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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. curriculum vitae	Marvin Cassman (partial) (1 page)	nd	b(6)

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

OA/Box Number: 43238

FOLDER TITLE:
WHCCAM Testimony, October 5-6, 2000 [1]

2011-0568-S
kc881

RESTRICTION CODES

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

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Divider Title: Rosenberg

Leon E. Rosenberg, M.D. is a Professor at Princeton University in the Department of Molecular Biology and the Woodrow Wilson School of Public and International Affairs. He also is President and Chief Executive Officer of Funding First, a medical research advocacy initiative of the Mary Lasker Charitable Trust. He formerly served Bristol-Myers Squibb Company as President of the Pharmaceutical Research Institute from 1991 to 1997 and as Senior Vice President to Scientific Affairs until February 1998.

Prior to joining Bristol-Myers Squibb, Dr. Rosenberg was the dean of the Yale University School of Medicine, a position he had held since 1984. During his twenty-six year affiliation with Yale, he worked as a research geneticist, teacher, clinician, and administrator. In 1965, he was appointed assistant professor of Medicine at Yale. He was named professor of Human Genetics, Pediatrics, and Medicine in 1972, the same year he helped establish the Department of Human Genetics at Yale and became its first chairman. A specialist in inherited metabolic disorders in children, Dr. Rosenberg and his colleagues conducted pioneering laboratory investigations into the molecular basis of several inherited disorders of amino acid and organic acid metabolism. For example, they discovered that children with a potentially lethal disorder of organic acid metabolism suffer from defective metabolism of vitamin B12. They then went on to demonstrate that supplements of B12 were remarkably beneficial clinically. Using another rare disorder as a model system, he and his associates provided crucial insights into the basic mechanism by which proteins synthesized in the cytoplasm are transported into mitochondria.

Born in Madison, Wisconsin in 1933, Dr. Rosenberg received his B.A. and M.D. degrees, both *summa cum laude*, from the University of Wisconsin in 1954 and 1957, respectively. He completed his internship and one year of residency training in internal medicine at Columbia-Presbyterian Medical Center in New York City. In 1959 he moved to Bethesda, Maryland, to begin a six-year association as an investigator with the metabolism service of the National Cancer Institute.

Dr. Rosenberg was elected a member of the National Academy of Sciences in 1985 and of the Institute of Medicine (IOM) in 1982. He received the Borden Award from the American Academy of Pediatrics for outstanding achievement in research relating to infant nutrition in 1973. Active in professional societies, he is a fellow of the American Academy of Arts and Sciences and the American Association for the Advancement of Science. He is a past president of the American Society of Human Genetics and of the Association of American Physicians.

The University of Wisconsin Medical School presented Dr. Rosenberg its Distinguished Alumni Citation in 1982; seven years later the University of Wisconsin awarded him an honorary Doctor of Science degree. He was awarded an Honorary Doctor of Science degree from Mt. Sinai School of Medicine in 1992.

Dr. Rosenberg currently serves on the Boards of Directors of the Lovelace Respiratory Research Institute, Research!America, the Association for Patient-Oriented Research, Kara Bio AB, Pharmaceutix, Ltd., Medicines for Malaria Venture, and Cellular Genomics, Inc. He is married, has four children, and lives in Lawrenceville, New Jersey.

IOM

Scientific Opportunities and Public Needs : Improving Priority Setting and Public Input at NIH

Committee on the NIH
Research Priority-Setting Process

Institute of Medicine

U.S. Preeminence in Medical Research

- The United States has fashioned a medical research system—with government, academia, and industry at its core—that is a source of great national pride and the envy of the world. The federal government is the single largest sponsor of this research, committing more than $16 billion of public funds in fiscal year 1998. Of this total, the vast majority—$13.6 billion—is appropriated to the National Institutes of Health (NIH). Given the size of this public investment and the likelihood that it will be increased significantly in the immediate future and given the mission of NIH—"to uncover new knowledge that will lead to better health for everyone"—there is intense interest in NIH.
- How could it be otherwise? Every one of us wants to live a long and healthy life. Every sick person—woman, man, or child—wants researchers to find new ways to make him or her well or to improve the quality of life for those who are disabled, regardless of whether the ailment is common or rare, acute or chronic, life-threatening or self-limiting.

NIH: A Successful Federal Agency

- NIH is the leading federal agency supporting research related to improving the nation's health. The quality and quantity of excellent science it has supported, and the outstanding basic and clinical researchers it has helped train and support have advanced both fundamental knowledge of human biology and better ways to treat or prevent disease and promote good health.
- The NIH budget, however large, will never be large enough to meet every need or fund every promising lead. Choices must be made and priorities must be set.

NIH's Objectives

To fulfill the agency's mission, NIH's leaders must pursue many objectives. Three of the most important are:

(1) to identify the public's health needs, reducing the burdens of disability and disease by developing better methods of prevention, diagnosis, treatment, and rehabilitation

(2) to extend the basic knowledge base to lead to even better methods in the future

(3) to communicate to the public and health providers the current state of scientific knowledge and the implications of research advances for improving the nation's health

NIH Constituencies

NIH interacts with various external constituencies who have a stake in research priority setting. These include:

- research scientists
- clinicians who apply research results and who can help identify research needs
- organized voluntary groups and individuals active in advocating for those with specific diseases or medical conditions
- organizations and individuals who represent population groups with special health problems
- Congress
- the media

NIH's Approach to Priority Setting

- Setting priorities is an awesome task. Not only must the leadership of NIH answer to the executive branch and the U.S. Congress, it must work with all of its constituencies before making its fateful decisions.
- In setting priorities, NIH must adapt to a changing policy environment in which: scientific opportunities have grown more rapidly than the budget; health problems have changed as the population's demographics have shifted; and globalization has exposed the U.S. population to new problems such as emerging or reemerging infectious diseases.

Sources of Concern about Priority Setting at NIH

- Some members of Congress believe that there should be more of a correlation between the allocation of research funds and the magnitude of disease burdens and costs in the population.
- An increasing number of disease-specific interest groups have campaigned for increases in NIH funding related to particular diseases. Some of these groups do not feel that NIH listens or responds to their inputs.
- The leadership of the health committees in Congress has become increasingly uncomfortable with intervening in research priority setting at NIH by mandating specific funding set-asides, new programs, or institutional structures.

Committee Charge

The IOM will review the research priority-setting process of the National Institutes of Health and make recommendations for possible improvement. The study will consider:

- the factors and criteria used to make funding allocations
- the process by which the funding decisions are made
- the mechanisms for public input
- the impact of congressional statutory directives.

The committee's report "shall set forth the findings, conclusions, and recommendations for improvements in the National Institutes of Health research funding policies and processes and for any necessary congressional action."

Data Sources

- Panel discussions with Institute and Office Directors and the NIH Director
- Panel discussions with interest groups at a "town meeting"
- Written comments from organizations and individuals
- Survey of NIH constituents (researchers, clinicians, advocates)
- Interviews with Congressional Staff
- Published reports and other information provided by NIH

NIH's Criteria for Setting Research Priorities

- public health needs
- scientific quality of the research
- potential for scientific progress (the existence of promising pathways and qualified investigators)
- portfolio diversification along the broad and expanding frontiers of research
- adequate support of infrastructure (human capital, equipment and instrumentation, and facilities)

NIH's Criteria
Conclusions

NIH's criteria were explicitly laid out in *Setting Research Priorities*, and the committee concluded that they are generally reasonable and useful both for allocating research resources and for enabling organized interest groups, members of Congress, and members of the public to understand and evaluate NIH's program.

NIH's Criteria *Recommendations*

Recommendation 1. The committee generally supports the criteria that NIH uses for priority setting and recommends that NIH continue to use these criteria in a balanced way to cover the full spectrum of research related to human health.

NIH's Criteria
Recommendations

Recommendation 2. NIH should make clear its mechanisms for implementing its criteria for setting priorities and should evaluate their use and effectiveness.

NIH's Criteria
Recommendations

Recommendation 3. In setting priorities, NIH should strengthen its analysis and use of health data, such as burdens and costs of diseases, and of data on the impact of research on the health of the public.

- It should be kept in mind that there is no simple metric for the use of these data.
- The relationship between such data and allocations of research funding will not be straightforward because health problems are not equally ripe for research advances.

NIH's Criteria
Recommendations

Recommendation 4. NIH should improve the quality and analysis of its data on funding by disease and should include both direct and related expenditures.

- Users of the data should know that such calculations reflect the best estimates of all NIH spending in particular areas and that fundamental science is essential to understanding the etiology and progression of disease.
- NIH should also collect and analyze data on health research spending by others, such as other federal agencies, industry, nonprofit health organizations that fund research, foundations, or other countries. This should help identify gaps, overlaps, and opportunities for joint effort.

NIH's Processes for Setting Research Priorities

Priority setting is decentralized at NIH, which is appropriate for a research organization in which those closest to a problem are in the best position to decide on approaches and in which expertise is highly specialized.

- The priority-setting processes vary from institute to institute and from area to area within institutes. Some such variation is appropriate.
- NIH is looking across traditionally independent institutes and centers and focusing on certain crosscutting needs and opportunities where joint or unified action is desirable.
- This trend stems from the growing realization that common biological processes underlie diseases that were previously seen as different.

NIH's Processes
Conclusions

The Office of the Director of NIH requires an increased capacity to analyze crosscutting needs and opportunities. NIH's processes require a more central role for the NIH director and more uniformity in the data and analyses presented to the Office of the Director.

NIH's Processes
Recommendations

Recommendation 5. In exercising the overall authority to oversee and coordinate the priority-setting process, the NIH director should receive from the directors of all of the institutes and centers multiyear strategic plans, including budget scenarios, in a standard format on an annual basis.

NIH's Processes
Recommendations

Recommendation 6. The director of NIH should increase the involvement of the Advisory Committee to the Director in the priority-setting process. The diversity of the committee's membership should be increased, particularly with respect to its public members.

- As the authority of the director is strengthened, greater accountability of the director's office could be achieved through a strengthened Advisory Committee to the Director, one that is more actively engaged in the NIH priority-setting process and that has a broader base of membership, especially among its public members.

NIH's Mechanisms for Public Input

- Patient advocacy groups have become better organized and more proactive on behalf of their interests and have greatly increased their appeals to Congress to intervene to adjust NIH research priorities.
- Congressional leaders have expressed a strong desire to avoid mandates and earmarks in favor of particular diseases and to let NIH set research priorities.
- The NIH director has increased his role in priority setting (partly by exercising additional authorities granted to him by Congress).

This confluence of events highlights the need for improved communication between the public and NIH.

Public Input
Conclusions

The committee found that NIH's interaction with various kinds of publics is generally weak compared with NIH's interaction with the research community. This is especially true for the Office of the Director of NIH, which does not have adequate channels through which members of the public can express their concerns to NIH or through which they can receive information about the broad scope of effort being made in the fields with which they are concerned.

Public Input
Recommendations

NIH should engage the public to a greater extent in informing the process by which NIH sets its research priorities. The following three recommendations are intended to provide the public with more opportunities to present their views regarding research needs and to receive information about research and the priority-setting process at NIH.

Public Input
Recommendations

Recommendation 7. NIH should establish an Office of Public Liaison in the Office of the Director and, where offices performing such a function are not already in place, in each institute. These offices should document, in a standard format, their public outreach, input, and response mechanisms. The director's Office of Public Liaison should review and evaluate these mechanisms and identify best practices.

