger. He'll have to do so much more to catch up after the surgery." While the Canavan literature lists retardation as a symptom, it is not clear at what age mental deterioration becomes irreversible. Jordana and Richard were convinced there was a bright little boy trapped in that body, and they based that on the light in his eyes and his beautiful smile. They were in a race against time to reach that trapped person before he disappeared forever.

THEY WERE NOT THE FIRST. THE KARlins of New Fairfield, Conn., were. In 1994, Canavan was diagnosed in Lindsay Karlin. Her father, Roger, an internist, and mother, Helene, a psychologist, began a frantic hunt for scientists doing gene therapy and found During and Leone nearby at Yale. At the time, the researchers were using Parkinson's disease to investigate ways to deliver genes into brain cells of rats. They were testing a nonharmful virus that could be loaded with replacement genes and would then transport those genes through the membranes of brain cells.

The Karlins brought Lindsay to meet During and Leone. After several visits, the researchers agreed to focus on Canavan. The disease offered an objective measure of gene therapy's effectiveness. If, after gene injection, a brain scan showed the children's NAA decreased and their myelin increased, it would be evidence that the implanted genes had done the job. There were human reasons, too, in the Karlins' favor. Like the Sontags, they were educated people who understood the ethics of offering up their daughter and promised to be able fund-raisers.

At that time, During, a native New Zealander, was being wooed to return to Auckland. While scores of labs in the United States were doing gene therapy, in New Zealand he would be first. He saw a chance to do more, faster, with greater resources. Indeed, shortly after returning to New Zealand, the pioneer geneticist was fielding phone calls from reporters. On March 6, 1996, he oversaw his first human gene trial — on Lindsay Karlin and on a second American child, Alyssa Mushin.

Though results were mixed, the Karlins were excited. Within weeks, they say, their daughter seemed to see more and do a better job holding up her head. Brain scans seemed to indicate a decrease in her NAA and increase in her myelin (although not for the other child). The Karlins were now anxious to have their daughter treated again and agreed with During that they should inject twice as much genetic material.

Dr. Margretta Seashore, the noted genetics professor at Yale.

That fall of 1996, the Sontags were just beginning to confront Jacob's illness when they heard of the New Zealand experiment. In their usual take-charge style, Jordana and Richard were soon coordinating the next round of injections in New Zealand, on eight more children, including Jacob. To insure that every family could make the trip, the Sontags offered to underwrite any expenses the others could not afford. When New Zealand officials sent questionnaires asking parents if they understood the risks, Richard faxed sample answers to each family, urging them to slightly change the wording to the responses. The experiment was described as testing only the safety of gene injection: "The best we can hope for is that the procedure is safe; anything over and above that will be a bonus." In Richard's advisory to parents he warned, "Do not say that you expect the gene therapy to save your child's life," although that was what most hoped. Three times the Sontags had plane tickets for New Zealand, and three times they canceled as committees there raised objections. A backlash was setting in. Articles had appeared in Science and Lancet, and letters were sent to Washington regulators questioning whether During was using a distant country to circumvent United States oversight.

Night after night, Richard and Jordana phoned and E-mailed New Zealand. But the treatment was slipping away. By June, that country's officials were accusing During of pushing through the first trial without sufficient public debate, while he questioned their ethics. Sitting on this side of the world, Richard took the long view: "They don't give a damn about our kids. These aren't New Zealand kids dying."

The day they got the word, Richard and Jordana took Jacob to the playground. They wanted to be alone. Richard held Jacob in his lap as they went down slides. A woman watching asked, "Is he getting physical therapy?" She wasn't being intrusive; she simply wanted to be sure they knew it could help. "Some people try to ignore it," said the woman.

Later, Richard said, "She was nice."

"Yeah," said Jordana.

"That's the first time a stranger realized," said Richard. Jordana nodded.

THEY STARTED OVER AGAIN IN THIS COUNTRY. Richard flew to Washington with Roger Karlin to meet with lawyers about how to best pressure officials at Yale and the National Institutes of Health. The Institutes' next quarterly review was in mid-September; the Yale committees would have to act by late August for the protocol to be considered at that mid-September Federal review. "We don't know if we should get politicians involved or give Yale lots of money or go to the press," said Karlin.

"That could backfire," said Barbara Mishkin, an attorney at the firm Hogan & Hartson who specializes in human experimentation. "You could just get the committee upset."

Bob Brady, another attorney, said: "We have to lower the decibel level, focus on the science. Inadvertently, the protocol has become notorious, both here and in New Zealand."

Richard favored being aggressive: "What we tried to do is call Yale's president and thank him for letting us deposit $250,000 in the Canavan research account and say to him, 'Who do we contact about giving more?'"

Mishkin replied: "The research budget at Yale is multimillions. To influence them, you'll need much more than a couple hundred thousand."

"You want us to tone it down," said Richard. "We want to bring it up." After two hours, he and

Karlin rose to leave. Karlin pulled out a photo to show the lawyers. "My daughter, Lindsay," he said. Richard pulled Jacob from his wallet. "The consequences if this is postponed?" Brady asked.

"They may go blind, become vegetables, die," Karlin said.

JORDANA HAD STOPPED WORKING AND WAS watching Jacob like a hawk for signs of changes. Was she the only one who could feel time slipping away? "He'll get to the point of no return," she said. "The gene therapy might prolong his life, but won't help him."

Sunday morning, July 20, Richard got him out of bed. Jacob looked pale and unhappy. "A cranky baby here," Richard announced and brought him downstairs. Jordana rubbed his arms, but couldn't get a smile. His lips were chalky white. He began making jerky motions; she tried to bend his legs, couldn't, then noticed his eyes rolling. "He's seizuring!" she screamed.

Doctors hospitalized Jacob for several days, but couldn't find a cause for his 103-degree fever. Not even Jordana could coax a smile from him. A dizzying parade of specialists visited. At one point, when Jordana asked a doctor a question, Richard started to answer, but she cut him off.

"You always do that," she said to Richard. "You jump in and answer my questions. I have important questions I don't get to ask."

"Write them down," Richard said.

"I don't have to write them down!" said Jordana. "I just don't want my son being dead because some doctor doesn't know how to treat a child with Canavan." Doctors said there should be no damage from the seizure, but the Sontags worried. Who was Jacob? A little boy with light in his eyes and a delicious smile, who liked best to be rocked in his mother's arms. There was no sign of that Jacob. Was he still in there?

For weeks they weren't sure. He was crankier, often seemed in pain. For the first time, he was having trouble sleeping, and they argued over how to handle it. When his crying persisted one night, Jordana picked him up. "Why'd you bring him out here?" said Richard. "Of course he's sweating when he's crying; he's crying himself to sleep. What's wrong? He's fine. Put him back."

