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EXPANDING HORIZONS OF HEALTHCARE

FIVE-YEAR STRATEGIC PLAN 2001-2005

National Center for Complementary and Alternative Medicine

NCCAM

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ACKNOWLEDGMENTS

National Center for Complementary and Alternative Medicine wishes to extend its sincerest gratitude to the many organizations and individuals who contributed to the development of this plan.

A special note of thanks goes to those who helped shape the draft strategic plan of NCCAM's predecessor, the Office of Alternative Medicine. Through their efforts, NCCAM was provided a well-developed foundation upon which to build.

We thank NCCAM staff and members of the National Advisory Council on Complementary and Alternative Medicine, who subsequently crafted and provided input to multiple iterations of the document as it evolved to its final form. We are also grateful to the directors and other senior officials at the National Institutes of Health (NIH) and the Department of Health and Human Services, whose broad perspectives have been incorporated to enrich the document substantially.

Finally, we acknowledge the efforts of over 200 individuals and organizations that reviewed the draft plan on NCCAM's Web site during the six-week period it was posted for public comment. It is their thoughtful responses that guided us in our attempts to create a document that is meaningful to multiple audiences and better accommodates the divergent sensibilities of our many stakeholders.

We look forward to collaborating further as we implement our first strategic plan.

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EXPANDING HORIZONS OF HEALTHCARE

FIVE-YEAR STRATEGIC PLAN

2001–2005

National Center for Complementary and Alternative Medicine

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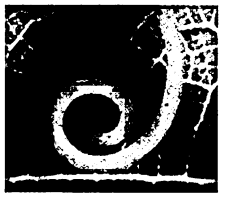

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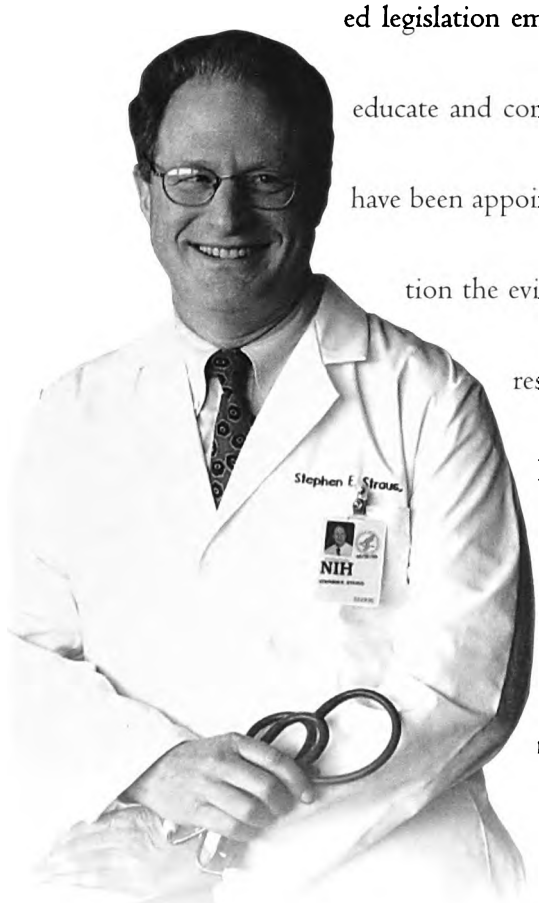
PREFACE

The growing appeal of complementary and alternative medicine (CAM) at the dawn of the 21st century creates both an opportunity and the obligation for scientific study and evaluation. As Americans become increasingly activist in their pursuit of sustained and improved health and well-being by exploring unconventional healthcare practices, so too, have we in the research community now joined in that exploration. We bring to that endeavor a curiosity and open-mindedness, motivated by the prospect of enhancing the healthcare repertoire, while at the same time mindful of the need to help protect the public from harm. • In establishing the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health (NIH) in 1998, Congress crafted legislation empowering us to conduct basic and clinical research, train researchers, and educate and communicate our findings to the public and professionals. I am honored to have been appointed the first Director of NCCAM; I am committed to bring to this position the evidence-based standards of science that have guided me though 23 years of research on important human infectious and immunologic diseases at the NIH. • I come to NCCAM cognizant of the formidable challenges that lie ahead, but with an optimistic vision of the value that scientific scrutiny can bring to the CAM field. Already there is mounting evidence—the result of initial rigorous investigations—that several therapeutic and preventative CAM modalities will be proven effective. We are also hopeful that advances in neuroscience will yield greater understanding of what



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WE BRING TO

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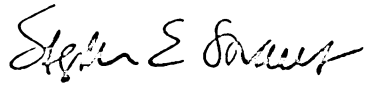
happens in acupuncture and meditation and what lies behind the placebo effect. Similarly, we expect that the basis for the effectiveness of selected herbal and nutritional supplements will be clarified and lead to their standardization and routine use, just as, a century ago, we learned what were the effective ingredients of willow and cinchona bark. Other modalities currently considered CAM will be found unsafe or ineffective, and an informed public will reject them. • As CAM interventions are incorporated into conventional medical education and practice, the exclusionary terms, "complementary and alternative medicine," will be superseded by the more inclusive, "integrative medicine." Integrative medicine will be seen as providing novel insights and tools for human health, practiced by healthcare providers skilled and knowledgeable in the multiple traditions and disciplines that contribute to the healing arts. • To achieve these goals and to ensure that our actions are commensurate with the public trust that has been given to NCCAM, we have developed our first strategic plan, *Expanding Horizons of Healthcare.* I am deeply grateful to my colleagues and the many organizations and individuals who have contributed to its development. Like the field of medicine itself, the Plan is a work in progress, and I look forward to our continued collaboration as our initiatives evolve. Together, we can strive to make NCCAM a recognized leader in the field within a vibrant, global research community.



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

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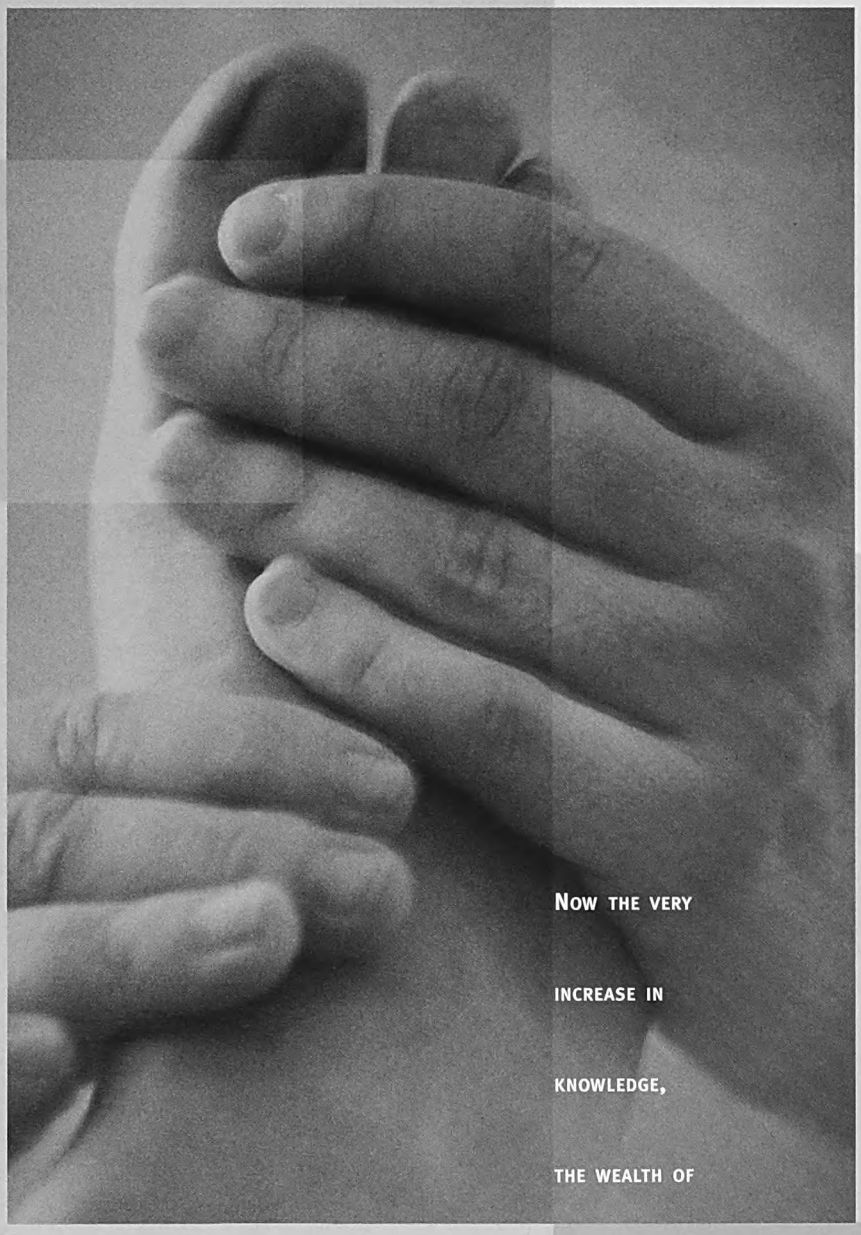

