

Withdrawal/Redaction Sheet

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	Panel Speakers (partial) (1 page)	nd	b(6)
002. testimony	Kerri Ann Gruninger (partial) (1 page)	01/23/2001	b(6)
003. testimony	Sherri Heitner-Margalit (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 [1]

2011-0568-S

kc822

RESTRICTION CODES

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

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

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
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PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Albrecht, Joan (NCCAM)

From: Yvonne R. Secreto RN [yvonne.secreto@inetmail.att.net]
Sent: Tuesday, January 30, 2001 1:41 AM
To: Whccamp (NCCAM)
Subject: Please forward to Dr. James Gordon

Please forward this message to Dr. James Gordon, who chaired the NYC Townhall meeting on 1/23/01. Thank You.

The Respite Foundation Inc.
Behavior and Stress Management using the Healing Arts
113-04 219th Street Queens Village, NY 11429
718 217-4461

WHCCAMP Town hall meeting Testimony NYC Panel # 22 Yvonne Secreto

Follow-up:

To: Dr, James S. Gordon, Chair of the Commission
From: Yvonne R. Secreto RN

Dr. Gordon,

This is a note to thank you for your enthusiasm concerning the idea of integrating the CHHA (Certified Home Health Agency) Model with a CAM Service to provide greater access and delivery of CAM services to a wider segment of the population which normally would not have access. This would include Medicare and Medicaid participants.

I have held this idea of several years. I have proposed it as a project focus in a previous application to Graduate school. I have started a very small Model of the idea though a Program entitled Wholistic Professionals.

In reference to Direct access to, delivery of and Reimbursement for CAM practices and interventions, we can use the CHHA (Certified Home Health Agency) Model along with the standard employment Agency Model as a perfect example of how CAM services can be delivered independently under the supervision of an MD. This model allows the public ready access to CAM practices and interventions with a Professional Medical team in the background and a Nurse as a liaison between the MD and the CAM practitioner who is delivering the service. This would insure safe and effective monitoring of service delivery and well as an already established reimbursement stream that could include Medicare and Medicaid.

I believe that most CAM practices and interventions should be reimbursable based on the MD's prescribed focus of delivery. The RN Coordinator would relay back to the MD her assessment of the effectiveness of the CAM intervention based on pre-set criteria.

Page 2

I have so much data on this idea that I did not want to send it all randomly. I am asking you the following questions so that I may prepare a presentation that best suits your needs and focus:

1- Should the idea be detailed as a pilot program ?

- 2- Should the idea be detailed as a research Project?
- 3- Would you like me to pick a few (1-3) CAM practices that would fit the Model?
- 4- Should I give examples of multiple CAM practices that would fit this Model.
- 5- Do you want the information in out-line form?
- 6- In the Reimbursement section would you like a separate breakdown for Medicare, Medicaid, Insurance and Other Payment?
- 7- Please make specific request for areas of information based on what I have provided so far.

I thank you for your consideration of this valuable Win/ Win solution to the issue of general public access to CAM.

Sincerely,

Yvonne R. Secreto RN



New York State Board for Professional Medical Conduct

5 Penn Plaza, Suite 603 New York New York 10001-1810 • (212) 268-6850

Antonia C. Novell, M.D., M.P.H., Dr. P.H.
Commissioner
NYS Department of Health

William P. Dillon, M.D.
Chair

Denise M. Bolan, R.P.A.
Vice Chair

Ansel R. Marks, M.D., J.D.
Executive Secretary

Dennis P. Whalen
Executive Deputy Commissioner
NYS Department of Health

January 23, 2001

Joseph M. Kaczmarczyk, D.O., M.P.H.
Senior Medical Advisor
White House Commission on Complementary
and Alternative Medicine Policy
6701 Rockledge Drive
Suite 1010, MSC 7707
Bethesda, MD 20817

Dear Dr. Kaczmarczyk:

Enclosed for examination by the Commission on Complementary and Alternative Medicine is a copy of the Annual Report of the New York State Board for Professional Medical Conduct. I believe this will expand on my all too brief remarks at the recent Town Hall Meeting.

Please feel free to contact me in the future to participate at any level involving these important matters of health care.

In closing may I thank you for inviting my recent participation in New York City.

Sincerely,

Ansel R. Marks, M.D., J.D.
Executive Secretary
Board for Professional Medical Conduct

Enclosure:

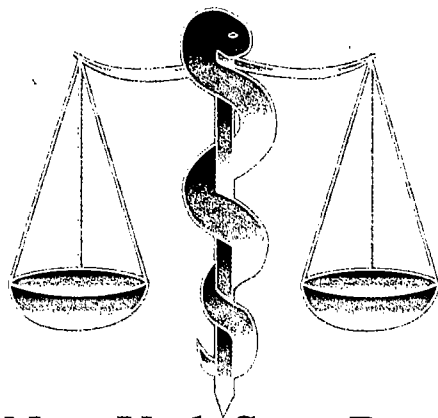
cc: James S. Gordon, M.D.
Stephen C. Groft, Pharm.D.

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New York State Department of Health

Board for Professional Medical Conduct

1999 Annual Report

Panel	Focus	Speaker Profile	Mailing address	Phone	Fax	Status
PANEL 1 Speaker 1	How do ethnic communities define CAM: ancestral practices	Frances Brisbane Dean of Social Work, SUNY		631-444-8239		Joe K
Speaker 2	what is the role of the traditional healer in the community? How are they perceived by the community and how do they fit into the health care system?	Social worker				
Speaker 3	What are the public health education challenges vis-a-vis CAM use in ethnic communities?	Social worker				
Speaker 4	What CAM access do consumers in an ethnic community want ? What coordination/ integration are they seeking in their health care?	Ethnic consumer				
Speaker 5	What do consumers want their traditional healers to know about conventional medicine? What do they want their conventional docs to know about CAM?	Ethnic consumer				
PANEL 2 Speaker 6	What are the utilization patterns for CAM in minority communities?		Fredi Kronenberg			Steve G
Speaker 7	What are the unique needs for CAM in the minority-focused health care system?	Experience in starting the Navigator program @ Harlem Hospital (nutrition/ lifestyle)	Harold Freeman North General Hospital, Bronx?	212-423-4111		
Speaker 8	What is a good model for integrative delivery of health care at the community level?	Contact Tony Curtain to build panel Exec Dir				Joe K
Speaker 9	What do communities want to improve CAM access/delivery (big picture perspective, looking at integration with other systems)	Board Member				
Speaker 10	What do practitioners need to provide good care?	Clinician				
Speaker 11	What do consumers want to improve CAM access/delivery?	Consumer				

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Panel	Focus	Speaker Profile	Mailing address	Phone	Fax	Status
PANEL 3 Speaker 12	Relationships with state regulatory medical boards	Serafina Corsello neuropsychologist	(b)(6) NY NY, 10019	(b)(6)	(b)(6)	Mi
Speaker 13		Jennifer Daniels diabetes, practicing herbal, diet, exercise	(b)(6) Syracuse, NY 13205	301-475-3393 office	315-475- 2524	
Speaker 14		Charles Gant using vitamin therapy to treat ADHD		(b)(6)		
PANEL 4 Speaker 15	What are CAM schools being taught about conventional medicine? How are they working with each other and conventional schools?	Andy Rubman Bridgeport Connecticut School of Naturopathy				
Speaker 16	What do CAM students want to know about conventional medicine? What other policy changes can promote CAM career choices?	4 th Year Naturopathy Student				
Speaker 17	what qualifications do CAM teachers have in conventional medicine? What basic standards of knowledge should be taught?	Michael Garber Emergency room MD and Naturopathic School Teacher: allopathic medicine				
Speaker 18	how are different CAM organizations within a given modality collaborating to develop national standards for education/ certification?	Steven Shinkman New York Holistic College				
Speaker 19	what challenges do graduates face, especially regarding licensure and the portability of licensure; what about debt burdens?	Student, Oriental College				
Speaker 20	more CAM school stuff	Jonathan Daniel, Oriental College Teacher				
Speaker 21	Development of clinical guidelines	Christopher Kent Council of Chiropractic				
PANEL 6 Speaker 22	what are medical students being taught about CAM?	Contact Frank Jones				
Speaker 23		Dean of Medical School				

Speaker 24		Dean of Nursing School				
Speaker 25		Dean of Dentistry School				
Speaker 26		Dean of School of Public Health				
Panel	Focus	Speaker Profile	Mailing address	Phone	Fax	Status
Speaker 27	what do leaders in the medical community think about integrative teaching programs?	Mark Fox				
28						
29						
PANEL 7 Speaker 30	How are hospitals systems approaching CAM use?	Contact Susan Waltman, Greater NY Hospital Assoc Medical Director				Gerry
Speaker 31		Director of Nursing				
Speaker 32		Director of Rehabilitation				
Speaker 33		Dennis Riveria Hospital Employees Union				
PANEL 8 Speaker 34	how is CAM integrated into palliative care?	Contact Kathy Foley, Pain and Palliative Care Project on Death in America		212-887-0150		Corinne
Speaker 35	what policies will increase access to CAM for palliative care?	Open Society rep				
Speaker 36	what is the impact of CAM on the families?	Family member?				
PANEL 9 Speaker 37	why is CAM a women's health issue? BIG perspective—what makes this important to women?	Gloria Steinem or Olympia Dukakis				Mi-Tom Chappell
Speaker 38	what are the patterns of CAM use among ethnic women?	Fredi Kroenberg				Steve
Speaker 39	How is CAM affecting the treatment of breast cancer?	Dr. Kameny NY Holistic College Breast Cancer study				Mi

Speaker 40	How is CAM affecting the treatment of menopause?	Dr. Frank Lipman private physician?				Mi
Speaker 41	How is CAM affecting fertility?	Robin Fins VP, Planned Parenthood		212-274-7289		Mi
Speaker 42	What are other health issues that women look to CAM to address?	Elaine Stern. MD				Mi
Speaker 43	ditto	Kerri Gruninger				
Panel	Focus	Speaker Profile	Mailing address	Phone	Fax	Status
PANEL 10 Speaker 44 (after 1:00)	what are models of integrative medicine education?	Contact James Dillard David Katz Griffin Hospital, Yale Affiliate				Mi
Speaker 45		William Prensky Mercy College Oriental Medicine Program				
Speaker 46		Ellen Tattelman Albert Einstein/Montefiore				
Speaker 47		Kenneth Gorfinkle Babies Hopsital Columbia/Presbyterian				
Speaker 48		Red Schiller Beth Israel				
Speaker 49		Woody Merrell Beth Israel				
PANEL 11 Speaker 50	How do communities in transition use CAM	Contact Howard Josepher Clinician				Corinne
Speaker 51						
Speaker 52		Ronnie Williams Betances				
Speaker 53		Dan Kamofsky psychiatrist consultant to Care for the Homeless in NY				
Speaker 54		Covenant House				
PANEL 12 Speaker 55	Cancer and CAM	Barrie Cassileth Memorial Sloan Kettering Cancer Center				Gerry

