Washington State Law
- Mandated Reimbursement
- Licensing, Certification &

ANNOTATED AGENDA* & LIST OF SPEAKERS

OCTOBER 30, 2000

8:30 a .m. – 9:00 a.m. Pre-registrant Check-in and On-site Registration

9:00 a.m. (15 min) Welcome and Introductions — Wayne Jones - Alaska; Sheila Quinn

GROFT TALKING POINTS:

- ACKNOWLEDGE THE ENTHUSIASM OF SEATTLE COMMUNITY IN HELPING US TO SET UP AND ORGANIZE THIS EVENT, IN PARTICULAR MEMBERS OF THE KING COUNTY 2010 PLANNING COMMITTEE AND COUNCIL.
  - Background
- ANNOUNCE NEW COMMISSIONERS: ↑ 15 → 20
  - TIERARONA LOW DOG, APPOINTED JULY 14 AND PRESENT AT THESE PROCEEDINGS, AS WELL AS THREE OTHERS:
  - VERONICA GUITIERREZ FROM ARLINGTON, WA
  - LINNEA LARSON
  - XIAO MING TIAN
  - OTHERS NOT PRESENT AT THESE PROCEEDINGS:
  - DONALD WARREN
  - DAVID BRESLER
  - Background Information — Task Force recommendation
- INVITE VISITS TO OUR NEW WEBSITE: WHCCAMP.HHS.GOV, INCLUDING RECENTLY REVISED SCHEDULE OF MEETINGS (ALSO INCLUDED IN PARTICIPANT FOLDERS)

- INVITE ON-SITE REGISTRANTS FOR LIMITED NUMBER OF SLOTS TO PROVIDE 3-MINUTE ORAL STATEMENTS AT THE END OF

* Scheduled times listed here are estimated. Speakers are asked to be present in the Hall at least 20 minutes before their panel is called.

TOMORROW'S PROGRAM (STARTING APPROX. 1:15 P.M.) THE RESPONSE TO OUR CALL FOR SPEAKERS WAS SO GREAT THAT WE HAVE A VERY LIMITED NUMBER OF OPEN SLOTS LEFT; IT WILL BE FIRST-COME, FIRST SERVED, BUT PLEASE DROP OFF YOUR WRITTEN COMMENTS, OR SEND THEM TO US THROUGH OUR WEBSITE.

- INTRODUCE DR. JAMES GORDON, CHAIR AND MODERATOR FOR THESE PROCEEDINGS.

GORDON TALKING POINTS

- ACKNOWLEDGE DIVERSITY OF ISSUES BEING REPRESENTED TODAY AND TOMORROW. WISH WE COULD STAY EVEN LONGER TO HEAR FROM EVERYONE. AS IT IS:

- WE WILL MOVE BRISKLY THROUGH THE AGENDA AND REQUEST THAT ALL SPEAKERS ADHERE TO THE 3-MINUTE RULE. MICHELE WILL PROVIDE A 1-MINUTE WARNING TO ALLOW YOU TO SUM UP YOUR STATEMENT.

- COMMISSIONERS WILL BE PROVIDED 8 MINUTES TO ASK QUESTIONS BEFORE WE MOVE ON TO THE NEXT PANEL.

- WISH TO INTRODUCE MY FELLOW COMMISSIONERS HERE TODAY AND ASK THEM IF THEY WOULD LIKE TO SAY SOMETHING BRIEFLY:

- Tom Chappell, Effie Chow, Joe Fins, Tieraona Low Dog, Linnea Larson, Veronica Gutierrez, Xiaoming Tian

* Scheduled times listed here are estimated. Speakers are asked to be present in the Hall at least 20 minutes before their panel is called.

1

2

3

4. Outcomes Research

5. Level Playing [illegible]

(6) Strengthen Accountability for Public Safety

(7) [illegible] for New Providers of [illegible]

(8) Credentialing

(9) Deeply Engage CAM Professions

(10) Practice / Training Envt ~~together~~

(11) Include Special Niche Population

– [illegible]

underserved, Poor Uninsured, [illegible]

(12) Reimbursement System needs careful Reconsidered

Prevention – Services Needs

(13) Critical need for Quality Safe to Public

(14) critical need for Quality of Natural Products

Safe, Reliable & effectiveness

2% of [illegible] → Public He

Value of Validation

Shared vision of [illegible]

Book / [illegible] tipping pt

NCCAM HEADLINE NEWS

Bi-weekly on-line news briefs for NCCAM staff

Volume 1:21, October 31, 2000
Editor: Anita Greene
Assistant Editor: Mentwab Wuhib

Highlights

- Christopher Baron Up-Close and Personal with the President, page 2
- Final *Washington Fax* story highlights Dr. Straus's 1st Year Achievements, page 2
- Latest on NIH Health Benefits Open Season, page 4
- More on NCCAM's Extramural Activities, page 5

Director's News

Speaking engagements have kept me on the road and quite busy spreading the NCCAM word. Within the last two weeks I delivered: the keynote speech at the Sisterhood of Washington Hebrew Congregation Symposium: "Alternatives to Complement Your Health Everyday," on October 17; the Mary E. Switzer Lecture to the Association of Schools of Allied Health Professions at their annual meeting in Las Vegas, on October 26; and the Hennepin County Medical Center Department of Medicine Alvin L. Schultz Visiting Professor Lecture on Tuesday, October 31.

In addition, I have begun a number of fruitful dialogues:
U.S. Pharmacopoeia - Linda Engel, Richard Nahin, Paul Coates (from the Office of Dietary Supplements) and I met with several representatives of the U. S. Pharmacopoeia (USP) on October 18. The USP is a non-profit, independent organization that establishes and disseminates officially recognized standards of quality and authoritative information for the use of medicines and health care technologies by health professionals, patients, and consumers. They are interested now in extending their experience and expertise in the drug area by developing a Quality Demonstration Program for Dietary Supplements. We look forward to receiving their proposal for future promising collaborations.

Health Research Services Administration - On the same day, Linda Engel, Neal West, and I met with Dr. Sam Shekar, Associate Administrator for Health Professions, Health Research Services Administration (HRSA), and his colleagues. The Bureau of Health Professions (BHPr), which Dr. Shekar directs, addresses problems of US communities that do not have enough healthcare providers to meet basic dental and general health needs. Of particular interest to NCCAM is the Bureau's program to train healthcare professionals and develop curricula for the schools in which they are educated. Here too, we look forward to exploring significant opportunities to collaborate and also work in a complementary fashion.

Robert Wood Johnson Foundation - On October 27, Linda Engel represented me at a meeting organized by the Robert Wood Johnson Foundation (RWJF), an organization that spends $500 million per year on issues related to healthcare and health. Dr. Michael McGinnis, Director of their Health Group, described their program and explored potential collaborative opportunities. Given RWJF's interest in insurance coverage and tracking system change (areas of focus in the healthcare arena), and with population health science and policy (an area of focus in the health program), there may indeed be interesting possibilities for collaboration with this organization.

Quote: "Daring ideas are like chessmen moved forward; they may be beaten, but they may start a winning game."

Goethe

Announcements...

Christopher Baron and President Bill Clinton

Who wants to meet the President? Chris Baron recently did....

Christopher Baron, NCCAM's Human Resources (HR) Specialist formerly served as HR specialist at the White House from 1993-1999. Here he is in a recent picture taken with our nation's foremost leader.

Science Policy, Communications and Public Liaison News

MEDIA NEWS

NBC News Interview - Bob Bazell, medical correspondent with NBC news interviewed Dr. Straus on October 25 on the topic of PC-SPES, a combination of popular Chinese herbal medications to treat prostate cancer. NCCAM's recently funded cancer center at the Johns Hopkins University will be conducting studies on this therapy. Favorable results of two studies on PC-SPES recently concluded will be published in the *Journal of Urology* and the *Journal of Clinical Oncology* shortly. The interview will air in the upcoming weeks.

Washington Fax – Here is the final *Washington Fax* story entitled "NCCAM's Straus Looks Back Over His First Year As Director of Alternative Medicine Research." The story chronicles Dr. Straus's first year achievements as NCCAM Director:

FW: Washington Fax: NCCAM's St...

Public Relations Society of America (PRSA) World Congress - Anita Greene, NCCAM's Press Communications Program Officer and a member of PRSA recently attended its annual international conference held October 22-25 in Chicago, Illinois. PRSA is the premier international professional association of public relations executives offering nationally recognized accreditation in the public relations field. Approximately 3,000 attendees were present, including representatives from foreign countries such as China, Africa, Germany, Italy, and Canada. The conference offers a series of general and plenary sessions on challenging and relevant topics of interest to public affairs professionals, and an opportunity to network with colleagues.

CAM NEWS

Little Convincing Evidence for Herbal Medicines to Treat Asthma - *BMJ Press Release*
Despite their widespread use among asthmatics, there is little scientific evidence that herbal medicines reduce asthma symptoms, according to a recent survey by the National Asthma Campaign:

FW: Little convincing evidence...

VHA Inc. Introduces Integrative Medicine Program; Partnership with Kaiser - *PR Newswire*
VHA Incorporated has signed an agreement with the Kaiser Institute to offer its health care organizations assistance in integrating alternative and complementary medicine programs into traditional care delivery systems:

Integrative Medicine Program w...

St John's Wort Linked to Kidney Rejection- *Reuters*
Two transplant recipients experienced acute rejection of their organs due to taking the herbal remedy St. John's wort, researchers announced at a recent American Society of Nephrology meeting:

FW: St. John's Wort Linked to ...

Study finds Fiber Supplements Increase Risk of Colon Polyps Returning - *ACS NewsToday*
A new study adds to growing evidence that fiber may not protect against colon cancer. But researchers who conducted the study and an American Cancer Society (ACS) expert say fruits and vegetables should continue to be an important part of a healthy diet.
<http://www.discoveryhealth.com/enews?c=300632>

Alternative Treatments Popular for Chronic GI Diseases - *UPI Science News*
As many as 75 percent of persons infected with hepatitis C, a chronic and sometimes fatal viral disease, are taking the herbal remedy milk thistle, according to a liver disease expert from the NIH:

FW: Alternative treatments pop...

Music Can Encourage Alzheimer's Patients to Eat- *Health Central*
Elderly people with dementia often forget to eat, leaving them with inadequate energy and nutrients to combat disease. But recent study findings suggest that music can motivate patients to eat more: <http://www.healthcentral.com/news/newsfulltext.cfm?ID=42979&src=n16>

FDA Asked to Adopt Ephedra Makers' Standards- *Health Central*
Groups representing makers of dietary supplements containing the herb Ephedra recently asked the FDA to adopt as nationwide standards guidelines already used by many manufacturers: <http://www.healthcentral.com/news/newsfulltext.cfm?ID=43466&src=n1>

Melatonin Sparks Sexual Desire- *Health Central*
While most people have heard that melatonin makes you drowsy, you may be surprised by a report that suggests the hormone can perk up a male's sex life--at least for rats, according to researchers in Italy: <http://www.healthcentral.com/news/newsfulltext.cfm?ID=42928&src=n29>

Vitamin E May Reduce Stroke Risk in Hypertensive Men - *Health Central*
For men with high blood pressure (hypertension), taking vitamin E supplements may decrease their risk of crippling or fatal stroke, according to researchers: <http://www.healthcentral.com/news/newsfulltext.cfm?ID=42998&src=n29>

Extramural Research & Grant Review News

Christine Goertz at NIH Workshop in Tennessee - Christine Goertz represented the NCCAM at an NIH workshop held at East Tennessee State University (ETSU) in Johnson City on October 18 and 19. Her involvement included a discussion on CAM funding opportunities to ETSU staff and faculty during an afternoon break-out session.

NCCAM Acupuncture Research - Christine Goertz gave a presentation entitled "Funding Acupuncture Research: The NCCAM Perspective," at the Society for Acupuncture Research Conference held on the University of Maryland campus in Baltimore on October 21.

Chronic Fatigue Syndrome Conference - Christine Goertz attended the Chronic Fatigue Syndrome State of the Science Conference held in Arlington, Virginia on October 23 and 24. Contact Christine at extension 2-1030 for conference materials.

Morgan Jackson Shares the Health at NIH Expo - Morgan Jackson participated in Share the Health, an Exposition of Health Resources from NIH to its Neighbors, held at the Natcher Conference Center on October 21. His talk, "The Mission and Focus of the National Center for Complementary and Alternative Medicine," drew an audience of approximately 75 attendees.

Administrative: Office Operations/Human Resources & Budget News

Health Benefits Open Season Period

The Health Benefits open season will be held from November 13 to December 11, during which time employees and retirees can change plans and options, or remain in the same plan. Participants may choose from the seven government-wide fee-for-service plans. A total of 245 total plans participate in the program, many of which are HMO's that cover a specific geographic area. In addition, 35 HMO's are leaving the Federal Employees Health Benefits Programs, which means 54,000 people will be required to choose a new plan for 2001. OPM will be providing that information to agencies and retirees before the open season begins. For more information, visit http://www.niehs.nih.gov/omhrmb/benefits/openseason.htm

Other Health News to Note...