NOW THE VERY INCREASE IN KNOWLEDGE, THE WEALTH OF DATABASES AND ANALYTIC TOOLS AND TECHNIQUES, ARE POINTING TO THE NEED FOR SYNTHESIS

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PART I The Case for Action

Advances in medical science in the 20th century, coupled with improvements in sanitation and public health, resulted in dramatic gains in the health and well-being of Americans and a remarkable increase in average life expectancy from 47 years in 1900 to 76 years today. This stunning success was largely the result of declines in deaths from acute infectious disease—for example, tuberculosis, diphtheria, influenza, pneumonia—made possible by the development of vaccines and the advent of antibiotic drugs. To be sure, new and re-emerging infectious diseases remain serious, both locally and globally, as the AIDS epidemic has taught us, but the challenges for conventional Western mainstream medicine[1] (also known as allopathy and biomedicine) come increasingly from chronic diseases prevalent among the growing ranks of mature and older Americans. These adults, more informed and more demanding than their forebears, have high hopes of living long and well, free of disease and disability. Yet many will experience chronic and degenerative diseases that can drain their energies and incomes, increase their pain and suffering, and diminish their quality of life. Despite impressive new treatments and technologies, chronic diseases often resist cure and even symptom relief. Moreover, the increased reliance on technology as well as the economic imperatives and time constraints of managed care mitigate against the expressions of care and concern that should characterize the physician-patient relationship, a dialogue that enhances the healing process beyond the immediate effects of drugs and other treatments.

These issues are emerging at a time when the triumphs of reductionist biology are a daily fact of life, climaxed by the stunning announcement of the sequencing of the human genome in June 2000. Indeed, the cumulative advances in cell and molecular biology over the past few decades have helped medicine evolve from art toward science. Now the very increase in knowledge, the wealth of databases and analytic tools and techniques, are pointing to the need for synthesis, for a way to put the information together to understand how living organisms work as a whole. For the research scientist, this means the need to balance reductionism with integrative biology. For the healthcare provider, it means the need to balance medicine as the science of genes and molecules with medicine as the artful interaction of genes, cells, organ systems, and the whole person with the social and physical environment, which together determine the state of health and well-being of the individual.

THE APPEAL OF NONTRADITIONAL APPROACHES

Frustrated by the inability of mainstream medicine to meet all their expectations and needs, many people have turned to complementary and alternative medicine (CAM) approaches. These developments have been facilitated by the revolution in information technology, which is enabling easy access to sources of CAM information on the Internet and in print and electronic media. The advertising and marketing of alternative and complementary medicine have also grown apace, assuring increased public awareness and exposure to new products and approaches. Not surprisingly, more and more Americans—as many as 42 percent of the public according to one recent estimate—are adopting CAM approaches to satisfy their personal healthcare needs. Between 1990 and 1997, the number of Americans using CAM increased by 38 percent from 60 million to 83 million. Figure 1 indicates that visits to CAM practitioners between 1990 and 1997 increased from an estimated 427 million to 629 million, almost half again as many. Conservative estimates put expenditures for alternative medicine professional services at $21.2 billion in 1997, with at least $12.2 billion paid out-of-pocket. Indeed, Americans spent more out-of-pocket for CAM than they paid out-of-pocket for all hospitalizations—an amount comparable to the projected 1997 out-of-pocket expenditures for all U.S. physician services.[2]

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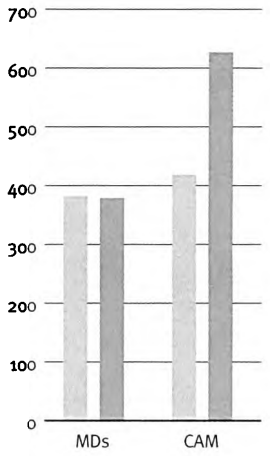


Figure 1
Growth of CAM Visits

From 1990 to 1997 the number of adults reporting use of CAM interventions increased from 60 million to 83 million. While the estimated number of visits to primary care physicians over the same time period remained stable, visits to CAM practitioners increased by 47 percent, exceeding visits to MDs by 243 million.

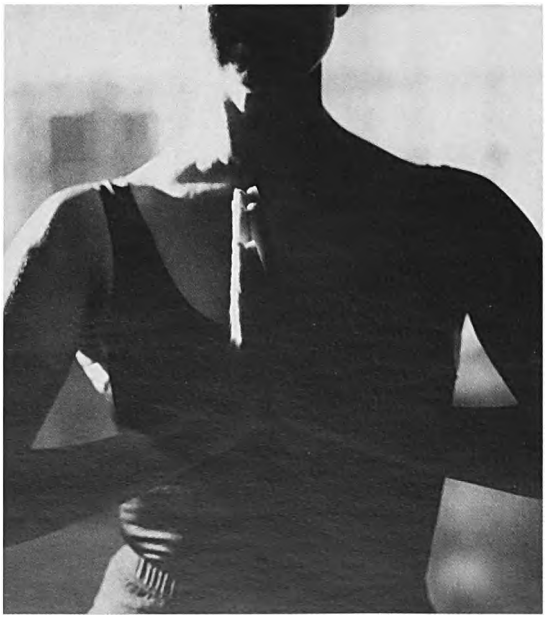
The five leading reasons for CAM visits were back problems, allergies, fatigue, arthritis, and headaches. (Eisenberg et al 1998).

CAM DESCRIBED

Complementary and alternative medicine practices are best described as those not presently considered an integral part of conventional medicine.[3] Implicit in this definition is the acknowledgement that as CAM practices are proven safe and effective, they may become adopted into mainstream healthcare practice. Generally, patients who choose CAM approaches are seeking ways to improve their health and well-being and to relieve symptoms associated with chronic or terminal illnesses or the side effects of conventional treatments. Interestingly, the overwhelming majority of patients adopting CAM approaches use them to complement conventional care, rather than as an alternative.[4] As diverse and abundant as the peoples and cultures of the world, CAM practices may be grouped in five major domains: alternative medical systems; mind-body interventions; biologically based treatments; manipulative and body-based methods; and energy therapies,[5] with some overlap across categories. For example, discrete practices such as meditation are considered mind-body interactions, but they are also included as part of some alternative systems of medicine. In addition to the examples below, Appendix I provides further information.

Alternative medical systems. Ayurvedic medicine, India's traditional medical system, is an example of an alternative system based on the principle that health is achieved by restoring the innate harmony of the individual. It emphasizes the equal importance of body, mind, and spirit. Many other non-Western societies embrace similar beliefs. Moreover, the dominant medical system in Europe from ancient Greece to the modern era was based on the belief that ill health resulted from an imbalance of the body's four humors (blood, phlegm, yellow bile, and black bile).

Mind-Body interventions. The practice of meditation, certain uses of hypnosis, prayer, and forms of art, music, and dance therapy are considered CAM mind-body interventions. Biochemical evidence of connections and interactions between the nervous system and endocrine and immune systems and evidence of benefit have led to the entry of certain mind-body interventions, for example, cognitive-behavioral therapies and various means of stress reduction, into mainstream medicine.



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Biologically based therapies. Herbal remedies, special diets, and food products used therapeutically are considered biologically based CAM practices. Herbs are defined as plants or plant products that produce or contain chemicals that act upon the body.

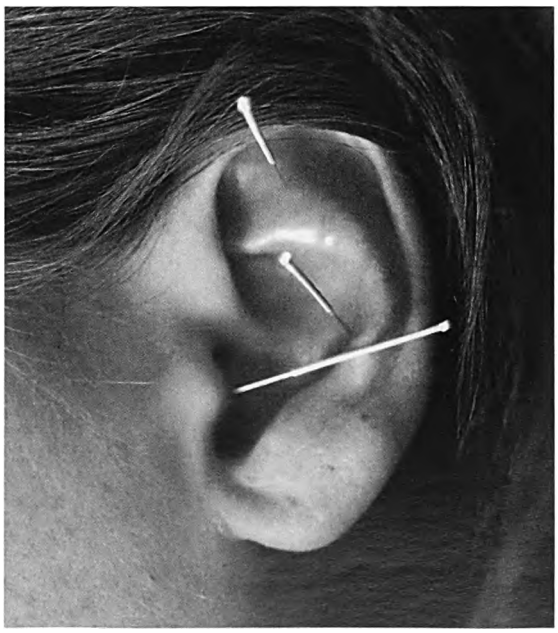
Manipulative and body-based methods. Chiropractic approaches in which the spine (primarily) is manipulated to restore health and function to the body is an example of a body-based method. Various forms of massage that involve manipulation of soft tissues and/or the musculoskeletal system are other examples.

