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Agenda – Topic II

Divider Title: _____

White House Commission on Complementary and Alternative Medicine Policy

Meeting Site: Academy for Educational Development
1825 Connecticut Avenue, N.W., Academy Hall, 8th Floor
Washington, DC

May 15-16, 2001

AGENDA II

DAY TWO: TUESDAY, MAY 15, 2001

Meeting Topic II. Complementary and Alternative Medicine: Research Challenges

12:30 p.m. **Opening Remarks**

- *Dr. James S. Gordon, M.D., Chair*
  White House Commission on Complementary and Alternative Medicine Policy

12:40 p.m. **Panel Session I: Overview of CAM Research Challenges**

20. *David Eisenberg, M.D.*
    Harvard University

- Discussion

1:25 p.m. **Panel Session II: Foundation Support for CAM Research**

21. *M. Bridget Duffy, M.D.*
    Medtronic Foundation

22. *Doriane C. Miller, M.D.*
    Robert Wood Johnson Foundation

23. *Susan Braun*
    Susan G. Komen Breast Cancer Foundation

24. *Ronald Chez, M.D.*
    Samueli Institute for Information Biology

- Discussion

2:35 – 2:50 p.m. **BREAK**

2:50 p.m. **Panel Session III: Approaches to Evaluating Research Literature**

25. *Donald A. Lindberg, M.D.*
    National Library of Medicine, NIH

26. *Douglas B. Kamerow, M.D., M.P.H.*
Agency for Healthcare Research and Quality

27. *Brian Berman, M.D.*
University of Maryland

◆ Discussion

4:10 p.m. **Panel Session IV: Concerns about CAM and CAM Research**

28. *William M. London, Ed.D., M.P.H.*
National Council Against Healthcare Fraud

29. *Simeon Margolis, M.D., Ph.D.*
Johns Hopkins University

30. *Arthur P. Grollman, M.D.*
State University of New York at Stonybrook

◆ Discussion

5:30 p.m. **ADJOURN**

DAY THREE: WEDNESDAY, MAY 16, 2001

7:30 a.m. **Registration Opens**

Meeting Topic II. Complementary and Alternative Medicine: Research Challenges (continued)

8:00 a.m. **Panel Session V: Research Methodology**

31. *John A. Chabot, M.D.*
Columbia University

32. *Marcia Angell, M.D.*
Editor-in-Chief, Emeritus, New England Journal of Medicine

33. *Jennifer Jacobs, M.D., M.P.H.*
American Institute of Homeopathy

34. *B. Alex White, D.D.S., Dr.P.H.*
Kaiser Permanente Center for Health Research

35. *Bruce Rabin, M.D., Ph.D.*
University of Pittsburgh

◆ Discussion

9:25 a.m. **Panel Session VI: Training of Conventional and CAM Investigators**

36. *Nancy Pearson, Ph.D.*
National Center for Complementary and Alternative Medicine, NIH

37. *Neal West, Ph.D.*
National Center for Complementary and Alternative Medicine, NIH

38. *Robert H. Blanks, Ph.D.*
University of California at Irvine

39. *Russell Phillips, M.D.*
Harvard University

40. *Richard Hammerschlag, Ph.D.*
Oregon College of Oriental Medicine

◆ Discussion

10:35–10:50 a.m. **BREAK**

10:50 a.m. **Panel Session VII: Publication of Peer-Reviewed CAM Research Results**

41. *Edward W. Campion, M.D.*
New England Journal of Medicine

42. *Jackie C. Wootton, M.Ed.*
Journal of Alternative and Complementary Medicine

43. *Phil B. Fontanarosa, M.D.*
Journal of the American Medical Association

44. *David Riley, M.D.*
Alternative Therapies in Health and Medicine

45. *Christine Laine, M.D., M.P.H.*
Annals of Internal Medicine

46. *Arnold Relman, M.D.*
Editor-in-Chief, Emeritus, New England Journal of Medicine

◆ Discussion

12:30–1:30 p.m. **LUNCH BREAK**

1:30 p.m. **Breakout: Small Group Discussion (CAM Research Challenges)**

2:50 p.m. **Group Reports and Discussion/Adjourn Meeting Topic II**

4:00 p.m. **BREAK**

4:15 p.m. **Public Comment Session: 3-Minute Oral Statements**

47. James Sensenig, American Association of Naturopathic Physicians
48. Candace Campbell, American Preventive Medical Association
49. Diane Davis Cole, University of Virginia Cancer Center
50. Katherine Jane Gorton, American Dietetic Association
51. Audrey Di Maria, Art Therapy Credential Board
52. Judy Simpson, American Music Therapy Association

◆ Discussion

53. Richard Goldberg, Private Practice
54. Nancy Kristine Haller, Feldenkrais Guild of North America
55. Christina Herlihy, National Certification Commission for Acupuncture and Oriental Medicine
56. Su Liang Ku, Florida Institute for Traditional Chinese Medicine
57. Sharon Stevenson, National Center for Homeopathy

◆ Discussion

58. ~~Barbara Moquin, National Navel Medical Center~~
59. Matt Ward Russell, National Integrative Medicine Council
60. Carolyn Jones Sabatini, Pharmavite Corporation
61. Christina Walker, The Shenk Human Energetic Institute
62. Alan Dumoff, Private Practice

◆ Discussion

5:30 p.m. **MEETING ADJOURN**

White House Commission on Complementary and Alternative Medicine Policy

Meetings on
CAM: Understanding Coverage and Reimbursement
CAM: Research Challenges

May 14-16, 2001

Academy for Educational Development, Washington, DC

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Recommendations

Divider Title: _____

Summary of Major Themes and Recommendations from October 5-6, 2000 Research Meeting

The following themes and recommendations drawn form the October 5-6, 2000 meeting on research have been placed under the panels in which they were discussed.

However, you will find considerable overlap of the issues and recommendations from panel to panel. Multiple panels may include references to research, research training, integrative academic centers, regulatory agencies, foundations, the private sector, and so forth.

Please keep in mind this list of themes and recommendations and the presentations and discussions from the May 15-16 research meeting when you discuss key issues and recommendations during your breakout sessions on the afternoon of May 16.

Panel I: Research Priorities and Public Input

The IOM recommendation to increase the public's voice in the NIH priority setting process can serve as a model for public input into the process of developing recommendations for CAM policy setting.

Encourage CAM practitioners to work within the current research system and aspire to the rigorous, blinded, randomized studies that are the gold standard, recognizing the ways by which reliabel, objective data on health and medicine may are obtained, such as observational data, pilot studies, case studies. **(Leon Rosenberg, Institute of Medicine, IOM)**

Encourage the NIH to expand its portfolio of clinical research with efforts that answer questions concerning modalities that are not going to be patentable and that will not have their research paid for by biotech or pharmaceutical or drug device industries. **(Leon Rosenberg, IOM)**

In addition to full support for NIH, a remarkably successful Federal research agency that has served the public so well, fund related Federal agencies, such as CDC, FDA, HRSA and others, adequately so that they may carry out their public health mandates, and include CAM-related activities as part of their mandate.

Panel II: Federally Funded CAM Research

One of the biggest hurdles facing CAM is opening up dialogue and collaboration with conventional practice and conventional clinical research. CAM practitioners interested in research must make their voices heard more strongly. Sponsor interdisciplinary workshops and conferences. Invite CAM practitioners and researchers to serve on interdisciplinary advisory groups and sit on committees.

The RCT is the preferred method of clinical study and can be applied successfully to some CAM questions. However, traditional clinical trials may not be very informative about the efficacy of many CAM treatments. CAM research questions are hard to validate. Some CAM regimens are difficult to study because they are complex, individualized, lack uniformity, and are hard to generalize. It is difficult to acquire preclinical information on many CAM patients. Survival as the endpoint may not apply to CAM treatments. Many CAM modalities are not presently reimbursed by Medicare.

NIH Institutes interested in studying CAM modalities may face a lack of validated data and reluctance of established investigators to do the research. To encourage established scientists to address CAM questions, define a measurable research question and explore ways of obtaining pre-clinical data . In developing protocols, there are methodologies other than the gold standard to employ. If necessary, the challenge exists to develop new ways of pursuing the question.

Define the types of questions that are and that are not appropriate for RCTs. Identify the

appropriate methodology for the type of (scientific) question being asked.

Develop alternative investigative methods for studies where there is concern about using a placebo as a standard part of the technique. Because of the risk of using uncertain measurement techniques to study untested CAM approaches, a grant should be announced to bring together experts with broad experience and interest in research methodology to explore, in a think tank effort, with CAM practitioners and trained researchers possible scientific approaches to various types of questions.

Many CAM practitioners are unfamiliar with research techniques and requirements. The lack of trained CAM investigators is a significant problem. Funds must be made available to train people interested in CAM. Fund and plan workshops to enhance communication and awareness in both communities, and to offer guidance on how to prepare grant applications and obtain grant funding. Promote research partnerships with CAM practitioners and researchers.

Increase funding for research, training, and infrastructure at CAM research institutions, and open doors to cross training and collaboration between conventional and CAM institutions.

Quality research leads to credibility and credibility leads to acceptance and integration of services. There needs to be a paradigm shift to respect the modality under study, and research training programs for clinicians, through academic partnerships, that allow them to stay in practice and become familiar with the clinical environment and clinical outcomes research.

Federal efforts in CAM are expanding. CAM research now has funding, better peer review, and credibility at NIH. There is still a need for research infrastructure and training at CAM centers. FDA policies and procedures also must address CAM issues.

The social sciences and behavioral sciences are receiving more recognition, and more attention is being paid to promoting health and preventing disease. CAM approaches contribute to general health and wellness. Opportunities to study these approaches to improve quality of life should be encouraged. CAM helps to envision what the future in medicine will be, especially given an aging society suffering with chronic illnesses, and a need to strengthen health maintenance in younger people.

There is overlap between CAM and conventional medicine in areas such as nutrition, analysis of plant and animal products, mind-body medicine, pain control and palliative care. Nutrition and prevention were once disregarded by conventional medicine; now they are becoming standard. Patients who suffer from chronic diseases like low back pain and arthritis often turn to CAM.

Encourage strengthened support for NCAAM and its collaborations with other NIH Institutes, the NCI best case series program, and the ODS, which is supporting such studies as the synergistic properties of blended compounds. Also support Federal funding for clinical research on nonpatentable modalities.

An important challenge is finding a way for the CAM community to work with the medical establishment. CAM needs to strengthen its reputation and reach out to people in conventional medicine who can make a contribution.

The absence of common and consistent definitions of CAM contributes to problems in communication.

Develop strategies to increase CAM cancer research needed to address the range of challenges—e.g., difficulty in establishing uniformity, complexity of individual regimens, difficulty replicating treatments in clinical settings—posed by the nature of the field. **(Jeffrey White, National Cancer Institute, NCI)**

More fully examine the potential of CAM's whole-patient approach to improve the quality and perhaps quantity of remaining life for cancer patients. **(Jeffrey White, NCI)**

Expand CAM research in ways that access the resources of the larger and more research-savvy conventional community. **(Jeffrey White, NCI)**

Provide resources to bridge the "two culture problem." Opportunities and resources are needed to foster communication and collaboration between CAM and conventional practitioners and researchers. Inherent problems in CAM clinical research, difficulty in standardizing interventions, culture problems between practitioner and research communities, general awareness about CAM, can be resolved by building appropriate interdisciplinary collaborations **(Jeffrey White, NCI)**

Use existing mechanisms of federal research support to train CAM practitioners areas in conventional research methodologies. **(Steven Hausman, National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIAMS)**

Look at low back pain as a vast potential opportunity for the integration of conventional and CAM modalities. **(Steven Hausman, NIAMS)**

Study the placebo effect more rigorously. **(Steven Hausman, NIAMS)**

Discourage rules barring Medicare payments for things Medicare does not normally cover, including many complementary and alternative modalities, which pose a significant obstacle for getting elderly people on Medicare to participate in CAM trials. **(Steven Hausman, NIAMS)**

Invite the public to give their views in setting CAM research priorities. **(Steven Hausman, NIAMS)**

Encourage research into dietary supplements to be evidence-based and structured like other medical research. **(Paul Coates, Office of Dietary Supplements, ODS)**

Support dietary supplement research activities that engage partnerships between research organizations, non-profits, and private industry with common interests in the field to help merge the sometimes conflicting impressions that (a) evidence supporting traditional CAM falls outside the American medical paradigm and should be ignored and that (b) traditional products don't need to be evaluated because of their long traditions of use. **(Paul Coates, ODS)**

Increase the number of workshops and conferences that focus on interdisciplinary approaches to medical research as a way of increasing the share of the research pie that goes to CAM activities. **(Paul Coates, ODS)**

Panel III: Academic Centers and Support for CAM Research

Encourage Federally-funded universities to develop programs that bring CAM clinical research into the academic health centers working with CAM practitioners/researchers. Create interdisciplinary collaborations with CAM institutions to develop research capability.

Increase the publication of valid CAM research findings in major medical journals and increase the readership of quality CAM journals. Lack of coverage limits further study

Increase awareness of physicians regarding CAM therapies their patients are using to avoid adverse reactions.

Create a steering committee that understands CAM to advise IRB's on applications they may not fully appreciate. **(Alfred Fishman, Penn)**

Integrate complementary and alternative therapists into the educational curriculum in places where it is appropriate to consider them. **(Alfred Fishman, Penn)**

Sponsor a meeting with a critical mass of people at institutions engaged in CAM research who want to exchange ideas. **(Alfred Fishman, Penn)**

Address the issue of a fundamental lack of research orientation in CAM institutions by partnering with institutions that have a research focus. **(Alfred Fishman, Penn)**

When creating a new CAM division, engage people with real opposition to the idea in the planning panel. **(Daniel Federman, Harvard University)**

Refrain from disparaging good, well-written anecdotes. Recognize that anecdotes are appropriately the precursor to rigorous scientific research. (**Daniel Federman, Harvard University**)

Connect CAM with existing institutional strengths by granting programs cooperatively. (**Daniel Federman, Harvard University**)

Develop an interdisciplinary, multi-disciplinary, interprofessional research agenda that employs social, clinical, and basic sciences, to integrate CAM and conventional medicine. (**William Meeker, Palmer College of Chiropractic, PCC**)

Train CAM scientists. Provide programs, incentives, pre and post-doc positions and career tracks for capable and interested young people. (**William Meeker, PCC**)

Create ways to encourage interdisciplinary, multidisciplinary and inter-professional collaborations between CAM institutions and tax-supported universities. (**William Meeker, PCC**)

Apply the entire universe of research project and program funding mechanisms to initiate, encourage and support CAM research, including bricks and mortar. (**William Meeker, PCC**)

Call for interdisciplinary conferences to explore scientific states-of-the-art on CAM topics and establish rigorous research agendas. Support the agendas with targeted research funding program announcements. (**William Meeker, PCC**)

Encourage the National Library of Medicine to include CAM topics and references in its indexing systems. (**William Meeker, PCC**)

Establish academic CAM clinical centers. (**William Meeker, PCC**)

Support CAM training institutions in the broadest possible sense, like all other health professions, in order to eliminate the dependence on tuition and provide the resources to develop a more effective and consistent research culture. (**William Meeker, PCC**)

Ensure that CAM professionals are routinely appointed and otherwise included in research policy making efforts. (**William Meeker, PCC**)
Consider something similar to the Centers of Excellence program in HRSA's Bureau of Health Professions to help jumpstart the research efforts of CAM professions and their institutions. (**William Meeker, PCC**)

Develop training programs and career tracks, so that people that have a natural inclination in this direction see that they can have a job and a career doing it. That has not existed in the CAM profession so far. (**William Meeker, Palmer College of Chiropractic**)

Panel IV: Research Support and Collaborations

Promote preclinical studies that look at mechanism behind a CAM intervention at the same time as studies on safety and efficacy and not merely pursue whim and anecdote. **(Stephen Straus, National Center for Complementary and Alternative Medicine, NCCAM)**

Reinforce the fact that science is a process not a philosophy. Support basic science and clinical science and encourage advocacy organizations, industry, and the broad sweep of the American public to get behind asking questions critically and credibly. This will serve the public well. **(Stephen Straus, NCCAM)**

Panel V: Facilitating CAM Research and Regulatory Challenges

If a substance affects the structure or function of the body and is used to treat or mitigate disease, it is considered a drug, including dietary supplements. The intended use dictates the category. A product can be marketed as a dietary supplement, but cannot make the drug claim. The product that is shown to be clinically effective no longer has to play the label game–an advantage to consumers and manufacturers.