Unlicensed HIV Test Sold on Web - *Health Central*
Hundreds of online shoppers may have unwittingly exchanged privacy for accuracy when they brought an unlicensed HIV home test, say authorities who are trying to find the buyers to warn them about the kit: <http://www.healthcentral.com/news/newsfulltext.cfm?ID=43412&src=n1>

Experts Examine How Women and Men Respond to Medical Care - *Health Central*
The role that gender plays in the way people experience and respond to different treatments for pain, addiction and sexually transmitted diseases was the topic of a two-day conference in New York recently, with researchers and health policy experts examining emerging trends in gender-based research:
<http://www.healthcentral.com/news/newsfulltext.cfm?ID=43444&src=n1>

Pet Dog May Help Control Blood Pressure During Stress - *Health Central*
For people with hypertension, controlling high blood pressure and heart rate may only be a bark away, new research suggests. According to scientists, dog owners caring for brain-injured spouses experienced significantly lower stress responses than their non-dog-owing peers did:
<http://www.healthcentral.com/news/newsfulltext.cfm?ID=43127&src=n1>

Most Sick Days Not for Sick, Says U.S. Study- *Health Central*
Calling in sick has more to do with being well in six out of every ten cases, according to a study released recently. Commerce Clearinghouse, a leading publisher of business information, said a poll of 150 human resources managers in 41 states and the District of Columbia found that personal illness accounts for about 40 percent of unscheduled absences:
<http://www.healthcentral.com/news/newsfulltext.cfm?ID=43123&src=n1>

Viagra Helps Some Men After Prostate Surgery- *Health Central*
Men who have undergone prostate removal surgery and have not recovered their ability to have an erection may benefit from Viagra, researchers report. However, the drug does not appear to help until about nine months after surgery:
<http://www.healthcentral.com/news/newsfulltext.cfm?ID=43135&src=n1>

Pill Gives Insulin Alternative to Pregnant, Diabetic Woman- *Discovery Health*
A pill already on the market can safely substitute for insulin injections in women who develop diabetes during pregnancy a study found:
<http://www.discoveryhealth.com/enews?c=300779>

Discovery May Improve Prediction of Breast Cancer Recurrence- *Discovery Health*
Italian scientists have made a discovery that could help more women survive breast cancer by making it easier to identify who is most likely to suffer a relapse:
<http://www.discoveryhealth.com/enews?c=300507>

Government Hikes Medicare Premiums for 2001- *Health Central*
Medicare beneficiaries will be shelling out sharply more for covered physician and other outpatient services in 2001 due to legislative changes, the government announced recently:
<http://www.healthcentral.com/news/newsfulltext.cfm?ID=42975&src=n1>

Study Finds Cause of Heart Disease - *Health Central*
Researchers have pinpointed an enzyme in the blood that could one day join high cholesterol as another strong predictor of heart disease. Several lifestyle factors, such as smoking and obesity, point to a heightened risk of heart disease:
<http://www.healthcentral.com/news/newsfulltext.cfm?ID=43031&src=n1>

Moderate Caffeine Intake May Reduce Parkinson's Risk- *Health Central*
New evidence supports the idea that people who consume one to three cups of coffee or other caffeine containing beverages daily have a decreased risk of developing Parkinson's disease, according to researchers from the Harvard School of Public Health:
<http://www.healthcentral.com/news/newsfulltext.cfm?ID=42978&src=n1>

Calendar of Meetings & Events

November 13 — **National Advisory Council for Complementary and Alternative Medicine (NACCAM)**
This one-day advisory council meeting will take place at the Neuroscience Conference Center, 6001 Executive Boulevard, Conference Rooms C and D, Rockville, Maryland. Any changes regarding the time or location will be announced on the NCCAM Information Line at 301-594-9632.

November 19-21 — **The Science of the Placebo: Toward an Interdisciplinary Research Agenda**
This conference is co-organized by the National Center for Complementary and Alternative Medicine and the National Institute of Diabetes and Digestive and Kidney Diseases at the Natcher Conference Center, NIH. Registration is due by October 20 and may take place through the conference Web site at http://placebo.nih.gov or through completed registration and payment forms. For program inquiries, contact conference

organizers John Kusek at 301-594-7735, kusekj@extra.niddk.nih.gov or Linda Engel at 301-496-1944, engell@od.nih.gov

December 3-6 **First HIV Drug Resistance Program Symposium: Understanding Antiviral Drug Resistance**
National Cancer Institute is hosting this conference, which will be held at the Westfields International Conference Center, Chantilly, Virginia. For registration, visit http://web.ncifcrf.gov/campus/symposium. For information, contact Margaret Fanning at 301-846-1995 or faaningm@ncifcrf.gov

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All health related articles included in *NCCAM Headline News* are for information purposes only Information contained in these articles is not intended as an endorsement or promotion of thes health practices by NCCAM.

NCCAM Headline News is a product of the Office of Science Policy, Communications, and Public Liaison (OSPCPL). We hope that the news covered in this issue is of interest to NCCAM staff. Future publication is dependent upon the continuous support of NCCAM staff by way of submitting news and interesting topics on an on-going basis. Archived issues can be accessed on the NCCAM Intranet: http://nccam.nih.gov/nccam-intranet/news-event

NCCAM Headline News is intended for **in-house use only.** Please do not distribute this publication to persons or groups that are not NCCAM staff. Failure to adhere to this restriction may force us to terminate this service. Your cooperation is appreciated.

Not sure this is relevant - just threw it in

Pollen, Gerry

From: Simon, Helen
To: Pollen, Gerry
Cc: Simon, Helen
Subject: Work Projects
Date: Tuesday, November 12, 1996 4:55PM

Between your AWS day and my retreat on GPRA, we have missed each other this week. I wanted to alert you to a change in your areas of responsibility and we can talk about them on Thursday. As you know, there have been some reorganizations within the NIAMS and there have been studies of resource allocations within the Institute. All of the Branches of extramural identified the need for a Program Analyst-type position, but it needs to be someone who really understands the programs. Examples include clinical protocol development and management, issues of multi-center activity coordination, coordinate responses for NIH-wide mechanisms, provide program/science based program evaluation reports, coordinate submissions of EP-wide reports .....It is also highly desirable that this person be based in the NIAMS Planning Office so they stay grounded in the overall Institute activities. In your position as Research Activities Coordinator, it is clear that you are the perfect person to assume these duties. You can develop narratives and bring your expertise and knowledge to all of the various projects, as well as issues that are of concern to our extramural staff. I congratulate you on this vote of confidence and will be happy to discuss these additional areas of responsibility with you.

Thanks --

Also developed and directed NIAMS Conference Logistics Team and wrote overall guidance - required project officer activities as well.

Kingsbury, Doris (NCCAM)

From: Chang, Michele (NCCAM)
Sent: Wednesday, October 18, 2000 4:51 PM
To: Kingsbury, Doris (NCCAM)
Subject: FW: email address's

-----Original Message-----
From: Devine, Danielle [mailto:Danielle.Devine@METROKC.GOV]
Sent: Wednesday, October 18, 2000 2:22 PM
To: Chang, Michele (NCCAM)
Cc: Zimmerman, Karlene; Snider, Pamela
Subject: email address's

Michele,

Hi. Here are some email address's that should get the announcement, letter and press release.

president@bastyr.edu
jcolchin@bastyr.edu
csummers@bastyr.edu
showk@nwrpca.org (this will then fan out to their database of community regional healthcare)
kmatsuda@krsa.gov (this will fan out to the following databases: Indian Nation, Pacific Islander and Office of Minority Health)

Can you cc me on everything you send so I can keep track of what is going where. I am going to follow up your email announcements with phone calls so knowing when they go out will be really helpful with time management.

Thanks so much.

Danielle

Chang, Michele (NCCAM)

From: Devine, Danielle [Danielle.Devine@METROKC.GOV]
Sent: Wednesday, October 18, 2000 3:24 PM
To: Chang, Michele (NCCAM)
Cc: Snider, Pamela; Zimmerman, Karlene
Subject: More Database info

Michele,

Here is further clarification on the databases that will receive your information. When you send your information to Karen Matsuda she will then send out to the following:

Minority Health
Office of Women's Health
Office on Family Planning
Asian and Pacific Islanders
Distance Learning

We are going to send out to the Health Professional Loan Repayment & Scholarship Program. In addition, we have a call into Washington Rural Health Association and will loop them in as well and have them send to their members. I will get you their email address as soon as we have it.

In an earlier email I gave you there address's at Bastyr that should receive your announcement. Once they get it they will then disseminate to the following:

Bastyr Staff, Faculty, Students, Alumni, Donors and Patients.

Danielle

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

October 13, 2000

TO: Dr. Stephen Croft

FROM: Dr. Jeffrey White

SUBJECT: White House Commission

Enclosed is a copy of my testimony to the White House Commission. If you need an electronic version of it please contact Dorthea Coates at 301-435-7980 or via e-mail at coatesdo@mail.nih.gov.

Sincerely,

Jeffrey D. White, MD

Jeffrey D. White, M.D.
Director, Office of Cancer Complementary and Alternative Medicine
National Cancer Institute
6130 Executive Boulevard
Executive Plaza North, Suite 102
National Institutes of Health
Bethesda, Maryland 20892
301-435-7890 (Office)
301-480-0075 (Fax)

White House Commission on Complementary and Alternative Medicine Policy
Research Part I
October 5,6 2000

Good morning and thank you for the opportunity to discuss the NCI's perspective on the challenges and potentials of complementary and alternative medicine (CAM) cancer research. I also extend greetings from the NCI Director, Dr. Klausner, and the Deputy Director of Extramural Science, Dr. Robert Wittes.

I am the director of the NCI's Office of Cancer Complementary and Alternative Medicine. This office was established in October 1998 and has four main functions: To coordinate the NCI's growing number of CAM activities, to provide liaison to the National Center for Complementary and Alternative Medicine (NCCAM), to develop and implement an institute agenda in CAM and to provide the NCI an interface with the general public and CAM and conventional practitioners and researchers on these issues.

As requested, I have provided a brief summary of NCI's current and planned CAM projects. Given the limited time, I will not be able to elaborate on them during my presentation but would be glad to respond to questions.

Prior to addressing the specific questions posed in the invitation letter I would like to state up front some principles we apply in developing NCI CAM initiatives and then briefly mentioned some of the challenges of CAM research.

The determination of value for both conventional and CAM modalities needs to be evidence-based. The same standards of evidence must be applied to both CAM and conventional cancer research. Also, the principles for determining priorities should be the same as in conventional research (that is credible evidence, testable hypothesis, quality of the science, availability of necessary resources and potential to advance the field). However, since CAM is already in the practice arena, those methods that are more heavily used by U.S. cancer patients may have a somewhat higher priority.

The Challenge of CAM Research

CAM practice is a loose association of modalities, many of which have few features in common. Consequently, thinking of CAM as a single entity is at times useful and in other situations may lead to dysfunctional solutions. For example, the same mechanism to support research for a well-standardized herbal product may not be suitable for increasing research for a diet therapy used by a single practitioner.

CAM regimens are often very complex and individualized. Consequently, these approaches are difficult to codify into a protocol and transplant to a clinical research setting. Many CAM approaches lack uniformly accepted standards of practice. Therefore, a study of one approach may not resolve the issue of efficacy.

It is difficult to obtain meaningful pre-clinical information for certain CAM interventions (e.g. complex multi-modal interventions). Strategies to increase CAM cancer research will need to address many of these challenges.

Some Challenges Common to CAM and Conventional Cancer Research
Conventional cancer research is beginning to evaluate more therapies that are not directly cytotoxic but rather have a potential for slowing the growth of the malignancy or inhibiting its spread to other sites. Traditional clinical trial designs that focus on tumor regression may be less informative about the potential efficacy of such therapies and controlled studies assessing survival and quality of life may be more appropriate.

These trials are more expensive and time consuming and often require complex logistics. At the same time, the percentage of adult cancer patients entering clinical trials is low (i.e. less than 5%).

Secondly, the dependence on survival as the most significant endpoint of comparative cancer trials lengthens the evaluation process. Validated intermediate endpoints of clinical significance are needed to allow more rapid screening of modalities for potential efficacy.

I mention these common challenges as areas of potential investment to increase the rate of evaluation of CAM therapies.

I will spend the remaining time addressing the areas of particular interest described in the letter of invitation. I hope my use of examples will help illustrate certain points without implying that the specific case is applicable to all other forms of CAM cancer research. I will be glad to expand on any of these points in the response to questions in the discussion period.

It is important to note that the NCI's approaches to promoting and supporting CAM cancer research are being designed to attempt to capitalize on some of the strengths of our programs (e.g. NCI-designated P30 cancer centers and cooperative clinical trials groups) and therefore some may not be applicable to other disease-types and other NIH institutes and centers.

Potential Contribution of CAM Perspectives and Approaches to Conventional Biomedical Research.
[Q. What can CAM perspectives and approaches contribute to investigators where there is overlap with conventional biomedical research (e.g. wellness/health promotions and disease prevention, pain management, self-care, treatment, care for the terminally ill)?]

Some CAM approaches purport to promote the general health of the patient rather than to directly impact the growth of cancer cells. Similarly, many systems within CAM advocate caring for the whole patient. This includes aspects of the patient's physical, psychological and spiritual health and can even extend to the patient's family and other support systems. This broadening of the focus away from a completely disease-focused approach is admirable, but it appears to be diminishing in conventional medical practice.

