WHITE HOUSE COMMISSION ON COMPLEMENTARY
AND ALTERNATIVE MEDICINE POLICY
Planning and Discussion Document - Draft
OCTOBER 5-6, 2000

I. Research Activity - Needs, Problems, and Incentives
- NCCAM - Dr. Stephen Straus
- NCI - Dr. Jeffrey White
- CDC Field Studies
- DOD, VA, DARPA, NSF
- Pharmaceutical Industry
- Foundations , Philanthropic Organizations - Oscher Foundation
- NCCAM Supported Research Centers - Dr. Brian Berman, Dr. William Meeker
- Dr. Al Fishman , Dr. Barrie Cassileth, Dr. Wallace Sampson, Dr. Joseph Pizzorno or Dr. Leanna Standish, Dr. Stephen Barrett

II. Regulatory Review of CAM Research
- Research Oversight - Drugs: Dr. Janet Woodcock, Dr. Robert Temple; Medical Devices: Dr. David Feigal; Nutritional Supplements: Joseph Levitt and Dr. Laurie Love
- Outcomes Research - AHRQ and COCHRANE Collection
- Monitoring of Adverse Events
- Standardization of Botanical Products

III. Reimbursement
- HCFA Requirements for Reimbursement
- Results of Research as a Basis for Reimbursement
- State Requirements - Washington (John Weeks, Laurie Bielinsky)
- HMO and Managed Care Organizations Experience

IV. Communication of Research Results
- Journal Editors - NEJM; JAMA; JACM - Jackie Wooton; ATH&M - Dr. Larry Dossey;
- Science Writers - Larry Altman - NY Times;
- TV - Robert Bazell - NBC NEWS
- Websites - Web MD

V. Emerging Energy Medicine Research
- Wallenchamp and Marilyn Schlitz
- NSF AND DARPA
- Placebo effect

Research Activity

- NCCAM — Straus
- NCCAM Supported Centers — Berman; Experience in Mainstreaming Res
- CDC Field Studies
- Outcomes Research < AHRQ — Cochrane Collaboration; use in other countries
- Pharmaceutical Industry — ~~[illegible]~~

+ CCAM
DOD
VA
~~HCFA~~

NSF
DARPA

Regulatory Review of CAM Research

- Research Oversight — need to Expand
- Monitoring of Adverse Events /
- ~~Needs to Expand~~ Areas
- Standardization of Botanical Products Dietary Supplements

① [illegible] Ann [illegible]
② Bob Temple
③ Janet Woodcock

Reimbursement

- HCFA Requirements for Reimbursement
- Results of Research

Communication of Research Results

- Journals — Needs & Concerns

NEJM JAMA
JAMA

FOCI

Incentives for Research on CAM Interventions

Complementary Therapies in Medicine (1994) 2, 217-220

EDUCATION

Improving health care through the evaluation and integration of complementary medicine

B. M. Berman and R. W. Anderson

Project for the Integration of Orthodox and Complementary Medicine, University of Maryland School of Medicine, USA

SUMMARY. **The need for health care reform in the USA is abundantly clear to consumers, providers, third parties and policy makers alike. This paper presents a rationale for the evaluation and integration of complementary approaches into the mainstream of modern medicine as a way of both decreasing costs and increasing the quality of care. A project aimed at building the necessary scientific basis for this is described. The ultimate goal of the project and this paper is to stimulate new thinking about health and illness, toward encouraging models of health care which attend as much to the person and their experience of 'illness' as to their symptoms and 'disease'.**

INTRODUCTION

Concern for safe, efficient and cost-effective treatments for spiralling health care problems is at an all-time high – particularly in the current climate of budget cutting and declining resources. Chronic health problems now on the rise in the USA are not being effectively addressed by present treatments, and this, too, has fuelled the fever for health care reform. The failure of segregated medical services for conditions involving more than just physical symptoms provides yet a third impetus for more broadly conceived, interdisciplinary approaches to diagnosis, treatment and prevention.

Under a variety of names, the popularity of alternative medicine has increased in the USA and Europe. A survey published recently in the *New England Journal of Medicine*[1] reported that alternative medicine has an 'enormous presence' in the USA, with data indicating that 1 in 3 Americans used at least one alternative therapy in the past year (predominantly for chronic conditions), with an estimated $13.7 billion in expenditures. This is consistent with other surveys in Europe[2,3] concluding (1) that these approaches are interesting to both consumers and health care providers, (2) that their integration holds promise for improving the quality of care and quality of life, and (3) that their scientific evaluation, although difficult, is possible and necessary. A recent pilot survey of our own[4] supported the interest of Maryland physicians in complementary-alternative medicine and the need for appropriate scientific outcome research.

Sweeping criticism of these approaches, however, tends to cast unwarranted aspersions and derail efforts to evaluate them. Such bias is detrimental to the health care agenda inasmuch as it may preclude the possible benefits to the American people of integrating validated complementary medicine where appropriate. This issue has not escaped national attention, as evidenced by the establishment of a new National Institutes of Health Office of Alternative Medicine (NIH–OAM) which expressly mandates federal funding for the evaluation of 'alternative medical practices'.

Brian M. Berman MD, Assistant Professor of Anesthesiology and Family Medicine, **Robert W. Anderson PhD**, Fellow/Instructor in Anesthesiology, University of Maryland School of Medicine, 419 West Redwood Street, Suite 470, Baltimore, Maryland 21201–1734, USA.

THE MARYLAND PROJECT

In September 1991, we began our Project for the Integration of Orthodox and Complementary Medicine at the University of Maryland School of Medicine, aiming to:

- Explore the efficacy and scientific foundation for the integration of complementary medicine and orthodox medical care.
- Expand awareness of alternative treatments and their potential usefulness.
- Integrate treatments such as acupuncture, homeopathy, and behavioral medicine with mainstream medical training and practice.
- Develop an interdisciplinary program with integrated clinical, educational and research objectives to educate the medical community and the public, to scientifically test these approaches in a university medical setting and to begin to develop models of their integration in the treatment of troublesome health care problems.

The project is directed by Dr Brian M. Berman, who has also been appointed to the NIH–OAM Advisory Board. The major goal of the project is not to replace conventional medicine, but to expand its boundaries and build a scientific foundation for integrating less well-understood approaches to improve the functional status of patients. Although it is a question we aim to investigate, we believe these approaches work at least in part because of the greater attention paid to the *person* with the disease, and their emotional experience of illness, often including fear, helplessness and anger.

THREE INTEGRATED PHASES

The Project for the Integration of Orthodox and Complementary Medicine encompasses 3 phases: clinical care, research, and education, over 5 years, with the principle objective of bridging the gaps between orthodox and alternative medicine, between science and practice and between vital undeserved health care needs and shrinking resources.

Clinical care

The initial effort, Phase I of the project, has focused on the development of an interdisciplinary staff and pain center offering comprehensive evaluation, treatment and preventive services. Over the 18 months since we began, our clinical volume has increased 400%. This interest, along with the experience of building the clinical team and developing a program incorporating complementary medicine, has stimulated a range of provocative questions including the role of techniques vs. the role of the *doctor-patient relationship* and patient expectations in treatment.

Specific therapies in our program include acupuncture, anesthesiology, behavioral medicine, clinical psychology, family medicine, group therapy/education, homeopathy, PT, relaxation training/biofeedback, Tai Chi, therapeutic touch, traditional Chinese medicine and yoga. The approach we use is person-centered, and the use of complementary therapies is guided by patient response. This makes financial as well as medical sense because, by attending to patients' experience and the results of scientific studies of treatment effects, we are able to conserve resources, empower people and develop the most efficient treatment plans.

Why chronic pain?

We selected chronic pain as our initial focus because it is pervasive and because it is well-suited to the collaborative, patient-involved treatment model we are developing. In addition to disrupting relationships and functional status, chronic pain often impairs the creative spirit and produces despair in people's lives. It is also a costly problem: estimated at 100 billion dollars, with up to 93 million work days lost annually in the USA. Because the causes of chronic pain are poorly understood (and it is often associated with drug dependency, anxiety, job loss, and excessive use of the health care system), traditional treatments have been stymied, thus increasing the costs of health care for all of us. With severe emotional, economic, physical, and social consequences, therefore, it is a metaphor for many chronic health problems.

Recent developments in behavioral medicine and interdisciplinary treatment have provided new avenues for addressing these dimensions of illness, and our own complementary therapies have shown promise with patients we have treated thus far. Moreover, research indicates that persons who participate in multidisciplinary chronic pain management programs tend to increase their functional activities, and decrease their use of addictive medications and visits to health care professions.[5] Again, we believe that increased attention to the person is an underestimated part of why these approaches work.

Scientific evaluation

Phase II has involved the establishment of a research staff and working database for ongoing investigation of the results of our own complementary and interdisciplinary treatments. Our efforts include a broad spectrum of developmental research from literature reviews and surveys (what is known) to clinical trials (efficacy), differential studies (what works with whom, under what conditions, what factors impact treatment response and outcome), and basic science (mechanisms). Research priorities must be forged out of critical appraisals of available literature and creative solutions to

the unique methodological problems posed by complementary medicine, requiring new kinds of collaborative effort.

It is clear that unsupported claims of efficacy or panacea need to be separated from reports of biomedical merit in rigorous scientific analyses. On the other hand, unexamined stereotypes of alternative medicine as 'quackery' or 'fraud' are equally obstructive when they threaten the balanced perspective essential to objective investigation – or simply keep the important questions from being posed by serious researchers. For this reason, we are as committed to documenting the kinds and conditions of *ineffective* approaches as we are in validating potentially *cost-saving*, *effective* therapies.

Thus far at the University there have been a healthy skepticism, but also a willingness to listen and collaborate that has been very encouraging. For example, the Departments of Epidemiology, Family Medicine, and Rheumatology in the School of Medicine, Biochemistry, Physiology, and Pharmacology in the Dental School, and the Cancer Center, have all expressed interest in collaboration. This interdisciplinary team effort has enabled us to bring together the clinical experts (in pain, osteo–arthritis, postoperative emesis, for example), the scientific experts (in research methodology and biostatistics), and experts in several complementary approaches. For our own part, we have a Western physician trained in Eastern medicine, a Chinese acupuncturist trained in Western science and physiology, and a clinical psychologist trained in methodology and interested in emotional, cultural, and spiritual influences on health. In this way, we are one of the few *medical university-based centers* engaged in *co–ordinated* clinical, educational and scientific efforts to evaluate alternative medicine.

Our initial clinical trials investigating the efficacy of acupuncture to treat osteo–arthritis and postoperative dental pain have shown encouraging results. We have also completed a survey of attitudes regarding complementary medical practices among primary care physicians, with a nationwide version in preparation. Other scientific efforts include investigations of anger and coping style among chronic pain patients, and a review of methodological problems which have stymied Western efforts to evaluate the effects of acupuncture.

More recently, we completed an invited chapter on the treatment for arthritis in the geriatric population including alternative approaches,[6] and are currently preparing a description of our integration of alternative medicine in multidisciplinary treatment of chronic pain for the *British Journal of Anesthesia.*

Education and training

Phase III of the project encompasses an overarching set of goals, not only to increase interest and training in complementary approaches, but to stimulate new thinking about health, illness and models of patient care. In our view, complementary medicine can reduce health costs in a number of ways by teaching healthy lifestyle and self-responsibility directly, but expanding the range of validated treatment options (some of which are less costly), and by modelling integrated care which targets functional status and quality of life. We are collecting data to support our belief that individuals with higher quality of life tend to use the health care system less.

Specific educational efforts to date include fellowships, training for residents, electives for medical students, and consultation for postdoctoral professionals, lectures on-campus and in the community, a journal club, and an international conference.[7] Underpinning all of these is our aim to raise the awareness of the medical community regarding the existence, efficacy and role of alternative medicine as a cost-saving component of optimal health care.

Interest in our work has increased referrals and media coverage from the community and on our own campus. We were included, for instance, as a cover story in the University of Maryland *Alumni Bulletin*,[8] and as a feature in this year's *Annual Report* for the UMD Medical Center.[9]

THE WAY FORWARD

In our view, effective evaluation of complementary medicine will enable massive preventive and educational efforts and provide a scientific basis for the selection of validated 'alternative' therapies to be used with standard medical approaches as appropriate. With the rising costs of many high-tech diagnostic and treatment procedures, the need for a wider range of less costly options is keen. Because of the nature and cultural origins of some complementary approaches, however, the scientific validation of 'demonstrated efficacy' may require some innovative research strategies – and perhaps new models of interdisciplinary and inter-speciality collaboration – if we are to capitalize these largely untapped resources.

The ultimate aim, therefore, is the establishment of an Institute of Integrated Medicine, with endowed professorships and lectureships to develop effective models of researching, teaching and integrating complementary approaches. In the UK as in the USA, the need for and interest in alternative care has grown dramatically. Though we believe one benefit of our plan will be the improvement of the quality and cost-effectiveness of care, the real goal is to improve the self-determination and quality of life of those who want effective, affordable, and personal health care – and who, after all, does not?

Acknowledgements

The project was jointly funded, and preparation of this paper supported, by the Maurice Laing Foundation and Thera Trust, London.

and the Department of Anesthesiology, University of Maryland School of Medicine, Baltimore, USA.

References

1. Eisenberg D M, Kessler R C, Foster C, Norlock F E, Calkins D R, Delbanco T L. Unconventional medicine in the United States: prevalence, costs, patterns of use. New Engl J Med 1993; 328(4): 246–252.
2. Reilly D, Taylor M. Developing integrated medicine: report of the RCCM Research Fellowship in Complementary Medicine, University of Glasgow 1987–1990. Compl Therap Med 1993; 1 Suppl 1.
3. Vaskilampi T, Merilaiman P, Sinkkonen S. The use of alternative treatments in the Finnish adult population. Compl Med Res 1992; 6(1): 9–20.
4. Berman B M, Anderson R W. Complementary-alternative medicine: survey of primary care physicians in Maryland. Baltimore: University of Maryland School of Medicine, 1993.
5. Flor H, et al. Efficacy of multidisciplinary treatment centers: a meta-analytic review. Pain 1992; 49: 221–230.
6. Daly M P, Berman B M. Rehabilitation of the elderly patient with arthritis. In Brummel-Smith K ed. Clinics in geriatric medicine: geriatric rehabilitation. Philadelphia: W B Saunders, 1993. pp 783–801.
7. Research and Clinical Applications of Acupuncture: 1993 symposium, AAMA and University of Maryland School of Medicine, Marriott Inner Harbor, Baltimore, May 1993.
8. Kercheval N. Easing the pain: the University of Maryland Pain Center blends orthodox and alternative medicine. Bull Med Alumni Assoc 1992; 77(3): 16–18.
9. Meyer K, Anderson R W. Building the scientific foundations for complementary medicine. The science of life (University of Maryland Medical Center Annual Report) 1992, no 14.

LETTER TO THE EDITOR

Dear Sir

Unconventional or physical?

Julian Kenyon's article[1] on back pain misrespresented the current evidence on the role of acupuncture in the treatment of back pain. While acknowledging that clinical tirals have thrown up conflicting results he still concludes that acupuncture is a 'relatively well-validated' treatment for lower back pain. In fact of 9 randomised controlled trials which fulfil minimal quality standards, only four [2-5] showed improved outcomes in the acupuncture groups compared to the control groups receiving no needling. In the other five [6-10] studies, which compared groups receiving acupuncture in the traditional Chinese meridians to groups receiving various types of needling in other parts of the back, none found any significant differences between groups in any outcome measured.

Furthermore, a meta-analysis[11] of 51 clinical studies on acupuncture for various types of chronic pain (including back pain) found none of the studies demonstrated an advantage of needling in the appropriate Chinese meridians over 'misplaced' needling.

The jury is still out on the role of acupuncture in the treatment of back pain and we await the reults of better quality trials, as even the 9 referred to above have substantial methodological waeknesses. Finally, if there is still uncertainty about the role of acupuncture in chronic back pain, there is virtually no trial evidence supporting its use in the treatment of acute back pain, in contrast to the good evidence[12] for manipulation in acute back pain. This does not mean that acupuncture is ineffective in acute back pain, but simply that a decision to treat with this method cannot be based on conventional scientific evidence of effectiveness.

Yours faithfully

Gene Feder BSc, MRCGP, MD
Senior Lecturer, Dept General Practice and Primary Care The Medical Colleges of St Bartholomew's and the Royal London Hospitals, London, UK.

References

1. Kenyon J. Back Pain: the alternatives considered. Compl Therap Med 1994; 2: 77–79.
2. Coan R M, Wong G, Ku S L, Chan Y C et al. The acupuncture treatment of low back pain: a randomized controlled trial. Am J Cin Med 1980; 8: 181–189.
3. Junnila SYT. Acupuncture therapy for chronic pain: a randomized comparison between acupuncture and pseudo-acupuncture with minimal peripheral stimulus. Am J Acupuncture 1982; 10: 259–262.
4. Lehmann T R, Russell D W, Spratt K F et al. Efficacy of electroacupuncture and TENS in the rehabilitation of chronic low back pain patients. Pain 1986; 26: 277–290.
5. Gunn C C, Milbrandt W E, Little A S et al. Dry needling of muscle motor points for chronic low back pain: a randomized clinical trial with long term follow-up. Spine 1980; 5: 279–291.
6. Gaw A C, Chang L W, Shaw L C. Efficacy of acupuncture on osteoarthritic pain. N Engl J Med 1975; 293: 375–378.
7. Edelist G, Gross A E, Langer F. Treatment of low back pain with acupuncture. Can Anaesth Soc J 1976; 23: 303–306.
8. Ghia J N, Mao W, Toomey T C, Gregg J M. Acupuncutre and chronic pain mechanisms. Pain 1976; 2: 285–289.
9. Mendelson G, Kidson M A, Loh S T et al. Acupuncture treatment of chronic low back pain. Clin Exp Neurol 1978; 15: 182–185.
10. Mendelson G, Selwood T S, Kranz H et al. Acupuncture treatment of chronic low back pain. A double-blind placebo-controlled trial. Am J Med 1983; 74: 49–55.
11. ter Riet G, Kleijnen J, Knipschild P. Acupuncture and chronic pain: a criteria-based meta-analysis. J. Clin Epidemiol 1990; 43: 1191–1199.
12. Shekelle P G, Adams A H, Chassin M R et al. Spinal Manipulation for low back pain. Ann Int Med 1992; 117: 590–598.

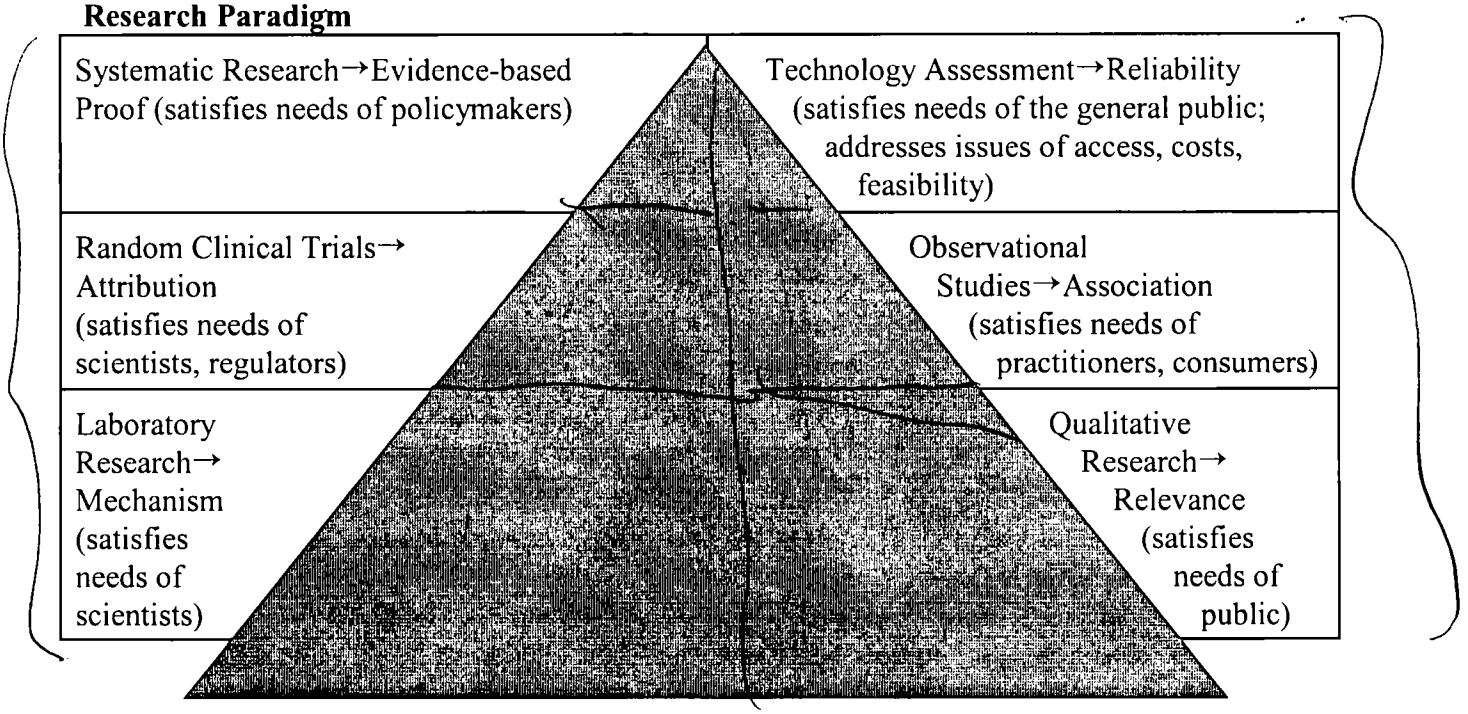
WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY

AGENDA FOR OCTOBER 5-6, 2000

Planning and Discussion Document - Draft

I. Providing Guiding Principles for Discussion: introduction of an expanded research paradigm with critical elements of equal legitimacy and importance (*Wayne Jonas*) — 10 minutes

Research Paradigm



II. Statement of Issues: (Research Activities - Needs, Problems, and Incentives)

1. **Prioritization and Coordination**
   - A. Managing public input
   - B. Special populations
   - C. Federal demonstration projects
   - D. ~~Broad Re~~

   Potential Speakers

   NCCAM - Dr. Stephen Straus (11:00 Presentation)

   NCI - Dr. Jeffrey White

   DOD, VA, DARPA, NSF

2. **Frontier Science**
   - A. Defining "frontier"
   - B. Stimulating research
   - C. Placebo Effect

   Potential Speakers

   Wallenchamp and Marilyn Schlitz

   NSF AND DARPA

NCCAM Supported Research Centers - Dr. Brian Berman, Dr. William Meeker Dr. Al Fishman , Dr. Barrie Cassileth, Dr. Wallace Sampson, Dr. Joseph Pizzorno or Dr. Leanna Standish, Dr. Stephen Barrett

C. Stimulation of Private Research

A. Patent requirements
B. Regulation of Products and Devices
C. Biotech investments
D. Regulatory Review of CAM Research

Potential Speakers

Pharmaceutical Industry
Foundations , Philanthropic Organizations - Oscher Foundation
Research Oversight - Drugs: Dr. Janet Woodcock, Dr. Robert Temple;
Research Oversight - Medical Devices: Dr. David Feigal;
Research Oversight - Nutritional Supplements: Joseph Levitt and Dr. Laurie Love

4. Outcomes Research

A. Developing facility: methodology
B. Special populations
C. Defining scope
D. Evaluation and Assessment

Potential Speakers

CDC Field Studies
AHRQ and COCHRANE Collection

5. Monitoring of Adverse Events

A. Standardization of Botanical Products
B. Collection of Adverse Events Reports
C. Standards and systems for alerting the public and health professionals

6. Reimbursement

A. HCFA Requirements for Reimbursement
B. Results of Research as a Basis for Reimbursement
C. State Requirements - Washington (John Weeks, Laurie Bielinsky)
D. HMO and Managed Care Organizations Experience

7. Communication of Research Results

A. Journal Editors - NEJM; JAMA; JACM - Jackie Wooton; ATH&M - Dr. Larry Dossey;
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White House Commission on Complementary and Alternative Medicine Policy