Public Input
Recommendations

Recommendation 8. The director of NIH should establish and appropriately staff a Director's Council of Public Representatives, chaired by the NIH director, to facilitate interactions between NIH and the general public.

Director's Council of Public Representatives

The Director's Council of Public Representatives—an advisory group made up of citizens who are either patients, family members of patients, or advocates for patients—serves to elevate public input into the priority-setting process to the highest level of NIH in a systematic and periodic manner. Importantly, the Council will not set priorities regarding the NIH budget or its research programs. That is, it is not intended to serve as a means for advocacy groups to lobby the NIH di ector fo research dollars.

Director's Council of Public Representatives

The Director's Council of Public Representatives should serve as a mechanism for two-way exchange:

- for NIH to receive valuable and thoughtful perspectives on its research programs from those who are in some way affected by disease and disability and who are therefore advocates for a healthy NIH
- for NIH to provide information about its research and priority-setting process.

Public Input
Recommendations

Recommendation 9. The public membership of NIH policy and program advisory groups should be selected to represent a broad range of public constituencies.

- In the institutes, these councils provide the second level of review of research programs and funding decisions. Thus, public representatives play a role in the priority-setting process and provide advice on funding decisions.
- NIH also reserves slots for public members on the Advisory Committee to the Director.
- It does not appear, however, that advocates for patients or special populations are regularly considered for these advisory committee memberships, despite numerous examples of cases in which such arrangements have been constructive and positive.
- Not using this mechanism to receive public input is a missed opportunity and has resulted in the perception of some groups that NIH does not encourage public input at the highest levels of its advisory processes.

The Role of Congress

Congress has always taken a special interest in NIH and has usually provided for larger budgets than administrations request. Congress has also often directed NIH in fairly specific ways, requiring the establishment of research programs, setting aside specific amounts of funding for research on designated problems, mandating the creation of research centers, institutes, or other specific mechanisms.

The Role of Congress *Continued*

Congress has the authority and the responsibility to intervene if it thinks that NIH is neglecting an opportunity or is not responsive to a need. Members of Congress recognize that it would be better for NIH to make the detailed decisions on how to approach problems.

The Role of Congress
Conclusions

The committee believes that if NIH revises its priority-setting system in the ways recommended above, Congress will be more likely to grant NIH, informed by stronger public input, the primary role in setting its research priorities.

The Role of Congress
Recommendations

Recommendation 10. The U.S. Congress should use its authority to mandate specific research programs, establish levels of funding for them, and implement new organizational entities only when other approaches have proven inadequate. NIH should provide Congress with analyses of how NIH is responding to requests for such major changes and whether these requests can be addressed within existing mechanisms.

The Role of Congress
Recommendations

Recommendation 11. The director of NIH should periodically review and report on the organizational structure of NIH, in light of changes in science and the health needs of the public.

- If NIH is to have more autonomy in organizing and managing its research programs, it is incumbent on the agency to engage in periodic reviews of its organizational structure and planning and budgeting systems and to explain the results to Congress and the public.

The Role of Congress
Recommendations

Recommendation 12. Congress should adjust the levels of funding for research management and support so that NIH can implement improvements in the priority-setting process, including stronger analytical, planning, and public interface capacities.

- The committee questions whether NIH, especially the Office of the Director, has adequate resources to operate an effective priority-setting system.
- Providing the Office of the Director of NIH with adequate resources for analysis and interface with the public would make research priority setting more effective.

Summary

- These recommendations are not intended to replace the existing criteria for priority setting.
- They are intended to enhance and reinforce existing NIH mechanisms through which the voices of the public can be heard in a constructive and open manner.
- The committee believes that public input, which has been important in sustaining the growth and stature of NIH, is an important component of the priority-setting process and, if used wisely by NIH when setting research priorities, will make for a stronger and more responsive NIH.
- It also believes that although implementation of these recommendations will not supersede or remove the potential for appeals to Congress, their enactment will reduce the need for such appeals.
- The new organizational mechanisms proposed to improve public input have the potential to increase, in the short term, organizational costs and complexity. In the long run, however, the committee believes that the contribution made by these offices and the Council will prove to be cost-effective in terms of carrying out NIH's mission to improve health through research and will contribute to overall goodwill on the part of the public and Congress toward NIH.

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White

Divider Title: _____

Jeffrey D. White, M.D., Director, Office of Cancer Complementary and Alternative Medicine, National Cancer Institute
Biographical Sketch

Dr. White graduated from Cornell with a B.S. in 1979 and received an M.D. from Howard University in 1984. He completed a residency in Internal Medicine in 1987 and fellowships in oncology and hematology in 1990 at The Washington Hospital Center in Washington, D.C. Dr. White joined the Metabolism Branch of the National Cancer Institute (NCI) in 1990 where he served in various positions culminating as Director of the Clinical Trials and Clinical Care Program. He also served as an oncology consultant to the NIH Office of Alternative Medicine and in October 1998 was chosen as the director of a new office in the NCI titled the Office of Cancer Complementary and Alternative Medicine. This office seeks to promote and support research in the various disciplines and modalities associated with the field of complementary and alternative medicine (CAM) as they relate to the diagnosis, prevention and treatment of cancer.

- Evidence Based -
- Priorities →
- Expansion of Best Care
  Gene Evaluation

(1) Nutrition
(2) Diet modification
(3) Micronutrients - Se, Vit A
(4) Analysis of Plant Products (Herbal) - Pre-Clinical Studies
(5) Mind Body / Behavioral
Support Group Studies
(6) Immune modulation
(7) Symptom/Modification
Side Effects

10/3/00

NCI CAM PROJECTS
October 2000

Research Development and Support Program
NCI-Supported CAM Clinical Trials
There are currently two special-initiative, CAM clinical trials jointly supported by the NCI and NCCAM (see below). A third trial is in the protocol development phase and should be open for accrual before the end of calendar year 2000. We anticipate funding to support new high-priority CAM cancer trials in FY 2001.

Phase III Randomized Study of Induction Chemotherapy and Radiotherapy With or Without AE-941, a Shark Cartilage Extract, in Patients With Stage IIIA or IIIB Unresectable Non-Small Cell Lung Cancer. This trial opened for accrual in April 2000 and is being performed at several centers across the U.S. and Canada and is coordinated by the MD Anderson Cancer Center in Houston, Texas. Detailed information about the trial is available via the NCI's PDQ program and is accessible via any of the following web sites: the Office of Cancer Complementary and Alternative Medicine (http://occam.nci.nih.gov) or the CancerNet (http://cancernet.nci.nih.gov) or CancerTrials (http://cancertrials.nci.nih.gov)

Prospective Study of Intensive Pancreatic Proteolytic Enzyme Therapy With Ancillary Nutritional Support in Patients With Stage II, III, or IV Adenocarcinoma of the Pancreas. This is a trial at Columbia University for patients with advanced pancreatic cancer with a nutritional regimen with oral pancreatic enzymes and a detoxification regimen (the Kelley/Gonzalez regimen). Detailed information about the trial is available via the NCI's PDQ program and is accessible via any of the following web sites: the Office of Cancer Complementary and Alternative Medicine (http://occam.nci.nih.gov) or the CancerNet (http://cancernet.nci.nih.gov) or CancerTrials (http://cancertrials.nci.nih.gov)

Letter RFA for Innovative CAM Research in NCI-designated Comprehensive Cancer Centers (P30s)
The NCI and NCCAM are jointly sponsoring an RFA targeted to support pilot project research with a strong potential for developing into R01 projects. This initiative will be for $2 million per year for 3 years and will be shared equally by the NCI and NCCAM. Consequently, the NCI's contribution will be $1 million per year for three years. The Letter RFA was released in July 2000. Applications are due November 13th for review by an NCI Special Emphasis Panel in January or February. Presentation of scores to the National Cancer Advisory Board will be at the May 2001 meeting and funding by July1, 2001.

Practice Assessment
Best Case Series Program
Since 1991, the National Cancer Institute (NCI) has had a process for evaluation of data from alternative medicine practitioners about groups of patients with cancer treated with alternative medical approaches. This process, called the Best Case Series Program,

provides an independent review of the medical records and primary source materials (medical imaging [e.g. radiographic, or ultrasound films] and pathology [cytology and surgical pathology]) and an overall assessment of the evidence for a therapeutic effect.

In 1999, the National Center for Complementary and Alternative Medicine (NCCAM) established a Cancer Advisory Panel for Complementary and Alternative Medicine (CAPCAM) which advises the NCCAM Director (Stephen Straus, M.D.) about promising CAM approaches for the treatment of cancer patients. The NCI works closely with this new body and case series are now presented to this panel for their review and assessment.

The Office of Cancer Complementary and Alternative Medicine (OCCAM) has recently initiated a promotion plan to increase the awareness of the program among the CAM practitioner community.

CAM Cancer Information Program

OCCAM Website (http://occam.nci.nih.gov)

The OCCAM web site provides an interface to the general public and extramural research and practice communities as well as intramural NCI and NIH program and administrative staff. The site contains updates on the status of current and planned NCI CAM projects and will serve to project a visible research agenda and to make more transparent the NCI's processes for handling CAM issues (e.g. best case series).

NCI/NCCAM Fact Sheets

NCI (OCCAM and OCC) and the NCCAM recently agreed to collaborate in the production of fact sheets on CAM topics. These documents will be produced though a contract to the Office of Cancer Communications and will be reviewed by the OCC, OCCAM and NCCAM. Each fact sheet will be available in English and Spanish.

PDQ Summary Reviews

The NCI's Physicians Data Query (PDQ) is developing in depth summaries of the literature regarding CAM modalities used to treat cancer. These summaries contain extensive references as well as glossaries to make them accessible to both medical professionals and the lay public. These summaries are available via the NCI's PDQ program and accessible via either of the following web sites: the Office of Cancer Complementary and Alternative Medicine (http://occam.nci.nih.gov) or the CancerNet (http://cancernet.nci.nih.gov).

Planned Projects

Practice Outcomes Monitoring and Evaluation System

This system will provide the capacity to gather either retrospective or prospective data from CAM practice environments that have demonstrated adequate preliminary evidence indicating clinically significant effects in cancer patients.

Catalogue of CAM Cancer Research
This project will identify the existent cancer CAM research (published as articles or abstracts and unpublished), determine how much of this research was funded by NCI and what were the other sources of funding. We will also identify the active CAM cancer investigators and query them about the obstacles and opportunities they perceive in CAM cancer research. This information will be used to identify research opportunities for new cancer CAM initiatives and will help decrease the duplication of efforts.

CAM Cancer Citation Database
This project will explore the feasibility of augmenting the cancer component of the existing NCCAM CAM Citation Index versus establishing an independent NCI controlled cancer CAM research database. This database will become a resource for NIH and extramural investigators interested in CAM research and will include articles and abstracts from many databases including Medline or Web of Science. The database will serve as a resource to facilitate systematic reviews.

Systematic Reviews of the CAM Cancer Literature
This activity will represent part of the process for assessing the state of the evidence for potential projects for the NCI CAM Clinical Trials program.