The potential for these approaches to improve the patient's quality and possibly, quantity of remaining life should be more fully examined in cancer research.

Other perspective and approaches worthy of being investigated may come from the CAM community. We are endeavoring to open communications on these issues with the CAM practice community via the Best Case Series Program which is discussed in materials I have submitted for the Commission's review.

Overlap between CAM and Conventional Research

[Q. Where are the overlapping areas of investigation between CAM research and conventional biomedical research (e.g. wellness/health promotion and disease prevention, pain management, self-care, treatment, and care for the terminally-ill)?]
[Q. What additional areas of opportunity exist for research on CAM interventions?]

Much of CAM cancer research is closely related to conventional cancer research. Consequently, every effort should be made to grow CAM research in ways that access the resources of the larger and more research-savvy conventional community.

There are several areas of overlap between CAM research and conventional biomedical cancer research and I will briefly discuss five.

1. Nutrition

There is a growing awareness of the importance of nutrition in cancer prevention. Also the therapeutic use of diet modification in cancer patients is slowly entering the conventional research realm (for example, low-fat diet interventions in breast and prostate cancer patients to prevent recurrence or progression). Research is in progress to assess the cancer prevention potential of micronutrients such as selenium and vitamin E. Where does conventional diet research begin and end? Certain types of diet and vitamin interventions might be readily accepted as fitting a definition of CAM whereas others would engender more debate or be uniformly designated "non-CAM". Reasonable people could disagree on the dividing line between CAM and conventional nutrition research.

2. The analysis of plant and animal products for medicinal agents

What is CAM and what is conventional? Much of the work with such products could be considered CAM-related. Researchers doing conventional natural products work would be appropriate collaborators with herbal therapist to investigate the laboratory and preclinical activity of herbal extracts and in providing quality control standards for clinical grade products.

3. Mind-Body Medicine

Behavioral research is expanding at the NCI. Recently the Behavioral Research Program was established in the Division of Cancer Control and Population Sciences. Support group interventions are components of the grant portfolio of this and other NCI programs. Certain of these interventions under investigation are CAM-related.

4. Immune Modulation

Therapies to support and stimulate the body's immune system are components of both CAM and conventional therapeutics

5. Symptom and Side-Effect Management
Management of nausea and vomiting by acupuncture is the clearest example in cancer management of a CAM modality moving into conventional acceptance.

These areas, and others, represent potentials for collaboration between practitioners and researchers as well as CAM academics and conventional biomedical researchers. NCI CAM projects are designed to encourage collaboration between CAM and conventional communities. However, we must recognize that there is a two-culture problem (both between practitioners and researcher and between CAM and conventional paradigms). Therefore, we need to provide opportunities and resources to foster communication and collaboration which, hopefully, will lead to a greater degree of mutual respect.

Additional areas of opportunity may unfold overtime as good quality grant applications are submitted in response to specific solicitations for CAM research. This will also depend on what the CAM practitioner community has the interest and courage to bring forward for investigation.

Expanding Federal Efforts to Research CAM
[Q. What is needed to expand current Federal efforts to bring CAM products and practices into mainstream biomedical research; for example, mechanisms of research support, research methodologies, incentives, education and the training of investigators?]

The NCI has implemented several programs to bring CAM products and practices into mainstream biomedical research. One example is the Best Case Series program, which provides an avenue for CAM practitioners to present documentation of an effective CAM cancer therapy. We have recently implemented an aggressive advertisement program to increase awareness of this opportunity among CAM practitioners. The Best Case Series program can expand if there is sufficient interest and commitment from the CAM practitioner community.

Other programs utilizing grants, contracts and cooperative agreements are under development to provide necessary preliminary data and to implement clinical trials of CAM modalities in cancer.

Obstacles and Possible Solutions
[Q. What are the obstacles (conceptual and otherwise) and possible solutions to accomplishing the goal of integrating CAM products and practices into mainstream biomedical research?]

The research community needs to see consistent support for specific fields of biomedical investigation. We must also encourage excellent individual researchers and institutions to enter the field. However, there is both the perception and reality of a limited potential for a respected and vigorously supported career in research of a CAM topic. Time and resources are needed to demonstrate a sustained growth potential for the field and consistent opportunities for funding. Both career CAM investigators and CAM-

knowledgeable conventional investigators are needed. We must support the integration of CAM research into conventional environments.

Similarly, the perception and reality that much of CAM lacks a secure science base deters many excellent investigators from participating in CAM research. The solution is to set and maintain high scientific standards for CAM research. Dissemination of the results of good quality CAM research at professional society meetings and via published articles in peer-reviewed journals will encourage participation by researchers, provide a greater background for reviewers and hopefully will encourage practitioners to collaborate with knowledgeable, experienced CAM investigators.

Other obstacles are that there are limited numbers of willing partners with complementary resources (e.g. companies that can and will supply product for clinical trials). This is not surprising since economic incentives for supporting research on products that are already commercially available are not obvious. This is compounded by a lack of clarity about regulatory status of certain products.

We need to encourage research on how best to tackle the problem of doing comparative trials with products and practices already in the public domain and trials of vastly different approaches (e.g. diet therapy vs. standard chemotherapy or hormonal therapy). And we need to explore innovative ways to make randomized trials comparing CAM and conventional therapies acceptable to patients, conventional and CAM practitioners and the research community.

Role of the Public in Setting Priorities

[Q. What role should the public have in setting research priorities for CAM research?]

Members of the general public participate on several NCI panels including the National Cancer Advisory Board, the Board of Scientific Advisors, and the Director's Consumer Liaison Group. There is also public representation on the internal review committees of many of the NCI-designated comprehensive cancer centers as well as the cancer clinical trials cooperative groups. The Cancer Advisory Panel for Complementary and Alternative Medicine, an important body that gives advice to the director of the NCCAM regarding research priorities, has a patient advocate as a voting member.

The NCI, in conjunction with the NCCAM, is also gathering data about what CAM approaches are used by U.S. cancer patients. We are doing this, through our Surveillance, Epidemiology and End Results program.

In conclusion, the NCI welcomes this dialog on CAM cancer research. I will be available for both days of the Commission's meeting and I will be glad to take questions or comments at the appropriate time.

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October 11, 2000

Steve Groft, Pharm.D.
Executive Director
White House Commission on Complementary and Alternative Medicine Policy
6701 Rockledge Dr., Suite 1010, MS-7707
Bethesda MD 20817-7707

Dear Steve,

I enjoyed meeting with you and having lunch with you a couple of weeks ago. I have been following the events of the White House Commission and you have certainly been busy.

I look forward to seeing you at the end of the month in Seattle. This should be a good town hall meeting for the Commission. A lot of work is being done to prepare for the meeting.

Also, I will be available to address the Commission when education is the topic in January/February. We also have on our staff Dr. Joe Chu, an M.D. who is our Vice President for Academics and Research. Dr. Chu has nearly 10 years experience as the Assistant Dean for Curriculum at the University of Washington School of Medicine and some years at Indiana University as well. He may also provide useful insight into curriculum development and educational processes for CAM providers.

Steve, again, it was a pleasure to meet you and I'll see you in Seattle in a few weeks.

Sincerely,

Thomas C. Shepherd, DHA
President

eFax Cover Sheet

To : S. GROFT \
Company : WHITE HOUSE COMMISSION ON CAM\
Fax # : 1-301-480-1691
From : Tony Martinez
Date : 10/14/00
Re : RUTHERFORD CASE

Number of pages (Including cover sheet): 12

STEVE -

THIS IS THE SUPREME COURT CASE I MADE REFERENCE TO IN ONE OF MY APPEARANCES BEFORE THE COMMISSION.

THIS CASE SHOULD BE INCLUDED IN THE BRIEFING MATERIALS FOR THE COMMISSIONERS FOR FUTURE HEARINGS. IT THE JURISPRUDENTIAL BASIS UPON WHICH THE FDA HAS ULTIMATE LEGAL AUTHORITY OVER ACCESS TO CAM THERAPIES AND SETS FORTH THE MESSAGE TO THE CONGRESS THAT IT IS FOR THE CONGRESS TO CHANGE THE LAW OVER WHO HAS THE RIGHT TO ACCESS NON-FDA APPROVED THERAPIES.

BEST REGARDS-

TONY MARTINEZ

U.S. Supreme Court

UNITED STATES v. RUTHERFORD, 442 U.S. 544 (1979)

442 U.S. 544

**UNITED STATES ET AL. v. RUTHERFORD ET AL.
CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT.**

No. 78-605.

**Argued April 25, 1979.
Decided June 18, 1979.**

Terminally ill cancer patients and their spouses brought this action to enjoin the Government from interfering with the interstate shipment and sale of Laetrile, a drug not approved for distribution under the Federal Food, Drug, and Cosmetic Act (Act). Section 505 of the Act prohibits interstate distribution of any "new drug" unless the Secretary of Health, Education, and Welfare approves an application supported by substantial evidence of the drug's safety and effectiveness. Section 201 (p) (1) of the Act defines a "new drug" to include "any drug . . . not generally recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling." Finding that Laetrile, in proper dosages, was nontoxic and effective, the District Court ordered the Government to permit limited purchases of the drug by one of the named plaintiffs. While not disturbing the injunction, the Court of Appeals instructed the District Court to remand the case to the Food and Drug Administration (FDA) for determination whether Laetrile was a "new drug" under 201 (p) (1), and, if so, whether it was exempt from premarketing approval under either of the Act's two grandfather clauses. After completion of administrative hearings, the Commissioner of the FDA found that Laetrile constituted a "new drug" as defined in 201 (p) (1) and fell within neither grandfather provision. On review of the Commissioner's decision, the District Court concluded that Laetrile was entitled to an exemption from premarketing approval under the Act's 1962 grandfather clause and, alternatively, that the Commissioner had infringed constitutionally protected privacy interests by denying cancer patients access to Laetrile. The Court of

Appeals, without addressing either the statutory or constitutional rulings of the District Court, held that the Act's "safety" and "effectiveness" standards have "no reasonable application" to terminally ill cancer patients and approved intravenous injections of Laetrile for such individuals.

Held:

The Act makes no express exception for drugs used by the terminally ill and no implied exemption is necessary to attain congressional objectives or to avert an unreasonable reading of the terms "safe" and "effective" in 201 (p) (1). Pp. 551-559. [442 U.S. 544, 545]

(a) Nothing in the legislative history suggests that Congress intended protection only for persons suffering from curable diseases. Moreover, in implementing the statutory scheme, the FDA has never exempted drugs used by the terminally ill. The construction of a statute by those charged with its administration is entitled to substantial deference particularly where, as here, an agency's interpretation involves issues of considerable public controversy, and Congress has not acted to correct any misperception of its statutory objectives. Pp. 552-554.

(b) The Court of Appeals erred in concluding that the safety and effectiveness standards of 201 (p) (1) could have "no reasonable application" to terminal patients. For purposes of 201 (p) (1), the effectiveness of a drug does not necessarily denote capacity to cure; in the treatment of any illness, terminal or otherwise, a drug is effective if it fulfills, by objective indices, its sponsor's claims of prolonged life, improved physical condition, or reduced pain. Nor is the concept of safety under 201 (p) (1) without meaning for terminal patients; a drug is unsafe for the terminally ill, as for anyone else, if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit. Finally, construing 201 (p) (1) to encompass treatments for terminal diseases does not foreclose all resort to experimental cancer drugs by patients for whom conventional therapy is unavailing. That 505 (i) of the Act makes explicit provision for carefully regulated use of certain drugs not yet demonstrated to be safe and effective reinforces the conclusion that no exception for terminal patients may be judicially implied. Pp. 554-559.

582 F.2d 1234, reversed and remanded.

MARSHALL, J., delivered the opinion for a unanimous Court.

Solicitor General McCree argued the cause for the United States et al. With him on the briefs were Assistant Attorney General Shenefield, Deputy Solicitor General Barnett, Elinor Hadley Stillman, Barry Grossman, and Richard M. Cooper.

Kenneth Ray Coe argued the cause for respondents. With him on the brief were Kirkpatrick W. Dilling and Dennis M. Gronek.*

[Footnote *] Briefs of amici curiae urging reversal were filed by Francis X. Bellotti, Attorney General, and Jonathan Brant, Assistant Attorney General, [442 U.S. 544, 546] for the Commonwealth of Massachusetts et al.; and by Grace Powers Monaco for the American Cancer Society, Inc.

Briefs of amici curiae urging affirmance were filed by David H. Gill II for the Committee for Freedom of Choice in Cancer Therapy; by Stephen Tornay for the McNaughton Foundation of California; by Kirkpatrick W. Dilling and Dennis M. Gronek for the National Health Federation; and by Daniel H. Smith for the Northwest Academy of Preventive Medicine.

Briefs of amici curiae were filed by George Deukmejian, Attorney General, Robert Philibosian, Chief Assistant Attorney General, Daniel J. Kremer, Assistant Attorney General, and Harley D. Mayfield and Robert M. Foster, Deputy Attorneys General, for the State of California; by Dennis S. Avery for the American Academy of Medical Preventics; by David Laufer for the Cancer Control Society; and by David S. King for the Save the United States Movement, Improving Public Health and Physical Fitness of the United States Citizens. [442 U.S. 544, 546]

MR. JUSTICE MARSHALL delivered the opinion of the Court.