Proposed Meeting Schedule

DATE	SITE	TYPE	TOPIC
September 8, 2000	San Francisco, CA	Town Hall (1)	
October 5-6, 2000	**Washington, D.C.**	**WHC (2)**	**RESEARCH**
October 30, 2000	Seattle, WA	Town Hall (2)	
November 3, 2000	Minneapolis, MN	Town Hall (3)	
December 4-5, 2000	**Washington, D.C.**	**WHC (3)**	**INFO DISSEM**
December 8, 2000	Albuquerque, NM	Town Hall (4)	
January 26, 2001	New York City	Town Hall (5)	
February 15-16, 2001	**Washington, D.C.**	**WHC (4)**	**ACCESS/DELIVERY**
March 5, 2001	Dallas/Houston, TX	Town Hall (6)	
March 6 or 7, 2001	Atlanta, GA	Town Hall (7)	
April 5-6, 2001	**Washington, D.C.**	**WHC (5)**	**TRAINING**
May 2001	(L. Das Mounik)	Palmer Chiropractic Symposium	CATCH-UP/ATTAIN
June 4-5, 2001	**Washington, D.C.** (Steve Call)	**WHC (6)**	**REVIEW DRAFT REPORT**
July 2001	*Carlotta		INTERIM REPORT DUE
August 2001			
September 2001			
October 25-26, 2001	**Washington, D.C.**	**WHC (7)**	**FINAL REVIEW**
November 2001			
(December 2001	**Washington, D.C.**	**WHC: FULL REPORT DUE (8)**	**FINAL REPORT)**
January 2002			
February 2002			
March 2002	**Washington, D.C.**	**WHC: CLOSING EVENT (9)**	

July 31, 2000 (12:27pm)

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White House Commission on Complementary and Alternative Medicine Policy

Proposed Meeting Schedule

DATE	SITE	TYPE	TOPIC
September 8, 2000	San Francisco, CA	Town Hall (1)	
October 5-6, 2000	**Washington, D.C.**	**WHC (2)**	**RESEARCH**
October 30, 2000	Seattle, WA	Town Hall (2)	
November 3, 2000	Minneapolis, MN	Town Hall (3)	
December 4-5, 2000	**Washington, D.C.**	**WHC (3)**	**INFO DISSEM**
December 8, 2000	Albuquerque, NM	Town Hall (4)	
January 26, 2001	New York City	Town Hall (5)	
February 15-16, 2001	**Washington, D.C.**	**WHC (4)**	**ACCESS/DELIVERY**
March 5, 2001	Dallas/Houston, TX	Town Hall (6)	
March 6 or 7, 2001	Atlanta, GA	Town Hall (7)	
April 5-6, 2001	**Washington, D.C.**	**WHC (5)**	**TRAINING**
May 2001			
June 4-5, 2001 change	**Washington, D.C.**	**WHC (6)**	**REVIEW DRAFT REPORT**
July 2001			INTERIM REPORT DUE
August 2001			
September 2001			
October 25-26, 2001	**Washington, D.C.**	**WHC (7)**	**FINAL REVIEW**
November 2001			
(December 2001	**Washington, D.C.**	**WHC: FULL REPORT DUE (8)**	**FINAL REPORT)**
January 2002			
February 2002			
March 2002	**Washington, D.C.**	**WHC: CLOSING EVENT (9)**	

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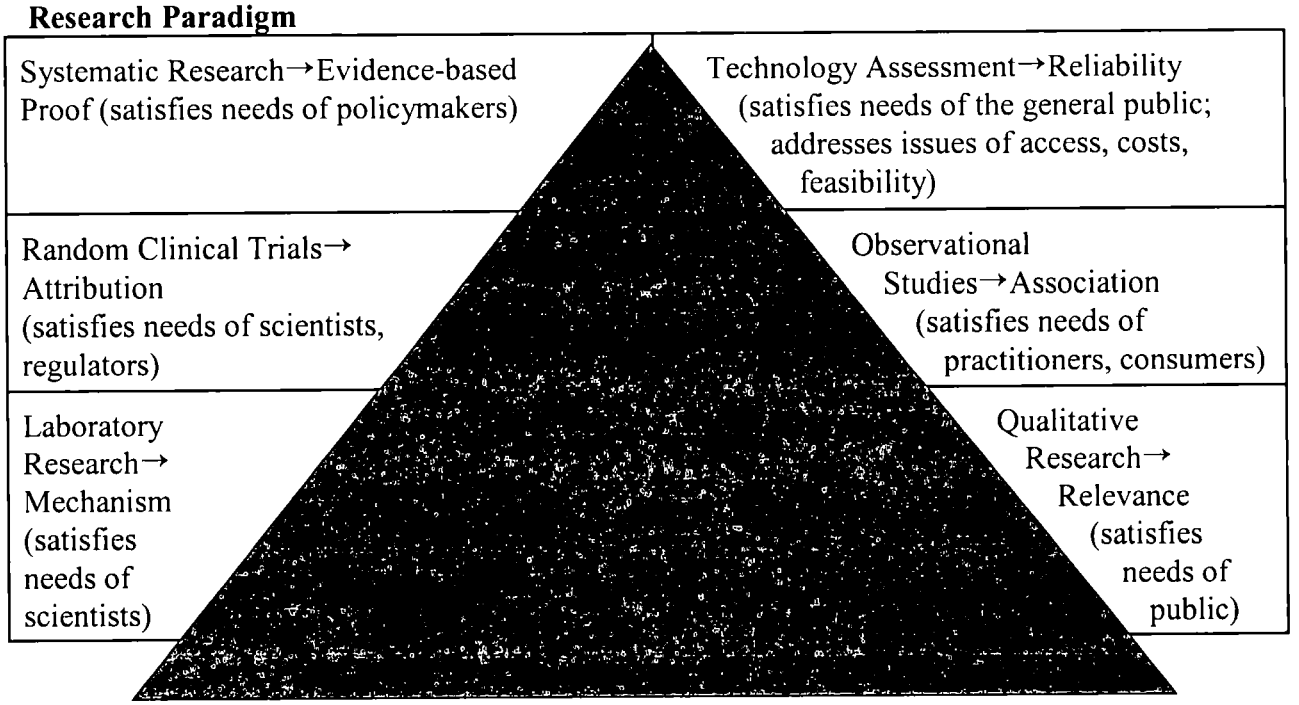
WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY

AGENDA FOR OCTOBER 5-6, 2000
Planning and Discussion Document - Draft

I. **Providing Guiding Principles for Discussion**: introduction of an expanded research paradigm with critical elements of equal legitimacy and importance (*Wayne Jonas)*

Research Paradigm



II. **Statement of Issues:** (Research Activities - Needs, Problems, and Incentives)

1. **Prioritization and Coordination**
   A. Managing public input
   B. Special populations
   C. Federal demonstration projects

   Potential Speakers
   NCCAM - Dr. Stephen Straus
   NCI - Dr. Jeffrey White
   DOD, VA, DARPA, NSF

2. **Frontier Science**
   A. Defining "frontier"
   B. Stimulating research
   C. Placebo Effect
   Potential Speakers
   Wallenchamp and Marilyn Schlitz
   NSF AND DARPA

NCCAM Supported Research Centers - Dr. Brian Berman, Dr. William Meeker
Dr. Al Fishman , Dr. Barrie Cassileth, Dr. Wallace Sampson, Dr. Joseph Pizzorno or
Dr. Leanna Standish, Dr. Stephen Barrett

C. Stimulation of Private Research

A. Patent requirements
B. Regulation of Products and Devices
C. Biotech investments
D. Regulatory Review of CAM Research

Potential Speakers

Pharmaceutical Industry
Foundations , Philanthropic Organizations - Oscher Foundation
Research Oversight - Drugs: Dr. Janet Woodcock, Dr. Robert Temple;
Research Oversight - Medical Devices: Dr. David Feigal;
Research Oversight - Nutritional Supplements: Joseph Levitt and Dr. Laurie Love

4. Outcomes Research

A. Developing facility: methodology
B. Special populations
C. Defining scope
D. Evaluation and Assessment

Potential Speakers

CDC Field Studies
AHRQ and COCHRANE Collection

5. Monitoring of Adverse Events

A. Standardization of Botanical Products
B. Collection of Adverse Events Reports
C. Standards and systems for alerting the public and health professionals

6. Reimbursement

A. HCFA Requirements for Reimbursement
B. Results of Research as a Basis for Reimbursement
C. State Requirements - Washington (John Weeks, Laurie Bielinsky)
D. HMO and Managed Care Organizations Experience

5. Communication of Research Results

A. Journal Editors - NEJM; JAMA; JACM - Jackie Wooton; ATH&M - Dr. Larry Dossey;
B. Science Writers - Larry Altman - NY Times;
C. TV - Robert Bazell - NBC NEWS
D. Websites - Web MD

Vogue - Framework Reports - Chair
Questions, Speakers, Other Issues

WHITE HOUSE COMMISSION ON COMPLEMENTARY
AND ALTERNATIVE MEDICINE POLICY
Planning and Discussion Document - Draft
OCTOBER 5-6, 2000

I. Research Activity - Needs, Problems, and Incentives
- NCCAM - Dr. Stephen Straus
- NCI - Dr. Jeffrey White
- CDC Field Studies
- DOD, VA, DARPA, NSF
- Pharmaceutical Industry
- Foundations , Philanthropic Organizations - Oscher Foundation
- NCCAM Supported Research Centers - Dr. Brian Berman, Dr. William Meeker
- Dr. Al Fishman , Dr. Barrie Cassileth, Dr. Wallace Sampson, Dr. Joseph Pizzorno or Dr. Leanna Standish, Dr. Stephen Barrett

II. Regulatory Review of CAM Research
- Research Oversight - Drugs: Dr. Janet Woodcock, Dr. Robert Temple; Medical Devices: Dr. David Feigal; Nutritional Supplements: Joseph Levitt and Dr. Laurie Love (no effect on DSHEA)
- Outcomes Research - AHRQ and COCHRANE Collection
- Monitoring of Adverse Events - consider Australia experience
- Standardization of Botanical Products
- Patents issues / intellectual property

III. Reimbursement
- HCFA Requirements for Reimbursement of Research
- Results of Research as a Basis for Reimbursement
- State Requirements - Washington (John Weeks, Laurie Bielinsky)
- HMO and Managed Care Organizations Experience

IV. Communication of Research Results
- Journal Editors - NEJM; JAMA; JACM - Jackie Wooton; ATH&M - Dr. Larry Dossey; (Kim Robert)
- Science Writers - Larry Altman - NY Times;
- TV - Robert Bazell - NBC NEWS
- Websites - Web MD

V. Emerging (Energy) ~~Medicine~~ Frontier Science Research
- Wallenchamp and Marilyn Schlitz
- NSF AND DARPA
- Placebo effect
- Energy
- Electromagnetic
- Homeopathy
- Prayer
- Consc

- Paradigm
= Rationale
= Research Issues

Some Possible White House Commission Collaborations and Recommendations

Area	Sub-topic	Group / Agency	Activity/Contact	Possible Recommendation
Gen.	how to assure incorporation of informed public concerns into ongoing decisions in CAM regulation	Institute of Medicine NCCAM Advisory Council	Ken Shine	Request this be addressed by IOM Definition and Prioritorization Report (a)
	develop a definition of CAM that a) clarifies the contributions CAM offers our health care system and b) b) the criteria that are important for prioritizing development of particular practices and approaches to integration c)	a)Commissio n members b) Institute of Medicine	Commission members Ken Shire	Commission report should address a) and IOM Definition and Prioritorization Report can address b)
Res.	how to set priorities for research and development	Institute of Medicine	Ken Shine	Request Definition and Prioritorization Report (a)
	how to stimulate private sector research	Patient Office		Develop a plan for patent protection of CAM inventions, products
	how to assure quality, low-cost natural products and CAM	FDA	Drs. Temple and Woodcock	Set up a Section on Natural Product Regulation at the FDA

	devices			
	how to address frontier claims and practices that lie outside conventional scientific conceptions	National Science Foundation	Rita Caldwell Peter Sturrock (Stanford)	Request plan for a process and set aside budget for frontier science (b)
	how to promote collaborative CAM research among various entities, including governmental, academic and private entities	Interagency CAM Coordinating Committee	Steve Straus Richard Nahin Michele Chang and CDC folk	Set up HHS coordination office on CAM research and practice
	how to explore the impact of integrated CAM systems on health care costs and outcomes	HHS SSA HCFA DOD VA	Members of these agencies CAM 2010 Group	Establish four to five "Demonstration" projects to examine the impact of fully integrated systems on major public health problems
Reg.	how to encourage appropriate forms of self-regulation for product manufacturers, and how to assess when statutory regulation is called for	FDA	Drs. Temple and Woodcock	Set up a Section on Natural Product Regulation at the FDA
	how to regulate the provision of CAM and integrated health practices	FSMB Milbank Memorial Fund	Bob Porter Roger Winn Dan Fox Pam Snider	Commission representative state and health regulators to develop standards of

		Integration project		practice certification and licensing
Edu.	how to ensure that medical school curricula include appropriate CAM education	NCCAM Josiah Macy Foundation AAMC AMSA	Alan Neims Al Fishman Jodan Cohen Roger Bulger	Follow-up of Macy Foundation Meeting on CAM education in Academic Medical Centers Nov. 2000
	how to ensure that CAM practitioners receive appropriate education in the principles and practice of Western or conventional medicine and their scope of practice	DOE ACA? NAAAOM Naturopaths	???? Robert Duggan Integration Project with Washington	
	how to develop common core elements in the curricula for all forms of health care practices	DOE	????	Request DOE produce guidelines for approval of CAM educational schools and curricula
Acce ss	guidelines and process for determining reimbursement	HCFA		Request HCFA suggest guidelines and a process for determing evidence-based
		AHRQ HCFA AHIA	As above plus John Weeks	Follow-up on recent "Summit" organized by Weeks of Main CAM HMO providers
	how to assure access of CAM services to			

	special populations			
		HRSA	Marilyn Gaston Joe Kaczmaarczyk	
	public health clinics	HRSA Integration 2010 (Region 10) CDC	Above John Lyons Pam Snider	
	Military	DOD	Sue Bailey	
	VA			Follow-up recommendations to recent VA evaluation of CAM
	women and children	OWH NICHD		
	Native Americans	IHS	Dr. Vanderwagon	
Info.	how to assure evidence is properly summarized for professionals and the public	AHRQ	Doug Kamerow Carolyn Clancy	Recommend that special centers for summary and provision of current CAM evidence is done - like the USPTF effort of clinical preventive services
	how to increase access to the public about CAM products and practices, including what works for what types of conditions or	HHS		Set up an center for CAM information or expand mission of NCCAM clearinghouse to include non-research information

	illnesses, directories of accredited CAM practitioners, and how these products and practices can or should be used in relation to more conventional medical care			
	how to assure that desired information goals, research designs and support and public information strategies are coordinated.	White House	Current Liason	Establish an Office for the Integration of CAM

Center for Mind-Body Medicine

5225 CONNECTICUT AVENUE, NW, SUITE 414 • WASHINGTON, DC 20015
TEL. (202) 966-7338 • FAX (202) 966-2589 • cmbm@idsonline.com • www.healthy.net/cmbm

July 30, 1998

Michelle Chang
731 Hart Senate Office Building
Washington, DC 20510

Dear Michelle,

Here is the proposal for the Commission for Peter, Tom, and you. I'm pleased with it, as is Wayne, and we hope that you are, too.

I'm sending along a disk so that you can make any changes you feel you want to. I can be reached at (202) 537-6837 all day today. I'm going to be down at the Rayburn Building, Room 2154, to testify at a hearing of Dan Burton's on NCI doing research in alternative medicine starting at 10 o'clock tomorrow (July 31).

If Peter or Tom wanted, I could stop over at the office when the hearing is finished. In any case, I look forward to hearing from them.

All the best,

James S. Gordon, MD
Director

Enclosures

A Proposal for a White House Commission on Integrated Health Care

Background:

Over the last 25 years, Americans have been participating in a vast, rapidly growing, and largely unorganized popular health movement. They are turning to therapies that are alternative to, or other than, those learned by physicians in medical schools, and to approaches which complement conventional Western medicine. Though many in this movement make use of particular therapies in symptomatic treatment – the herb echinacea to forestall a cold, a chiropractic adjustment for a stiff neck – there is a strong desire for a new kind of integrative medicine which includes the best of complementary and alternative as well as conventional therapies, a medicine which understands the needs, perspectives, and whole lives of patients and makes them full partners in their own care.

People have become part of this movement for several reasons. First and foremost, they have begun to look outside of conventional medical practice because the treatment of chronic illness is (in contrast to its capacity to deal with trauma or surgical and medical emergencies) inadequate or fraught with side effects that can be almost as distressing as the illness. (For example, a recent study in the *Journal of the American Medical Association* showed that conventional treatment, *properly administered*, is now one of the leading causes of death and is responsible for over 10% of the hospitalizations in the US.) In addition, many who are fatigued, depressed, and feel unwell, but have no easily diagnosable condition are also looking for healing approaches – like acupuncture, mind-body therapies and nutrition – which appear tailored to enhancing health, rather than treating illness. Finally, an aging population is reaching out to find any and all means to stay well and prevent illness. Ninety-five percent of all those who use complementary and alternative therapies do so in conjunction with conventional treatment, but few are able to find both in the same practitioner or practice.

Americans are also looking for more caring relationships, as well as more effective treatment. In a time when managed care has made many physicians less attentive, as well as more hurried and harried, patients want more respect, more kindness and more time. They believe – often with some justification – that those who offer a holistic approach or who use alternative therapies are more likely to stand against the tide of assembly-line medicine, to pay more attention to them as whole people with lives as well as lab values.

A study published in the *New England Journal of Medicine* (in 1993) indicated that 34% of American adults had used complementary and alternative therapies in 1990. In 1997 the figures were at 42%, and at over 50% among women. At present, Americans make substantially more visits each year to alternative medicine practitioners that to conventional primary care physicians. The public's out-of-pocket expense for products and services is equal to that paid out-of-pocket for conventional physicians' services, and it is three times the amount they pay out-of-pocket for hospital expenses.

This public interest has been matched by a significant and rapidly growing response in the professional community and the health care industry. Seventy American medical schools now offer electives in complementary and alternative medicine, and several are already incorporating required lectures and seminars into their core curricula. In 1970 there were virtually no non-Asian acupuncturists in the US; today, there are more than 15,000, of whom some 5,000 are physicians. Twenty million Americans use chiropractors each year and a number of bright college graduates are choosing to become chiropractors, acupuncturists, naturopaths, or Chinese medical doctors, rather than MDs. Meanwhile, every major managed care organization and insurance company is grappling with how to "cover" alternative medicine (and therefore attract new subscribers); hospitals in every part of the country are hurrying to open "integrative care centers;" and the natural food, supplement and herbal businesses are booming.

Though most of the surveys indicate that primary users of complementary medicine are adult, white, and middle or upper-middle class, there is every reason to believe that larger numbers of people with less income would use these therapies if they were covered by insurance. In addition, it is clear that the number of poor people already using these approaches is

underestimated in the surveys; the overall percentages are likely to be significantly higher than 42% for many of those who do not have telephones: migrant workers, as well as recent immigrants from Latin America, Asia and Africa for whom the therapies that we call complementary and alternative are both the traditional and the primary sources of health care.

This movement is immensely hopeful. It is, however, only minimally integrated into our health care system, with potential and real adverse effects. One in five Americans uses herbal formulations or vitamins in high doses in combination with conventional drugs, and neither their physicians nor the public know if they are being harmed. Research on complementary and alternative therapies is in its infancy and is grossly underfunded. Licensing of non-physician practitioners varies greatly from state to state and is often arbitrary. Procedures for feedback about adverse effects of alternative therapies are as haphazard as provision of information about their benefits.

Finally, it is interesting to note that the use of these therapies – and passionate advocacy on their behalf – is distributed among people of every political persuasion, in the general public as well as in Congress. Progressive Democrats, moderate Republicans and arch conservatives all use these therapies. And the vast majority agree that there should be easier access to them, greater insurance coverage for them, more research into and more readily available knowledge about them, more informed regulation of them, and better integration with conventional medicine.

It is no longer a question of whether complementary and alternative medical approaches will become part of health care, but of how this process of integration will proceed. In the past, changes in medicine and health care have followed particular discoveries (the introduction of antibiotics), the rise of powerful interest groups (the AMA in the latter part of the 19th century), the passage of wide-reaching new legislation (Medicare and Medicaid), or market forces (the creation of managed care organizations). The movement toward an integrated medicine is larger, less coherent and insistently populist. It holds out the promise of a health care that is far more comprehensive, more effective and more responsive to people's human needs. There is already some evidence to suggest that this approach may be far more cost-effective as well.

The Commission

Membership:

The Commission would be composed of 15-20 people who are committed to the creation of a system of health care that is responsive to the public's diverse needs, respectful, effective, and integrative. Members will include those who have been leaders in creating an integrative medicine, as well as those who have been working within the medical establishment (as researchers, clinicians and administrators) to enlarge its perspective; visionaries in the area of health policy, as well as citizen advocates who grapple each day with the medical system; representatives of the business community concerned with their employees' health; and ordinary men and women who are struggling to create their own programs of integrative health care.

The Chair of the Commission would be a leader in creating an integrative medicine and articulating its scope and importance – someone thoroughly grounded in the practice of complementary and alternative as well as conventional medicine. This person must be skilled in balancing diverse points of view and gifted at making the Commission's recommendations intelligible and useful to the general public and the health care community. The Chair would work in close collaboration with the White House on all aspects of the Commission's work.

Timetable, Staffing and Budget:

The Commission would be convened for a two-year period. It would have a coordinating staff to support its work in collecting background information, soliciting expert and public testimony, holding hearings, and assembling work groups on particular topics. Estimated personnel: seven. Estimated cost: $5 million.

A White House Commission on Integrative Medicine would examine the changes that are underway; evaluate the state of the art of complementary and alternative therapies; assess the promise of a holistic or integrated approach for improving the health of Americans; deal with issues of regulation and safety; and establish guidelines for the integration of this approach and these therapies into all aspects of health care, including patient care, research, professional training and health education. It is entirely likely that such a Commission would not only provide guidelines for integration, but a new model for what all health care should be.

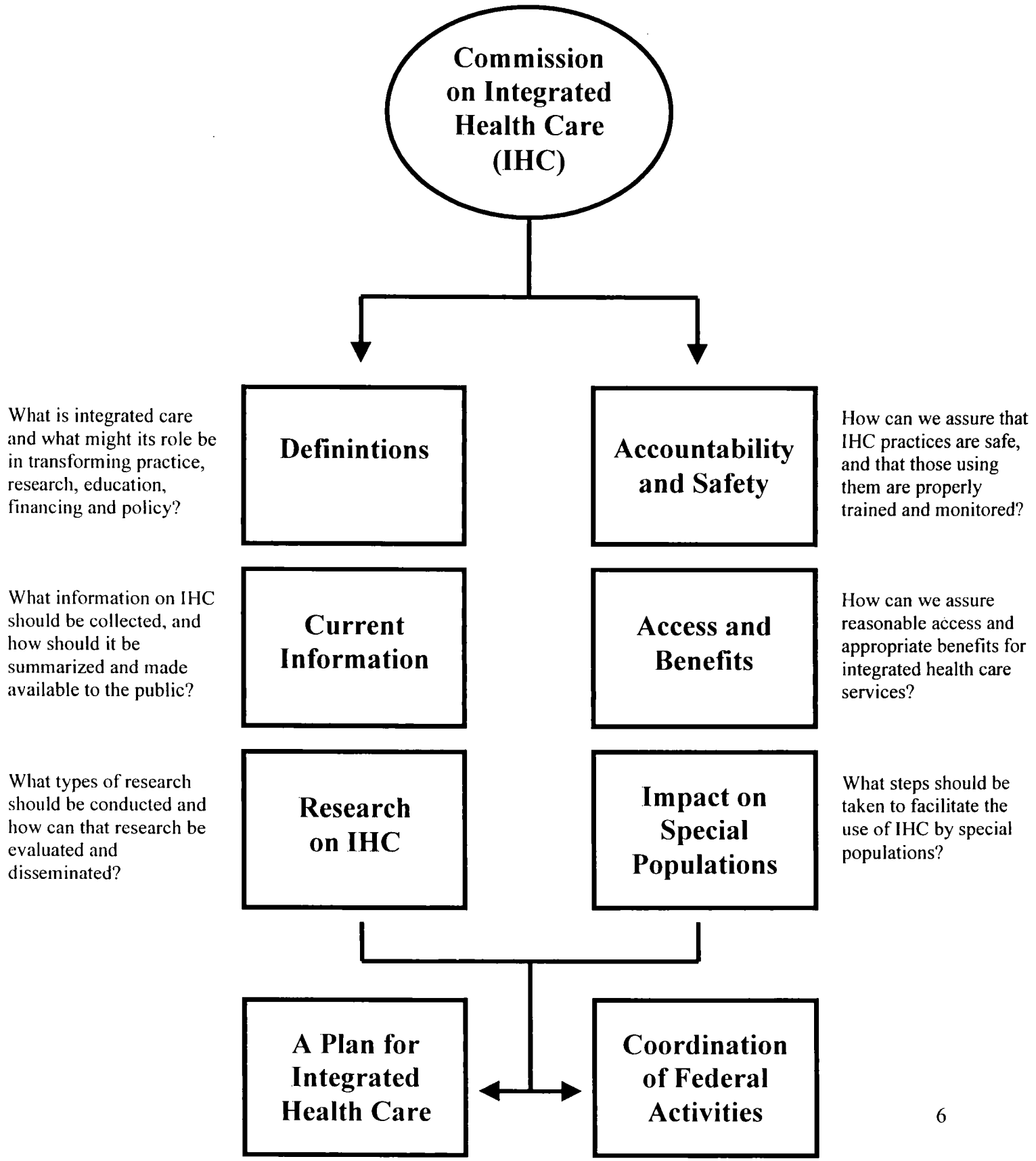
The Tasks of the Commission:

Specifically the Commission would

- Address the public's need for a system of integrated health care that is responsive to their needs and reflects their concerns
- Formulate strategies for gathering and evaluating information about complementary and alternative therapies and the role they can play in an integrated health care
- Develop research agendas and priorities for the government and help guide private efforts in the study of the most promising therapies
- Provide guidelines for the safe use of natural products and of new therapies, and for the ongoing reporting of both adverse effects and benefits
- Establish criteria for training, credentialling, licensing, and monitoring integrated health care professionals
- Develop models for offering health benefits in federal and private programs
- Develop guidelines for the integration of education about integrative health care and its various perspectives and practices in all programs of health professional education
- Develop a blueprint for distributing responsibility for all aspects of integrative health care among the various federal agencies
- Suggest mechanisms of on-going coordination among federal agencies and between federal agencies, professional groups and the general public
- Offer guidance in the development of proposals for funding model integrative health programs for people with specific illnesses (e.g. cancer) and for special populations which so far have the least access to these areas of care: the poor, minorities, veterans, and children

(See diagram for visual image of these tasks)

Developing a National Plan for Integrated Health Care



A Research Prioritization Process in Complementary and Alternative Medicine
A Request to the Institute of Medicine

Introduction. In 1996 the Institute of Medicine (IOM) developed a proposal for assisting the NIH Office of Alternative Medicine in defining and prioritizing research options in complementary and alternative medicine (CAM). After consideration of this proposal it was decided that a more general set of guidelines was needed for defining the scope of CAM inquiry for the biomedical, practitioner and public communities rather than for NIH research alone. A clear and authoritative set of guidelines for defining and prioritizing CAM research and inquiry is still urgently needed, especially as public use of CAM practices and products increases. As request from congress to the IOM to produce such guidelines would greatly assist all public and private groups seeking to support and conduct research and evaluation of CAM.