Speaker 56		Raymond Chang				
Speaker 57		Lung cancer patient				
Speaker 58						
Speaker 59						
Panel	Focus	Speaker Profile	Mailing address	Phone	Fax	Status
PANEL 13 Speaker 60	What are the challenges faced by the regulatory medical boards re CAM?	Head of Office of Professional Medical Conduct, NY				Steve/ Joe
Speaker 61		Principal Investigator				
Speaker 62		Other investigators, etc				
63						
PANEL 14 Speaker 64	Athletic performance	Phil Shinnick				
Speaker 65		Pat Connelly women's sports				
Speaker 66		Bob Lipsight Sports writer for NYT				
Speaker 67		Gary Wadler Physician/Author for peak performance issues				
PANEL 15 Speaker 68	what role can the print media play in educating the public about CAM	Maura Schulman Parents Magazine		212-499-2049		Mi/Troy
Speaker 69	What role can the broadcast media play in educating the public about CAM	producer				
PANEL 16 Speaker 70	Counterpoint	Paul Kurtz				Mi



White House Commission on Complementary and
Alternative Medicine Policy

New York City Town Hall
January 23, 2001

Commissioners Briefing Materials

Gilberto Cardona, M.D.

Acting Regional Director, Department of Health and Human Services (Region II)



9:15am PANEL I

1. Ansel R. Marks, MD, JD (key)

Executive Secretary for the Board of Professional Conduct

New York State Department of Health, Board of Professional Medical Conduct



Outline - will send more information

7000

2. Margaret B. Buhrmaster

NYS Department of Health, Office of Regulatory Reform

Health Regulations
State Government Rule
CAM Education Curriculum ← Physician Training
Herb Patients
CME

3. Caroline V. Rider, Attorney at Law

The gist will be that we consumers need freedom to choose our CAM providers...that since most CAM practices are gentle, low-risk interventions, LICENSURE IS NOT NEEDED and will both restrict access and increase cost. Disclosure and accountability should be all that is required for legal CAM practice in any state. As an attorney I can see several simple ways in which that could be implemented.

- No Uniform Requirements
- Consumer Rights to choose

4. Stephen Lee Lockwood, Lockwood & Golden, Esqs.

Federal legislation should be enacted to protect complementary and alternative physicians from discriminatory disciplinary proceedings by state regulatory bodies whose staffs are uninformed about and therefore biased against safe and effective CAM treatment modalities which compete with current accepted methods of conventional care, many of which are often neither safe nor effective. The impact of current regulatory enforcement schemes deprives patients of their constitutional right to choose among various complementary and alternative treatment modalities by discouraging physicians from pursuing CAM therapies for fear of being the subject of disciplinary actions designed to revoke their licenses. Disciplinary proceedings against CAM physicians are costly to defend. The mere threat of such disciplinary actions has a chilling effect on the use of non-conventional treatments by CAM physicians even though many such treatments are far safer, more cost effective and more efficacious than the accepted conventional treatments. The result is considerably higher health care costs to patients and the nation. Several states have enacted legislation to provide some protection to physicians who use non-conventional treatments; however these laws are neither uniform nor sufficient to protect CAM physicians from unfair disciplinary proceedings. New York State's Alternative Medical Practices Act serves as an example. Passed in 1994, the Act mandates at least two of the more than 200 members of the Board Of Professional Medical Conduct be physicians who devote a significant

portion of their practice to the use of non-conventional treatments yet there is no requirement mandating that such CAM members of the Board serve on the panels in disciplinary proceedings against CAM physicians. New York's Office of Professional Medical Conduct utilizes medical experts unfamiliar with CAM therapies to evaluate CAM physicians during its investigations. New federal legislation could be part of a Patients' Bill of Rights designed to protect patients' constitutional right to choose health care treatments.

LD

5. Simone Charlop

As a user of many alternative practices, I do not want to see any restrictions put on any practitioner - I am well able to decide for myself which practices may be beneficial to my health. Also, most practitioners use a variety of techniques taking from many disciplines so how could there be any possible way to license practitioners. The important thing to remember is that these practices do no harm but can be very beneficial. Let me choose.

Individual Person ^{LD} choose the modality

(10)

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 reduction 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 1/2 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.

13

Elaine Stern, L.Ac.
150 Fifth Avenue #706
New York, NY 10011
(212) 633-1687

January 23, 2001

I am a licensed acupuncturist, national board certified in acupuncture and Chinese herbal medicine. My education includes formal training and apprenticeship both here and in China. I have been in private practice for 17 years and have taught Chinese medicine throughout my career. My practice is primarily internal medicine, with a focus on women's health.

Chinese medicine is very effective in the treatment of women's health problems. Some of the more common gynecologic conditions seen in my practice include: amenorrhea, dysmenorrhea, irregular menstruation, premenstrual syndrome, menopausal complaints, menorrhagia, infertility and polycystic ovary syndrome¹.

I do not have statistics for "success rates" in treatment, however, many women experience significant improvement, or complete alleviation of the presenting problem. The measurement of success ranges from subjective reduction or disappearance of symptoms, to objective changes in sonography and/or hormone levels.

Chinese medicine is by no means a panacea for women's health, but we do have a valuable contribution to make. Many women are able to avoid, reduce or eliminate medications with uncomfortable or dangerous side effects. Many babies are conceived without the need for strong hormonal medications, to say nothing of the expense.

In my practice, some patients are treated completely with complementary medicine, whereas some are treated in conjunction with biomedical interventions such as medication or surgery. In most cases the best situation **for the patient** would be a cooperative effort between the biomedical and complementary branches of their treatment. It is not uncommon for me to direct a patient to her gynecologist either to rule out a concern or because the Chinese medicine alone is not sufficient. It would be a tremendous boon to my practice, and to the practice of complementary medicine in general, were this cooperation more prevalent and easier to effect.

My recommendations to this commission focus in two areas.

The first is to foster cooperation between practitioners of biomedical and complementary medicine. This point must be addressed in several ways.

- 1) Complementary practitioners cannot afford to "vilify" mainstream medicine; nor can mainstream physicians continue to ridicule and dismiss complementary practitioners.
- 2) Both biomedical and complementary practitioners should be aware of each others' capabilities. Biomedical practitioners should understand when complementary treatment is useful and complementary practitioners should learn how to interact with and refer patients for biomedical treatment.

¹ See "Polycystic Ovary Syndrome: three cases treated with acupuncture, herbs and nutrition" *Clinical Acupuncture and Oriental Medicine* pp19-29, Vol. 1, No. 1, 1999

I recommend we develop a series of seminars. These would be classes designed by practitioners for practitioners. The curriculum should be assembled as a joint effort and the seminars presented in a way that it is possible for busy, overworked professionals in both fields to attend. These seminars, in addition to providing much-needed education for practitioners, would act as a meetingplace and a forum for further discussion and cooperation. Perhaps this type of seminar would yield good research concepts as well.

My second recommendation concerns research in complementary medicine. Both interest and funds for this purpose are increasing, but there is so much to be done and so much controversy about how best to go about conducting this research.

I recommend that we create a board of complementary practitioners that advises biomedical researchers and reviews research projects. This would help to bridge the gap between complementary practitioners and biomedical researchers.

I hope to be able to participate further in this discussion, in the future. Thank you for your consideration.

6. Martin Rossman, Academy for Guided Imagery



Mind Body Spirit

meditation Comments

PANEL 2

7. Grace Marie Arnett, The Galen Institute

"Maximizing the Economic Impact of Assimilation of CAM Modalities through 1) Enhancing Market Forces, 2) creating Efficiencies through Individual Empowerment and 3) Waste Reduction by Targeting Root Causes" (Co-panelist with Camilla Rees and Joseph Loizzo, M.D.)



8. Camilla R. G. Rees, Strategic Communications Counsel



9. Joseph Loizzo, Columbia Presbyterian Eastside



10. Kevin Chen, UMDNJ - New Jersey Medical School

Many scientists are not willing to get involved in the study of CAM because of (1) lack of incentives (funding is very limited in comparison with other areas; (2) lack of resources and knowledge in the area (hard to find collaborators or good therapists); (3) discrimination from the peer and the funding sources -- afraid of affiliate their names with non-scientific area of research and may lose their future funding in the conventional research areas.



11. Leo Galland, Foundation for Integrated Medicine

Because they derive from a perspective that equates illness with disease entities, conventional clinical trials exclude patients with complex co-morbidities. CAM trials should embrace the problems of patients excluded from conventional trials and take as endpoints global health status, quality of life and costs of service.



Phone Call / E mail

Fail of Respect for diversity

Illness is a result of imbalance or disharmony

① Med Education - introduction to balance / harmony

- People have choices for reimbursement - Kallie has been pursuing
- Nutritional Counseling

PANEL 3

12. Fredi Kronenberg, Rosenthal Center for Complementary and Alternative Medicine,
Columbia University



13. Elaine Stern



14. Kerri Ann Gruninger, Rosenthal Center



Complementary and Alternative Medicine: Issues for Women and Minorities

Testimony Submitted to:

The White House Commission on Complementary & Alternative Medicine Policy

Town Meeting, New York City
January 23, 2001

by

Fredi Kronenberg, Ph.D.

The Richard and Hinda Rosenthal Center for Complementary & Alternative Medicine
and
Center for Complementary & Alternative Medicine Research
in Aging & Women's Health

Columbia University
College of Physicians & Surgeons
New York, NY

Complementary and Alternative Medicine: Issues for Women and Minorities

Women and minorities have long been the primary users of alternative medicine and now lead the way in the use of CAM

Women, in fact are a driving force in this new market.

So, it is imperative that we look at women and minorities examine how they use CAM and what they are using.

How women use CAM speaks to a national trend

Increasingly women seek alternatives to **common surgical procedures** such as hysterectomy and cesarean section.