He was having trouble lifting his head, too. On Aug. 15, Jordana said: "Something's definitely not the same. I can't pinpoint it yet. Richard thinks one of his eyes is starting to turn; the muscle has weakened. None of the therapists noticed anything, but it seems he used to see me sooner when I came into a room. If he was on the couch and I walked from the kitchen to the front door, he'd see me, want me and cry."

Romping with Jacob — aka Boo, Bubbles, Mr. Head or Little Man — at home.

Jordana knew the optical nerve can degenerate without myelin and on Aug. 20 took Jacob for a checkup. The ophthalmologist found significant deterioration and strengthened Jacob's glasses. This scared her. "I can't imagine what it would be like if he couldn't see my face or Richard's," she said. "If something started to go wrong with his eyes — it's unacceptable to me."

Jordana got United States Senators involved. One Canavan child was from South Dakota, and an aide to that state's senior Senator, Tom Daschle, was particularly aggressive about pressing Yale. Still, many at Yale did not feel the same urgency. At a Sept. 2 biosafety meeting, members said there were still too many questions and postponed a decision. The earliest Federal action would now be the December quarterly meeting. Jacob would be nearly 2.

"Jordana's going to explode," said Richard. "She's holding everything in. She's talking about chaining herself to the White House fence."

Little things were destroying her: a 2-year-old niece asking when Jacob would stop being a baby. Even his pockets depressed her. "A little boy his age starts enjoying his pockets," she said, "putting different things in there, and he doesn't even know they are there." Richard would come home from work and there was nothing in the refrigerator. She had stopped grocery shopping. "It made me crazy," said Richard. "I'd say, 'Jordana what's going on — no food in the house?' She'd say to Jacob, 'Your Daddy thinks I'm crazy.'"

She had tried to explain how difficult it was taking Jacob shopping, but Richard always had an answer: "Put him in the baby seat. What's the problem?" She didn't tell Richard, but she couldn't do that to Jacob, a 1½-year-old sitting flopped in an infant seat. "It's not that I care what people think," she said. "It's making Jacob a spectacle when I'm shopping."

PHOTOGRAPH BY JAMES ESTRIN/THE NEW YORK TIMES

Jacob would wake at 4 A.M., they'd struggle to get him to sleep and then were up until morning, arguing. They began seeing a marriage counselor. Jordana complained Richard bullied her; Richard complained Jordana was running from life.

In mid-September, she asked for a divorce. Richard wanted to know if there was someone else. Jordana said there was not a soul — that was the problem. She was finding she couldn't talk to anyone about Jacob. "Every day there's some stupid new development, we're so immersed," she said. "It's so lonely. Even when Richard and I talk, we have totally different views." They disagreed about things as basic as the gene therapy. Richard was hardheaded: he expected the small improvements Lindsay Karlin's parents had reported, but felt a cure was years away. "I'm not in la-la land on this," he said.

Jordana thought Jacob would thrive, because he'd been an advanced Canavan child and would get twice the dose of genes that the first two girls received in New Zealand. "At some point, not right after, I see him lifting his head," she said. "Maybe he'll say the words he knows now, loud and clear.

"What I envision is this little boy coming out of his shell — 'I'm here! Hi! Here I am!' I want him to be set free in a way. I hope he'll walk. He has the desire to walk. I put him down, he tightens his leg. You know, I'll be grateful if he can just sit up, play on his own, grab things.

"If he could just roll over. I put him to bed at night on his belly. In the morning, I come in, he's in the same position. I think about how nice it would be for him, if he could roll over and stretch — so there are my hopes."

Knowing those hopes, it was easier to understand why each new delay seemed the cruelest. On Sept. 18, Yale's biosafety committee again met without deciding. On Sept. 19, the Sontags were invited to attend a memorial service at the Jewish Guild for the Blind in Manhattan for 7-year-old, 30-pound Morgan Gelblum, who died over the summer. On Sept. 24, Jordana told Richard that whether or not he came, she and Jacob were going to Yale to confront Seashore and anyone else she could find. Richard would later say, "I was on the fence about going," but he went, as much to save his marriage as his son.

SEASHORE DIDN'T TELL THE SONTAGS, but she, too, thought Yale's biosafety committee was stalling, afraid to make the leap. However, she also saw a need for caution. "If you just tell people we're putting foreign DNA into the brains of small children, jaws drop," she said.

There were other reasons members did not feel an urgency: many doubted it would work. While gene therapy had captured the imagination of the public and media (most hometown newspapers had done a hopeful feature on their local Canavan child), the scientific community was skeptical. An article in Nature that fall of '97 reviewed all gene protocols to date, including treatments for cancers, heart disease and immunodeficiencies and put it bluntly: "Although more than 200 clinical trials are currently under way worldwide with hundreds of patients enrolled, there is still no single outcome that we can point to as a success."

It wasn't a question of whether they could deliver genes to the cells. They could. It was how many and how long they'd work. Matthew During estimated that the new genes would reach 10 million of the 100 billion brain cells, or 1 in 10,000. Delivery was primitive: They shot the genetic fluid into a liquid cavity of the brain known as the ventricle and hoped it would be absorbed by adjoining brain cells. This was like pouring it into a river and seeing how much was absorbed by the surrounding land; you'd find a lot in the riverbed, some along the banks, but not much inland. The low "hit" rate was the major misgiving voiced by committee members. Even if inserting the genes proved benign, the surgery had a risk. Implanting the plastic reservoir in the brain to pump genes into the ventricle carried a 5 percent risk of serious infection, possibly death. Put another way: for the 16 children waiting, there was a 1-in-20 chance of a life-threatening crisis.

Complicating matters was During's status. He was a hero to parents, but because the protocol had bounced from Yale to New Zealand and back and was publicly criticized, some at Yale regarded him as a cowboy. Committee members questioned how successful the procedure really was in New Zealand. While both girls had a temporary decrease in NAA, the more important indicator, myelin growth, was less clear-cut. To ensure uniformity, the committees decided that all M.R.I.'s would be done in one place, Children's Hospital of Philadelphia.

With During still in New Zealand, Yale had taken the unusual step of asking Seashore to shepherd the protocol, though she was not involved in the research. "Acrimonious things were said about Matt During that weren't fair," she said. "But I would not let that happen to me. If I had to be the bad guy to parents, I'd be the bad guy."

Seashore remembered too well what had happened to her longtime friend and colleague, Dr. Reuben Matalon. At Miami Children's Hospital in the 1980's, Matalon made the key breakthroughs in Canavan research, including identifying the mutation responsible for the disease. Canavan parents considered him a godsend. In 1990, he thought he had another score, a Canavan screening for pregnant women. What happened next has never been reported in the media, but it stunned geneticists who pieced the facts together. In a 1992 issue of the Journal of Inherited Metabolic Diseases, Matalon published a paper detailing how his test on pregnant women had correctly predicted whether a baby would be born with Canavan 13 of 13 times. His conclusion: "It is possible to determine Canavan disease prenatally." But then, in a last-minute postscript, came the shocker: "Note Added in Proof: Subsequent to the submission of this manuscript, we determined that one *Continued on page 78*

CANAVAN

Continued from page 63

of the pregnancies predicted to be normal resulted in an affected baby."