Purpose. The congressional request would ask the IOM to develop guidelines and a process for defining and prioritizing CAM inquiry. The guidelines would address the values and assumptions underlying the public increase in CAM use; the information domains needed for full understanding of CAM; the research methods best able to obtain the information needed in CAM; quality guidelines for assuring that research methods are properly applied; a process by which the values and assumptions and information about CAM can be translated into health care in a fair and rational way.

Goals. The following questions outline the main issues congress would ask the IOM to address.

1. What are the main values and assumptions represented by CAM?

    a. Systems/ecological approach to the person
    b. Autoregulation/stimulus-response model of treatment
    c. General health support and maintenance interventions
    d. Methods for pragmatic investigation of clinical observations
    e. Attention to non-dominate theoretical models and practice modalities

2. By what method (or process) can the evolving values and assumptions of CAM are clarified?

3. What are the main knowledge domains required for a complete science in CAM?

    a. The existence and mechanisms of underlying CAM claims
    b. The central reasons that the public seeks out CAM
    c. The efficacy evidence for CAM claims
    d. The degree of effectiveness and magnitude of effects of CAM practices
    e. Degree of certainty and guidelines for proof of CAM claims

f. The degree of generalizibility of CAM practices into current health care

4. What scientific methods do we have to access knowledge in those domains?

(we are collecting a growing list of methods)

5. What guidelines should be followed to assure (improve) validity in the application of those methods?

(we are collecting research quality guidelines for the above methods)

6. How (by what process) can we assure that the values, assumptions and knowledge of CAM are translated into the following research activities?

a. prioritizing research possibilities for support
b. clarifying research goals for CAM
c. developing methods to accomplish research goals
d. interpreting data appropriately
e. evaluating completed research for its value in addressing CAM goals

7. What procedures are needed so that the above translation process (values, assumptions, knowledge, goals, methods, activities, interpretations, evaluations) is done rationally and fairly? These procedures must:

a. maximize objectivity and reduce bias
b. provide a systematic, explicit, comprehensive method
c. be fair, democratic, and use a diversity of expertise
d. provide for balanced application of rational, *a priori* criteria

Activities. The IOM will provide congress with a set of proposed procedures, groups and individuals and a timeline and budget for addressing these questions and producing their recommendations. After approval of this process by a small congressional working group (organized by the House Committees on Health and Government Reform), the IOM will convene the working members of the Panel (and any subcommittees needed) for producing the report.
The report would have five parts.

1. A preamble describing the underlying assumptions and values underlying the public's interest in CAM and the definition of what is included in CAM.
2. An outline of the scientific principles involved in doing research on complementary and alternative medicine and the guidelines for applying those principles in research.
3. A decision matrix for defining, prioritizing and evaluating research areas and projects in CAM
4. A process for the fair application and management of judgment processes when using the decision matrix.

5. Recommendations for specific government agencies and for private organizations on how to increase research and evaluation of CAM for the health care system.

Developing Scientific Inquiry into Areas of Public Interest:
A Request to the National Science Foundation

Introduction. The rate of information exchange is accelerating and is rapidly leading us to a global community. As this occurs the scientific community is increasingly asked to investigate areas that have been traditionally fallen outside usual scientific inquiry. The growing use of complementary and alternative medicine which also falls outside usual biomedical research has further stimulated the scope and importance of scientific inquiry into these areas. Thus a process in needed that can help fill the increasing gap between these areas of high public interest but low scientific activity. It is requested that the National Science Foundation provide congress with recommendations for how to identify and foster scientific activity in areas of high public interest but low scientific inquiry. These are those areas traditionally labeled "anomalous" or "pseudo-scientific" by the conventional scientific community.

Purpose. The purpose of the National Science Foundation Panel on "Fostering Scientific Inquiry into Areas of Public Interest" would be to provide congress and the American public with recommendations as to how to provide identify and support areas of high public interest but low scientific inquiry - areas traditionally labeled "anomalous" or "pseudo-scientific" by the conventional scientific community.

Goals. The Panel will address the following questions.

1. What topical areas are of high public interest but are normally excluded from conventional scientific inquiry because the are "implausible", "impossible", "anomalous", or conceptually outside the orthodox "paradigm" or world-view?
2. What are the obstacles to fostering scientific inquiry into these area?
3. What processes are needed to address those obstacles?
4. How can public supported agencies and organizations facilitate scientific inquiry into these areas?
5. How can the private sectors be encouraged to invest in scientific investigation of these areas?
6. What specific activities are needed by the NSF, NAS, HHS, DOD, NASA and other official, publicly supported agencies involved in scientific activity to actualized the panels recommendations.

Activities. The NSF will provide congress with a set of proposed procedures, groups and individuals and a timeline and budget for addressing these questions and producing their recommendations. After approval of this process by a small congressional working group (organized by the House Committees on Science and Government Reform), the NSF will convene the working members of the Panel and producing the report.

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A COMMISSION ON INTEGRATED HEALTH CARE

BACKGROUND

Complementary and alternative medical (CAM) products and practices are being extensively and increasingly used by the American people. Eighty-three million American adults (42% of the population) now use CAM on a regular basis. There are substantially more visits each year to alternative medicine practitioners than to conventional primary care physicians. The public's out-of-pocket expenses for CAM products and services is equal to that paid out-of-pocket for physician services and is three times that paid out-of-pocket for hospital expenses.

CAM use is the public's health care reform. The American people are seeking out health care services to complement conventional medicine when its side effects, costs, and effectiveness are inadequate or unacceptable. Values in health care are changing as the prevalence of chronic disease rises in an aging population. The public increasingly desires to participate in health care practices that use less invasive and more natural means. They are seeking out more holistic approaches to health care - approaches that reduce symptoms, improve well-being, and simultaneously prevent and treat chronic illness. And they are combining them with conventional medicine.

The promotion of CAM is unmonitored, unguided and places the public at risk. Twenty percent of Americans on prescription medications are also taking herbal or high dose vitamins - risking unknown and possibly dangerous interactions. The competence and scope of practice of CAM providers is variable, unevaluated and largely unregulated. Only a minority of patients disclose CAM use to their doctor and few doctors ask about or have the expertise to advise on the benefits and risks of these practices. In response to patient demand, hospitals and health insurers are increasingly providing CAM benefits using variable and unknown standards.

The science behind CAM remains uncollected and unevaluated. The quantity and quality of evidence for the safety and effectiveness of unconventional practices is unknown. CAM practitioners (and many patients) claim tremendous benefits. Conventional medicine warns of the risks from unproven therapies and quackery. Current laws provide a disincentive for private research on the preventative and therapeutic benefits of CAM products. The public sector provides a small amount of support for researching these areas.

Integrated health care (IHC) - the wise combination of alternative and conventional medicine - is needed. Over 95% of those who use CAM products and practices do so in conjunction with conventional medicine - not in place of it. A plan for addressing the two main vulnerabilities of integrated health care - research evidence and regulatory oversight - is crucial for the safety and benefit of the American public. Such a plan should include, but not be dictated by, a wide range of governmental, scientific, medical, private and public groups. Such a plan must be grounded in the ethical principles of autonomy and beneficence, use science as a guide, and be responsive to the changing values and needs of the American people. A Commission on Integrated Health Care is needed to develop such a plan.

PURPOSE

The purpose of a Commission on Integrated Health Care is to develop a National Plan for Integrated Health Care. The Plan will provide guidelines and a guidance process for the integration of complementary and alternative practices into current health care. The Commission will assure input from all relevant constituencies - especially the public - into the Plan.

GOALS

The Commission's National Plan for Integrated Health Care would address the following.

Definitions. *What should the focus of integrated health care be for practice, research and policy?*

1. What practices and products should be addressed in these guidelines?
2. What aspects of policy, practice and research should be addressed? Possible areas include:
    - Surveillance and monitoring of potential adverse effects from CAM use
    - Accountability of emerging alternative health care professions
    - Access to alternative medicine products and practices
    - Priorities for funding research on integrated health care
    - Criteria for the provision of integrated health care benefits
    - Areas of frontier and anomalous sciences that are of interest to the public
    - Use of traditional and indigenous medical practices along with modern medicine

Current Information. *What information on integrated health care should be collected and how should it be summarized and made available to the public?*

1. What IHC research and practice literature should be collected, organized and made accessible to the public?
2. How should the research literature be evaluated to determine the current state-of-the-science of IHC for making evidence-based decisions about practice, research and policy.

Research on IHC. *What types of research should be conducted and what areas of IHC should be monitored?*

1. How should biomedical research be prioritized and what topics in CAM and IHC need development and support through basic science and clinical trials?
2. How can the discoveries of health care practitioners be identified, investigated and developed?
3. When is monitoring the outcomes of IHC practices sufficient for practice and policy decisions?

Accountability and safety. *How can we assure that IHC practices are safe and that those using them are properly trained and monitored?*

1. What methods should be used to monitor possible adverse effects of IHC practices and products? How should these methods be established?
2. What standards of training, credentialing, licensing and monitoring of service quality is needed for IHC practices?

Access and benefits. *How can we assure reasonable access and appropriate benefits to integrated health care services?*

1. What is the appropriate balance of risk and access for IHC products and practices?
2. What process and criteria should be used to determine what benefits for integrated health care services should be provided?

Impact on special populations. *What steps should be taken to determine the impact that IHC may have on special populations?*

1. What steps are needed to determine the impact IHC may have for disadvantaged, elderly, veterans, children, women, and minority populations? Who will make those determinations?

Developing a National Plan for Integrated Health Care

Definitions

What should the focus of integrated heath care be for practice, research and policy?

Current Information

What information on integrated health care should be collected, and how should it be summarized and made available to the public?

Research on IHC

What types of research should be conducted and what areas of IHC should be monitored?

Accountability and Safety

How can we assure that IHC practices are safe, and that those using them are properly trained and monitored?

Access and Benefits

How can we assure reasonable access and appropriate benefits for integrated health care services?

Impact on Special Populations

What steps should be taken to determine the impact that IHC may have on special populations?

ORGANIZATIONS AND AGENCIES INVOLVED

The Commission may want to call on the input and advice of a number of organizations. Key organizations would be:

Association of American Medical Colleges
Association of Health Insurers of America
American Board of Medical Specialties
Agency of Health Care Policy and Research
Agency for International Development
Bureau of Primary Health Care
Bureau of Health Professionals
Centers for Disease Control and Prevention
Complementary and Alternative Medicine Consortium
Department of Health and Human Services
Department of Defense
Department of Education
Food and Drug Administration
Federation of State Medical Boards
Government Reform and Oversight Committee
Health Care Financing Administration
Health Resources and Services Administration
Institute of Medicine
National Academy of Sciences
National Institutes of Health
National Library of Medicine
Office of Alternative Medicine
Professional Health Care Associations
Veteran's Affairs
The World Bank

TIMELINE AND RESOURCES

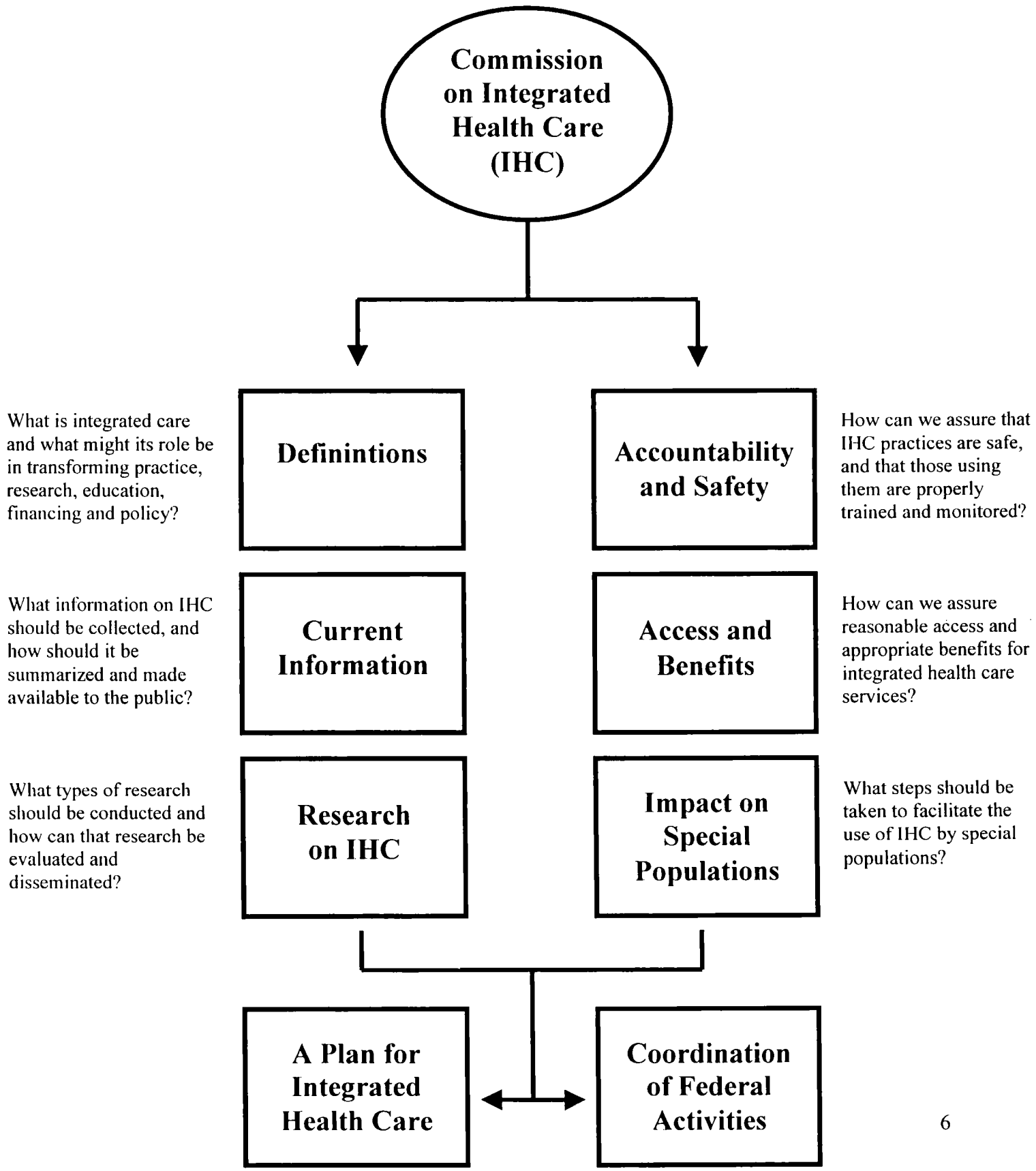
The Commission would be convened for a three year period. It would be allotted sufficient resources and a coordinating staff to support the Commission, solicit expert advice, collect relevant background information and obtain public input on all areas.
Estimated personnel - 7.
Estimated cost - $ 3 million.

MEMBERSHIP

The Commission should be composed of 25 - 30 knowledgeable and prominent citizens of the country. They should represent the health care practice, policy, scientific and public communities and be drawn from both the public and private sectors.

The Chair should be a respected member of the health care establishment with experience in all aspects of medicine and health care and with an openness to innovative alternative practices and an ability to balance a wide diversity of views.

Developing a National Plan for Integrated Health Care



Commission for Complementary and Alternative Medicine Policy:
Possible Structure of the Report and Groups Involved

Wayne B. Jonas

8.01.00

Below is a possible structure for the report and approach for producing it.

1. **General**: The Commission's report should build in recommendations to help government agencies effectively implement its recommendations. We don't want the report to just gather dust as can easily happen on recommendations to the government.

   Recommendations:

- Develop a special Office for the Integration of CAM that would work with all federal agencies to coordinate implementation of the Commission's recommendations and keep track of new developments.
- Develop full time liaisons with strategic agencies and congressional offices to help coordinate the commission's recommendations into a coherent health care policy.
- I think that six special sub-committee's (or more) made up of Commission members and outside consultants and experts should be created to write the core background documents and draft recommendations. Theses subcommittees should each address one of the topics above and perhaps others. Finding an expert who will write and be the lead for producing each section is the most effective approach in my experience.
- States were considerable efforts at CAM integration are already underway (such as Maryland, Washington, California and Minnesota, etc.) should be consulted for their experience and input. See the summary of activities in Washington State as an example.

2. **Definitions**: A definition and description of CAM is crucial. The current definition of CAM as those practices that are excluded from conventional medicine is inadequate. The definition should clarify the contributions CAM offers our health care system and the criteria that are important for prioritizing development of particular practices and approaches to integration. An emphasis on
   a) health promotion and prevention
   b) health support (that create
   c) wellness) as a primary orientation to treatment of
   d) chronic disease are key. In addition providing a
   e) holistic approach to medical care that values

f) subjective and
g) low-impact approaches that can
h) reduce costs should be a focus.

Recommendation:
Special Committee on Background of CAM of the WHC

3. **Information**: Providing reliable and useful information about CAM requires identifying the primary uses for which different types of information are produced. Different audiences value different types of information and use it in different ways. Clarification of the primary types of information needed and how to development and provide the public with these types of information should be addressed. There are six primary audiences and therefore six information domains that should be produced.

   Recommendation:
   WHC Sub-committee and recommendations to AHRQ; request they (AHRQ or HHS) produce a report for CAM similar to the US Preventive Task Force Report on Clinical Preventive Services

4. **Research strategies**: Once the types of information desired are clarified a coordinated research strategy can be developed to obtain that information. Thus Commission task (b), coordinated research, follows Commission task (c), identification of information needs. Not only is a clear process for prioritizing the many possibilities in CAM research needed, also mechanisms to assure public input (as recommended by a recent IOM report) into this process must be established. Ways to support basic science research (into areas of public interest in CAM) and to stimulate private investment into knowledge and technology transfer of CAM discoveries are especially important.

   Recommendations:
   IOM Definition and Prioritization Report (a);
   NSF recommendations and plan for a set aside budget for frontier science (b);
   Patent revisions;
   FDA section for Natural products;
   Trans-agency CAM research Coordinating Committee (expansion of NCCAM's Trans-HHS committee?) to include SSA, DOE, DOD, VA, NASA, NSF, etc.

5. **Education and training** includes:
   1) the minimum knowledge, skills and attitudes needed by conventional health care professionals for the proper management of CAM areas,
   2) standards for assuring quality expertise and professionalism of CAM specialists.
   In addition, issues such as
   3) training in evidence and ethics-based skills,
   4) culturally-sensitive health care delivery,
   5) patient education and
   6) adequate self-care are integral parts of all health care provider education and training. The Commission may also want to comment on public training (in schools and pubic health efforts) concerning these issues.

   Recommendations: AAMC; AMC; FSMB; NBME; CAM education groups (4-5 national ones that I know of), Macy Foundation; DOEd

6. **Access and payment**: Decisions about access and payment for CAM products and services involves a combination of values and evidence. Methods of assuring the quality of:
   products (supplements, drugs and devices) and
   practitioners (trained, licensed or certified and peer-monitored) are needed and should be standard across disciplines. The evidence and values criteria for deciding on reimbursement must be consistently applied. Methods for managing personal bias and judgement flaws should be part of this process. Access for special populations (women, children, minorities, the elderly, the poor, veterans and the military, etc.) must be considered and special efforts taken to assure these populations have access to effective CAM therapies and are protected from dangerous ones.

   Recommendations:
   FDA section for natural products; HSRA; HCFA; DOD; VA; SSA;
   Association of Health Plans, etc.
   The "Summit" Group,

7. **Public training and input**: CAM is a public phenomenon and so input and understanding of public motivations for CAM use are essential. In addition, methods of training public members and incorporating public concerns into ongoing decisions about information dissemination, education and training, coordination of research, and access to CAM are needed.

Recommendation:
Include in IOM Definition and Prioritization Report (a)
See OAM report on Judgement Management and
RAND work on "appropriateness" of chiropractic practices

White House Commission on Complementary and Alternative Medicine Policy

Proposed Meeting Schedule

DATE	SITE	TYPE	TOPIC
September 8, 2000	San Francisco, CA	Town Hall (1)	
October 5-6, 2000	**Washington, D.C.**	**WHC (2)**	**RESEARCH**
October 30, 2000	Seattle, WA	Town Hall (2)	
November 3, 2000	Minneapolis, MN	Town Hall (3)	
December 4-5, 2000	**Washington, D.C.**	**WHC (3)**	**INFO DISSEM**
December 8, 2000	Albuquerque, NM	Town Hall (4)	
January 26, 2001	New York City	Town Hall (5)	
February 15-16, 2001	**Washington, D.C.**	**WHC (4)**	**ACCESS/DELIVERY**
March 5, 2001	Dallas/Houston, TX	Town Hall (6)	
March 6 or 7, 2001	Atlanta, GA	Town Hall (7)	
April 5-6, 2001	**Washington, D.C.**	**WHC (5)**	**TRAINING**
May 2001			
June 4-5, 2001	**Washington, D.C.**	**WHC (6)**	**REVIEW DRAFT REPORT**
July 2001			INTERIM REPORT DUE
August 2001			
September 2001			
October 25-26, 2001	**Washington, D.C.**	**WHC (7)**	**FINAL REVIEW**
November 2001			
(December 2001	**Washington, D.C.**	**WHC: FULL REPORT DUE (8)**	**FINAL REPORT)**
January 2002			
February 2002			
March 2002	**Washington, D.C.**	**WHC: CLOSING EVENT (9)**	

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DRAFT FIVE-YEAR STRATEGIC PLAN

The National Center for Complementary & Alternative Medicine

A MESSAGE FROM THE DIRECTOR

May 10, 2000

I was appointed as the first Director of the National Center for Complementary and Alternative Medicine (NCCAM) in October 1999, drawn by the opportunity to address the major public health challenges that CAM represents. To fulfill the trust the public has placed in my staff and me, we must proceed according to well-reasoned principles and a well-articulated strategy. To this end, we are developing NCCAM's first Strategic Plan, composed of four parts.

Part I, "Preamble: The Case for Action," and Part II, "Into the Future: Aligning Challenges and Opportunities," provide the rationale for Part III, "Guidance for the Next Five Years: Our Strategic Plan." Within this last section, we state our mission, define our vision, identify our stakeholders, and outline five cardinal strategic areas and the broad goals within them that will guide us through the next five years. Part IV includes nine appendices, which contain supporting information.

NCCAM's vision will be realized only by creating and sustaining close partnerships with the broad spectrum of CAM stakeholders. Therefore, through June 21 we are providing the opportunity to comment on this draft before it is finalized and re-posted at this web site this Fall, thus completing the first step in an ongoing planning process. I look forward to receiving your comments and hope that you will continue to provide input in later stages of our planning process.