Co-sponsorship of NCCAM Grants Initiatives
NCI anticipates co-sponsorship of RFAs/PAs that develop from two concepts recently approved by the National Advisory Council on Complementary and Alternative Medicine (Clinical trials of phytoestrogens for breast cancer and CAM at the end-of-life for cancer and HIV/AIDS)

Claude Lenfant, MD

DIRECTOR

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Dr. Claude Lenfant has been Director of the National Heart, Lung, and Blood Institute (NHLBI), a component of the National Institutes of Health (NIH), since July 1982. The Institute's mandate is to improve the public health through research on cardiovascular, lung, and blood diseases, sleep disorders, and transfusion medicine. The NHLBI conducts and supports a full spectrum of research activities, including basic and applied studies, population-based investigations, clinical trials, and demonstration and education projects. Its current annual budget is nearly $2 billion.

Prior to his appointment to that position, Dr. Lenfant was director of the NIH Fogarty International Center (1981-1982) and Director of the NHLBI Division of Lung Diseases (1972-1980).

Dr. Lenfant came to the NIH from the University of Washington, Seattle, where he was a Professor of Medicine and Physiology and Biophysics. He received his medical degree from the University of Paris in 1956, and subsequently completed research fellowships at the University of Buffalo and Columbia University.

Dr. Lenfant has been recognized, nationally and internationally, for his exceptional leadership and achievements. His honors include receipt of the American Medical Association's Dr. Nathan Davis Award and election to the Institute of Medicine of the National Academy of Sciences, to the USSR (now Russia) Academy of Medical Sciences, to the French National Academy of Medicine, and to the Royal College of Physicians (London). He is the recipient of the Presidential Distinguished Executive Rank Award.

Dr. Lenfant is the author or co-author of more than 200 scientific publications and the executive editor of the series of monographs "Lung Biology in Health and Disease," which comprises 150 volumes. He has served on the editorial boards of numerous scientific publications, including the American Journal of Physiology, the American Review of Respiratory Disease, the Proceedings of the Society for Experimental Biology and Medicine, and Continuing Education for Family Physicians.

- Nutrition
- Prevention
- Integrated CAM -
→ Need to Get into Mainstream of Practice
→ Education + training of Research Investigators
→ How we set Priorities -
Large Populations of Patients
Public Voice of All Med is not currently hearing all
Advisory Council - Public needs to one Fourth of Group
their views -
- Need to Validate Intervention

3 Criteria for Review
- Issue of Great Public Health Dr
- Affordable Research
- What comes from validation - can it be applied

National Heart, Lung, and Blood Institute
Activities With Regard to Complementary and Alternative Medicine

Research Projects:

The NHLBI research portfolio includes a number of projects in the area of complementary and alternative medicine. Representative topics include the following:

cardiovascular benefits of soy phytoestrogens;

role of dietary n-3 fatty acids in inhibiting thrombo-occlusive graft failure of arteriovenous shunts in hemodialysis patients;

effects of zinc supplementation on growth and body composition in patients with sickle cell disease;

family-based behavioral pain management in patients with sickle cell disease;

effects of oral L-arginine, administered during vaso-occlusive crises in patients with sickle cell disease, on health and quality of life;

effectiveness of Ginko biloba in decreasing the incidence of dementia, slowing cognitive decline and functional disability, reducing the incidence of cardiovascular disease, and decreasing total mortality;

relationship between hypoalgesia (diminished sensitivity to pain) and high blood pressure.

Solicited Research:

During the past several years, the NHLBI has collaborated with the National Center for Complementary and Alternative Medicine (NCCAM) and other NIH components on several grant solicitations, some of which have resulted in awards:

Centers for Complementary and Alternative Medicine, which included innovative approaches to asthma (e.g., hypnotic suggestion, acupuncture, homeopathy, herbal remedies, Ayurvedic medicine, breathing techniques);

Centers for Mind/Body Interactions and Health, which included study of the relationship between mental states and cardiovascular, lung, and blood diseases and sleep disorders;

Centers for Dietary Supplements Research: Botanicals, which included investigation of the molecular basis of how botanicals affect diseases of the heart, blood vessels, lungs, and blood;

Self-Management Strategies Across Chronic Diseases, which included a focus on blood diseases (e.g., deep vein thrombosis, sickle cell disease, hemophilia);

Biobehavioral Pain Research, which supported the project on hypoalgesia and high blood pressure, mentioned above;

Acupuncture Clinical Trial Pilot Grants, which targeted acute pain in sickle cell disease, angina pectoris and cardiac arrhythmias, asthma, and hypertension and vascular disease.

Workshops:

"Complementary and Alternative Medicine in Cardiovascular, Lung, and Blood Research" was cosponsored by the NHLBI and the NCCAM in June 2000. Its goal was to exchange information and ideas, identify opportunities, and foster collaboration among scientists. Areas of focus included the historical and cultural perspective of complementary and alternative medicine, methodological issues in clinical trials, herbal medicine, chelation therapy, mind/body approaches (biofeedback), and acupuncture.

A workshop on magnesium and asthma, held in September 2000, was cosponsored by the NHLBI and the NCCAM.

"The Science of the Placebo: Toward an Interdisciplinary Research Agenda," cosponsored by the NHLBI and other NIH components, will be held in November 2000.

September 2000

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P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

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

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

[001]

CURRICULUM VITAE

NAME : Marvin Cassman, Ph.D.

POSITION: Director, NIGMS

BIRTHPLACE : (b)(6)
AND DATE :

EDUCATION : B.A., 1954 University of Chicago
B.Sc., 1957 University of Chicago
M.S., 1959 University of Chicago
Ph.D., 1965 Albert Einstein School of Medicine

EXPERIENCE : 1996-Present Director, National Institute of General Medical Sciences, (NIGMS), NIH

1993-1996 Acting Director, National Institute of General Medical Sciences, (NIGMS), NIH

1989-1996 Deputy Director, (NIGMS), NIH

1985-1989 Director, Biophysics and Physiological Sciences Program, NIGMS, NIH

1985-1986 Senior Policy Analyst, Office of Science and Technology Policy, Executive Office of the President

1982-1983 Staff, House Subcommittee on Science and Technology

1978-1984 Chief, Molecular Basis of Disease Section, Cellular and Molecular Basis of Disease Program, NIGMS, NIH

1975-1978 Health Science Administrator, Cellular and Molecular Basis of Disease Program, NIGMS, NIH

1967-1974 Assistant Professor, University of California, Santa Barbara

1965-1967 NIH Postdoctoral Fellow, University of California, Berkeley

1959-1961 Research Fellow, Northwestern University Medical School

Mission of the National Institute of General Medical Sciences

The National Institute of General Medical Sciences (NIGMS) primarily supports basic biomedical research that is not targeted to specific diseases or disorders. Because scientific breakthroughs often originate from such untargeted studies, NIGMS-funded work has contributed substantially to the tremendous progress that biomedical research has made in recent years. The Institute's training programs help provide the most critical element of good research: well-prepared scientists. NIGMS is one of the National Institutes of Health (NIH), the principal biomedical research agency of the Federal Government. NIH is a component of the U.S. Department of Health and Human Services.

Each year, NIGMS-supported scientists make major advances in understanding fundamental life processes. In the course of answering basic research questions, these investigators also increase our knowledge about the mechanisms involved in certain diseases. Other grantees develop important new tools and techniques, many of which have applications in the biotechnology industry. In recognition of the significance of their work, a number of NIGMS grantees have received the Nobel Prize and other high scientific honors.

Understandable Principle of all Molecular & Chemical Sys
Chem, Physics, Mathematical
- Provide federal support for basic/applied research
- Fundamental research - all molecular components
- Complex Systems / Individual Mechanisms
- Measurable quantities are needed to investigate how system work

Brief Biography for Dr. Steven J. Hausman

Dr. Hausman graduated with an B.A. from the University of Pennsylvania in 1967 and received his Ph.D. from the same institution in 1972 in the field of immunogenetics and transplantation biology. He was then a postdoctoral fellow at the Institute for Cancer Research in Philadelphia and, in 1975, became a Staff Fellow in the intramural research program of the National Institute on Aging (NIA) located at the Gerontology Research Center in Baltimore. In 1977, Dr. Hausman became Special Assistant to the Associate Director for Arthritis, Bone and Skin Diseases of the then-named National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD). Subsequently, in 1978, he became Director of the Arthritis Centers program in the same Institute. In 1986 he became Deputy Director of the Division of Arthritis and Musculoskeletal and Skin Diseases in the (renamed) National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases (NIADDK).

When the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) was established in 1987 he became Deputy Director of the Extramural Program. In 1990 he was appointed Deputy Director of the NIAMS. Dr. Hausman was appointed Acting Director of the Extramural Program in 1995 (and was made permanent Director of the Extramural Program in 1998) and currently serves the Institute in both capacities. Dr. Hausman has served on a variety of boards and committees at the NIH, including both the STEP Committee and the Grants Associates Board. He has a long-standing interest in computer technology issues. In addition, he served for several years as Chair of the Public Health Service Advisory Committee on Employment of Persons with Disability and continues to lecture on disability awareness and reasonable accommodation at the NIH. Among the awards he has received are the NIH Director's Award and the PHS Exceptional Achievement Award Recognizing his activities as Chair of the PHS Advisory Committee for Employment of Persons with Disabilities.

Chronic, Costly, Crippling, Curing
Research Grants, (Placebo Workshop)
training — in traditional Research Methods
SBIR — Grants
Opportunities — Area for
Obstacles — Validated Evidence, Interdisciplinary Research
Collaboration, Collaboration, Collaboration
— Medicare (Reimbursement) — Beneficiaries — Pay for service
part of treatment —

Synopsis of CAM-Related Projects in the National Institute of Arthritis and Musculoskeletal and Skin Diseases

Alternative Medicine for Preventing Frailty in Elders -

The major objectives of this study are to (1) provide a mechanism to systematically evaluate the effectiveness of selective alternative medicine therapies for enhancing functional capacity and quality of life while decreasing physical disability and frailty in older women and men; (2) provide clinical, scientific, and technical assistance to alternative medicine clinicians to aid them in the objective assessment of their specific therapy; (3) promote an understanding of alternative medicine, especially alternative medicine research to enhance the physical functioning of older persons among transitional and alternative medicine communities; and (4) disseminate responsible information regarding alternative medicine.

Center in Alternative Medicine Pain Research & Evaluation -

A center for alternative medicine pain research and evaluation will be developed in this project. This center will promote research on alternative therapies for the treatment of pain. The investigators plan to examine the effectiveness of ethnomedicine, structural manipulation, bioelectromagnetic, and mind-body control therapies and lifestyle changes on several types of pain.

Alternative Therapy for Chronic Illness -

This project will create a center that will investigate CAM therapies as they are applied to common chronic medical conditions. The center will initially review and assess CAM research opportunities in the areas of: (l) low back pain; and, (2) ischemic heart disease. This assessment will also include an investigation of specialized methodological issues relating to placebo; specifically, the extent to which belief, expectation, conditioning, patient preferences and patient provider interaction predict or influence an individual patient's response to any therapy, conventional or alternative. In addition, this center will investigate legal issues which may affect research involving the integration of CAM and conventional medical therapies.

RCT – Acupuncture Safety/efficacy in Knee Osteoarthritis -

The goal of this research is to determine the efficacy and safety of Traditional Chinese Acupuncture [TCA] in patients with osteoarthritis of the knee. A three arm RCT (randomized clinical trial) using sham TCA, true TCA, and an education/attention comparison group with a total sample of 525 is planned. The primary hypothesis to be tested is that patients randomized to true TCA will have significantly more improvement in pain and function as measured by the Womac Pain and Function Scales and patient global assessments than patients randomized to the sham acupuncture and education/attention control groups. Secondary aims of the study are to 1) determine if improvement with TCA differs between patients below age 65 vs. those aged 65 and

above, 2) to determine if improvement with TCA differs by racial/ethnic group (ie., Caucasian, Black, Hispanic), and 3) to determine if improvement with TCA differs by stage of radiographic severity of knee OA at baseline (KL grade 2,3 or 4).