They seek alternative therapies during many natural hormonal related life phases – during menstrual cycle, pregnancy and childbirth, natural hormonal changes as they age, and during illness such as breast cancer.

In many cases they seek a **therapy with fewer side effects** than pharmaceutical drugs; or seek to avoid drugs entirely as during pregnancy.

They use alternative medicine for pain management, weight loss, to reduce the impact of stress – Eastern practices such as yoga and meditation are increasingly sought out. They are no longer the exotic and rare, but rather, are becoming **pervasive and accepted**, as evidenced by their being offered increasingly in medical settings, as well as being integrated into daily life to help optimize health and well-being.

Women have long used vitamins and herbs.

A number of years ago we conducted a survey of women over 40 through a popular magazine and received 15,000 responses from across the country. 1/3 were using hormone therapy. 72% of these were ALSO doing something alternative.

But, there are **not enough medical data** to support the safety and effectiveness of these remedies

And, while women are not going to wait for the scientific data (they are good at coping with uncertainty in daily decision making), women want to, and have the right to:

- 1) know that alternative remedies are safe
- 2) know that CAM remedies really work
- 2) know that their doctors are knowledgeable about CAM, at least to the extent of referring them to and working with quality CAM practitioners

Minority groups who come to the US bring the medicines from their own cultures and traditional medical systems

Women and minorities may obtain CAM goods and services in different ways –

In fact, there seems to be a 2 tiered way of obtaining and using CAM remedies.

Many **women**, particularly those more recent users of CAM, buy products, sold commercially, at **increasingly high costs**.

Minorities often seek and use CAM in their own neighborhoods, often in small local shops, and from local (sometimes family) healers, most often at very low cost.

Yet here too, there is little research to help people (both the users and conventional practitioners) understand when these traditional approaches are equal to or even better than Western alternatives, and when Western medicine might be the best choice.

Since women certainly won't hold their breath and wait for appropriate government action, they are using CAM without clear guidelines or full disclosure and information.

It is incumbent upon government fund research on remedies for women and minorities to provide users/consumers with appropriate information.

- 1) Is it safe?
- 2) Is it effective?
- 3) How do CAM remedies/practices interact with conventional medicines?
- 4) Are doctors informed?
- 5) Is the information reliable?

Yet in the danger in making policy is one of **over-regulating, over-medicalizing**.

So the challenge is: How can we increase the accessibility and quality of CAM and not detract from what makes it appealing and successful – and that is, often availability outside of conventional medical venues.

Policy and funding is critically needed to drive this research in a timely fashion and to provide the impetus to educate physicians and other healthcare providers in mainstream medicine

Danger overmedicalizing

Co-funded

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002. testimony	Kerri Ann Gruninger (partial) (1 page)	01/23/2001	b(6)

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[002]
14
Kerri Ann Gruninger

(b)(6)

New York, New York 10024

January 23, 2001

I am present to testify as a patient that has utilized traditional and complimentary medicine. Over the past 15 years I have been diagnosed with numerous medical problems. At first, I would try the routine route for the treatment of cancer and chronic pain but would find that complimentary treatments were also beneficial in treating my health problems.

The practices of meditation, hypnosis, imagery and yoga have been a part of my daily routine for over 15 years. After being diagnosed with Hodgskins disease and choosing traditional chemotherapy and radiation I decided that I needed to "do" something else to reach remission. Through a close friend I learned meditation and self-hypnosis, which soon became part of my morning ritual. A psychotherapist worked with me on imagery and soon Pac Man was eating the "bad guys" that had invaded my body. Yoga was the final part of the equation. Creating a center and a balance for both my mind and body.

In 1993, I was involved in an automobile accident. Once again I chose the traditional route of surgery, medicine, physical therapy and an array of tests and procedures. Unfortunately, chronic pain soon became part of my life along with a neurogenic bowel and bladder.

Less than 6 months after my last back surgery I was diagnosed with Stage IIB Breast Cancer. I was only 31 years old. My family has a history of breast and ovarian cancer but, I held the distinction of being the youngest. My body had not fully recovered from the

last 8-hour surgery and 10 day hospitalization and it had a new challenge. After the initial biopsy to confirm the diagnosis, I chose to have a mastectomy with reconstruction followed by 8 months of chemotherapy. I discussed all the options for pain control with my physicians and decided that drugs were not the answer for me. I also wanted to aid my immune system to put up the best possible fight while on chemotherapy. My oncologist was upfront when he said he did not know enough about vitamins and herbs but he had an open mind and was willing to work with me. I discussed pain control with my orthopedist who suggested narcotics and I asked about acupuncture. Unfortunately, my counts were too low during chemotherapy to try acupuncture so, physical therapy, massage, yoga and imagery were my choices. Most importantly for my treatment was group therapy with other women diagnosed with breast cancer between the ages of 20-40, sharing, laughter and hugs are great medicines.

During my course of chemotherapy I experienced “chemical menopause”, hot flashes I thought were for women in there fifties. Herbal remedies were the only help. After finishing chemotherapy, my menstrual cycle returned and brought with it migraines, another new experience for which I have utilized complimentary medicine in the form of English feverfew, peppermint and acupuncture.

Acupuncture has become a very important part of my treatment. Through acupuncture my back pain is controlled, migraines are more manageable, my immune system functions at a higher level and most importantly I feel better.

My current and previous acupuncturists are licensed Medical Doctors and I tend to seek out a doctor who practices complimentary medicine. My supplements, both vitamins and herbs, were prescribed also by a licensed doctor. But, if I were ever to be admitted as an inpatient to the hospital of my choice my

“Complimentary” Physicians would not be allowed to treat me with acupuncture or additional herbs as an inpatient. However, I could continue my morning ritual, a few people might stare but who cares. Most importantly, if we are going to work together to find or create the best care for the patient, a hospital must allow the practice of non-traditional therapies. More research and funding is needed to find complimentary therapies that are safe but, patients should have the right to receive treatment that has proved successful for their specified condition.

I am blessed by the fact, that my physicians listen and take the time to do the research. We work as a team that communicates and educates one another. We now need a system that can do the same for all patients.

FRANK LIPMAN MD

I speak to you as a practitioner with 20 years of clinical experience, most of it in Integrative Medicine. I would like to share with you what that experience has taught me and how it could be helpful to the next generation of practitioners.

I have learnt from books, workshops and master teachers, but by far, my best teachers have been my patients. From the books I learnt the science of medicine, from my patients I learnt the art of medicine. Getting to see real patients, developing interpersonal skills and seeing that every patient is unique, in how they present, how they cope with disease and how they respond to various treatments, should be a major part of any teaching program. Clinical training should be the gold standard for practitioner training.

— Doing this in a multidisciplinary setting, where no discipline or system dominates, is best for patients and practitioners alike. I have gained tremendous insights and knowledge from working together with practitioners of other systems. In fact most of my finest teachers have not been medical physicians.

Finally, Integrative Medicine is more than integrating complementary therapies into our current model. To me, it is about helping my patients become more integrated. To help them become more integrated, I had to become more integrated. What has helped me do that, has been a regular consistent yoga practice. It has helped me be more present and centered, which improves my ability to listen to, to educate and to treat my patients. I feel strongly that teaching self-awareness techniques to practitioners, should be an essential part of any training program.

Date: January 23, 2001

To: White House Commission on CAM Policy

From: Faye Schenkman, Director of the Wholistic Health Center New York College for
Wholistic Health Education and Research

Regarding: Policy Recommendations

Good morning. My name is Faye Schenkman and I am the Director of the Wholistic Health Center at the New York College For Wholistic Health Education and Research. I am a practitioner of Amma Therapeutic Massage, a diplomate in Oriental Herbalism and Bodywork and have personally been involved in the field of complementary and alternative medicine since 1976. The subject of breast cancer and alternative and complementary approaches to treatment of the disease is very complex. I am here today to speak very briefly on the need to incorporate wholistic modalities such as massage, acupuncture and herbalism into the fight against breast cancer.

The public is distressed by increased cancer incidence and the absence of real treatment gains for the major cancers despite the decades and billions of dollars spent since the initiation of the war on cancer. Breast cancer has reached epidemic proportions on Long Island where I reside and work, and is the leading cause of cancer death in women throughout the industrialized world and in many developing countries. There is a great deal of fear and no clear understanding of why the incidence of breast cancer has increased so substantially. Many women who have cancer are exploring alternative treatment especially if their recommended treatment is very difficult to endure or doesn't produce the desired effects. Most oncologists are not familiar with alternative and complementary therapies used by many of their patients. Chemotherapy's side effects have become increasingly difficult for women to tolerate as we all desire more gentle, as well as, effective treatments. The FDA is seen as ignoring research on natural, herbal products that have been standard treatment in Europe, for example, in favor of expensive technology and expensive drugs. Many women feel helpless and frightened. They do not understand why oncologic medicine does not incorporate non-toxic herbal remedies, nutrition and energy based modalities that are standard in other nations that help to alleviate stress and diminish symptoms. The United States is behind many European countries in integrating complementary modalities to enhance conventional oncologic care. We are also behind in the concept of preventative medicine.

The concept of prevention of breast cancer in the United States is limited to early detection, i.e., regular mammograms. From a wholistic standpoint, a great deal can be done to educate women and the public at large on ways to take responsibility for their health. There is a great deal of evidence showing many environmental toxins, especially pesticides, and dietary factors like high fat diets, processed foods, fast foods with trans fatty acids and low nutritional value all play a role in potentiating this rapid rise in breast cancer. Allopathic medicine has recently begun to acknowledge that the consumption of fruits, vegetables, legumes and whole grains and anti-oxidants can help reduce cancer risk. Oriental medical modalities, such as Amma massage, acupuncture and herbalism offer treatments designed to enhance the body's ability to defend itself against disease

and alleviate stress in addition to improving the quality of life and helping those who are sick to manage their symptoms and the effects of their treatments.

It is imperative that oncologists offer their patients a supportive environment in which patients can feel free to discuss what complementary therapies they are using. And it is even more imperative that physicians are educated in these therapies so that they can understand how these modalities can enhance their own treatments. Physicians need to be open about both the limitations and the achievements of western medicine. The benefits of complementary practices, their comforting, non-toxic approaches, can merge well with conventional oncology practices to enhance the patient's well-being and quality of life.