A barrier to CAM research is the fact that the drug development system was set up for synthetic drugs and the regulatory framework is tailored to them.

FDA has published guidelines on how to study botanicals and deal with the approval process. The guidance urges people to consider doing controlled trials and emphasizes the importance of gathering substantive information early on. If a product has been marketed as a supplement or has been used as a drug in other countries and the experiential data have been collected, that information could form the basis for conducting a clinical trial.

Regulatory changes in combination-product regulations, as identified by the FDA, could promote CAM research on botanicals. The FDA document is a good start, but takes the single chemical entity paradigm and overlays it with botanical requirements.

A hurdle for CAM is the FDA expectation that new drugs will be characterized by their criteria, including botanicals. The testing of complex substances is often difficult and additional chemistry and manufacturing standards might be required. Substances that are not plants might also be considered drugs and the same reasoning applied to them. Getting a botanical into a clinical trial is easy, but to move further, the botanical must meet every standard that a chemical entity must meet. Also, FDA will need additional staff with the appropriate background to evaluate the human research data.

FDA is prepared to provide assistance and guide people through the steps. People who submit INDs can get advise through the pre-IND program. FDA can help small and new businesses through the process. Small manufacturers can request a user-fee waiver, similar to orphan drug

product waivers.

More funds are needed to adequately address integration of CAM products into a broader regulatory process, including staff positions to assist people not experienced in drug development. Staff well-versed in CAM spend their time reviewing synthetic drugs. A core team should be created that deals with CAM and has connections to the outside community. The work is labor intensive and there is no formal process for assigning resources except as Congress dictates.

Regulation should foster and direct development of good data. When regulators look for excessive data up front, they drive away good products and freeze research. The ongoing debate over regulation is encouraging.

Is there a way to allow previous human experience to count? Are changes needed in the regulations? Because it is costly to bring a substance to FDA's attention, how do we stimulate funding from the private sector, which is motivated by the profit motive. Without patent protection, manufacturers will need some form of regulatory exclusivity.

Few devices require approval; there are no separate classifications for CAM devices. Devices such as copper bracelets and similar products should have a process for submission of evidence but do not, despite the fact that they make a claim. A CAM practitioner often promotes new uses for an old device. Advertising is regulated by the Federal Trade Commission.

Congress has made the medical technology industry more responsible for the quality of their products. This has been a key component in fostering innovation, because it bolsters consumer confidence. However, bioengineering is not well funded.

FDA's goal is to fully implement DSHEA; maintain a high level of competence in labeling; and follow a science-based regulatory approach. New dietary ingredients will have to come to FDA prior to marketing. The Center has a very small staff to devote to this program and until resources are adequate, progress will be incremental. DSHEA allows a claim to be made based on evidence, without great cost. It also promotes better labels and better third-party information.

A permanent natural products OTC panel should be established, rather than using ad hoc experts, to make decisions about safety and efficacy and to allow stronger claims. This would upgrade DSHEA, and would result in a panel of experts focused on natural product health care.

FDA should allow elimination of the disclaimer on a DSHEA label if a certain level of proof is reached.

The Commission on Dietary Supplement Labels recommends setting up monograph equivalents for botanicals, setting the standard for making claims.

Botanicals, which have potential beyond over-the-counter products and the DSHEA marketplace, test the law because they are manufactured like a biological under heavy process control, sold as a food or dietary supplement by Congressional fiat, and used as therapy by the public.

There should be more focus on folk medicine, which has been used widely, but does not fall within the DSHEA model. Good anecdotal information should be considered.

There should be more international outreach and access to European safety data. Better information systems would be helpful.

Because it is difficult to give exclusive rights for substances used for many centuries, natural products research has shut down and FDA has approved very few preventive medicines.

Submit comments related to new guidelines, Botanical Drug Products, designed to open the door for the study of traditional botanicals without the barriers that currently exist, which are designed for synthetic drugs. **(Janet Woodcock, FDA, Center for Drug Evaluation and Research)**

Provide input on proposed changes in combination product regulations, which were originally written for purified drugs and are being revised to help botanicals move through the approval stage more quickly. **(Janet Woodcock, CDER)**

Provide additional resources to assist small companies to get through the FDA drug review. **(Janet Woodcock, CDER).**

Encourage the FDA to promulgate additional chemistry and manufacturing standards to accommodate the reproducibility and stability and constant dose issues raised by plants.**(Janet Woodcock, CDER)**

Create a place in FDA with sufficient staffing that could work with groups at various levels to assess the appropriate classification of botanicals as treatments. **(Janet Woodcock, CDER)**

Define the safety standard for dietary supplements. As yet, the law is silent on the question of their benefits, and only speaks to their safety, though what degree of safety and confidence is still being determined. **(Joe Levitt, Food Center at FDA)**

Panel VI: Research in the Regulatory Framework

State medical boards protect the public from unqualified physicians. Some CAM practices lack scientific validation. Three areas of harm are outlay of money on ineffective treatments, delay in seeking appropriate care, and direct harm. Guidelines are being developed to educate and regulate all physicians. Regulators must have solid information about interventions and research on effectiveness. If chelation is effective, medical boards should hold doctors responsible for not using it. If not, physicians who use it should go before the state medical boards. Medical boards

do not want to create barriers to legitimate research, but their first priority is public safety. Once the Federation establishes a process, the states pick it up.

The Federation of State Medical Boards should consider a process for state medical boards to meet with CAM practitioners who want to conduct research but whose treatments are considered nonstandard or fraudulent by the state.

A practitioner who goes through an IRB, may need help in navigating the process.

Include CAM practitioners as members or consultants on state medical boards. Also, IRBs and study sections should include panelists familiar with CAM.

CAM practitioners who believe in practice-based research need an environment that allows for thinking outside of the box and the development of new methodologies. There is precedent for waiving the gold standard. FDA did it for interleukin-2 based on a pilot study. Changes need to be made so that medical boards work with and not against people trying to validate their procedures.

Lack of insurance reimbursement, fear of losing one's license, lack of time and money, and bias in the system stand in way of moving ahead with research. Most people cannot be both a clinician and researcher. Many clinicians have data on which to build, but do not want to hand it over for fear of what is going to happen to them. More needs to be learned about these problems, while preserving the goal of protecting the public.

Include in the guidelines for fraudulent and deceptive practices those guidelines standards for assessing the work of a non-institution based physician who is engaged in research. **(James Winn, Federation of State Medical Boards, FSMB)**

Include on medical boards CAM consultants to assist in their evaluation of cases and any kind of complaint that comes forward. **(James Winn, FSMB)**

Invite patent lawyers to address the issue of exclusive rights to botanical extracts. . **(Floyd Leaders, Botanical Enterprises, Inc.)**

Rather than bring foreign plants to the US for research, work in a partnership within that country. **(Floyd Leaders, Botanical Enterprises, Inc.)**

Allow the elimination of the disclaimer on a DSHEA regulated label if a certain threshold of evidence is achieved, or give it over-the-counter drug status. **(Robert McCaleb, Herb Research Foundation)**

Increase the focus on traditional medicine, recognizing that DSHEA leaves that out. **(Robert McCaleb, Herb Research Foundation)**

Develop ways to look at historical information on herbs and using this information in the evaluation of their efficacy and safety. **(Robert McCaleb, Herb Research Foundation)**

Facilitate international outreach in terms of accessing the information from European and Asian clinical practice. **(Robert McCaleb, Herb Research Foundation)**

Cut through the maze of information and try to get information, especially for consumers and practitioners that is quality evaluated, so people can trust the information and utilize in their decision-making process. **(Robert McCaleb, Herb Research Foundation)**

More funding is needed for libraries and collaboration to utilize the resources that are currently untapped. **(Robert McCaleb, Herb Research Foundation)**

Appoint a panel of experts, who are really specifically focused in this area of natural product health care, to look at the evidence on herbs and make decisions. **(Robert McCaleb, Herb Research Foundation)**

Adequately fund alternative medicine research centers so that they can collaborate with orthodox medicine. **(Anthony Rosner, Foundation for Chiropractic Education and Research, FCER)**

Address anti-chiropractic sentiments in the composition and proceedings of institutional review panels and boards. **(Anthony Rosner, FCER)**

Require an equitable number of individuals within each study section of a grant proposal, who are familiar with and sensitive to the conduct of CAM therapeutic regimes to be tested. **(Anthony Rosner, FCER)**

Place far greater emphasis on cohort studies and case series in reaching research goals rather than to assume categorically that they provide inferior guidance to the clinical decision-making than RCTs. **(Anthony Rosner, FCER)**

Panel VII: Outcomes Research Part I – Interface between CAM Research and Regulatory Agencies

The NCI best case series program is dependent on practitioners feeling comfortable giving documentation of their practices to the federal government. Changes in regulation need to be explored to change the regulations so that best case series can become more productive.

Some very excellent researchers have had difficulty getting INDs. Perhaps NIH research Institutes, such as NCI, could establish procedures to explore this concern with the FDA.

Develop a forum for alternative practitioners or scientists who believe they are being harassed unfairly.**(Nicholas Gonzalez, Private Practice)**

Use the threat of cuts in Medicare or Medicaid funding to force the states to protect new ideas.(**Nicholas Gonzalez, Private Practice**)

Use health departments to identify the top 35 public health problems in the United States and aim therapies at them, also see what is working in clinical settings and use that evidence as a starting point for understanding why. (**Ann McCombs, Private Practice**)

Explore how regulation could help the Best Case Series program become more productive since some CAM practitioners are not willing to come forward because they feel they need to practice in secret. (**Jeffrey White, National Cancer Institute, NCI**)

Learn more about problems with getting INDs for certain herbal products and the effect that is having on inhibiting some cancer research. (**Jeffrey White, NCI**)

Panel VIII: Private Sector Support for CAM Research

Develop a model for coordination of research between the Federal, private, and not-for-profit sectors.

Private industry should be encouraged to endorse coordinated research programs to transform medical science into products wanted and needed by the public. NIH should support more effective integration of Federal and private efforts. Incentives and intellectual property issues need to be resolved to allow for marketing protection, as well as appropriate regulatory pathways

Nature has been a fruitful source of new medications. The largely empirical screening methods of the natural product-derived drug discoveries have fallen into disfavor, viewed as labor-intensive and unproductive. DSHEA is allowing fresh interest in plant medicine. Impending changes in the regulation of botanical drugs could stimulate more development and research. Botanicals must be evaluated by the highest standards. The level of investment in this area needs to be comparable to that of pharmaceuticals. The return on investment is an issue; corporations need protection for their work and incentives.

A primary obstacle is the lack of recognition of the benefits of herbs. The German regulatory system recognizes the benefits and half of the herbs sold in Germany are doctor recommended or prescribed. Much of European research was done on proprietary commercial products. Some European companies are concerned about their research being "borrowed" and used unfairly by competitors.

DSHEA has been a stimulus for herbal research and there are many examples of private sector funding by the herb industry. However, incentives are needed, such as rights to exclusivity claims and market protections. Modification of the dietary supplement disclaimer allowing removal from a product that has had some clinical study review should be considered, as well as tax incentives. FDA approval of structure/function claims could promote research. The

government should consider establishing an expert review panel to evaluate the safety and appropriateness of both the structure/function claims under DSHEA and as OTC drugs. Herbs do not qualify for composition-of-matter patents. Since the passage of DSHEA, some process and use patents have been granted, but use patents may not be able to withstand public domain and traditional use challenges. Trademark protection should be available as a motivator for research investment, and there should be a way to protect small companies.

Industry should also share information from incomplete studies in order to guide other efforts, provide substances for clinical trials, assist in the preparation of appropriate placebos, and offer industry-sponsored symposia with CAM practitioners. Products with defined standards should be used in studies, and industry should form partnerships with clinicians and academia and participate on NIH advisory panels.

Pharmaceuticals, OTCs, and herbals need to provide a competitive advantage; exclusivity is a major issue. Another concern is that a single study might not be accepted as sufficient. There are many intellectual property issues. The company has the ultimate responsibility for the safety of its product. FDA guidance will facilitate getting to Phase II trials. Depending on the size of the market, a process use patent would be a solid incentive.

FDA guidelines suggest that with a minimal preclinical package, moving some of these materials directly into Phase 2 studies might be possible, and instead of taking the individual components out of the plants, one can look at how the combination is working. However, there is the question of safety moving straight to Phase II. In some cases, safety documentation from elsewhere is strong, other times it is not.

Looking at the genomes of plants will eventually allow us to see what happens with the entire plant, and this is where corporate interests lie. Even when looking at health and wellness as a unified field, the cultural aspects are not for a company to determine, but rather fall to the provider.

DSHEA requires that the product deliver what the label says. Industry is about to undertake a third-party testing program. Companies will pay a licensing fee for periodic testing in return for receiving a seal.

The Federal government should compile a primer on funding mechanisms and make funding opportunities more visible. Hold a conference on completion of relevant studies and develop a database including privately-supported study results.

To overcome barriers, meetings should be held with journal editorial boards to solicit recommendations to increase acceptance of papers submitted by industry.

Involve companies up front in developing a system of appropriate regulation. **(Randy Burkholder, Advanced Medical Technology Association, AMTA)**

Provide incentives for developing CAM related medical devices with private or public reimbursement mechanisms. **(Randy Burkholder, AMTA)**

Facilitate research collaborations with private sector research organizations, and take advantage of such mechanisms as Small Business Innovation Research grants. **(Raymond Ruddon, Johnson & Johnson, J&J)**

Provide incentives for private industry's involvement in CAM research by resolving intellectual property issues through something akin to legislative exclusivity remedies like the Ortho-Drug program. **(Raymond Ruddon, J&J)**

Provide proprietary protection around the process, extraction, production, and use of unique mixtures or combinations of agents for single herbs. **(Raymond Ruddon, J&J)**

Expand communication between traditional and conventional medical experts. **(Raymond Ruddon, J&J)**

Increase the availability of private and federal funding for CAM research. **(Raymond Ruddon, J&J)**

Develop a rigorous review process involving both academic and industry scientists to evaluate scientific-merited CAM research proposals. **(Raymond Ruddon, J&J)**

Design discovery research projects in CAM using such tools as gene expression arrays or proteolytics to identify new bioactive substances in natural products and pharmacogenomics to individualize therapies. **(Raymond Ruddon, J&J)**

Address the anti-CAM bias in subsequent editions of Goodman and Gelman's, "Textbook of Pharmacology." **(Raymond Ruddon, J&J)**
Create incentives for the private sector to invest more substantially in research and development of natural medicines like a Waxman-Hatch type data or marketing exclusivity period that would allow the investor to fully develop the medical and commercial potential of natural medicines. **(Frank Sciavolino, Pfizer)**

Allow early access to Phase II trials to help lower attrition rates for new neutraeuticals and to reduce overall development costs. **(Frank Sciavolino, Pfizer)**

Explore the CDSL recommendation that label disclaimers mandated by DSHEA could be modified or removed if a botanical product met certain requirements for research. **(Mark Blumenthal, American Botanical Council)**.