Creating the Consortial Center for Chiropractic Research -

The purpose of this project is to establish the Consortial Center for Chiropractic Research (CCCR), that will provide an infrastructure to examine the potential effectiveness and validity of chiropractic health care, and to provide appropriate assistance to chiropractic researchers in developing high-quality research projects. Chiropractic is considered to be one of the most prevalent forms of alternative/complementary health practice, used by approximately 10% of the U.S. population annually, and by about 40% of all patients with low back pain. The specific aims of the CCCR are to: 1) establish linkage of academic centers with which chiropractic investigators are associated; 2) establish an advisory committee to provide program advice; 3) establish a bibliographic resource on chiropractic topics; 4) develop a program of assistance activities to provide clinical/scientific/technical assistance to potential chiropractic investigators; 5) develop and implement research workshops, seminars, and educational materials; 6) act as an institutional focus for formal training in research methodology, bioethics, biostatistics, clinical trial design, epidemiological and health services studies, and basic laboratory methods; 7) evaluate the feasibility of using data from chiropractors for research projects; 8) establish a network of chiropractic clinicians and investigators in specific topic areas; 9) link investigators to the technical expertise necessary to pursue research goals; 10) prioritize research topics related to chiropractic treatment of musculoskeletal conditions; 11) develop a mechanism for scientific/technical merit review of research proposals; 12) implement selected research projects; and 13) evaluate the CCCR in terms of process and outcomes.

Trial of Acupuncture for Carpal Tunnel Syndrome -

This project will test the feasibility of studying traditional Chinese acupuncture in the context of a large, randomized controlled clinical trial (RCT). 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 that can be used at any study site performing an RTC, 3) to demonstrate that patient recruitment for and retention in an RCT of acupuncture for CTS us sufficient to justify a full-scale RCT, 4) to determine, in a small 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.

Paul M. Coates, Ph.D.
Director
Office of Dietary Supplements, National Institutes of Health (1995)

Dr. Coates was appointed Director of the Office of Dietary Supplements at the NIH in 1999. In that capacity, he oversees efforts to enhance and stimulate research in dietary supplements at the NIH. ODS activities currently include: the Botanical Supplement Research Centers Program; research projects and conferences sponsored in conjunction with NIH and other federal agencies; databases devoted to current literature in dietary supplements (IBIDS) and to federally funded research in dietary supplements (CARDS, under construction); and dietary supplement fact sheets for consumers. Dr. Coates is Co-Chair of the joint DHHS/USDA Steering Committee that developed the National Nutrition Summit. He also is a member of the Federal Steering Committee that oversees the development of the Dietary Reference Intakes.

Prior to this, he was Deputy Director, Division of Nutrition Research Coordination (DNRC), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). In that role, Dr. Coates participated in the coordination of human nutrition research efforts, both at the NIH and between the NIH and other government agencies. Among these was Healthy People 2010, the DHHS effort at setting public health goals for the nation; he co-led the development of the Nutrition/Overweight chapter. Prior to joining the DNRC, he was NIDDK's Program Director for Type 2 Diabetes Research and Project Officer for the multi-center clinical study called Epidemiology of Diabetes Interventions and Complications. Also at NIDDK, he maintained a Career Development and Fellowship Training Program in the Division of Diabetes, Endocrinology, and Metabolic Diseases.

Before coming to the NIH, Dr. Coates was on the faculty of the University of Pennsylvania School of Medicine and The Children's Hospital of Philadelphia, where he was Research Professor in the Departments of Pediatrics and Biochemistry/Biophysics. His Ph.D. degree in human genetics was from Queen's University in Canada and his postdoctoral training took place in the Department of Human Genetics and Biometry at University College London. His major research interests for many years focussed on inborn errors of human lipid metabolism. He conducted some of the early studies of fatty acid oxidation disorders in infants and children, and with an international team of collaborators, was responsible for defining many of the known genetic defects of human mitochondrial fatty acid oxidation. He has also studied the metabolism of intestinal and hepatic lipoproteins in man, with a view to defining metabolic defects in the inherited hyperlipidemias. These studies have led to new understanding of the role of environmental factors (e.g., diet) in the manifestation of genetic disease. He has written more than 100 publications and has edited two books in these areas of research.

Center - Multidisciplinary personnel involved in projects
- 4 Centers - designed to be interactive with many groups
- CAM Integration

OFFICE OF DIETARY SUPPLEMENTS, NATIONAL INSTITUTES OF HEALTH

Background

Dietary supplements can have an important impact on the prevention and management of disease and on the maintenance of health. Dietary supplements in the United States are usually defined as comprising plant extracts, enzymes, vitamins, minerals, and hormonal products that are available without prescription and may be consumed in addition to the regular diet. Considerable research on the effects of dietary supplements has been conducted in Asia and Europe where plant products, in particular, have a long tradition of use. However, the overwhelming majority of supplements have not been studied scientifically. It is important to conduct objective research to determine the benefits and risks of promising dietary supplements and to interpret data for the public. Recognizing these issues, Congress in November 1994 passed Public Law 103-417, the Dietary Supplement Health and Education Act (DSHEA). This bill amended the Food, Drug, and Cosmetic Act and focused on further defining aspects of that law that related to the definition, regulation, and labeling of dietary supplements. DSHEA also included authorization for the creation of the Office of Dietary Supplements (ODS) at the NIH and a Presidential Commission on Dietary Supplement Labels. The ODS was formally established on November 27, 1995 within the Office of Disease Prevention, Office of the Director, at the National Institutes of Health. Bernadette M. Marriott, Ph.D., was appointed the first Director of ODS in 1995. Paul M. Coates, Ph.D., became Director of ODS in October 1999. Information about ODS and its activities can be found on the following website: http://dietary-supplements.info.nih.gov/.

ODS Strategic Plan

ODS is committed to meeting a number of goals, as outlined in our Strategic Plan (on the website noted above). These are:

1) To evaluate the role of dietary supplements in the prevention of disease and reduction of risk factors associated with disease;
2) To evaluate the role of dietary supplements in physical and mental health and in performance;
3) To explore the biochemical and cellular effects of dietary supplements on biological systems and their physiological impact across the life cycle;
4) To improve scientific methodology as related to the study of dietary supplements; and
5) To inform and educate scientists, healthcare providers, and the public about the benefits and risks of dietary supplements.

How Does ODS Implement Its Strategic Plan?

1) Research Initiatives: The ODS supports a network of comprehensive, multidisciplinary research centers devoted to dietary supplements. These are funded in collaboration with other NIH partners, including NCCAM, NIGMS, and ORWH. Currently, 4 such Centers

have been funded that have an emphasis on botanical supplements. The ODS also supports research projects that are co-funded with other partners at NIH.

2) Conference/Workshop Support: Each year, the ODS sponsors numerous workshops in collaboration with other Institutes and Centers at NIH, as well as with outside organizations. Among the topics covered this year are: molecular techniques for characterizing botanicals, bioavailability of ingredients in dietary supplements, and metals in medicine. These workshops are often used to help us and our NIH partners to develop a research agenda. Such is the case with the last of the three examples provided above.

3) Databases: ODS supports an International Bibliographic Information on Dietary Supplements (IBIDS) database in collaboration with the Food and Nutrition Information Center of USDA's National Agricultural Library and is in the process of developing a database of federally funded research in the area of dietary supplements called Computer Access to Research in Dietary Supplements (CARDS).

4) Supplement Fact Sheets: ODS has published a series of vitamin and mineral fact sheets for the public in collaboration with the Clinical Center at NIH. A similar process has been developed for publication of botanical and herbal fact sheets, in collaboration with NCCAM. These are factual, peer-reviewed information sheets that will be evaluated periodically to ensure their accuracy and completeness.

5) Inter-Agency and Public-Private Collaborations: ODS continues to partner with USDA in developing the IBIDS database mentioned in 4) above. ODS has begun to collaborate with the Consumer Healthcare Products Association, by sponsoring a session at their annual dietary supplements symposium and also by sponsoring a jointly-produced annual bibliography of significant literature in dietary supplements. ODS is also partnering with others to sponsor next year's International Society for Technology Assessment in Health Care and next year's International Scientific Conference of Complementary, Alternative and Integrative Medicine Research.

6) Emerging Initiatives: These include an effort to develop systematic reviews of key dietary supplements. The first of these was on chromium and diabetes, and will be extended to other key dietary supplements in the coming year. These reviews will inform discussions about the state-of-the-art for these modalities and in developing research agendas for ODS and its partners. We will also initiate a career development and training program (pending availability of funds). We believe that the field is need of trained scientists in areas relevant to dietary supplements, particularly in pharmacognosy.

Clinton Presidential Records
Digital Records Marker

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

Divider Title: Fishman

ALFRED P. FISHMAN, M.D.

Alfred P. Fishman, M.D. is the William Maul Measey Professor Emeritus of Medicine and Senior Associate Dean for Program Development at the University of Pennsylvania School of Medicine. He received his A.B. and M.S. degrees from the University of Michigan, and his M.D. from the University of Louisville. He has had extensive research training in physiology, pathology and medicine largely under the sponsorship of the National Institutes of Health and the American Heart Association. In 1966, he became Professor of Medicine at the University of Chicago and Director of the Cardiovascular Institute at Michael Reese Hospital and Medical Center. In 1969, he joined the faculty of the University of Pennsylvania as Professor of Medicine and Associate Dean of Research. His background in physiology, pathology and medicine has been primarily directed at research in cardiovascular and pulmonary medicine. Between 1990 – 1996, he served as Chair of the Department of Rehabilitation Medicine. He is Chair of the Health Promotion and Disease Prevention Council and Chair of the Steering Committee of Complementary Medicine at the University of Pennsylvania.

Dr. Fishman has been a consultant to the executive office of the President of the United States; a member of the National Heart, Lung and Blood Institute and Chairman of the Health Sciences Policy Board, Institute of Medicine, NAS. He has served on numerous editorial boards, as editor of the Journal of Applied Physiology, and as Chairman of the Publications Committee of the American Physiological Society and as a member of the Board of Directors of the American Heart Association. He has served as special consultant to the Health Commissioner, New York State, Dr. David Axelrod and as Chair of the New York State Cardiology Planning Committee. He is currently a member of the Board of Directors of the National Space Biomedical Research Institute.

Dr. Fishman was President of the American Physiological Society, and is or has been a member of several national societies, including the American Society for Clinical Investigation, the Association of American Physicians, the Institute of Medicine of the National Academy of Sciences, the Interurban Clinical Club, and Royal Society of Medicine (London) and the American Academy of Arts and Sciences. He was Chairman of the United States National Committee of the International Union of Physiological Sciences. He has served on a succession of committees and the Cardiopulmonary Council of the National Institutes of Health and is currently Chair of the Steering Committee of the National Emphysema Treatment Trial which involves 18 medical centers in the United States. Dr. Fishman serves on a number of Boards of Directors, and is on the Board of Visitors of several medical institutions. He is the Immediate Past President of the College of Physicians of Philadelphia. He has edited nine books and published over 250 scientific articles.