Policy Recommendations:

I offer the following recommendations to enhance the integration of CAM therapies into conventional medicine:

- Medical schools should be required to teach courses in Oriental medicine – not simply introductory courses but in-depth instruction in the fundamental principles of Oriental medicine so that they can understand the viewpoint and how diagnosis and treatment is made. Not necessarily so they can practice it themselves, but so that they can make appropriate referrals, collaborate, and integrate their treatments with the CAM treatments their patients are already having. Without an understanding of the concept of the energy system, it is impossible for Oriental modalities such as acupuncture, bodywork, herbalism to have any meaning to a Western trained physician.
- Physicians should have in-depth courses in herbal remedies, nutrition and supplementation taught by acknowledged experts in these fields.
- Physicians need to develop a reliable network of referrals in different CAM specialties.
- Government should foster a climate of understanding and collaboration by allowing complementary and alternative therapies, such as acupuncture, massage, herbalism, chiropractic, biofeedback to practice in hospitals, in the armed forces.
- Government should help promote insurance reimbursement for CAM therapies. Currently many patients pay out of pocket for treatment and this limits their ability to receive these modalities.
- Research to better understand how to incorporate non-toxic herbal remedies, nutrition and energy based modalities such as acupuncture and massage therapy, that are standard in other nations and help to alleviate stress and diminish symptoms with conventional oncological treatment.

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[003]

(17)

Tuesday, January 23, 2001

(b)(6)

NY, NY 10024

To: The White House Commission on Complimentary and Alternative Medicine

From: Sherri Heitner/Margalit, Patient Advocate, Breast Cancer Survivor
SHARE Representative - NYC

I am here today as a voice for women whose cancers have recurred. Today I am fifty-one years old - it is my birthday. I attribute the fact that I am alive and healed to my medical care, my family and friends support and love, and to complimentary treatments.

When I was 44 years old I was diagnosed and treated for breast cancer with a mastectomy, CAF chemotherapy, and a saline implant reconstruction. The disease was quite a shock, but after treatment I wanted to go on with my life like it was before cancer. That just did not happen. Three years later I recurred with a Local Recurrence with the same breast cancer, on the same side. At that point despite varied medical opinions, I participated in a Phase II Clinical Trial with High Dose Chemotherapy and Stem Cell Rescue at NY Presbyterian Hospital, which was promoted as a 'cure' and my best chance for 'long term disease-free survival.'

Of course now we know that Professor Bezwoda of South Africa falsified his data, but it has taken 1 1/2 years to disprove his information, and by then many hundreds, perhaps thousands more women had participated in Phase Two Clinical Trials with high dose chemotherapy/stem cell rescue. Currently, it has still not been proven that high dose chemotherapy/ stem cell transplants do increase disease-free survival. We know that HDC/SSR continues to be promulgated as a 'cure' to increasing long term disease-free survival, and offered as treatment alternatives in government sponsored clinical trials. Yet, we also know of the horrific, many times irreversible, side effects of high dose treatments, despite the fact that these drugs at those dosages are ever proven effective as treatments.

During and after each of my medical treatments I employed complimentary treatments to help sustain and heal my physical body, as well as my emotional-spiritual side. I have had a thirty year history of following a vegetarian diet, practicing yoga, employing meditation techniques, massage therapy, and herbal remedies. Yet, my background could not prepare me for dealing with such toxic substances and their side effects. My body was stripped of it's natural immunity which has literally taken years to recover, and I am still wrestling with each winter flu season. I continue to suffer peripheral neuropathy in my feet, as well as osteo arthritis in my back and knees almost three years later due to the Taxol. I have had to fight with insurance carriers to give me a minimum of PT and OT services, for fine motor and gross motor problems due to the chemotherapy treatments. The transplant oncologists knew how to administer these high dose, highly toxic treatments, but not how to reverse their traumatizing effects. Initially, I had been paralyzed from the high dose Taxol, unable to move, walk, or lift a cup without assistance. I required 24 hour care for six weeks.

I had to learn to walk again with a walker and a cane. Did being so debilitated warrant stopping the treatment? Not to the transplant doctors who wanted to give me more high doses of different chemos. I decided not to proceed with further high dose treatment. I felt that it would be ironic to die from the side effects of breast cancer treatment, than the breast cancer itself.

Since that point of transplant almost three years ago, I have lobbied for supplementary services to be provided by the hospital as After Care. These services were not and are still not in place at NY Presbyterian Hospital, where my treatment was done. Patients should not be sent home with a lack of follow-up care, especially if a large portion of their medical treatment was done on an outpatient basis.

I put together my own 'umbrella of supplemental treatments' to help sustain me, but much was out of pocket expenses, because they were not covered through insurance. If government can fund incredibly expensive chemical treatments, why should there not be supportive, supplemental services available for Patient After Care? There should be a center providing traditional Chinese medicine, acupuncture, massage, nutrition counselors, rehabilitative water exercise, counselors to deal with the post traumatic shock of treatment, homeopathy, and herbal remedies, vitamins and supplements, movement and yoga classes, as well as aromatherapy and music therapy. I propose linking research dollars for After Care treatment in these types of Clinical Trials. No IRB's should permit HDC/SSR on human participants without these supportive After Care services.

Thank you for your time listening to this proposal.

15. Frank Lipman



16. Faye Schenkman

As Director of the Wholistic Health Center at the New York College, my remarks will focus on the current breast cancer research study that the College is about to begin utilizing CAM therapies in conjunction with conventional medical care. I will also discuss the need for preventative medicine via CAM modalities in the area of breast cancer.



17. ~~Carol~~ Sherri Margalit, SHARE

I am a six year, two time bc pt who recd chemotherapy, tamoxifen and had a saline implant upon initial diagnosis, and had further chemotherapy, radiation and participated in a HDC stem cell clinical trial upon recurrence. I have suffered severe side effects from the medical treatment including initial paralysis, peripheral neuropathy, menopausal symptoms, heightened cholesterol and osteopenia. Frequently the medical doctors have had no answers for the treatment of side effects from the highly toxic drugs which were used for the bc treatment. I have had to find complementary treatments to counter those effects on my own. I would like to see hospitals and medical centers begin to incorporate more preventative and supplementary services at their sites to make access more user-friendly for the pts. In addition these services should be covered by insurance co-payments, like doctor visits generally would. In addition I would like to see more accountability by hospitals and institutional review boards with respect to the clinical trials that are conducted, especially in the area of high dose chemotherapy.



BREAK

11:15am PANEL 4

18. Ann E. Fonfa, The Annie Appleseed Project

I am a (breast) cancer patient who runs a website for those interested in complementary/alternative therapies. I speak at meetings, either as invited speaker or speak out to represent patients' interest. I have spoken to many healthcare providers too, in an effort to bridge the information gap between patients and their providers. I have been recommending certain types of clinical trials in order to explore CAM issues of greatest importance to patients. I will discuss these at greater length.



The Annie Appleseed Project 153 East 32 Street #3C New York, NY 10016-6029
www.annieappleseedproject.org (212)545-0050 fax (212)545-0025 Ann Fonfa

I am Ann Fonfa, founder of The Annie Appleseed Project. The Project was formed to help inform, educate and advocate for cancer patients and concerned others. Our special area of focus is complementary/alternative, natural therapies.

Since studies show that up to 87% of patients are interested in this area, and that they rarely discuss issues with their healthcare providers, The Project works to bridge this information gap providing a website with lots of downloadable information, including patient perspectives at all times.

Today I would like to talk about the need for a new research direction-often called paradigm shift. I would urge this panel to use its powers to help create this shift. I sometimes refer to it as the Patient Track.

Presenters at the last three annual conferences of the American Association for Cancer Researchers proudly offered very positive studies of green tea. Yet no cancer patient I know would take green tea alone. We ALL combine elements and the study of natural, nontoxic combinations is part of the Patient Track. Looking at what we do NOW would yield information of the highest quality and usefulness.

Studies done on the Patient Track would look at combinations of therapies, such as antioxidants with chemotherapy or radiation. It would examine the use of herbs in combination, and with dietary supplements. Many of us juice daily and do detoxification routines as well as mind/body medicine. Patients' real life regimens should be studied under conditions approximating their use in our real world.

A study of patient use of CoQ10 along with anthracycline-based chemotherapy regimens might be included for possible reduction of cardiotoxicity, or the use of taxanes and alpha-lipoic acid for possible prevention of neuropathy.

Pharmaceutical companies might have much to gain from such studies. If it could be shown that the use of dietary supplements might enhance conventional therapy, this would benefit many of the stakeholders.

As a cancer patient myself, I know the frustrations of having to make treatment decisions with little or no evidence of efficacy. Yet in the 9 years since I have been using natural therapies, I have successfully achieved tumor reduction with three different regimens. And if I can do it, so can other needy patients.

I consider myself a highly educated patient, having attended literally ninety to a hundred conferences, meetings and events. I read journals, newsletters, books and articles. I have met health practitioners of every persuasion. Many are open to new ideas. Some say they oppose alternative medicine-a statement that clearly indicates ideology and not science. At the same time, patients are asking questions of their providers and it is important to get answers.

And still 9 years later I have to make treatment decisions by my GUT. At just about every meeting I have attended, I rise to ask when will we have answers on various natural regimens. The response has always been "We have no studies on that" or "That hasn't been studied yet". If I had waited for the studies, it would now be 9 years later with NO answers. And maybe I would not be here for them anyway.

We patients cannot afford to wait. We need answers now so that we do not have to waste our money and our time-our precious time, on the wrong things. The Annie Appleseed Project offers information on alternative therapies as possibilities. We believe if they have worked for someone, they may work for someone else. As in the conventional therapies world, not all things work for everyone. We are forced to pick and choose among many options, most of which have not been studied in humans. Certainly almost none at the highest level of evidence as required by FDA-randomized, multi-center, double-masked studies.

I heard it said in reports of clinical trials, that there were NO unexpected effects. Just because they were expected does not excuse the highly toxic and painful effects of conventional cytotoxic drugs. Just because we call them "side effects" does not reduce their damage, often permanent. Great marketing idea calling them "side" effects although they are not aside of anything. Often larger numbers of patients experience the unwanted effect than the desired one.

When discussing dietary supplements, one complaint is that we do not know the effects. At FDA meetings I hear lots of references to safety. Considering that cancer patients are routinely given highly toxic medicines, this concern for safety in the alternative use of dietary supplements and nutrition, seems VERY overstated. Thinking about this seriously, knowing as I do that vitamin overdoses can be reversed without permanent damage, unlike cytotoxic drugs, I often wonder when did we fall down the rabbit hole?