Find a viable balance among free market and competitive issues, science, regulation, and the need to respect cultural heritage, and traditional use. **(Mark Blumenthal, ABC)**

Help promote research by making structure/function claims approvable by FDA, modifying the dietary supplements disclaimer following some clinical study review, allowing process and use patents for botanicals, providing tax credits for research funding. (**Mark Blumenthal, ABC**)

Establish an expert review panel similar to Commission E to evaluate the safety and appropriateness for claims for herbal products, both the structure/function claims under DSHEA and as OTC drugs. (**Mark Blumenthal, ABC**)

Encourage the CAM industry to submit its studies to peer review journals for publication and provide data from its unpublished studies to assist in selection of therapies for further study and to contribute to study design. (**Annette Dickenson, Council for Responsible Nutrition, CRN**)

Encourage the supplement industry to cosponsor symposia or conferences to provide networking opportunities between researchers and clinicians. (**Annette Dickenson, CRN**)

Convene meetings with journal editorial boards to solicit recommendations which would increase the acceptance of papers submitted by the supplement industry. (**Annette Dickenson, CRN**)

Encourage the supplement industry to generate a clinical trials guidance document outlining the standard components and proper design of study protocols. (**Annette Dickenson, CRN**)

Encourage the supplement industry to form partnerships with clinicians or academia, depending on the type of study. (**Annette Dickenson, CRN**)

Establish a special web site to facilitate communications regarding ongoing research needs and opportunities. (**Annette Dickenson, CRN**)

Develop a primer on funding mechanisms for research and conferences within government agencies that apply to industry should also be compiled to explain, for example, cooperative research and development agreements, small business grants, investor-initiated grants, and contracts. (**Annette Dickenson, CRN**)

Develop a document for industry use, explaining, how each research agency determines its research agenda. (**Annette Dickenson, CRN**)

Develop a government-industry partnership to conduct testing to confirm the safety of the product not simply in terms of lack of any knowledge of un-safety, but in terms of proactive, positive demonstration of lack of teratogenicity and for safety during pregnancy. (**Annette Dickenson, CRN**)

Give the FDA more enforcement authority to assure that products are what they are supposed to be. (**Annette Dickenson, CRN**)

Panel IX: Not-for-Profit Sector Support for CAM Research

Not-for-profit organizations can stimulate CAM research by providing seed money; supporting grants and publication of research, offering financial awards for medical school and research training; and convening conferences. The lack of awareness of existing research is a problem. The solution is publication of studies in peer reviewed journals. To increase funding and partnerships for CAM research, improve the rigor of proposed studies. Find incentives to stimulate mentors who can help develop new CAM researchers. Include studies on mechanisms of action and cost effectiveness, and fund conferences to review strengths and weaknesses of existing research and propose new, well-designed studies.

Productive partnerships should be created between Federal agencies and foundations that focus on communication and opportunities for collaboration. Each should host meetings and plan site visits to CAM research centers, where information about current research and the federal grant process is available. Agencies should seek more foundation representation on their panels, and include them on mailing lists. Foundations should stimulate CAM research by funding more small pilot studies, often a requirement for government funding, and by creating a pool of research funds among themselves to diminish risk.

Identify foundations interested in finding and supporting new, cutting-edge areas to research.

Some investigators are not affiliated with institutions, but both government and not-for-profit institutions usually do not support individuals. Should changes in not-for-profit law be recommended to permit grants to fund individuals? .

Improve funding access for CAM by improving the methodical rigor of proposed studies. (**John Templeton, Jr., John Templeton Foundation, JTF**)

Encourage new researchers in CAM therapies with mentors trained in scientific research. (**John Templeton, Jr., JTF**)

Develop better coordination between non-profit and federally supported CAM research by convening a jointly funded consensus conference to review in depth the strengths and weaknesses of existing research and propose new studies to build the science behind CAM. (**John Templeton, Jr., JTF**)

Because the scientific study of spirituality is in its infancy, and as spirituality is hard to define, I think it is important to try and pick some aspect of spirituality that a group that practices a certain type of spirituality embraces and then study their intervention. (**John Templeton, Jr., JTF**)

Promote a consensus conference to suggest ways of studying spirituality. (**John Templeton, Jr., JTF**)

Train medical students and residents to understand that it is appropriate to take a spiritual or religious history. (**John Templeton, Jr., JTF**)

Host introductory, face-to-face meetings and site visits among foundation people with representatives of existing CAM research centers currently funded by the NIH. (**Dyanne Hayes, Conrad N. Hilton Foundation**)

Be more aggressive in seeking opportunities for foundation representatives to participate on panels such as this to discuss their experiences and perceptions regarding CAM and CAM research. (**Dyanne Hayes, Hilton Foundation**)

Include foundations on mailing lists and publicize the those grants that do or have had public/private funding support. (**Dyanne Hayes, Hilton Foundation**)

Encourage foundations to be more willing to fund small pilot projects. (**Dyanne Hayes, Hilton Foundation**)

Encourage foundations interested in CAM research to create a pooled fund of monies and announce the competition for projects up to so many dollars. The collaborative would set up a scientific advisory board of reputable scientists knowledgeable in the area in which the proposals are being submitted. (**Dyanne Hayes, Hilton Foundation**)

Address the sense of separation between Eastern and Western cultures that pervades relations between the two communities. (**Dyanne Hayes, Hilton Foundation**)

Help the foundation community stay better informed on relevant symposia as well as what has been funded. (**Dyanne Hayes, Hilton Foundation**)

Conduct research on why people are drawn to CAM, what people who are drawn to it, what do they mean by what we say works, and what do they find satisfying about it that they don't find satisfying in the rest of medicine? (**Daniel Callahan, Hastings Center**)

Keep the discussion of Medicine as art and science alive. (**Daniel Callahan, Hastings Center**)

Utilize CAM as a lens to help us envision the future of medicine when an aging population with chronic ills will share the national stage with a younger population that will need to learn how to take better care of itself. (**Daniel Callahan, Hastings Center**)

Find some better ways of formalizing means of investigation other than randomized clinical trials in which one can have confidence. (**Daniel Callahan, Hastings Center**)

Develop a think tank that brings together research methodologists, not just people interested in CAM, to discuss the methodological problems of investigating CAM. (**Daniel Callahan,**

Hastings Center)

Encourage private philanthropy to fund CAM research to get things going to a point where federal funding, based on other criteria can be used. **(Daniel Federman, Harvard University)**

Develop a generally accepted definition of CAM to ensure the everyone is talking about the same thing. **(Teri Ades, American Cancer Society)**

Protect patient access to CAM, while providing oversight and accountability by governmental, public, and private entities that are needed to protect the public. **(Teri Ades, ACS)**

Support NCCAM and its stress on the importance of systematic and scientific approaches to studying various medicines, as well as the NCI's Best Case Studies program.**(Teri Ades, ACS)**

Support additional funding for mentoring programs that help those with promising therapies to collect quality data and take part in the necessary research. **(Teri Ades, ACS)**

Invest more efforts in understanding the limits of randomized clinical trials in CAM and in finding other research approaches that work better. **(Teri Ades, ACS)**

Rather than consider incentives, consider setting the expectation that all therapies must be proved to be safe and effective so the public does not have to question their therapy. **(Teri Ades, ACS)**

Have NCCAM serve as coordinator for a group of public, private, and governmental agencies convened to discuss how to better coordinate federal support for CAM research. **(Teri Ades, ACS)**

Panel X: Outcomes Research Part II – CAM Research and Experimental Design

Schools of Public Health are the ideal environment for CAM research. Many faculty are involved in CAM-related projects. Most of the schools of chiropractic health care have some course work in public health and chiropractors belong to the APHA. Their special interest section has been planning a syllabus in public health education for chiropractic colleges. A working group made up of schools of public health and chiropractic colleges will collect and analyze baseline data for developing a curriculum for future students.

Provide funding and trust-building for the Best Case Series Program. NCCAM funded centers could play a very important role in the Best Case Series Program by providing methodological support to clinicians **(Leanna Standish, Bastyr University)**

Create partnerships between CAM academic centers and CAM practitioners for developing Best Case studies, especially in the cancer area, and have that collaborative work be funded by the NCI. **(Leanna Standish, Bastyr University)**

Encourage institutional review boards to be flexible in assessing joint CAM/conventional medicine research efforts. **(Leanna Standish, Bastyr University)**

Have practitioners develop algorithms to describe the "if then" nature of CAM treatments and formalize them, to facilitate doing individualized therapy inside of a clinical study. **(Leanna Standish, Bastyr University)**

In assessing CAM, analyze a therapeutic approach that is not too refined and examine the entire system and include elements like lifestyle, exercise, plus the addition of dietary modification or we will miss the forest for the trees. **(Elaine Cramer, Center for Disease Control and Prevention, CDCP)**

Put together an integrated team of researchers from both the CAM and conventional communities who are open-minded practitioners, who are really willing to collaborate and randomize patients to CAM treatment arms as well. **(Elaine Cramer, CDCP)**

Use integrative research to study integrative medicine. The way to properly evaluate any outcomes is through a team-based approach using existing methods. **(Elaine Cramer, CDCP)**

To implement these strategies in a community setting, solicit proposals from integrated research teams which are comprised of both CAM and conventional practitioners who demonstrate the ability to collaborate on, not just the study design, but case definitions, the selection of exposures, and the designation of CAM and conventional treatment sites. **(Elaine Cramer, CDCP)**

Assign a research mentor not only to CAM practitioners who are interested in evaluating CAM therapies, but whoever needs research and who really needs some assistance with both protocol and study design development. **(Elaine Cramer, CDCP)**

Establish experienced research teams that are comprised of scientists, subject matter experts and send them out en masse to selected research sites to really expedite development and implementation of the protocols for CAM evaluation. **(Elaine Cramer, CDCP)**

Conduct clinical outcomes research on CAM to determine what is efficacious, what is effective, what is safe, and to give the patient a wider choice of treatment modalities. **(Lydia Segal, Kaiser Permanente)**

Develop research training programs for clinicians that allow them to stay in their practice, be it a mentoring program or a partnership with academic or government institutions, while bringing researchers into the clinical environment. **(Lydia Segal, Kaiser Permanente)**

Develop research designs to accommodate the patient specific nature of CAM treatments to make different treatments statistically comparable. **(Lydia Segal, Kaiser Permanente)**

Encourage collaborative research efforts between conventional and CAM academic institutions. **(Douglas Lloyd, Association of Schools of Public Health,ASPH)**

Panel XI: Federal Agency Support for CAM Research

Increase funding for other federal health agencies involved in CAM research-related activities.

In the last 10 years, the VA has funded $60 million in CAM research, while VA. investigators have participated in other CAM research projects worth $92 million in funding during that same time. Additional CAM research has been done without funding. Among the areas studied are biofeedback, acupuncture, electromagnetic therapy, and others covering the entire spectrum. The VA is doing an omnibus report of these numerous studies. Concerns are variability of training, credentials of CAM practitioners, stability of funding, and safety.

Most research is done by the VA's intramural research scientists, and they are the only ones eligible for the grants. Initiatives come from the field. Research is organized into four basic types: basic, bench, rehabilitation, and outcomes. If they opened the door to a special interest, other groups would ask for the same treatment.

The VA is the ideal place to do demonstration projects.

To the Zuni Indian Tribe, CAM is standard. Traditional healing practices vary among the 500-plus tribes. The IHS is authorized to provide health services, not research, but some community organizations have an interest in it. NIH has funded centers for health research for Native Americans. Such centers must be governed by the Indian people, not by researchers.

IHS identifies native healers as mental health technicians. It is difficult to measure practice utilization, failure, etc. The healers are willing to push the limit rather than be constrained by conventional measures. They put their attention beyond biology and disease. This is a challenge for American Indian physicians who are researchers. The great belief is in the power of the healer.

A good contact point for Native American medicine is the National Indian Health Organization, which reflects the health interests of tribal governments nationwide. Also consider contacting the National Council of Rural Indian Health.

Work with tribal governments to establish research priorities for investigating traditional practices utilized by American Indians and Alaska Natives. Priorities and policy should set by Native Americans, not by researchers. **(Craig Vanderwagen, Indian Health Service, IHS)**

Examine how CAM might reach out to tribal communities and offer them tools and techniques for examining internally the effectiveness of their providers. **(Craig Vanderwagen, IHS)**

Methodology Example (addendum)

The preferred method is the RCT because chart documentation is uneven in observational studies and data collection will be limited by the lowest common denominator available on all the charts. In addition, there are inherent differences in patients that can be factored into a study, but only a randomized study can deal with the unknown differences. If two patients receive the same treatment, one might also experience an improved quality of life, so qualitative survey instruments need to be in the study design from the outset. Finally, for experimental study design, the most important feature of a valid study is the comparison group. This requires expanding the study arena beyond one CAM practitioner. For these reasons we elected to move to an experimental study design of randomized treatment. If the study keeps in mind the modality being evaluated, there is no need for alternative methods or a redesign. The need is to be careful about what it is that is being measured and what the outcome is. The entire or aggregate system is analyzed rather than one unit of measure. If the entire system or modality shows promise, then go back and do the chemical analyses and basic science on those that work. The findings should be as valid and reproducible as possible. The problem is in over-interpreting data. There will be difficulties adjusting for all the differences. Data could be collected in standardized form. And patients could fill out an evaluation after they are seen.

A potential solution to the issue of individuality is to look into using an algorithm and doing flow charts on how the practitioner decides to do a type of therapy. It would be possible to do individual therapy inside a study and examine what makes certain practitioners effective and then teaching that.

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Divider Title: Research Overview

Prepared 05/08/2001

David Eisenberg, M.D.
Center for Alternative Medicine Research

David M. Eisenberg, MD is the Director of the Center for Alternative Medicine Research and Education at Beth Israel Deaconess Medical Center and Associate Professor of Medicine at Harvard Medical School, Boston, and Massachusetts. He recently was named to head the new Harvard Medical School Division for Research and Education in Complementary and Integrative Medical Therapies.

Dr. Eisenberg's major research interests include the evaluation of complementary and alternative medical therapies in terms of their prevalence, safety, efficacy, cost-effectiveness and mechanisms of action.

Dr. Eisenberg is also the Director of two Harvard Medical School courses devoted to complementary and alternative medicine. One course is offered through the Department of Medicine and the other through the Department of Continuing Education.

From 1994-1998 he served as a member of the National Institutes of Health Alternative Medicine Program Advisory Council. He is currently a member of the FDA Subcommittee responsible for post market surveillance of dietary supplements. He has authored numerous scientific articles involving complementary and alternative medicine practice.

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Testimony to The White House Commission On CAM Policy

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Enclosures

1) **Summary of Recommendations**

2) **Background Information with citations**

3) **Harvard Medical School Press Release**

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Recommendations to The White House Commission on CAM Policy

1. Quality assurance of herbs and other dietary supplements is a prerequisite for credible research and is essential for public safety.

2. The Commission should argue for enhanced surveillance of adverse effects pertaining to herbs, vitamins and other dietary supplements. Examples of direct and indirect toxicity should be included in such a surveillance system. Ideally, the United States should participate in an international post-market surveillance of herb, vitamins and supplements, as these products are now sold on a global basis.

3. Improved standards for licensure and credentialing of CAM practitioners must be more consistent across states and across CAM disciplines in order to: a) conduct generalizable research; b) allow medical professionals to make appropriate referrals and treatment decisions; and c) provide relevant guidelines for the general public.

4. Issues of malpractice liability and ethical practice associated with CAM therapies and/or co-management of patients by conventional and CAM providers must be anticipated and studied.

5. Federal agencies should be encouraged to increase fiscal resources for basic science, clinical research and health service research involving CAM therapies. Any one of these lines of inquiry, in the absence of the other two, will be insufficient to change medical management, policy and general perceptions pertaining to scientific evidence base regarding CAM therapies.

6. The research trajectory for CAM is unlike that of most conventional medical fields. Specifically, epidemiological and clinical investigations have preceded basic science (i.e., mechanistic) research in this area. It is imperative that mechanistic research be augmented and that plausible explanatory models be pursued if CAM/Integrative Medicine is to be satisfactorily incorporated into mainstream health care and biomedicine.