Complementary/Alternative Medicine in the University of Pennsylvania Health System

Alfred P. Fishman, M.D.

Introduction

Approximately three years ago, the CEO/Dean of the University of Pennsylvania Health System (UPHS) created a "Working Group" to define the role of Complementary/Alternative Medicine in the Academic Medical Center. After one year of deliberations, punctuated by periodic reviews by experts both from within and without the UPHS, the conclusions were accepted by the central administration for implementation. The consensus was that The University of Pennsylvania, in its roles as a research university and as the hub of a health system, should evaluate, conduct, research and instruct students and faculty about complementary/alternative therapies. Four categories of recommendations were proposed and have either been implemented or are in the process of being implemented: general; clinical; educational; research.

General

The institution remains firmly committed to scientific medicine in its clinical, educational and research activities. Research is viewed as interlinked with clinical practice and teaching. The mechanisms used for evaluating traditional Western medicine will be applied to unconventional and unproven therapies that are being considered for inclusion in the practice of conventional medicine. Each unconventional therapy included under the rubric of Complementary/Alternative Medicine will be evaluated separately making full use of pertinent information such as state licensing authorities, specialty boards, the Cochrane collection and the American College of Physicians reports. The designation "complementary" will be used in the UPHS for individual therapies; "alternative" will be reserved for systems, such as homeopathy or ayurveda.

The Working Group has been continued as a "Steering Committee" to develop programs and to advise credentialling bodies (Medical Affairs, Human Resources, Legal Affairs, Departments, Centers and Institutes). The Steering Committee includes experts on complementary and alternative therapies along with clinical scientists and members of the UPHS credentialling process. Provision is made for the Committee can to be enlarged or modified as necessary.

Clinical Practice

Practice of proven complementary therapies by practitioners privileged to do so will be done at multiple sites in the UPHS with concentrations at several sites to serve particular populations, e.g. the elderly, women's health programs, well-being center and cancer center. Together, these sites constitute a "Virtual Center" with links for communication.

The process for evaluating a proposed complementary therapy will be the same as for any novel therapy in conventional medicine using existing offices (Medical Affairs, Human

Resources and Legal Affairs) and pathways for administrative approval. The Steering Committee will be advisory to these offices.

Provisions have been made for patient access, dissemination of information (Penn Web Page and Penn Net), and cost-effectiveness. A business plan has been prepared.

Education

Since neither medical students, house staff nor practicing physicians are well-informed about complementary/alternative therapies, provision has been made for incorporating information about unconventional therapies and systems at appropriate places in the revised curriculum. The major focus is on learning, particularly with respect to safety, efficacy, benefit/risk, and quality of life. Spontaneous gatherings of medical students for instruction in complementary therapies and alternative systems will continue to be encouraged. Electives offer the opportunity for hands-on experience. Seminars and lectures supplement curricular activities and provide post-graduate education (e.g. conference co-sponsored by NIH office of CAM, Working Group and Penn Ethics Center on "Ethics and Alternative Medicine".

Research

The Working Group concluded that unproven therapies may provide excellent opportunities for research. Research on any unconventional therapy will follow the same guiding principles and be subject to the same review mechanisms as for conventional medicine. The Steering Committee will encourage research on complementary therapies.

A research pathway to generate faculty trained to conduct research on CAM has been established. This pathway is essentially the same as for conventional medicine, and includes fellows, trainees and young faculty, all with proper mentoring. A year-out medical student program for research training is available through the "Four Schools" program sponsored by the Markey Trust.

Partnering with other components of the Medical Center and University is an essential strategy of the training program. Currently, two members of the faculty in the Department of Internal Medicine and another in the Department of Anesthesia are enlisted in the two-year Master's degree program of the Center for Epidemiology and Biostatistics; This Center is nationally prominent in the epidemiology of pharmacologic agents and expert in clinical trials and outcome research. Each trainee has two mentors: one in a complementary therapy, e.g. acupuncture; the other expert in clinical trials and outcomes research via epidemiology and biostatistics. Other faculty members are collaborating with members of the University of the Health Sciences in Philadelphia who are expert in determining the composition of herbs and in defining their proper usage.

Allied health professionals, such as nurses and physical therapists, are engaged in CAM-related research programs and are working in close collaboration with experts in CAM modalities, such as electrical fields, massage therapy, Yoga and Tai Chi. Several programs are concerned with the effectiveness of spirituality as a healing modality.

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SENIOR DEAN FOR ALUMNI RELATIONS
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OF MEDICINE AND MEDICAL EDUCATION

DANIEL D. FEDERMAN, M.D.
Senior Dean for Alumni Relations and Clinical Teaching
Carl W. Walter Distinguished Professor of Medicine and Medical Education
Harvard Medical School
Boston, Massachusetts

Dr. Daniel D. Federman was born in New York City and graduated summa cum laude from Harvard College and magna cum laude from Harvard Medical School. His clinical training at Massachusetts General Hospital was followed by research training at the National Institutes of Health.

Dr. Federman served on the faculty of Harvard Medical School from 1960 to 1972, and was simultaneously on the staff of the Massachusetts General Hospital. From 1972-77 he was Chairman of the Department of Medicine at Stanford Medical School. He then returned to Harvard Medical School as Dean for Students and Alumni and Professor of Medicine. In 1989 he was appointed Dean for Medical Education and in 1992 he was named the Carl W. Walter Professor of Medicine and Medical Education. In July, 2000 he became the Senior Dean for Alumni Relations and Clinical Teaching.

Dr. Federman has served as Chairman of the American Board of Internal Medicine, Chairman of the Federated Council for Internal Medicine, and President of the American College of Physicians. He is a member of the Institute of Medicine. In 1994 he was named Massachusetts Physician of the Year by the American College of Physicians, and in 1995 received the ACP Distinguished Teacher Award. The Endocrine Society honored him with their Distinguished Educator Award in 1999.

Project Update 2000

Harvard Medical School Division for Research and Education in Complementary and Integrative Medical Therapies and Beth Israel Deaconess Medical Center, Center for Alternative Medicine Research and Education

David Eisenberg, MD, Director
Ted J. Kaptchuk, OMD, Associate Director

I. **Survey Research** (selected ongoing analyses)

- CAM use in the elderly
- CAM use in individuals with anxiety/depression
- CAM use in the pediatric population
- CAM use in breast cancer survivors
- National Alternative Medicine Ambulatory Care Survey
- Perceptions of CAM use and reasons for nondisclosure

II. **Clinical Trials**

HMO RCT: Usual care vs. choice of "expanded benefits," (i.e., usual care, chiropractic, acupuncture or massage therapy) for acute low back pain (n= 480). Funded by NIH. Patient recruitment underway.

HMO RCT: Chiropractic vs. acupuncture vs. massage vs. usual care for chronic low back pain in older adults (> 65; n= 120), with 30 subjects per treatment arm. Funded by NIH. To begin winter 2001.

HMO RCT: Mindfulness meditation vs. Tai Chi vs. massage vs. usual care for chronic low back pain in older adults (>65; n=120), with 30 subjects per treatment arm. Funded by NIH. To begin winter 2001.

HMO RCT: Usual care vs. acupuncture vs. massage for chronic low back pain (n= 262). Completed. Manuscript under review.

Placebo RCT: Do medical devices have enhanced placebo effects? (n= 270). Funded by NIH. To begin fall 2000.

Fellows' Pilot Studies:

- Simple magnets as Rx for knee osteoarthritis – approved. To begin fall 2000.
- Cervical manipulation for children with chronic otitis media awaiting tube replacement. Approved, to begin fall 2000.
- Milk Thistle as Rx for chronic Hepatitis C - Protocol under development.
- CAM for congestive heart failure -- Protocols under discussion.

III. Basic Science

Optimization of botanical therapies – Ginkgo Biloba as a model. Funded by NIH. To begin fall 2000.

Mechanisms of acupuncture analgesia in migraine patient populations. NIH grant submission under review.

IV. Education

NIH T-32 Clinical Research Fellowship in Complementary and Alternative Medicine. Two fellows in place. (Note: This is the first NIH funded fellowship program in this area.)
Harvard Medical School Courses in CAM: Dept. of Medicine Elective and (required) tutorials for all third year students.
Housestaff Clinical Conferences pertaining to CAM.

CME Courses:

- Harvard-Stanford, Complementary and Alternative Medicine: Practical Applications and Evaluations, October 28-31, 2000, Kauai, Hawaii
- Harvard-UCSF, Herbal Therapies and Other Dietary Supplements – What the Practicing Physician, Pharmacist or Nurse Needs to Know, November 9-11, 2000, UCSF, San Francisco, California
- Harvard, Complementary and Alternative Medicine: Implications for Clinical Practice and State-of-the-Science Symposia, February 11-14, 2001, Boston, MA
- Harvard-UCSF, Scientific Symposium on Integrative, Complementary and Alternative Medicine Research, May 17-19, 2001, San Francisco, California

V. Placebo Research

- "Sham device, pill placebo or treatment for arm pain" – See placebo RCT above.

VI. Future Directions

- Development of Harvard-wide research initiatives in CAM emphasizing interdepartmental and inter-hospital collaboration
- Increased emphasis on basic science evaluations of CAM
- Developing models for integrative care clinical facilities within Academic Hospitals
- Conventional and CAM providers as a "team"
- Credentialing of CAM providers
- Formulary/Pharmacy criteria
- Toxicity/Safety issues as highest priority
- Medical/Legal liability issues
- Interface with electronic medical record/standardized data tracking
- Clinical and cost offsets evaluated through controlled trials
- Training facility for integrative care providers/investigators
- Can these models be fiscally responsible without being elitist?

Joseph E. Pizzorno, Jr., N.D.

President Emeritus, Senior Advisor to the President,
Bastyr University
14500 Juanita Drive NE
Kenmore, WA 98028-4966
(425)602-3003

Joseph E. Pizzorno, Jr., N.D, is one of the world's leading authorities on science-based natural medicine. A physician, educator, and expert spokesperson, Dr. Pizzorno is co-founder and founding president of Bastyr University, the first fully accredited, multidisciplinary university of natural medicine in the United States. Dr. Pizzorno is the author of *Total Wellness* and co-author of the internationally acclaimed *Textbook of Natural Medicine* and best-selling *Encyclopedia of Natural Medicine*. In 1996 he was appointed to the Seattle/King County Board of Health, the first natural medicine practitioner in the country to receive such an appointment. In 1999, Dr. Pizzorno was elected Chair of the American Public Health Association Special Primary Interest Group on Complementary and Alternative Medicine.

In June 2000, Dr. Pizzorno retired from the presidency of Bastyr University. He has been granted the title of President Emeritus and serves as the Senior Advisor to the President. In September, the Cancer Treatment Centers of America recognized him as Humanitarian of The Year. He currently travels worldwide, lecturing about and promoting science-based natural medicine and integrative healthcare and has co-founded a company to bring natural medicine concepts to corporate health promotion programs.

September 2000

White House Commission on Complimentary and Alternative Medicine

October 5, 2000

Dr. Joseph E. Pizzorno, N.D.
President-Emeritus and founding President
Bastyr University

Dr. Pizzorno

Dr. Pizzorno is one of the world's leading authorities on science-based natural medicine. For over 20 years, beginning with the founding of Bastyr University, the first accredited institution of natural medicine in the U.S., he has worked to bring science and accountability to natural medicine and to educate the public, legislators and other health care professionals on the value this medicine has to substantially improve health and well-being. He is currently licensed as a naturopathic physician in the Washington State, President-Emeritus of Bastyr University, and Medical Director of Expert Health Systems, a company created to bring natural medicine to corporate health promotion programs.