In conclusion, I urge this commission to take the Patient Track. Work for and sponsor studies that will yield immediately useful information for patients and their caregivers, healthcare practitioners and ultimately our society.

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Johanna Antar
Statement for WHCCAM
January 23rd, 2001

The best way I can express my opinion on the situation of Complementary and Alternative Medicine in this country is to tell you a story. I have a very dear friend that has been diagnosed with liver cancer – one of those fast growing kinds. The doctors gave her 3 months to live. That was over 2 years ago. My friend decided to use alternative therapies to handle the growth of her tumor. It has obviously worked because she's not only still standing, but she's feisty as hell.

That's the good part of the story. Here's the not so good part. To receive her alternative therapies she had to go to a facility in Mexico. Her church helped by raising some money to send her there, since her family is of limited means. The types of alternative therapies that she needs to keep her tumor in check are either unattainable or not approved of in this country. The practitioners to help her maintain these therapies are not approved of in this country. All expenses for these therapies are out of pocket for them.

Last week I was speaking to her husband and I was telling him about another alternative therapy that they might want to look into and he looked me straight in the eye and said "We can't. We have no more money."

What is wrong with this picture? Here we have a family, a good family who has made an obviously good choice for her health care. It has worked and continues to work for her. They aren't the new-age fringe types you might think about when you think alternative medicine. He's a cop, she's a housewife, they have 3 kids, two of them are adopted, they go to church on Sunday. We're talking a family any community would gladly have. So why do they have to fly to another country to exercise their freedom of choice in health care? And why must they totally deplete the family's financial resources to exercise their freedom of choice in health care?

This is America. Some of us still believe the words of the Declaration of Independence – that we are "endowed by our Creator with certain unalienable rights, that among these are Life, Liberty and the pursuit of Happiness." To many many people, being able to openly and easily pursue Alternative Medicines and Therapies IS our way of exercising our unalienable rights of Life, Liberty and the pursuit of Happiness. And for my friend, it's now her ONLY way of protecting her life, liberty and happiness.

Alternative Medicine must be made attainable and legal, and yet at the same time it's basic nature and integrity must be protected. Alternative Medicine cannot be clumped within the traditional western medicine framework, because that framework will put a chokehold on how Alternative Medicine operates. It's time to start thinking outside the box in terms of integrating Alternative Medicines into our health care system – so people may exercise their rights of life, liberty and their pursuit of happiness, their way.

(21)

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

Good morning Commissioners;

My name is David Molony. I am an Oriental Medicine professional and the Executive Director of the American Association of Oriental Medicine.

As health care providers, we appreciate your efforts to gather information about traditional and modern methods of health care diagnosis and intervention. We have been surprised at how many have come forth to comment before your commission, and we look forward to receiving the compilation of your efforts so we can better work with our patients as they wander the maze of "alternative" therapies.

We believe that quality standards of care are best developed and assured through high standards of education and examination. Our goal is to develop the professional doctorate degree as the standard for the practice of Oriental Medicine in the United States, as it is also being developed in the European Union, and as it has been found to be best practiced in the Asian countries from which it originates. Of course, in any field of medicine, there is room for many levels of health care providers, from vocational to professional, and many niches to be filled by these varying levels of education, even within Oriental Medicine.

While standards vary from state to state, we have come a long way since 1973, when no licensing existed for our profession. Today, we are licensed in most states.

One of our nationally accredited exams is in Chinese Herbal Medicine. Recently, there has been some misleading reports in the press about the dangers of certain Chinese herbs, and we expect another of the same this week. The FDA has forced the recall and destruction of products for which there have been no reports of illness or injury.

Nearly ten years ago, a number a kidney failures were reported in Belgium after patients took a cocktail of drugs and herbs prescribed for weight loss, including the Fen-Phen drug combination. Who prescribed them? Licensed medical doctors with little or no herbal training who used their reading skills to create cocktails much like a bartender would. They knew little or nothing about Chinese herbal medicine, proven by the fact that those herbs are never used in that form, for that reason, or for that length of time, so that any toxic results could not have been predicted. Not only that, but they were also the incorrect herbs because of misidentification, which once again goes along with a poor education. Two more similar cases appeared in Great Britain in 1998, once again resulting from failure to seek the advice of a qualified Chinese herbal practitioner who might have noticed that the herbs being taken had been misidentified, misused, and/or combined inappropriately with conventional medications.

How can such illnesses and injuries be minimized? Simply by adopting the educational and examination standards that are already in place for Chinese Herbal Medicine in the United States and China. It's an easy and effective choice. While FDA-approved drugs prescribed by medical doctors kill hundreds of thousands of people in this country, Chinese herbal medicine, in the hands of qualified practitioners, is not only effective, it is relatively benign. In the hands of untrained individuals, however, we can make no guarantees.

Please feel free to contact us with any questions on this and any other subject relative to Oriental Medicine.

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

Oral Comments by David P. Yens, Ph.D., New York College of Osteopathic Medicine,
New York Institute of Technology, Old Westbury, NY 11568

For many Complementary and Alternative Medicine therapies it is difficult to assemble a sufficient number of patients in one place who have the same kind of problem and require the same kind of treatment. For other therapies, such as osteopathic manipulation, a given problem may be treated in different ways by different physicians depending upon collateral conditions that may exist. For both of these situations, some kind of National data collection and analysis mechanisms need to be developed and supported so that a sufficient number of cases can be assembled for scientific analysis. The creation of an osteopathic electronic SOAP note will be used to illustrate what is needed and the problem that must be addressed.

About osteopathic medicine

The philosophy and science of osteopathic medicine were first described in 1874 by Andrew Taylor Still, MD, DO, a physician who lived from 1828 to 1917. In 1892, Dr Still founded the American School of Osteopathy in Kirksville, Mo. The members of the osteopathic medical profession are designated as "physicians and surgeons, DO." They are qualified to render complete healthcare. Osteopathic medicine is a complete system of medical care with a philosophy that combines the needs of the patient with the current practice of medicine, surgery and obstetrics. Osteopathic philosophy also emphasizes the interrelationship of structure and function, as well as the body's ability to heal itself. Osteopathic medicine cooperates with all other branches of medical science. It maintains its independence to develop and perpetuate for everyone this unique and inclusive system of medicine.

D.O.s understand how all the body's systems are interconnected and how each one affects the others. They focus special attention on the musculoskeletal system, which reflects and influences the condition of all other body systems. D.O.s know that the body's structure plays a critical role in its ability to function. They can use their eyes and hands to identify structural problems and to support the body's natural tendency toward health and self-healing.

What is "alternative" about osteopathic medicine? The National Center for Complementary and Alternative Medicine considers the manipulation component to be "alternative." D.O.s are widely recognized for their incorporation of manipulative medicine into their spectrum of care. However, it is this manipulation component that is hard to study.

While manipulative medicine is commonly associated with physical ailments such as low back pain, this far-reaching treatment modality can also be used to relieve the discomfort or musculoskeletal abnormality associated with a number of disorders, including Asthma, Sinus Disorder, Carpal Tunnel, Migraines, and Menstrual Pain. OMT can relieve muscle pain associated with a disease, and can hasten recovery from illness by promoting blood flow through tissues. A large variety of manipulative techniques can be used to treat these, and other, problems, and the specific technique or techniques used depend upon the physician's training and what they sense through their musculoskeletal examination. Thus, a diagnosis of otitis media may be treated in different ways depending upon the severity of the condition, identification of collateral problems, and the nature of the cranial bones and passages the ear and nose.

The Problem and The Need

Scientific research, designed to determine the most effective treatment for a given problem, requires that a

consistent technique be used to treat the problem. Appropriate outcome measures, or dependent variables, must be selected to evaluate the effectiveness of the treatment. However, the complexity of the situation makes this hard to do. With the growing need for outcomes based research in the osteopathic profession, there is an increasingly urgent need for a standardized format for reporting the incidence, severity, treatment of and outcomes related to somatic dysfunction. If the profession is to compete in the increasingly competitive arena of health care provision, it must provide information on those concepts which are central to its treatment and how the disturbances it professes to treat almost uniquely in the health care field, are distributed in the population.

The Louisa Burns Osteopathic Research Committee of the Academy of Osteopathy has designed a form (osteopathic SOAP note) that is to be used by practicing osteopathic clinicians to gather data on their osteopathic examination, the somatic dysfunctions found, the treatment regime used and the response obtained to treatment. This form is designed to capture subtle nuances of the diagnosis and treatment process. The process to be studied is the provision of osteopathic evaluation and treatment as part of the management of a patient's health care. The outcomes being sought are a modification of the somatic dysfunction and the patient's health problems. The data sought will come from the patient records and the physician's description of the treatment performed.

To be usable, all the data collected via these forms must be collected together, or aggregated, to permit analysis. However, this requires uniformity in description of the problem(s) in description of the treatment, and measurement of the outcomes. How can this be done?

The only viable approach to solving this problem is the use of a computer record that provides sufficient precision for input that these variables can be accurately identified and aggregated for analysis. With a very large number of levels of variables and shades of meaning this is a difficult task that can only be handled by gathering very large numbers of cases. Thus, some kind of computer network, with a centralized database, is required. The Louisa Burns Committee is initially addressing this task by creating a computerized SOAP note that replicates the paper SOAP note mentioned above. The plan is to create a standardized program whereby uniform data can be gathered from private physician's offices, residency programs, and hospitals that is transmitted to a central data storage facility for analysis. Of course, many security issues must be addressed; this is being done. The major problem is the expense of developing and maintaining such a system. The osteopathic profession is not able to support a project of this magnitude. Identifying other funding sources for such a project has been difficult; we are still searching. Although medical information databases have been developed, we are aware of none of the complexity required for our purpose.

I believe that the problems we are addressing are not limited to the osteopathic profession; similar problems are probably faced by other complementary and alternative approaches to health care. The magnitude of the problem, combined with the potential for providing effective outcomes analyses for a variety of CAM therapies, implies that Federal support for such programs would facilitate the creation of reliable and valid knowledge about these therapies. I urge the establishment of a funding program for this purpose.

Thank you for permitting me to make these comments.

*Sections of these comments were adapted from a grant proposal prepared by the Louisa Burns Osteopathic Research Committee.

19.Cecile Schey

I have been interested in alternative care for 30 years. I had severe asthma (took injections weekly) and medication - condition remained. When I started alternative care , I no longer suffered from asthma. I am 77 years old and in very good health. Alternative care should be included in our medical system.