The question presented in this case is whether the Federal Food, Drug, and Cosmetic Act precludes terminally ill cancer patients from obtaining Laetrile, a drug not recognized as "safe and effective" within the meaning of 201 (p) (1) of the Act, 52 Stat. 1041, as amended, 21 U.S.C. 321 (p) (1).

I

Section 505 of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1052, as amended, 21 U.S.C. 355, prohibits interstate distribution of any "new drug" unless the Secretary of Health, Education, and Welfare approves an application supported by substantial evidence of the drug's safety and effectiveness.1 As defined in 201 (p) (1) of the Act, 21 U.S.C. 321 (p) (1), the term "new drug" includes

> "[a]ny drug . . . not generally recognized, among experts [442 U.S. 544, 547] qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling . . . ." [442 U.S. 544, 548]

Exemptions from premarketing approval procedures are available for drugs intended solely for investigative use2 and drugs qualifying under either of the Act's two grandfather provisions.3

In 1975, terminally ill cancer patients and their spouses brought this action to enjoin the Government from interfering with the interstate shipment and sale of Laetrile, a drug not approved for distribution under the Act.4 Finding that Laetrile, in proper dosages, was nontoxic and effective, the District Court ordered the Government to permit limited purchases of the drug by one of the named plaintiffs. 399 F. [442 U.S. 544, 549] Supp. 1208, 1215 (WD Okla. 1975).5 On appeal by the Government, the Court of Appeals for the Tenth Circuit did not disturb the injunction. However, it instructed the District Court to remand the case to the Food and Drug Administration for determination whether Laetrile was a "new drug" under 201 (p) (1), and, if so, whether it was exempt from premarketing approval under either of the Act's grandfather clauses. 542 F.2d 1137 (1976).

After completion of administrative hearings,6 the Commissioner issued his opinion on July 29, 1977. 42 Fed. Reg. 39768 (1977). He determined first that no uniform definition of Laetrile exists; rather, the term has been used generically for chemical compounds similar to, or consisting at least in part of, amygdalin, a glucoside present in the kernels or seeds of most fruits. Id., at 39770-39772. The Commissioner further found that Laetrile in its various forms constituted a "new drug" as defined in 201 (p) (1) of the Act because it was not generally recognized among experts as safe and effective for its prescribed use. See 42 Fed. Reg. 39775-39787 (1977). In so ruling, the Commissioner applied the statutory criteria delineated in Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 629-630 (1973), and concluded that there were no adequate well-controlled scientific studies of Laetrile's safety or effectiveness. 42 Fed. Reg. 39775-39787 (1977).7 [442 U.S. 544, 550]

Having determined that Laetrile was a new drug, the Commissioner proceeded to consider whether it

was exempt from premarketing approval under the 1938 or 1962 grandfather provisions. On the facts presented, the Commissioner found that Laetrile qualified under neither clause. See id., at 39787-39795. First, there was no showing that the drug currently known as Laetrile was identical in composition or labeling to any drug distributed before 1938. See 21 U.S.C. 321 (p) (1); n. 3, supra. Nor could the Commissioner conclude from the evidence submitted that, as of October 9, 1962, Laetrile in its present chemical composition was commercially used or sold in the United States, was generally recognized by experts as safe, and was labeled for the same recommended uses as the currently marketed drug. See 107 (c) (4), 76 Stat. 789; n. 3, supra.

On review of the Commissioner's decision, the District Court sustained his determination that Laetrile, because not generally regarded as safe or effective, constituted a new drug under 201 (p) (1). 438 F. Supp. 1287, 1293-1294 (WD Okla. 1977). The court also approved the Commissioner's denial of an exemption under the 1938 grandfather clause. However, concluding that the record did not support the Commissioner's findings as to the 1962 grandfather provision, the District Court ruled that Laetrile was entitled to an exemption from premarketing approval requirements. Id., at 1294-1298. Alternatively, the court held that, by denying cancer patients the right to use a nontoxic substance in connection with their personal health, the Commissioner had infringed constitutionally protected privacy interests. Id., at 1298-1300.

The Court of Appeals addressed neither the statutory nor the constitutional rulings of the District Court. Rather, the [442 U.S. 544, 551] Tenth Circuit held that "the `safety' and `effectiveness' terms used in the statute have no reasonable application to terminally ill cancer patients." 582 F.2d 1234, 1236 (1978). Since those patients, by definition, would "die of cancer regardless of what may be done," the court concluded that there were no realistic standards against which to measure the safety and effectiveness of a drug for that class of individuals. Id., at 1237. The Court of Appeals therefore approved the District Court's injunction permitting use of Laetrile by cancer patients certified as terminally ill. However, presumably because the Commissioner had found some evidence that Laetrile was toxic when orally administered, see 42 Fed. Reg. 39786-39787 (1977), the Court of Appeals limited relief to intravenous injections for patients under a doctor's supervision. 582 F.2d, at 1237. In addition, the court directed the FDA to promulgate regulations "as if" the drug had been found "`safe' and `effective'" for terminally ill cancer patients. Ibid.

We granted certiorari, 439 U.S. 1127 (1979), and now reverse.

II

The Federal Food, Drug, and Cosmetic Act makes no special provision for drugs used to treat terminally ill patients. By its terms, 505 of the Act requires premarketing approval for "any new drug" unless it is intended solely for investigative use or is exempt under one of the Act's grandfather provisions. See nn. 2, 3, supra. And 201 (p) (1) defines "new drug" to encompass "[a]ny drug . . . not generally recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling." See supra, at 546-547.

When construing a statute so explicit in scope, a court must act within certain well-defined constraints. If a legislative purpose is expressed in "plain and unambiguous language, . . . the . . . duty of the courts is to give it effect according to its terms." United States v. Lexington Mill & Elevator Co., 232 U.S. 399, 409 (1914). See Andrus v. Sierra Club, ante, p. 347. [442 U.S. 544, 552] Exceptions to clearly delineated statutes will be implied only where essential to prevent "absurd results" or consequences obviously at variance with the policy of the enactment as a whole. Helvering v. Hammell, 311 U.S. 504, 510-511 (1941). See TVA v. Hill, 437 U.S. 153, 187-188 (1978); United States v. Key, 397 U.S. 322, 324-325

(1970); United States v. American Trucking Assns., 310 U.S. 534, 543-544 (1940). In the instant case, we are persuaded by the legislative history and consistent administrative interpretation of the Act that no implicit exemption for drugs used by the terminally ill is necessary to attain congressional objectives or to avert an unreasonable reading of the terms "safe" and "effective" in 201 (p) (1).

A

Nothing in the history of the 1938 Food, Drug, and Cosmetic Act, which first established procedures for review of drug safety, or of the 1962 Amendments, which added the current safety and effectiveness standards in 201 (p) (1),8 suggests that Congress intended protection only for persons suffering from curable diseases. To the contrary, in deliberations preceding the 1938 Act, Congress expressed concern that individuals with fatal illnesses, such as cancer, should be shielded from fraudulent cures. See, e. g., 79 Cong. Rec. 5023 (1935) (remarks of Sen. Copeland, sponsor of the Act); 83 Cong. Rec. 7786-7787, 7789 (1938) (remarks of Reps. Phillips and Lea). Similarly, proponents of the 1962 Amendments to the Act, including Senator Kefauver, one of the bill's sponsors, [442 U.S. 544, 553] indicated an understanding that experimental drugs used to treat cancer "in its last stages" were within the ambit of the statute. See, e. g., 108 Cong. Rec. 17399 (1962) (remarks of Sen. Kefauver); id., at 17401 (comments of Sen. Eastland). That same understanding is reflected in the Committee Reports on the 1962 Amendments. Both Reports note with approval the FDA's policy of considering effectiveness when passing on the safety of drugs prescribed for "life-threatening disease."9

In implementing the statutory scheme, the FDA has never made exception for drugs used by the terminally ill. As this Court has often recognized, the construction of a statute by those charged with its administration is entitled to substantial deference. Board of Governors of FRS v. First Lincolnwood [442 U.S. 544, 554] Corp., 439 U.S. 234, 248 (1978); Bayside Enterprises, Inc. v. NLRB, 429 U.S. 298, 304 (1977); Udall v. Tallman, 380 U.S. 1, 16 (1965). Such deference is particularly appropriate where, as here, an agency's interpretation involves issues of considerable public controversy, and Congress has not acted to correct any misperception of its statutory objectives. See Red Lion Broadcasting Co. v. FCC, 395 U.S. 367, 381 (1969); Zemel v. Rusk, 381 U.S. 1, 11-12 (1965).10 Unless and until Congress does so, we are reluctant to disturb a longstanding administrative policy that comports with the plain language, history, and prophylactic purpose of the Act.

B

In the Court of Appeals' view, an implied exemption from the Act was justified because the safety and effectiveness [442 U.S. 544, 555] standards set forth in 201 (p) (1) could have "no reasonable application" to terminally ill patients. 582 F.2d, at 1236. We disagree. Under our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy. See Anderson v. Wilson, 289 U.S. 20, 27 (1933). Only when a literal construction of a statute yields results so manifestly unreasonable that they could not fairly be attributed to congressional design will an exception to statutory language be judicially implied. See TVA v. Hill, 437 U.S., at 187-188. Here, however, we have no license to depart from the plain language of the Act, for Congress could reasonably have intended to shield terminal patients from ineffectual or unsafe drugs.

A drug is effective within the meaning of 201 (p) (1) if there is general recognition among experts, founded on substantial evidence, that the drug in fact produces the results claimed for it under prescribed conditions. See Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S., at 629-634; n. 7, supra. Contrary to the Court of Appeals' apparent assumption, see 582 F.2d, at 1236, effectiveness does not necessarily denote capacity to cure. In the treatment of any illness, terminal or otherwise, a drug is

effective if it fulfills, by objective indices, its sponsor's claims of prolonged life, improved physical condition, or reduced pain. See 42 Fed. Reg. 39776-39786 (1977).

So too, the concept of safety under 201 (p) (1) is not without meaning for terminal patients. Few if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk.11 Thus, the Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use.12 For [442 U.S. 544, 556] the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit. Indeed, the Court of Appeals implicitly acknowledged that safety considerations have relevance for terminal cancer patients by restricting authorized use of Laetrile to intravenous injections for persons under a doctor's supervision. See 582 F.2d, at 1237; supra, at 551.

Moreover, there is a special sense in which the relationship between drug effectiveness and safety has meaning in the context of incurable illnesses. An otherwise harmless drug can be dangerous to any patient if it does not produce its purported therapeutic effect. See 107 Cong. Rec. 5640 (1961) (comments of Sen. Kefauver). But if an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties, the consequences can be irreversible.13 For this reason, even before the 1962 Amendments incorporated an efficacy standard into new drug application procedures, the FDA considered effectiveness when reviewing the safety of drugs used to treat terminal illness. See nn. 8, 9, supra. The FDA's practice also reflects the recognition, amply supported by expert medical testimony in this case, that with diseases such as cancer it is often impossible to identify a patient as terminally ill except in retrospect.14 Cancers vary considerably in behavior [442 U.S. 544, 557] and in responsiveness to different forms of therapy. See 42 Fed. Reg. 39777 (1977).15 Even critically ill individuals may have unexpected remissions and may respond to conventional treatment. Id., at 39777, 39805. Thus, as the Commissioner concluded, to exempt from the Act drugs with no proved effectiveness in the treatment of cancer "would lead to needless deaths and suffering among . . . patients characterized as `terminal' who could actually be helped by legitimate therapy." Id., at 39805.

It bears emphasis that although the Court of Appeals' ruling was limited to Laetrile, its reasoning cannot be so readily confined. To accept the proposition that the safety and efficacy standards of the Act have no relevance for terminal patients is to deny the Commissioner's authority over all drugs, however [442 U.S. 544, 558] toxic or ineffectual, for such individuals. If history is any guide, this new market would not be long overlooked. Since the turn of the century, resourceful entrepreneurs have advertised a wide variety of purportedly simple and painless cures for cancer, including liniments of turpentine, mustard, oil, eggs, and ammonia; peat moss; arrangements of colored floodlamps; pastes made from glycerin and limburger cheese; mineral tablets; and "Fountain of Youth" mixtures of spices, oil, and suet.16 In citing these examples, we do not, of course, intend to deprecate the sincerity of Laetrile's current proponents, or to imply any opinion on whether that drug may ultimately prove safe and effective for cancer treatment. But this historical experience does suggest why Congress could reasonably have determined to protect the terminally ill, no less than other patients, from the vast range of self-styled panaceas that inventive minds can devise.

We note finally that construing 201 (p) (1) to encompass treatments for terminal diseases does not foreclose all resort to experimental cancer drugs by patients for whom conventional therapy is unavailing. Section 505 (i) of the Act, 21 U.S.C. 355 (i), exempts from premarketing approval drugs intended solely for investigative use if they satisfy certain preclinical testing and other criteria.17 An application for clinical testing of Laetrile by the National Cancer Institute is now pending before the Commissioner. Brief for United States [442 U.S. 544, 559] 35 n. 23. That the Act makes explicit provision for carefully regulated use of certain drugs not yet demonstrated safe and effective reinforces our conclusion that no exception for terminal patients may be judicially implied. Whether, as a policy

matter, an exemption should be created is a question for legislative judgment, not judicial inference.