Energy therapies. Therapies based on the activation or generation of energy fields either originating in the body or acting externally on the body are examples of energy therapies. Qi gong (pronounced 'chee gung') is a component of traditional Chinese medicine that combines movement, meditation, and regulation of breathing to enhance the flow of vital energy (qi) in the body to improve circulation and enhance immune function.

CAM YESTERDAY; MAINSTREAM HEALTHCARE TODAY

As noted, CAM practices once considered unorthodox in the United States can become part of the mainstream healthcare repertoire following demonstration of safety and efficacy by rigorous scientific investigation. For example, before Nixon went to China in 1971 and James Reston's compelling memoir that same year,[6] acupuncture was considered arcane. Today acupuncture is often prescribed to manage pain and sometimes to control the nausea associated with chemotherapy. More recently, investigators have reported positive results in the use of acupuncture to treat cocaine addiction.[7] (See the textbox.) Among the first drugs for treatment of high blood pressure was reserpine from the herb *Rauwolfia serpentina*, described many centuries ago in Indian Ayruvedic monographs. Indeed, some of our most important drugs, while not originating as CAM therapies, are derivatives of the active ingredients identified in herbal remedies. Such drugs of botanical origin include digitalis for the treatment of congestive heart failure and vincristine, and more recently, taxol, for treatment of cancers. There are indications that other herbal remedies and CAM practices may prove effective in preventing and treating chronic diseases, possibly reducing the costs of healthcare, as well as advancing our understanding of how healing works. At present, however, few of these practices have been tested for safety and effectiveness. Still others await discovery and validation of their worth.

Acupuncture for Addiction
53.8 percent of cocaine addicts treated five times a week with acupucture at sites in the ear tested free of the drug at the end of an eight-week study, In comparison, researchers reported that only 23.5 percent of addicts given sham acupuncture and 9,1 percent of subjects who watched relaxation videos were drug-free when tested in the final week. Further studies are needed to confirm these encouraging results.



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RESOLVING THE ISSUES

Despite their potential, untested CAM therapies may have unintended negative consequences.[8] They may interfere with or displace effective treatments (see Figures 2 and 3); they may expose patients to potentially toxic substances; and they may absorb resources that might be better invested in more appropriate treatment. Thus, it is critical to evaluate widely used CAM treatments for both safety and efficacy, as determined experimentally in rigorously conducted clinical trials. As appropriate, CAM therapies should also be evaluated for effectiveness (the measured outcome of routine use within the general population).

Beyond testing prevalent CAM interventions, it is also important to identify promising CAM approaches that merit more intensive study. To pursue these investigations, we must train, encourage, and support skilled investigators in both CAM and conventional medical academic communities. Furthermore, we must present credible, rather than anecdotal, data to a curious public. Finally, we must broaden the knowledge base of CAM and conventional healthcare practitioners to encompass the full repertoire of safe and effective healthcare practices—truly expanding the horizons of healthcare. These practices can then be integrated into optimal interdisciplinary treatment plans developed in cooperation with patients. These imperatives dictate serious efforts in research, training, education, and communication, along with strategies to facilitate their interdisciplinary integration.

A Cautionary Tale

Figure 2 indicates the promise of St. John's wort as an antidepressant in a study showing that it compares favorably with a standard antidepressant, imipramine, and that both are significantly better than placebo[9]

However, **Figure 3** indicates that if St. John's wort is taken by subjects who are also taking indinavir, an HIV protease inhibitor, levels of indinavir in the blood are reduced below the level required to block HIV multiplication.[10]

Figure 2

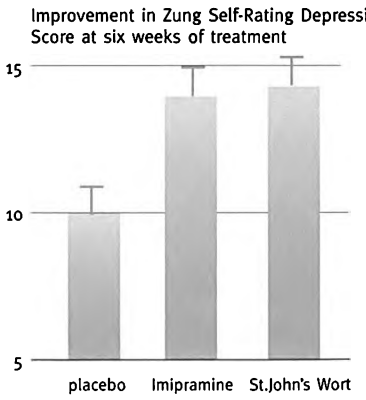
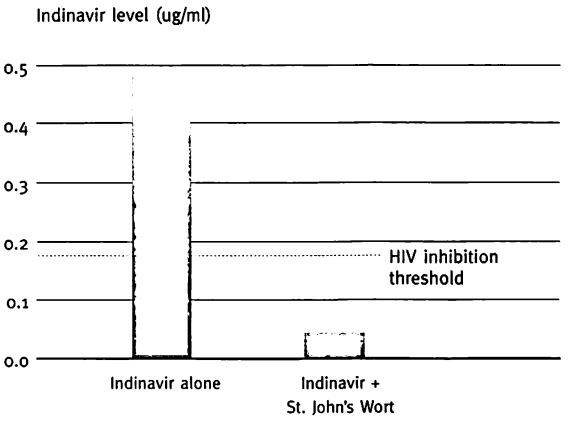


Figure 3



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RESPONDING TO PUBLIC DEMAND

In 1993, Congress formally established the Office of Alternative Medicine (OAM) at the National Institutes of Health.[11] In 1998 Congress expanded the status, mandate, and authority of the Office by enacting legislation to create the National Center for Complementary and Alternative Medicine (NCCAM).[12] NCCAM is charged to "conduct basic and applied research (intramural and extramural),[13] research training, and disseminate health information and other programs with respect to identifying, investigating, and validating CAM treatments, diagnostic and prevention modalities, disciplines and systems." Congress has expressed growing support for NCCAM's mission by providing progressive budget increases for the Center. (*See Figure 4.*)

Succinctly, NCCAM is dedicated to exploring complementary and alternative healing practices in the context of rigorous science, training researchers, and disseminating authoritative information. NCCAM's legislative history and milestones are summarized in Appendix II.

Figure 4

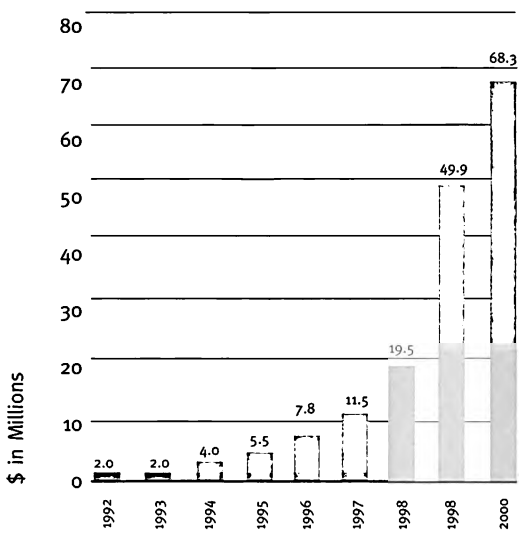

Figure 4

NCCAM funding. Appropriations increased dramatically following the establishment of grant-making authority to NCCAM in 1998, totaling $68.3 million in FY 2000. The additional investment in CAM research by other Institutes and Centers brings the total investment in CAM research at NIH in FY 2000 to approximately $161 million.