Stephen E. Straus

Stephen E. Straus, M.D.

REVIEW REPORT ENTER COMMENTS

DRAFT FIVE-YEAR STRATEGIC PLAN

The National Center for Complementary & Alternative Medicine

PART I - PREAMBLE: THE CASE FOR ACTION

SUCCESS BRINGS CHALLENGES

During the 20th Century, medical science advanced considerably and, coupled with improvements in sanitation and public health, resulted in dramatic improvements in health and a near doubling of life expectancy. With these stunning successes come new challenges for conventional medicine[1], which has now to manage chronic diseases prevalent in an aging population that expects and demands continued good health. Despite the current abundance of new treatments and technologies, physicians are sometimes unable to cure their patients or offer them relief from their symptoms. Moreover, the reliance on technology and the economic imperatives of managed care have affected the privileged physician-patient relationship, depriving it of the rich dialogue that can extend the healing process beyond that afforded by drugs and other treatments alone. Facilitated by globalization of information and the accessibility of resources, increasing numbers of patients are using complementary and alternative medicine to satisfy their personal healthcare needs[2]. By recent estimate, over 42% of Americans utilize complementary and alternative medicine (CAM) to address their health and wellness concerns. In 1997, Americans spent more out-of-pocket for CAM than they paid out-of-pocket for all hospitalizations and an amount "comparable with the projected 1997 out-of-pocket expenditures for all US physician services"[3].

CAM EXPANDS THE HEALTHCARE REPERTOIRE

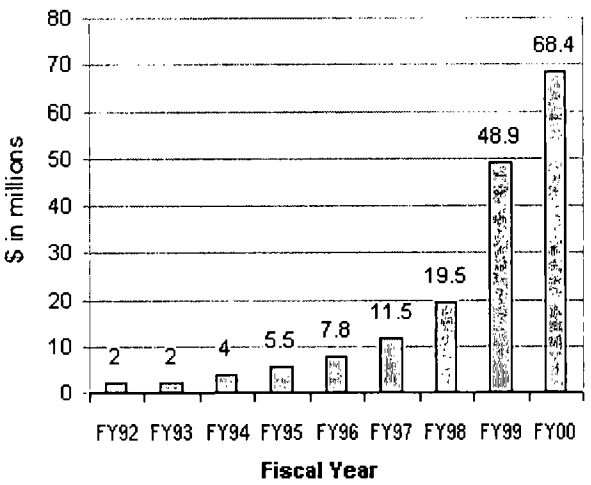
CAM is defined as healthcare practices that are not an integral part of conventional medicine. As diverse and abundant as the peoples of the world, these practices may be grouped within five major domains: alternative medical systems; mind-body interventions; biologically-based treatments; manipulative and body-based methods; and energy therapies[4]. Brief explanations of each are provided in Appendix I.

As CAM practices once considered unorthodox in the United States are proven safe and effective by rigorous scientific investigation, they become part of the mainstream healthcare repertoire. For example, radiation therapy, once regarded as a radical approach to treating cancer, is now considered a standard of care. Today, relaxation, spinal manipulation, and acupuncture are often prescribed to manage pain; and acupuncture is sometimes practiced to manage nausea associated with chemotherapy. Among the first drugs for treatment of high blood pressure was reserpine from the herb *Rauwolfia serpentina*, described many centuries ago in traditional Indian Ayruvedic monographs. Indeed, some of our most important drugs are derivatives of the active ingredients identified in herbal remedies. Such drugs of botanical origin include digitalis for treatment of congestive heart failure, vincristine, and more recently taxol, for treatment of cancers. There are indications that additional herbal remedies and contemporary CAM practices have the potential to prevent and treat chronic diseases, reduce healthcare costs, and expand our understanding of how healing works. However, few of these practices have been tested for safety and effectiveness. Still others await discovery and validation of their worth.

THE NEED TO INVESTIGATE, TRAIN, COMMUNICATE, AND INTEGRATE

Though ever promising, untested CAM therapies may impart unnecessary negative consequences. Their use may interfere with or displace effective treatments; patients may be exposed to potentially toxic substances; and resources that might be better invested in more appropriate treatment, may be wasted on ineffective or unsafe CAM therapies. Thus, it is crucial to rigorously evaluate widely-used CAM treatments for safety and efficacy. It is also important to identify promising approaches that are worthy of more intensive study. To pursue these investigations we must train, encourage, and support skilled investigators in both the CAM and conventional medical academic communities. Furthermore, we must present credible, rather than anecdotal, data to an intensely curious public, and we must educate CAM and conventional healthcare practitioners about the repertoire of healthcare practices that prove safe and effective so that they may be integrated into optimal interdisciplinary treatment plans for their patients. These challenges dictate serious efforts in research, training, communication, as well as those to facilitate such interdisciplinary integration.

THE AMERICAN PEOPLE DEMAND ACTION



CAM Funding History

In 1991, Congress established the Office of Alternative Medicine (OAM) at the National Institutes of Health, and in 1998 expanded its status, mandate, and authority by enacting legislation to create the National Center for Complementary and Alternative Medicine (NCCAM)[5].

NCCAM is charged to "...conduct basic and applied research (intramural and extramural[6]), research training, and disseminate health information and other programs with respect to identifying, investigating, and validating CAM treatments, diagnostic and prevention modalities, disciplines and systems." Congress has expressed growing support for NCCAM's mission by providing progressive budget increases for the Center (Figure 1[7]). NCCAM's legislative history and milestones are summarized in Appendix II.

PART II - INTO THE FUTURE: ALIGNING CHALLENGES AND OPPORTUNITIES

NCCAM presently supports a broad-based portfolio of research, research training and educational grants and contracts, which are summarized in Appendix IV, as well as several outreach activities, including the CAM Clearinghouse that disseminates information and the NCCAM Web site (http://nccam.nih.gov) that receives nearly 500,000 hits monthly. A more

complete list and description of NCCAM's outreach activities are provided in Appendix V. Building upon this foundation, NCCAM will continue to expand its research base and develop the infrastructure needed to move the CAM field forward. The additional opportunities to invest in research, train investigators to conduct CAM research, and disseminate information are many, as are the possibilities to promote interdisciplinary healthcare delivery. Our priorities for each of these areas are outlined below.

RESEARCH

Clinical Research: The extensive use of untested CAM practices by the American public dictates that NCCAM must make clinical research its highest priority and the centerpiece of its research portfolio. In this regard, NCCAM's approach differs significantly from that of the other NIH Institutes and Centers. While their research agendas are usually driven by basic science discoveries, CAM consumers and healthcare practitioners want to know now whether available options are safe and effective. Thus, NCCAM must study promising CAM substances and modalities even before knowledge is available about their active ingredients, mechanisms of action, stability and bioavailability.

To help identify fertile areas for clinical investigation and the appropriate level of investment in these areas, the Center relies on evidence-based reviews (described in Appendix VI). Indeed, these analyses reveal that information regarding the efficacy and safety of contemporary CAM therapies spans a continuum ranging from anecdotes through encouraging data derived from small, well developed Phase I and II clinical trials. Several additional factors, such as utilization by the American public, the potential for public impact, the strength of the preliminary data, the opportunity to expand the science base, feasibility, and cost are also considered in no priority order in selecting which and to what level promising treatments should be studied.

Accordingly, NCCAM will support definitive (Phase III) clinical trials of CAM substances and modalities that appear from evidence-based reviews to be the most promising and important. A number of trials are already underway, such as those to evaluate the use of St. John's Wort for depression (in collaboration with the National Institute of Mental Health and the Office of Dietary Supplements), *Ginkgo biloba* for dementia (in collaboration with the National Institute on Aging, the National Heart, Lung, and Blood Institute, and the National Institute of Neurologic Disorders and Stroke), glucosamine and condroitin sulfate for osteoarthritis (in collaboration with the National Institute of Arthritis and Musculoskeletal and Skin Diseases), and acupuncture in the treatment of osteoarthritis of the knee. Many more widely used, promising therapies are deserving of definitive study, including milk thistle for chronic liver disease, *Echinacea* for respiratory virus infections, and melatonin for sleep disorders. For other, less well studied, but still promising approaches, NCCAM will fund initial Phase I-II trials to establish the scientific rationale and methodological feasibility needed to justify large, randomized clinical trials. NCCAM will also invest in careful studies of popular interventions for which reports of efficacy are only anecdotal and no rational biomedical explanation as to how the modality might work has been provided, such as magnet therapy. Only through an open and fair appraisal of these approaches will NCCAM address their value for the American public.

In addition to investigating individual therapies, NCCAM will also study entire systems of traditional and indigenous medicine that have been practiced over the centuries. Such studies may identify additional health tools of potential use to the American public and may present opportunities to address health disparities and the needs of special populations, an area highlighted for attention across the NIH. Moreover, NCCAM plans to pursue studies of placebo

effects and how the practitioner - patient relationship can influence healing.

Appropriate evaluation of CAM techniques and products will require that experts in the use of a given CAM modality are intimately involved in the design, conduct and oversight of these studies. Also, diverse research designs will be needed to assess the spectrum of CAM techniques and products, since it is not possible to examine some CAM modalities (e.g., massage) through double-blind trials and others involve combinations of therapies that are custom-tailored to each patient's needs. Notwithstanding the difficulties in designing some CAM studies, NCCAM will demand the same high standard of scientific excellence that is required throughout the NIH.

Basic Science Research: While clinical research is the centerpiece of NCCAM's research portfolio, NCCAM will take full advantage of opportunities to build a base of CAM-related basic science discoveries. Some studies will be planned solely for the purpose of elucidating basic mechanisms. In addition, randomized clinical trials will be designed not only to test treatments, but also, to the extent possible, to determine underlying mechanisms of their action, discover biomarkers, define pharmacokinetics, identify the active components in natural products, and collect data on the natural presentation and progression of the diseases under study. For example, NCCAM's current trial of *Ginkgo biloba* is designed to ascertain not only whether this ancient natural product delays the onset and progression of dementia, but also represents the single largest prospective study of intellectual decline in aging Americans to date. Moreover, research projects such as those designed to understand the neurobiological basis for acupuncture-mediated analgesia and the essential components of St. John's Wort that ameliorate depression may contribute to the knowledge base of conventional biomedical researchers and inspire novel treatment approaches and rational drug discovery.

NIH Areas of Emphasis: NCCAM shares the NIH-wide imperative to address pressing public health concerns, and our research aims are closely aligned with the NIH's designated areas of emphasis. To this end, the Center will contribute toward the collective effort to study the biology of brain disorders, develop new preventive strategies against disease, and identify new avenues for the development of therapeutics. The potential contribution of NCCAM with respect to this latter area is substantial. NCCAM also will participate in the trans-NIH effort to understand and eliminate the health disparities observed between minority and majority populations. To this end, NCCAM is developing a strategic plan to address health disparities, to be incorporated into this overall strategic plan upon its completion.

Collaboration: The efficiency with which we advance our research agenda will be enhanced by leveraging the resources and expertise of our colleagues in other NIH Institutes and Centers, in other government agencies, in other research institutions, in the broader academic and international communities, and in industry. The opportunities for such collaborations are rich and numerous; it is most gratifying that many investigators in the other Institutes and Centers at the NIH, at other government agencies[8], and at academic and clinical centers of excellence throughout the world are already expressing interest in working with us.

TRAINING

NCCAM's ability to achieve its research goals is critically dependent on the availability of a cadre of skilled investigators in both the CAM and conventional communities. Thus, NCCAM must encourage skilled researchers to investigate CAM approaches and train CAM and conventional practitioners to conduct or participate in rigorous studies if we are to achieve the critical mass of investigators needed to execute excellent CAM research. Similarly, if we are to

capitalize on the vast opportunities to further the scientific maturation of the CAM community and achieve changes in both the CAM and conventional healthcare communities, we must provide increased opportunity for eager medical and post-professional students to become educated about CAM. With this information, they may knowledgeably guide and refer patients toward safe and effective CAM applications and practitioners experienced in delivering them.

INFORMATION DISSEMINATION

We are also obligated to steer the public, which today is immersed in media reports and Internet claims regarding CAM approaches, towards the most venerable and effective practices and away from those that are risky or unsafe. Using Internet technologies, holding town meetings, pursuing media opportunities, and distributing fact sheets, we must disseminate credible not anecdotal data to an intensely curious public that deserves complete and accurate information.

INTEGRATION

Finally, we must work to overcome the reluctance of conventional physicians to consider CAM therapies for their patients. Only by holding CAM therapies to the highest standards of evidence, will we best facilitate the creation of an integrated healthcare delivery system in which conventional physicians and CAM practitioners work as an interdisciplinary team.

PART III - GUIDANCE FOR THE NEXT FIVE YEARS: OUR STRATEGIC PLAN

NCCAM has been entrusted by the public with the authority to fund grants and contracts and a rapidly increasing budget to support them. Thus, we must fulfill greater expectations and perform our work with vigor, creativity, and a heightened sense of responsibility, proceeding according to a thoughtful, methodical, and clearly articulated strategy that reflects the aforementioned philosophical principles. For this reason, we have modified and expanded upon the 1998 Draft Strategic Plan created by the then-Office of Alternative Medicine to create this first NCCAM Strategic Plan. In our plan, we state our mission, define our vision, identify our stakeholders, and outline five cardinal strategic areas and the broad goals within them that will guide us in achieving our vision over the coming five years. Its elements reflect the cumulative wisdom of our staff, advisory councils, workshops, numerous healthcare providers, and consumers. It represents the first step in an ongoing planning process that will be used periodically to refine priorities for subsequent five-year periods, to assure that its priorities remain in alignment as the field matures, and that they reflect an appropriate balance between pursuing scientific opportunity and addressing public health needs. Throughout, the planning process, described in Appendix VIII, will rely significantly on input from the public and our many other diverse stakeholders.

OUR MISSION

The mission of the National Center for Complementary and Alternative Medicine is to prevent and alleviate human suffering and promote health through rigorous research on the safety and effectiveness of complementary and alternative medicine modalities, research training, and information dissemination for healthcare providers and consumers.

OUR VISION

Having borrowed from many rich traditions and by applying an uncompromising standard of excellence in research to identify safe and effective CAM practices, the nation's investment in NCCAM-supported research will yield novel insights and tools for better health, while enabling an informed public to reject ineffective or unsafe practices. Even more importantly, NCCAM will facilitate the merger of valuable CAM and conventional approaches into a practice of "integrative medicine," in which multiple healthcare professionals work as an interdisciplinary team, thereby expanding the repertoire of ways to achieve and maintain health.

OUR STAKEHOLDERS

- Patients and the General Public
- CAM Healthcare Researchers, Educators and Practitioners
- Conventional Healthcare Researchers, Educators and Practitioners
- Academic and Professional Associations
- NIH Institutes and Centers
- Other Federal Agencies
- Nonprofit Research and Educational Institutions and Foundations
- International Research Organizations
- Companies within the Pharmaceutical and Biotechnology Sector

NCCAM's vision will be realized only by creating and sustaining close partnerships across the spectrum of CAM consumers, investigators, and healthcare providers, and by reaching out to diverse stakeholder groups for advice and information.

STRATEGIC AREAS

To achieve our vision, we identified five cardinal strategic areas: Investing in Research; Training CAM Researchers; Expanding Outreach; Facilitating Integration; and Practicing Responsible Stewardship. Each of these strategic areas evolves from and will mature through an ongoing process of planning and evaluation, with substantial input from the National Advisory Council on Complementary and Alternative Medicine (see Appendix IX for a list of current members), and our stakeholders.

STRATEGIC AREA 1: INVESTING IN RESEARCH

NCCAM will seek to continually increase research support by encouraging and supporting CAM research projects according to the philosophies and priorities outlined in the previous section entitled, "Into the Future: Aligning Challenges and Opportunities," and in alignment with the NIH's areas of emphasis. NCCAM's highest priority is clinical research, both with respect to individual therapies and entire systems of medicine. While NCCAM will pursue investigations at all levels of the hierarchy of evidence outlined in Table 1, our largest investment will be in Phase III trials; and proportionately smaller expenditures will be made in areas for which less evidence is available.

Systematic Reviews	▶ Large randomized clinical trials
	▶ Small randomized clinical trials
	▶ Uncontrolled trials
	▶ Observational studies
	▶ Case studies
	▶ Anecdotes

Table 1 - Hierarchy of Evidence

NCCAM will also support basic science research, not only through studies whose primary aim is to elucidate basic mechanisms, but also by exploiting opportunities afforded by clinical trials.

Moreover, the Center will build research capacity and infrastructure, both intramural and extramural, domestic and international. Throughout these endeavors, the Center will pursue the many advantages afforded by collaborations both abroad and in the United States, with the other NIH Institutes and Centers, other government agencies, and industry.

Goal 1: Stimulate submission of high-quality applications in CAM priority areas.

Objectives:

- Sponsor interdisciplinary conferences to stimulate broad-based research.
- Assist extramural CAM researchers and practitioners to develop and participate in high-quality research applications.

Goal 2: Expand the scope of the NCCAM extramural research portfolio and subject participation.

Objectives:

- Support a broad base of rigorous CAM research, including, but not limited to, studies elucidating mechanisms of action, outcomes research, pharmacologic investigations, epidemiology, and all phases of intervention trials (I-III).
- Support research to address health disparities among women, minorities, children, and other under-represented populations.
- Emphasize investigator-initiated research as the time-proven vehicle for advancing science on broad fronts.
- Solicit applications and proposals in areas for which the opportunities for impact are great and there is a paucity of investigator-initiated research.

Goal 3: Create an NCCAM intramural research program.

Objectives:

- Design, conduct, analyze, and report rigorous CAM research, including but not limited to,

studies elucidating mechanisms of action, outcomes research, pharmacologic investigations, epidemiology, and all phases of intervention trials (I-III).
- Conduct clinical and laboratory-based CAM research studies in close collaboration with extramural CAM scientists and with intramural staff of the other NIH Institutes and Centers.

Goal 4: Establish a global NCCAM research enterprise.

Objectives:

- Establish programs of research on traditional and indigenous health practices in the United States and in those countries in which the most promising opportunities for CAM research are identified, in coordination with international organizations.
- Align these programs with existing NIH-funded international research programs, to ensure the immediate availability of research expertise in the field and the infrastructure to support it.

STRATEGIC AREA 2: TRAINING CAM RESEARCHERS

NCCAM will develop a critical mass of investigators in CAM research by providing appropriate career development opportunities; by increasing the knowledge, experience, and capacity of CAM practitioners to conduct rigorous research; and by enhancing conventional practitioners' and researchers' knowledge and experience in specific CAM areas.

Goal: Increase the number, quality, and diversity of CAM investigators.

Objectives:

- Stimulate collaborations between CAM practitioners and experienced investigators in the conventional academic medical community.
- Develop programs to train individuals in CAM-related laboratory and epidemiological research.
- Train doctors of medicine, osteopathy, chiropractic, and naturopathy, and others with advanced degrees in clinical disciplines, to conduct CAM-related clinical research.
- Enhance the quality of research training at NCCAM-funded research centers.
- Increase the number of trainees from under-represented populations.
- Establish an interdisciplinary, intramural NIH research training program.

STRATEGIC AREA 3: EXPANDING OUTREACH

NCCAM will use a variety of methods, media, and technologies to provide a timely source of evidence-based, CAM information and actively seek input from its stakeholders.

Goal 1: Establish an effective dialogue with CAM stakeholders.

Objectives:

- Sponsor Town Hall Meetings to provide a forum for the public to contribute input, and for NCCAM to share information regarding important research efforts and findings with the community.
- Seek ongoing, substantive input from leaders of CAM practice communities, advocacy

groups, the mainstream academic and scientific communities, industry, and partners in other NIH Institutes and Centers and Federal agencies.
- Exhibit NCCAM-funded discoveries and opportunities at conventional scientific meetings and those of our CAM constituents.
- Develop media opportunities and strategies to disseminate research information and increase public understanding of NCCAM's mission.

Goal 2: Make reliable scientific information readily available to the public.

Objectives:

- Disseminate accurate and timely information about CAM research and practices to consumers, practitioners, investigators, the media, and other CAM stakeholders.
- Collaborate on information dissemination with other NIH Institutes and Centers, Federal agencies, international organizations, and government agencies.

STRATEGIC AREA 4: FACILITATING INTEGRATION

Goal 1: Facilitate development of health education curricula that respect and incorporate insights and opportunities afforded by validated CAM and conventional practices.

Objectives:

- Fund educational grants to develop model curricula regarding CAM practices for schools of medicine and allied disciplines.
- Fund educational grants to develop model curricula regarding conventional medical practices for schools of complementary and alternative medicine disciplines.

Goal 2: Facilitate coupling of effective CAM and conventional practices within a coordinated, interdisciplinary healthcare delivery system.

Objectives:

- Sponsor national meetings, consensus conferences, and workshops on validated CAM therapies to enable practitioners to identify effective interventions for use in treating their patients.
- Disseminate CAM research findings to healthcare providers.
- Identify and develop methods to overcome barriers to the integration of safe and effective CAM practices.
- Support demonstration projects focusing on how to most effectively translate CAM research findings into practice. These projects will emphasize the development of partnerships between researchers and healthcare systems and organizations that have incorporated CAM practices into the delivery of clinical care.
- Facilitate integration of effective CAM practices into routine healthcare delivery for the NIH Clinical Center patients.

STRATEGIC AREA 5: PRACTICING RESPONSIBLE STEWARDSHIP

NCCAM, as a growing organization, will expand and continue to develop its valuable human resources, sound management practices, efficient business systems, and emphasis on customer service in ways that reflect the trust placed in it by the American public.

Goal 1: Develop NCCAM's human resources.

NCCAM's most valuable asset is our staff, who must be highly qualified, well trained, committed to our vision, and provided the resources needed to be successful in performing their respective roles.

Objectives:

- Align NCCAM's human resources with its mission, priorities, and requirements.
- Develop an effective management structure and system, within which the roles and responsibilities of each staff member are clearly defined.
- Develop a workforce that is motivated, well trained, versatile, and flexible.
- Foster diversity among NCCAM employees and enhance understanding and appreciation of cultural differences.
- Promote a work culture characterized by integrity, mutual respect, teamwork, and open communication.
- Encourage staff career development through practical experience, training, and other methods.

Goal 2: Establish effective management practices.

Objectives:

- Define performance expectations, emphasizing customer service.
- Develop exacting management systems.
- Review and enhance management practices.
- Evaluate major NCCAM functions

Goal 3: Engineer for efficiency.

Objectives:

- Streamline and automate business activities.
- Maintain a state-of-the-art information technology infrastructure.
- Provide training for staff to enhance core competencies to maximize use of systems, technology, and equipment.

PART IV - APPENDICES

APPENDIX I: MAJOR DOMAINS OF COMPLEMENTARY & ALTERNATIVE MEDICINE

Complementary and alternative healthcare and medical practices are those healthcare and medical practices that are not currently an integral part of conventional medicine[1]. The list of practices that are considered CAM changes continually as CAM practices and therapies that are proven safe and effective become accepted as "mainstream" healthcare practices. Today, CAM practices may be grouped within five major domains[4]: (1) alternative medical systems, (2) mind-body interventions, (3) biologically-based treatments, (4) manipulative and body-based methods, and (5) energy

therapies. The individual systems and treatments comprising these categories are too numerous to list in this document. Thus, only limited examples are provided within each.

I. ALTERNATIVE MEDICAL SYSTEMS

Alternative medical systems involve complete systems of theory and practice that have evolved independent of and often prior to the conventional biomedical approach. Many are traditional systems of medicine that are practiced by individual cultures throughout the world, including a number of venerable Asian approaches.

Traditional oriental medicine emphasizes the proper balance or disturbances of qi (pronounced chi), or vital energy, in health and disease, respectively. Traditional oriental medicine consists of a group of techniques and methods, including acupuncture, herbal medicine, oriental massage, and qi gong (a form of energy therapy described more fully below). Acupuncture involves stimulating specific anatomic points in the body for therapeutic purposes, usually by puncturing the skin with a needle.

Ayurveda is India's traditional system of medicine. Ayurvedic medicine (meaning "science of life") is a comprehensive system of medicine that places equal emphasis on body, mind, and spirit, and strives to restore the innate harmony of the individual. Some of the primary Ayurvedic treatments include diet, exercise, meditation, herbs, massage, exposure to sunlight, and controlled breathing.

Other traditional medical systems have been developed by Native American, Aboriginal, African, Middle-Eastern, Tibetan, Central and South American cultures.

Homeopathy and naturopathy are also examples of complete alternative medical systems. Homeopathy is an unconventional Western system that is based on the principle that "like cures like," i.e., that the same substance that in large doses produces the symptoms of an illness, in very minute doses cures it. Homeopathic physicians believe that the more dilute the remedy, the greater its potency. Therefore, homeopaths use small doses of specially prepared plant extracts and minerals to stimulate the body's defense mechanisms and healing processes in order to treat illness.