The judgment of the Court of Appeals is reversed, and the case is remanded for further proceedings consistent with this opinion.18

So ordered.

Footnotes

[Footnote 1] Section 505, as set forth in 21 U.S.C. 355, provides in part:

"(a) . . . No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.

"(b) . . . Any person may file with the Secretary an application with [442 U.S. 544, 547] respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use . . . .

. . . . .

"(d) . . . If the Secretary finds . . . that (1) the investigations . . . required to be submitted to the Secretary . . . do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; . . . (4) . . . he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) . . . there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. . . . As used in this subsection . . ., the term `substantial evidence' means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

. . . . .

"(i) . . . The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. . . ."

The Secretary has delegated his approval authority to the Commissioner of the Food and Drug Administration. See 21 CFR 5.1 (a) (1) (1978).

[Footnote 2] The requirements for investigative use are set forth in 505 (i) of the Act, 21 U.S.C. 355 (i)

See n. 1, supra.

[Footnote 3] In the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1041, Congress exempted from the definition of "new drug" any drug that was subject to the Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768, if its labeling retained the same representations concerning conditions of use made prior to 1938. This exemption is currently contained in 201 (p) (1) of the Act, as codified in 21 U.S.C. 321 (p) (1). The Drug Amendments of 1962 added a second grandfather clause, which provides:

> "In the case of any drug which, on the day immediately preceding the enactment date [October 10, 1962], (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201 (p) of the basic Act as then in force, and (C) was not covered by an effective [new drug] application under section 505 of that Act, the amendments to section 201 (p) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day." 107 (c) (4), 76 Stat. 789.

[Footnote 4] The suit was originally instituted by a cancer patient, Juanita Stowe, and her husband, Jimmie Stowe. After Ms. Stowe's death, two other patients, Glen L. Rutherford and Phyllis S. Schneider, and Ms. Schneider's husband, filed an amended complaint on behalf of a class composed of all cancer patients and spouses responsible for the costs of treatment. By order entered April 8, 1977, the District Court certified a class consisting of terminally ill cancer patients. 429 F. Supp. 506 (WD Okla.). The Government did not seek review of that order.

[Footnote 5] The District Court subsequently entered similar orders for other individuals who submitted affidavits averring their membership in the certified class of terminally ill cancer patients. See App. 1-6.

[Footnote 6] The Commissioner initiated proceedings with an announcement in the Federal Register seeking public comment. 42 Fed. Reg. 10066-10069 (1977). Notice was also afforded to certain known proponents of Laetrile. See id., at 39785-39786.

[Footnote 7] The Act does not define what constitutes general recognition of a drug's safety and effectiveness under 201 (p) (1). However, based on the structure and purpose of the statutory scheme, this Court in Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S., at 629-634, [442 U.S. 544, 550] interpreted 201 (p) (1) to require an "expert consensus" on safety and effectiveness founded upon "substantial evidence" as defined in 505 (d) of the Act, 21 U.S.C. 355 (d). See n. 1, supra.

[Footnote 8] Under the 1938 Act, a "new drug" was one not generally recognized by qualified experts as safe for its recommended use. 201 (p) (1), 52 Stat. 1041. The Drug Amendments of 1962, Pub. L. 87-781, 76 Stat. 789, redefined the term to include drugs not generally recognized as effective or safe for their intended use. 201 (p) (1), 21 U.S.C. 321 (p) (1). See supra, at 546-547, 551. In addition, the Amendments provided that no new drug application may be approved absent substantial evidence that the drug is effective as well as safe under prescribed conditions. 505 (d), 21 U.S.C. 355 (d). See n. 1, supra.

[Footnote 9] The Senate Report states:

> "The Food and Drug Administration now requires, in determining whether a `new drug' is safe, a showing as to the drug's effectiveness where the drug is offered for use in the treatment of a life-threatening disease, or where it appears that the `new drug' will occasionally produce serious toxic or even lethal effects so that only its usefulness would justify the risks involved in its use. In such

> cases, the determination of safety is, in the light of the purposes of the new drug provisions, considered by the Food and Drug Administration to be inseparable from consideration of the drug's effectiveness. The provisions of the bill are in no way intended to affect any existing authority of the Department of Health, Education, and Welfare to consider and evaluate the effectiveness of a new drug in the context of passing upon its safety." S. Rep. No. 1744, 87th Cong., 2d Sess., pt. 1, p. 15 (1962).

See also H. R. Rep. No. 2464, 87th Cong., 2d Sess., 3 (1962).

The FDA's practice was further amplified by HEW Secretary Ribicoff in testimony on the bill that ultimately became the 1962 Amendments:

> "If the drug is offered for treatment of progressive or life-threatening diseases, such as cancer, . . . we now consider its effectiveness. In such cases the determination of safety is, in the light of the purpose of the new drug provisions, inseparable from consideration of the drug's effectiveness." Hearings on S. 1552 before the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary, 87th Cong., 1st Sess., 2588 (1961).

[Footnote 10] To be sure, it may not always be realistic to infer approval of a judicial or administrative interpretation from congressional silence alone. See, e. g., Helvering v. Hallock, 309 U.S. 106, 119-121 (1940); Toucey v. New York Life Ins. Co., 314 U.S. 118, 140-141 (1941). But once an agency's statutory construction has been "fully brought to the attention of the public and the Congress," and the latter has not sought to alter that interpretation although it has amended the statute in other respects, then presumably the legislative intent has been correctly discerned. Apex Hosiery Co. v. Leader, 310 U.S. 469, 487-489 (1940). See United States v. Bergh, 352 U.S. 40, 46-47 (1956). See, e. g., Pub. L. 94-295, 90 Stat. 575; Pub. L. 94-278, 90 Stat. 411; and Pub. L. 91-513, 84 Stat. 1281 (amending 201 of the Act, 21 U.S.C. 321).

The issue presented in this case plainly has not escaped public or legislative notice. Whether Laetrile should be freely accessible to cancer patients has been a frequent subject of political debate. Seventeen States have legalized the prescription and use of Laetrile for cancer treatment within their borders, and similar statutes have been defeated in 14 other States. See CCH F. D. Cosm. L. Rep. ¶ 42,292 (1978); Comment, Laetrile: Statutory and Constitutional Limitations on the Regulation of Ineffective Drugs, 127 U. Pa. L. Rev. 233, 234 n. 8 (1978). That Congress is aware of the FDA's policy concerning Laetrile is evident from Senate Subcommittee hearings on the Commissioner's 1977 ruling. See Hearing before the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources, 95th Cong., 1st Sess. (1977).

[Footnote 11] See L. Goodman & A. Gilman, The Pharmacological Basis of Therapeutics 325-339 (5th ed. 1975).

[Footnote 12] See statement of Dr. Theodore Klumpp, Chief, Drug Division, FDA, June 23, 1941, CCH F. D. Cosm. L. Rep. ¶ 71,053.59 (1977); n. 13, infra.

[Footnote 13] See, e. g., 42 Fed. Reg. 39768, 39787 (1977) (statement of Dr. Carl Leventhal, Deputy Director of the Bureau of Drugs, FDA, and Assistant Professor of Neurology and Pathology at Georgetown University) ("The safety of a drug for human use depends, in large measure, on the therapeutic effectiveness of the particular drug. . . . In the case of cancer, treatment with an ineffective drug will . . . inexorably lead to the patient's death"); ibid. (statement of Dr. George J. Hill II, Chairman of the Department of Surgery at Marshall University School of Medicine, W. Va.) (Ineffectual treatment

can lead to delay in accepted modes of therapy and needless deaths; thus, "[i]n the absence of scientific evidence of effectiveness, no drug intended for use in treating cancer can be regarded as safe").

[Footnote 14] See, e. g., id., at 39805 (statement of Dr. Peter Wiernik, Chief of the Clinical Oncology Branch of the National Cancer Institute's Baltimore Research Center) ("[N]o one can prospectively define the term `terminal' with any accuracy. A patient can be said to be terminal only after he dies. Many patients who are critically ill respond to modern day management of cancer"); ibid. (statement of Dr. Joseph Ross, Professor of Medicine, University of California School of Medicine at Los Angeles) ("[T]he distinction of `terminal' patients from `non-terminal' patients may not be reliably determined and an assumption that Laetrile may be given to [`terminal'] patients with impunity may deprive such patients of therapeutic measures which could help them").

[Footnote 15] The Commissioner noted that these unexpected behavior patterns may account for anecdotal claims of Laetrile's effectiveness. Users of Laetrile who experience spontaneous remissions or delayed responses to conventional therapy after its abandonment may ascribe their improvement to Laetrile without any objective basis for that attribution. See, e. g., id., at 39777 (statement of Dr. Daniel S. Martin, researcher in cancer immunology and chemotherapy); id., at 39800 (statement of Dr. Emil J. Freireich, Chief of the Division of Oncology at University of Texas Medical School at Houston); ibid. (statement of Dr. Melvin Krant, Director of Cancer Project at the University of Massachusetts Medical Center). Particularly since accepted cancer treatments such as chemotherapy and radiation often have painful side effects, the Commissioner concluded that patients who subjectively perceive improvement after substituting Laetrile for these modes of therapy may erroneously believe that their condition has been arrested or ameliorated. See id., at 39777, 39799-39800.

[Footnote 16] CCH Fed. F. D. Cosm. L. Admin. Reps., 1907-1949, p. 745 (1951); id., at 1408; id., at 1170-1171, 1298-1299; id., at 224; FDA Ann. Reps., 1950-1974, pp. 309, 464; id., at 45; id., at 412.

[Footnote 17] See n. 1, supra. At present, some 300 experimental drugs are available to critically ill cancer patients at authorized institutions. See Brief for United States 34 n. 23; National Cancer Institute, Extramural Clinical Trial Programs of the Division of Cancer Treatment, General Overview and Scope of Contract-Supported Activities (1979). During 1977, over 90,000 cancer patients participated in investigative programs under the auspices of the National Cancer Institute or the Veterans' Administration. Brief for United States 35 n. 23.

[Footnote 18] Respondents urge that we consider the District Court's rulings on the constitutional and grandfather clause questions as alternative bases for sustaining the judgment below. However, since the Court of Appeals addressed neither issue, we remand the case for further consideration of respondents' claims. See Vermont Yankee Nuclear Power Corp. v. National Resources Defense Council, Inc., 435 U.S. 519, 549 (1978); Arlington Heights v. Metropolitan Housing Dev. Corp., 429 U.S. 252, 271 (1977).
[442 U.S. 544, 560]

Proposal for a Biofield Therapeutics panel at the WHCCAMP meeting on Research April 9 & 10, 2001

While not in the current bio-medical textbooks, the biofield* has been recognized as a functional component of human beings since at least the third Egyptian Dynasty, when it was identified by the hieroglyph ☥ (pronounced Ankh, translated as "Life Force"). There is considerable evidence that early forms of biofield therapies were the main healing modalities in the Caves of Asclepius in ancient Greece as well as in the Egyptian healing temples called "Houses of Life" (Per Ankhs).

In spite of a widespread but scientifically unfounded disbelief in the existence of the biofield, biofield therapeutics have grown rapidly in the United States over the past twenty-five years, usually through the actions of former doubters who became convinced by their own responses to biofield treatments. Recent estimates indicate that over one million people in the Western nations alone practice at least one form of biofield therapeutics; approximately ten percent are in the medical, nursing and allied professions.

The prevailing disbelief is being challenged by a growing number of medical doctors, nurses and other medically allied professionals who have become convinced by the consistent beneficial results of therapeutic applications of the biofield. Braving the prevalent skepticism, a number of researchers have undertaken personally funded studies that demonstrate effectiveness for a wide range of common aliments. While there are differences in conceptual and operational theories, all of the current forms of biofield therapeutics have clearly demonstrated the reduction of (and often the complete elimination of) prescription and over-the-counter medicines previously necessary for pain, anxiety, sleeplessness and stress. All have shown accelerated recovery from illness and surgery and some have demonstrated effectiveness with severe disorders such chronic anxiety, panic disorder, eating disorders and the post-traumatic stress disorders.

An unreasonable number of bars to the design of and acceptance of research studies currently hinder further scientific validation of the clinical effectiveness of biofield therapeutics. Little formal funding has been available for studies, such studies as have been completed are not sent out for review by the first-line medical journals and unreasonable design factors are demanded by members of IRB's that do not understand the process or its requirements, or simply disbelieve.

Research into this potent group of modalities should be fostered instead of hindered; it is unlikely that any other complimentary or alternative medical process holds as much promise for the general health and well being of the public – and for the reduction of cost of medications – as do the biofield therapeutic modalities.

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* **Biofield**: 1) a *fluxive, massless medium* with the distinctive property of being *bioeffective, or having an effect on biological material*. The biofield penetrates and extends outward from the physical body a finite distance. The term **Aura** is commonly used to denote the portion of the biofield that is external to the physical body.