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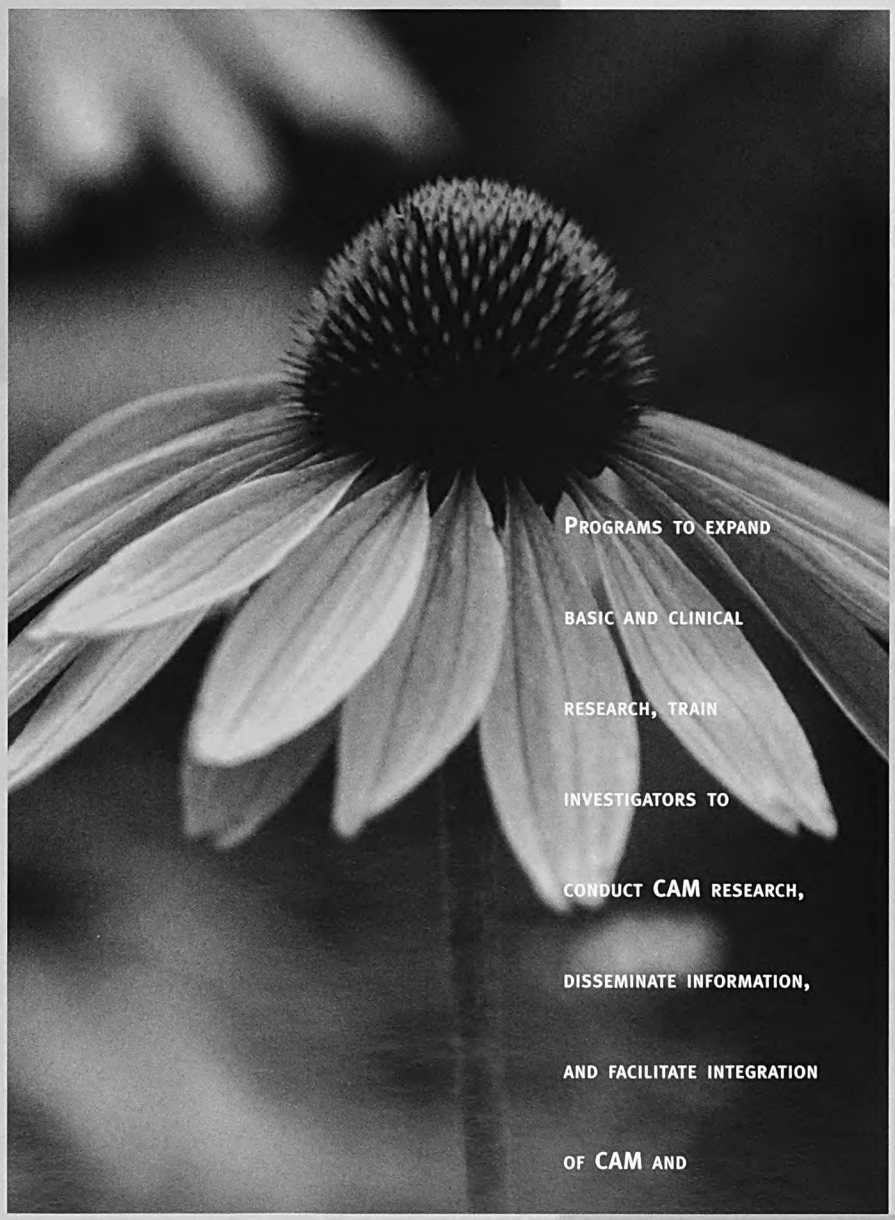

PROGRAMS TO EXPAND BASIC AND CLINICAL RESEARCH, TRAIN INVESTIGATORS TO CONDUCT CAM RESEARCH, DISSEMINATE INFORMATION, AND FACILITATE INTEGRATION OF CAM AND CONVENTIONAL HEALTHCARE DELIVERY ARE ESSENTIAL

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PART II Future Directions

NCCAM presently supports a broad portfolio of research,[14] research training and educational grants and contracts, which are summarized in Appendix IV. In addition, the Center conducts outreach activities, including the dissemination of information through the NCCAM Clearinghouse and the NCCAM Web site (http://nccam.nih.gov), which receives close to half a million hits a month. (See Appendix V for a more complete description of NCCAM outreach activities.) Programs to expand basic and clinical research, train investigators to conduct CAM research, disseminate information, and facilitate integration of CAM and conventional healthcare delivery are essential in moving the CAM field forward. Our priorities in each of the four areas of research, research training, information dissemination, and integration are outlined below.

RESEARCH

The Clinical Imperative. The extensive use of untested CAM practices by the public dictates that NCCAM make clinical research[15] its highest priority and the centerpiece of its research portfolio. In this regard, the Center's approach differs significantly from that of the other NIH Institutes and Centers where the emphasis is on the discovery of new knowledge through basic research. In contrast CAM consumers and healthcare practitioners want to know now whether available options are safe and effective. Thus, while essential basic information will be sought in parallel, NCCAM is committed to the clinical study of promising CAM substances and modalities before knowledge becomes available about their active ingredients, mechanisms of action, stability, and bioavailability.

To help identify fertile areas for clinical investigation and the appropriate level of investment in these areas, the Center relies on evidence-based reviews (described in Appendix VI). These analyses indicate that information regarding the efficacy and safety of CAM therapies spans a continuum ranging from anecdotes and case studies through encouraging data derived from small, well-developed Phase I and II clinical trials (Table I).

Several additional factors, such as the extent of utilization by consumers, the potential for public impact, the opportunity to expand the science base, feasibility, and cost are also considered, in no priority order, in selecting which treatments should be studied and at what depth.

Accordingly, NCCAM will support large (Phase III) clinical trials of CAM substances and modalities that appear from evidence-based reviews to be the most promising and important. A number of such trials are already underway, such as those to evaluate the use of St. John's wort for depression, research conducted in collaboration with the National Institute of Mental Health and the Office of Dietary Supplements; *Ginkgo biloba* to prevent dementia, in collaboration with the National Institute on Aging, the National Heart, Lung, and Blood Institute, and the National Institute of Neurologic Disorders and Stroke; glucosamine and chondroitin sulfate for osteoarthritis, in collaboration with the National Institute of Arthritis and Musculoskeletal and Skin Diseases; and acupuncture in the treatment of osteoarthritis of the knee. Many more widely used, promising therapies are deserving of definitive study, including milk thistle for chronic liver disease, Echinacea for respiratory virus infections, and melatonin and valerian for sleep disorders. For other, less well-studied, but still promising approaches, NCCAM will fund initial Phase I or Phase II trials to establish the scientific rationale and methodological feasibility needed to justify large, randomized clinical trials. NCCAM will also seek to determine the potential for toxic or adverse reactions and for interactions with prescription and over-the-counter medications. Finally, NCCAM will invest as well in careful studies of popular interventions

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for which reports of efficacy are only anecdotal and no rational biomedical explanation for the mechanism of action has been proposed, such as magnet therapy. NCCAM also plans to pursue studies of placebo effects and how interactions between practitioners and patients may influence healing.

In addition to investigating individual therapies, NCCAM also aims to study entire systems of traditional and indigenous medicine that have been practiced over the centuries. Such studies may identify additional health tools of potential use to the American public and may present opportunities to address health disparities and the needs of special populations. This is an area highlighted for attention across the NIH and reflects the changing demographics of America. By 2050 it is estimated that the numbers of Latino, black, and Asian and Pacific Islander racial and ethnic groups will exceed the white non-Hispanic population. Many of these individuals will have absorbed traditions of healthcare and specific modalities practiced in their families and their countries of origin for generations.

Appropriate evaluation of CAM techniques and products will require that experts in the use of a given CAM modality are intimately involved in the design, conduct, and oversight of these studies. Also, diverse research designs will be needed to assess the spectrum of CAM techniques and products. For example, it is not possible to examine some CAM modalities (for example, massage) through double-blind trials, while others involve combinations of therapies that are custom-tailored to each patient's needs. In this regard, it is helpful that recent studies suggest that observational studies can be sufficiently well designed to yield data comparable to those of some randomized, controlled trials.[16,17,18] Notwithstanding the difficulties in designing some CAM studies, NCCAM will demand the same high standard of scientific excellence that is required throughout the NIH.

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

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

Table 1
Hierarchy of Evidence

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Collaboration. The efficiency with which we advance our research agenda will be enhanced by leveraging the resources and expertise of our colleagues in other NIH Institutes and Centers, other government agencies,[19] research institutions, the academic and international communities, and industry. The opportunities for such collaborations are abundant and it is gratifying that we have already found many partners at NIH and other agencies, and that centers of excellence throughout the world have expressed interest in working with us.

TRAINING

Our ability to achieve our research goals is dependent on the availability of a critical mass of skilled investigators in both CAM and conventional communities. Thus, NCCAM must encourage skilled researchers to investigate CAM approaches and train CAM and conventional practitioners to conduct or participate in rigorous studies. To this end, NCCAM will fully exploit the range of options within NIH's purview to promote the training and professional development of researchers. Specifically, we will make awards to both individuals and institutions, for both mentored and independent research, ranging from basic through clinical research projects. NCCAM also will work to promote collaborations between CAM and conventional practitioners and researchers, which are essential to moving the field forward.