7. Additional controlled studies designed to document the presence or absence of clinical and financial cost offsets of CAM/integrative medical care must be

undertaken in order to inform reimbursement policies and procedures. Several options can be considered, including:

a) more targeted funding from federal agencies such as the NIH, CDC, etc., for health services research in this area;

b) additional funding for the Agency for Healthcare Research and Quality, arguably the federal agency with the most experience implementing health services research and the development of best practice guidelines;

c) incentives for HMOs, indemnity insurers, large corporations and large employer groups to sponsor CAM related health service research with or without matching federal funds; and

d) some combination of the above-mentioned public and private sector commitments.

8. Consider opportunities to fund a critical mass of academic health centers (i.e., medical institutions affiliated with universities and medical schools) with sufficient resources and infrastructure to perform CAM/integrative medicine:

- Research (basic, clinical and health services)
- Education/training of research and clinical experts
- Responsible delivery of integrative care services

These centers/institutes must also be informed by successful demonstration projects from the private sector as well as consumer demand and regulatory constraints. In this regard, the Consortium of Academic Health Centers for Integrative Medicine and the Federation of State Medical Boards as well as other relevant organizations should be consulted.

9. Encourage the NIH in its efforts to develop evidence-based, financially sustainable models of CAM/integrative care clinical delivery. Ideally, such integrative care models should participate in organized research and should utilize comparable data tracking of both clinical and financial outcomes. In this way, clinical and financial data can be accrued on a national basis and answer questions pertaining to CAM safety, efficacy, cost-effectiveness or the lack thereof.

10. CAM therapies shown to be effective must be made available to all individuals regardless of insurance status or ability to pay.

11. Detailed epidemiologic surveys of CAM patterns of use by minority populations must be made a priority. This information is essential to inform public policy and to protect particularly vulnerable populations.

12. Consider opportunities to create and sustain a national (or perhaps international) Society for CAM Research. Such an organization, if successfully organized, can help inform public policy in the years ahead. In addition, the non-US members of such a society can inform US policy through scientific research and clinical/financial experience elsewhere in the world.

13. The Commission should consider opportunities to increasingly engage the private sector, specifically HMOs, insurance carriers, pharmaceutical companies and Fortune 1000 employers, to secure resources to support basic, clinical and health service research involving the CAM therapies and models of integrative care. Sponsored research from these groups can and will likely exceed the resources available from Federal and State agencies. Consortia of this type can augment the research currently directed by NIH and other federal agencies and will, likely, be met with enthusiasm by investigators from universities, medical schools and other academic institutions.

14. One of the greatest impediments to CAM research is the current lack of faculty development in our medical and nursing schools, schools of pharmacy and allied health. In addition, the absence of exposure to CAM therapies and integrative care practices by the current allopathic healthcare workforce makes it difficult, if not impossible, to create suitable training environments for the next generation of CAM clinical and research scholars. Attention must therefore be placed on undergraduate, post-graduate and faculty development. Additional opportunities for "cross training" involving both CAM and conventional medical practitioners (and students) should be pursued.

David Eisenberg, MD
White House Commission
May 15, 2001

COMPLEMENTARY, ALTERNATIVE AND INTEGRATIVE MEDICAL THERAPIES EPIDEMIOLOGY AND OVERVIEW

I. Definitions and Terminology

"Complementary", "Alternative", and "Integrative" Medical Approaches

Alternative medical therapies encompass a broad spectrum of practices and beliefs (1). From an historical standpoint, they may be defined "... as practices that are not accepted as correct, proper, or appropriate or are not in conformity with the beliefs or standards of the dominant group of medical practitioners in a society" (2). From a functional standpoint, alternative (a.k.a. "complementary") therapies may be defined as interventions neither taught widely in medical schools nor generally available in hospitals (3). Ernst et al. contend that "complementary" medical techniques "[complement] mainstream medicine by contributing to a common whole, by satisfying a demand not met by orthodoxy or by diversifying the conceptual frameworks of medicine" (4). The terminology currently in use to describe these practices remains controversial. Many commonly used labels (e.g., "alternative," "unconventional," "unproven") are judgmental and may inhibit the collaborative inquiry and discourse necessary to distinguish useful from useless techniques (5). "Complementary and Alternative Medicine" (CAM) is the language currently used by the NIH and U.S. federal agencies to describe this field of inquiry.

"Integrative medicine" refers to ongoing efforts to combine the best of conventional and evidence-based complementary therapies while emphasizing the primacy of the patient-provider relationship and the importance of patient participation in health promotion, disease prevention and medical management. "It (integrative medicine) views patients as whole people with minds and spirits as well as bodies and includes these dimensions into diagnosis and treatment" (6). In the January 2001 *British Medical Journal* edition devoted entirely to Integrated Medicine, the Journal's editor, Richard Smith, wrote: "It mightn't be too pretentious (although it might) to say that such a growth (of integrative medicine) might restore the soul to medicine – the soul being that part of us that is the most important but the least easy to delineate" (7). Several recently published articles and editorials wrestle with the challenges of properly labeling and describing this field of inquiry (6, 8-13).

Dietary Supplements

The Dietary Supplement Health and Education Act defines dietary supplements as a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, mineral, amino acid, herb or other botanical; or a dietary substance for use to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above; and intended for ingestion in the form of a capsule, powder, softgel, or gelcap, and not represented as a conventional food or as a sole item of a meal or the diet.

II. Prevalence, Costs, and Patterns of Use of CAM Therapies in the United States

Findings from a 1997 follow-up national survey of complementary and alternative medicine (CAM) prevalence, costs, and patterns of use (14) include the following:

Between 1990 and 1997:

- The prevalence of CAM use increased by 25% from 33.8% in 1990 to 42.1% in 1997.
- The prevalence of herbal remedy use increased by 380%.
- The prevalence of high-dose vitamin use increased by 130%.
- The total number of visits to CAM providers increased by 47% from 427 million in 1990 to 629 million in 1997.
- The total visits to CAM providers (629 million) exceeded total visits to all primary care physicians (386 million) in 1997.
- In 1997, adults made an estimated 33 million office visits to professionals for advice regarding the use of herbs and high-dose vitamins.
- Estimated expenditures for CAM professional services increased by 45% exclusive of inflation and in 1997 were estimated at $21.2 billion dollars.
- Out-of-pocket expenditures for herbal products and high-dose vitamins in 1997 were estimated at $8 billion.
- Out-of-pocket expenditures for CAM professional services in 1997 were estimated at $12.2 billion. This exceeded the out-of-pocket expenditures for all U.S. hospitalizations.
- Total out-of-pocket expenditures relating to CAM therapies were conservatively estimated at $27.0 billion. This is comparable to the projected out-of-pocket expenditures for all U.S. physician services.
- An estimated 15 million adults in 1997 took prescription medications concurrently with herbal remedies and/or high-dose vitamins. These individuals are therefore at risk for potential adverse drug-herb or drug-supplement interactions.
- Current use of CAM services is likely to under-represent utilization patterns if insurance coverage for CAM therapies increases in the future.
- Despite the dramatic increases in the use and expenditures associated with CAM services, the extent to which patients disclose their use of CAM therapies to their physicians remains low. Fewer than 40% of CAM therapies used were disclosed to a physician in both 1990 and 1997.

The authors concluded that CAM use and expenditures increased substantially between 1990 and 1997, attributable primarily to an increase in the proportion of the population seeking CAM therapies, rather than increased visits per patient.

Other nationally representative surveys of CAM prevalence and patterns of use have provided additional useful information. These include a study by Astin (15) which concluded that "...the majority of alternative medicine users appear to be doing so not so much as a result of being dissatisfied with conventional medicine, but largely because they find their health care alternatives to be more congruent with their own values, beliefs and philosophical orientation towards health

and life. Druss and Rosenheck's national survey (16) found that practitioner-based CAM therapies appear to serve more as a complement than an alternative to conventional medicine; and, individuals in the top quartile of numbers of physician visits were more than twice as likely as those in the bottom quarter to have used CAM therapies during the prior year. Two recent analyses of national survey data provide additional information regarding CAM patterns of use in adults over age 65 (17) and adults with anxiety or depression (18).

The above-mentioned surveys are all based on nationally representative random samples of adult Americans. In addition, there have been a number of convenience samples investigating CAM therapy use among individuals with a particular condition or disease. Examples include surveys involving CAM therapy use among individuals with: cancer (19-28), rheumatologic disorders (29-31), self-reported disability (32), HIV (33), inflammatory bowel disease (34) and rhinosinusitis (35), as well as surgical patients (36) and patients in an emergency department (37).

National surveys performed outside the United States suggest that CAM is popular throughout the industrialized world (38). The percentage of the population who used CAM therapies during the prior twelve months has been estimated to be 10% in Denmark (1987) (39), 33% in Finland (1982) (40), and 49% in Australia (1993) (41). Public opinion polls and consumers' association surveys suggest high prevalence rates throughout Europe and the United Kingdom (42-45). The percentage of the Canadian population who saw a CAM therapy practitioner during the previous twelve months has been estimated at 15% (1995) (46). The wide range of utilization rates can be explained, in part, by the disparity in definitions of CAM therapy and the selection of therapies assessed.

III. Top Herbal Products, Vitamins and Non-Herbal Dietary Supplements Sold in the U.S.

U.S. Vitamins and Minerals Sales

	$Millions
Multivitamins	839
Vitamin E	373
Calcium	340
Vitamin C	230
Vitamin B-complex	90
Vitamin B	82
Iron	57
Vitamins A & D	34
Zinc	28
Potassium	14

(*Drug Store News*, May 2000)

U.S. Herbal Products Sales

	$Millions		$Millions
Gingko biloba	147	Valerian	10
St. John's wort	104	Evening primrose	9
Ginseng	84	Grape seed	8
Garlic	77	Milk thistle	8
Echinacea	72	Bilberry	6
Saw palmetto	45	Black cohosh	6
Kava kava	18	Pycnogenol	5
Soy	18	Ginger	2

(*Drug Store News*, May 2000)

Non-Herbal Dietary Supplement Sales

	$Millions
Glucosamine / chondroitin	288
CoQ-10	41
Melatonin	31
Amino acids	21
Fish oil / omega fatty acid	14
DHEA	11
Acidophilus	11
Lecithin	10
Gelatin	8
Glucose	7
Shark cartilage	6

(*Drug Store News*, May 2000)

Top Herbs, U.S. vs. Europe

	United States†	Europe‡
1	Gingko biloba	Gingko biloba
2	St. John's wort	St. John's wort
3	Ginseng	Horse chestnut
4	Garlic	Yeast
5	Echinacea	Hawthorn
6	Saw palmetto	Myrtle
7	Kava kava	Saw palmetto
8	Soy	Stinging nettle
9	Valerian	Ivy
10	Evening primrose	Mistletoe

† *Drug Store News*, May 2000

‡ *German Commission E*, 1998

IV. Educational Programs in the United States

A recent survey of courses involving CAM at U.S. medical schools was published in the 1998 *JAMA* theme issue devoted to medical education (47). This article, by M. Wetzel et al, included the following results: 64% of the U.S. medical schools reported offering courses on CAM. Of the 123 courses reported, 68% were stand alone electives and 31% were part of required courses. Common topics included chiropractic, acupuncture, homeopathy, herbal therapies and mind-body techniques. The American Association of Medical Colleges has established a Special Interest Group devoted to CAM, and this topic continues to be discussed at the AAMC's annual meetings.

The Department of Medicine at the University of Arizona College of Medicine is currently the only school with an "integrative medicine" clinical fellowship training program (48). In 1999, the NIH awarded its first (T-32) Research Fellowship Training Grant in CAM to Harvard Medical School. Additional NIH-funded CAM Fellowship training programs are to be anticipated.

For the past seven years Harvard Medical School has offered a Department of Medicine elective entitled, "Alternative Medicine: Implications for Clinical Practice and Research." The principal objective of this course has been to provide physicians in training with sufficient knowledge and management skills to responsibly advise patients who use or request CAM therapies. A series of four cases and relevant bibliographies used in this course can be obtained from Harvard Medical School. Continuing education courses devoted to CAM are increasingly popular. For the past several years, Columbia University has offered a one-week intensive course on the topic of herbal therapies. This year, the NIH awarded educational grants intended to incorporate CAM information into the medical, dental, nursing and allied health professional school curriculums, residency training programs, and into continuing education courses.

V. Research Issues

Prior to 1994, relatively little was known about the relative safety, efficacy, cost-effectiveness and mechanism of action of individual alternative therapies. Increasingly, however, the peer-reviewed medical literature has included consensus conferences, systematic reviews, case studies and randomized trials involving CAM therapies. In November 1998, the *JAMA* and AMA specialty journals published more than eighty articles devoted to CAM. Additional studies have subsequently been published in leading medical journals. Noteworthy examples of recently published reviews and original trials include:

Examples of Articles/Consensus Reports Suggesting Efficacy

1) Chiropractic for Acute Low Back Pain (49, 50)
2) Mind/Body Techniques for Pain, Insomnia (51)
3) Acupuncture for Nausea and Dental Pain (52)
4) Psychosocial Support Groups for Cancer (53)
5) Homeopathy as Distinct from Placebo (54)
6) St. John's wort for the Treatment of Depression (55)
7) St. John's wort vs. Imipramine vs. Placebo (56)
8) Gingko for the Treatment of Alzheimer's Type Dementia (57, 58)
9) Chinese Herbs for the Treatment of Irritable Bowel Syndrome (59)
10) Saw Palmetto for the Treatment of Benign Prostatic Hyperplasia (60)
11) Garlic for Hypercholesterolemia (61-63)
12) Glucosamine and Chondroitin for Osteoarthritis (64, 65)
13) Kava Kava for Anxiety (66)
14) Homeopathy for Vertigo (67)
15) Homeopathy for Allergic Rhinitis (68)
16) Osteopathic Manipulation for Low Back Pain (69)
17) Moxibustion for Breech Presentation (70)
18) Acupuncture for Recurrent Headaches (71)
19) Acupuncture for Post-operative Nausea (72)
20) Acupuncture for Fibromyalgia (73)
21) Distant Healing (74)
22) Intercessory Prayer (75)

Examples of Articles/Studies Suggesting Lack of Efficacy

1) Acupuncture for Peripheral Neuropathy (76)
2) Hydroxycitric Acid for Obesity (77)
3) Chiropractic vs. Physical Therapy vs. Education for Low Back Pain (78)
4) Acupuncture for Tinnitus (79)

Over the past year, the medical literature has included several reports of clinically significant adverse events caused by the direct or indirect toxicity of herbal products. These include:

Examples of Articles Describing Significant Drug-Herb Interactions and/or Toxicity

1) Case Studies Involving the Most Commonly Used Medicinal Plants (80)
2) Adverse Reactions Between St. John's wort and Prescription Drugs (81)
3) Open-label Study Showing St. John's wort Decreases Indinavir Concentrations (82)
4) Association of a Chinese Herb (*Aristolochia fangchi*) with Renal Failure and Urothelial Carcinoma (83)
5) Letter to *Lancet* Editor regarding St. John's wort Induced Heart Transplant Rejections (84)
6) Summary of Ephedra's toxicity (85)

In 1992, the National Institutes of Health established the Office of Alternative Medicine. In November of 1998, Congress established the National Center for Complementary and Alternative Medicine (NCCAM). The Congressional mandate establishing the NCCAM stated that the Center's purpose is to "facilitate the evaluation of alternative medical treatment modalities" to determine their effectiveness. The mandate also provides for a public information clearinghouse and a research training program. The NCCAM does not serve as a referral agency for various alternative medical treatments or individual practitioners. The NCCAM facilitates and conducts research. The Center is located on the NIH campus in Bethesda, Maryland. The NIH National Center for Complementary and Alternative Medicine (NCCAM) conducts and supports basic and applied research and training and disseminates information on complementary and alternative medicine to practitioners and the public. Currently, the NIH supports more than 200 studies involving complementary and alternative medicine therapies. (Additional information on NCCAM can be found at: **http://www.nccam.nih.gov**.