Naturopathy views disease as a manifestation of alterations in the processes by which the body naturally heals itself and emphasizes health restoration rather than disease treatment. Naturopathic physicians employ an array of healing practices, including diet and clinical nutrition; homeopathy; acupuncture; herbal medicine; hydrotherapy (the use of water in a range of temperatures and methods of applications); spinal and soft-tissue manipulation; physical therapies involving electric currents, ultrasound, and light therapy; therapeutic counseling; and pharmacology.

II. MIND-BODY INTERVENTIONS

Mind-body interventions employ a variety of techniques designed to facilitate the mind's capacity to affect bodily function and symptoms. Only a subset of mind-body interventions are considered CAM. Many that have a well-documented theoretical basis, for example, patient education and cognitive-behavioral approaches are now considered "mainstream." On the other hand, meditation, certain uses of hypnosis, dance, music, and art therapy, and prayer and mental healing are categorized as complementary and alternative.

III. BIOLOGICAL-BASED THERAPIES

This category of CAM includes natural and biologically-based practices, interventions, and

products, many of which overlap with conventional medicine's use of dietary supplements. Included are herbal, special dietary, orthomolecular, and individual biological therapies.

Herbal therapies employ individual or mixtures of herbs for therapeutic value. An herb is a plant or plant part that produces and contains chemical substances that act upon the body. Special diet therapies, such as those proposed by Drs. Atkins, Ornish, Pritikin, and Weil, are believed to prevent and or control illness as well as promote health. Orthomolecular therapies aim to treat disease with varying concentrations of chemicals, such as, magnesium, melatonin, and mega-doses of vitamins. Biological therapies include, for example, the use of laetrile and shark cartilage to treat cancer and bee pollen to treat autoimmune and inflammatory diseases.

IV. MANIPULATIVE AND BODY-BASED METHODS

This category includes methods that are based on manipulation and/or movement of the body. For example, chiropractors focus on the relationship between structure (primarily the spine) and function, and how that relationship affects the preservation and restoration of health, using manipulative therapy as an integral treatment tool. Some osteopaths, who place particular emphasis on the musculoskeletal system, believing that all of the body's systems work together and that disturbances in one system may have an impact upon function elsewhere in the body, practice osteopathic manipulation. Massage therapists manipulate the soft tissues of the body to normalize those tissues.

V. ENERGY THERAPIES

Energy therapies focus either on energy fields originating within the body (biofields) or those from other sources (electromagnetic fields).

Biofield therapies are intended to affect the energy fields, whose existence is not yet experimentally proven, that surround and penetrate the human body. Some forms of energy therapy manipulate biofields by applying pressure and/or manipulating the body by placing the hands in, or through, these fields. Examples include Qi gong, Reiki and Therapeutic Touch. Qi gong is a component of traditional oriental medicine that combines movement, meditation, and regulation of breathing to enhance the flow of vital energy (qi) in the body, to improve blood circulation, and to enhance immune function. Reiki, the Japanese word representing Universal Life Energy, is based on the belief that by channeling spiritual energy through the practitioner the spirit is healed, and it in turn heals the physical body. Therapeutic Touch is derived from the ancient technique of "laying-on of hands" and is based on the premise that it is the healing force of the therapist that affects the patient's recovery and that healing is promoted when the body's energies are in balance. By passing their hands over the patient, these healers identify energy imbalances.

Bioelectromagnetic-based therapies involve the unconventional use of electromagnetic fields, such as pulsed fields, magnetic fields, or alternating current or direct current fields, to, for example, treat asthma or cancer, or manage pain and migraine headaches.

APPENDIX II: IMPORTANT EVENTS IN THE HISTORY OF THE NATIONAL CENTER FOR COMPLEMENTARY & ALTERNATIVE MEDICINE

October 1991	Office of Alternative Medicine (OAM) established in the Office of the Director, NIH, with the appropriation for fiscal year 1992 of $2 million to

	more adequately explore unconventional medical practices.
	Stephen C. Groft, Pharm.D. appointed Acting Director, OAM.
September 1992	Workshop on Alternative Medicine convened in Chantilly, Virginia to discuss the state of the art of the major areas of alternative medicine and to direct attention to priority areas for future research activities.
October 1992	Joseph J. Jacobs, M.D., M.B.A., appointed as first Director, OAM.
June 1993	OAM established by Congressional mandate within the Office of the Director, NIH, under provisions of the National Institutes of Health Revitalization Act of 1993 (P.L.103-43) to facilitate study and evaluation of innovative medical practices, and to disseminate the resulting information to the public.
September 1993	First OAM research project grants funded through the National Center for Research Resources.
December 1993	Alternative Medicine Program Advisory Council established.
September 1994	Alan I. Trachtenberg, M.D., M.P.H., appointed Acting Director, OAM.
January 1995	Wayne B. Jonas, M.D., appointed as second Director, OAM.
October 1995	Research Centers Program established to provide a nationwide focus for interdisciplinary CAM research in academic institutions.
October 1996	Information Clearinghouse established.
November 1996	OAM designated as a World Health Organization Collaborating Center in Traditional Medicine.
September 1997	First Phase III clinical trial funded.
December 1997	Trans-agency CAM Coordinating Committee established by the NIH Director to foster OAM's collaboration across the Department of Health and Human Services and other Federal agencies.
October 1998	National Center for Complementary and Alternative Medicine established, by Congressional mandate, under provisions of the Omnibus Appropriations Bill (P.L. 105-277). This bill amended Title IV of the Public Health Service Act.
January 1999	William R. Harlan, M.D., named Acting Director, NCCAM.
February 1999	Charter creating NCCAM and making it the 25th independent component of the National Institutes of Health signed. The law gave the Director of the NCCAM control of the Center's day-to-day financial and administrative management, as well as broad decision-making authority and fiscal responsibility for grants and contracts. Dr. Donna E. Shalala, Secretary, Department of Health and Human Services (DHHS), approved the Center on

	February 1, 1999, its first official business day.
May 1999	NCCAM independently awards its first research project grant.
	NCCAM Trans-Agency CAM Coordinating Committee (NTACCC) established to foster NCCAM's collaboration across the Department of Health and Human Services and other Federal agencies.
June 1999	Special Emphasis Panel chartered to enable NCCAM to conduct peer review of mission-specific CAM applications.
July 1999	Cancer Advisory Panel for Complementary and Alternative Medicine (CAPCAM) created to assess preliminary clinical data related to treatment of cancer submitted by CAM practitioners.
August 1999	National Advisory Council on Complementary and Alternative Medicine chartered.
October 1999	Stephen E. Straus, M.D., appointed as first Director, NCCAM (Biosketch attached as Appendix III).

APPENDIX III: BIOGRAPHICAL SKETCH, STEPHEN E. STRAUS, M.D., DIRECTOR NATIONAL CENTER FOR COMPLEMENTARY & ALTERNATIVE MEDICINE

Dr. Stephen E. Straus was appointed the first director of the National Center for Complementary and Alternative Medicine (NCCAM) on October 6, 1999. Born on November 23, 1946, in New York City, Dr. Straus received his B.S. in life sciences from the Massachusetts Institute of Technology in 1968 and his M.D. from the Columbia University College of Physicians and Surgeons in 1972. His postgraduate training included an internship and residency in medicine at Barnes Hospital, St. Louis, MO, and a fellowship in infectious disease at Washington University, St. Louis, Missouri. Dr. Straus is board certified in internal medicine and infectious diseases.

Dr. Straus began his NIH career in 1973 as a research associate in the National Institute on Allergy and Infectious Diseases (NIAID), and he returned to NIAID in 1979 upon completion of his training in St. Louis. In pursuit of his research interests in molecular biology, pathophysiology, and treatment and prevention of human viral and immunological diseases, Dr. Straus has conducted both basic and clinical research. Dr. Straus has published over 300 research articles and edited several books. Since joining NIAID, he has assumed progressively higher levels of leadership, serving first as senior investigator and subsequently as Head of the Medical Virology Section in the Institute's Laboratory of Clinical Investigation and then as Chief of the Laboratory, a position he continues to hold concurrently with the Directorship of NCCAM.

Among Dr. Straus' accomplishments is his demonstration that acyclovir suppresses recurrent genital and oral herpes, and the characterization of a previously unrecognized genetically determined disease, the autoimmune lymphoproliferative syndrome. The recipient in 1999 of the Dutch National ME Fond Award (the leading national prize from the Netherlands for research in myalgic encephelomyelitis, chronic fatigue syndrome), Dr. Straus' professional achievements have been recognized by election to the Infectious Diseases Society of America, the Association of American Physicians, and the American Society for Clinical Investigation. He is a recipient of five medals and other commendations from the U.S. Public Health Service, including the Distinguished

Service Medal for innovative clinical research, and the DHHS Secretary's Distinguished Service Award for drafting the blueprint to reinvigorate clinical research at the NIH. He serves on the editorial boards of a several scientific journals, including the *Journal of Virology* and *Virology*.

APPENDIX IV: NCCAM PORTFOLIO OF RESEARCH AND RESEARCH TRAINING[9]

NCCAM supports a diverse portfolio of research and research training activities, many co-funded with other NIH Institutes. Research activities include the conduct of clinical trials to test the safety and efficacy of CAM modalities that are currently in wide use; the establishment of Centers to develop infrastructure and the capacity for CAM research and research training; and research programs initiated by individual investigators.

RESEARCH GRANTS

Clinical Trials

NCCAM supports Phase I (to evaluate safety), Phase II (to assess clinical activity) and Phase III clinical trials (to determine clinical efficacy) to test a range of CAM therapies.

Acupuncture

Evaluating the Efficacy of Acupuncture for Back Pain (Daniel Cherkin, Dr.PH, Center for Health Studies, Seattle, Washington) *Cofunded with the Agency for Healthcare Research and Quality* - The goals of this Phase II study are 1) to develop and evaluate methods for improving randomized trials to assess the efficacy of acupuncture, and 2) to use this information to design and pilot-test a randomized clinical trial of acupuncture for persistent low back pain. The trial will compare acupuncture to standard medical care, and standardized to individualized acupuncture treatment.

Acupuncture Treatment of Depression During Pregnancy (Rachel Manber, MD, Stanford University) *Cofunded with the Agency for Healthcare Research and Quality* - The primary study objective of this Phase II trial is to determine if the efficacy of acute (short term) acupuncture treatment for depression during pregnancy or post-partum is substantial enough to warrant a large-scale clinical trial. Since it is known that the mother's psychological state affects the infant's health, the trial will also assess the effect of treatment on infant well-being.

RCT – Acupuncture Safety/Efficacy in Knee Osteoarthritis (Brian Berman, MD, University of Maryland, Baltimore) - This multisite, Phase III trial is designed to determine the short and long term safety and efficacy of acupuncture in the treatment of patients with osteoarthritis of the knee in elderly using three randomly assigned participant groups for comparison: (1) true acupuncture group, (2) sham acupuncture group, and (3) education and attention control group.

Ginkgo biloba

Ginkgo biloba Prevention Trial in Older Individuals (Steven DeKosky, MD, University of Pittsburgh) *Cofunded with the National Heart, Lung, and Blood*

Institute, the National Institute on Aging, and the National Institute of Neurological Disorders and Stroke - This is a multi-center, randomized, double-blind, placebo-controlled Phase III trial to determine the effect of 240mg/day of *Ginkgo biloba* in decreasing the incidence of dementia, in general, and Alzheimer's disease, specifically. The subjects will be aged 75 years and older. Secondary outcomes, including changes in cognitive function, incidence of cardiovascular disease and total mortality, will also be measured.

Glucosamine and Chondroitin

Study of the Efficacy of Glucosamine and Glucosamine/Chondrotin Sulfate in Knee Osteoarthritis (Daniel Clegg, MD, University of Utah) *Cofunded with the National Institute of Arthritis and Musculoskeletal and Skin Diseases* - This four-year, multi-site, Phase III study will determine whether glucosamine, chondroitin sulfate and/or the combination of glucosamine and chondroitin sulfate are more effective than placebo and whether the combination is more effective than glucosamine or chondroitin sulfate alone in the treatment of knee pain associated with osteoarthritis of the knee.

The "Gonzalez Protocol"

RCT: Gonzalez Regimen (Karen Antman, MD, Columbia University, supplement to Cancer Center Support Grant) *Cosponsored with the National Cancer Institute* - This is a randomized, controlled, Phase III trial comparing the efficacy of the Gonzalez Regimen versus standard care in the treatment of inoperable pancreatic adenocarcinoma. The Gonzalez Regimen consists of intensive pancreatic proteolytic enzyme therapy with ancillary nutritional support and detoxification procedures.

Melatonin

Melatonin for Sleep Disorders in Parkinson's Disease (Glenna Dowling, RN, PhD, University of California, San Francisco) *Cofunded with the National Institute of Nursing Research* - The purpose of this Phase III, multi-site, double blind study is to compare the effects of melatonin given at two different doses (5mg and 50mg) and placebo on nocturnal sleep. The clinical design, a placebo-controlled, double crossover trial, will also allow for assessment of any adverse events associated with melatonin related to its safety and tolerability. This research may lead to the development of safer, more physiologic therapies for treating sleep disturbances in patients with Parkinson's Disease.

St. John's Wort

A Placebo-Controlled Clinical Trial of a Standardized Extract Hypericum perforatum in Major Depressive Disorder (Jonathan Davidson, MD, Duke University) *Cofunded with the National Institute of Mental Health and the Office of Dietary Supplements* - The purpose of this multi-site, Phase III trial is to study the acute efficacy and safety of a standardized extract of Hypericum perforatum in the treatment of patients with major depression. This 3-arm, double-blind clinical efficacy study will compare a standardized extract of hypericum to placebo over an eight week period. Subjects responding to treatment will be followed for an additional four

months. A third treatment group, using a selective serotonin reuptake inhibitor, will be included to ensure the validity of the trial.

Saw Palmetto

Saw Palmetto Extract in Benign Prostatic Hyperplasia (BPH) (Andrew Avins, MD, Veterans Affairs Medical Center, San Francisco) *Cofunded with the National Institute of Diabetes and Digestive and Kidney Diseases* - This is a Phase III, double-blind placebo-controlled, randomized clinical trial of the effect of 160 mg (taken twice daily) saw palmetto extract on symptoms, objective parameters of disease severity, and quality of life in men with moderate-to-severe benign prostatic hyperplasia. The primary outcome measurement is the American Urological Association Symptom Index score; the secondary outcome measures are peak urinary flow rate, post-void residual urine volume, and BPH Impact Index.

Shark Cartilage

Shark Cartilage Trial (Charles Loprinzi, MD, North Central Cancer Treatment Group) - Although the protocol is still underdevelopment, the intent of this multi-site, Phase III, randomized, blinded, controlled trial is to test the efficacy and safety of a power preparation of shark cartilage for the treatment of patients **with breast or colorectal cancer**.

Shark Cartilage Trial (Roy Herbst, PhD., MD, University of Texas/M.D. Anderson Cooperative Research Base - This is a multi-site, randomized, controlled, double-blind Phase III trial comparing the efficacy of purified shark cartilage and placebo in 500 individuals with inoperable, non-small cell lung cancer. All individuals will also receive standard chemotherapy and radiotherapy with survival as the primary outcome measure.

Research Centers

NCCAM supports a number of centers. CAM Specialized Centers provide focal points for initiating and maintaining state-of-the-art multidisciplinary CAM research, develop core research resources, the careers of new CAM investigators, and expand the research base through collaborative research with scientists and clinicians. Botanical Centers, co-funded with the NIH Office of Dietary Supplements, the Office of Research on Women's Health, and the National Institute of General Medical Sciences, foster multidisciplinary research to identify potential health benefits and develop a systematic evaluation of the safety and effectiveness of botanicals available as dietary supplements.

Specialty Research Centers

1. **Pediatric** Center for Complementary/Alternative Medicine (Fayez Ghishan, MD, University of Arizona) - The goal of this Center is to study integrative approaches in pediatrics. Three Phase II trials investigate the role of alternative approaches to very common pediatric problems for which there are no good conventional medical therapies:

- a randomized controlled trial of the use of craniosacral osteopathic;

manipulation treatment and of botanical treatment on recurrent otitis media in children;
- treatment of functional abdominal pain in children: evaluation of relaxation/guided imagery and chamomile tea as therapeutic modalities; and
- randomized controlled trials of the use of self-hypnosis, acupuncture and osteopathic manipulation on muscle tension in children with spastic cerebral palsy

2. Center for **Addiction** and Alternative Medicine Research (Thomas Kiresuk, PhD, Minneapolis Medical Research Foundation) - This Center will focus on the utilization, applicability, and effectiveness of selected CAM modalities in the treatment of addictive, health and psychological complications of substance abuse. The Center is studying:

- herbal treatment of hepatitis C in methadone maintained patients (Phase I clinical trial); and
- electroacupuncture examined for its effects and mechanisms of action regarding self-administration of major addictive substances.

3. Complementary and Alternative Medicine Research Center for **Cardiovascular** Diseases (Steven Bolling, MD, University of Michigan) - This center focuses on the investigation of CAM modalities to treat and prevent cardiovascular disease. Additionally, the Center will stress CAM education and promotion of validated CAM treatments for cardiovascular well-being. Individual research projects being conducted within the Center include the following Phase II clinical trials to determine the:

- effectiveness of Hawthorn in the treatment of heart failure;
- effect of Reiki on Post-stroke Rehabilitation Patients; and
- chronic diabetic painful neuropathy and cardiovascular risk factors in non-insulin dependent diabetes mellitus (NIDDM): an alternative approach

4. Oregon Center for CAM in **Neurological Disorders** (Barry Oken, MD, Oregon Health Sciences University) - The Center is investigating whether:

- three anti-oxidant regimens, ginkgo biloba, alpha-lipoic acid/essential fatty acids and vitamin E/selenium are effective in decreasing multiple sclerosis disease activity (Phase I clinical trial);
- a standardized ginkgo biloba extract can prevent or delay cognitive decline in elderly patients (Phase II clinical trial);
- hatha yoga has palliative benefits on the cognitive and behavioral changes associated with aging and neurological disorders in multiple sclerosis patients and in the healthy elderly (Phase III clinical trial); and
- vitamin E and ginkgo biloba extract will be as effective as sodium azide and no treatment in reducing oxidative end-products in transgenic and wild-type mice

5. **Craniofacial** Complementary & Alternative Medicine Center (Alexander B. White, MD, Kaiser Foundation Research Institute) - The Center will investigate via Phase II clinical trials to determine whether:

- acupuncture, chiropractic therapy, and bodywork therapy are as effective as

standard treatment for tenderness and pain caused by temporomandibular disorders (TMD);
- naturopathic medicine and traditional Chinese medicine are as effective as standard treatment for tenderness and pain caused by TMD; and
- three naturopathic medicines (glutamine, Connective Tissue Nutrient Formula, and adaptogenic herbs) are as effective as a placebo in alleviating clinical signs and symptoms of adult periodontitis

6. Center for CAM, **Minority Aging and Cardiovascular Disease** (Robert Schneider MD, Maharishi University of Management) - This Center focuses on Vedic Medicine, a form of traditional Ayurvedic Indian medicine that incorporates herbal formulations and meditation, in the older African American population. The emphasis of the Center's research is on testing the efficacy and effectiveness of Vedic medicine for reducing mortality and morbidity associated with cardiovascular disease (CVD). The Center is conducting three single-blind, randomized, controlled Phase II clinical trials to determine the:

- basic mechanisms of meditation and CVD in older blacks;
- effect of transcendental meditation on carotid artery intima-media thickness toward reducing hypertension; and
- effects of herbal antioxidants on CVD in older blacks

7. Center for Alternative Medicine Research of **Arthritis** (Brian Berman, MD, University of Maryland) - The center will investigate the:

- cost effectiveness of and long-term outcomes following acupuncture treatment for osteoarthritis of the knee (Phase III clinical trial);
- effectiveness of mind/body therapies for fibromyalgia (Phase II clinical trial);
- mechanism of action and effects of Electroacupuncture on persistent pain and inflammation; and
- mechanism of action of an herbal combination with immunomodulatory properties.

8. Center for CAM Research in **Aging** (Fredi Kronenberg, PhD, Columbia University) - The Center will investigate:

- the influence of a macrobiotic diet, as compared to the addition of a single food to a typical diet, on various biochemical and cardiovascular parameters that may be influenced by estrogens (Phase II clinical trial);
- whether these natural dietary sources of estrogen prevent postmenopausal bone loss (Phase II clinical trial);
- whether treatment with black cohosh is effective in reducing the frequency and intensity of menopausal hot flashes (Phase II clinical trial); and
- the bioactivity, mechanisms of action, and potential risks of a widely-used Chinese Herbal formula in cell culture and in vivo.

9. Consortial Center for **Chiropractic** Research (William Meeker, DC, MPH, Palmer College of Chiropractic) - The faculty and administrators from five chiropractic institutions (the Palmer Center for Chiropractic Research, Palmer College of Chiropractic, Davenport, Iowa; University of Iowa, Iowa City, Iowa; Los Angeles

College of Chiropractic, Whittier, California; National College of Chiropractic, Lombard, Illinois; Kansas State University, Manhattan, Kansas; and Wolfe-Harris Center for Clinical Studies, Northwestern College of Chiropractic, Bloomington, Minnesota) have formed the Center to provide an infrastructure to examine the potential effectiveness and validity of chiropractic healthcare and to provide the appropriate clinical, scientific, and technical assistance to chiropractic researchers in developing high-quality research projects. The Center is investigating the:

- load distribution during bilateral thoracic manipulation;
- effectiveness of chiropractic for chronic pelvic pain (Phase I clinical trial)
- **effectiveness of chiropractic relative to conservative medical care for sciatica and neck pain**;
- effects of spinal manipulation on immune function;
- utility of joint end-play assessment (palpation);
- effect of spinal manipulation on muscle excitability;
- effect of vertebral loads on sympathetic nerve regulation; and
- facet capsule biomechanic

Botanical Centers

10. **Botanical Dietary Supplements for Women's Health** (Norman Farnsworth, PhD, University of Illinois at Chicago) - This Center is studying the clinical safety and efficacy of botanicals used to treat women's health with particular emphasis on therapies for menopause. Additional studies are addressing mechanisms of action, identification of active compounds, and characterization of metabolism, bioavailability and pharmacokinetics of active species contained in these botanicals. The Center also provides information about botanicals to the public and health professionals. Four research projects are underway to:

- standardize botanical dietary supplements and elucidate the structure of active compounds using bioassay-guided fractionation;
- isolate active compounds for structure elucidation by bioassay-guided fractionation, and carry out biochemical studies to determine the mechanism(s) of botanicals used for women's health;
- develop and apply novel in vitro methods for the study of metabolism, absorption and toxicity of active compounds in botanicals, and to evaluate immunotoxicity of botanical preparations; and
- carry out Phase I and Phase II clinical trials of black cohosh (*Cimicifugae racemosa*) and red clover (*Trifolium pratense*).

11. UCLA Center for Dietary Supplements Research on Botanicals (David Heber, MD, PhD, University of California, Los Angeles) - This Center is studying:

- how yeast-fermented rice may reduce cholesterol levels in the body;
- whether green tea extract and soy help stop tumor growth;
- the hypothalamic effects of St John's wort; and
- levels of active compounds in several botanicals available as dietary supplement

ADDITIONAL RESEARCH GRANTS

NCCAM has made additional awards to study a number of health conditions and research topics.

Acupuncture

Acupuncture in the Treatment of Depression (John Allen, Ph.D., University of Arizona) - This randomized, double-blind, placebo-controlled Phase III trial is testing the efficacy of acupuncture to treat major depression. The study is unique in that treatment effects will be assessed from the perspectives of both western psychiatry and Chinese medicine.

Acupuncture and Hypertension: Efficacy and Mechanisms (Kaplan, Norman M., MD University of Texas Southwestern Medical Center) - Using a randomized, double-blind placebo-controlled design for their Phase II trial, the investigators will test two major hypotheses: (1) electroacupuncture produces a long-lasting reduction in sympathetic nerve activity, thereby providing a safe and effective complementary treatment of human hypertension; (2) a major mechanism mediating the blood pressure lowering effect of acupuncture is the activation of somatic afferents which trigger a naloxone-sensitive reflex suppression of central sympathetic outflow. Acupuncture has been advocated as safe and effective treatment of essential hypertension and other cardiovascular disorders (e.g., heart failure, myocardial ischemia) which have sympathetic neural components.