INFORMATION DISSEMINATION

We regard as one of our highest priorities the need to inform the public, which today is immersed in media reports and Internet claims regarding CAM approaches, towards the safest and most effective practices and away from those that are risky or unsafe. Using all forms of communication, we must disseminate credible, not anecdotal data to a curious public that deserves complete and accurate information. Thus, we will aim to make available an abundance of timely and relevant materials for distribution, not only through the interactive capabilities of the Internet, but also as hard copy. Critical materials will be translated for non-English readers, as appropriate. We will hold open forums to engage the public in dialogue and interact with the scientific community at professional meetings.

INTEGRATION

Finally, NCCAM must work to overcome the reluctance of conventional healthcare providers to consider CAM therapies for their patients. If we are to capitalize on the opportunities to achieve changes in both the CAM and conventional healthcare communities, we must increase opportunities for training medical and post-graduate professional students to become educated about CAM. With this information, they may knowledgeably guide and refer patients toward safe and effective CAM applications and practitioners experienced in delivering them.

While many agree in principle regarding the merits of an integrated healthcare delivery system, there are numerous policy issues that await resolution before such a system can be fully implemented. These matters, including development and enhancement of clinical training programs, insurance reimbursement, licensing of CAM practitioners, and the relative roles of CAM and conventional providers, are not within the purview of NIH. Rather, their resolution falls to NIH's sister agencies in the Department of Health and Human Services, actions based on the findings of the White House Commission on Complementary and Alternative Medicine Policy, and concerned organizations.

As a component of NIH, NCCAM's role is to provide the scientific evidence to inform policy makers adequately. It is by holding CAM therapies to the highest standards of evidence, that we believe we will best facilitate the creation of an integrated healthcare delivery system in which conventional physicians and CAM practitioners work as an interdisciplinary team.

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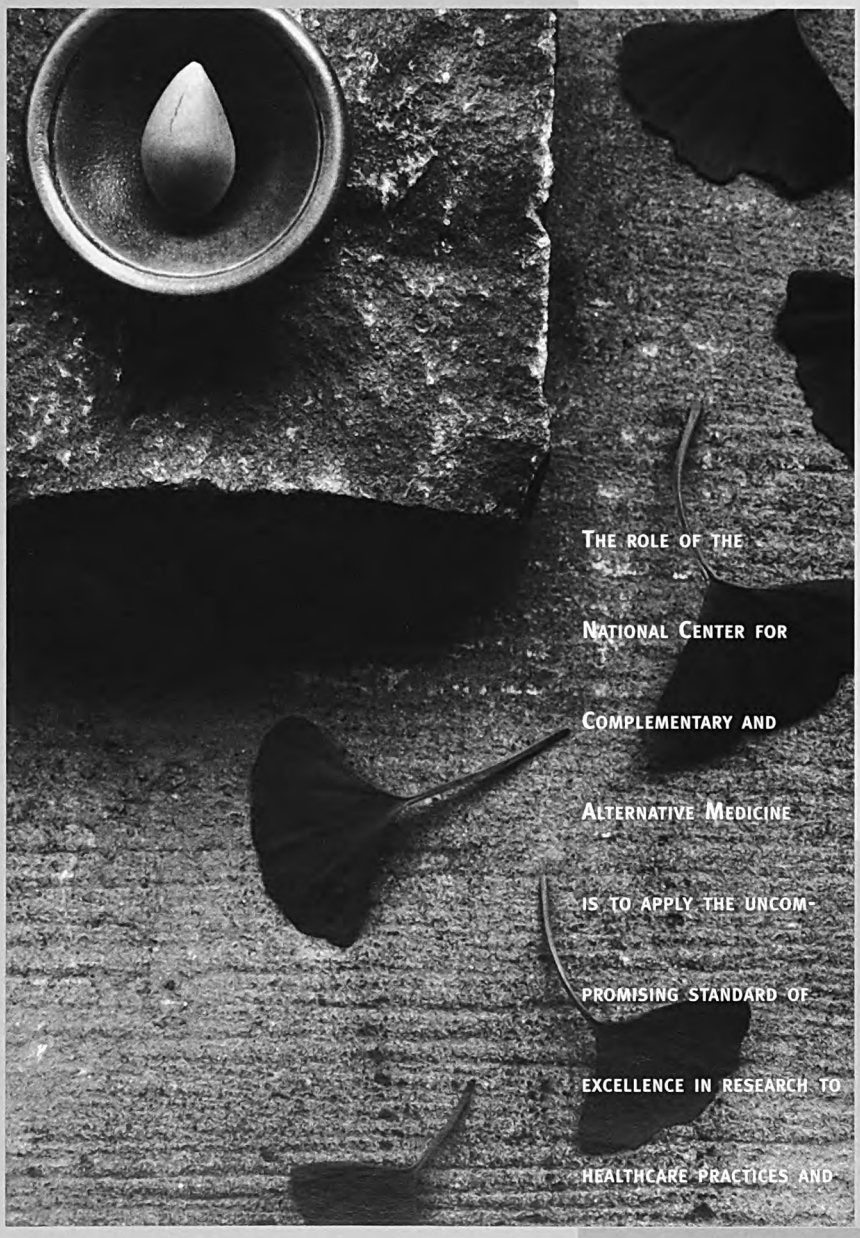

The role of the National Center for Complementary and Alternative Medicine is to apply the uncompromising standard of excellence in research to healthcare practices and products derived from many rich traditions.

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PART III NCCAM Strategic Plan

2001– 2005

The confidence of Congress in authorizing NCCAM to fund grants and contracts and providing increasing budgets to support them has served as the impetus for a review of Center activities with an eye to targeting its efforts toward expanding options of healthcare. For these reasons, we modified and expanded the 1998 Draft Strategic Plan developed by the then Office of Alternative Medicine to create this first NCCAM Five-Year Strategic Plan. The Plan embodies the principles discussed in Part II, articulates our mission and vision, identifies principal stakeholders, proposes strategic initiatives and goals, and specifies the management principles under which NCCAM will operate in carrying out its mission. We are indebted to our staff and NIH colleagues, advisory councils, workshop attendees, numerous healthcare providers, and the public at large for the cumulative wisdom that has informed the Plan. It represents the first step in an ongoing planning process that will be used periodically to ensure that our priorities match developments in the field as it matures, and that they reflect an appropriate balance between pursuing scientific opportunity and addressing the healthcare needs of the public in promoting health and in preventing and treating disease. The ongoing planning process (described in Appendix VIII) will continue to solicit and consider input from the public and our many other stakeholders, facilitated by our Office of Public Liaison.

Our Mission

We are dedicated to exploring complementary and alternative healing practices in the context of rigorous science, educating and training CAM researchers, and disseminating authoritative information to the public and professionals.

Our Vision

NCCAM will advance research to yield insights and tools derived from complementary and alternative medicine to benefit the health and well-being of the public, while enabling an informed public to reject ineffective or unsafe practices.

The role of the National Center for Complementary and Alternative Medicine is to apply the uncompromising standard of excellence in research to healthcare practices and products derived from many rich traditions. We will employ best-in-the-world practices for the conduct of science and the management of research, training, and related activities. We are committed to the timely dissemination of research findings to the communities we serve, and in so doing regard it as of the highest importance to facilitate the merger of valuable CAM and conventional approaches into a practice of "integrative medicine." Such a practice will involve multiple healthcare professionals working as an interdisciplinary team, thus expanding the repertoire of ways to achieve and maintain health.

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

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Our Stakeholders

- Patients and the General Public
- Patient Advocacy Groups
- CAM Healthcare Researchers, Educators, and Practitioners
- Conventional Healthcare Researchers, Educators, and Practitioners
- Academic and Professional Associations
- NIH and other Government Agencies
- Research and Educational Institutions and Foundations
- International Research Organizations
- The Pharmaceutical, Nutriceutical, Dietary Supplement, and Biotechnology Industries
- The Media
- Congress
- Health Insurers

STRATEGIC AREAS

To achieve our vision, we have identified four strategic areas: Investing in Research, Training CAM Researchers, Expanding Outreach, and Facilitating Integration. Each of these strategic areas has evolved and will mature through an ongoing process of planning and evaluation, with substantial input from the National Advisory Council for Complementary and Alternative Medicine (Appendix IX lists members), and our stakeholders.

STRATEGIC AREA 1: INVESTING IN RESEARCH

NCCAM will advance research by encouraging and supporting CAM research projects according to the philosophies and priorities outlined in Part II.[20] The Center's highest priority is clinical research, both with respect to individual therapies and entire systems of medicine. While NCCAM will pursue investigations at all levels of the hierarchy of evidence outlined in Table I, our largest investment will be in Phase III clinical trials, with proportionately smaller investments in areas for which less evidence is available. NCCAM will also support basic science research, not only through studies whose primary aim is to elucidate basic mechanisms, but also by exploiting opportunities afforded by clinical trials.