The NIH has also established the Office of Dietary Supplements (ODS). The scientific goals of the ODS include:

Goal 1: Evaluate the role of dietary supplements in the prevention of disease and reduction of risk factors associated with disease.
Goal 2: Evaluate the role of dietary supplements in physical and mental health and in performance.
Goal 3: Explore the biochemical and cellular effects of dietary supplements on biological systems and their physiological impact across the life cycle.
Goal 4: Improve scientific methodology as related to the study of dietary supplements.
Goal 5: Inform and educate scientists, health care providers and the public about the benefits and risks of dietary supplements.

(Additional information on the ODS can be found at **http://odp.od.nih.gov/ods/about/about.html**)

VI. Future Considerations

1. Description of Current Environment

In spite of the creation of the NIH National Center for Complementary and Alternative Medicine, the current status quo may be described as follows:

- There is an enormous popular demand and increasing interest on the part of employers and third party payors.
- CAM treatments including herbal products and other dietary supplements lack standardization and include both relatively safe and toxic interventions.
- The training, licensing, and credentialing of CAM providers, including practitioners who dispense herbs and other dietary supplements is highly inconsistent.
- Malpractice liability issues remain unclear. Note: This past year the Federation of State Medical Boards established a committee to develop explicit policy in this area.
- Toxicity issues pertaining to individual herbs, vitamins and supplements remain inadequately studied and are not readily available.
- Accepted professional guidelines whereby medical doctors advise patients regarding the use or avoidance of individual CAM therapies are absent.
- Explicit criteria by hospital Pharmacy and Therapeutics Committees, medical organizations and regulatory authorities regarding the recommended use or avoidance of individual herbs and dietary supplements do not yet exist.
- Formal evidence-based policies to advise patients about the use or discontinuation of herbs and supplements prior to surgery do not exist. (The American Society of Anesthesiologists has published information pamphlets for patients and for physicians (86); however, no formal guidelines exist due to lack of authoritative data.)
- There is a paucity of research aimed at documenting the cost-effectiveness (or lack thereof) of individual CAM therapies or integrative care approaches to the management of common diseases.
- Until now, there has been relatively little basic science (i.e., mechanistic) investigation involving individual CAM therapies.
- Until now, there has been no sustainable financial model for the successful delivery of CAM therapies.

2. Advising the Patient Who Seeks Alternative Medical Care

The *Annals of Internal Medicine* article entitled "Advising Patients Who Seek Alternative Medical Therapies" (87) provides a strategy whereby conventionally trained physicians discuss the use or avoidance of CAM therapy with their patients. This strategy highlights the need for a formal discussion of patients' preferences and expectations, the maintenance of symptom diaries, a list of questions to be asked of the CAM provider, the need for follow-up visits to monitor for potentially harmful situations, and the importance of shared decision making. It is hoped that more detailed strategies for patients with specific illnesses (e.g., cancer, musculoskeletal pain, coronary artery disease, neurologic deficits) will be published and incorporated into routine, best patient practices. Explicit professional recommendations regarding the use or avoidance of commonly used herbs and supplements are urgently needed.

3. Unaddressed Policy Issues

A selected list of relevant policy issues includes the following:

- Distinction between CAM and Integrative Medicine.
- Labeling and standardization of herbal products and other dietary supplements.
- Liability and malpractice concerning referrals to CAM providers and recommended use of herbs and dietary supplements. (See also item 4 below.)
- Specific referral guidelines unique to each of the CAM professions.
- A review of educational requirements for licensed CAM providers (including education requirements by those recommending herbs and supplements).
- Suggested educational requirements for allopathic physicians with regard to CAM practices including a working knowledge of safety and efficacy data pertaining to herbs and supplements.
- Heterogeneous reimbursement patterns which now include paid benefits and/or a range of reduced fee-for-service products and CAM "carve-outs." (Note: This will likely involve proposed coverage for selected herbs, vitamins and supplements.)
- The need for coordination with the Federation of State Medical Boards and other licensing organizations.
- The role of the newly established Presidential Commission on CAM Policy. The Commission will address issues of: (1) training and education, (2) coordination of research, (3) provision of useful information; and, (4) guidance for appropriate access to and delivery of CAM services. Increasing consumer demand for enhanced regulatory authority over herbs, vitamins and other dietary supplements (88).
- The addition of CAM specific examination questions to possible future medical licensure exams and subspecialty board examinations.
- The role of the newly established Consortium of Academic Health Centers for Integrated Medicine.

4. Credentialing and Malpractice Liability Concerns

With regard to the delivery of CAM therapies, the oversight of educational requirements, credentialing, malpractice insurance and scope of practice vary from state to state (87, 89). A tabular summary of state licensing patterns for chiropractic, acupuncture, massage therapy, homeopathy and naturopathy is available elsewhere (87, 90).

David Studdert, JD, PhD and Troy Brennan, MD, JD of the Harvard Law School and Harvard School of Public Health, working as co-investigators with Drs. Eisenberg, Kaptchuk and others, examined malpractice insurance claims data from both the conventional (MD) and CAM (i.e., chiropractic, acupuncture, massage) communities (90). Their findings, published in the *Journal of the American Medical Association,* 1998 included the observation that claims against licensed CAM practitioners occurred less frequently and typically involved injury that was less severe than claims against physicians during the same period. This article also described specific

situations in which referral by a medical doctor to a licensed CAM practitioner will or will not likely be construed as negligent. The texts by Michael Cohen (91, 92) also highlight many CAM related legal concerns. Malpractice liability with regard to the recommended use of herbal products and dietary supplements will, no doubt, become an increasingly complicated aspect of medical care.

5. Education and Training

The following opportunities for improved training should be considered:

- The standardized medical school curricula pertaining to CAM theory, practice, safety and efficacy.
- The development of residency training opportunities as concerns: (a) appropriate and responsible discussion and referral; (b) the possibility of clerkships by MDs in the offices of CAM practitioners; and (c) the possibility of clerkships by licensed CAM students-in-training (e.g., acupuncturists, chiropractors) in allopathic hospitals and clinics.
- Improved continuing medical education courses for physicians, nurses and allied health professionals.
- Faculty development for selected faculty who wish to supervise the above mentioned training programs.
- The possibility of specific fellowship training grants for primary care and subspecialty physicians. The notion here is to train "resident experts" (e.g., oncologists, rheumatologists, general internists, pharmacists) who, in addition to their conventional expertise and responsibilities, are knowledgeable about the state of the science pertaining to CAM treatments and integrative medical approaches for specific patient populations. Such individuals would fill an important educational role for medical students and housestaff who will require mentoring in this complicated area. These issues are currently being discussed by the American Association of Medical Colleges Special Interest Group in CAM.
- The Macy Foundation recently held a national conference devoted to the future of CAM education (93).

6. Attitudes Within the Medical Profession

There is a need to address the challenge posed in a 1998 editorial by Drs. Angell and Kassirer, editors of the *New England Journal of Medicine*, who wrote, "There cannot be two kinds of medicine – conventional and alternative. There is only medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work" (11). At the same time, there is a parallel need to acknowledge the importance of sociological, cultural and pragmatic factors as they relate to investigation of CAM (and conventional) therapies. This sentiment, articulated by David Grimes in an editorial in *JAMA*, reframes this same challenge. Grimes, writing about the use of medical technology wrote, "Doing everything for everyone is neither tenable nor desirable. What is done should be inspired by compassion and guided by science and not merely reflect what the market will bear" (94).

7. Exploring Health Service Models for the Delivery of Complementary and Alternative Medical Therapies

Increasingly, hospitals, managed care organizations, health insurers and large, self-insured corporations are developing models whereby complementary and alternative therapies are made available to members/subscribers/employees. The spectrum of existing models, all relatively new, is broad and includes:

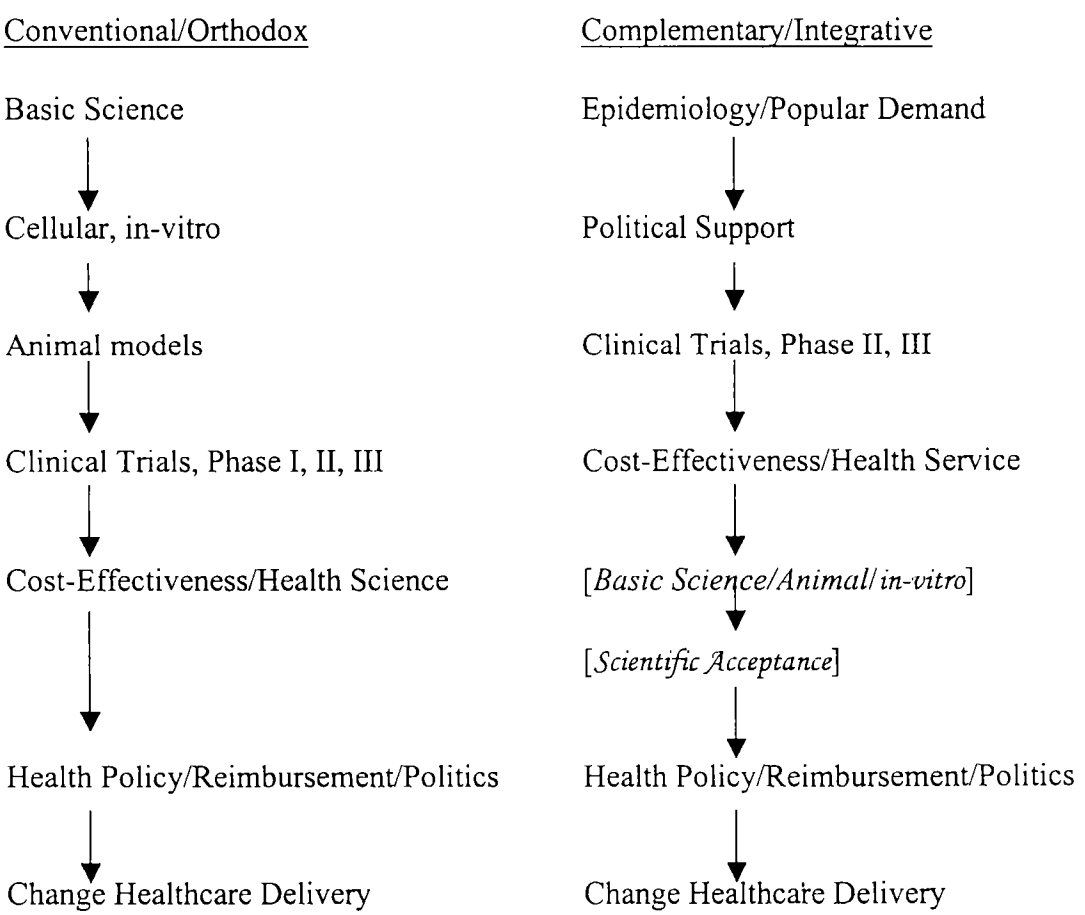
- The establishment of networks of "credentialed" complementary and alternative therapy practitioners.
- Reduced "fee-for-service" models whereby members/subscribers/employees receive a discount on routine CAM services provided by "credentialed" networks of identified practitioners in a given geographic area. (Note: This model does not typically include reimbursement for or liability assurance regarding the delivery of CAM services.)
- Covered benefits, which include a predetermined maximum of complementary and alternative therapy services for selected medical conditions (usually with a required referral from an MD).
- Covered CAM benefits without a required referral from an MD.
- "Integrated" medical services which typically include both conventional and complementary/alternative services, usually in an outpatient (ambulatory) setting. Reimbursement options vary as do referral requirements.
- "Integrated" consultation services, i.e., the provision of complementary and alternative therapies for inpatients in hospitals.
- Specialized integrative care teams consisting of conventional and complementary care providers who share a single clinical focus (i.e., the treatment of musculoskeletal pain, cancer, cardiovascular disease, women's health issues, etc.).
- The incorporation of complementary and alternative (a.k.a. "integrative") services as part of an individual medical practice, a group medical practice, a managed care organization, a PPO, an insurance product, a community hospital, or university affiliated teaching hospital.

Unlike hospitalizations and physician services, complementary and alternative therapies are only infrequently included in insurance benefits. The percentage of CAM users who paid entirely out-of-pocket for these services did not change significantly between 1990 (64%) and 1997 (58.3%) (14). Even when alternative therapies are covered, they tend to have high deductibles and co-payments and tend to be subject to stringent limits on the number of visits or total dollar coverage. Because the demand for health care (and presumably alternative therapies) is sensitive to how much patients must pay out-of-pocket, current use is likely to under represent utilization patterns if (and when) insurance coverage for alternative therapies increases in the future (14). Trends involving insurance coverage for CAM therapies have recently been reviewed by Pelletier et al. (95, 96). Clearly, more and more third party payors (and employers) are considering the inclusion of CAM therapies within their benefits programs.

Regrettably, there is a paucity of rigorous prospective studies that could provide conclusive evidence of differences in costs and outcomes between complementary and orthodox medicine (97).

VII. The Role of Scientific Inquiry and Discovery Involving Complementary, Alternative and Integrative Medicine

1) How CAM/Integrative Medicine Research has followed a different trajectory



2) "Breakthrough ideas" are more likely to occur as a result of collaborative projects involving investigators from disparate disciplines (e.g., neuroscience, acupuncture and experimental radiology; dietary intervention, mental health and molecular biology, etc.), working as teams to explore focused questions of common interest relating to complementary and integrative approaches to patient care.

Examples of CAM-Related Topics Requiring Multi-disciplinary Research Teams

- Neuro-imaging of CAM, mind-body techniques and placebo responders
- Mechanisms of CAM treatment for pain management
- CAM therapies as immuno-modulators
- CAM/lifestyle (e.g., diet, stress management) effects on gene regulation

- Mechanisms of herb/supplement effects, interactions
- Developing sustainable financial models of Integrative Care delivery
- Identifying objective correlates of and plausible explanatory models for energy-related healing phenomena (e.g., magnets, homeopathy, non-touch therapies).

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Divider Title: Foundation Support

Questions for the Panel on Foundation Support:

Does your foundation support CAM research and/or research training? If so, how does your foundation determine what (CAM) research or research training it will fund?

What types of research are you currently funding or are considering funding? Does your foundation support health services research related to CAM?

What role can foundations play in stimulating CAM research, e.g., seed money, research grants, publication of research results, research training support, conferences?

What are the obstacles and possible solutions to accomplishing your foundation's goals in this area regarding CAM?

Do you work collaboratively with other foundations to stimulate CAM research and research training? What do you think might be done to enhance collaboration among foundations active in this area? What do you think might be done to increase collaboration with foundations that are not active in this area?

How can CAM research coordination be enhanced between the Federal government and the not-for-profit sector?

Do you consider areas of interest to the public in your decision making on funding priorities?

What policy recommendations can your foundation offer regarding CAM research for the Commission's consideration as it develops its report to the President and Congress?

M. Bridget Duffy, MD

Dr. Duffy is Medical Director, Medtronic, Inc., Minneapolis, Minnesota. She is responsible for the development and implementation of integrative patient care programs: programs that foster the convergence of information, technology and a humanistic delivery of that care. In this capacity she is involved in patient-centered care initiatives that look beyond the company's traditional product-centered focus. This approach recognizes that there are critical factors – in addition to technological interventions – that impact patient outcomes as well as the effectiveness of the implanted devices. Central to this approach is designing programs that address the chronic nature of cardiovascular and neurologic disease, thereby ensuring earlier and more appropriate management of the disease. As Medical Director of the Medtronic Foundation, she oversees programs that support the development of these new models of care. To date, grantees for work in Integrative Medicine include Harvard, Stanford, Duke, Scripps, Allina, Beth Israel NY, and St. Barnabas Healthcare System.

In addition to this patient-centered initiative, Dr. Duffy is responsible for developing relationships with health care leaders worldwide. Through Medtronic's Alliance Program, Dr. Duffy conducts executive education and leadership forums that connect these leaders to other health care professionals. These leaders also develop critical relationships with Medtronic, further enhancing the company's position in the worldwide health care market.