2) The primary operative mechanism in healing modalities using proximate touch and related hands-on techniques.

Note: The terms **"Energy," "Energy Body," "Energy Field," "Human Energy Field," "Subtle Energy Field,"** and other derivations that have been commonly used to identify the biofield are, or incorporate, an improper and unclear usage of previously and precisely defined scientific terms. This misuse of terms has long caused confusion and brought derision from the other scientific disciplines that originally defined energy as *"the capacity of a system to do work"* and field as *"a region of space characterized by a physical property, such as gravitational or electromagnetic force or fluid pressure."* Additionally, since all fields in physics have energy, the concept of an energy field is ambiguous, confusing and has no meaning in science. To rectify this, the editors of *Alternative Medicine: Expanding Medical Horizons, the Report to the NIH on Alternative Medicine*, (1992) unanimously adopted the unambiguous definition "Biofield." The term has since been adopted by the National Center for Complementary and Alternative Medicine, NIH.

#2

Testimony to Commission on Complementary & Alternative Medicine Policy

International Community Health Services
Dorothy Wong, Executive Director

I am the Executive Director at the International Community Health Services, a community health center that primarily serves the limited English speaking Asian and Pacific Islander immigrant population in Seattle and King County. Alongside allopathic Western primary medical and dental care, we provide traditional Chinese medicine services, which includes acupuncture, moxibustion, herbs, and cupping.

(1) Complementary and alternative medicine is a very common practice among Asian and Pacific Islander immigrants. Given the access barriers to mainstream medical care (including lack of insurance, need for interpretation, limited knowledge about the medical care system), immigrants will often choose the more culturally familiar traditional ethnic (Chinese, Vietnamese, etc.) health care practices, such as acupuncture, herbs, massage, cupping, coin rubbing, traditional healers, etc. Research needs to be funded to assess the practice of these traditional methods, particularly looking at any interactions with concurrent allopathic medicine, as well as the potential hazards and benefits of the traditional practices themselves.

(2) Acupuncture and herbal medicine research should not be taken out of context from their cultural background. Much of current research is done under the 'gold standard' of randomized trials. This means that treatments must be standardized in order to compare treatment options. But traditional acupuncture and herbal treatment cannot be standardized for 'neck pain,' for example. Since the treatment would be individualized according to specific imbalances in energy flow of the different body meridians, traditional Chinese medicine would involve a different treatment for each individual presenting with the same problem. Unfortunately, much of current research being funded does not allow for these traditional means of diagnosis and treatment, wanting to standardize the therapy. Other research methodologies will need to be developed to assess these therapies in their cultural context.

3 Complementary and alternative medicine seems to be beneficial to a wide range of conditions that are not well treated by allopathic medicine. Chronic neck and back pain, neuropathic or nerve related pains, chronic tendonitis or irritation in tendons, such as tennis elbow, pregnancy related nausea and vomiting are some of these conditions. These conditions are not easily or successfully managed with medications, or the side effects of medications have significant complications in themselves. Access to complementary and alternative medicine needs to be available and consistent. In California, for instance, work-related injuries and Medicaid patients have coverage for complementary and alternative medicine, but in Washington state these same patients are not covered for these services. Traditional Chinese medicine should be similarly covered from state to state. Practice guidelines for common ailments should include and integrate complementary and alternative medicine with allopathic medicine, particularly for these chronic conditions. Reimbursements for these services should uniformly be covered following these practice guidelines. This would allow for provider and patient options in the management of these conditions.

Acupucture Servicves and Patients

(From 1/1/2000 to 8/31/2000)

By Revenue Sources				
Resource	Visits		Patients	
3rd Party Ins	180	10.5%	33	11.4%
Basic Health	427	24.9%	67	23.2%
Basic Health & Medicaid	3	0.2%	1	0.3%
ICHS Staff/Family	8	0.5%	4	1.4%
Medicaid Healthy Option	4	0.2%	1	0.3%
Self Pay	1090	63.7%	183	63.3%
TOTAL	1712	100.0%	289	100.0%
By Ethnicity				
Ethnicity	Visits		Patients	
AFR AMERICAN	3	0.2%	2	0.7%
CHINESE	892	52.1%	130	45.0%
FILIPINOS	7	0.4%	3	1.0%
IRANIAN	2	0.1%	1	0.3%
JAPANESE	4	0.2%	2	0.7%
KOREAN	154	9.0%	44	15.2%
LAOTIAN	5	0.3%	2	0.7%
MEIN	7	0.4%	2	0.7%
NATIVE ALASKA	7	0.4%	1	0.3%
NATIVE AMERICAN	94	5.5%	15	5.2%
OTHER	66	3.9%	11	3.8%
THAI	13	0.8%	1	0.3%
VIETNAMESE	364	21.3%	50	17.3%
WHITE	94	5.5%	25	8.7%
TOTAL	1712	100.0%	289	100.0%

Acupuncture Visit Counted by Dx (1/1/2000 - 8/31/2000)	
Description	Visits
Alopecia Unspecified/ Hair loss/ Baldness	5
Anal/Rectal fissure	1
Bell's palsy	165
Breast tenderness/ Numbness/ Paresthesia	80
Breech presentation, Antepartum	6
Bursitis,subacromial	1
Carpel tunnel syndrome	4
Chronic fatigue syndrome	1
Diabetes Mellitus,type I (insulin dependent)	2
Dysphagia/ diffficult in swallowing	28
Dysphasia/ Speech disturbance,other	1
Epicondylitis,lateral/Tennis elbow	16
Headache/facial pain	68
Hearing problem	6
Hydrocele, unspecified	1
Hypertension,benign	2
Menopause/ Symptoms:hot flashes,sleepless	2
Menorrhagia/prolong,heavy bleeding	1
Neoplasm, digestive system unspecified nature	1
Pain,abdominal/infantile colic	25
Pain,ankle	17
Pain,arm/finger/foot/leg/limb/heel/thumb/toe	196
Pain,back unspecified	359
Pain,elbow	6
Pain,hand joint	31
Pain,joint; arthralgia unspecified	1
Pain,knee	158
Pain,menstruation/ Dysmenorrhea	8
Pain,musculoskeletal/Generalized pain/Myalgia	1
Pain,neck	60
Pain,Sciatic	9
Pain,shoulder	154
Polyarthritis NOS	1
Rheumatoid arithritis	17
Rotator cuff syndrome,other/ Tendonitis	2
Sinusitis,chronic/Post nasal drip/Unspecified	16
Skin rash	18
Sleep disturbance, unspecified	50
Spotting,intermenstrual irregular	1
Stiff neck/ torticollis	10
Tendonitis	8
Tinnitus, Unspecified/ Ringing in the ear	5
Tobacco abuse	9
Trigeminal neuralgia	8
Weakness general/Malaise and fatigue,other	151
	1712

#6

Lori L. Bielinski, LMP, Sr. Health Care Policy Analyst
Office of the Insurance Commissioner
Testimony
White House Commission on Complementary and Alternative Medicine Policy
Town Hall Meeting – Seattle, WA
October 30, 2000

In 1993 Health care reform legislation was enacted in Washington that assured consumers could buy health insurance even if they were sick or had changed jobs. Simultaneously, provider groups pursued inclusion of all licensed health care providers for insurance reimbursement within their respective practice scopes. To preserve insurers' ability to select competent providers, the final legislation settled on the term "every category" without mandating inclusion of every individual practitioner. Subsequent revisions preserved these reforms and the Office of the Insurance Commissioner promulgated rules to implement that intent.

An unusual footnote is that of the many sections of these reforms, this is one of the few portions of the law that remains. It has stood the challenges through both Democratic and Republican majorities of the legislature, it has generated the

most controversy, and is the most popular as well as having been upheld by the US Supreme Court.

There are specific criteria that must be met. The CAM professions must be regulated by the Department of Health with licensure or certification. The scope of practice must allow the provider to treat the condition that the patient presents. The provider must be *contracted* to be eligible for reimbursement. And, finally the patient must have benefits covering a condition that is within the scope of practice of the chosen provider.

This is not an "any willing provider" law, nor is it a mandated benefit law. It allows consumers access to a choice of the provider who will treat the condition in which they are seeking care.

Carriers have the right to credential providers as long as the standards are consistent with those established by the Department of Health. Carriers must set network adequacy requirements based on the number of covered lives in a jurisdiction where they are responsible for providing coverage.

Carriers have the right to set the coverage limits, including services of CAM providers. The OIC has established rules that state these limits may not be unreasonable and may not be set

by provider type, but can be set by covered services. And, the carrier may not exclude a particular category of provider altogether, nor can it cover certain provider types only by a separately priced optional benefit.

Thus, it became very important to clarify to insurers, providers and the public that the law relates to ALL regulated health professions, and not just those considered alternative. Additionally, the law does not mandate a benefit for anyone - it allows patient access to the provider of their choice for covered conditions.

The initial environment impacted by the threat of ongoing litigation. After many discussions, parties agreed how to establish a joint work group and to hire outside facilitation. It was agreed that the OIC would convene clinicians from the carriers and the professional associations to focus on clinical issues. The full workgroup agreed that all decisions would be made by a planning committee, made up of a smaller group of the whole, to assure all parties were represented in the decision-making process.

Participants included outside facilitation, CAM professional association representatives from acupuncture, chiropractic, dieticians, massage therapy, licensed midwives and

naturopathic physicians, medical directors from carriers and CAM provider networks. In the second and third years we expanded the workgroup to include primary care physician organizations, educational institutions that train CAM professions, and the State Department of Labor and Industries, our workers compensation program.

The group's '97 work was spent developing trust, building working relationships, and establishing an agenda. The '98 agenda was aggressive, including coverage decisions, technology assessment, medical necessity, and most significant was the training of CAM practice guidelines. The '99 CWIC activities were focused on the known integrated clinics and additional training on practice guideline development.

The most important deliverables were the final report and draft seed algorithms for at least one condition for each profession. They are in Appendix I of the report with the stipulation that they are drafts, and have not yet been tested, implemented, refined or subjected to peer review. Each profession has been encouraged to continue developing algorithms using the peer review process.

In this process we learned that developing trust and understanding of each other's language was critical to a positive

outcome. Continuous representation assured participants that everyone was invested in the process and could build on those relationships.

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

This is a consumer demand and we, as policymakers, have the responsibility to move the decision making into well rounded, deliberate discussions about cost, access and outcomes.

#16

Presentation to the
White House Commission on Complementary and Alternative Medicine Policy
Town Hall Meeting, Seattle, WA, October 30, 2000

Richard Hammerschlag, Ph.D.
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Members of the Commission: Good morning. I am Richard Hammerschlag, Research Director of the Oregon College of Oriental Medicine in Portland. I also serve as President of the national Society for Acupuncture Research and for 25 years, up to 1995, I was engaged in biomedical research in neurobiology. Research is my profession and my passion and it is a challenge to apply my training in biomedical research to CAM research in general and acupuncture research in particular. It is especially exciting to be part of the unique CAM research community in Portland, which is home to *two* of the 15 currently funded NIH NCCAM Centers.

I will focus my remarks on three questions essential to research:

- What kinds of CAM research are needed?
- How can CAM research findings be better disseminated to health care providers, policy-makers and insurers?
- What strategies can be developed to facilitate the incorporation of research-supported CAM therapies into conventional health care settings?

In talking about research, we should acknowledge that "evidence-based medicine", the current watchword at NIH, means research-based medicine.[1] It follows that CAM research, similar to conventional biomedical research, must be held to rigorous standards. But what kinds of CAM research should be encouraged?

I suggest that greater consideration *and funding* be given to research that compares real-world treatment options.[2] Just as models of Integrative *Medicine* are being created, we also need integrative research. When CAM therapies are tested side-by-side with conventional therapies, a richness of questions arise with major implications for clinical practice. These questions address how CAM and conventional treatments compare in terms of therapeutic effectiveness, long-term effectiveness, side effects, and cost-effectiveness. The Portland-based NCCAM Center at Kaiser's Center for Health Research is initiating such comparative

research in partnership with Portland-area CAM colleges of Oriental Medicine, Naturopathy, Chiropractic and Massage.

The CAM community also needs to be more proactive in ensuring that its research findings reach the wider health care community. One approach is to prepare informational packets that summarize research findings as well as educate health care administrators, providers and policy-makers in how to assess the quality of research articles. This would help to correct a major inconsistency in contemporary health care: We hear strong calls for evidence-based medicine, yet we have a health care community that is poorly trained to seek out, and assess the quality of, CAM research.

Lastly, we need to identify the obstacles that are slowing the incorporation of evidence-based CAM practices into mainstream medicine. Three approaches are: surveys to document attitudes to CAM; discussions on CAM at national meetings of hospital administrators; and demonstration hospitals where the integration of CAM practices can be evaluated.

In summary, I urge the Commission *first,* to call for research that compares real-world CAM and conventional treatments; *second,* to explore means of more widely disseminating CAM research findings; and *third,* to develop strategies to better ensure that CAM *research* benefits health care consumers.

Thank you.

[1] "There is no alternative medicine. There is only scientifically proven, evidence-based medicine supported by solid data or unproven medicine, for which scientific evidence is lacking. Whether a therapeutic practice is "Eastern" or "Western", is unconventional or mainstream, or involves mind-body techniques or molecular genetics, is largely irrelevant except for historical purposes and cultural interest."