20.Johanna Frances Antar

As consumers, many CAM practices are preferred as our primary health care system. However, many people cannot avail themselves to CAM practices because they are not covered by insurance programs and therefore we are "forced" to either use health care systems we are not comfortable with and not get any CAM care because of the costs involved



21.David E Molony, American Association of Oriental Medicine

Educational requirements for Oriental Medicine have been rising to meet the rising expectations of our patients needs as we see more chronically ill people and we become aware of what is truly needed to function well within the Oriental Medicine paradigm in any of its modalities.



22. **David Yens**, NY College of Osteopathic Medicine, NY Institute of Technology

For many CAM therapies it is difficult to assemble a sufficient number of patients with the same kind of problem requiring the same kind of treatment in one place for a study. For other therapies, such as Osteopathic manipulation, a given problem may be treated in different ways by different practitioners depending upon collateral conditions that may exist. For both of these, some type of National data collection and analysis mechanisms need to be developed and supported so that a sufficient number of cases can be assembled for scientific analysis. The creation of an Osteopathic Electronic SOAP Note will be used as an illustration of what is needed and the problems that must be addressed.



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23. **Prabhat Kumar Pokhrel**, M.S., M.D., Ph.D. (candidate), New York College for Wholistic Health, Education and Research

Hello, I am Dr. Prabhat Pokhrel and I am serving as a Director of Research at the New York College for Wholistic Health, Education and Research....One of the problems I am facing is the lack of IND numbers for most herbal or other type of supplements. It would be very helpful to the area of CAM research if a government agency like FDA would train some of the CAM researchers on how to apply for IND numbers, or develop IND number themselves for some commonly used products or product with long safety record or waive IND for specific products that are already in the market and are being used by thousands of people. Thank you.



**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.herb-alph.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 Response CR+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

PANEL 5

24. Jennifer Daniels, MD, MBA Family Medicine, Solo Practice

Dr. Jennifer Daniels MD MBA is a family physician, practicing solo in Syracuse, New York. She built her own clinic and opened its doors on March 18, 1991. Dr. Daniels' practice is located in the impoverished south-side neighborhood in which she grew up.

Essentially, I properly diagnosed a patient as diabetic. We discussed insulin and I told him that diet and exercise might control his diabetes without insulin. He had a Bahamas trip already planned and did not want to pack insulin and needles. I advised diet, exercise and vitamins. He followed my instruction and his blood sugar came down from 465 to 138. He did well on his trip. Upon returning to the states, his compliance became poor. He went to an emergency room where his glucose was found to be 565 and insulin was started. He was in the hospital for 2 days and is now doing fine. A report was made to the office of professional conduct and I am now being investigated. OPMC requested a copy of my records, and then decided that an informal hearing is needed. I attended an informal hearing with my lawyer and followed it with a letter of clarification; attached. It was then decided that the matter was quite serious and an office review of records is needed. My new lawyer, Catherine Gale, is delaying this. OPMC called Gale Esq. to schedule a time to enter my office. She informed them that she would move to quash and they told her she could not and they would charge me with unprofessional conduct for non co-operation. Later they called her back and said they were mistaken but that if she moves to quash (prevent the next stage of the investigation) they would just charge me with something else.

I am accused of a pattern of inappropriate care. I have checked with the hospitals where I have privileges and they told me my record is squeaky clean and they wish the department heads had records as clean as mine and they would testify to this. To my knowledge, there is only this one case.



25. Charles E. Gant, MD, PhD., Private Practice

My talk will focus of the OPMC (Office of Professional Conduct), a branch of the NY State Health Department, and their attempts to criminalize healing in New York. The consequences of persecution of alternative physicians prevents the shift to potentially safer, more effective and less costly paradigms of CAM treatments, because doctors are fearful of prosecution. This chilling effect on the medical community to innovate and explore alternatives takes precedence over all other issues (e.g., research, reimbursement, economic, education and training) because CAM could never be brought into mainstream medicine in an environment of paranoia, regardless of other incentives and opportunities. My entanglements with the OPMC specifically stemmed from my work on ADHD and finding ritalin alternatives. I threatened a pharmaceutical ideology and it has cost me over \$90,000 in legal fees, 3 years of interrogations and office raids, missed sleep and stress. Most of all, patients who would have otherwise have been able to access safer and more effective CAM treatments have been harmed.

26. **Serafina Corsello, Corsello Centers for Integrative Medicine**

Serafina Corsello, MD, FACAM is the founder and executive medical director of the Corsello Centers for Integrative Medicine in Manhattan and Huntington, New York. She is cofounder of the Foundation for the Advancement of Innovative Medicine (FAIM). Dr. Corsello was one of the 25 physicians who, in 1992, participated in the formation of the Office of Alternative Medicine within the National Institute of Health. Her approach is based on the use of noninvasive diagnostic testing and natural therapies, integrating mainstream treatments when necessary. Rather than simply alleviating symptoms, the Corsello Centers' staff focus on restoring the body's own healing process, including natural menopause management, nutrition education, weight management, smoking cessation, detoxification, toxic metal chelation, stress management and counseling. Professional staff includes medical doctors, physician assistants, nurse practitioners, registered nurses, nutritionists, stress management therapists, biofeedback specialists and acupuncturists.



26. **Arnold Gore, Consumers Health Freedom Coalition**

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 it is now six years old 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 have been violating the Alternative Medical Practice act in respecting the rights of physicians to use these treatments. Prescription drugs have been found to cause 2.2 million injuries and 106,000 deaths from prescription drugs correctly prescribed and taken as directed. This was reported in the Journal of the American Medical Association. 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. 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 four years, and had 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 impartiality of the Drug approval process. Something must be done to expedite this approval.



28

Edna Fishman

Just here

I have benefitted greatly from change of diet and recommended diet and herbs. Cholesterol lowering drugs were very disruptive but the above lowered my cholesterol. I feel that people who are trained to perform special non-invasive treatments should be allowed to do so legally. Their training and teachings have helped so many people in so many ways, especially me.



29.

Helen Choat

Just here

I have always been greatly interested by alternative medicine practices and I feel the opportunity to enjoy them should be available to all people, everywhere. And information regarding these should be available to everyone



I first realized many years ago that I wanted to be a dancer. I went to college and studied with the best professors and instructors that money can buy. But ultimately, it was my uniqueness and skills that would land me job opportunities. It was what I could do that made my services sought after, most prominently, in teaching. No one ever asked to see my license to dance or to teach dance for that matter. It was understood. So, I've lead the life most Americans dream of: absolute freedom of choice and persuit of happiness in my work-until now.

Learning reflexology seemed a very natural extension of my dance career. I am already in the business of adjusting bodies, strengthening muscles and postures through movement. I offer sound advice based on my experience in the trade. When I was informed that I would have to go to massage therapy school and obtain a massage therapists license to do reflexology (this in addition to the years of study already in the field). I was angered at first, then confused. Reflexology is not the same as massage therapy. That's when I found out about all the other healing modalities that must lie in wait to be discovered because licensing is not available in their field.

Natural healing practitioners need not fear being accused of practicing medicine without a license. They do not claim to be medical doctors. We practitioners must be able to practice our art. We are a vital part of society. In some societies, we existed before western medicine ever set a penicillen coated, pharmeceutically driven foot on it. They have their place in the world but so do we. Must we be judged by their standards solely?

✓ My solution to this situation is simple. Let the practitioners govern themselves. Allow them to provide full disclosure of their pertinent information to their clients/consumers. Perhaps their training was in an institute of higher learning or through time honored traditions past from generation to generation. Let the professional affiliations and referrals lend credibility, where they exist. Does it really make sense for me to get a cosmetology license to be able to perform reflexology? I guess it would if I also wanted to paint toenails.

Ultimately, a consumer will persue what brings them happiness and a sense of well-being, it just makes things a whole lot easier when it can be done legally.

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New York State 1994 Legislative Session

S-3636 A-5411

THE Alternative Medical Practice Act

Providing complementary
options to conventional care

AN ACT to amend education law in relation to the use of alternative and complementary medical therapies by licensed physicians. Would provide guidelines for the use of these therapies; would prohibit charges of professional misconduct based solely on the use of alternative or complementary medical therapies with the patient's informed consent.

The objective is to bring professional medical conduct statute in conformity with case law and allow patients to receive the treatment options that they seek from licensed physicians.

SPONSORED

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COURTESY OF

Monica Miller and Tim Sheridan, representing the
Foundation for the Advancement of Innovative Medicine
(518) 758-1763

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(32)

REPORT OF THE
PHYSICIAN DISCIPLINE PROCESS EVALUATION PANEL
ON NON-CONVENTIONAL MEDICINE

By Chapter 735 of the Laws of 1992, the New York State Legislature created the Physician Discipline Review Panel ("Panel") to review the structural and procedural aspects of the physician discipline process in New York State. The Panel is charged with assessing the overall goals and objectives of physician discipline, how well the goals are being met, and whether and to what degree the process serves to minimize or deter misconduct.

By Chapter 558 of the Laws of 1994, the New York Legislature expanded the scope of the Panel's charge by directing it to make recommendations to the Governor and the Legislature by June 1, 1995, concerning:

- (1) The use of experts, including experts in medical specialties or experts in non-conventional medicine by the office of professional medical conduct in the investigation of complaints which involve issues of clinical practice, and
- (2) the appointment of physicians, including physicians in a medical specialty and physicians practicing non-conventional medicine, to committees on professional medical conduct hearing a case in

P R
Crusade for Patients' Rights

which a physician in such specialty or a physician practicing non-conventional medicine is the respondent.

In addition, the Chapter expressly authorized physicians' use of "whatever medical care, conventional or non-conventional, which effectively treats human disease, pain, injury, deformity or physical condition." It also provided that there shall be at least two physicians appointed to the physician discipline board "who dedicate a significant portion of their practice to the use of non-conventional medical treatments that may be nominated by New York State medical associations dedicated to the advancement of such treatments." Further, the legislation provided that the investigation committee could retain experts to aid in the investigation of cases referred to the investigation committee who also might be recommended by associations "dedicated to the advancement of non-conventional medical treatments."

We understand that this legislation was generated by concern that physicians practicing non-conventional medicine were being unfairly punished for their use of their unorthodox methods of treatment. We sought to determine whether, in fact, this was true.