That affected baby was Molly Green, born June 18, 1991, in Arlington, Va. Molly's parents, David, a lawyer, and Wendy, a psychologist, had already buried one Canavan child, Eli, in 1990. After hearing of Matalon's new test, Wendy got pregnant again. "He told us it was experimental," said David, "but there was nothing like an informed consent procedure or peer review. We were desperate to have a child. Our attitude was, sounds good enough to me." The pregnant Wendy sent a fluid sample to Matalon. "We were informed the results were sparkling," said David. "We were having a healthy baby."

Molly seemed perfect at birth and was even chosen as the poster baby for the National Tay-Sachs and Allied Diseases Association, which was undertaking its annual fund-raiser. Three months later, after Molly had gone floppy and her parents knew the truth, one of the first calls the father made was to the foundation. "Rip up all those postcards of Molly," he said. "She has it." She died March 1, 1992. Three more women with sparkling screenings gave birth to Canavan babies, and two of those sued and later settled. "Reuben made a mistake," Seashore said, "but he was pressed very hard by the families to bring something into clinical service before it was ready."

In the end, the Canavan protocol was approved at Yale for very human reasons. The children were as disabled as any on the planet, and they probably would not be harmed and might benefit, or at least provide insight for researchers. I asked Dr. Charles Duncan, one of the nation's pre-eminent pediatric neurosurgeons and the man slated to operate on Jacob, "Would you do it if it were your child?" "Oh yes," he said. "I wouldn't be doing the surgery if I didn't think so."

There was more good news. The National Institutes of Health had recently made a policy change: under streamlined guidelines, Yale's approval meant the Federal committee did not have to give its go-ahead.

Seashore, however, insisted that the protocol go for that Federal review anyway. "I don't want to be the first protocol that doesn't," she said. Leone, who had worked so closely with the parents, fought her. "They saw me as an obstacle," Seashore conceded. "I saw them as loud. It was only a couple more weeks."

THAT NOVEMBER, THE Sontags hired divorce lawyers and put the house up for sale. The previous spring it had felt to Richard like a symbol of his power, but now, as winter neared, he seemed to have lost control of things that mattered, and the big house embarrassed him. Many rooms were still unfurnished.

Just before Thanksgiving, Jacob had a brain scan scheduled in Philadelphia to establish a baseline for myelin before gene therapy. Richard and Jordana took separate cars — agreeing to meet there. On the George Washington Bridge, Richard spotted Jordana and Jacob and waved. He knew she'd be nervous about driving alone, and sure enough, she pulled behind him. As they caravaned south on the New Jersey Turnpike, he picked up his car phone and dialed her in the Cherokee. They talked for 20 minutes, their first conversation in weeks.

Trying to get the IV in for the anesthetic was always the worst moment of an M.R.I. Jacob's arms were flaccid and nurses had trouble pricking a vein. He cried as Richard and Jordana held him. Soon they were sobbing, too, their tears falling together on their son. The nurse tried to comfort them, saying that the IV really didn't hurt Jacob much, but that was not why the Sontags were crying.

That night, they left Jacob with their sitter and took a hotel room.

BY DEC. 18, THE FEDERAL agencies had given their approval. Jacob's therapists prepared evaluations, to measure changes that might come later. Vivian Kahn Adler, the speech therapist, noted deterioration in recent months. When she started, "he used at least five different sounds — 'hi,' 'more,' 'ma.' At that age it was very encouraging; he was a baby. Now he's not

using many." She didn't know why Jacob had lost speech. It could be physical — his breath support had weakened. Or maybe, she said, cognitive. She was trying to get him to communicate by gazing at the food he wanted on his tray. During her Dec. 18 lesson, he sneezed and his head fell on his chest; he couldn't lift it. His eyes were crossed now, too. "A lot of kids you feel are stuck at the 3- to 6-month level," Adler said. "With Jacob, I feel there's a bright little kid in there. Sometimes he can wave. It'll take a while. If you don't have patience, you'll miss that wave."

The researchers decided the Sontags or Karlins would go first. They'd worked the hardest and raised the most money. At a diner, they flipped a coin. Jacob won. Jordana felt like a pioneer. She was hearing from families from around the world. "I feel great," she said, "like we've spared them the pain of all the fighting we've been through. I saw a video this family in Canada sent of their baby — his name's Jacob, too. He's 5 months, lifting his head, looking around. Can you imagine what this could do for him?"

SURGERY WAS TO BE done in two phases. On Friday, Jan. 2, at 8 A.M., Duncan used an air drill to cut a 9-millimeter hole in Jacob's skull. A tube was lowered into the ventricle; then a plastic, egg-shaped reservoir was attached to the tube and imbedded below the scalp, making a bump over Jacob's forehead. The reservoir would remain to facilitate future injections. This took less than an hour. Then Jacob was to be observed that weekend for signs of infection, and on Monday the genes would be implanted.

It was not to be. Sunday night he had a 103-degree fever, and Richard slammed the nearest table. "Twelve hours away!" he said. Duncan came to the hospital past midnight to get a sample of Jacob's brain fluid to test for infection. While Richard held his son, a young doctor assisting Duncan put the syringe into the reservoir to withdraw a specimen. Jacob's brain fluid came rushing out, splashing on the floor. Richard's eyes widened; brain surgery wasn't like he'd envisioned. Duncan felt Jacob just had the flu, but didn't want to take chances. He said he'd have to consult Seashore before deciding when to proceed.

"If Dr. Seashore makes the call," Richard moaned, "we'll be waiting another year." At 10 the next morning, Leone wheeled in a cart with a black plastic container. Richard could not stop staring. The genes they had been waiting so long for, the genes that could change their son's life, had arrived, in an ice bucket that looked borrowed from a Motel 6.

For days, Jacob was too sick with flu for the injection. On Jan. 9 at 6 A.M., Jordana was watching him sleep when she noticed his pinkie finger tremble, then his arms, then the whole body. His eyes opened wide and she thought he was dying. The nurses could not stop the seizure and moved him to intensive care. Would there be anything left of him to save?

Not until Jan. 22 was he strong enough. The actual procedure was so simple that it was done in an examination room. Jacob was laid on his stomach, screaming, Richard and Jordana holding him down. Duncan took a syringe and inserted it into a pin in Jacob's scalp that looked like the needle used to blow up a football. With his left hand he injected the syringe's fluid and with his right thumb he pumped the implanted reservoir 16 times. After 14 months, it was over in three minutes. The new genes were floating down the river Jacob.