Fontanarosa PB, Lundberg GD (1998) Alternative medicine meets science, *JAMA* 280:1618-1619.

[2] Hammerschlag R, Morris MM (1997) Clinical trials comparing acupuncture with biomedical standard care: a criteria-based evaluation of research design and reporting, *Complement Ther Med* 5:133-140.

KING COUNTY

1200 King County Courthouse
516 Third Avenue
Seattle, WA 98104

Adopted August 14, 2000

Motion 10991

A MOTION to support local initiatives designed to establish a coordinated vision and innovative strategic plan for the integration of complementary and alternative health care delivery in King County.

WHEREAS, the King County integrated health care 2010 project will be a two-phased, community-based process that will bring together major stakeholders in a collaborative environment to craft and implement a ten-year strategic plan, and

WHEREAS, many forces make 2000 an ideal time to reinvigorate this task: escalating demand for complementary and alternative medicine; growing data supporting its effectiveness; expanding networks of groups and agencies addressing the integration of complementary and alternative medicine (CAM) and conventional medicine (CM); and a strong history of health care innovation and leadership by the county, and

WHEREAS, among the potential issues to be addressed in a coordinated way are:

Research;

Clinical practice, quality of care and delivery systems;

Underserved and special needs populations;

Professional and public education;

Public health and environmental health;

Regulation and access to products;

Federal, state and local benefit programs and regulations; and

Reimbursement and insurance, and

WHEREAS, in February 1999, a meeting, hosted by metropolitan King County council districts one and nine, laid the groundwork for a public forum to address where King County would like to take natural medicine by the year 2010, and

WHEREAS, metropolitan King County is in a position to initiate and facilitate an effective process. Many factors contribute to this moment of opportunity:

The *Puget Sound region* has a national reputation for leadership in health care reform, including the Washington State "every category of provider" law, which became effective in 1996;

The *Northwest region* enjoys national visibility for education, leadership, clinical services, and research in both CAM and CM. University of Washington, Bastyr University, Northwest Institute of Oriental Medicine, Seattle Midwifery School, Western States Chiropractic College, several massage schools and others are located in the region;

Consumer usage of complementary and alternative medicine is rising nationally and in King County. Studies indicate that the rate of consumer usage of CAM increased from 34 percent in 1993 to 40 to 69 percent in 1998. The CAM credentialled workforce will grow by 88 percent between 1994 and 2010. The CM workforce using or referring for CAM therapies is also growing steadily; some studies suggest referral and usage rates range from 7.9 percent to 73 percent;

The *metropolitan King County council* has a demonstrated commitment to innovating and advocating for the integration of natural medicine, establishing the King County natural medicine clinic in 1995, the first publicly funded integrated natural medicine clinic in the country. The recent appointment of a naturopathic physician to the Harborview Hospital Board of Trustees is another example; and

The *King County board of health* has demonstrated its recognition of the importance of natural medicine by being the only such board in the country with a naturopathic physician as a member and by creating a task force investigating natural medicine integration into public health programming, and

WHEREAS, funding for phase I of the project will be provided by stakeholder participants and sponsors;

NOW, THEREFORE, BE IT MOVED by the Council of King County:

The metropolitan King County council supports the strategic planning efforts of the King County integrated health care 2010 project through participation of King County councilmembers and staff on the project steering committee and through appropriate departmental assistance should any or all of the 2010 initiatives receive grant funding.

#18

Comments on Appropriate Roles the Federal Government Can Play Concerning Complementary and Alternative Medicine

Robert D. Mootz, DC
Associate Medical Director for Chiropractic
Washington State Department of Labor and Industries

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

Ladies and Gentlemen, thank you for allowing me the honor to briefly present some of my observations regarding appropriate and constructive roles the Federal Government can play concerning complimentary and alternative medicine (CAM). First of all, I must applaud you for seeking information about this important and rapidly growing area of health care services. The perspectives I offer come from the following three vantage points: thirteen years in private practice as a doctor of chiropractic; eight years in academia and research; and six years as the first doctor of chiropractic to hold a full-time policy and research position within a government agency.

As you know, recent studies have shown that Americans make nearly twice as many visits to practitioners of alternative medicine than they do to practitioners of family medicine. They spend more money out-of-pocket for CAM services than they do for out-of-pocket hospital payments. Further, the past decade has seen an exponential growth in the use of alternative medicine. Chiropractic care and massage are the most utilized of all CAM approaches with nearly 15% of the US population visiting a chiropractor every year. This accounts for a third of all visits to CAM providers. Additionally, patient satisfaction data has also consistently demonstrated higher levels of satisfaction with many CAM approaches such as chiropractic care.

Obviously, the marketplace is already incorporating CAM approaches and providers into the "mainstream" in terms of preference, utilization, and expenditures. However, government and the health care system at large often proceed as though CAM merely represents some kind of "fringe" practice or a passing fad. From my perspective there are three key areas that the Federal government has both an interest and obligation in, as well as the ability to constructively influence the future of CAM and health care to meet needs for all Americans:

1. Provide meaningful federal support for CAM research and education

The CAM professions and their institutions need to develop and enhance their own educational and research missions, particularly research capacity and infrastructure development. Education and research are obviously the domain of the respective professions for they have the most knowledge and passion regarding it. Federal support need only be patterned after what exists currently for other disciplines.

Other than qualification for some federal student loan guarantee programs, government support of CAM educational institutions is nearly non-existent. This creates an incentive that fosters tuition dependence and focuses curriculum on basics that neglect important but costly residency and apprentice training, development of multidisciplinary exposure, collaboration with universities, and deters development of a culture of scholarship. This is important to federal policy makers in that this results in a loss of preparation for graduates of CAM professions to more seamlessly interface with the contemporary health care system and contributes to needlessly high default rates. Two distinct needs are related to this:

- Educational development grants, infrastructure grants, support for post graduate fellowships and advanced degree programs are examples of the kinds of support widely available for medicine, osteopathy, dentistry, and psychology programs but exclude CAM professions such as chiropractic, acupuncture or naturopathy.
- Level the playing field for students in legitimate CAM training programs in terms of student loan repayment options. Defaults need to be decreased though additional deferment options available to other health professions such as post-graduate residency and fellowship programs.

Barriers to research in CAM exist at many levels. Again these barriers have exceptional relevance to the federal government and to the American public at large. With out necessary research funding, the ability to delineate effective from ineffective procedures is reduced. Further, information necessary to the CAM professions themselves for their own quality improvement efforts is absent, placing these providers at a competitive disadvantage. This kind of policy reduces both choice and access for consumers, a key mission of many federal programs (eg, rural health care and caring for disadvantaged individuals and families). Key barriers include: inadequate scientific career training; limited science related career opportunities; bias, isolation from and ignorance of chiropractic with the wider science and health care communities; and inadequate representation in government research and policy circles. There are several distinct needs in this area:

- Post-doctoral training programs and incentives for CAM related scientists
- Establish incentives for dual degree training (e.g., MPH) for matriculates and graduates of CAM programs.
- Establish incentives for more partnerships, consortia, and collaborations between CAM institutions and universities. For example, joint conference sponsorships similar to the DHHS Health Resources and Services Administration (HRSA) funded geriatrics program (GRECC Symposium) with St. Louis University School of Medicine and Logan College of Chiropractic.
- Fund and establish more clinical research centers at CAM institutions.
- The National Library of Medicine indexes very few CAM journals and many of similar quality and content are rejected out of hand as irrelevant. This reduces retrievability of legitimate scientific and clinical information for policy makers and conventional scientists and practitioners. Relevant CAM subject index headings can be improved as well.

- Consider training support options in chiropractic and CAM disciplines to the same extent as supported in dentistry, medicine and other disciplines in order to reduce the climate of tuition and encourage development of widespread legitimate research cultures within CAM institutions.
- Consider the need for special support to "prime" scientific activity at CAM institutions, e.g., expansion of the Centers of Excellence programs being funded at HRSA.

2. Attain consistency in Federal programs with national trends and priorities

The Federal government is incredibly far behind the curve of social norms in its own health care programs. Chiropractic care for example, is a core benefit in personal injury protection coverage, most workers' compensation programs, and in health indemnity plans. Although managed care exclusions exist, meaningful chiropractic benefits can be found in a majority of insurance plans. On the other hand, Medicare, Medicaid, Veterans and Military Benefits, and Federal Workers' Compensation programs all have highly restricted coverage or exclude chiropractic care altogether. Even many managed care programs have not restricted or established the kinds of non-clinical, arbitrary and discriminatory policies on chiropractic care that exist in most Federal programs, although many are increasingly relying on these Federal programs as a template to justify such exclusions.

At the state level, patient's bill of rights legislation, court precedent and innovations such as Washington State's "every category of provider" laws are establishing that consumers and taxpayers want CAM services and they want their social institutions for health care to get along. On a social level, the potential for improvements in quality of life, satisfaction with care, and demonstrated cost efficiency in various circumstances have been documented in some situations. Chiropractic care for the people who have low back or neck problems, and headaches are just one example of how inclusion of CAM approaches (even within existing condition-oriented health plans) can offer direct tangible benefits to consumers and taxpayers alike.

CAM needs resources for quality improvement and CAM practitioners can improve their practices just like the rest of health care. The need for health services research and policy development that both explores CAM and includes CAM in government health policy circles is obvious. For example, there is only one DC employed within all of the federal government health care agencies and this only occurred within the past year or so at the National Center for Complementary and Alternative Medicine. Further, as far as I have been able to find out, my policy and research position within the Washington State Department of Labor and Industries is the only such position in existence at the state level. Many examples of benefits to both the state agency, the chiropractic profession and to the business and labor constituencies have accrued as a result. For example, the joint research between the Washington State Chiropractic Association, the Department, and the University of Washington led to the adoption of an evidence-based fee schedule for chiropractic services. This has provided more robust coverage for chiropractic care,

helped reduce administrative burden on doctors and department staff, and has made constructive progress in policy development without adversity, litigation, or excessive expenditure of resources by government or the community at the Legislature.

The precedent set by the absence of policy roles for CAM professions at the federal level permeates to state and local government as well. Although there is progress with DCs in ad hoc and advisory roles, more needs to be done, not only in chiropractic, but for many of the CAM professions. The value and contributions of such participation not only benefits respective CAM disciplines, it brings new perspective and insight to existing policy development efforts. I have seen this first hand in my work at the state agency level.

3. Promote collaboration and integration of CAM and expand the role of CAM within conventional health care delivery

One of the most important points to be made regarding integration of CAM within conventional delivery models is that a distinction must be made between the incorporation of certain *CAM procedures* into conventional medical practice and the integration of *CAM providers* into patient care pathways. An example from my discipline is the procedure of spinal manipulation compared to chiropractic care.

The procedure of manipulation has been used by many disciplines including medicine, osteopathy, and physical therapy for many years. In these settings it may be applied as an ancillary modality with the context of overall medical management, usually focusing on increasing joint range of motion and reducing pain. Although manipulation for specific conditions has a positive benefit, chiropractic management is truly distinctive, considering how body structure impacts physiology and function generally. Improved clinical outcomes and superior patient satisfaction with chiropractic care have been demonstrated repeatedly. Management approaches and non-specific effects of care are acknowledged as important variables in both clinical care and scientific research, yet these issues are often neglected in conventional delivery and research settings. However, for CAM providers, these issues are important basic elements of practice and research. CAM is a growing component of commonly used health care services in this country – not some separate, isolated, fringe element of society. The system might work better and towards everyone's advantage with a higher degree of support for and collaboration with individuals and institutions within the CAM disciplines.

Overall management perspectives, lifestyle approaches, and doctor-patient relationships are pivotal in health care. Tossing a few CAM modalities into general family practice is not the same as integrating practitioners in a constructive clinical environment who bring unique and extensive training, skills, and perspectives to the decision-making table. Consider the reverse: having a chiropractor incorporate suturing and NSAID medication into her or his practice seems unlikely to serve as a replacement for family practice medicine.

The federal government can play an extremely positive role through its policy leadership, better reflecting the social needs and trends of the American public, its direct impact on the marketplace via federal reimbursement in its own health care programs, and its substantial role as opinion leader and benchmark for the health care system, delivery settings, and health insurance plans.

Here in Washington State, provider choice is law, both in general health insurance and in workers compensation. Integration of CAM is not a medical profession issue, it is a social and marketplace issue. Exploring integration will require gradual exposure, training, and scientific research to accomplish. This exposure must involve all parties as the conventional science and medical communities have to move as far in their understanding of CAM approaches as CAM providers have to move in there understanding and skill in conventional methodologies and rationales. There are no simple "fixes." Rather, there is a need to continue to level the playing field, provide all interested parties with necessary tools for constructive engagement and bring reasoned appraisal both to discussions on integration and policy development at government levels.

Federal programs directed to these ends help stimulate economic advantages for consumers, tangible benefits in improving both patient choice, and improving the effectiveness of health care services. I urge you to recommend prioritizing only a small, but meaningfully proportional amount, of federal resources to this important, but long-neglected segment of the US health care system. The benefits accrued to the general public through better quality of care, innovations and improved effectiveness of treatment strategies, and realignment of priorities in prevention, lifestyle, and self-care so characteristic of CAM approaches will have yield beyond the small costs associated with it.