Prior to joining Medtronic, Dr. Duffy established, and was medical director for one of the first "Hospitalist" services in the country – an inpatient care service designed to improve the clinical, economic and quality of life outcomes of hospitalized patients. She also was instrumental in the development of community-based health care programs in Central America and the British West Indies, and helped develop a migrant children's health program in Colorado.

Dr. Duffy attended medical school at the University of Minnesota, and completed her residency in Internal Medicine at Abbott Northwestern Hospital in Minneapolis, Minnesota. She was an attending physician at Abbott Northwestern Hospital and in this role served as an educator and mentor to medical students and residents. She also served in a volunteer capacity at NIP (Neighborhood Involvement Program) and the Excelsior Teen Clinic. Dr. Duffy is a member of the American College of Physicians.

Dr. Duffy's passion for patient-centered initiatives is inherent in her professional goals. This includes being meaningfully involved in the creation of health care environments that treat the "whole patient," and understanding the role of the physician and the application of medical technology in this new, innovative model of care.

WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY RESEARCH CHALLENGES

SUBJECT: Not-for Profit Support for CAM Research
PRESENTER: M. Bridget Duffy, MD, Medical Director, Medtronic, Inc.

1) Does your foundation support CAM research and/or research training?

ANSWER: The Medtronic Foundation supports research efforts that seek to identify clinical care models that will improve the lives of people living with chronic cardiac or neurologic conditions. We do not support the study of specific CAM modalities.

2) What type of research are you currently funding or are considering funding?

ANSWER: We have identified several of the top cardiovascular and neurological centers of excellence in the country who have the executive and physician leadership in place to build integrative models of care for these specific patient populations. We are interested in developing new standards of care, or clinical algorithms for these patients.

3) What does your foundation hope to accomplish through support in this area?

ANSWER: We hope to transform the way care is delivered to individuals with chronic disease. We recognize that pharma and technology alone do not restore individuals to "full life," and the mission and culture at Medtronic supports programs that "restore people to full life."

4) How does your foundation determine who you will support?

ANSWER: Institutional and program criteria for funding under Medtronic Foundation's Health Center Leadership Grant program include: nationally recognized thought leaders driving the initiative, support at the executive level within the institution, strategies in place for system-wide adoption of successful integrative care models, nationally recognized clinical and research centers of excellence in cardiovascular and neurologic care, interdisciplinary integrative care team, integrative programs and services that care for the "whole person", mechanisms in place to measure and disseminate best practices.

5) What are the obstacles and possible solutions to accomplishing your foundation's goals in this area?

ANSWER: The greatest obstacle is **not the absence of data**, rather it is the "perception" that we are supporting the use of alternative therapies, when in fact we are seeking to restore "healing" to healthcare. What we believe is at the center of healing, is relationship. The current system does not value the healing and needed relationship

that benefits a patient with chronic disease. According to our informal survey, physicians, followed by administrators are the greatest obstacle to the adoption of integrative care models. Nurses are clearly the champions and possess most of the knowledge and expertise in this area. A solution would be to create experiential leadership and training opportunities for physicians and administrators.

6) Do you work collaboratively with other foundations to stimulate CAM research and training? How might collaboration among foundations be enhanced?

ANSWER: To date, we have not worked collaboratively in this area, however we see great opportunity for this to occur. To do this effectively, a clearinghouse should exist to pair or match institutional initiatives with foundations that share a similar mission or vision. Clearly, philanthropic collaboration will help to accelerate this field.

7) How can CAM research coordination be enhanced between the Federal government and the not-for-profit sector?

ANSWER: Philanthropy is poised to rapidly support the development and implementation of successful integrative patient care models. Federal government should play a **proactive** role in assessing needed policy and reimbursement changes.

8) Do you consider areas of interest to the public in your decision making on funding priorities?

ANSWER: The Medtronic Foundation supports numerous national patient advocacy and support groups. We are very interested in supporting their initiatives in advancing access and reimbursement of needed care and of new models of care.

9) What policy recommendations can your foundation offer regarding CAM research for the Commission's consideration as it develops its report to the President and Congress?

ANSWER: Support of unique educational initiatives that seek to restore healing to healthcare is as important, if not more than proving which alternative therapy works or doesn't work. Both of these must be studied, but to date, the focus has been on the use and efficacy of the modality alone vs. the context in which it is delivered. The Commission can play a significant role in improving healthcare in this country by refocusing or broadening its mission to include these issues as they look at the adoption of CAM in this country.

Doriane C. Miller, M.D.

Dr. Miller joined the Robert Wood Johnson Foundation staff as program vice president in July 1997. She brings to the Foundation 15 years' experience as a community-based primary care provider who has worked with under-served, minority populations with special issues in mental health and substance abuse. She most recently served as medical director of the Maxine Hall Health Center of the San Francisco Department of Health, while also serving as assistant clinical professor of medicine in the Department of Medicine at San Francisco General Hospital, University of California, San Francisco.

As a 1993 winner of an RWJF Community Health Leadership Award, she directed the Grandparents Who Care Support Group, which she co-founded in 1989. The Program provides psychological help and community resources to relatives who are raising children because the child's parents are mentally ill, incarcerated or have substance abuse problems.

At the Foundation, she heads the Clinical Care Management Team of the Health Care Group. She is responsible for coordinating strategies and funding in the area of clinical care management and quality improvement. Dr. Miller continues her professional practice by volunteering at the Chandler Clinic in New Brunswick a half day per week.

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TESTIMONY TO

WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY

RESEARCH CHALLENGES

BY

DORIANE C. MILLER, M.D.

PROGRAM VICE-PRESIDENT

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Thank you Chairman and members of the committee for inviting me to testify today on the subject of not for profit support of Complementary and Alternative Medicine (CAM) research. My name is Doriane Miller. I am a vice-president at The Robert Wood Johnson Foundation. I am a physician and general internist by training, with a background in the care of underserved populations, particularly with co-existing substance abuse, mental health issues and HIV. In my previous positions at the San Francisco Department of Public Health and the University of California, San Francisco, I

served as medical director of a community public health center that provided both traditional and CAM services to a poor, inner city population. My work at The Robert Wood Johnson Foundation is in the areas of clinical care management, community health, health and behavior and care of the underserved.

The Robert Wood Johnson Foundation, established as a national philanthropy in 1972, is dedicated to the improvement of the health and health care of the people of the United States. We fund programs that fall into three major goal areas: 1) increasing access to health care services, 2) providing care and support for people with chronic health conditions and 3) reducing the harm from substance abuse. From an asset base of approximately $8 billion, we will fund $400 million in grants this calendar year.

The committee has asked this panel representing the health philanthropic sector to comment on current support of CAM research and to address the following issues:

- How our foundation decides to fund CAM
- The role foundations could play in stimulating the field of CAM
- Some of the obstacles in funding of CAM research
- The barriers to translating CAM research into practice
- The role public-private funding partnerships can play in CAM research
- The role the public should have in the decision making process about funding CAM research
- Policy recommendations to the committee regarding CAM research.

In preparation for my testimony today, I reviewed The Robert Wood Johnson Foundation's grantmaking in the area of CAM for the committee. You will find a summary of those grants attached. However, for the purposes of our discussion today, I think that it will be more helpful to you if I shared our grantmaking approach at The Robert Wood Johnson Foundation. A description of our grantmaking approach will answer some of the questions posed to this panel by the committee.

In my opening comments I mentioned the major funding areas of The Robert Wood Johnson Foundation: improving access to care; improving the care of the chronically ill and reducing the harm caused by substance abuse. Within these broad goals narrower focus areas help the foundation staff direct their programmatic development and grantmaking and helps grant applicants to understand our strategic priorities. I am direct program development and grantmaking in the Clinical Care Management area and I assist in the areas of Health and Behavior, Community Health and Care of the Underserved. Within each of these areas, staff link program development and grantmaking to measurable strategic objectives. We base our program development and funding decisions on a specific project's ability to contribute to achieving these strategic objectives. The Robert Wood Johnson Foundation funds projects that use the tools of research and policy analysis, demonstration, education and training, communications and evaluations to achieve our strategic objectives.

The goal of Clinical Care Management is to narrow the gap between what is known and what is practiced in health delivery systems today for people with chronic medical

conditions. We attempt to effect change in three strategic areas: 1) changing purchaser behavior to support the delivery of evidence-based medicine, 2) improving delivery system capacity to provide evidence-based medicine and 3) engaging people both as consumers and as patients to become more involved in evidence-based medical care. The projects funded to date are cross-cutting and disease-specific. Examples of such projects include a project in Edina, MN, that has developed a protocol for depression screening at an adult day center; a project in Lafayette, CO that is working to improving the use of community resources to support chronic illness self-management within a low-income Spanish speaking population; and a project at the Medical University of South Carolina that is testing the benefits of group visits in low income people with type 2 diabetes. The agenda for the Clinical Care Management team is a translational one, that is, translating research in best practices into health delivery settings with a focus on the strategic elements I described earlier.

How does this translational agenda affect our view of funding CAM research? If there were sufficient evidence that a particular CAM approach to treatment could positively affect the outcome of treatment of a condition we are targeting, we would consider funding CAM as a part of a total program or system of care. CAM is not an area of strategic funding for The Robert Wood Johnson Foundation, nor are we considering making it a funding priority for the foundation. To the extent that current and future CAM research and implementation could help to make improvements in our strategic funding areas, we would consider funding on a case by case basis.

In 'Crossing the Quality Chasm', the Institute of Medicine promotes a consumer/patient-centric model of care. I think that the public as consumers of health care and as patients should have a voice in establishing an agenda for research in this area. The creation of the Federal Office of Alternative Medicine is an example of such interest.

The Robert Wood Johnson Foundation has tremendous experience in the area of convening, training and demonstrations in the health field. If we chose to become more active in the area of CAM, we would draw upon those experiences to help stimulate more activity and interest in CAM. We would also welcome public and private funding partners in this endeavor.

Thank you for your time today. I look forward to your questions and comments.

Appendix : Sample of CAM Grants from The Robert Wood Johnson Foundation
White House Commission on Complementary and Alternative Medicine Policy
Doriane C. Miller, M.D.
5/14-5/15/01

National Forum on Uterine Fibroids and African-American Women
Grantee: The Wholistic Health and Healing Association, Roseville, CA
Summary: Funding provided support for a national conference to explore the combination of allopathic diagnostic and evaluative techniques and holistic modalities in the treatment of uterine fibroids.
1/1/2000-4/30/2000 Amount: $49,989

Preparation of an Updated Book on Surviving Cancer
Grantee: National Coalition for Cancer Survivorship
Summary: Funding provided support for the author to write a revised edition of the book, 'Hanging in There: Living Well on Borrowed Time,' by Natalie Davis Spingarn, a 25 year cancer survivor, cancer activist and medical journalist. The book addressed both traditional and nontraditional approaches to cancer treatment and support including stress reduction activities
1/1/98-12/31/98 Amount: $14,500

National Program: Strengthening the Patient-Provider Relationship in a Changing Health Care Environment
Grantee: University of California, San Francisco
Summary: Funding supported an investigation of patients and physicians' concerns regarding discussions about complementary and alternative medicine, leading to the development of guidelines on how physicians should discuss CAM and how health care systems can facilitate discussions between physicians and patients regarding CAM.
5/1/2000-4/30/01 Amount: $305,624

Assessing the Workforce of Physicians and Non-Physicians Providing Clinical Services
Grantee: Medical College of Wisconsin
Summary: Funding supported the acquisition and analysis of data for both physician and non-physician clinicians looking at workforce supply and scope of work. Non-physician clinicians included provides of CAM services such as chiropractors, naturopaths and acupuncturists.
2/1/97-7/31/98 Amount: $200,000

Appendix : Sample of CAM Grants from The Robert Wood Johnson Foundation
White House Commission on Complementary and Alternative Medicine Policy
Doriane C. Miller, M.D.
5/14-5/15/01

National Program: Research Development Program to Improve Patient Functional Status
Grantee: University of North Carolina at Chapel Hill School of Medicine
Summary of Project: Assessment of spinal manipulation as an effective therapy in the management of low back pain
4/1/84-3/31/86 Amount: $72,432

Focus Group Sessions for Latino Consumers and Providers on Primary and Preventive Care Access Issues
Grantee: Lake, Snell and Perry Associates
Summary: Qualitative research project addressed issues of primary care and preventive services for Latinos including attitudes and beliefs and practices regarding traditional and CAM services including the use of curanderos and botanicas.
11/15/2000-2/14/01 Amount: $128, 900

Partnerships in Healing Conference
Grantee: Grace Counseling Center, Madison, NJ
Summary: Funding was provided for a conference that presented a paradigm for integrating spirituality and health and how this approach can be integrated into cancer treatment.
10/1/98-10/31/98 Amount: $10,000

Establishment of Breast Cancer Survivors Camp
Grantee: Breast Cancer Recovery Foundation, Inc. of Madison, WI
Summary: Funding provided start up support for the creation of a breast cancer survivors' camp. The purpose of the camp is to help women who have developed breast cancer to learn mind-body healing approaches that have been demonstrated to increase ten-year survival rates for breast cancer.
11/1/97-10/31/98 Amount: $49,965

Planning for a Study of the Effects of a Stress Reduction Program on Health Care Utilization, Costs and Patient and Provider Satisfaction
Grantee: University of Massachusetts Medical Center, Worcester, MA
Summary: Funding provided support for the development of a multiyear controlled, randomized, prospective study of the economic and clinical impacts of a meditation and relaxation program called Mindfulness-Based Stress Reduction.
2/1/98-10/31/98 Amount: $49,660

The Susan G. Komen
Breast Cancer Foundation
National Headquarters

Susan Braun
President and CEO
Susan G. Komen Breast Cancer Foundation

Susan Braun, president and chief executive officer, joined the Susan G. Komen Breast Cancer Foundation in July 1996. She works together with the Foundation staff and Board of Directors to fulfill the organization's mission: to eradicate breast cancer as a life-threatening disease by advancing research, education, screening and treatment. Her commitment to this mission is fueled by her professional background and her personal losses to breast cancer. Among her present appointments and responsibilities, Ms. Braun serves on leadership committees for several organizations, including: the National Action Plan on Breast Cancer, American Society of Clinical Oncology (international and health services research), American Society for Breast Disease (ASBD), World Society of Breast Health, Editorial Board of the Breast Journal, and Americorps NCCC.

The Susan G. Komen Breast Cancer Foundation was established in 1982 by Nancy Brinker to honor the memory of her sister, Susan G. Komen, who died of breast cancer at the age of 36. From its inception through the end of fiscal year 1998, the Foundation has raised more than $214 million for breast cancer research, education, screening and treatment programs. The Foundation has more than 35,000 volunteers working through a network of U.S. and international Affiliates and Komen Race for the Cure® events to eradicate breast cancer as a life-threatening disease by advancing research, education, screening and treatment. The Foundation runs one of the most innovative, responsive grant programs in breast cancer today, having awarded more than $45 million in research grants since its inception. In addition to funding research, the Foundation and its Affiliates fund non-duplicative, community-based breast health education and breast cancer screening and treatment projects for the medically underserved.

Prior to joining the Komen Foundation, Ms. Braun served in various positions within the Oncology/Immunology Division at Bristol-Myers Squibb in Princeton, New Jersey. Prior to joining Bristol-Myers Squibb, Ms. Braun was an executive with the health care consulting firm Pracon Incorporated and the Center for Economic Studies in Medicine.

Ms. Braun received a bachelor's degree in English and sociology from George Mason University and a master's degree in health sciences from the University of Maryland. She also completed the graduate program in international marketing at the University of Muenster in Muenster, Germany.

Overview of remarks by Susan Braun, President and CEO of the Susan G. Komen Breast Cancer Foundation.