"RICHARD AND I HAVE this joke," Jordana said. "Jacob will sit up and say, 'I don't know about this gene therapy.'" Jordana's mother urged, "Keep your camera out for when he lifts his head." They upped physical therapy to five days a week to capitalize on any improvement and thought they saw a million little things. "I was feeding him," said Jordana. "He put his hand on the spoon three or four times. He's done that before, but it was like right on my hand." When Richard held him, Jacob seemed to lift his head off Richard's chest more to look around. "Every day is exciting," said Jordana. "Lots of hope."

What was not encouraging was Jacob's sleeping patterns. He was constantly waking at night now and often would not go back to bed. "We're exhausted," said Jordana in mid-February. "We haven't had a good night's sleep in a month and a half." Their pediatrician prescribed a sedative for Jacob, but Jordana resisted. "We didn't want to do that," she said. "I hate giving in to this disease." For his part, Richard had surrendered. His attitude was, "Get the chloral hydrate!" The researchers told the Sontags his wakefulness might be positive, a sign gene therapy was working. They reasoned the new genes had so stimulated his brain, a sensory rush was keeping him awake.

Or it could be that Jacob was experiencing the classic sleep problems of an aging Canavan child.

Exhausted, Jordana no longer cared. The researchers didn't have to get up with him at 4 A.M. On Feb. 20, she was in tears. "Jacob did not sleep at all," she said. "I'm sorry we did the procedure. The only thing we got out of all this — he can't sleep! It's so cruel."

Plus, they were pushing

him for any physical gain while the new genes were fresh. With Jacob screaming, his physical therapist put on his stiff leg supports and led him a few steps. Richard placed him on the floor, legs crossed in a yoga position, his head flopped on his chest, and pleaded, "Lift it — come on Boo," but the head did not budge.

On Feb. 24, Jacob turned 2. They celebrated quietly, the three of them. At one point, Richard left the room so Jordana would not see him cry.

That week, Jordana gave in. She explained her decision to medicate Jacob this way: "I think we're better off as a family if the baby sleeps." They began giving him Klonopin, a muscle relaxant. It was the turning point. The muscle relaxant relaxed the parents, too.

Jacob's stiffness decreased; he stopped grinding his teeth. "Jacob is doing phenomenal," Richard said in mid-April. "He is in a fabulous mood." Why? "He's stoned," said Richard. "It's hard to know how much is Klonopin or the gene therapy or physical therapy five times a week. There are so many variables."

Jordana's fantasy, that he'd sit up, hadn't happened. "Not yet," she said. "In the past, I'd be devastated. But I feel I don't have to worry now. We got him the gene therapy; we've done all we can. I guess if I had to choose between motor skills and the cognitive, I'd choose this. He'll hang out in bed with us. We just lay him flat and play with him. Everything is funny to him now. Richard brought him in the other morning. I said, 'Little Man.' He starts smiling. 'Hi, Little Man.' He says, 'Hi.' I heard him!"

Jordana did not wait for During's lab to call with the latest results; she phoned Philadelphia herself and wormed it out of the M.R.I. people. "They gave me an unofficial report that Jacob has myelin!" she said on June 5. "They still have to do a comparison with the last M.R.I., but I have a feeling it's in the area that controls cognition."

Four days later, she left a message: "Wanted to let you know we received the report, and it says there have not been significant changes. He does have myelin, but it's the myelin he had prior to gene therapy."

JORDANA RETURNED to work part time. They sold the big house and moved to an attractive ranch house that was half the price. It was a nice fit, on one floor, easy for Jacob. All the rooms had furniture.

She was busy raising money for the Canavan Research Fund the families had founded. She spoke with rabbis and doctors about publicizing the new prenatal screening test for Canavan that was developed in the mid-1990's after Matalon's failure.

On June 19, the Sontags met with a lawyer about a "wrongful birth" lawsuit they had filed against the doctors Jordana used when she was pregnant with Jacob. In the lawsuit, Jordana claims she had repeatedly requested all relevant prenatal screening tests and had been given several but not the new one for Canavan. During the meeting, Jordana held Jacob and explained how they had struggled to enrich his life. So it wasn't until the end that the lawyer, Bruce Clark asked the awkward question, "You would have had an abortion had you known?"

"Absolutely," said Jordana. "Even with this little man in my arms, I would."

"It's not fair," said Richard. "Trapped in that body."

THE PREVIOUS YEAR, RICHard had dismissed the National Tay-Sachs and Allied Diseases conference as too touchy-feely, but this year they went and were the last to leave a seminar on how people with a disabled child can hold a marriage together. The therapist had couples take a personality test, and it turned out Richard was a "fixer" while Jordana was a classic "turtle." And when the turtle complained, the fixer felt he had to make everything all right, scaring the turtle instead of just giving that little turtle a hug. "I know this sounds totally ridiculous," Jordana would say later, "but it made perfect sense at the time."

The next day, the three Sontags were at a deli getting Jacob his matzoh-ball soup when Jordana realized she'd forgotten an appointment to visit a school for Jacob. "I know why," she told Richard. They had run into three families just back from a Little League game, all these messy, jumpy, little noodgie boys, and here the Sontags were heading to some depressing handicapped school. "I don't know why you're feeling that way," Richard started, but Jordana cut him off. "We're not even away from this marriage seminar for 24 hours," she said, "and you're trying to fix everything, Mr. Fixer," which made Richard laugh. The turtle was out of her shell, snapping.

ON SEPT. 9, JACOB WENT to Yale for his second injection. He was home in two days. Thomas Jefferson University Hospital, in Philadelphia, where During and Leone now work, was also doing the procedure.

THAT MONTH, NINE THERapists and social workers gathered to discuss the new program Jacob was starting at the Saint Agnes rehabilitation center, where the typical disabled child receives $33,000 a year in government-financed services. Jacob's home

Continued on page 112

Continued from page 82

therapists were there to advise the school therapists who would be taking over.

Richard and Jordana took turns rocking their 2½-year-old and giving him a bottle. "He has been making tremendous strides," Richard said. Adler, the speech therapist, explained how much of her time was spent working on chewing and swallowing. She didn't say it, but most Canavan children wind up on feeding tubes. "He'll drink from a cup, but there's still spillage on the sides," she said. She warned that he sometimes choked on solids, "a bit of a safety issue." As if on cue, Jacob began gagging on a waffle Jordana was feeding him, coughing and turning red. The room went dead. "Breathe," said Jordana. There was a moan and Jacob's normal color returned.

"He never used to cough so well," said Nancy Wolff, his physical therapist. "This is good."

Someone asked if he could flip a switch, and his occupational therapist said no. When the center's medical director, Dr. Maria Pici, asked what gains he had made, the physical therapist said he could roll on his side if she helped. "If I give him minimal facilitation depending on his mood and I tell him, 'Jacob bring your arm over, bring your leg over,' and of course I'm aligning him, he can roll," Wolff said.