Bastyr University

Bastyr University, founded in 1978, has become one of the world's premier natural medicine academic health centers. Some specifics:

- Enrollment: 1,200
- Accreditation: Northwest Association of Schools and Colleges, and the specialized accrediting bodies for each of its degree programs
- Accredited degree programs: naturopathic medicine, acupuncture and Chinese medicine, nutrition, psychology, applied behavioral sciences
- Research: one of the largest CAM research centers in the U.S. with multiple publications in the peer-review scientific journals
- Teaching clinic: 50,000 patient contacts per year
- Campus: 50 acres surrounded by 450 acre state park on Lake Washington

Bastyr University Research Institute

- Research at Bastyr University began in 1983
- Initial research funded through donations and natural products industry
- Large number of studies published in peer-reviewed medical journals
- First NIH OAM research center in 1994, AIDS/HIV
- Key to success has been cross-trained researchers:
    - Dr. Standish: PhD, ND, MS (AOM)
    - Dr. Calebrese: ND, MPH

Key Policy Recommendations

- Remove language from existing legislation and rules which excludes CAM researchers and research institutions
- Prioritize funding for the creation of CAM academic health centers
- Establish an institute for integrated CAM and public health research
- Fund research into whole systems of healing, not isolated therapies
- Hold a consensus conference on CAM research protocols

Palmer Center for Chiropractic Research

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Biography:

William C. Meeker, DC, MPH

Dr. Meeker is Director of Research for the Palmer Center for Chiropractic Research at Palmer Chiropractic University in Davenport, Iowa. He is also the Principal Investigator for the Consortial Center for Chiropractic Research (CCCR), a collaboration of nine institutions established by an award from the National Center for Complementary Alternative Medicine (NCCAM). He is a member of the Advisory Council of NCCAM. Dr. Meeker has been the Project Director for the "National Conference to Establish the Chiropractic Research Agenda" for the last six years, which is supported by a contract with the Bureau of Health Professions of the Health Resources and Services Administration. From 1989-1995, Dr. Meeker was President of the Consortium for Chiropractic Research, a non-profit organization facilitating collaborative research in chiropractic institutions in North America. He was elected to the Governing Council of the American Public Health Association in 1996, and received the Distinguished Service Award from the Chiropractic Health Section there in 1998. He is the Editor of the Journal of the Neuromusculoskeletal System, the official scientific publication of the American Chiropractic Association. In addition, he is on the editorial boards of the Journal of Manipulative and Physiological Therapeutics, the Journal of Chiropractic Technique, the Back Letter, and Advances in Chiropractic. Dr. Meeker's professional career has focused on the clinical research and public health aspects of chiropractic, neuromusculoskeletal conditions, and complementary and alternative medicine (CAM). He is a proponent of the evidence-based approach to health care and is a strong advocate for the development of research capacity in the CAM professions.

and that there was a need for a stronger chiropractic research infrastructure and better scientific training and experience in the profession. To meet these needs, the CCCR is structured as a consortium of six chiropractic colleges, the University of Iowa, Kansas State University, State University of New York at Stonybrook, and the University of Calgary. The specific aims are to: establish linkage of academic centers with which chiropractic investigators are associated; establish an Advisory committee to provide research program advice; establish a bibliographic resource on chiropractic topics; develop a program of assistance activities to provide clinical research, basic scientific and technical assistance to potential chiropractic investigators; develop and implement research workshops, seminars, and educational materials; act as an institutional focus for formal training in research methodology; evaluate the feasibility of using data from chiropractors for research projects; establish a network of chiropractic clinicians and investigators in specific topic areas; link investigators to the technical expertise necessary to pursue research goals; prioritize research topics related to chiropractic treatment of musculoskeletal conditions; develop a mechanism for scientific and technical merit review of research proposals; and implement selected research projects (listed below):

Multisite Pilot of Chiropractic for Chronic Pelvic Pain: C. Hawk et al.: Palmer Center for Chiropractic Research, University of Iowa, Northwestern Health Sciences University, National University of Health Sciences.

A Pilot Study of Conservative Therapies for Sciatica: G. Bronfort et al.: Northwestern Health Sciences University, Palmer Center for Chiropractic

Conservative Treatments for Neck Pain: A Pilot Study: G. Bronfort et al.: Northwestern Health Sciences University, Palmer Center for Chiropractic Research

Load Distribution During Bilateral Manipulation: S. Kirstukas et al.: National University of Health Sciences, Palmer Center for Chiropractic Research

Effect of Vertebral Loading on Sympathetic Nerve Regulation: J. Pickar et al.: Palmer Center for Chiropractic Research, Kansas State University

Studies on Effects of Spinal Manipulation on the Immune Response: S. Injeyan: Canadian Memorial Chiropractic College

The Clinical Utility of Cervical End-play Assessment: M. Haas et al.: Western States Chiropractic College

Changes in Health Measures in HIV+ Chiropractic Patients: L. Caputo et al.: Western States Chiropractic College

Changes in Muscle Excitability After Spinal Manipulation: E. Suter, University of Calgary

Facet Capsule Biomechanics from Physiological Spinal Motions: P. Khalsa et al.: State University of New York

Palmer Center for Chiropractic Research
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The Palmer Center for Chiropractic Research (PCCR) is a component of the Palmer Chiropractic University Foundation in Davenport, Iowa. In the last five years, the PCCR has grown dramatically in terms of external funding and research productivity. Notably, the National Institutes of Health, Office of Alternative Medicine (now the National Center for Complementary and Alternative Medicine, NCCAM) awarded a center grant to establish the Consortial Center for Chiropractic Research (CCCR). This event was seminally important because it was the first significant NIH research funding ever awarded to the profession in its 100+ year history. The Director, nine faculty members, three research fellows, one post-doctoral fellow, and fourteen technical and administrative staff members are assigned full-time. The principal areas of scientific interest are: 1) Neurophysiology and Anatomy, 2) Clinical Biomechanics, and 3) Clinical Trials and Epidemiology. In addition to Research Administration, there are three research support cores: the Office of Data Management (ODM), the Animal Care Facility, and the Research Clinic.

The goal of the Neurophysiology and Anatomy program is to understand the contribution of neural input from paraspinal tissues to physiological and pathophysiological functions of the vertebral column. For example, experiments are conducted to examine: 1) the response of segmental (dorsal horn), suprasegmental (propriospinal) and supraspinal (medullary and thalamic) neurons in the central nervous system to vertebral loading, and 2) the reflex effects (somato-motor and viscero-motor) elicited by stimulation of primary afferents from the lumbar spine. It is expected that understanding the neural responses to vertebral joint movement will provide the rational basis for understanding the sensory mechanisms that may contribute to any effects of spinal manipulation.

The goal of the Clinical Biomechanics program research is to understand the biomechanics of the human body with a special focus on the effects of chiropractic spinal manipulations on the human spine. For example, experiments are conducted with unembalmed cadavers, isolated spine specimens, healthy subjects, and low back pain patients as well as computer models of the spine. Measurements of external loads, three-dimensional motion using optical sensors, three-dimensional forces, spinal intradiscal pressures, and ligament strains during manual treatment procedures are used.

The Clinical Trials and Epidemiology Research program can be discussed in three categories: randomized clinical trials and outcome studies, the Palmer Practice Based Research Program, and health services research projects. A major function of the PCCR is to conduct randomized controlled clinical trials of chiropractic care in selected patient populations. Data are also compiled from a network of 200 practicing chiropractors. Health services research in conducted using major public-use surveys.

The goal of the Consortial Center for Chiropractic Research (CCCR) is to examine the effectiveness and validity of chiropractic care and to provide assistance to researchers in developing high-quality research projects. The rationale for establishing the center came with the recognition that there was a small and incomplete body of chiropractic research,

Palmer

Center for Chiropractic Research

Presentation by William C. Meeker, DC, MPH

To

The White House Commission on Complementary and Alternative Medicine

October 5, 2000

741 Brady Street, Davenport, Iowa 52803
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Presentation by William C. Meeker, DC, MPH, Director of Research, Palmer Center for Chiropractic Research, Davenport, Iowa

The CAM movement and the values it represents are congruent with the desire for a more human-oriented health care system, and CAM research has the potential to help that transformation. It also interesting to note that CAM research is helping the move to evidence-based health care. Demands for evidence of the effectiveness of CAM has highlighted the lack of evidence for many established medical procedures and substances. Ironically, CAM may help make all of medicine more scientific.

I want to address two major points and put them in context.

First, the professions that are most interested in it will accomplish the best CAM research, because it is their professional duty. It is the obligation of chiropractic, for example, to develop its research capacity and conduct research in its training institutions, just like all the other health professions.

Second, which is a logical extension of the first, is that the Federal government has the duty and obligation as an agent of the public, to assist the development of the research capacity of the CAM professions, particularly chiropractic, just as it has for the other health professions.

The chiropractic profession already has a large role in health delivery in the U.S. With over 60,000 professionals, chiropractic is the 3rd largest doctorate health profession in the United States; and is by far the largest, most popular, best organized, and most regulated of the CAM professions. Between 11% and 15% of the U.S. population visits a chiropractor every year. This translates to almost 200 million annual patient visits to chiropractors, which are about 30% of total visits to all CAM professionals. This translates economically to an estimated $8-9 billion in expenditures for chiropractic care. For contrast, visits to primary care medical doctors are not quite 400 million.

The Council on Chiropractic Education accredits all the 17 U.S. chiropractic-training institutions, which is in turn approved by the U.S. Department of Education. After years of work, Chiropractic Health Care is now an official section of the American Public Health Association. Spinal adjustments and manipulations have been studied in over 70 randomized clinical trials, and the procedure has been approved as a treatment option for back pain by the U.S. Agency for Health Care Policy and Research (now AHRQ). Chiropractors also deliver a large proportion of other CAM procedures and substances. Patients are a cross-section of U.S. demographics and present predominantly with musculoskeletal complaints. Studies also show that patients are very satisfied with chiropractic care and that they are willing to pay out-of-pocket for it.

Thus, I would submit that from many perspectives chiropractic is a mainstream health practice, and a considerably large one at that. In fact, a well-known CAM researcher at a famous medical school once told me that if we consider CAM to be a room, then chiropractic is the elephant standing in the middle. It simply cannot be ignored any longer.

For additional perspective, the implications of the buzzword "integration" must be understood as it relates to the CAM professions, particularly chiropractic. There is a major distinction to be made between procedures and substances; and professions. For example, chiropractic is a profession; the spinal adjustment or manipulation is a procedure.

Research on a treatment procedure or substance generally requires epidemiological and biological methods, while research on a health profession must be broader and should include at least the disciplines of sociology, economics, health services, anthropology, law, education, etc.

Procedures and substances are not synonymous with a profession and this has implications for a research agenda. Notice that effective new procedures and substances are relatively easy to integrate into conventional medical practice and there are

established pathways and a history of doing that. That process, which is rarely as scientific as we would like to think, defines the progress of medical innovation.

On the other hand, it is an entirely different thing to "integrate" professions; especially health professions that have historically been at odds. Although integration already occurs at the health consumer level, because patients choose and integrate the health care they want within the limits of convenience and cost, it is not happening on any large scale at the doctor-to-doctor level, at least not yet.