The Center is also committed to building research capacity and infrastructure, both intramurally and extramurally, in the United States and abroad. Throughout these endeavors, the Center will pursue the many advantages afforded by collaborations nationally and internationally, as well as with fellow NIH Institutes and Centers, other government agencies, and industry.

GOAL 1

Stimulate submission of high-quality applications in CAM priority areas by both CAM and conventional investigators.

Objectives:

- Exhibit NCCAM information at professional meetings and conduct grant-writing workshops.
- Sponsor interdisciplinary conferences to stimulate broad-based research.
- Assist extramural CAM researchers and practitioners to develop and participate in high-quality research applications.

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GOAL 2:

Expand the scope of the NCCAM extramural research portfolio and participation by research subjects.

Objectives:

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

GOAL 3:

Create an NCCAM intramural research program.

Objectives:

- Design, conduct, analyze, and report rigorous CAM research, including, but not limited to, studies elucidating basic biology and pathogenesis mechanisms of action, outcomes research, pharmacologic investigations, epidemiology, and all phases of intervention trials (I–III).
- Conduct clinical and laboratory-based CAM research studies in close collaboration with extramural CAM scientists and with intramural staff of the other NIH Institutes and Centers.
- Provide an environment for training scientists and clinicians from diverse backgrounds in the healthcare professions in the conduct and analysis of CAM research studies, employing the highest standards of trial design and ethics.

GOAL 4:

Establish a global NCCAM research enterprise.

Objectives:

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

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STRATEGIC AREA 2: TRAINING CAM INVESTIGATORS

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

GOAL 1:

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

Objectives:

- Stimulate collaborations between CAM practitioners and investigators in the conventional academic medical community.
- Develop programs to train individuals in CAM-related laboratory and epidemiological research.
- Train doctors of medicine, osteopathy, chiropractic, and naturopathy, and others with advanced degrees in relevant clinical disciplines,[21] to conduct CAM-related clinical research.
- Initiate quality research training programs.
- Increase the number of trainees from under-represented populations.
- Establish an interdisciplinary, intramural NIH research training program.

STRATEGIC AREA 3: EXPANDING OUTREACH

NCCAM will strive to create a public image that conveys our dedication to exploring complementary and alternative healing practices and pursuing rigorous science, providing extensive, accurate information to consumers with sensitivity and compassion, and involving our broad range of stakeholders in shaping the Center's agenda. To this end, NCCAM will use a variety of methods, media, and technologies to provide a timely source of evidence-based, CAM information, and actively seek input from its stakeholders.

GOAL 1:

Enhance NCCAM's capacity to provide information to consumers, practitioners, and investigators.

Objectives:

- Develop and disseminate reliable scientific information that is culturally sensitive, engaging to the reader, and updated frequently to reflect the pace of change in the field.
- Respond with compassion and understanding to inquiries from consumers, directing them as appropriate, to a network of resources.
- Collaborate on information dissemination with other NIH entities and government agencies, international organizations, and foreign government and nongovernment agencies.

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GOAL 2:

Establish an effective dialogue with CAM stakeholders.

Objectives:

- Sponsor regional Town Hall Meetings to provide a forum for the public to contribute input and for NCCAM to share information regarding important research efforts and findings with the community.
- Seek ongoing, substantive input from leaders of CAM practice communities, CAM training institutions, advocacy groups, the mainstream academic and scientific communities, industry, partners in other NIH Institutes and Centers, and Federal agencies.
- Exhibit NCCAM-funded discoveries and opportunities at conventional scientific meetings and those of our CAM constituents.
- Develop media opportunities and strategies to disseminate research information and increase public understanding of NCCAM's mission.

STRATEGIC AREA 4: FACILITATING INTEGRATION

NCCAM will work to facilitate a more integrated practice of medicine. Within this paradigm, CAM and conventional healthcare professionals would function as interdisciplinary teams to deliver an expanded repertoire of safe and effective treatments that include a focus on the whole person. This goal is consistent with the increasing interdisciplinary nature of health-related research and the renewed focus on integrative biology. Only by holding CAM therapies to the highest standards of evidence will we best accomplish this broad aim.

GOAL 1:

Facilitate development of health education curricula that respect and incorporate insights and opportunities afforded by safe and effective CAM and conventional practices.

Objectives:

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

GOAL 2:

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

Objectives:

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

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PRACTICING RESPONSIBLE STEWARDSHIP

NCCAM will enhance customer service and continue to develop its valuable human resources, effective leadership, sound management practices, and efficient business systems in ways that reflect the trust placed in it by the American public.

GOAL 1:

Develop NCCAM's human resources.

Objectives:

- Exploit all available strategies to recruit and retain a motivated, highly qualified, well-trained, versatile, and flexible workforce that is committed to NCCAM's vision.
- Define roles and responsibilities of each staff member clearly.
- Vest staff with authority, accountability, and autonomy.
- Provide the resources staff needs to be successful in performing their respective roles.
- Foster diversity among NCCAM employees and enhance understanding and appreciation of cultural differences.
- Promote a work culture characterized by integrity, mutual respect, teamwork, and open communication.
- Reward excellence.
- Foster staff career development through practical experience, training, and other methods.
- Emphasize quality of work life.

GOAL 2:

Establish effective leadership, management, and administrative practices.

Objectives:

- Elevate standards of performance.
- Emphasize customer service.
- Enhance administrative infrastructure.
- Evaluate major NCCAM functions.

GOAL 3:

Engineer for efficiency.

Objectives:

- Streamline and automate business activities based on benchmarking best practices.
- Provide training for staff to enhance core competencies to maximize use of systems, technology, and equipment.
- Develop exacting management systems.

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ENDNOTES

1 Conventional medicine refers to medicine as practiced by holders of MD (medical doctor) or DO (doctor of osteopathy) degrees and their allied health professionals, some of whom may also practice complementary and alternative medicine.

2 Eisenberg, D.M. et al. "Trends in Alternative Medicine Use in the United States," 1990–1997. *JAMA.* 1998; 280:1569–1575.

3 This is the definition that NCCAM chooses to employ. There are others as well. For example, the definition assigned by Ernst, E. et al (Complementary medicine - a definition. Br J Gen Pract. 1995;45:506), and adopted in a slightly altered form by the Cochrane Collaboration (see Appendix VI) is "diagnosis, treatment and/or prevention which complements mainstream medicine by contributing to a common whole, by satisfying a demand not met by orthodoxy or by diversifying the conceptual frameworks of medicine."

4 Astin, J.A. "Why Patients Use Alternative Medicine—Results of a National Study." *JAMA.* 1998;279:1548–1553.

5 These are the categories within which NCCAM has chosen to group the numerous CAM practices; others employ different, broad groupings. Note also that only limited examples are provided within each category, and that no attempt was made to be exhaustive. Thus, the absence of any one CAM modality does not in any way imply its intentional omission.

6 *The New York Times.* July 26, 1971:1,6.

7 Avants, S.K., Margolin, A., Holford, T.R., Thomas R. Kosten, T.R. "A Randomized Controlled Trial of Auricular Acupuncture for Cocaine Dependence." *Arch Intern Med.* 2000;160(15):2305–2312.

8 Nortier, J.L., Martinez, M.M., Schmeiser, H.H., Volker, M.A., Bieler, C.A., Petein, M., Depierreux, M.F., DePauw, L., Abramowicz, D., Vereerstraeten, P., Vanherweghem, J.L. Urothelial Carcinoma Associated with the Use of a Chinese Herb (*Aristolochia fangchi*), *New England Journal of Medicine.* 2000;342(23):1686–1692.

9 Philipp, M., Kohnen, R., Hiller, KO. "Hypericum Extract Versus Imipramine or Placebo in Patients with Moderate Depression: Randomised Multicentre Study of Treatment for Eight Weeks." *BMJ.* 1999;319:1534–1539.

10 Piscitelli, S.C., Burstein, A.H., Chaitt, D., Alfaro, R.M., Falloon, J. "Indinavir Concentrations and St. John's Wort." *Lancet.* 2000; 355(9203):547–548.

11 Previous legislation provided $2 million in Fiscal Year 1992 to establish the Office of Alternative Medicine.

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

13 Approximately 82 percent of NIH's overall investment is made through approximately 35,000 grants and contracts supporting research and training in more than 2,000 research institutions throughout the U.S. and abroad. These grants and contracts comprise the NIH Extramural Research Program. Approximately 10 percent of the budget goes to NIH's Intramural Research Programs, the more than 2,000 projects conducted mainly in its own laboratories. About 8 percent of the budget is expended to administer the extramural and intramural research programs.