They asked what Jacob liked. "Human contact," said Wolff. "And silliness. He loves silliness."

"Gassy noises, he loves them," Richard said.

"He's there," his physical therapist said. "Definitely," his occupational therapist said.

Jacob's Oct. 21 report from Children's Hospital in Philadelphia showed no new myelin. While researchers kept the other children's results confidential, parents talked, and Jordana learned that none of the children's M.R.I.'s showed myelin. Or, as Jordana put it, "at least not yet." Still, she saw potential in another new development. Jacob's ophthalmologist had found evidence of new myelin in his eyes. It wasn't likely to help Jacob see better, but the doctor found it "fascinating."

Some families grew discouraged. One dropped out, and even Helene Karlin had mixed feelings. "I don't even want to talk to the other parents," she said. "I don't want them to hear any discouraging note. They need to fight." There was another setback. The 5 percent risk from implanting the reservoir — it happened. In September, one child developed a serious complication and the reservoir was removed. Doctors sought to determine if there was brain damage.

SOME STORIES DO NOT END AS YOU expect. A year and a half ago, I could see the two central themes clearly. First, the curse of science: how a new medicine like gene therapy could seem to offer so much hope and yet cause so much pain, because it is still only promise. And second, the blessing of science: how the pursuit of new medicine could lead to a prenatal screening that would allow the Sontags to have a healthy baby the next time. I envisioned the story closing joyously, with Jordana giving birth to a new child.

What I witnessed instead was the hardships of the pioneer family. At the Sontags' meeting with the lawyer last summer, he asked if they would try to have another child. "We've only started to discuss that," Richard said softly.

Last month, Richard called as I was finishing the article. He was concerned I hadn't seen Jacob in weeks. "He's a whole new child," said Richard. "They love him at school," said Jordana.

On Nov. 5, I spent the day with Jacob. That morning at Saint Agnes, a well-staffed, bright, state-of-the-art rehab center, Jacob fell asleep while two speech therapists were having him practice eating a Ritz Bits cracker. In class, it took more than an hour to feed him a puréed lunch. His teachers and aides talked about how much he loved the computer, but when placed in front of it, he fell asleep again.

Then at home that night, Jacob was another child. His face lit up when Richard returned from work and kissed him hello. For two hours, the Sontags roughhoused. They called him Boo and Bubbles, Mr. Head and Little Man, and the noisier and louder and sillier they all grew, the more Mr. Stinky Butt beamed and his eyes shone. It was wonderful to see, and for once I stopped trying to guess how much was going on inside. This was medicine more remarkable than new genes, Klonopin or physical therapy five times a week — a parent's love. ■

Testimony prepared for delivery before the

White House Commission on Complementary and Alternative Medicine Policy

January 23, 2001
New York City

by

Grace-Marie Arnett
President
Galen Institute

Thank you, Mr. Chairman and members of the commission, for the invitation to speak briefly here today.

My name is Grace-Marie Arnett, and I am president of the Galen Institute, a public policy research organization based in Alexandria, VA that is devoted to ideas that advance a more vibrant consumer-driven health sector.

Many Americans are increasingly frustrated with the U.S. health system because they face barriers to care. For 43 million Americans, that means a lack of health insurance. For millions of others, it means that access to the care they want – sometimes complementary or alternative health treatments – is blocked by either financial obstacles or by a lack of information about the full range of treatments available.

As we speed into the Information Age, Americans are frustrated with a system that puts someone else – either a private or a public-sector bureaucracy – in charge of deciding what health care they will or will not receive.

Unfortunately, the roots of these problems are based in the way we subsidize health care in this country. Because of the way subsidies are structured, we literally give control over life and death decisions to bureaucrats and politicians who have never met us – people who care more about a balance sheet than about our health and well being. Until we get financial power back into the hands of the American people, these frustrations will continue to grow.

Let me explain what I mean about the way we subsidize care: People who are poor or old or young are very likely to qualify for one of several government health care programs –

Medicaid, Medicare, or the State Childrens Health Insurance Program. In these programs, government officials make up lists of what medical treatments those who qualify for these programs are entitled to receive.

Those who have health coverage through the workplace are eligible for the health plan – or, if they are lucky, the health plans – their employer selects for them, and the benefits that those plans provide. It is virtually impossible for even the smallest firm to provide coverage that suits the particular needs of each employee. Most have just one option regarding health insurance – take it or leave it.

Why is this relevant to an investigation into complementary and alternative medicine? Because, Mr. Chairman, in Washington we are at a crucial point when real policy changes are possible that will begin to put power and control back into the hands of individual consumers.

I describe the ideas in a book I edited, entitled *Empowering Health Care Consumers through Tax Reform.* The ideas in this book have been adopted by President Bush as part of his plan to increase access to and affordability of health coverage.

The centerpiece of this plan would provide tax credits worth nearly $2,000 to families to purchase their own health insurance.

While this is only a start, it could be a transformative change. For the first time, subsidies would be structured to allow people to begin deciding for themselves the shape of their health plans rather than having them dictated by politicians or bureaucrats.

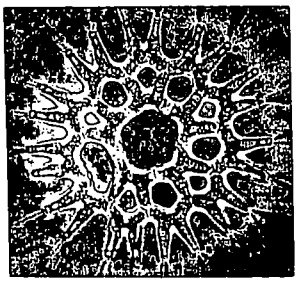
This change also would dramatically increase the opportunities for patients to have access to CAM treatments.

My primary recommendation would be that the commission investigate further changes in tax policy that would lead to greater availability of complementary and alternative medicine treatments. In a new world, instead of having the power structures decide what treatments are and are not covered, people would be able to choose for themselves.

The idea of providing tax credits to help people obtain their own health insurance has strong bi-partisan support in Congress. This issue will be front and center as Congress begins the debate over tax cuts, and it would be very helpful for political leaders to hear from people who understand this important connection between federal subsidies for health insurance and consumer choice of health care.

Our motto at Galen is: "Whoever controls the money controls the choices." If we put power and control back into the hands of consumers, they will have access to a much broader range of health care options.

I would be happy to describe our ideas in detail. Thank you for the opportunity to present this brief overview.



White House Commission on Complementary & Alternative Medicine
Tuesday, January 23, 2001
By Camilla Rees

Panel theme: *"Maximizing the Economic Impact of Assimilation of CAM Modalities Through Enhancing Market Forces, Creating Efficiencies through Individual Empowerment, and Waste Reduction by Targeting Root Causes of Illness"*

Good morning. Thank you for this opportunity.

My name is Camilla Rees. I speak to you today from the perspective of a patient who has had chronic health problems for 5 years

I was very surprised by what I learned being a patient in our health care system—especially the crushing realization that the insurance premiums I had paid bought me—and millions of others with chronic illness—little value. Most of what was helpful I paid out of pocket and would fall into the category of CAM.