Thus, at the more structurally organized health system and policy levels, the key concept and challenge for integration is "interdisciplinary practice." But, there is only a very small amount of scientific literature in this area. The conclusion is this: if true CAM and conventional medicine integration is supposed to be the end result of CAM research, then the research agenda must be very broad and deep indeed; multidisciplinary, and inter-professional. And these attributes need to be elaborated explicitly in Federal polices designed to facilitate CAM research.

To reiterate my first point, the best CAM research will arise from the professions that are most interested in it; and from their organizations and institutions. To be more specific – the best chiropractic research will arise from the chiropractic profession and its training institutions. But the chiropractic profession needs help.

Let me be clear. The primary responsibility for chiropractic research lies squarely on the shoulders of the chiropractic profession. I accept this. It is not a choice; it is a professional obligation and duty. The chiropractic (and CAM) professions must develop their own inquisitive research culture. They must develop their theories, test hypotheses, refine their ideas, and communicate with the wider scientific community and the public. It is a professional obligation to continually strive to not prove - but to improve practice. Only by engaging in the scientific process will the CAM professions, including chiropractic, maintain professional autonomy, respect and jurisdiction over their futures.

If you believe as I do, that research is a profession's ultimate responsibility; and if you believe as I do that the best quality research will be arise from the profession that values it the most, then I hope you will logically agree with my second point. That is: the Federal government, which represents the will of the public, can and should assist the CAM professions and institutions in every possible way to develop their capacity to engage in high quality research and education.

As many of the presentations here today and tomorrow will demonstrate, the Federal government has many powerful ways to assist research. All of them should be brought to bear to help chiropractic, and other CAM professions, develop their own research capacities, just they have developed the research capacities of the other conventional health professions.

Chiropractic does not have an adequate research infrastructure. The fight with organized medicine, which was settled by an historic anti-trust lawsuit only a bit more than a decade ago, essentially kept chiropractic out of the scientific community and barred it from access to public-funded scientific and educational resources. Unfortunately, this engendered an anti-scientific attitude among some chiropractors that is just now beginning to diminish. Federal research funding to chiropractic institutions began only 6 years ago with a program established at the Health Resources and Services Administration. This has amounted to approximately $350,000 per year. In 1997, only 3 years ago, the NIH Office of Alternative Medicine awarded a 5-year center grant of $2.7 million to the Palmer Center for Chiropractic Research, which I head. That is not much money considering the size and impact of chiropractic. Our institutions are still almost completely tuition dependent and are run on shoestring budgets that would strangle any modern university department. Needless to say, resources for research are meager and what advances have been made are pure bootstrap labors of love. There is a scholarly community and peer-reviewed and indexed journals in chiropractic, but the effort needs to be much bigger and more productive.

Barriers to a larger research capacity in chiropractic include the aforementioned isolation from the wider health care and scientific communities; ignorance on the part of non-chiropractic health scientists; lack of scientific career training, mentorship and job opportunities; and particularly, the lack of chiropractic representation in research policy-making and political circles. To give just one very illustrative example, it is almost mind-boggling to realize that there is just one person, a single individual only, working in the Federal research bureaucracy who has chiropractic training. Only in the past 2 years have chiropractors been appointed to NIH study sections. To give another example from the private sector, the prestigious PEW Health Commissions Report, "Recreating Health Professional Practice for a New Century" never once uses the word chiropractic, even though it alludes to CAM and recommends that health education programs require interdisciplinary competence in their students. Chiropractors are not tracked as part of HRSA's health care workforce projections. I will however, acknowledge that the National Center for Complementary and Alternative Medicine now has two chiropractors on its Council. I am one of them.

What can be done? Here is a beginning of things that not only apply to chiropractic, but other CAM professions as well.

- Train CAM scientists. Provide programs, incentives, pre and post-doc positions, and career tracks for capable and interested young people.

- Create ways to encourage interdisciplinary, multidisciplinary, and inter-professional collaborations between CAM institutions and tax-supported universities.

- Apply the entire panoply of research project and program funding mechanisms to initiate, encourage, and support chiropractic and CAM research, including "bricks and mortar."

- Call for interdisciplinary conferences to explore scientific states-of-the-art on CAM topics and establish rigorous research agendas. Support the agendas with targeted research funding program announcements.

- Encourage the National Library of Medicine to include CAM topics and references in its indexing systems.

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

- Ensure that chiropractors and other CAM professionals are routinely appointed and otherwise included in research policy-making efforts. This would include the hiring of chiropractors at the same level as other doctors in the Department of Health and Human Services.

- Finally, consider that CAM professions and their institutions might benefit from special attention in order to jump-start their research efforts; perhaps something similar to the "Centers of Excellence" program in HRSA's Bureau of Health Professions.

In summary, I want to thank the organizers once again for this opportunity to speak my mind. CAM professions, as distinct from CAM procedures and substances, will, if supported properly and fairly, eventually produce the best quality CAM research. The full financial force and creative power of the government can and should be brought to bear to increase research in this way.

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Straus

Divider Title: _____

National Center for COMPLEMENTARY & ALTERNATIVE Medicine

Stephen E. Straus, M.D., Director
National Center for Complementary and Alternative Medicine

Biographical Sketch

Following an extensive nationwide search, Dr. Stephen E. Straus was appointed director of the National Center for Complementary and Alternative Medicine (NCCAM), a component of the National Institutes of Health (NIH), by the Department of Health and Human Services (DHHS) Secretary Donna E. Shalala. Officially assuming this position on October 6, 1999, Dr. Straus became the first permanent director of the NCCAM (formerly the Office of Alternative Medicine) after Congress elevated the Office to a fully-fledged Center in February 1999.

A nationally and internationally recognized expert in clinical research and clinical trials, Dr. Straus was Chief of the Laboratory of Clinical Investigation at NIH's National Institute of Allergy and Infectious Diseases (NIAID). He has extensive basic and clinical research experience related to many conditions, for which there are alternative or complementary remedies, including chronic fatigue syndrome, Lyme disease, AIDS/HIV, chronic hepatitis B virus and genital herpes infections and chronic post-herpetic pain. Dr. Straus is widely regarded for his clinical knowledge and studies involving patients with CFS, which began in 1979, even before the syndrome was named. He has an extensive background in investigations of the molecular biology, pathogenesis, treatment and prevention of human viral infections and immunologic diseases. Among his accomplishments in these areas was his demonstration that acyclovir suppresses recurrent genital and oral herpes, and the characterization of a previously unrecognized genetically determined disease, the autoimmune lymphoproliferative syndrome.

Dr. Straus' scientific training began at the Massachusetts Institute of Technology, where in 1968 he obtained his Bachelor of Science degree in life sciences in 1968. In 1972, he received his medical degree from the Columbia University College of Physicians and Surgeons. After his internship at Barnes Hospital in St. Louis, Missouri, Dr. Straus accepted a research associate position in the NIAID's Laboratory of the Biology of Viruses. Returning to Barnes Hospital for his residency, he earned a fellowship in infectious diseases at the Washington University. In 1979, he returned to NIAID as a senior investigator. Dr. Straus is board certified in internal medicine and infectious diseases. He has enjoyed a fruitful and challenging research career at the NIH for approximately 23 years.

Throughout his professional career, Dr. Straus has received numerous honors and recognition for his research contributions. The recipient of the 1999 Dutch National ME Fund Award for his CFS research, Dr. Straus' professional achievements have been recognized by election to many prestigious professional societies, including the Association of American Physicians and American Society for Clinical Investigation, and by appointment to the editorial boards of several scholarly journals. He is a recipient of five medals and other commendations from the U.S. Public Health Services, including the Distinguished Service Medal for innovative clinical research, and the HHS Secretary's Distinguished Service Award for drafting the blueprint to reinvigorate clinical research at the NIH. Dr. Straus has published over 300 research articles and edited several books.

Recent national surveys have confirmed the American public's increasing interest and use of complementary and alternative therapies for medical conditions and ailments that afflict them. Competently responding to the urgent public need for scientific evidence, clinical guidance and reliable information about the benefits, risks, and safety of many unconventional therapies, is what Dr. Straus credits as the foremost challenges underlying his decision to spearhead this effort by assuming the position as NCCAM's director.

Crafting a National Agenda for CAM Research

Address to
The White House Commission
for CAM Policy

October 5, 2000

Stephen E. Straus, M.D.
Director
National Center for Complementary and Alternative Medicine

NCCAM

CAM Domains

- Alternative Medical Systems
- Mind-Body Interventions
- Biologically-Based Treatments
- Manipulative and Body-Based Methods
- Energy Therapies

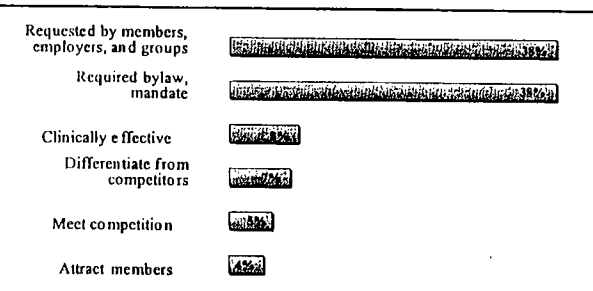
NCCAM

Choices and Expectations

- Most use is **complementary**, i.e as an adjunct to conventional care
- The minority use is as an **alternative** to conventional medical care
- Largely utilized with the hope of improving wellness and for relief of symptoms attributable to chronic degenerative or fatal illnesses

NCCAM

Most Important Reasons HMOs Add Alternative Care



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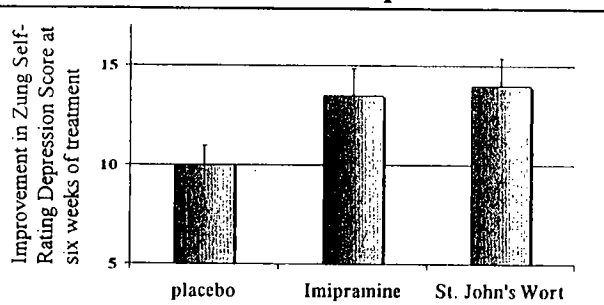
Landmark Health Care Report 1999

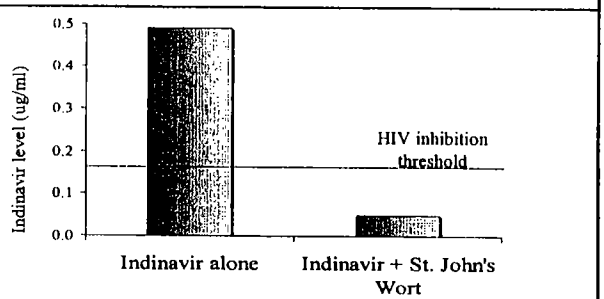
NCAM

St. John's Wort Improves Depression Scores as well as Imipramine



NCAM

St. John's Wort Lowers Blood Levels of the HIV Protease Inhibitor Indinavir



NCAM

Public Health Opportunities

- CAM practices are increasingly available to Americans.
- Some practices may sustain and improve health; some may not.
- The public deserves definitive guidance as to which practices are safe and effective.