14 NCCAM's portfolio does not yet reflect the desired balance across all potential CAM practices. This is in part due to the lack of a research tradition in some fields of practice. To redress this situation, NCCAM will work with CAM communities to develop the requisite expertise. NCCAM also will seek to enlist experienced investigators with the expertise needed to undertake research across all CAM domains. These include areas such as neuroscience, bioimaging, and molecular biology.

15 For an overview of the concepts and practices involved in clinical trials, see http://clinicaltrials.gov.

16 Concato, J., Shah, N., Horwitz, R.I. "Randomized, Controlled Trials, Observational Studies, and the Hierarchy of Research Designs." *New England Journal of Medicine.* 2000;342:1887–1892.

17 Benson, K., Hartz, A. "A Comparison of Observational Studies and Randomized, Controlled Clinical Trials." *New England Journal of Medicine.* 2000;342:1878–1886.

18 Pocock, S.J., Elbourne, D.R. "Randomized Trials or Observational Tribulations?" 2000;342:1907–1909.

19 To foster NCCAM's collaboration within the Department of Health and Human Services and with other Federal agencies, NCCAM has organized the NCCAM Trans-agency CAM Coordinating Committee (NTACCC), which carries forward the work of the Trans-agency CAM Coordinating Committee established in 1997 by the NIH Director. The Committee comprises representatives of 22 of the NIH Institutes and Centers and the NIH Offices of AIDS Research, Behavioral and Social Sciences Research, Dietary Supplements, Extramural Research, Rare Diseases, Medical Applications of Research, Research on Minority Health, and Research on Women's Health. The Departments of Agriculture, Education, and Defense also are represented, and the Department of Health and Human Services sends representatives from multiple components (the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, Substance Abuse and Mental Health Services Administration). The White House Commission on Complementary and Alternative Medicine Policy is also represented.

20 Information for those interested in applying for grants may be found at http://nccam.nih.gov.

21 Note: The appropriate advanced degree varies by discipline.

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PART IV Appendices

APPENDIX I

MAJOR DOMAINS OF COMPLEMENTARY AND ALTERNATIVE MEDICINE

Complementary and alternative healthcare and medical practices are those healthcare practices that are not currently an integral part of conventional medicine.[1] The list of practices that are considered CAM changes over time as CAM practices and therapies that are proven safe and effective become accepted as mainstream healthcare practices. NCCAM groups CAM practices within five major domains, acknowledging that other groupings are possible: (1) alternative medical systems, (2) mind-body interventions, (3) biologically based treatments, (4) manipulative and body-based methods, and (5) energy therapies. The individual systems and treatments comprising these categories are too numerous to list in this document. Instead, we are providing examples within each domain. The absence of any one CAM modality in no way implies its intentional omission. Note also that there is some overlap across domains so that a CAM practice chosen as an example within one domain might also be classified within one or another of the five domains.[2]

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

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

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

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

Homeopathy and naturopathy are also examples of complete alternative medical systems. Homeopathy is an unconventional Western system developed in Germany that is based on the principle that "like cures like," i.e., that the same substance that in large doses produces the symptoms of an illness, in very minute doses cures it. Homeopathic physicians believe that even dilute remedies have great potency, provided that they are precisely selected based on detailed evaluations of symptoms to determine a patient's sensitivity. Therefore, homeopaths use small doses of specially prepared plant extracts and minerals to stimulate the body's defense mechanisms and healing processes in order to treat illness.

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

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

III. BIOLOGICALLY BASED THERAPIES — This category of CAM includes natural and biologically based practices, interventions, and products, many of which overlap with conventional medicine's use of dietary supplements. Included are herbal, special dietary, orthomolecular, and individual biological therapies.

Herbal therapies employ individual herbs or mixtures of herbs for therapeutic purposes. Herbs are plants or plant parts that produce and contain chemical substances that act upon the body. Special diet therapies, such as those proposed by Drs. Atkins, Ornish, Pritikin, and Weil, are believed to prevent and/or control illness as well as promote health. Orthomolecular therapies aim to treat disease with varying concentrations of chemicals, such as, magnesium, melatonin, and megadoses of vitamins. Biological therapies include, for example, the use of laetrile and shark cartilage to treat cancer and bee pollen to treat autoimmune and inflammatory diseases.

IV. MANIPULATIVE AND BODY-BASED METHODS — This category includes methods that are based on manipulation and/or movement of the body. For example, chiropractors focus on the relationship between structure (primarily the spine) and function, and how that relationship affects the preservation and restoration of health, using manipulative therapy as an integral treatment tool. Some osteopathic physicians practice osteopathic manipulation, a full-body system of hands-on techniques to alleviate pain, restore function, and promote health and well-being. Massage therapists manipulate muscle and connective tissue to promote optimal function of those tissues and promote relaxation and well-being.

V. ENERGY THERAPIES — Energy therapies focus either on fields believed to originate within the body (biofields) or those from other sources (electromagnetic fields).

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

Bioelectromagnetic-based therapies involve the unconventional use of electromagnetic fields, such as pulsed fields, magnetic fields, or alternating current or direct current fields. These therapies have been used to treat asthma or cancer or manage pain and migraine headaches, among other conditions.

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APPENDIX II

IMPORTANT EVENTS IN NCCAM HISTORY

October 1991	Legislative action (P.L.102–170) provides $2 million in funding for FY 1992 to establish an office within the NIH to investigate and evaluate promising unconventional medical practices.
	Stephen C. Groft, PharmD, appointed Acting Director of the new Office of Alternative Medicine (OAM).
September 1992	Workshop on Alternative Medicine convened in Chantilly, Virginia, to discuss the state of the art of the major areas of alternative medicine and to direct attention to priority areas for future research activities.
October 1992	Joseph J. Jacobs, MD, MBA, appointed first Director, OAM.
June 1993	OAM formally established under the National Institutes of Health Revitalization Act of 1993 (P.L.103– 43) to facilitate study and evaluation of complementary and alternative medical practices and to disseminate the resulting information to the public.
September 1993	First OAM research project grants funded through the National Center for Research Resources.
December 1993	Alternative Medicine Program Advisory Council established.
September 1994	Alan I. Trachtenberg, MD, MPH, appointed Acting Director, OAM.
January 1995	Wayne B. Jonas, MD, appointed second Director, OAM.
October 1995	Research Centers Program established to provide a nationwide focus for interdisciplinary CAM research in academic institutions.
October 1996	Public Information Clearinghouse established.
November 1996	OAM designated as a World Health Organization Collaborating Center in Traditional Medicine.
September 1997	First Phase III clinical trial funded to test the efficacy of *Hypericum perforatum* for treatment of depression.
October 1998	National Center for Complementary and Alternative Medicine established, by Congressional mandate, under provisions of the Omnibus Appropriations Bill (P.L. 105-277). This bill amended Title IV of the Public Health Service Act and elevated the OAM to an NIH Center.
January 1999	William R. Harlan, MD, named Acting Director, NCCAM.

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February 1999	Charter creating NCCAM, making it the 25th independent component of the National Institutes of Health signed. The law gave the NCCAM Director control of the Center's day-to-day financial and administrative management, as well as broad decision-making authority and fiscal responsibility for grants and contracts. Dr. Donna E. Shalala, Secretary, Department of Health and Human Services (DHHS), approved the charter of the Center on February 1, 1999, its first official business day.
May 1999	First independently awarded NCCAM research project grant made.
	NCCAM Trans-Agency CAM Coordinating Committee (TCAMCC) established by the NCCAM Director to foster NCCAM's collaboration across the Department of Health and Human Services and other Federal agencies. This committee superseded a trans-agency committee established by the NIH Director in 1997.
June 1999	Special Emphasis Panel chartered to enable NCCAM to conduct peer review of CAM research project grant applications.
July 1999	Cancer Advisory Panel for Complementary and Alternative Medicine (CAPCAM) created to assess preliminary clinical data related to treatment of cancer submitted by CAM practitioners.
August 1999	National Advisory Council on Complementary and Alternative Medicine chartered.
October 1999	Stephen E. Straus, MD, appointed first Director, NCCAM.