Biomechanics

Biomechanical Effect of Acupuncture Needling (Langevin, Helene M., MD, University of Vermont) - This investigation will lead to quantification of needle grasp by measuring the peak force required to pull out acupuncture needles inserted at acupuncture points and control points in 80 normal human volunteers. Needling operations will be carried out by a computer controlled device, eliminating potential investigator bias. All needling parameters will be consistent with clinical practice. The investigators will also study varying dwell times after insertion and different types of needle manipulation. They will correlate the force required to withdraw the needle with the depth of its insertion into muscle and subcutaneous tissue, which will allow determination of which tissue is most responsible for needle grasp.

Botanicals

Method for Making an Improved St. John's Wort Product (Castor, Trevor P., PhD, Aphios Corp.) - The project seeks to develop an improved St. John's Wort product that can be manufactured in a standardized and reproducible manner, and in strict accordance with current Good Manufacturing Practices of the Food and Drug Administration.

Cancer

Self-transcendence in Breast Cancer Support Groups (Doris Coward, PhD, University of Texas, Austin) *Cofunded with the National Institute of Nursing Research* - This randomized, Phase II open trial proposes to expand the traditional role of breast cancer support groups by conscious promotion of self-transcendence views and behaviors, and to document, over time, changes in measures of

self-transcendence, well being and immune function in support group participants. It is projected that 80 women will be recruited into both the intervention group and a wait list control group, and that the findings of this study will increase knowledge of the relationship of lymphocyte metabolic function to sense of well-being.

Cardiovascular Diseases

Effects of meditation on mechanisms of Coronary Heart Disease (C. Bairey Merz, MD, Cedars-Sinai Medical Center) - This project is a randomized controlled, single-blinded, Phase II trial investigating whether transcendental meditation will reduce cardiac events in patients with coronary heart disease. The control groups will participate in a cardiology education program. The primary outcome is arterial vasomotor dysfunction (brachial artery reactivity) and the secondary outcome is autonomic nervous system imbalances (heart rate variability).

General Medicine

Melatonin and Cerebral Blood Flow Autoregulation (Mohan Viswanathan, PhD, Children's Research Institute) - The present project will attempt to define the physiological role of melatonin receptors in cerebral blood flow. The study will focus on functional studies and signal transduction mechanisms of melatonin receptors in the cerebral arteries and pharmacological characterization of melatonin binding sites.

Information Dissemination

Complementary and Alternative Medicine Data Archive (Eric L. Lang, PhD, Sociometrics Corporation) - The goal of this project is to facilitate access to, and statistical analysis of, outstanding scientific datasets and documentation on CAM through the creation of an international CAM Data Archive.

Liver Disease

Herbal Remedies and the Treatment of Liver Disease (Mark Zern, MD, Thomas Jefferson University) - The objective of this study is to investigate the effectiveness of a number of herbal remedies, employing a rigorous scientific approach, to determine the relative effectiveness of these agents and the mechanisms by which they may be inhibiting liver injury and fibrosis. Both in vitro models of liver cell injury and rat models of liver injury and fibrosis will be employed.

Mental Health

Oxidative Cell Injury in First Episode Psychotic Patients (Sahebarao Mahadik, PhD, Medical College of Georgia) - This project seeks to establish that the increased oxidative cell injury exists at the onset of psychosis and probably continued injury contributes to deteriorating course of illness in some patients. Results from this study could provide a mechanism by which dietary antioxidants might reduce some abnormal pathologies leading to psychosis.

Omega-3 Fatty Acids in Bipolar Disorder Prophylaxis (Andrew Stoll, MD, McLean Hospital) *Cofunded with the National Institute of Mental Health* - The

purpose of this Phase III clinical trial is to assess the efficacy of omega-3 fatty acids in preventing recurrence in patients with bipolar disorder, type I. 120 outpatients with bipolar disorder, type I, will be randomly assigned to receive add-on treatment with omega-3 fatty acids or placebo, for one year. The primary goal is to assess the prophylactic effects of omega-3 fatty acids in a cohort of bipolar patients with a relatively high risk of recurrence.

Neurology

Neuroprotective Agents from Oriental Medicines (Tae H. Oh, PhD, University of Maryland) - These studies are designed to elucidate and establish the mechanism(s) of neuroprotection demonstrated by isolates of oriental medicines (*Panax ginseng*, *Cynanchum wilfordii*, *Scrophularia buergeriana*). Specifically, will investigate whether Rg3 (a gingenoside fraction prepared from *Panax ginseng*) and MCA (a p-methoxy-trans-cinnamic acid prepared from *Scrophulara buergeriana*) exert neuroprotective activities by inhibiting Ca++ influx by determining their effects on Ca++ influx in vitro; whether Rg3, cynandione A and MCA exert neuroprotective activity by inhibiting neuronal apopotosis by assessing their effects on apoptosis and its markers in vitro and in vivo; and whether neoline ameliorates deficits in short-term memory by influencing central cholinergic transmission in the brain. In addition the study addresses issues involved in drug delivery across the blood brain barrier.

Neurobiology of Acupuncture Analgesia (Ji-Sheng Han, MD, Beijing Medical University) - This study is examining the effects of electro-acupuncture on gene and protein expression in a rat model. Specifically, the investigator exploring the regulation of the endogenous opioid system in the nervous system.

Pain

Nonpharmacologic Analgesia for Invasive Procedures (Elvira Lang, MD, Beth Israel Deaconess Medical Center) - It is proposed that the use of nonpharmacologic analgesia (a combination of relaxation training, hypnosis and guided imagery) during invasive radiologic procedures will reduce the need for intravenous drugs, improve patient safety and prove cost effective. To test these hypotheses, the relative performance of nonpharmacologic analgesia will be compared to standard care in a randomized, Phase III trial.

Efficacy of Acupuncture in the Treatment of Fibromyalgia (Dedra A. Buchwald, MD, University of Washington) - 96 patients with fatigue will be recruited for a 12-week, 24-treatment, 3-arm, randomized, controlled Phase II clinical trial. The active treatment group will receive true acupuncture. Control groups will be treated with acupuncture for an unrelated condition, receive needle insertion at nonchannel, nonpoint locations, or a true placebo. Short and long-term efficacy and side effects will be measured using both subjective and objective measures of overall health and pain to determine the optimal time length of treatment; and examine the concordance of allopathic and acupuncture-based measures of outcome.

Pilot Study of Acupuncture in Fibromyalgia (Daniel J. Claw, MD, Georgetown University Medical Center) - A randomized, blinded, sham-controlled, 2 by 2 factorial Phase II trial will be conducted to examine the individual and synergistic effects of

both needle placement and of needle stimulation on the efficacy of acupuncture as a therapeutic modality in fibromyalgia. The design allows determination of dose-effect for the analgesic effect of acupuncture.

Effect of High Dose Vitamin E on Carotid Atherosclerosis (Ishwarlal Jialal, MD University of Texas Southwestern Medical Center) - The primary aim of study is to test the effect of high dose alpha tocopherol (AT) supplementation on the progression of carotid atherosclerosis in patients with coronary artery disease (stable angina pectoris or previous myocardial infarction) in a 2-year, placebo-controlled, Phase II randomized trial. Since AT supplementation decreases low density lipoprotein oxidation and certain pro-atherogenic properties of activated monocytes, these parameters will also be studied and correlated with carotid atherosclerosis. While the patients will be monitored for clinical events during the study, this will not constitute a major aim since the study is not powered to adequately assess this. Thus, this study will determine if high dose AT supplementation is beneficial in retarding carotid atherosclerosis.

Acupuncture for Dental Pain: Testing a Model (Lixing Lao, DDS, PhD, University of Maryland) - This double-blind, randomized controlled trial tests the hypothesis that acupuncture can produce better analgesic effects than control procedures on postoperative dental pain caused by extraction of a partially impacted third molar model. The first pilot phase will develop and validate two sham procedures to test the efficacy of acupuncture. This Phase II trial will test the efficacy and safety of real acupuncture compared to the sham model developed in the Phase I study.

Usual Care vs. Choice of Alternative Therapy for Low Back Pain (David M. Eisenberg, MD, Beth Israel Deaconess Medical Center) - Patients with uncomplicated acute low back pain will be randomized in this Phase III trial to either usual care or choice of expanded benefits (chiropractic, acupuncture or massage therapy). It is hypothesized that patients offered their choice of expanded benefits will experience a more rapid improvement in symptoms, a faster return to baseline functional status, a decrease in utilization of conventional medical services, and will be more satisfied with their care.

Acupuncture and Moxa For Chronic Diarrhea in HIV Patients (Joyce K. Anastasi, RN, PhD, LAc, Columbia University Health Sciences) - This study is designed to assess the efficacy of two alternative medicine treatments for chronic diarrhea associated with HIV in a prospective, Phase III, randomized, controlled, blinded, parallel groups study under the intent-to-treat principle. True acupuncture, moxibustion, and combination therapy, in which specific meridian points are stimulated according to protocol, will be compared to each other and with the control group. Endpoints will include diarrhea frequency and stool consistency.

Trial of Acupuncture for Carpal Tunnel Syndrome (Arthur Weinstein, MD, George Washington University Medical Center) - The major specific aim of this pilot study is to demonstrate that using a "single blind-mute" methodology, true and sham acupuncture can be administered in a standardized and unbiased fashion. The condition to be studied is carpal tunnel syndrome (CTS), a common, well delineated syndrome causing hand pain with characteristic clinical and objective electrodiagnostic findings. Other aims of this study are: 1) to identify and standardize

the most appropriate sham acupuncture points for CTS, 2) to develop a manual which standardizes the administration of true and sham acupuncture can be used at any study site performing a randomized clinical trial (RCT) 3) to demonstrate that patient recruitment for and retention in an RCT of acupuncture for CTS is sufficient to justify a full-scale RCT, 4) to determine, in a small Phase II RCT, whether true acupuncture provides meaningful benefit for pain in CTS compared to sham acupuncture and whether the frequency of administration of acupuncture influences the outcome.

Women's Health

Study of Women's Health Across the Nation (SWAN) (Ellen B. Gold, MD, University of California, Davis) *Cofunded with the National Institute on Aging and the National Institute of Nursing* - A multi-site study to describe and contrast menopausal transition in relation to ethnicity, SWAN aims to contribute substantive new knowledge on the menopause transition through its prospective design, multi-ethnic/racial composition, representation of defined populations, and comprehensive measurement and power. A major goal of the project is to collect and analyze data on demographics, health and social characteristics, race/ethnicity, reproductive history, pre-existing illness, physical activity (includes activity limitations), health practices" (includes diet, smoking, use of over-the-counter medications, use of CAM treatments) as potential predictor variables and to describe the multiethnic community-based samples of mid-life women.

RESEARCH TRAINING

Postdoctoral Fellowships

NCCAM provides individual National Research Service Awards (NRSA) to postdoctoral fellows with the aim of developing a cadre of investigators capable of conducting rigorous CAM research.

Yihui He, PhD, Beth Isreal Deaconess Medical Center
Antihyperglycemic Activities of Bamboo Shoot Phytosterol - Dr. He will examine a potential antihyperglycemic effect of bamboo shoot and its ethanol and methanol extracts using diabetic rodent models and 3T3-L1 (preadipocyte) and L6 (myoblast) cell lines. The proposed study aims at (1) identifying active antihyperglycemic phytosterols present in the solvent extracts using a genetic diabetic mouse model; (2) testing the active phytosterols for their effects on oral glucose tolerance and insulin sensitivity in streptozotocin diabetic rats fed a high-fructose diet; and (3) examining the effects of the phytosterols on glucose uptake and GLUT4 mRNA levels in both the adipocyte and muscle cell lines.

Shujia Pan, PhD, University of Texas at Austin
Ginseng's Effects on MRNA Profiles in a Diabetes-2 Model - The objectives of this postdoctoral fellowship training are to study (1) the effects of herbal medicine on diabetes and metabolism; (2) the effects of complementary intervention (including diet and exercise); and (3) molecular biology techniques on the control of gene expression.

CAREER DEVELOPMENT AWARDS

Research Scientist Development Award (provides support of a scientist, committed to research,

in need of both advanced research training and additional experience)

Raymond G. Devries, PhD, St. Olaf College
An Ethnographic Study of Institutional Review Boards - This Mentored Scientist Development Award in Research Ethics supports detailed, comparative ethnographic research of Institutional Review Boards. The research has two aims: (1) to promote the development of the applicant as a scholar in the ethics of research on human subjects, and (2) to address the behavior and effectiveness of IRBs. This study, with its use of ethnographic and historical research methods and its careful consideration of several sources of data, will allow description of the social influences on IRBs and the decisions generated there.

Mentored Patient-Oriented Research Career Development Award (provides support for the career development of an investigator who has made a commitment to focus his/her research endeavors on patient-oriented research, for three to five years of supervised study and research for clinically trained professionals who have the potential to develop into productive, clinical investigators)

Bruce Barrett, MD, PhD, University of Wisconsin Medical School
Mentored Patient-Oriented Research Career Development - Dr. Barrett will design and implement randomized trials of *Echinacea* for upper respiratory infection (URI) to test the efficacy of *Echinacea* as early treatment for URI.

INSTITUTIONAL TRAINING GRANTS

NCCAM awards grants to institutions to establish programs to provide opportunities for individuals to train for careers in CAM-related research. Where opportunity exists, NCCAM also supplements grants awarded by other Institutes and Centers to support trainees whose specific focus is CAM-related research.

Fellowship Training Program in Alternative Medicine (Russell Phillips, MD, Beth Israel Deaconess Medical Center) - The overall goal of this program is to prepare general internists for careers as academic research faculty and educators in general and complementary-alternative internal medicine.

Cardiovascular Disease Prevention Training Program (William L. Haskell, Ph.D., Stanford University School of Medicine, *Cofunded with the National Heart, Lung, and Blood Institute*) - NCCAM provides support for two postdoctoral fellows to receive research training in cardiovascular disease prevention with an emphasis on complementary and alternative therapies.

Multidisciplinary Respiratory Diseases Research Training (Marvin I. Schwarz, MD, University of Colorado Health Sciences Center (UCHSC), *Cofunded with the National Heart, Lung, and Blood Institute* - NCCAM provides funds for a nurse anaesthetist to fulfill the requirements of the UCHSC School of Nursing's doctoral program, with a focus on the use of complementary and alternative medicine approaches in operative and peri-operative anaesthesiology.

UCLA/RAND Health Services Research Training Program (Ronald M. Anderson, PhD., *Cofunded by the Agency for Healthcare Research and Quality*) - NCCAM provides funds for one postdoctoral trainee, working in the area of chiropractic research, to complete the two-year

master's degree program in the Department of Epidemiology in the UCLA School of Public Health.

APPENDIX V: NCCAM OUTREACH ACTIVITIES

NCCAM Clearinghouse (PO Box 8218, Silver Spring, MD 20907, Ph: 888-644-6226, Fax: 301-495-4957) – The NCCAM Clearinghouse disseminates information to the public and healthcare providers about the NCCAM's programs and research findings through CAM fact sheets, information packages, publications, and a quarterly newsletter distributed to 6,000 public subscribers. During the first 10 months of FY 1999, the Clearinghouse received more than 18,000 requests for information, distributed more than 37,000 copies of publications, and made nearly 13,000 referrals to other NIH organizations, NCCAM's research centers, other governing agencies, or CAM organizations.

Web Site (http://nccam.nih.gov) – Established in 1996, the NCCAM's Web site, which receives nearly 500,000 hits per month, offers comprehensive information of interest to healthcare consumers and practitioners, and to researchers.

CAM Citation Index (CCI) (http://nccam.nih.gov/nccam/resources/search.cgi) – The CCI consists of approximately 175,000 bibliographic citations dated from 1963 through 2000 assembled by the NCCAM from the National Library of Medicine's MEDLINE database. Users can perform a search of the bibliographic data or review citations organized by CAM system, disease, or method.

Combined Health Information Database (CHID) (http://chid.nih.gov) – In February 1999, NCCAM joined CHID, a cooperative effort among several Federal agencies that was organized to consolidate information related to health and disease contained in individual government databases within a single database. CHID also contains some health information materials not available in other government databases. Currently, CHID contains approximately 1000 records covering the spectrum of CAM assembled by the NCCAM Clearinghouse or that are publicly available elsewhere.

Town Meetings – NCCAM will convene town meetings for CAM consumers and practitioners. The first such meeting was held on March 15, 2000, in Boston in collaboration with the Center for Alternative Medicine Research and Education, Beth Israel Deaconess Medical Center, Harvard University.

Conferences – The Center sponsors national conferences on areas of CAM practice and research, for example:

- "Placebo and Nocebo Effects: Developing a Research Agenda" December 1996
- Complementary and Alternative Medicine in Chronic Liver Disease, August 22-24, 1999, with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the Office of Dietary Supplements (ODS), NIH, and the American Association of Naturopathic Physicians.
- A trans-NIH conference on the placebo co-sponsored with the National Institute for Diabetes and Digestive and Kidney Diseases is scheduled for November 20-21, 2000. The goal of the conference is to develop a research agenda to move the field forward based on a scholarly assessment of this subject area.

APPENDIX VI: EVIDENCE-BASED REVIEWS

To help identify fertile areas for clinical investigation and the appropriate level of investment in each, NCCAM examines the scientific evidence regarding the effectiveness of CAM treatments. This hierarchy of evidence ranges from anecdote through case studies, observational studies, uncontrolled trials, and small randomized controlled trials to large randomized clinical trials, Systematic reviews may be conducted at and across all levels. NCCAM taps a number of resources to obtain evidence-based reviews.

1) Centers for Disease Control and Prevention (CDC) - NCCAM has engaged the CDC to develop effective methods of identifying and enlisting the cooperation of practitioners who claim to have observed effective new therapies and subsequently will work with CDC representatives to review their case files in a systematic fashion. The goal of this activity is to identify practices worthy of scientific study by NCCAM.

2) Cancer Advisory Panel for Complementary and Alternative Medicine (CAPCAM) - The NCCAM, in collaboration with the National Cancer Institute (NCI), established the federally-chartered CAPCAM to enable discovery of new, promising CAM cancer treatments. Members of the 15-person panel (listed in Appendix VII) represent a cross section of expertise from the CAM and mainstream oncology communities. CAPCAM's members review and assess clinical data submitted by CAM scientists and clinicians, including evaluation of best case series (retrospective analyses of data from patients treated with a specific modality in order to assess specific therapeutic benefit). Based on these evaluations, CAPCAM will identify therapies worthy of more rigorous scientific study by NCCAM.

3) Agency for Healthcare Research and Quality ((AHRQ), formerly the Agency for Health Care Policy and Research—AHCPR) - NCCAM contracts with AHRQ to carry out systematic reviews though the Agency's Evidence-based Practice Program, which supports 12 Evidence-based Practice Centers (EPCs) in the United States and Canada. Under this program, the EPC at the University of Texas, San Antonio evaluated the use of garlic for cardiovascular disease and the use of *Silybum marianum* (milk thistle) in treatment of liver disease and cancer. Currently, the Southern California Evidence-based Practice Center—RAND, Santa Monica, CA is surveying the state of CAM science to identify promising "frontiers of CAM investigation" for which they will subsequently conduct full systematic reviews.

4) The Cochrane Collaboration (CC) - The Cochrane Collaboration (http://www.cochrane.dk) is an international nonprofit organization founded on belief in the need to rely on systematic reviews of scientific evidence, rather than only on beliefs, traditions, common practices or case histories. The CC's mission is to prepare, maintain, and disseminate systematic, up-to-date reviews of randomized controlled clinical trials across all areas of health care. A group of Fields/Networks represent the interests of specific groups of patients or specific types of treatment (such as child health, vaccines, and rehabilitation and related therapies). The Complementary Medicine (CM) Field, supported by NCCAM and coordinated by Brian Berman, M.D., was added in 1996 (http://www.compmed.ummc.umaryland.edu).

The Cochrane Field Groups work in collaboration with approximately 50 Cochrane Research Groups (CRGs), arranged by disease specialty to carry out systematic reviews related to their disease specialty. The CRG with which the Field works is determined by the research question. For example, examining whether massage is effective in increasing the weight of low birth weight

infants is being done in collaboration with the Neonatal CRG, whereas exploring whether homeopathy is effective for asthma is being done in collaboration with the Airways CRG. Since formation of the CM Field, staff have produced the Cochrane Registry of Randomized Controlled Trials in Complementary Medicine. As of March 2000 the registry holdings include approximately 4,700 RCTs, 5400 possible RCTs, 204 systematic reviews, and 1,812 hard copy reports in the archive. The registry is available on the Cochrane Library Controlled Clinical Trials Registry (CCTR).

5) NIH Consensus Development Conferences - NCCAM supports NIH consensus conferences on CAM-related areas through the Office of Medical Applications and Research at the NIH. "Integration of Behavioral and Relaxation Approaches Into the Treatment of Chronic Pain and Insomnia," a technology assessment conference held in October 1995, was cosponsored with nine NIH components[10]. "Acupuncture: An NIH Consensus Development Conference" was held in 1997 to review the efficacy of acupuncture in therapeutic and preventive medicine, jointly with the Office of Medical Applications of Research and seven components of the NIH[11].

APPENDIX VII: CANCER ADVISORY PANEL FOR COMPLEMENTARY & ALTERNATIVE MEDICINE (CAPCAM)

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ELLENBERG, Susan S., Ph.D.
Director Division of Biostatistics and Epidemiology
Center for Biology Evaluation and Research
Food and Drug Administration
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FAIR, William R., M.D.
Director Prostate Diagnostic Center
Attending Surgeon, Urology Oncology Services
Memorial Sloan-Kettering Cancer Center
New York, New York 10021

GORDON, James S., M.D.
Director Center for Mind-Body Medicine
Georgetown University School of Medicine
Washington, D.C. 20015

JACOBS, Frances A., R.N.
Clinical Nurse Coordinator
Adult Oncology Unit
Rush-Presbyterian-St. Luke's Medical Center
Chicago, Illinois 60612

MOSS, Ralph W., Ph.D.
Director The Moss Reports
Brooklyn, New York 11217

WEED, Douglas L., M.D., Ph.D.
Chief, Preventive Oncology Branch Division of Cancer Prevention
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Rockville, Maryland 20852

WHITE, Jeffrey D., M.D.
Director Office of Cancer Complementary and Alternative Medicine
Office of the Deputy Director of Extramural Sciences
National Cancer Institute, NIH
Bethesda, Maryland 20892

WOOD, Lauren V., M.D.
Senior Clinical Investigator
HIV & AIDS Malignancy Branch
National Cancer Institute, NIH

Bethesda, Maryland 20892

HUFFORD, David J., Ph.D.
Professor Medical Humanities, Behavioral Science, and
Family Medicine
The Pennsylvania State University College of Medicine
Hershey, Pennsylvania 17033

EX OFFICIO

STRAUS, Stephen E., M.D.
Director National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, Maryland 20892

EXECUTIVE SECRETARY

NAHIN, Richard, Ph.D.
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, Maryland 20892

APPENDIX VIII: STRATEGIC PLANNING PROCESS

The NCCAM Strategic Plan builds upon the Strategic Plan originally drafted by OAM. The OAM strategic planning process benefited from significant input from a broad base of stakeholders garnered through a series of meetings. These include the 1993 "Chantilly Meeting," which resulted in a report to the National Institutes of Health (NIH) entitled, *Alternative Medicine, Expanding Medical Horizons*; meetings in 1994 of the Alternative Medicine Program Advisory Council (AMPAC); and several strategic planning workshops in 1995-1996 to outline the challenges for CAM research and how they might be addressed by the OAM. The draft report was reviewed in 1997 and 1998 by a Strategic Planning Advisory Group and the AMPAC. Members of these groups included representatives of both the CAM and conventional scientific communities, both from within and outside NIH. A subsequent draft Report and Plan was distributed to a wide variety of organizations for review. The final revision served as a departure point for this document.

NCCAM's Strategic Plan is also being shaped at each stage of the process by input from the Center's broad range of stakeholders. Evolving drafts have been reviewed by NCCAM staff, members of the National Advisory Council on Complementary and Alternative Medicine, senior officials at NIH, and opinion leaders within the conventional and CAM communities. The public-at-large and the broad research community also have been afforded the opportunity to comment on the penultimate draft, which has been posted on NCCAM's web site.

With completion of this first five-year plan, NCCAM will initiate an ongoing planning process. that will be employed periodically to refine priorities for subsequent five-year periods, to assure that its priorities remain in alignment as the field matures, and that they reflect an appropriate balance between pursuing scientific opportunity and addressing public health needs. Throughout, NCCAM will continue to rely significantly on input from the public and our many other diverse stakeholders.