NCCAM

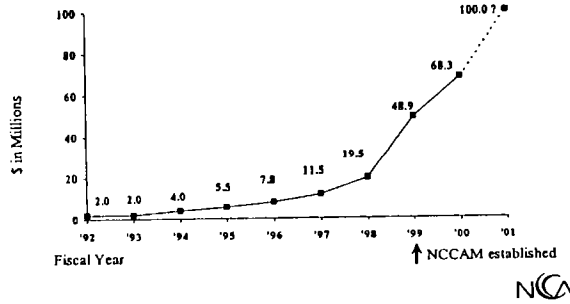
The Legislated Mandate

The general purposes of the National Center for Complementary and Alternative Medicine (**NCCAM**) are the conduct and support of basic and applied research.....research training, and other programs with respect to identifying, investigating, and validating complementary and alternative treatment, diagnostic, and prevention modalities, disciplines and systems.

P.L. 105-277

NCCAM

CAM Funding History



NCCAM

Strategic Areas

- Investing in Research
- Training CAM Investigators
- Expanding Outreach
- Facilitating Integration

NCAM

A Hierarchy of Evidence

Systematic Reviews

Large Randomized Clinical Trials
Small Randomized Clinical Trials
Uncontrolled Trials
Observational Studies
Case Studies
Anecdotes

NCAM

Investing in Research

- Clinical research
- Centers
- Basic science research
- Tied to NIH areas of emphasis
- Leveraged via collaboration

NCAM

Setting Research Priorities

- The most credible preliminary data
- The simplest study designs
- The ability to learn new science
- Use by the U.S. public
- Public health impact
- Adequate patient volunteers
- Availability of methodological expertise
- Study cost

NCCAM

Botanical Centers Program

- Identify and characterize botanicals
- Assess bioavailability and activity
- Explore mechanisms of action
- Conduct preclinical and clinical evaluations
- Training and career development
- Help select the product to be tested in RCTs

Developed with the NIH ODS

NCCAM

NCCAM Research Centers

- Cancer
- Arthritis
- Pediatrics
- Addiction
- Botanicals
- Cardiovascular Disease (CVD)
- Chiropractic
- Craniofacial Health
- Neurological Disorders
- Aging and Women's Health
- Minority Aging and CVD

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NCCAM-Funded Cancer Centers

Location	Johns Hopkins University
P.I.	Adrian S. Dobs, MD
Focus	Prostate and breast cancer • Oxidative stress in cells • Natural products in rodent pain models • Phase II study of PC SPES in prostate cancer • Prayer on breast cancer recurrence in Black Women

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NCCAM-Funded Cancer Centers
(cont.)

Location	University of Pennsylvania
P.I.	Stephen R. Thom, MD
Focus	Hyperbaric oxygen therapy in head and neck cancers • Efficacy trial • Hyperbaric oxygen effects on angiogenesis and tumor growth • Hyperbaric oxygen on cell adhesion • Effects of hyperbaric oxygen or nitric oxide synthesis

NCAM

Multicenter RCTs

Hypericum for depression	Duke U.	NIMH
Shark cartilage for lung cancer	CCOPs	NCI
Ginkgo biloba to prevent dementia	U. of Pittsburgh	NIA
Acupuncture for osteoarthritis pain	U. of Maryland	NIAMS
Glucosamine/chondroitin sulfate for osteoarthritis	U. of Utah	NIAMS

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Key Principles of CAM Research

- Use the same designs and outcome instruments as for definitive studies of conventional practices
- Randomized, double-blind controlled trials are the 'gold standard'
- Some modalities can not be blinded
- Studies of whole CAM 'systems' require creativity and flexibility
- CAM experts and patient advocates should be included in study design and oversight

NCCAM

CAPCAM

A 18 member, Federally-chartered advisory panel with expertise in: oncology, CAM, clinical trials, statistics, pathology, radiology, and bioethics.

Charge:

- Advise the Director, NCCAM
- Identify novel and promising research opportunities for CAM management of cancer
- Help communicate research results

NCCAM

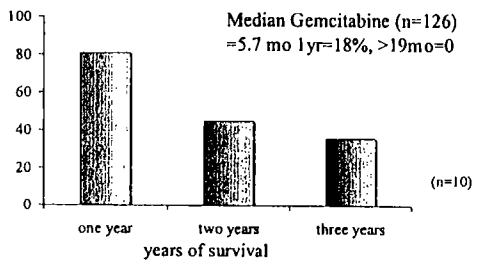
The Best Case Series

An NCI-designed instrument to identify promising CAM treatments through a retrospective review of a small number of cases

- The practitioner selects cases for review
- The diagnosis and outcome are documented
- The CAM treatment is well-described
- No confounding factors
- The survival time is unexpectedly long

NCCAM

Survival with Complex Regimen for Advanced Pancreatic Cancer



Gonzalez, *Nutrition and Cancer*, 1999

NCCAM

Gonzalez Regimen

Location	Columbia University
P.I.	Karen Antman, MD
Focus	Clinical trial to compare the efficacy of the Gonzalez regimen vs. standard care for treatment of inoperable pancreatic cancer
Therapy	Pancreatic enzyme therapy, ancillary nutritional support and detoxification procedures
Co-sponsor	NCI

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New NCCAM Cancer Research Opportunities

- Biobehavioral Pain Research
- Botanical/Drug Interactions
- CAM at the End-of-Life for Cancer and HIV/AIDS
- Quick Trials of Novel Cancer Therapies

NCCAM

Biobehavioral Pain Research

Goal	Examine the behavioral components of pain as well as promising interventions
Opportunities	Hypnosis, massage, spinal manipulation, acupuncture
Study Designs	Basic and clinical research
Mechanism	R01
Funding	Supported by NCCAM + 10 IC's

NCAM

CAM at the End-of-Life for Cancer and HIV/AIDS

Goal	Expand end-of-life care options for cancer and HIV/AIDS
Current Use	7-64% of cancer patients 27-100% of AIDS patients
Opportunities	herbals, vitamins, massage, acupuncture, mind-body, exercise
Study Designs	Phase I and II clinical trials
Mechanism	R01 and R21
Funding	Up to $2.5 million per year for 4 years

NCAM

Quick-Trials of Novel Cancer Therapies

Goal	Support novel, innovative studies for the treatment of cancer
Opportunities	Relaxation, imagery, meditation, support groups, herbals, dietary supplements, enzymes, Coley's toxin, antineoplastons
Study Designs	Phase I and II clinical trials
Mechanism	R21
Funding	Supported by NCCAM and NCI

NCAM

Training and Career Development

Pre- and Post-Doctoral Fellowships	F's and T's
Junior Faculty	K01, K02, K08, K23
Mid-Career Faculty	K24
Senior Faculty	K05
Curriculum Development - Research design, statistics, ethics, etc. - CAM for conventional clinicians and researchers	R25

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Facilitating Integration

- Research Portfolio
- Integration Initiative
- Extramural and Intramural Centers
- Training and Curriculum Development
- Communications

NCCAM

Outreach

- NCCAM Website
  http://nccam.nih.gov
- Information Clearinghouse
  (888) 644-6226
- CAM Citation Index
  http://nccam.nih.gov/nccam/resources/cam-ci/
- NCCAM Newsletter
- Town Meetings

NCCAM

Clinton Presidential Records
Digital Records Marker

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

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

Divider Title: Woodcock

#12 FDA Janet Woodcock?

Synopsis of Major FDA Regulations Affecting Research Related to Complementary and Alternative Medicine (CAM) Practices and Products

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Regulation for Dietary Supplements Structure or Function Claims (Effective 2/7/00, 21 CFR 101.93)

- Dietary supplement labels or labeling may, subject to certain requirements, bear statements "that describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, provided the statements are not disease claims" (21 CFR 101.93(f)).

- "Disease claims" are defined as "damage to an organ, part, structure, or system of the body such that it does not function properly ... or a state of health leading to such dysfunctioning ..., except that diseases resulting from essential nutrient deficiencies are not included in this definition ..." (21 CFR 101.93(g)(1)).

- FDA will determine whether a statement is a disease claim based on criteria identified under 21 CFR 101.93(g)(2).

Draft Guidance for Industry – Botanical Drug Products – (Issued 8/10/2000 for Public Comment (within 60 days)).

- Definition of "botanical drug": A product that contains as ingredients vegetable materials, which may include plant materials, algae, macroscopic fungi, or combination thereof, that is used as a drug, not including fermentation products and highly purified [or chemically modified] botanical substances.

- Guidance describes requirements for developing a botanical drug product, either for initiating an IND or for obtaining final NDA approval under section 505(b) of the Federal Food, Drug and Cosmetic Act, and how IND or NDA requirements may differ, as compared to the requirements for synthetic or highly purified drugs, with regard to the timing, sequence and/or extent of required preclinical testing.

- Regulatory requirements to initiate human studies will depend on
  - History of the product
  - Investigational use of the product
  - Degree of modification (from the "traditional" use) and
  - Novelty of the therapy.

Food, Drug and Cosmetic Act (FD&C)

CHAPTER II - DEFINITIONS

SEC. 201. [321]

(g)(1) The term "drug" means

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) of this title or sections 403(r)(1)(B) and 403(r)(5)(D) of this title, is made in accordance with the requirements of section 403(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

Subpart A—General Provisions

Sec.
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312.2 Applicability.
312.3 Definitions and interpretations.
312.6 Labeling of an investigational new drug.
312.7 Promotion and charging for investigational drugs.
312.10 Waivers.

Subpart B—Investigational New Drug Application (IND)

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312.31 Information amendments.
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312.34 Treatment use of an investigational new drug.
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Subpart C—Administrative Actions

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312.41 Comment and advice on an IND.
312.42 Clinical holds and requests for modification.

[redacted]4 Termination.
[redacted]5 Inactive status.
312.47 Meetings.
312.48 Dispute resolution.

Subpart D—Responsibilities of Sponsors and Investigators

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312.52 Transfer of obligations to a contract research organization.
312.53 Selecting investigators and monitors.
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312.56 Review of ongoing investigations.
312.57 Recordkeeping and record retention.
312.58 Inspection of sponsor's records and reports.
312.59 Disposition of unused supply of investigational drug.
312.60 General responsibilities of investigators.
312.61 Control of the investigational drug.
312.62 Investigator recordkeeping and record retention.
312.64 Investigator reports.
312.66 Assurance of IRB review.
312.68 Inspection of investigator's records and reports.
312.69 Handling of controlled substances.
312.70 Disqualification of a clinical investigator.

Subpart E—Drugs Intended to Treat Life-threatening and Severely-debilitating Illnesses

312.80 Purpose.
312.81 Scope.
312.82 Early consultation.
312.83 Treatment protocols.
312.84 Risk-benefit analysis in review of marketing applications for drugs to treat life-threatening and severely-debilitating illnesses.
312.85 Phase 4 studies.
312.86 Focused FDA regulatory research.
312.87 Active monitoring of conduct and evaluation of clinical trials.
312.88 Safeguards for patient safety.

Subpart F—Miscellaneous

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Subpart G—Drugs for Investigational Use in Laboratory Research Animals or in Vitro Tests

312.160 Drugs for investigational use in laboratory research animals or in vitro tests.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371; 42 U.S.C. 262.

SOURCE: 52 FR 8831, Mar. 19, 1987, unless otherwise noted.

Subpart A—General Provisions

§ 312.1 Scope.

(a) This part contains procedures and requirements governing the use of investigational new drugs, including procedures and requirements for the submission to, and review by, the Food and Drug Administration of investigational new drug applications (IND's). An investigational new drug for which an IND is in effect in accordance with this part is exempt from the premarketing approval requirements that are otherwise applicable and may be shipped lawfully for the purpose of conducting clinical investigations of that drug.

(b) References in this part to regulations in the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.