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#26

White House Commission on Complementary & Alternative Medicine Policy

Testimony: Town Hall Meeting, Seattle, WA, October 30, 2000

I am **Arlene Darby of Bellevue** and have been a participant as well as an advocate for CAM for 23 years.

Praise for each one, including President Clinton, plus all who inspired him and and were involved in any way to make the White House Commission on CAM possible.

Praise for the professionals and all participants who are, and will be, a part of the paradigm shift called CAM.

When a Paradigm shift occurs it brings about the challenge of change. Often some chaos occurs before one can celebrate the change and paradigm shift.

Some Participants here today have found themselves not only working to bring about the greatest degree of health possible, or, at least, the best quality of life under the cir cumstances, but, also, participating in the process of defending their practitioners.

Protocol – *Standard of care* is often the problem. Updating protocol is a basic premise to the shift of the paradigm in health care.

Pushes and **Pulls** of the political forces—not just government, but other political forces - is a reality.

With Pen in hand and **Paper**— legal documents— the power base in Olympia and other states , plus the political strategy, strength and support of the power in Washington DC, CAM can become legal.

What
Potential is possible if practitioners and patients could truly talk to each other about all possible facets of care.

Pecuniary, or money matters, are very powerful, perhaps more powerful than political powers. Actually, pecuniary matters and political powers are intertwined.

All
Participants for CAM will need miraculous negotiating skills – skills as awesome as those of people who have done the impossible in every field of endeavor throughout history.

Planes – Boeing, that is – and Microsoft, along with the whole high tech field, have given people, projects, programs and products an opportunity to be all over the world. However, people, projects, programs and products have also arrived here. Included are cultural differences in health care. CAM is a part of all this.

Again
Praise for all leaders in the Puget Sound area, and beyond, for their vision, persistence and perseverance, in pursuing the challenge of the paradigm shift in healing and health care so that safe and effective CAM therapy will be made legal..

Please Pursue all efforts on behalf of making CAM possible and legal.

Thank you.

Testimony of Bruce Milliman, ND
White House Commission on CAM
Town Hall Meeting, Seattle, WA
October 30, 2000

I have been a naturopathic physician in private family practice for 18 years and have worked in an integrated setting since my graduation, first for three years with Chandra Sharma, MD, in London, UK and most recently with Fernando Vega, MD in Seattle. I am past president of the Washington Association of Naturopathic Physicians (WANP), 1995-1998 and have authored or been co-investigator on several peer-reviewed papers. (1) I was awarded "physician of the year" in 1996 by the American Association of Naturopathic Physicians (AANP) and continue to serve as an active member of the health insurance committee.

During my tenure as WANP president, the "All Category" Law came into force and mandated that all health insurance plans provide in all of their products sold in Washington State, unfettered access to all categories of licensed care for all conditions covered in the basic health plan; provided that said service is within the providers scope of practice. Naturopathic physicians have the third broadest scope of practice, next only to MD's and DO's. (2)

Prior to the January 1, 1996 implementation date of the "All category" mandate, I was invited to meet with the medical directors of several health plans to propose how our profession might be included into third party reimbursement. I stated that as we were qualified and trained in fully accredited naturopathic medical schools, that we were required to pass State administered naturopathic medical boards, that we were licensed and regulated by the State of Washington, that our educational curricula were at least as comprehensive and required at least as many contact hours as conventional medical (CM) schools, that for basic medical sciences we used the same texts used by CM schools, that we had overlapping administrators and instructors with CM schools, that we were covered by malpractice insurance to the same extent and by the same insurers as by our CM counterparts and that we were trained as primary care providers and designated as such by our State Secretary of Health, we should be incorporated into the various products marketed by the health plans on a "level playing field" with our CM counterparts. We recommended the following:

1) Direct access by patient choice to naturopathic medical services provided by licensed naturopathic physicians who function as PCP's, and
2) Reimbursement for those services equal to CM, based exclusively on CPT (procedure) codes, for all ICD-9-CM (diagnostic) codes, for all care provided within our licensed scope of practice.

We have attained direct access by patients to our services and comparable reimbursement from two of the largest health plans in the State of Washington. Other major health plans

have created obstacles for patients to naturopathic medical care and to equal reimbursement in four ways:

1) By limiting patient access to care to a restricted list of diagnoses; and
2) By limiting patient access to services rendered to an amount not to exceed a specified dollar cap (typically $500/year) of the combined value of services of all "CAM" providers; and
3) By limiting access to care by a requirement that the patient must be referred to a naturopathic physician primary care provider (PCP) by a CM PCP; and
4) By limiting patient access to a narrow panel (aka "network") of providers, in some instances administered without any discernible peer review oversight.

The naturopathic PCP and primary prevention model, in which as a licensed profession we have been schooled continuously for nearly a century, has been popular, efficacious and cost-effective here in the Northwest. It should be replicated throughout the United States. Additionally, it is recommended to the Commission that:

1) All licensed, accredited CAM services be reimbursable by all federally funded programs, and
2) CAM services be required to be delivered by providers degreed in accredited CAM programs, and
3) Funding be made available to form inter- and intra-disciplinary CAM peer-review committees, convened to advise insurers, regulators, hospitals and other entities. Such committees would then
    a) Make profession-specific recommendations and determinations regarding medical necessity, and
    b) Make profession-specific recommendations and determinations regarding utilization, and
    c) Orchestrate funded, profession-specific guideline writing.
4) Funding be made available to assure access to residency training for all CAM Professions.

I encourage the Commissioners to make these recommendations to the Congress and regulatory agencies at the national level, thereby helping all Americans enjoy the benefits residents of Region X enjoy: Reimbursable access to the licensed, credentialed, accountable health care providers of their choice.

Naturopathic physicians are educated to the same standards as CM providers in fully accredited naturopathic medical schools. Their health care services are an underutilized national treasure especially as our population is aging, and should be part of the solution set to heal an ailing national quality of health and an ailing national health care system. Thank you for the opportunity to submit testimony. Please feel free to contact me for clarification.

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Milliman testimony: Footnotes

(1) Milliman, W Bruce. Childhood immunity-review article. J. Naturopathic Med. 1994;5(1):44-50.

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(In press; to be submitted upon publication). Demographic, Training and Practice Characteristics of Licensed Acupuncturists, Chiropractors, Massage Therapists and Naturopathic Physicians in Four States.

(2) See Washington State RCW18.36A for scope of practice of naturopathic physicians; see "Issues in Coverage for Complementary and Alternative Medicine", January 2000, page 29 (published by the Washington State Office of the Insurance Commissioner) for the text of the "All Category" law, RCW 48.43.045.

#34

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ASSIMILATION VS INTEGRATION

Frederick W. Bomonti, D.C.
Presentation before:
White House Commission on Complementary and Alternative Medicine
Seattle, WA
October 30, 2000

Thank you for the opportunity to speak today. My name is Fred Bomonti, I am a chiropractor and I have been in private practice for over 30 years. I had the good fortune, or the bad fortune, to be in training and begin practice as the AMA began its organized effort "to contain and eliminate the chiropractic profession". I have been an observer of the assimilation of osteopathy by the allopathic profession and now the beginning assimilation of the other vitalistic professions, including my own.

To "maximize the benefits to Americans of complementary and alternative medicine" it is important, in my opinion, that we understand that allopathic medicine and the, so called, complimentary and alternative (CAM) professions are not and cannot be considered by the same standards. They are two different paradigms of health care with a common focus. That focus, the health of a human being. Allopathic medicine has a history and a focus of treatment and prevention of disease by attacking the disease to preserve life. It is the offensive unit. Alternative medicine has a history and a focus of treating people, promoting health, to increase the quality and span of life. We could call it the defensive unit. Both viewpoints are valid and are the "flip-side" of each other. Both are necessary. Procedures of each can be used "offensively" or "defensively". One is "vitalistic", promoting the innate, inborn, healing ability of the body, and one is "atomistic", promoting the "scientific" imposition of treatment on the body.

For the past 100 years the mechanistic, atomistic, philosophy of health care, represented by the allopathic profession, has been the dominate political force in the U.S.A.. It has

ruthlessly attempted to stifle, crush, eliminate, assimilate or destroy all opposing viewpoints for its own maintenance of power. This attempt continues today. Without acknowledging the political conflict of interest and the lack of objectivity brought by our various backgrounds of training we will not get an objective analysis of the potential benefits of the so called "CAM professions". The focus will be on the "atomistic" philosophy remaining in power, or from the "vitalistic" side, "what do I have to do to survive?". Until we recognize that the "maximizing benefits to Americans", or maximizing the health of people, is our overall purpose, not perpetuating a particular political point of view, we will not be able to obtain those maximum benefits.

In other words, the integration of members of the recognized, accountable healing modalities, on **their** terms, into the mainstream health care system, can improve the health of individual human beings and thus society. Assimilation of CAM procedures by members of the allopathic community and calling it "alternative" will do nothing but continue the present insanity we call health care. Insanity being defined as, "Doing the same thing over and over again expecting a different result". I believe it was Einstein who said, "The same mind that created the problem, cannot solve the problem". It is incumbent upon all professions to focus on the person, not the method. The goal, health, not the one who gets the credit.

To accomplish this the, so called, "alternative" professions must be judged according to their own vitalistic standards, not by the standards of the allopathic "atomistic" professions. These standards are based on measures of health, not disease. Quality of life, not merely existence. It is accepted, however, that standards and metrics must be in place and each profession must be held accountable to those appropriate standards.

The practice of CAM procedures by unqualified members of the allopathic professions, who go to a few weekend courses or learn from being treated a few times, must not be allowed to continue. Certification by allopathic licensing boards of CAM procedures must stop. A team effort with mutual respect for each others abilities and each others limitations must begin. Recognizing that each point of view has a right to exist, that neither is "wrong", and that together we create **A** way (note - not "the way") for the people we serve to improve the quality and duration of their lives, is the most important first step we must take.

In closing, with all due respect and with sincere appreciation of the apparent intent and personal integrity of the fifteen people who are on this commission, I must state, that given the past, I do not hold much hope that anything more than a small possibility exists that anything will change as a result of this process we have begun. To make any substantive change will require each of you to become more than who you were when you were appointed to this commission, as distinguished as that may have been, and to overcome not only the obvious politics of Washington, D.C., but to rise above our own personal belief systems and professional, tribal, politics to focus on how all of us can become a team for our common purpose. I wish you well and support you in that quest.

Thank you for your time.

#39

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

I am the clinical director of alternative services at Group Health Cooperative. Group Health is a consumer-governed HMO which was founded in 1947 and provides prepaid comprehensive, coordinated care to approximately 590,000 enrollees in the state of Washington. We are the largest consumer governed healthcare system in the nation. Since 1996 most of our consumers have had access to a program of covered CAM services, and my comments today reflect what we have learned in the last 4 years. I will briefly discuss 3 assertions and make several recommendations.

The first assertion is that consumers value CAM services and are looking to their conventional medical providers to guide them. That they value CAM does not need much elaboration, as it's the primary reason we are all gathered in this room today. But they are being bombarded with information that is often confusing, inaccurate or incomplete, and they want their conventional providers to be able to give them objective, reliable information. These providers need help in order to fulfill these expectations.

My second assertion is that health care systems and mainstream medical training facilities need to take primary responsibility for initiating the dialogue with CAM professions. In the face of an ageing population, marked increases in chronic conditions and rising dissatisfaction with conventional medical care it becomes obvious that no one system of care can provide all the answers. Taking the initiative will become easier once our experience in Washington has been thoroughly analyzed and broadly disseminated.

Assertion 3: collaboration precedes integration. There is far too much focus on the goal of integrated medicine without enough focus on how to get there. True integration requires major behavioral changes on the part of both CAM and conventional providers. This degree of change does not occur quickly and will require collaboration at multiple levels: At the most basic level patients and their conventional providers need to be comfortable talking to each other about CAM. Another level involves leaders of conventional and CAM professional organizations dialoguing with one another and being able to find common ground, such as the Clinician Workgroup on Integration and now the King County 2010 initiative. Most importantly, training institutions need to find ways to collaborate with each other. Within the greater Seattle metropolitan area are premiere training institutions for conventional medical professionals, naturopathic physicians, acupuncturists, massage therapists and licensed midwives. We have barely begun to mine this richness of resources.

Recommendations:

- Establish a clearinghouse for all CAM related articles published in peer reviewed scientific journals which would be easily accessible to all medical professionals (for example, an internet site with monthly updates)
- Work with the FDA or other appropriate agency to develop mandatory manufacturing standards for producers of herbal products
- Support efforts of CAM professions in guideline development, benchmarking and practice profiling
- Encourage conventional medical schools to require at least one course about CAM including observation of CAM practices and personal experience
- Encourage CAM training institutions to teach their students fundamental skills needed to work with health plans such as coding, billing and documentation standards.
- Fund analysis and dissemination of currently existing cost and utilization information to guide health plans contemplating CAM coverage
- Finally, involve consumers (including skeptics) at all levels of information gathering and decision making

Thank you for this opportunity to speak.

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