APPENDIX IX: NATIONAL ADVISORY COUNCIL FOR COMPLEMENTARY & ALTERNATIVE MEDICINE

CHAIR

STRAUS, Stephen E, M.D.
Director National Center for Complementary and Alternative Medicine
National Institutes of Health
9000 Rockville Pike
Building 31, Room 5B37, MSC 2182
Bethesda, Maryland 20892

MEMBERS

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Complementary Medicine Research Institute
California Pacific Medical Center
2300 California Street, Suite 204
San Francisco, California 94115

CHUNG, Mary K. President and CEO
National Asian Women's Health Organization
250 Montgomery Street, Suite 810
San Francisco, California 94104

GRIMM, Richard H., Jr., M.D., Ph.D.
Director Department of Internal Medicine
Berman Center for Outcomes and Clinical Research
Hennepin County Medical Center
Minneapolis Medical Research Foundation
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Minneapolis, Minnesota 55415

HOLLORAN, Susan
Researcher and Writer
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Senior Research Scientist
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Center for Research on Women
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Silver Spring, Maryland 20910

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Naturopathic Family Care, Inc.
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Assistant Professor of Medicine
Harvard Medical School
Beth Israel Deaconess Medical Center
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Boston, Massachusetts 02215

LAWRENCE, Dana J., D.C.
Director Department of Publications and Editorial Review
National College of Chiropractic

MEEKER, William C., D.C., M.P.H.
Director of Research
Palmer Center for Chiropractic Research
Palmer Chiropractic University Foundation
741 Brady Street
Davenport, Iowa 52803

OLNESS, Karen N., M.D.
Professor Department of Pediatrics
School of Medicine
Case Western Reserve University
Rainbow Babies and Children's Hospital
11100 Euclid Avenue
Cleveland, Ohio 44106-6038

PARDES, Herbert, M.D.
Vice President for Health Sciences and
Dean of the Faculty of Medicine
Department of Psychiatry
College of Physicians and Surgeons
Columbia University
630 West 168th Street
New York, New York 10032

RAMIREZ, Gilbert, Ph.D.
Associate Professor and Vice-Chairman for Academic Affairs
7400 Merton Minter Blvd.
San Antonio, Texas 78284

RHOADES, Everett R., M.D.
Associate Dean for Community Affairs
University of Oklahoma School of Medicine
40 Stanton L. Young Boulevard, Room 357
Oklahoma City, Oklahoma 73104

SCHLITZ, Marilyn J., Ph.D.
Director of Research
Department of Research
Institute of Noetic Sciences
475 Gate 5 Road, Suite 300
Sausalito, California 94965

STANDISH, Leanna, N.D., Ph.D. L.Ac.
Research Co-Director
Bastyr University
14500 Juanita Drive NE
Kenmore, Washington 98028

---

[1] The term conventional medicine refers to medicine as practiced by holders of M.D. (medical doctor) or D.O. (doctor of osteopathy) degrees, some of whom may also practice complementary and alternative medicine. Other terms for conventional medicine are allopathy, Western, regular, and mainstream medicine, and biomedicine.

[2] Astin, J.A. Why Patients Use Alternative Medicine - Results of a National Study. JAMA. 1997;279:1548-1553.

[3] Eisenberg, D.M. et. al. Trends in Alternative Medicine Use in the United States, 1990-1997. JAMA. 1997; 280:1569-1575.

[4] These are the categories within which NCCAM has chosen to group the numerous CAM practices; others employ different, broad groupings.

[5] The legislation also established the White House Commission on Complementary & Alternative Medicine Policy to study and report to the President and the Congress on public policy issues related to CAM.

[6] Approximately 82 percent of NIH's investment is made through grants and contracts supporting research and training in more than 2,000 research institutions throughout the U.S. and abroad. These grants and contracts comprise the NIH Extramural Research Program. Approximately 10 percent of the budget goes to NIH's Intramural Research Programs, the more than 2,000 projects conducted mainly in its own laboratories. About 8 percent of the budget is for both intramural and extramural research support.

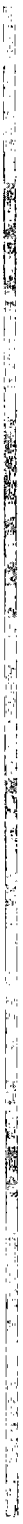
[7] The additional investment in CAM research by other Institutes and Centers brings the total investment in CAM research at NIH in Fiscal Year 2000 to $160.7 million.

[8] To foster NCCAM's collaboration within the Department of Health and Human Services and with other Federal agencies, NCCAM has organized the NACCAM Trans-agency CAM Coordinating Committee (NTACCC), which carries forward the work of the Trans-agency CAM Coordinating Committee established in 1997 by the NIH Director.

[9] As of October 9, 1999.

[10] Office of Medical Applications of Research; National Cancer Institute; National Heart, Lung, and Blood Institute; National Institute on Aging; National Institute of Arthritis and Musculoskeletal Diseases; National Institute of Dental and Craniofacial Disorders; National Institute of Mental Health; National Institute of Neurological Disorders and Stroke; and National Institute of Nursing Research.

[11] National Cancer Institute; National Heart, Lung, and Blood Institute; National Institute of Allergy and Infectious Diseases; National Institute of Arthritis and Musculoskeletal Diseases; National Institute of Dental and Craniofacial Disorders; National Institute on Drug Abuse; and the Office of Research on Women's Health.



July 31, 2000

Rose Marie Martinez, ScD.
Division Director, Board on Health Promotion
and Disease Prevention
Institute of Medicine
2101 Constitution Avenue, N.W.
Washington, D.C. 20418

Dear Dr. Martinez:

I apologize that I have not followed up with you on our conversations in May about a position with the Institute of Medicine. As I mentioned, I was hoping to be tapped for a detail with the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP). If you recall, I was not optimistic at that time.

However, to my great surprise and pleasure, not only was the Commission launched on July 13th, but I have been asked to serve as the Executive Secretary for the Commission. I was ushered into the job at the beginning of July and have been unbelievably busy since my first day.

You may be interested to know that Stephen C. Groft, Pharm.D., Director of the Office of Rare Diseases (NIH), was appointed the new Executive Director of WHCCAMP as of June 27th. He was the first acting director of the Office of Alternative Medicine, now the National Center for Complementary and Alternative Medicine under Dr. Steve Straus, and has considerable support among both the conventional medical and unconventional health provider communities.

You had mentioned possible interest at the Institute of Medicine in complementary and alternative medicine for a study group. If so, please do not hesitate to contact either Dr. Groft or myself to discuss possible collaborative and integrative opportunities with the Commission's work and final report.

Please accept my sincere apologies in not following up with you more quickly to let you know of my status. I remain very interested in pursuing work with the Institute of Medicine in the future and hope that we will keep in touch.

Sincerely,

Michele M. Chang, M.P.H.
Executive Secretary

cc: Dr. Stephen C. Groft
Executive Director

Groft, Steve (NCCAM)

From: Pollen, Geraldine (OD)
Sent: Monday, August 14, 2000 5:53 PM
To: 'jsgordon@mindspring.com'
Cc: Groft, Steve (NCCAM)
Subject: Draft Materials

Jim,

Attached is a copy of a redraft of the first three panels of the Commission's October research meeting based on our discussion during the conference call last week. Questions have been added as a guide to speakers and possibly discussion.

As discussed last week, the first 3 panels were developed for the first meeting (Part 1) with Panels 4 and 5 included as a reference to what's coming next.

Also attached, is a list of names of potential speakers identified during the conference call plus names that were added later.

Please let me have your comments. I would like to send the drafts to the other planning members tomorrow, if possible.

I am also faxing this package to you.

Gerry


agendamatrix.wpd


agendanames.wpd

Groft, Steve (NCCAM)

From: Chang, Michele (OD)
Sent: Monday, August 14, 2000 5:35 PM
To: Effie Chow (E-mail); Marie Hew (E-mail)
Cc: Groft, Steve (NCCAM)
Subject: WHCCAMP

Effie:

As discussed, here are the questions that we will be publicizing to stimulate guided discussion at the Town Hall Meetings. Use at your convenience.

Here are the action items we discussed from Ottowa today:

(1) please contact Mayor Willie Brown and Nancy Pelosi regarding their interest in attending the first Town Hall Meeting of the White House Commission.....Medicine Policy. We will follow up with a formal invitation (signed by Steve, Jim and yourself) as soon as you notify us of their interest. They will be invited to make 3-5 minute welcoming remarks.

(2) We will prepare a "dear colleague" letter that can be sent out under Steve, Jim and your signatures to people on your mailing list.

(2a) Your office will modify this note to be sent out electronically on your listservs.

(2b) We will mail out letters to anyone NOT on your listserv for whom you can provide us a mailing address.

(3) please send us a list of "speakers," members of the community whose comments you particularly want to hear on Sept 8. We need their name and contact info so that we can send them a letter of invitation.

If at all possible, please send us this information by Friday of this week so that we can get announcements out ASAP.

Thanks, Effie, and travel home safely!

questions.doc

Michele M. Chang, MPH
Executive Secretary
White House Commission on Complementary
and Alternative Medicine Policy
(tel) 301-435-6232
(fax)301-480-1691

White House Commission On Complementary
And Alternative Medicine Policy

Proposed Agenda
Research on Complementary and Alternative Medicine
October 5-6, 2000
Planning and Discussion Document

PART ONE

Panels/Sessions	Questions	Topics	Speakers
Opening Session		World View Discussion	*(full Commission/ defining itself/its mission)*
	Preface: When thinking about the questions below, please consider what has already been achieved in CAM research and the opportunities for future research, as well as the obstacles/barriers to achieving these opportunities, and what the solutions to overcoming the obstacles might be. These questions are intended to help guide--not limit--the presentations.		

Panels/Sessions	Questions	Topics	Speakers
Panel I. Federal Support for CAM Research: Achievements, Opportunities, Obstacles, and Solutions	What is needed to expand current Federal efforts to bring CAM products and practices into mainstream medical research; for example, mechanisms of research support, incentives, education and training of investigators? Where are the overlapping areas of investigation between CAM research and conventional medical research (e.g., wellness/health promotion and disease prevention, pain management, treatment)? What additional areas of opportunity exist for research on CAM interventions? What are the obstacles (conceptual and otherwise) and possible solutions to accomplishing the goal of integrating CAM products and practices into mainstream medical research?	**A. NIH:** * NCCAM * ODS *(Dietary Supplements)* * Other NIH Institutes *(maybe 2, one supporting [NCI] and one not supporting CAM research [NIGMS])* * **DISCUSSION** **B. Other Federal Research Agencies:** * (CDC, AHRQ, DoD, VA, HRSA, NSF, EdD *(FDA, HCFA, and NLM to be heard from during panel presentations related to their missions)* * **DISCUSSION** **C. Academic-Based Centers:** * NCCAM Centers * Other Medical Centers *(Duke, UCSF, Columbia, MD, Harvard)* * **DISCUSSION**	Steve Straus Richard Klausner Marvin Cassman Wallace Sampson Alfred Fishman Joseph Pizzorno Bill Meeker

Panels/Sessions	Questions	Topics	Speakers
Panel. II Public Sector Support for CAM Research: Achievements, Opportunities, Obstacles, and Solutions	How can the public/private sector stimulate CAM medical research? What are the obstacles/barriers and possible solutions to accomplishing this goal, e.g., incentives? How can public/private sector CAM research be better coordinated with Federally-supported CAM research?	**A. Overview** Utilization of CAM Interventions and Products by the Public **B. Public Sector Support** * Philanthropic Organizations * Foundations * **DISCUSSION** **C. Private Sector Support** * Pharmaceutical Companies * Manufacturing Companies * Biotechnology Companies * **DISCUSSION**	David Eisenberg PHARMA NIKKEN (Industry Assoc.)

Panels/Sessions	Questions	Topics	Speakers
Panel III. Facilitating CAM Research: Achievements, Opportunities, Obstacles, and Solutions	How are current regulations being applied to CAM? How can research methods and approaches be expanded to address the safety and efficacy of CAM products and practices, and what are the obstacles? What is required to move ahead on basic research in CAM?	**A. Regulatory Approaches to CAM Research** * Center for Drug Evaluation and Research, FDA * Center for Devices and Radiological Health, FDA * Center for Food Safety and Nutrition, FDA * **DISCUSSION** **B. Expanding Research Methods and Approaches** * Practice-Based Research/ State Medical Boards * Outcomes Research * Observational Research * Health Services Research/Demonstration Projects * Basic Research * Clinical Research/Trials * **DISCUSSION** **C. Policy Research** * NAS/IOM *AAMC * **DISCUSSION**	Brian Berman Marilyn Schlitz Bill Haskell

White House Commission on Complementary and Alternative Medicine Policy

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PART TWO

Panels/Sessions	Questions	Topics	Speakers
Panel IV. Dissemination of Research Results: Achievements, Opportunities, Obstacles, and Solutions		* Journal Editors * Science Writers * NLM *Popular Press *World Wide Web * **DISCUSSION**	

Panels/Sessions	Questions	Topics	Speakers
Panel V. Research Results as a Basis for Reimbursement: Achievements, Opportunities, Obstacles, and Solutions		* HCFA *Managed Care Companies *Fee-for-Service Insurance Companies *Specialty Insurance Companies *State Medical Boards * **DISCUSSION**	

Foundations

Robert Wood Johnson
MacArthur Foundation
Howard Hughes Medical Institute
Macy Foundation
Gladys T. McGeary Medical Foundation
Pew Charitable Trust
Ford Foundation
John A. Hartford Foundation

Speakers

Berkley Bedell
Schneider (Duke)
David Eisenberg (Harvard)
Menhet Oz
Marilyn Schlitz (Institute of Noetic Sciences)
Nicholas Gonzalez
_____Berzinsky
Alfred P. Fishman (U of Penn/Integrative CAM Center)
Joseph Pizzorno (Bastyr U)
Brian Berman (MD/NCCAM Res. Center)
Wallace Sampson (Palo Alto, CA)
Bill Meeker (Palmer Chiropractic/Iowa)
Michael Cohen (regulatory issues)
Bonnie O'Connor (Brown U)
M. Brownell Anderson (Assoc. VP AAMC)
Edward Eckendfeld ?
Victor LaCerva (Medical Director, NM Dept. of Health)

Examples

NSF, organization that overcame obstacles
Columbia, turned down $s rather than conduct CAM research

NIH

Cassman, NIGMS
Klausner, NCI,

(Lenfant, NHLBI
Katz, NIAMS)

White House Commission On Complementary
And Alternative Medicine Policy

Proposed Agenda
Research on Complementary and Alternative Medicine
October 5-6, 2000
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PART ONE

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	Preface: When thinking about the questions below, please consider what has already been achieved in CAM research and the opportunities for future research, as well as the obstacles/barriers to achieving these opportunities, and what the solutions to overcoming the obstacles might be. These questions are intended to help guide--not limit--the presentations.		

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Panels/Sessions	Questions	Topics	Speakers
Panel III. Facilitating CAM Research: Achievements, Opportunities, Obstacles, and Solutions	How are current regulations being applied to CAM? How can research methods and approaches be expanded to address the safety and efficacy of CAM products and practices, and what are the obstacles? What is required to move ahead on basic research in CAM?	**A. Regulatory Approaches to CAM Research** * Center for Drug Evaluation and Research, FDA * Center for Devices and Radiological Health, FDA * Center for Food Safety and Nutrition, FDA * **DISCUSSION** **B. Expanding Research Methods and Approaches** * Practice-Based Research/ State Medical Boards * Outcomes Research * Observational Research * Health Services Research/Demonstration Projects * Basic Research * Clinical Research/Trials * **DISCUSSION** **C. Policy Research** * NAS/IOM *AAMC * **DISCUSSION**	Brian Berman Marilyn Schlitz Bill Haskell

White House Commission on Complementary and Alternative Medicine Policy

Proposed Agenda
Research on Complementary and Alternative Medicine

PART TWO

Panels/Sessions	Questions	Topics	Speakers
Panel IV. Dissemination of Research Results: Achievements, Opportunities, Obstacles, and Solutions		* Journal Editors * Science Writers * NLM *Popular Press *World Wide Web * **DISCUSSION**	

Panels/Sessions	Questions	Topics	Speakers
Panel V. Research Results as a Basis for Reimbursement: Achievements, Opportunities, Obstacles, and Solutions		* HCFA *Managed Care Companies *Fee-for-Service Insurance Companies *Specialty Insurance Companies *State Medical Boards * **DISCUSSION**	

Access + Accountability
Mainstream (1) Educational Side — NCCAM / Natl Board Med Examiners / AAMC (Sen Lamer Florida) (50 med schools to RFA for curriculum development)
- NIH Stimul
(- Macy Fndn - Medical Education
{ David Eisenberg in CAM)
{ Hamid Ayemont - Georgetown Physician
non Mainstream - Chiropractor, N thery, Naturopathic Doctor, L Ac Acupuncture
Bill Mates
Scott Haldeman DC, MD, A.
Acupuncture ACCOAM
→ Bob Duggan, Dipl(Ac)
Pam Snyder
Dean Oregon School of Naturopathic Physician
(? former Dean of DO School)
- Dept of Education
(curriculum Development)

(2) Licensing + Certification - Richard Wagner
* Fed of State Med Board
* Nat'l Board of State Legislature
* Dan Fox - Milbank Memorial Mtg - Healthcare Licensing/Mgt
CA, MD, MO, WA, OR

Coverage Reimbursement
- HCFA
- John Weeks - Summit Mtg
David Lawrence - CEO Kaiser Foundation
Ken Pelletier

e. Special Populations / Dick Lyon
- Joe Kaczmarczyk

Information + Quality Assurance — Doug Kennedy / Carolyn Clancy {Copper goals}

Literature Evaluation → Proper Communication — AHRQ
Systematic Review / Meta Analyses — Cochrane Collaboration
U.S. Preventive Task Force
CAM Task Force Report — American [illegible] Public [illegible]

- Communication
  - Public (lay summary)
  - Professional

Wayne — CAP CAM
[illegible] of Judgement
mgt of public Input
com + into process

British Medical Society
B — Clinical Medical Evidence (Best Evidence)
QA Quality Assurance — for Integrative Medicine
— Info about — existing Hospital
licensed individuals

- Types of Information → Goal of Information
  - professional want probability of success
  - Scientists / Physicians — Does it work — mechanism of Action
  - public want stronger [illegible]

* Policy — Proof / Cost / QoL → Move to Research Strategies Discussion

---

Coordination — Public Input
— Coordinates Research
— Social Mgt of Success

Personal Service Contract

400/day

HCFA = Planning

= Review Comments

— " Plans

20%

IAP

SOW

Description

Document all Statements

Tuesday Aug 21

Copy of Planning Documents

White House Commission On Complementary
And Alternative Medicine Policy

Proposed Agenda
Research on Complementary and Alternative Medicine
October 5-6, 2000
Planning and Discussion Document

Panels/Other Items	Questions	Topics	Speakers
Opening Session		World View Discussion *(full Commission/ defining itself/its mission)*	
	Preface: When thinking about these questions, please consider what has already been achieved in CAM research and the opportunities for future research, as well as the obstacles/barriers to achieving these opportunities, and what the solutions to overcoming the obstacles might be. The questions below are intended to help guide--not limit--the presentations.		

8:30 - 5:30

Panel I	How can Federally-supported research most effectively bring CAM products and practices into mainstream medicine? *(traditional support mechanisms, incentives, education and training of investigators)* Where do see areas of investigation overlapping between CAM research and conventional medical research? *(wellness/health promotion and disease prevention, pain management, treatment)* What are the conceptual obstacles to accomplishing the goal of integrating CAM and conventional health care?	**Panel I. Federal Support for CAM Research: Achievements, Opportunities, Obstacles, and Solutions** * NCCAM * Other NIH Institutes *(maybe 2, one supporting [NCI} and one not supporting CAM research [NIGMS])* * Other Federal Research Agencies (CDC, AHRQ, DoD, VA, HRSA, NSF, EdD *(FDA, HCFA, and NLM to be heard from duringpanel presentations related to their missions)* * NCCAM Centers * Other Medical Centers *(Duke, UCSF, Columbia, MD, Harvard)* * **DISCUSSION**	

Panel II	How can the public sector advance the integration of CAM into mainstream health care? What incentives would be necessary to accomplish this goal?	**Panel. II Public Sector Support for CAM Research: Achievements, Opportunities, Obstacles, and Solutions** * Philanthropic Organizations * Foundations * Pharmaceutical Companies * Manufacturing Companies * Biotechnology Companies * Insurance Companies * NAS/IOM * AAMC * **DISCUSSION**

Panel III	How are current research methods and approaches being applied to CAM? How can research methods and approaches be expanded to address the safety and efficacy of CAM products and practices, and what are the obstacles? What is required to move ahead on basic research in CAM?	**Panel III. Facilitating CAM Research: Achievements, Opportunities, Obstacles, and Solutions** * Center for Drug Evaluation and Research, FDA * Center for Devices and Radiological Health, FDA * State Medical Boards * NCCAM Research Centers * Basic Research * Clinical Research/Trials * Outcomes Research * Observational Research * Health Services Research/Demonstration Projects * Practice-Based Research * Qualitative Research * Cultural Healing Practices * **DISCUSSION**	
Lunch		Day 1: Public Relations Update Day 2: Town Hall Meeting Debriefing	

Open Floor		Public Comments: 1 hour each day	
Next Meeting		Announcements/Plans	
Adjournment			

NEXT MEETING ON CAM RESEARCH

Foundations

Robert Wood Johnson
MacArthur
Gates (?)

Speakers

Berkley Bedell (?)
Schneider (Duke)
Dubeny (UCSF)
David Eisenberg (Harvard)
Mehmet Oz (Columbia) → Downstate Med Ctr
Marilyn Schlitz (methods and approaches) – Institute
Gonzalez
Bershinsky

Examples

NSF, organization that overcame obstacles
Columbia, turned down $$ rather than conduct CAM research

NIH

Kassman, NIGMS
Klausner, NCI,

(Lenfant, NHLBI
Katz, NIAMS)

Potential consultant to working group (Michele)

Speaker

Alfred P. Fishman (?)
U of Penn Medical School
Senior Associate Dean, Integrative CAM Center

U Penn
Joe Ruggiano, ND Bastyr
Brian Berman, MD
William Lampson (CA)

WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY

PROPOSED AGENDA FOR OCTOBER 5-6, 2000
Planning and Discussion Document

Opening Session: World View Discussion
(full Commission/defining itself/its mission)

Panel I. Federal Support for CAM Research: Achievements, Opportunities, Obstacles, and Solutions
* NCCAM
* Other NIH Institutes *(maybe 2, one supporting [NCI} and one not supporting CAM research [NIGMS])*
* Other Federal Research Agencies (CDC, AHRQ, DoD, VA, HRSA, NSF, EdD *(FDA, HCFA, and NLM to be heard from duringpanel presentations related to their missions)*
* NCCAM Centers
* Other Medical Centers *(Duke, UCSF, Columbia, MD, Harvard)*
* **DISCUSSION**

Panel. II Public Sector Support for CAM Research: Achievements, Opportunities, Obstacles, and Solutions
* Philanthropic Organizations
* Foundations
* Pharmaceutical Companies
* Manufacturing Companies
* Biotechnology Companies
* Insurance Companies
* NAS/IOM
* AAMC
* **DISCUSSION**

Panel III. Facilitating CAM Research: Achievements, Opportunities, Obstacles, and Solutions
* Center for Drug Evaluation and Research, FDA
* Center for Devices and Radiological Health, FDA
* State Medical Boards
* NCCAM Research Centers
    * Basic Research
    * Clinical Research/Trials
    * Outcomes Research
    * Observational Research
    * Health Services Research/Demonstration Projects
    * Practice-Based Research
    * Qualitative Research

* Cultural Healing Practices
* **DISCUSSION**

Panel IV. Dissemination of Research Results: Achievements, Opportunities, Obstacles, and Solutions
* Journal Editors
* Science Writers
* NLM
* Popular Media
* World Wide Web
* **DISCUSSION**

Panel V. Research Results As a Basis for Reimbursement: Achievements, Opportunities, Obstacles, and Solutions
* HCFA
* Managed Care Companies
*Fee-for-Service Insurance Companies
* Speciality Insurance Companies
* State Medical Boards
* **DISCUSSION**

General Discussion of Issues Raised
(Full Commission)

(two hours of public comment each meeting day)

Statement by Stephen E. Straus, M.D., Director, National Center for Complementary and Alternative Medicine before the Senate Appropriations Subcommittee on Labor - HHS - Education and Related Agencies on the Fiscal Year 2001 President's Budget Request for the NCCAM, Thursday, March 30, 2000

Mr. Chairman and Members of the Committee:

I am pleased to present the President's non-AIDS budget request for the National Center for Complementary and Alternative Medicine for FY 2001, a sum of $71,362,000, which reflects an increase of $3,381,000 over the comparable Fiscal Year 2000 appropriation. Including the estimated allocation for AIDS, total support requested for the National Center for Complementary and Alternative Medicine is $72,392,000, an increase of $3,381,000 over the Fiscal Year 2000 appropriation. Funds for the National Center for Complementary and Alternative Medicine efforts in AIDS research are included within the Office of AIDS Research budget request.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's first performance report that compares our FY 1999 results to the goals in our FY 1999 performance plan. As our performance measures mature and performance trends emerge, the GPRA data will serve as indicators to support the identification of strategies and objectives to continuously improve programs across the NIH and the Department.