I suspect most individuals, including policymakers—unless they have had close personal or family experience with serious or chronic illness—do not realize there are deeply rooted, misguided orientations in the health care system today that fuel costs, and that contribute to poor outcomes that further fuel costs.

I will focus today on 5 issues I found to contribute to inefficiency and waste. My overriding policy recommendation to you is to see these qualitative issues become quantified. **I firmly believe the dialogue with policy makers needs to focus on the economic ramifications of the *quality of care* today--the root of the problem—and to associate CAM with the solution.**

If these economic ramifications were communicated to the corporate market, they too would act quickly to support CAM, providing important horsepower.

For background, in my own case, it took 3 years of endless doctors appointments and lost productivity before I arrived at root causes of autoimmune conditions, which I was told were unknown, but which turned out to be environmental.

The 5 issues are:

1) Doctors seem to have very little **education** about how to support health, and focus narrowly on drug solutions. *Patients need information on how the human being works—not medical consensus on how to live our lives—but on what supports life, across all dimensions, and why.*

2) The health care system is not oriented to looking for **root causes** of serious illness, including environmental causes that are very significant. *We need to have courage to work at the root level, and to conduct research into programs and methodologies that address root issues. It is only when we look at root issues that we can find solutions.*

3) There exists a **slow "serial" approach** to treatment based on a single practitioner's limited knowledge, instead of on a much broader body of knowledge that exists. *We need to lay out information as broadly as possible for each condition, covering multiple perspectives—and acknowledge that patients' wisdom and intuition are then crucial aspects of choosing the right solution. We need acknowledgment of the value of multiple perspectives, and investment in information infrastructure.*

4) Physicians who practice outside of the orthodox norms are marginalized, if not investigated, resulting in a **fear-based culture**, patient hesitation and confusion, delay in getting care and often unnecessary duplication of medical support. *We need to stop private medical and dental associations from essentially using the power of the state, through licensing boards, to enforce narrow medical protocols—stifling competition in the name of fighting fraud. We need to support CAM practitioners—at a minimum through equal representation on licensing boards.*

And finally,

5) The health care system is **not oriented to results**—there is no "health" goal in health care, and no accountability.

We talk about inflation in the health care sector, but no one is counting the dollars spent by people who never get helped in the allopathic model, and whose situations escalate, resulting in more intensive usage. No one is counting the people with chronic illness who go from doctor to doctor but never get well, because there is no model for supporting health.

We need independent leadership in this sector—to honestly highlight the structural flaws in the system, shine a light on their sources, understand their economic implications, and create vision for what the health care system could become.

Thank You.

Camilla Rees is a strategic business consultant in private practice in New York. She is also an executive coach, and counsels business people on taking a multi-faceted approach to supporting health and performance. She was formerly in investment banking, and during the health care reform debates in 1994 co-produced a white paper entitled "The Economic Impact of Health Care Reform" (with co-panelist Grace Marie Arnett) on behalf of Montgomery Securities. Camilla combines 15 years of business experience in investment banking, venture capital, marketing communications and corporate identity with 5 years as an active student of health optimization, wisdom traditions and technologies fostering integrated wellness.

To: Michelle Chang, White House Commission on Complementary/Alternative Medicine
From: Joseph Loizzo, M.D., Columbia-Presbyterian Center for Meditation and Healing
Re: Policy recommendations on CAM's role in healthcare waste-reduction

From the vantage of complementary psychiatry, the single largest source of waste in American healthcare today is the neglect of complementary methods of teaching consumers and providers time-tested, evidence-based practices of self-healing and health promotion such as mindfulness-based stress-reduction (MBSR). The disease-fighting strategies and provider-driven interventions of American medicine are at best incomplete and at worst inherently wasteful, because they are reactive rather than preventive; and because they systematically ignore the single most important variable in disease-prevention and health-promotion: consumer health behavior. While mainstream medicine has made remarkable strides in its fight against the obvious killers of modern civilization—heart disease, substance abuse, mental illness and cancer—it has hardly begun to face the insidious killer behind all these masks: our own stress-driven, disease-prone habits. Fifty years of stress research have shown beyond any reasonable doubt that disease-prone habits of mind and action exert a pervasive, corrosive effect on natural systems of defense and healing, leaving us prey to diseases of all kinds. Fortunately, stress research has also brought the good news that stress-reduction methods can tame the killer within by teaching skills to unlearn disease-prone habits and build the natural self-healing competence of our body and mind. The most effective methods of stress-protection and health-promotion to emerge from the new "mind/body medicine"—such as Herbert Benson's relaxation response, Jon Kabat-Zinn's MBSR, James Gordon's mind/body skills learning and Dean Ornish's lifestyle therapy—in fact distil the time-tested self-healing traditions preserved in the Asian healthcare systems of Ayurveda, Chinese and Tibetan medicine (i.e., systems designed to heal without our high-cost, high-risk technological methods). These methods deserve to be singled out as the cutting edge of complementary and alternative medicine, both because they have been shown to be among the safest and most evidence-based of CAM practices, and also because they directly target the largest source of waste in American healthcare: the systematic neglect of the patient's responsibility and right to act in pursuit of his or her own health. Based on this analysis, my policy recommendations to the committee are simple.

- In the short run, to put teeth into the March 1999 National Institute of Health initiative to develop mind-body medical centers by advancing legislation (such as a patients' bill of rights) supporting insurance reimbursement of mind/body programs such as those mentioned above or comparable programs to teach the basic concepts and skills of self-healing.

- In the long run, to build public and professional awareness of the need to complement the reactive, provider-driven paradigm of modern medicine with the proactive, consumer-driven paradigm of self-healing preserved in Asian healthcare systems and applied in mind/body medicine, by seeing that courses in stress-protection and self-healing become required in the basic education of all health professionals.

Some Major Obstacles for CAM Research

Testimony at the Town Hall Meeting in New York City by the White House Commission on Complementary and Alternative Medicine Policy (January 23rd, 2001)

Kevin Chen, *Ph.D. MPH*
Department of Psychiatry, UMDNJ—New Jersey Medical School
30 Bergen St. ADMC 1419, Newark, NJ 07107
(Email: chenke@umdnj.edu)

I am an assistant professor of psychiatry at UMDNJ—New Jersey Medical School, a research scientist who is interested in the study of effectiveness of CAM, especially Qigong. In the past few years I have witnessed many miracles among Qigong practitioners and Qigong healers, such as disappearance of breast tumor in minutes; "incurable" leukemia patient being completely cancer-free in a few months; a blood sugar level reducation from 292 to 110 in one week, chronic arthritis pain disappeared completely in one or two Qigong treatments. As a scientist I feel challenged by these unexplainable miracles, and I believe, these so-called "miracles" could not have existed by chance but in accordance with certain rules and reasons. However, when I started exploring these rules and reasons seriously, I find myself in a very disadvantaged situation. I would like to use my few minutes to talk about some major obstacles in CAM research, and try to offer some recommendations for this area.