Non-conventional medicine is not defined in the statute. We adopt for our purposes, however, the definition used by the New

England Journal of Medicine (Eisenberg, et. al., "Unconventional Medicine in the United States", January 25, 1993 at 246-252) as "medical practices that are not in conformity with the standards of the medical community" and as "medical intervention not taught widely at U.S. medical schools or generally available at U.S. hospitals."¹

Using these definitions, we have identified eight physicians practicing non-conventional medicine who have been disciplined since 1988. We have reviewed each of these cases and we conclude that none of the doctors was disciplined for practicing

¹ The Office of Alternative Medicine of the National Institutes of Health classifies seven separate types of "alternative medical practices": (1) Structural and energetic therapies, including, for example, acupressure, chiropractic, massage therapy; (2) pharmacological and biological treatments including anti-oxidating agents, metabolic therapy and cell treatment; (3) bio-electro magnetic applications including use of electro-magnetic fields, electro-stimulation, artificial light treatment; (4) diet, nutrition and lifestyle changes, including macrobiotics and megavitamin treatment; (5) mind and body control, including bio-feedback, relaxation techniques and hypnotherapy; and (6) traditional and ethnomedicine, including acupuncture, homeopathic medicine, Native-American medicine and other ethnic remedies which are significantly different than prevailing western medicine; and (7) herbal therapies.

non-conventional medicine per se.² Rather, the physicians were disciplined for failing to adhere to universal standards of care applicable to all physicians, whatever their philosophy concerning appropriate treatment. In most of the cases, the physician failed to take adequate patient histories; failed to undertake proper diagnostic procedures; failed to properly advise patients of their condition; failed to keep adequate records of patient progress; or failed to refer patients to specialists when their condition warranted such referrals. In many of the cases, the hearing committee expressly declined to consider the appropriateness of the alternative therapy used. Thus, we do not find that physicians practicing non-conventional medicine are being unfairly treated in the physician discipline process.

Of course, the efficacy and appropriateness of a particular form of therapy cannot be ignored in any proceeding

² One physician was disciplined for treating patients with nutritional therapy that the hearing committee found to be a fraud on his patients. This determination was based, in part, upon the committee's belief that there was no scientific evidence to support the therapy and that the physician failed to obtain patients' informed consent to perform experimental treatment. This determination was reversed by the Board of Regents, which found the Committee's conduct of the hearing to be flawed and its reasoning unsupported by the evidence.

Another physician was disciplined for treating patients with agents unapproved for the treatment of cancer that had been shown by scientific study to be ineffective. However, he was also disciplined for failing to refer the patients for hospital treatment and for improper record-keeping. In a subsequent disciplinary proceeding, the same physician was disciplined for persistent errors in diagnosis, record-keeping, and other practices unrelated to the form of treatment.

challenging a physician's competence. In this regard, we note that Chapter 558 allows physicians to use non-conventional medicine "which effectively treats human disease, pain, injury, deformity or physical condition." Where a physician undertakes a course of treatment which has not been shown to be at all effective for the patient's condition, such treatment could raise questions of competence and outright fraud.

We have reviewed the literature relating to non-conventional or alternative medicine, met as a group with Dr. James Gordon, Chair of the Advisory Committee for NIH's, Office of Alternative Medicine, about the myriad forms of non-conventional medicine, and have received the Position Paper of the Foundation for the Advancement of Innovative Medicine. We are aware that many of today's accepted procedures were once considered non-conventional. We recognize the desire of patients, especially those faced with conditions that conventional medicine cannot effectively treat, to try experimental therapies which have not been shown to be effective through controlled studies, and therefore are not generally accepted by the medical community.³

³ In allowing physicians to use non-conventional medical care which "effectively treats human disease, pain, injury, deformity or physical condition," the Legislature may have unduly limited patients' opportunities to try alternative therapies. As Dr. Gordon points out, "people leave conventional medicine and go looking for something else, not because they're sure the other thing is going to work, but because they want to see whether it might work." (emphasis in the original). Gordon, "Why Patients Choose Alternative Medicine." The Internist, September 1994 at 7.

In such cases, we believe it is imperative that the physician adequately disclose to the patient the experimental and untested nature of the therapy proposed and advise the patient of the availability of conventional therapies. Non-conventional treatment without such disclosure is, in our opinion, medical misconduct.

We now proceed to review the specific issues referred to us by the Legislature.

I. Use of Experts in Non-Conventional Medicine In the Investigation of Complaints.

Where appropriate, the Office of Professional Medical Conduct ("OPMC") should be free to use experts in non-conventional medicine to investigate complaints concerning physicians practicing in that field. However, OPMC should not be bound by any requirement to use such experts since the charges against such physicians may involve deviations from standard medical practice. As licensed physicians, those practicing non-conventional medicine must still adhere to accepted standards of practice, including use of appropriate diagnostic procedures, the provision of full and accurate information to the patient and the referral of the patient to appropriate specialists or other caregivers where appropriate.

II. Appointment of Physicians Practicing Non-Conventional Medicine To the Hearing Committees.

We agree with the Legislature's decision to include physicians practicing non-conventional medicine in the physician discipline process. However, we believe that legislation mandating the appointment of such physicians to every hearing committee involving the discipline of a physician practicing non-conventional medicine should be rejected for three reasons:

First, it is not necessary to have on the hearing committee an expert practicing in the same specialty or form of medicine as the respondent in order to determine whether the physician practiced universally-accepted standards of medicine. Where procedures particular to a specialty or form of non-conventional medicine are at issue, the OPMC and the respondent are free to call expert witnesses to educate the hearing committee.

Second, such a rule would embroil OPMC in unnecessary and undesirable legal challenges over the non-conventional credentials of hearing committee members.

Finally, OPMC never has been required to constitute its hearing committees to conform to the particular specialty or field

of expertise of the physician respondent. To require it to do so now would only complicate the already severe difficulties that OPMC has in constituting hearing committees and scheduling hearings. The Legislature's policy of having physicians judged by their peers has obvious advantages; but it also has the disadvantage of making it more difficult to bring hearing committees together for the many multi-day hearings that must be conducted. Requiring physicians practicing the same non-conventional medicine as the respondent to be part of the hearing committee would create an administrative nightmare.

June 1, 1995

Respectfully submitted,

PHYSICIAN DISCIPLINE
PROCESS EVALUATION PANEL



George F. Carpinello, Chair
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**Comments on the Report of the Physicians Discipline Process Evaluation Panel
Pursuant to Chapter 558, Laws of 1994**

dated June 1, 1995, released June 21, 1995

On behalf of the Foundation for the Advancement of Innovative Medicine

We are surprised by the departure of this report from the mandates of §4 of C.558, L.1994, which was a specific request for a report limited to two issues defined as 1) using similarly practicing experts in investigations of misconduct and, 2) using similarly practicing physicians in hearings on misconduct.

Two immediate concerns arise from our review of this document:

- The report is dominated by a misplaced, and yet cursory, investigation of the claim that non-conventional physicians have been treated unfairly in the past. In addition to stepping well beyond the bounds of the panel's charge, this preoccupation has given rise to erroneous conclusions in regard to the issues that were mandated by the statute.
- The report indulges in a quasi-judicial opinion which is wholly inappropriate within the parameters set forth for this panel by §4 of C.558, L.1994 and §6 of C.735, L.1992¹ viz., opining that the use of non-conventional treatment without adherence to a criteria beyond the requirements of law (the panel's prescribed disclosure), constitutes misconduct.

In explaining further the particulars of our first concern, it should be noted that the review of misconduct cases involving non-conventional practitioners cases appears to have been very brief. No information is given regarding the breadth and depth of the review, and whether hearing transcripts were read in full. This point is crucial because of C.558, L.1994. Before, it was common for the hearing committees to decline to give time to considering the appropriateness of the non-conventional treatment because the assumption was that by being non-conventional, the treatment, and all that led to it, was inappropriate. The change of law in 1994 eliminated that assumption and the exclusion of evidence and expert testimony² that resulted from it. The relevance of non-conventional cases prior to the change of law in 1994 to the mission charged to this panel is directly impacted by that change, which can only be evaluated by reviewing the full transcripts of the hearings and re-assessing the evidence based a upon the new standard of inclusion. There is no indication in this report that such a reassessment took place. Instead, given the brevity of the presentation, it appears that the review of those cases included only hearing committee or administrative review reports both of which, of course, include only that which substantiates their findings.

¹ §6 of C.735, L.1992 originally constituted this panel to assess the goals, objectives, and performance of the physician discipline process and whether its outcomes are in the public interest.

² It is this point, the exclusion of evidence, which led to the Regent's last reversal, to which a footnote in the report did allude, but did not explain, and which the report ignored in determining there had been no unfairness.

The report's first conclusion, that there should be no requirement for the use of experts from the field of non-conventional medicine to investigate complaints against non-conventional physicians, fails to consider that the deviations from standard medical practice may be medically appropriate to the non-conventional treatment and the patients using it, and hence, that an expert practicing similarly must be a part of any investigation where such clinical decision making is at issue. The discussion here also fails to even mention the merits of such linkage where quality of conventional care is at issue.

The report has three reasons for then concluding that there is no need to mandate a non-conventional physician for hearing committees judging non-conventional physicians:

First, that any physician can determine misconduct against "universally accepted standards," and that panelists may be educated to more specific concerns by expert witnesses. The reliance on expert witnesses to educate the panel would be appropriate were the case heard by a jury panel of lay persons, or an administrative law judge alone. But the system in New York is review by peers for the purpose of having access to certain knowledge and experience in the assessment of proper medical conduct. Case law has settled that the expected level of assessment is accomplished by physicians possessing the "requisite knowledge and expertise," Enu v. Sobol 171 A.D.2d 378.

Second, that such a rule would "embroil" OPMC in litigation challenging the credentials of panelists. Perhaps — but, we can imagine wording for such a rule that would give format for that challenge within the procedure and preempt costly judicial review.

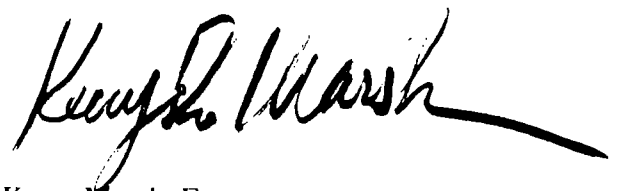
Their *third* reason is two-fold. Appropriate peer-review is simply unnecessary because it has never been required before, and that there is already enough difficulty in constituting panels for review without adding further requirements. Citing the difficulty in constituting panels of working professionals may be a fair assessment of current operating conditions. But, to give this situation greater weight than the advantages afforded by appropriate peer-review — which the report does recognize as the legislature's policy — without the analysis which the legislature requested of the panel, is prejudicial.