At the outset, I should note that NCCAM's work reflects the growing public interest in complementary and alternative medicine (CAM) and the belief that various CAM therapies may play a role in improved public health. Approximately 42 percent of U.S. healthcare consumers spent $27 billion on CAM therapies in 1997. CAM enjoys particular popularity among baby boomers. A number of practices, once considered unorthodox, have proven safe and effective and assimilated seamlessly into current medical practice. Diet and exercise are today commonly used to prevent and control disease. Acupuncture is routinely applied to manage chronic pain and nausea associated with chemotherapy. Some of our most important drugs – digitalis, vincristine, and taxol – are of botanical origin.

Additional CAM practices have the potential to prevent and treat chronic disease, to improve understanding of how healing works and to be integrated into the routine practice of medicine. Absent definitive evidence of effectiveness, however, alternative practices may impart untoward consequences for large numbers of people.

As the NCCAM's first permanent director, I am excited by the challenge afforded me to help provide the American public the guidance it deserves. As CAM use by the American people has steadily increased, many have asked whether reports of success with these treatments are valid. It is critical that untested but widely used CAM treatments be rigorously evaluated for safety and efficacy. It is similarly important to identify promising new approaches worthy of more intensive study. The promising areas for future investments are numerous.

In order to best seize these opportunities, the NCCAM's strategy must differ from that used by other NIH Institutes and Centers. Others' projects are usually driven by basic science discoveries. In contrast, the NCCAM must focus first on definitive clinical trials of widely utilized modalities that, from evidence-based reviews, appear to be the most promising. Credible, not anecdotal, data must be provided to the public, and we must educate conventional medical practitioners about the panoply of effective CAM practices, so they can be integrated into patient

care. In recognition of these needs, Congress responded in 1998 by elevating the NIH Office of Alternative Medicine (OAM), expanding its mandate, creating the NCCAM, and affording it administrative authority to design and manage its own research portfolio. The Congress continued to reflect the growing interest in CAM by further increasing funding for the Center in FY 2000 to $68.4 million. We are indeed appreciative of this support. The Congress vested the NCCAM with a broad statutory mandate to conduct and support CAM research, support research training, and disseminate information on validated CAM therapies. Accordingly, the NCCAM is currently developing a strategic plan to ensure that our continued growth, development and research directions are consistent with these responsibilities. Five strategic areas have been identified: Investing in research; training CAM investigators; expanding outreach; facilitating integration; and practicing responsible stewardship.

In seeking to fulfill its mandate, the NCCAM has undertaken a number of initiatives, established critical contacts with CAM practitioners, and begun to fashion the scientific underpinning that will enable future research discoveries.

Before describing these activities, I want to share with the Subcommittee my vision of where I expect complementary and alternative medicine to be in the years to come. As a result of rigorous scientific investigation, several therapeutic and preventative modalities currently deemed elements of CAM will prove effective. Therefore, in future years, these interventions will be integrated into conventional medical education and practice, and the term "complementary and alternative medicine" will be superseded by the concept of "integrative medicine." The field of integrative medicine will be seen as providing novel insights and tools for human health, and not as a source of tension that insinuates itself between and among practitioners of the healing arts and their patients. Advances in neurobiology will reveal more about ancient practices such as acupuncture and meditation, as well as the phenomenon of "the placebo effect" as we tap the healing power of the mind. The medical basis for effectiveness of selected herbal and nutritional supplements will be clarified, leading to their standardization and routine use. Other modalities will be found unsafe or ineffective, and an informed public will reject them.

My vision is an optimistic one. However, I am confident that, as it is realized, the NCCAM will have not simply expanded in those ways required to meet its research mission. Rather, owing to a tradition of superb science and consumer service, the NCCAM will become the leader – and recognized as such – within a vibrant, and global, CAM research community.

Already, I have begun to recruit key experts to join me in developing our programs in intramural research, clinical research, international and traditional health studies, and traditional medicine and indigenous systems. We will continue to grow our intellectual capital and research capacity. Setting these cornerstones in place will enable us, together with our partners in CAM research, to provide definitive answers regarding CAM treatments.

CURRENT RESEARCH STUDIES

In its first year, NCCAM has developed a diverse research portfolio in partnership with the other NIH Institutes and Centers. I am pleased to highlight for you our support of some of the largest, and certainly the most definitive Phase III clinical trials ever undertaken for a range of CAM therapies.

For centuries, extracts from the leaves of the *Ginkgo biloba* tree have been used as Chinese herbal medicine to treat a variety of medical conditions, including age-related decline in memory. A new NCCAM study, in collaboration with the National Institute on Aging (NIA), may help resolve these questions. This study includes four clinical centers and will enroll almost 3,000 participants who will receive either *Ginkgo biloba* or a placebo.

Arthritis is a major public health problem for older Americans. Accordingly, in collaboration with NIAMS, NCCAM has mounted two critical clinical trials for the treatment of osteoarthritis. One is the first U.S. multi-center study to investigate the dietary supplements glucosamine and chondroitin sulfate – two natural substances, found in and around joint cartilage. The other study is an evaluation of acupuncture for the treatment of pain associated with osteoarthritis.

I am pleased to report that our study of St. John's wort for depression is nearing completion. This study, sponsored by the NCCAM, NIMH, and the NIH Office of Dietary Supplements (ODS),

represents the largest and most rigorous assessment of the effectiveness and safety of St. John's wort. Investigations of St. John's wort illustrate the complex challenges afforded by some CAM modalities. A recent study reported in *The British Medical Journal* showed that St. John's wort is more effective than placebo in treatment of depression, and perhaps as effective as an older generation anti-depressant drug Imipramine. NCCAM's study, which is considerably larger than the European trial, compares St. John's wort with placebo and with Zoloft, currently one of the most commonly used anti-depressants. However, the therapeutic promise of St. John's wort and of botanical products like it, is accompanied by risks that the public has largely ignored. An NIH study published February 12th in the *Lancet* found that St. John's wort, when taken together with the important HIV protease-inhibiting drug, Indinavir, increased the rate at which Indinavir was eliminated from the bloodstream, to the extent that blood levels fell below the acceptable level for effective AIDS treatment.

NCCAM continues support for four Specialized Research Centers (cardiovascular disease, substance abuse, pediatrics and chiropractic) funded originally by the Office of Alternative Medicine. By the end of FY 1999, NCCAM made five additional Specialty Research Center awards. The nine Center grants total approximately $63 million. Each focuses on one of several areas, including pediatrics, addiction, cardiovascular disease (CVD), minority aging and CVD, aging, neurological disorders, craniofacial health, arthritis, and chiropractic medicine. In addition to these nine Centers, NCCAM and ODS jointly established two Dietary Supplements Research Centers to advance the science of botanicals, including issues of their composition, safety, and biological action. Another request for Center grant applications focusing on asthma and cancer recently was released for FY 2000. This, coupled with our anticipated solicitation of one more botanical center in FY 2000, will likely bring our total number of NCCAM-supported centers to as many as 15.

Benign prostatic hyperplasia (BPH), or non-cancerous enlargement of the prostate, is the most common benign tumor found in men. Anecdotal reports suggested that the botanical product saw palmetto decreases prostate swelling. To determine the validity of these observations, NCCAM, in collaboration with National Institute on Diabetes and Digestive and Kidney Diseases (NIDDK), is supporting the first rigorously designed, placebo-controlled study to evaluate the effect of saw palmetto extract on symptoms and quality of life in men.

FUTURE SCIENTIFIC PLANS AND PROJECTS

Because of the dearth of credible scientific evidence on CAM practices, there is unprecedented opportunity for determining the efficacy and safety of CAM modalities. We have developed the following initiatives to address them:

NCCAM has planned a collaboration on the treatment of liver disease with the NIDDK and the National Institute of Allergy and Infectious Diseases (NIAID). The project will examine the efficacy of milk thistle extract – *Silybum marianum* – when used to treat Hepatitis C and other hepatic diseases.

NCCAM has already begun a number of activities that will serve to facilitate the integration of validated CAM therapies into conventional medical practice. The NCCAM plans to make awards to foster incorporation of CAM information into the curricula of medical and allied health schools and continuing medical education programs. Also, the NCCAM must educate eager medical students about CAM so that they may knowledgeably guide an avid patient base toward safe and effective CAM applications. We must also work to overcome the reluctance of conventional physicians to consider validated CAM therapies and to assimilate proven ones into their practice. The Center has established a Clinical Research Curriculum Award (CRCA) to attract talented individuals to CAM research and to provide them with the critical skills that are needed.

A majority of the CAM modalities practiced in this country have arisen from the traditional healing practices of other nations. Some of the practices have "evolved" or been adapted to work within the context of our society, and often in parallel with conventional medical practices. Moreover, most of these practices are not well documented within the context of their native cultures or understood within the context of our own. Unraveling these issues will provide some important insights into how these CAM modalities are practiced and impact upon the health of U.S. minority populations – new immigrants like Hmong (from southeast Asia) and established groups like the Navajo. Likewise, the development of culturally sensitive studies will enable NCCAM to

establish methodological feasibility and strengthen the scientific rationale for proceeding to full-scale, randomized, clinical trials on the application of traditional, indigenous systems. The ability to validate some of these therapies will also expand healthcare options for those who are primarily consumers of convention medicine. The international character of CAM necessitates that the NCCAM develop a broad-based international research program that reaches out to CAM practitioners across the world. Therefore, in collaboration with several other ICs, NCCAM is committed to support locally-based, traditional, indigenous research projects in countries where the opportunities for promising CAM research are greatest. That process will ensue with the forthcoming appointment of a Director for International and Traditional Medicine Studies, who will develop a long-range plan for the pursuit of studies on a global scale. Foreshadowing this appointment, I have already authorized NCCAM support, in collaboration with the NICHD, for international studies of traditional medical approaches to the health of women and children.

The NCCAM will establish an Intramural Research Program that will develop a critical mass of CAM research to stimulate collaboration in the NIH Clinical Center with other Institutes and Centers, our Federal research partners, and others. The intramural program will serve as a focus for training future CAM researchers. Last month I formed a search committee to identify the Director of this program.

INFORMATION DISSEMINATION

Specific statutory authority enables the NCCAM to disseminate information regarding the safety and effectiveness of CAM therapies to healthcare providers and the public. A focal point for information about NCCAM programs and research findings, the NCCAM Information Clearinghouse develops and disseminates fact sheets, information packages, and publications to enhance public understanding about CAM research supported by the NIH. Its quarterly newsletter, *Complementary & Alternative Medicine at the NIH* is distributed to 6,000 subscribers. The NCCAM's award winning World Wide Web site, first established two years ago, reflects the NCCAM's growth in size and stature. Averaging more than 460,000 hits per month, the site includes links to NCCAM program areas, news and events, research grants, funding opportunities, and resources. Assembled by NCCAM from the National Library of Medicine's (NLM) MEDLINE database, the CAM Citation Index (CCI) affords the public access to approximately 175,000 bibliographic citations searchable by CAM system, disease, or method. Also, in February 1999, NCCAM joined the federally supported Combined Health Information Database (CHID), which includes a variety of health information materials not available in other government databases, including nearly 1,000 CAM citations not available elsewhere.

To facilitate our outreach to the general public, I have initiated a series of town meetings; the first was held on March 15 in Boston, in conjunction with the Center for Alternative Medicine and Education of Beth Israel Deaconess Medical Center. Over 500 attendees heard presentations on the importance of CAM research. Many substantive issues were raised in the public forum portion of the program. The opportunity for dialog at the local level is important for us, not only for disseminating key research findings, but also for the public to provide perspective and help us shape our overall research strategy.

I am now happy to take your questions about these or any other of NCCAM's activities and plans.

NCCAM Home / News and Events Site Menu...

Please send questions and comments to nccam-info@nccam.nih.gov.
Last Updated: March 30, 2000

Harvard Medical School
Department of Continuing Education

Stanford Center for Research in Disease Prevention
Stanford University School of Medicine

Center for Alternative Medicine Research and Education
Department of Medicine
Beth Israel Deaconess Medical Center

Second Annual Conference

Complementary and Alternative Medicine: Practical Applications and Evaluations

Hyatt Regency Kauai
Resort and Spa
Island of Kauai
Koloa, Hawaii

October 28-31, 2000

Photo courtesy of Hyatt Regency Kauai Resort and Spa

Under the Direction of:

David M. Eisenberg, MD Kenneth R. Pelletier, PhD William L. Haskell, PhD

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Koloa, Hawaii

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Shabert, MD, MPH, RD
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Obstetrics, Gynecology,
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Michael J. Smith, MR, PharmS., ND
Associate Dean of Research
Canadian College of Naturopathic Medicine
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Cora M. Tellez
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John Weeks
Publisher/Editor
THE INTEGRATOR for the Business of Alternative Medicine

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Director of the Program in Integrative Medicine
Clinical Professor of Internal Medicine
Clinical Assistant Professor of Family and Community Medicine
University of Arizona

Douglas W. Wilmore, MD
Senior Staff Surgeon
Brigham and Women's Hospital
Frank Sawyer Professor of Surgery
Harvard Medical School

James R. Winn, MD
Executive Vice President
Federation of State Medical Boards, Inc. of the United States

Saturday, October 28, 2000

7:00 am	*Registration and Continental Breakfast*
7:30 am - 7:35 am	Introduction and Welcome **David M. Eisenberg, MD** **Kenneth R. Pelletier, PhD** **William L. Haskell, PhD**
7:35 am - 8:30 am	Opening Ceremony **Hawaiian Consortium**
8:30 am - 9:15 am	CAM Utilization and Overview **David M. Eisenberg, MD**
9:45 am - 10:30 am	Emerging Models of Medicine **Regina Herzlinger, DBA**
10:30 am - 11:15 am	CAM Coverage Overview **Kenneth R. Pelletier, PhD**
11:15 am - 12:00 pm	Panel Discussion
12:15 pm - 1:30 pm	Network Services Workshop **Kenneth R. Pelletier, PhD** Moderator American Specialty Health Plans **George T. DeVries** Kaiser Foundation Health Plans, Inc **Carol Chieko Taketa, RN, BSN** Blue Cross and Blue Shield of South Carolina **Derrick Anton Gallion, BA** Hawaii Medical Service Association **Alfred J. Fortin, PhD** Triad Healthcare, Inc. **Louis Sportelli, DC**

Sunday, October 29, 2000

7:00 am	*Continental Breakfast*
7:30 am - 8:15 am	CAM Research Overview **William L. Haskell, PhD**
8:15 am - 9:00 am	Training Future CAM Providers **Andrew T. Weil, MD**
9:30 am - 10:15 am	Survey of Provider Practices **Daniel C. Cherkin, PhD**
10:15 am - 11:00 am	Panel Discussion
11:15 am - 1:00 pm	Clinical Programs Workshop **David M. Eisenberg, MD** Moderator Saint Barnabas Health System **Adam I. Perlman, MD, MPH** CHW O'Connor Hospital **Sylver Quevedo, MD, MPH** North Hawaii Community Hospital **John McNeil** The Marino Center for Progressive Health **Donald B. Levy, MD** Stanford Hospital Complementary Medicine Clinic **RoseAnn Kushner, RN, BSN, M.Ed** Beth Israel New York **Woodson C. Merrell, MD**

*These sessions are appropriate for one hour each of Continuing Education Risk Management Category 11 credits in accordance with regulations of Risk Management study by the board of Registration in Medicine for physicians licensed in Massachusetts.

Monday, October 30, 2000

7:30 am	*Continental Breakfast*
8:00 am - 8:45 am	Evidence-based Medicine Resources **Brian M. Berman, MD**
8:45 am - 9:30 am	Medical Regulation of CAM* **James R. Winn, MD**
10:00 am - 10:45 am	Medical Liability and CAM* **Michael H. Cohen, JD, MBA, MFA**
10:45 am - 11:30 am	Panel Discussion
11:45 am - 1:15 pm	Fiscal and Risk Management Workshop* **David M. Eisenberg, MD** Moderator Reimbursement **John Weeks** Billing **Linda L. Bedell-Logan** Credentialing **Michael H. Cohen, JD, MBA, MFA**
5:30 pm - 7:00 pm	Corporate Health Programs Workshop **Kenneth R. Pelletier, PhD** Moderator American Airlines **David K. McKenas, MD, MPH** Lucent Technologies **Pamela A. Krol** Wellpoint/Blue Cross of California **Maria J. Avila** Health Net **Cora M. Tellez** Ford Motor Company **Walter J. Talamonti, MD, MPH** PacifiCare Health Plans **Brad Bowlus**

Tuesday, October 31, 2000

7:30 am	*Continental Breakfast*
8:00 am - 8:45 am	Incorporating Chiropractic Into Models of Integrative Care **William C. Meeker, DC, MPH**
8:45 am - 9:30 am	Primary Care and CAM **Joseph M. Kaczmarczyk, DO, MPH**
10:00 am - 10:45 am	National Center for Complementary and Alternative Medicine **Richard Nahin, MPH, PhD**
10:45 am - 11:30 am	Panel Discussion
11:45 am - 1:15 pm	Dietary Supplements and Herbs: Trends East and West Workshop* **Douglas W. Wilmore, MD** Moderator Nutrition **Judith Kay Shabert, MD, MPH, RD** Traditional Chinese Medicines **Paul Pui-Hay But, PhD, MBA** Medical Use of Herbal Products **Michael Smith, MR, PharmS., ND** Liability and Regulation **Michael Cohen, JD, MBA, MFA**

GENERAL INFORMATION

Accreditation
This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) by Harvard Medical School and Stanford University School of Medicine. Harvard Medical School and Stanford University School of Medicine are accredited by the ACCME to provide continuing medical education to physicians.

Harvard Medical School designates this educational activity for a maximum of 19 hours in Category 1 credit towards the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

Continuing Education Credit
Nurses
This activity is pending approval by the Hawaii Nurses Continuing Education Committee, appointed by the Hawaii Nurses Association Board of Directors as approvers of continuing education in nursing.

Healthcare Executives
Individuals wishing to have this program considered for ACHE Category II credit should list their attendance when applying for advancement and recertification in the American College of Healthcare Executives.

Risk Management
Please see schedule.

Registration Information
Registrations postmarked *on* or *before* September 6, 2000
Tuition Fee: $695 (U.S.)
Reduced Fee for Residents/Fellows in Training: $595 (U.S.)
(with letter of verification from Department Chairman)
Payment must accompany registration form and must be postmarked on or before September 6, 2000.

Registrations postmarked *after* September 6, 2000
Tuition Fee: $795 (U.S.)
Reduced Fee for Residents/Fellows in Training: $695 (U.S.)
(with letter of verification from Department Chairman)

Register Early. Space is limited.
All foreign payments must be made by a draft on a United States bank. If paying by check, make it payable to *Harvard Medical School* and mail with the registration form to:
Harvard MED-CME
P.O. Box 825
Boston, MA 02117-0825

If paying by credit card, fax the completed registration form to 617-432-1562 or mail to above address. Inquiries should be directed to the above address, made by phone: 617-432-1525, Monday - Friday, 10 am to 4 pm (Eastern Time), or by e-mail: hms-cme@hms.harvard.edu

Refund Policy
A handling fee of $50 is deducted for cancellation. Refund requests must be received by mail one week prior to the course. No refunds will be made thereafter.

Accommodations and Travel
Hotel rooms in Hawaii are limited. You are urged to make your reservations early.
A limited number of rooms have been reserved at: **Hyatt Regency Kauai Resort and Spa**, (Telephone: 808-742-1234) until **September 27, 2000**. Please specify that you are enrolled in this course to receive a reduced room rate.

For information on reduced airfare, call Harvard MED-CME at 617-432-1525, Monday - Friday, 10 am to 4 pm (Eastern Time).

Online Information
To view course information online, visit our home page at: http://www.med.harvard.edu/conted/

UPCOMING EVENTS

Joint Harvard/UCSF Program
Herbal Therapies and Other Dietary Supplements
November 9-11, 2000
San Francisco, California
For more information call 415-476-5208

Complementary and Alternative Medicine: Implications for Clinical Practice
February 11-14, 2001
Boston, Massachusetts
For more information call 617-432-1525

Joint Harvard/UCSF Program
Scientific Symposium on Integrative Medicine
May 17-19, 2001
San Francisco, California
For more information call 617-632-7770

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Course # 201594

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Please check one:

❑ Check is enclosed ❑ Bill my credit card ❑ VISA ❑

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COURSE DESCRIPTION

Complementary and alternative therapies (CAM) encompass a broad range of clinical practices. Increasingly, there is evidence that practitioners, hospitals, managed care organizations, health insurers, and large, self-insured corporations are implementing CAM services and coverage.

Given these trends, there is a pressing need for professional education regarding the practical implementation and evaluation of CAM services for both clinical and cost effectiveness. Additionally, it is essential to identify practical models of CAM delivery in clinics, hospitals, MCOs, and corporate medical benefits that have evidence of effective delivery.

WHO SHOULD ATTEND:

- **Executives and Administrators at**
  - Hospitals
  - Insurance Companies
  - Health Systems
  - PPOs
- **Medical Directors**
- **Corporate Medical Directors**
- **Benefits Officers**
- **Actuaries**
- **Attorneys**
- **Managed Care Providers**
- **Group Practice Representatives**
- **Human Resource Administrators**
- **Physicians**
- **Psychologists**
- **Nurses**
- **Alternative Medicine Providers**

THIS COURSE WILL PROVIDE YOU WITH:

- A comprehensive understanding of the variety of models of implementing CAM therapies
- State-of-the-art update on policies and future directions in CAM coverage by managed care insurers and large corporations
- Understanding of the legal, ethical, and financial aspects of CAM practice, including reimbursement, licensure, and malpractice liability
- Strategies for implementing and evaluating CAM therapies for both clinical and cost effectiveness
- Insights from prototype clinics and managed care plans offering CAM, to be used to refine and further develop responsible and financially viable CAM delivery

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WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY - ACTIVITIES

1. Commission Meetings (7-8)

2. One Major Issue Each Meeting
   Meeting #1 October 5-6 Research Activities, Needs, and Incentives and Discussion of Reimbursement, Regulatory Review of CAM Research, communication of Research Results

3. Public Hearings/Town Hall Meetings (4)
   Seattle and San Francisco September 7-9

4. Website Development/Public Comments

5. Budget Meetings with NCCAM

6. Staff Dr. Joe Kaczmarczyk, Dr. Ken Fisher (Part Time)

7. Naturopathic Doctors

WHCCAMP
October 5-6, 2000 (1)

Session

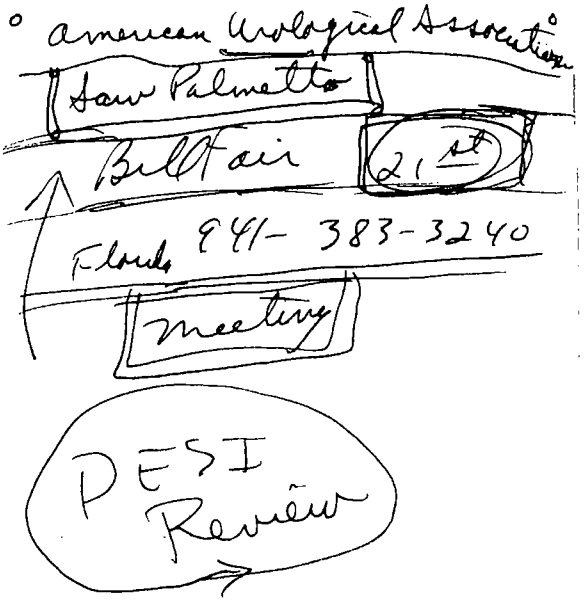
I Research Activity – Updates and Needs / Incentives
- NCCAM / NCI — Steve Straus, Jeff White
- NCCAM Supported Centers – Berman, – Experience in Munsterm
- CDC Field Studies — Bill Meeker, Barrie Cassileth (M.) Memorial Sloan Kettering
- DOD, VA, DARPA, NSF (Energy)
- Pharmaceutical (Activity) Industry — Osher Clinic, UCSF
- Foundations – Philanthropic Groups — Osher Fndn (Govt Private Co funding) — Dr. Fitzgerald

II Regulatory Review of CAM Research – Foreign Experience
- Research oversight – FDA – Janet Woodcock (Bob Temple)
- Outcomes Research < AHRQ Cochrane Collaboration — Devices
- Monitoring of Adverse Events — Dr. Lori Love — Nutritional Supplements
- Standardization of Botanical Products — Joel Levitt

USP

III Reimbursement
- HCFA Requirements for Reimbursement
- Results of Research as a Basis for Reimbursement
- HMO / MCO

IV Communication of Research Results
- Journals
  - NEJM
  - JAMA
  - JACM – Jackie Wootton
  Alternative Therapies in Health & Medicine – Larry Dossey
- Websites
  - WebMD, etc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