The Susan G. Komen Breast Cancer Foundation was founded in 1982 by Nancy Brinker after her sister Susan Komen died from breast cancer at the age of 36. Our mission is to eradicate breast cancer as a life threatening disease by advancing research, education, screening and treatment. The Komen Foundation Grant Program is regarded as the most innovative and responsive grant program in breast cancer today. As a pioneer in the funding of groundbreaking breast cancer research, the Komen Foundation is often the only source of funding for cutting-edge research, much of which has led to landmark discoveries in our quest to find a cure and eventually prevent breast cancer. Since its inception, the Komen Foundation has awarded more than $68 million for breast cancer research projects.

Patient empowerment through access to information; the dramatic change in the physician/patient relationship; and increasing pressure for flexibility and funding from public and private institutions are radically altering our research and treatment landscape. Complementary medicine research is an important component of our research portfolio. In 2000, the Komen Foundation instituted a separate study section for complementary and alternative medicine. Prior to that time, we had never excluded this area of research, but in 2000 we began to actively foster it.

Through a grassroots network of 115 Affiliates across the country, we disseminate information on CAM to diminish myth and rumor and encourage participation in clinical trails that seek to legitimize CAM products. The challenge of CAM is that we are researching substances already in current use, but where there's been some anecdotal history of effectiveness. The Komen Foundation aims to support the use of CAM products that are safe and effective, and to combat potential market forces regulating procedures that encourage CAM entrance in the market without sufficient testing.

Not all non-traditional therapies have the potential for dramatic change. But because we have yet to find a cure for cancer, the Komen Foundation is not willing to rule out any reasonable, safe therapy that could be a breakthrough in the prevention, control or cure of cancer or in the quality of life for cancer patients.

Ronald Chez, M.D.

Samueli Institute for Information Biology

#24

RONALD A. CHEZ, MD
Abstract of CV

Present Position:

1989- *University of South Florida College of Medicine*
Professor of Obstetrics and Gynecology
Director Ambulatory Services
University of South Florida College of Public Health
Professor of Community and Family Health

Training:

1950-1953 AB	Johns Hopkins University
1953-1957 MD	Cornell University Medical College
1958-1964 Resident	UCLA, Obstetrics and Gynecology
1964-1966 Fellowship	Harvard Medical School, Biophysics

Previous Appointments:

1966-1971 *University of Pittsburgh School of Medicine*
Professor, Obstetrics and Gynecology
Associate Dean of Academic Affairs

1971-1977 *National Institutes of Health*
National Institute of Child Health and Human Development (NICHD):
Chief, Pregnancy Research Intramural Branch
Clinical Director
Georgetown University School of Medicine
Clinical Professor of Obstetrics and Gynecology
George Washington University School of Medicine
Professor of Obstetrics and Gynecology
Howard University School of Medicine
Clinical Professor of Obstetrics and Gynecology
Professor of Obstetrics and Gynecology [1977-1978]

1978-1982 *Pennsylvania State University School of Medicine*
Professor & Chair, Obstetrics and Gynecology

1986-1989 *New Jersey Medical School*
Clinical Professor of Obstetrics and Gynecology [1983-1986]
Professor & Vice Chair, Obstetrics and Gynecology

Certifications:

American Board of Obstetrics and Gynecology
Maternal-Fetal Medicine Subspecialty

Bibliography:

Author or co-author of over 500 basic science research, clinical research and continuing education articles and audiovisual learning aids.

The Samueli Institute

Supporting Research on Information Biology

The Samueli Institute is a non-profit medical research organization supporting the scientific investigation of information biology and its application in health and disease.

Information Biology

As used by the Institute, the term "information biology" refers to the interaction of biological systems with non-molecular (i.e. informational) signals. It is especially interested in how biological systems interact with signals separated or demodulated from their molecular and electromagnetic carriers.

The Institute focuses on several types of non-molecular signals. Examples are:

- ultra low dose hormetic and homeopathic exposures,
- non-ionizing and non-thermal electromagnetic and magnetic signals,
- so called "biofield" or "subtle energy" signals that emanate off the body,
- digitally produced signals, both computer generated and electronically imprinted and,
- the family of signals that accompany consciousness, such as mental intention, the transfer of meaning (semiotics), the placebo effect, and aspects of spirituality.

In addition, the Institute supports the development of biologically and technologically based systems for the detection and measurement of these signals such as biosensors.

A Network of Investigators

The Samueli Institute conducts its research through a network of laboratory programs around the world with a planned faculty and staff of over 200 individuals. Institute programs are guided by a Board of Directors, a Scientific Advisory Council and a Vision and Planning Group for the creative and rigorous scientific exploration of Institute topics.

Science and Discoveries

The Samueli Institute's scientific programs are organized into four research areas.

1) physical chemistry that investigates the nature of informational signals on molecular structure and function with methods such as nuclear magnetic resonance, infra-red and Raman spectroscopy and High Performance Liquid Chromatography coupled with ICP mass spectroscopy;
2) cellular biology that investigates cellular function and dynamics with techniques such as gene microarray and functional genomics methods, RT-PCR, ion and protein flux monitoring and examines the effects of informational therapies in animal models;
3) neuroscience that explores brain function using technology such as functional MRI, multi-channel EEG/EKG, and SPECT scanning;
4) clinical investigation and epidemiology that explore the effects of informational therapy and detection methods on health promotion, quality of life, symptom reduction, and healing processes in the treatment and prevention of disease.

The current foci of scientific investigation are to determine whether stable water complexes exist in homeopathic and informational preparations, to identify informational signals that alter cell function and gene regulation, to map the effects of informational signals on neurological function, and to determine if informational signals can reduce symptoms, improve health and quality of life and alter the course of disease.

Applications

Potential applications from Samueli Institute research include the development of biosensors in which biological systems are used to detect subtle environmental signals; digital pharmacology in which specific treatments are produced and delivered by computer; a method for creating conditioned healing spaces that enhance recovery; and, electromagnetic treatments that alter the progression of cancer, degenerative brain disease and atherosclerosis.

Education and Creativity

Meetings, conferences and educational programs sponsored by the Samueli Institute will probe the fundamental nature of reality. Topics of interest are the direction and boundaries of causation, the relationship between discovery and creation, the biophysics of multi-dimensional space, mechanisms of homeopathic action, the meanings and mechanisms underlying placebo effects, and the intersection of science and spirituality.

Points of Contact:

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Email: rchez@siib.org

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Divider Title: Evaluating Research Literature

Questions for the Panel on Approaches to Evaluating Research Literature:

Donald Lindberg:

What criteria are used when deciding to include a peer-reviewed journal or other information sources in the NLM database? How are CAM journals and other sources identified?

What recommendations can you offer regarding CAM research for the Commission's consideration as it develops its report to the President and Congress?

Douglas Kamerow:

What criteria are used by the agency when deciding on topics for evidence-based practice reports?

How does AHRQ assess the quality of the research it includes in its systematic reviews/meta-analyses?

Has AHRQ supported and published evidence-based assessments of CAM practices and products? If so, what evidence-based assessments in CAM have you conducted?

How does AHRQ collaborate with other agencies; e.g., NIH, CDC? Please comment on AHRQ's collaboration on evidence-based reviews of dietary supplements with the NIH Office of Dietary Supplements.

Does AHRQ conduct research evaluating health services (health services research)? If so, is CAM part of the research portfolio? What aspects of CAM have been investigated? If not, are there plans to include CAM in the future?

Please comment on national data, such as MEPS data, and the agency's future plans on the use of such data to examine CAM utilization.

Does AHRQ conduct any research studies, and if so, are any studies related to CAM?

What is the role, if any, of public input in the selection and dissemination of research information on CAM?

What recommendations can you offer regarding CAM research for the Commission's consideration as it develops its report to the President and Congress?

Brian Berman:

Does the Cochrane Collaboration for Evidence-based Medicine include in its database information on CAM practices and products? What criteria are used in your selection process with regard to CAM topics? How does the Cochrane Collaboration assess the quality of the research it includes in its systematic reviews/meta-analyses?

Does the Cochrane Collaboration consider public input when selecting and disseminating research information on CAM?

What policy recommendations can you offer regarding the evaluation of research literature in CAM for the Commission's consideration as it develops its report to the President and Congress?

Additional questions for Brian Berman:

Please give us your views and recommendations on the training of CAM practitioners to become research investigators, and any recommendations you may have on this issue.

Please comment on the difficulties of integrating CAM research into conventional academic institutions, and any recommendations you may have on this issue.

Donald A. Lindberg, M.D.
National Library of Medicine

Testimony of
Donald A.B. Lindberg, M.D.
Director, National Library of Medicine
Before the White House Commission on
Complimentary and Alternative Medicine Policy
May 15, 2001

Thank you for inviting me to participate on this panel that is addressing Approaches to Evaluating Research Literature. The Commission is making an important contribution to advancing research on complementary and alternative medicine (CAM) and to disseminating reliable information on CAM to health care providers and the public. I know that several of my fellow NIH institute directors already have testified before the Commission and I appreciate the opportunity to contribute this discussion. In addition, last March, Sheldon Kotzin, Chief of the National Library of Medicine's (NLM) Bibliographic Services Division testified before your Commission, focusing on access to complimentary and alternative medicine (CAM) resources available through NLM databases. He highlighted our collaborative effort with NIH's National Center for Complementary and Alternative Medicine to create CAM on PubMed. Today I will discuss the coverage of CAM journals in MEDLINE, the process by which items are selected for inclusion in our databases, and the expansion of CAM terms in the thesaurus of medical subject headings (MESH).

The users of MEDLINE are many and varied, including researchers, health care practitioners, educators, administrators, and students in this country and abroad. Now that MEDLINE is easily accessible via the World Wide Web, we also count the general public among our main audiences. Our database, therefore, must reflect this diversity and include journals in many disciplines related to the health sciences broadly. Because

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much important research is done in other countries, and published in languages other than English, our scope must be worldwide.

MEDLINE has always contained literature concerning complimentary and alternative medicine. Historically, most of the referenced articles were from non-CAM-related journals. However, in recent years more journals with CAM content have been recommended for inclusion in MEDLINE. The expansion of our coverage of CAM literature relied significantly on advice that we received in 1997 from Dr. Jonas when he was head of the NIH National Center for Alternative and Complimentary Medicine (CAM). The Center compiled a list of 695 journals that published most of the articles in the field. NLM then sent the list to 14 organizations specializing in complementary and alternative medicine for their recommendations. Of the 695, it was found that NLM already held in its collection 79 percent of the titles. Six more titles were added to the Library's collection as a result of that initial review.

We currently index in MEDLINE 75 primarily CAM journals. Appendix A provides a sample list showing the range of CAM journals in MEDLINE. It is important to emphasize that in addition to journals specifically devoted to CAM subjects, articles concerning CAM may be selected from any of the 4,500 journals currently indexed in MEDLINE. Indeed, if one searches CAM on PubMed, you will find more than 230,000 citations.

The Library uses a NIH chartered committee, the Literature Selection Technical Review Committee (LSTRC), to review all new journal titles and recommend those to be indexed. The members of LSTRC, whose appointments are approved by the Director of NIH, come from a broad range of fields in biomedicine, allied health, and life sciences.

They include medical scientists and administrators, health practitioners, and librarians. Although some of the reviewers have knowledge of CAM subject matter, we plan to expand our expertise in this field in the future. The Committee also seeks outside expertise, including from professional societies and through collateral reviews.

LSTRC meets three times each year and considers more than 140 journals at each session, regularly including reviews of CAM journals. Primary and secondary reviewers are assigned to each journal. Based upon the ratings assigned by the Committee to each journal, approximately 25-30% are recommended for inclusion in MEDLINE. Each year, NLM also conducts subject reviews and considers all the journals in a particular subject field. Last year the Committee reviewed pharmacology journals and this year they are considering public health journals.

The final selection is based upon my judgement and that of the reviewers, but NLM has published guidelines that provide a consistent set of critical elements that we use in making these decisions. The scientific merit of a journal's content is the primary consideration in the selection of journals for inclusion in the database. The key factors in determining quality are the journal contents' validity, importance, originality, and contribution to the field. Sometimes journals fill a special niche that is not otherwise well covered in the literature.

Another key factor we consider is the editorial quality of the journal. The process by which the journal selects articles, conducts peer review, ensures objectivity, and adheres to ethical guidelines all contribute to the Committee's rating. Production quality also is important. Reviewers look at the quality of the layout, printing, graphics, and illustration of each journal. Lastly, reviewers consider the value of non-U.S. journals that

Do it new, True, & Important

report on local or regional health conditions. Fifty-five percent of PubMed's use is from outside the United States and today 59 percent of MEDLINE's journals are published outside the United States. While 85 percent of the journals are in English, foreign material on indigenous health conditions and treatments is vital in today's world where we are all more closely connected and health problems arise on a global scale.

If you look at the content of journals indexed in MEDLINE it generally fits into one of the following categories:

1. Reports of original research
2. Original clinical observations accompanied by analysis and discussion
3. Analysis of philosophical, ethical, or social aspects of the health professions or biomedical sciences
4. Critical reviews
5. Statistical compilations
6. Descriptions of evaluations of methods and procedures
7. Case reports with discussions

I hope that this description provides you with an understanding of how NLM selects items, including those with CAM content, for our databases. I would like to conclude my remarks by highlighting a recent NLM initiative to enhance public access to CAM literature that I believe is of interest to the Commission. NLM has funded 53 projects in 34 states and the District of Columbia to provide training in retrieving online health information for professionals in public libraries and other location institutions. Working through our National Network of Regional Medical Libraries, we have expanded the ability of librarians at local libraries to answer patron questions about

resources for health information and to direct them to useful sites on the Internet, such as CAM on PubMed.

We have received a great deal of positive feedback about the value of this effort for introducing the public to reliable, up-to-date health information. Surveys indicate that while most people search for health information on the Web from the privacy of their own homes, they often find out about these online resources through public libraries and other local institutions. We believe that the kind of programs that NLM sponsors for training local public librarians and for expanding consumer outreach will contribute substantially to making the public aware of helpful information concerning complementary and alternative medicine.

Appendix A

Representative Alternative Medicine Titles in Medline

AAOHN Journal; American Association of Occupational Health Nursing
Acta Pharmaceutica Sinica; Yao Hsueh Hsueh Pao
Acta Pharmacologica Sinica; Chung-Kuo Yao Li Hsueh Pao
Acupuncture and Electro-Therapeutics Research
Acupuncture Research; Chen Tzu Yen Chiu; Zhen Ci Yen Yan Jiu
Advances in Mind Body Medicine
Alternative Medicine Review
Alternative Therapies in Health and Medicine
American Journal of Acupuncture
American Journal of Chinese Medicine; Mei-Chou Chung-Kuo I Hsueh Tsa Chih
American Journal of Clinical Nutrition
American Journal of Health Promotion
American Journal of Preventive Medicine
Annual Review of Nutrition
Applied Psychophysiology and Biofeedback
Arzneimittel-Forschung
British Homoeopathic Journal
British Journal of Clinical Pharmacology
British Journal of Nutrition
China Journal of Chinese Materia Medica
Chinese Journal of Integrated Traditional and Western Medicine
Chinese Journal of Preventive Medicine
Chinese Medical Journal
Chiropractic History
Complementary Therapies in Medicine
Complementary Therapies in Nursing and Midwifery
Culture, Medicine and Psychiatry
Drugs under Experimental and Clinical Research
Environmental Health Perspectives
Forschende Komplementarmedizin
Fortschritte der Medizin
Health Affairs
Holistic Nursing Practice
Hospital Medicine
Human Nutrition. Applied Nutrition
Human Nutrition. Clinical Nutrition
Indian Journal of Experimental Biology
Indian Journal of Medical Research
International Journal for Vitamin and Nutrition Research
International Journal of Psychophysiology
International Journal of Psychosomatics
Journal of Alternative and Complementary Medicine

Alternative Medicine Titles in Medline (Continued)

Journal of Chinese Medicinal Materials
Journal of Ethnopharmacology
Journal of Holistic Nursing
Journal of Manipulative and Physiological Therapeutics
Journal of Natural Products
Journal of Nutrition
Journal of Nutritional Science and Vitaminology
Journal of Psychoactive Drugs
Journal of Spinal Disorders
Journal of Substance Abuse
Journal of the American College of Nutrition
Journal of the American Dietetic Association
Journal of the American Osteopathic Association
Journal of Traditional Chinese Medicine
Medical Anthropology
Medical Hypotheses
Metabolism: Clinical and Experimental
Nutrition and Cancer
Nutrition and Health
Nutrition Reviews
Orvosi Hetilap
Pain
Pharmacology, Biochemistry and Behavior
Phytomedicine
Phytotherapy Research
Planta medica
Proceedings of the Nutrition Society
Progress in Clinical and Biological Research
Social Science and Medicine
Veterinary and Human Toxicology
Women and Health
Women's Health Issues

In addition to these 74 journals, another 600-700 journals included in MEDLINE also publish articles in the field of Complementary and Alternative Medicine. For example, these include such titles as Lancet, British Medical Journal, Canadian Medical Association Journal, the Journal of Biological Chemistry, JAMA, and the American Journal of Physiology.