In conclusion, we can only attribute the wayward execution of this report to the desire of the panel to meet some purpose other than that which was placed before them by the legislature. This report avoids the real analysis and discussion of the pros and cons of specialty or modality specific peer-review which was called for by the legislature. This has the effect of diminishing the overall value of peer review, and it falls short of the effort anticipated by the statute.

Sincerely,



Monica Miller
June 26, 1995



Kerry Marsh, Esq.
Marsh and Associates, P.C.

NEW YORK STATE
LAWS OF 1994 CHAPTER 558

Senate bill 3636-c/ Assembly bill 5411-c
Amendments to law are underlined

1 Section 1. Subdivision 4 of Section 6527 of article 131 (The Practice of
2 Medicine) of Title Eight (The Professions) of the education law is amended to
3 read as follows:

4 4. This article [Article 131.] shall not be construed to affect or prevent the
5 following:

- 6 a. The furnishing of medical assistance in an emergency.
7 b. The practice of the religious tenants of any church.
8 c. A physician from refusing to perform an act constituting the practice of
9 medicine to which he or she is conscientiously opposed by reason of religious
10 training or belief.
11 d. The organization of a medical corporation under article forty-four of the
12 public health law or the organization of a professional service corporation
13 under article fifteen of the business corporation law.
14 e. The physician's use of whatever medical care, conventional or non-
15 conventional, which effectively treats human disease, pain, injury, deformity,
16 or physical condition.

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19 Section 2. Subdivision 1 of section 230 (Professional Medical Conduct) of the
20 public health law as amended by chapter 606 of the laws of 1991, is amended
21 to read as follows:

22 1. A state board for professional medical conduct is hereby created in the
23 department in matters of professional misconduct as defined in sections sixty
24 five thirty and sixty five thirty one of the education law. Its physician
25 members shall be appointed by the commissioner at least eighty five percent
26 of whom shall be from among nominations submitted by the medical society
27 of the state of New York, the New York state osteopathic society, the New
28 York academy of medicine, county medical societies recognized by the council
29 of medical specialty societies, and the hospital association of New York state.
30 Its lay members shall be appointed by the commissioner with the approval of
31 the governor. The Board of Regents may also appoint twenty percent of the
32 members of the board. Not less than eighty five percent of the physician
33 members appointed by the Board of Regents shall be from among
34 nominations submitted by the medical society of the state of New York, the
35 New York state osteopathic society, the New York academy of medicine,
36 county medical societies recognized by the council of medical specialty
37 societies, and the hospital association of New York state. Any failure to meet
38 the percentage thresholds stated in this subdivision shall not be grounds for
39 invalidating any action by or on authority of the board for professional
40 medical conduct or a committee or a member thereof. The board for

1 professional medical conduct shall consist of not fewer than eighteen
2 physicians licensed in the state for at least five years, two of whom shall be
3 doctors of osteopathy, not fewer than 2 of whom shall be physicians who
4 dedicate a significant portion of their practice to the use of non-conventional
5 medical treatments who may be nominated by New York state medical
6 associations dedicated to the advancement of such medical treatments, and
7 not fewer than seven lay members. An executive secretary shall be
8 appointed by the chairperson and shall be a licensed physician. Such
9 executive secretary shall not be a member of the board, shall hold office at
10 the pleasure of, and shall have powers and duties assigned and the annual
11 salary fixed by, the chairperson. The chairperson shall also assign such
12 secretaries or other persons to the board as necessary.

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15 Section 3. Paragraph (a) of subdivision 10 of section 230 of the public health
16 law as amended by chapter 606 of the laws of 1991, is amended to read as
17 follows:

18 (a) Investigation. (i) The board for professional medical conduct, by the
19 director of the office of professional medical conduct, may investigate on its
20 own any suspected professional misconduct, and shall investigate each
21 complaint received regardless of the source.

22 (ii) If the investigation of cases referred to an investigation committee
23 involves issues of clinical practice, medical experts shall be consulted.
24 Experts may be made available by the state medical society of the state of
25 New York, county medical societies and specialty societies, and by New York
26 state medical associations dedicated to the advancement of non-conventional
27 medical treatments.

28 Any information obtained by medical experts in consultations, including
29 the names of licensees or patients, shall be confidential and shall not be
30 disclosed except as otherwise authorized or required by law.

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33 Section 4. Amends chapter 735 of the laws of 1992 to read as follows:

34 The panel shall also report to the governor and the legislature by June 1,
35 1995 concerning (i) the use of experts, including experts in medical
36 specialties or experts in non-conventional medicine by the office of
37 professional medical conduct in the investigation of complaints which involve
38 issues of clinical practice and, (ii) the appointment of physicians, including
39 physicians in a medical specialty and physicians practicing non-conventional
40 medicine, to committees on professional medical conduct hearing a case in
41 which a physician in such specialty or a physicians practicing non-
42 conventional medicine is the respondent.

NEW YORK
STATE
SENATE
ALBANY, NEW YORK 12247



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558
July 20, 1994

Elizabeth D. Moore
Counsel to the Governor
Executive Chamber
State Capital
Albany, NY 12224

RE: Legislative Sponsor's Memorandum in Support of S. 3636C

Dear Ms. Moore:

It is my understanding that the above referenced legislation has passed both houses of the Legislature and will shortly come before the Governor for Executive action. I would like to lend the following comments in support of the legislation.

The bill is a result of negotiations with the State Department of Health, the State Office of Professional Medical Conduct and the Higher Education Committees of the New York Senate and Assembly.

This legislation recognizes the role of licensed physicians in the practice of legitimate non-conventional medical treatments. It does so by stating in Article 131 of the Education Law, which deals with the practice of medicine, that nothing in that section of law shall be construed to affect or prevent a licensed physician from using medical care conventional or non-conventional which EFFECTIVELY treats human disease, pain, injury, deformity or physical condition.

The first part of the bill does nothing more than specifically acknowledge non conventional medicine in Education Law as to what they already should be able to do.

The language for the new paragraph in subdivision 4 of section 6527 is actually a restatement or affirmation of the language in section 6521 which defines the practice of medicine in New York State as treating for any human disease, pain, injury, deformity or physical condition.

Just last year the New England Journal of Medicine (the accepted journal of standard, conventional doctors) admitted that 1 in 3 Americans have used alternative or non-prevailing medical therapies, with visits to alternative practitioners exceeding those to primary care physicians in 1991. If we prevent or discourage physicians from non conventional treatments, it is clear that the estimated 6 million New Yorkers who seek these treatments will be undeserved and we will force them to resort to unlicensed providers rather than our highly trained and skilled doctors.

Case law already overwhelmingly extends the rights of patients to make non conforming medical decisions and extends that right to enable licensed physicians to assist in those decisions. [*Schloendorff v. New York Hospital*, 211 NY 125 (NY's highest court) and *Atkins v. Chassin* NYS 2nd (1993)]. The Federal government has recognized non conventional medical practice and in fact Senator Harkin sponsored and implemented a \$12 million study allocated to the National Institute of Health (NIH). Columbia University Medical College and Albert Einstein Medical College both have existing Departments of Alternative Medicine. Albany Medical College now offers classes in alternative medicine pursuant to requests by the medical students.

The next specific act of this legislation amends section 230 (1) of the Public Health Law to provide that at least 2 of the licensed physicians who serve on the existing State Board for Professional Medical Conduct shall be physicians who devote a significant portion of their practice to the use of non conventional treatments. Licensed physicians who are investigated

and charged with professional misconduct pursuant to Public Health Law must undergo a peer review process to determine the validity of the charges and what, if any, penalty should be imposed. The peer review hearing committee consists of 3 people from the membership of the State Board for Professional Medical Conduct. The process is supposed to ensure that a doctor charged with misconduct receives fair consideration by those best qualified to judge his practice and treatments. Since there are currently no non conventional doctors who are members of the Board, no legitimate peer review currently exists. Therefore, this bill would add 2 peers to the Board.

The Assembly sponsor and I agreed to 2 members since it was suggested as a fair representation by the Counsel for the NYS Department of Health. Actually, by my calculations since there are 230 members currently on the Board (18 is the statutory minimum) and there are approximately 71,000 doctors in NY, then a weighted representation would be that each Board member should represent 323 doctors. Since about 1,000 of those 71,000 doctors currently provide non conventional therapies, there should be 3 members on the Board.

Again, this section simply addresses that the potential for abuse exists in a peer review system that does not have any peers. According to the community of non conventional doctors they are judged prejudicially by conventional doctors who discount their treatments and often impose upon them penalties more severe than those assessed against conventional doctors found guilty of equivalent charges. This bill does not provide representation to one type of specialist. Alternative Medicine is not a specialty but rather treatments that differ from the prevailing. In fact, there are various specialties of Alternative Medicine but this bill does not address those specialties just as existing law regarding the Board does not address conventional specialties.

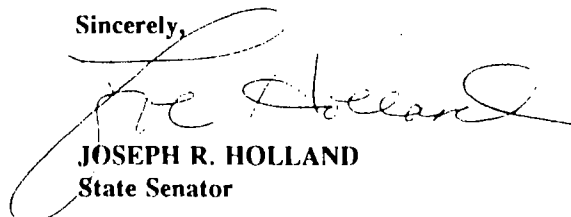
The bill also allows the investigation committee to consult experts that can be made available from non conventional medical associations.

The last subject that the bill deals with is simply a directive to a current study panel to study issues of non conventional and specialty physicians as related to the Office of Professional Medical Conduct (OPMC).

Accordingly, this legislation is designed to safeguard patient's rights and guarantee legitimate due process for non-conventional physicians by removing institutional disincentives to the use of sound non-conventional physicians on the board for professional medical conduct, a degree of equity will be restored to the process. No rights or privileges would be granted to non-conventional physicians through this legislation that are not also granted or do not already exist for conventional medical doctors. Most importantly, quality of care will be enhanced through the constructive participation of non-conventional physicians in the disciplinary process. Providing for nominations and other contributions from organization of New York physicians supporting these therapies will encourage the development of responsible community standards. Ultimately, by protecting the rights of non-conventional physicians throughout the misconduct process, this legislation secures the rights and freedom of patients to choose their medical treatments.

Thank you for your time and consideration.

Sincerely,



JOSEPH R. HOLLAND
State Senator

JRH: sbk