More and more practitioners, policy-makers and consumers seem to realize that CAM cannot really fly without the full support of solid research and reliable verification. However, if you look around carefully, you will find something very strange. Although an increased number of consumers are getting help from CAM, there are very few scientists who are seriously involved in research of CAM, and there is not much scientific literature available to verify or support alternative therapies like Qigong, Reiki or Yoga, even though these therapies have originated thousand of years ago. Why? Here are just a few of the many obstacles that discourage scientists to get involved in research of CAM:

1. Fear of losing credibility among peers and funding agents. Scientists, like other people, tend to believe only what they consider "reasonable" or "acceptable", and have a lot of prejudice or discrimination against non-conventional medicine or not-approved therapy. There is a huge burden for any scientist to get involved in serious research of CAM therapy because he may either simply consider the effectiveness of CAM healing placebo effect, or consider it against common sense of science, not worth the time for research.

   I became interested in the study of Qigong after I observed so many people benefiting from it. When I told my former boss, a well-known scientist, that I want to study how a Qigong master could make a breast tumor shrink or disappear, she told me not to waste my time, she said, "you are a scientist, how could you believe something like that?" When I expressed my interest in research of Qigong to our department, the reaction from one of my vice chairs was to question my prowess as a scientist. After I invited the Qigong master to our University to treat breast cancer cells in vitro with

Qigong, and found consistent differences between the Qigong treated group and the sham treated group, my colleague who used her lab and directed the entire study refused to put her name on the report, because she thought that the association of her name with this type of research might jeopardize her future funding opportunities from NCI.

Some people in the scientific community simply do not believe in alternative therapy, no matter what the data said or the patients said, since it cannot be explained by current science. However, let us not forget that, once upon a time, science believed that the Sun revolved around the Earth, and the electron was the smallest element.

2. Lack of minimum funds to conduct high-quality research. If you are curious about the effectiveness of CAM and want to conduct studies to examine it carefully, you may have to use your own time and money since there is simply lack of funding for CAM research. We all agree that extraordinary claims from CAM need extraordinary proof or verification, ideally we need more serious money to attract the top scientists to examine the effectiveness of various CAM therapies. It is true that NCCAM has had increased funding in the past 2 to 3 years, but there is still too little to get, or to attract scientists to apply for, compared to the availability of fund in other areas of medical research. The projected budget of NCCAM in 2001 is about $90 millions, which is less than ½ of 1% of the NIH budget of $20 Billions. {There are about 7 to 10 NIH-funded centers for the study of CAM, with an average annual budget around $300K to $600K each, which is not too bad; but there are 53 NIH-funded cancer research centers, with an average annual budget of $1.5 to 3 millions each. I know a Qigong practitioner who claimed his method of cancer therapy had a history of 90% effective rate, better than any cancer hospital in the world; however, except his students and benefited patients, no one in medicine seems to believe in him, and no one in cancer centers seems to be interested in conducting research on his method at this moment.}

Two months ago I submitted a grant application to NCCAM with my colleagues in response to a RFA called "program project for frontier medicine," one of the newest mechanisms NCCAM created to promote research on CAM therapies. Each program project is like a mini-center, including 3 to 4 separate but interrelated projects plus a center core, with the maximum annual budget of $600K, including indirect costs. This sounds like a lot of money. However, when we actually planned the budget for our 4 projects plus a central core, with 57% indirect that cannot be used in the research, we end up with about $70K per year per project, which was even smaller than the FIRST award ($75K) that NIH used to encourage young scientists to transit their careers. With this kind of budget limitation, how could we attract the top scientists or career-oriented researchers to get involved in serious CAM research?

3. Lack of basic training and knowledge of CAM among scientists. Most scientists do not know the basic rules of CAM therapies and don't know what to look for in research of CAM. Even if someone becomes interested in CAM research, it's going to be hard for him to find a qualified practitioner who is willing to collaborate with him on a long-term basis. This is due to the fact that many projects are designed by scientists who lack CAM knowledge, or simply do not respect the practitioner's perspective, and ignore the basic rules or internal integration of CAM therapy, only focusing on issues such as double-blind design and balanced control, etc. However, most practitioners simply do not want

to be considered just as research subjects, but also as a researcher who follows the rules of their own profession. One of the big problems in CAM research is that, the experienced scientists do not want to get involved into CAM research due to lack of incentives, while those who are interested in CAM research usually lack the high-quality research experience that the NIH is looking for.

4. It is very risky for a medical scientist to make the career transition from conventional scientific research to CAM research. You may lose the opportunities to publish (since there are very limited journals in this area), to get grants (lack of availability) and to get promotions, or you may even lose your job completely if you cannot get a large grant in a timely manner and cannot get a lot of publications. As for academic freedom, the department or school may not directly oppose you to conduct research in CAM, but they will kindly warn you about the huge risks you may run into. Allow me to remind you that if about 1/3 of university budgets come from the pharmaceutical companies, the school would not risk losing those funds by supporting research that may have obvious conflicts with pharmaceutical industry. As for those established scientists, the belief, credibility and the amount of funding are still the major considerations for their involvement into research of CAM.

In short, we have few scientists who are funded to conduct CAM research, and it is still very risky for scientists to get involved in serious research on CAM therapies. There is social burdens, financial burdens and ideological burdens for them to make the move. If the study has no positive finding, the risk becomes even higher, although consumers desperately want to know what works and what does not. I hope the policy-makers will realize these burdens, and help scientists to overcome them as soon as possible. My recommendations in this matter are as following:

1. Dramatically increase the budget or funding for the CAM research – both consumers and scientists need it -- and the sufficient money will attract more scientists into the field.

2. To avoid the inference of various interest groups, expand NCCAM into independent research institute, and/or add more special offices of CAM research in each NIH Institute so that they can conduct independent research with its knowledgeable staff and fellows.

3. Establish more centers for the study of CAM, fund them appropriately so that they can play the active roles of both education and research, and decide what to study more flexibly.

4. Establish some special mechanisms of funding at NIH to encourage more scientists to make career transition to become specialists in CAM research, something similar to the FIRST award.

5. Pay more attention to education and training, and educate current and future scientists and medical practitioners about various CAM therapies, let CAM therapies that really work be part of modern medicine and medical education.

Testimony prepared for delivery before the

White House Commission on Complementary and Alternative Medicine Policy

January 23, 2001
New York City

by

Grace-Marie Arnett
President
Galen Institute

Thank you, Mr. Chairman and members of the commission, for the invitation to speak briefly here today.

My name is Grace-Marie Arnett, and I am president of the Galen Institute, a public policy research organization based in Alexandria, VA that is devoted to ideas that advance a more vibrant consumer-driven health sector.