Donald A.B. Lindberg, M.D.
Director
National Library of Medicine

Donald A.B. Lindberg, M.D., a scientist who has pioneered in applying computer technology to health care beginning in 1960 at the University of Missouri, in 1984 was appointed Director of the National Library of Medicine, the world's largest biomedical library (annual budget $246,351 million; 600 career staff). From 1992-1995 he served in a concurrent position as founding Director of the National Coordination Office for High Performance Computing and Communications (HPCC) in the Office of Science and Technology Policy, Executive Office of the President (annual budget $1.1 billion; 12 federal agencies, including DOD, DOE, NSF, NASA, HHS, VHA, DOC, EPA). In 1996 he was named by the HHS Secretary to be the U.S. Coordinator for the G-7 Global Healthcare Applications Project.

In addition to an eminent career in pathology, Dr. Lindberg has made notable contributions to information and computer activities in medical diagnosis, artificial intelligence, and educational programs. Before his appointment as NLM Director, he was Professor of Information Science and Professor of Pathology at the University of Missouri-Columbia. He has a current academic appointment as Adjunct Professor of Pathology at the University of Maryland School of Medicine.

Dr. Lindberg was elected the first President of the American Medical Informatics Association (AMIA). As the country's senior statesman for medicine and computers, he has been called upon to serve on many boards including the Computer Science and Engineering Board of the National Academy of Sciences, the National Board of Medical Examiners, the Council of the Institute of Medicine of the National Academy of Sciences.

Dr. Lindberg is the author of three books: The Computer and Medical Care: Computers in Life Science Research; and The Growth of Medical Information Systems in the United States, several book chapters, and more than 200 articles and reports. He has served as editor and editorial board member of nine publications including the Journal of the American Medical Association.

Dr. Lindberg graduated **Magna cum Laude** from Amherst College and received his M.D. degree from the College of Physicians and Surgeons, Columbia University. Among the honors he has received are Phi Beta Kappa, Simpson Fellow of Amherst College, Markle Scholar in Academic Medicine, Surgeon General's Medallion, recipient of the First AMA Nathan Davis Award for outstanding Member of the Executive Branch in Career Public Service, the Walter C. Alvarez Memorial Award of the American Medical Writers Association, the Presidential Senior Executive Rank Award, Founding Fellow of the American Institute of Medical and Biological Engineering, the Outstanding Service Medal of the Uniformed Services University of the Health Sciences, *Federal Computer Week's* Federal 100 Award, Computers in Healthcare Pioneer Award, Association of Minority Health Professions Schools Commendation, RCI High Performance Computing Industry Recognition Award, U.S. National Commission on Libraries and Information Science Silver Award, Council of Biology Editors Meritorious Award, Presidential Rank Award of Meritorious Executive in the Senior Executive Service, Medical Library Association President's Award, American College of Medical Informatics Morris F. Collen, M.D. Award of Excellence, Johns Hopkins University School of Medicine Ranice W. Crosby Distinguished Achievement Award, New York Academy of Medicine Information Frontier Award, 2001 Cosmos Club Award, Fellow of the American Association for the Advancement of Science, and honorary doctorates from Amherst College, the State University of New York at Syracuse and the University of Missouri-Columbia.

May 2001

#24

RONALD A. CHEZ, MD

Abstract of CV

Present Position:

1989- *University of South Florida College of Medicine*
Professor of Obstetrics and Gynecology
Director Ambulatory Services
University of South Florida College of Public Health
Professor of Community and Family Health

Training:

1950-1953 AB	Johns Hopkins University
1953-1957 MD	Cornell University Medical College
1958-1964 Resident	UCLA, Obstetrics and Gynecology
1964-1966 Fellowship	Harvard Medical School, Biophysics

Previous Appointments:

1966-1971 *University of Pittsburgh School of Medicine*
Professor, Obstetrics and Gynecology
Associate Dean of Academic Affairs

1971-1977 *National Institutes of Health*
National Institute of Child Health and Human Development (NICHD):
Chief, Pregnancy Research Intramural Branch
Clinical Director
Georgetown University School of Medicine
Clinical Professor of Obstetrics and Gynecology
George Washington University School of Medicine
Professor of Obstetrics and Gynecology
Howard University School of Medicine
Clinical Professor of Obstetrics and Gynecology
Professor of Obstetrics and Gynecology [1977-1978]

1978-1982 *Pennsylvania State University School of Medicine*
Professor & Chair, Obstetrics and Gynecology

1986-1989 *New Jersey Medical School*
Clinical Professor of Obstetrics and Gynecology [1983-1986]
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1) physical chemistry that investigates the nature of informational signals on molecular structure and function with methods such as nuclear magnetic resonance, infra-red and Raman spectroscopy and High Performance Liquid Chromatography coupled with ICP mass spectroscopy;
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3) neuroscience that explores brain function using technology such as functional MRI, multi-channel EEG/EKG, and SPECT scanning;
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The current foci of scientific investigation are to determine whether stable water complexes exist in homeopathic and informational preparations, to identify informational signals that alter cell function and gene regulation, to map the effects of informational signals on neurological function, and to determine if informational signals can reduce symptoms, improve health and quality of life and alter the course of disease.

Applications

Potential applications from Samueli Institute research include the development of biosensors in which biological systems are used to detect subtle environmental signals; digital pharmacology in which specific treatments are produced and delivered by computer; a method for creating conditioned healing spaces that enhance recovery; and, electromagnetic treatments that alter the progression of cancer, degenerative brain disease and atherosclerosis.

Education and Creativity

Meetings, conferences and educational programs sponsored by the Samueli Institute will probe the fundamental nature of reality. Topics of interest are the direction and boundaries of causation, the relationship between discovery and creation, the biophysics of multi-dimensional space, mechanisms of homeopathic action, the meanings and mechanisms underlying placebo effects, and the intersection of science and spirituality.

Points of Contact:

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AHRQ, CAM, and EBM

Douglas B. Kamerow, M.D., M.P.H.
Assistant Surgeon General
Agency for Healthcare Research and Quality

Overview

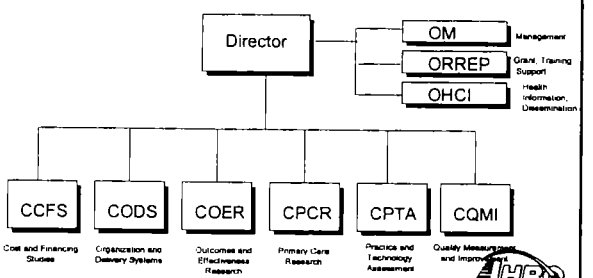
- Agency for Healthcare Research and Quality
- Complementary and Alternative Medicine at AHRQ
- AHRQ's Evidence-based Practice Centers
- EPCs and CAM

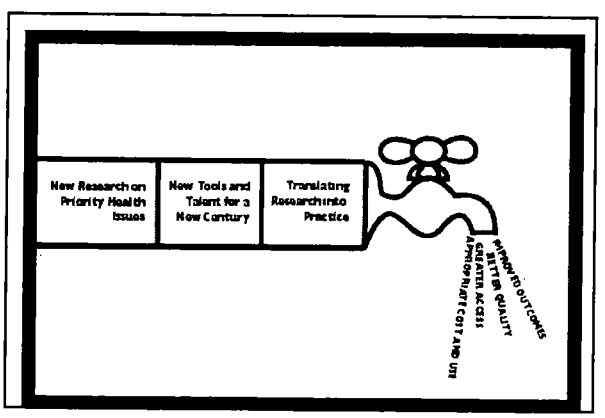
@ AHRQ.GOV

AHCPR is Now AHRQ!

- Became official on December 5, 1999 when President signed reauthorization legislation
- Mission: support, conduct, and disseminate research that improves access to care, reduces its cost, and improves the outcomes, quality, and appropriate use of health care services
- Lead Federal agency in improving health care quality through health services research
- FY 2001 budget: $260 million

AHRQ Structure





Overview of AHRQ CAM Activities

- Outcomes and effectiveness research
  - Mainly on back pain, investigating chiropractice and acupuncture
- Surveys
  - Medical Expenditure Panel Survey (MEPS
  - Nationally representative household survey
  - Collecting data on CAM usage by individuals
- Synthesis
  - Evidence-based Practice Centers (EPCs)

Chiropractic

- Chiropractic vs. physical therapy - a randomized trial (included monograph comparing chiropractic and medical school education)
- Low back pain outcomes and efficiency of care (included chiropractic)
- Manual therapy in primary care of acute low back pain
- Chiropractic vs. medical care for low back pain

Acupuncture and Other Alternative Therapies

- Alternative therapies for back pain - a randomized trial (traditional Chinese acupuncture and therapeutic massage)
- Evaluating the efficacy of acupuncture for back pain (pilot study co-funded with NCCAM)
- Acupuncture treatment of depression during pregnancy (pilot study co-funded with NCCAM)

Medical Expenditures Panel Survey (MEPS)

- Annual household survey of 27,000 Americans
- Representative of civilian non-institutionalized population
- Tracks health services and costs
- 1996 data was available in January 2000

MEPS and CAM

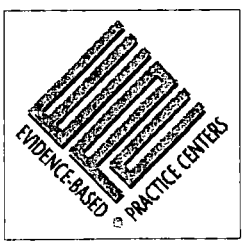
- Tracks use of these CAM therapies:
  - Acupuncture
  - Nutritional
  - Massage
  - Herbal
  - Biofeedback
  - Meditation
  - Homeopathy
  - Spiritual
  - Hypnosis
  - Chinese/Indian/ayurvedic

MEPS and CAM

- Counts of use
- Cost of visit
- Allows comparison of use of CAM and conventional therapies

Evidence-based Practice Centers (EPCs)

- Created in 1997
- 12 centers
- Produce evidence reports/technology assessments
- Work with public and private sector partners
- User driven



Evidence-based Practice Centers

- BC/BS
- Duke U.
- ECRI
- Johns Hopkins U.
- McMaster U.
- MetaWorks
- New Eng. Med. Ctr.
- Oregon HSU
- So. Calif. - RAND
- RTI - UNC
- UCSF - Stanford U.
- U. Texas San Antonio

Potential Uses -- To Develop...

- Clinical practice guidelines
- Performance measures
- Quality improvement programs
- Coverage policies

Systematic Reviews

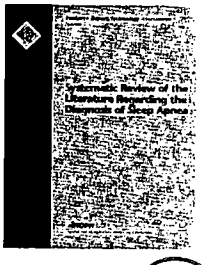
- Concise summaries of the best available evidence addressing sharply defined clinical questions, using explicit and rigorous methods to identify, critically appraise, and synthesize relevant studies (Mulrow C, Cook, D *Systematic Reviews*, ACP, 1998)

Evidence Reports

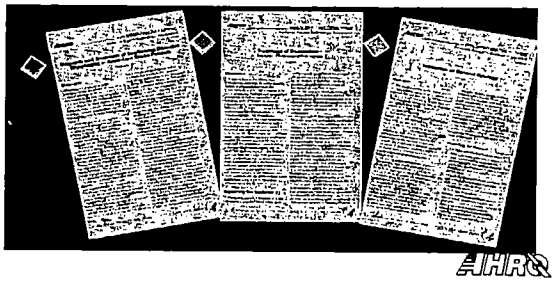
- "Front end" of guidelines, QI programs, coverage decisions
- Focused on a few specific questions
- Systematic and thorough reviews
- Peer reviewed
- Published and widely disseminated

Full Text of EPC Evidence Reports

- Includes all analyses
- Evidence tables and references
- Search strategies
- Available from AHRQ Clearinghouse: 1-800-358-9295



Four-Page Summaries of EPC Evidence Reports



EPCs and CAM

- Sponsored by National Center for Complementary and Alternative Medicine, NIH
  - Routine evidence reports
    - Garlic and heart disease/cancer
    - Milk thistle and liver disease
  - Multi-year task order with RAND
    - Three topics completed, more underway
- Sponsored by the Office of Dietary Supplements
  - Ephedra, others to come

RAND CAM Topics

- Mind-body medicine and gastrointestinal disease
- Ayurvedic medicine and diabetes mellitus
- Methods report on evaluation of non-randomized trials with meta-regression
- More topics in coming year

Uses of AHRQ CAM Evidence Reports

- What works and what has been proven
- What has promise for more research
- Methods and bibliographic research

Douglas B. Kamerow, M.D., M.P.H.

Assistant Surgeon General, USPHS

Dr. Douglas Kamerow, an Assistant Surgeon General in the U.S. Public Health Service Commissioned Corps, is currently Director of the Center for Practice and Technology Assessment (CPTA) of the Agency for Healthcare Research and Quality (AHRQ) in Rockville, Maryland. Since October 1994, Dr. Kamerow has led AHRQ's programs to improve the quality of health care in the U.S. through the development and implementation of evidence-based tools. These tools have included the 19 AHRQ clinical practice guidelines, which were widely disseminated and very influential. CPTA's current programs include 12 Evidence-based Practice Centers, the U.S. Preventive Services Task Force, the National Guideline Clearinghouse, and research on implementation of evidence-based recommendations into health care.

Before joining AHRQ, Dr. Kamerow was for six years Director of the Clinical Preventive Services Staff of the PHS Office of Disease Prevention and Health Promotion (ODPHP). He was managing editor of the first and second editions of the report of the U.S. Preventive Services Task Force, the *Guide to Clinical Preventive Services*. He also conceived and directed the development and implementation of the PHS national clinical preventive services education campaign, "Put Prevention into Practice," including editing the first edition of the *Clinician's Handbook of Preventive Services*, published in 1994.

A family physician with training in epidemiology, Dr. Kamerow graduated with honors from Harvard College and received his medical degree from the University of Rochester and a master's degree in public health from Johns Hopkins University. He is board-certified in family practice and in preventive medicine. During his PHS career, Dr. Kamerow also has served as a general practitioner in the National Health Service Corps and as the Director of the Primary Care Research Program of the National Institute of Mental Health (NIMH).

Dr. Kamerow is also the PHS alternate delegate to the American Medical Association's House of Delegates, working with the Surgeon General to present PHS policies and positions to the AMA. He holds the rank of Clinical Professor in the Department of Family Medicine at Georgetown University, where he teaches medical students and family practice residents.

Dr. Kamerow has edited three books and authored or co-authored more than 40 articles, editorials, book chapters, and monographs on evidence-based medicine, guidelines, preventive services, and mental disorders in primary care. He has received numerous awards for his work at AHRQ, ODPHP, and NIMH, including most recently the DHHS Secretary's Award for Distinguished Service, the AHRQ Administrator's Distinguished Service Award, and the Surgeon General's Exemplary Service Medal.

A native of the District of Columbia, Dr. Kamerow lives in Chevy Chase, Maryland with his wife, Celia Shapiro, and their three children.

12/99