Many Americans are increasingly frustrated with the U.S. health system because they face barriers to care. For 43 million Americans, that means a lack of health insurance. For millions of others, it means that access to the care they want – sometimes complementary or alternative health treatments – is blocked by either financial obstacles or by a lack of information about the full range of treatments available.

As we speed into the Information Age, Americans are frustrated with a system that puts someone else – either a private or a public-sector bureaucracy – in charge of deciding what health care they will or will not receive.

Unfortunately, the roots of these problems are based in the way we subsidize health care in this country. Because of the way subsidies are structured, we literally give control over life and death decisions to bureaucrats and politicians who have never met us – people who care more about a balance sheet than about our health and well being. Until we get financial power back into the hands of the American people, these frustrations will continue to grow.

Let me explain what I mean about the way we subsidize care: People who are poor or old or young are very likely to qualify for one of several government health care programs –

Medicaid, Medicare, or the State Childrens Health Insurance Program. In these programs, government officials make up lists of what medical treatments those who qualify for these programs are entitled to receive.

Those who have health coverage through the workplace are eligible for the health plan – or, if they are lucky, the health plans – their employer selects for them, and the benefits that those plans provide. It is virtually impossible for even the smallest firm to provide coverage that suits the particular needs of each employee. Most have just one option regarding health insurance – take it or leave it.

Why is this relevant to an investigation into complementary and alternative medicine? Because, Mr. Chairman, in Washington we are at a crucial point when real policy changes are possible that will begin to put power and control back into the hands of individual consumers.

I describe the ideas in a book I edited, entitled *Empowering Health Care Consumers through Tax Reform.* The ideas in this book have been adopted by President Bush as part of his plan to increase access to and affordability of health coverage.

The centerpiece of this plan would provide tax credits worth nearly $2,000 to families to purchase their own health insurance.

While this is only a start, it could be a transformative change. For the first time, subsidies would be structured to allow people to begin deciding for themselves the shape of their health plans rather than having them dictated by politicians or bureaucrats.

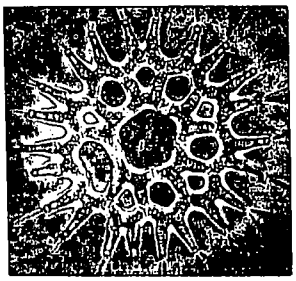
This change also would dramatically increase the opportunities for patients to have access to CAM treatments.

My primary recommendation would be that the commission investigate further changes in tax policy that would lead to greater availability of complementary and alternative medicine treatments. In a new world, instead of having the power structures decide what treatments are and are not covered, people would be able to choose for themselves.

The idea of providing tax credits to help people obtain their own health insurance has strong bi-partisan support in Congress. This issue will be front and center as Congress begins the debate over tax cuts, and it would be very helpful for political leaders to hear from people who understand this important connection between federal subsidies for health insurance and consumer choice of health care.

Our motto at Galen is: "Whoever controls the money controls the choices." If we put power and control back into the hands of consumers, they will have access to a much broader range of health care options.

I would be happy to describe our ideas in detail. Thank you for the opportunity to present this brief overview.



White House Commission on Complementary & Alternative Medicine
Tuesday, January 23, 2001
By Camilla Rees

Panel theme: *"Maximizing the Economic Impact of Assimilation of CAM Modalities Through Enhancing Market Forces, Creating Efficiencies through Individual Empowerment, and Waste Reduction by Targeting Root Causes of Illness"*

Good morning. Thank you for this opportunity.

My name is Camilla Rees. I speak to you today from the perspective of a patient who has had chronic health problems for 5 years

I was very surprised by what I learned being a patient in our health care system—especially the crushing realization that the insurance premiums I had paid bought me—and millions of others with chronic illness—little value. Most of what was helpful I paid out of pocket and would fall into the category of CAM.

I suspect most individuals, including policymakers—unless they have had close personal or family experience with serious or chronic illness—do not realize there are deeply rooted, misguided orientations in the health care system today that fuel costs, and that contribute to poor outcomes that further fuel costs.

I will focus today on 5 issues I found to contribute to inefficiency and waste. My overriding policy recommendation to you is to see these qualitative issues become quantified. **I firmly believe the dialogue with policy makers needs to focus on the economic ramifications of the *quality of care* today--the root of the problem—and to associate CAM with the solution.**

If these economic ramifications were communicated to the corporate market, they too would act quickly to support CAM, providing important horsepower.

For background, in my own case, it took 3 years of endless doctors appointments and lost productivity before I arrived at root causes of autoimmune conditions, which I was told were unknown, but which turned out to be environmental.

The 5 issues are:

1) Doctors seem to have very little **education** about how to support health, and focus narrowly on drug solutions. *Patients need information on how the human being works—not medical consensus on how to live our lives—but on what supports life, across all dimensions, and why.*

2) The health care system is not oriented to looking for **root causes** of serious illness, including environmental causes that are very significant. *We need to have courage to work at the root level, and to conduct research into programs and methodologies that address root issues. It is only when we look at root issues that we can find solutions.*

3) There exists a **slow "serial" approach** to treatment based on a single practitioner's limited knowledge, instead of on a much broader body of knowledge that exists. *We need to lay out information as broadly as possible for each condition, covering multiple perspectives—and acknowledge that patients' wisdom and intuition are then crucial aspects of choosing the right solution. We need acknowledgment of the value of multiple perspectives, and investment in information infrastructure.*

4) Physicians who practice outside of the orthodox norms are marginalized, if not investigated, resulting in a **fear-based culture**, patient hesitation and confusion, delay in getting care and often unnecessary duplication of medical support. *We need to stop private medical and dental associations from essentially using the power of the state, through licensing boards, to enforce narrow medical protocols—stifling competition in the name of fighting fraud. We need to support CAM practitioners—at a minimum through equal representation on licensing boards.*

And finally,

5) The health care system is **not oriented to results**—there is no "health" goal in health care, and no accountability.

We talk about inflation in the health care sector, but no one is counting the dollars spent by people who never get helped in the allopathic model, and whose situations escalate, resulting in more intensive usage. No one is counting the people with chronic illness who go from doctor to doctor but never get well, because there is no model for supporting health.

We need independent leadership in this sector—to honestly highlight the structural flaws in the system, shine a light on their sources, understand their economic implications, and create vision for what the health care system could become.

Thank You.

Camilla Rees is a strategic business consultant in private practice in New York. She is also an executive coach, and counsels business people on taking a multi-faceted approach to supporting health and performance. She was formerly in investment banking, and during the health care reform debates in 1994 co-produced a white paper entitled "The Economic Impact of Health Care Reform" (with co-panelist Grace Marie Arnett) on behalf of Montgomery Securities. Camilla combines 15 years of business experience in investment banking, venture capital, marketing communications and corporate identity with 5 years as an active student of health optimization, wisdom traditions and technologies fostering integrated wellness.