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APPENDIX III

STEPHEN E. STRAUS, MD, NCCAM DIRECTOR
Biographical Sketch

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

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

Among Dr. Straus's accomplishments is his demonstration that acyclovir suppresses recurrent genital and oral herpes, and the characterization of a previously unrecognized genetically determined disease, the autoimmune lymphoproliferative syndrome. The recipient in 1999 of the Dutch National ME Fund Award (the leading national prize from the Netherlands for research in myalgic encephelomyelitis/chronic fatigue syndrome), Dr. Straus's professional achievements have been recognized by his election to the Infectious Diseases Society of America, the Association of American Physicians, and the American Society for Clinical Investigation. He is a recipient of five medals and other commendations from the U.S. Public Health Service, including the Distinguished Service Medal for innovative clinical research, and the DHHS Secretary's Distinguished Service Award for drafting the blueprint to reinvigorate clinical research at the NIH. He serves on the editorial boards of several scientific journals, including the Journal of Virology and Virology.

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APPENDIX IV

NCCAM RESEARCH AND RESEARCH TRAINING PORTFOLIO[3]

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

RESEARCH PROJECTS

NCCAM has made awards to study a number of health conditions and populations. Included are a large number of Phase I (to evaluate safety), Phase II (to assess clinical activity) and Phase III clinical trials (to determine clinical efficacy) of a range of CAM therapies.

ARTHRITIS

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

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

CANCER

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

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

Shark Cartilage Trial (Charles Loprinzi, MD, North Central Cancer Treatment Group, Mayo Clinic) — The intent of this multisite, Phase III, randomized, blinded, controlled trial is to test the efficacy and safety of a powder preparation of shark cartilage for the treatment of patients with breast or colo-rectal cancer.

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

CARDIOVASCULAR DISEASES

Acupuncture and Hypertension: Efficacy and Mechanisms (Norman M. Kaplan, MD University of Texas Southwestern Medical Center) — Acupuncture has been advocated as safe and effective treatment of essential

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hypertension and other cardiovascular disorders (for example, heart failure, myocardial ischemia) that have sympathetic neural components. Using a randomized, double-blind placebo-controlled design for their Phase II trial, the investigators will test two major hypotheses: (1) electroacupuncture produces a long-lasting reduction in sympathetic nerve activity, thereby providing a safe and effective complementary treatment of human hypertension; (2) a major mechanism mediating the blood pressure lowering effect of acupuncture is the activation of somatic afferents, which trigger a naloxone-sensitive reflex suppression of central sympathetic outflow.

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

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

DENTAL DISORDERS

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

DIGESTIVE DISORDERS

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

GENERAL MEDICAL SCIENCES

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

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

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

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

LIVER DISEASE

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

MENTAL HEALTH

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

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

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

Omega-3 Fatty Acids in Bipolar Disorder Prophylaxis (Andrew Stoll, MD, McLean Hospital) *Cofunded with the National Institute of Mental Health* — The purpose of this Phase III clinical trial is to assess the efficacy of omega-3 fatty acids in preventing recurrence in patients with bipolar disorder, type I. One hundred and twenty outpatients with bipolar disorder, type I, will be randomly assigned to receive add-on treatment with omega-3 fatty acids or placebo, for one year. The primary goal is to assess the prophylactic effects of omega-3 fatty acids in a cohort of bipolar patients with a relatively high risk of recurrence.

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

MUSCULOSKELETAL DISORDERS

Efficacy of Acupuncture in the Treatment of Fibromyalgia (Dedra A. Buchwald, MD, University of Washington) – Ninty-six patients with fibromyalgia will be recruited for a 12-week, 24-treatment, 3-arm,

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randomized, controlled Phase II clinical trial. The active treatment group will receive true acupuncture. Control groups will be treated with acupuncture for an unrelated condition. These patients will receive needle insertion at nonchannel, nonpoint locations, or a true placebo. Short- and long-term efficacy and side effects will be measured using both subjective and objective measures of overall health and pain, to determine the optimal duration of treatment and examine the concordance of allopathic and acupuncture-based measures of outcome.

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

Pilot Study of Acupuncture in Fibromyalgia (Daniel J. Claw, MD, Georgetown University Medical Center) — A randomized, blinded, sham-controlled, 2-by-2 factorial Phase II trial will be conducted to examine the individual and synergistic effects of needle placement and stimulation on the efficacy of acupuncture as a therapeutic modality in fibromyalgia. The design allows determination of dose-effect for the analgesic effect of acupuncture.

Trial of Acupuncture for Carpal Tunnel Syndrome (Arthur Weinstein, MD, George Washington University Medical Center) — The major specific aim of this pilot study is to demonstrate that using a "single blind-mute" methodology, true and sham acupuncture can be administered in a standardized and unbiased fashion. The condition to be studied is carpal tunnel syndrome (CTS), a common, well-delineated syndrome causing hand pain with characteristic clinical and objective electrodiagnostic findings. Other aims of this study are: (1) to identify and standardize the most appropriate sham acupuncture points for CTS, (2) to develop a manual that standardizes the administration of true and sham acupuncture that can be used at any study site performing a randomized clinical trial (RCT)(3) to demonstrate that patient recruitment for and retention in an RCT of acupuncture for CTS is sufficient to justify a full-scale RCT, (4) to determine, in a small Phase II RCT, whether true acupuncture provides meaningful benefit for pain in CTS compared to sham acupuncture and whether the frequency of administration of acupuncture influences the outcome.

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

NEUROLOGICAL DISORDERS

***Ginkgo biloba* Prevention Trial in Older Individuals** (Steven DeKosky, MD, University of Pittsburgh) — *Cofunded with the National Heart, Lung, and Blood Institute, the National Institute on Aging, and the National Institute of Neurological Disorders and Stroke* — This is a multicenter, randomized, double-blind, placebo-controlled Phase III trial to determine the effect of 240mg/day of *Ginkgo biloba* in decreasing the incidence of dementia, in general, and Alzheimer's disease, specifically. The subjects will be aged 75 years and older. Secondary outcomes, including changes in cognitive function, incidence of cardiovascular disease and total mortality, will also be measured.

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

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

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

UROLOGICAL DISORDERS

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

WOMEN'S HEALTH

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

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

RESEARCH CENTERS

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

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SPECIALIZED RESEARCH CENTERS

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

- Craniosacral osteopathic manipulation and botanical treatment of recurrent otitis;
- Relaxation/guided imagery and chamomile tea as therapeutic modalities to treat functional abdominal pain; and
- The use of self-hypnosis, acupuncture, and osteopathic manipulation on muscle tension in children with spastic cerebral palsy.

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

- Herbal treatment of hepatitis C in methadone maintained patients (Phase I clinical trial); and
- Electroacupuncture examined for its effects and mechanisms of action.

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

- Effectiveness of Hawthorn in the treatment of heart failure;
- Effect of Reiki on noninsulin dependent diabetes mellitus patients with chronic diabetic painful neuropathy or deficits in cardiovascular autonomic function; and
- Effect of Qi gong and spirituality/psychosocial factors on wound closure, pain, medication usage and hospital stay in post-operative cardiac patients.

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

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

Craniofacial CAM Center (Alexander B. White, DDS, DrPH, Kaiser Center for Health Research) — The Center will investigate via Phase II clinical trials to determine whether:

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

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

- Basic mechanisms of meditation and CVD in older blacks;
- Effect of transcendental meditation on carotid artery intima-media thickness toward reducing hypertension; and
- Effects of herbal antioxidants on CVD in older blacks.

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

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

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

- The influence of a macrobiotic diet, as compared with the American Heart Association (AHA) Step I Diet, and an AHA diet plus flaxseed, on various endocrine, biochemical and cardiovascular parameters that might be influenced by estrogens and phytoestrogens (Phase II randomized clinical trial);
- Whether phytoestrogens provided in a macrobiotic diet influence bone metabolism in postmenopausal women (Phase II randomized trial);
- Whether treatment with black cohosh (*Cimicifuga racemosa*) reduces the frequency and intensity of menopausal hot flashes and other menopausal symptoms (Phase II, double blind, randomized, clinical trial); and the biological activities and mechanism of action of a Chinese herbal formula (whole formula and individual component herbs) on breast cancer cells in vitro and in vivo, as well as possible risks and/or benefits for women with breast cancer.

Consortial Center for **Chiropractic** Research (William Meeker, DC, MPH, Palmer College of Chiropractic) — The faculty and administrators of the Palmer Center for Chiropractic Research, Palmer College of Chiropractic; University of Iowa, Los Angeles College of Chiropractic, National College of Chiropractic, Kansas State University, and Wolfe-Harris Center for Clinical Studies, Northwestern College of Chiropractic have formed the Center to provide an infrastructure to examine the potential effectiveness and validity of chiropractic healthcare and to provide the appropriate clinical, scientific, and technical assistance to chiropractic researchers in developing high-quality research projects. The Center is investigating the:

- Load distribution during bilateral thoracic manipulation;
- Effectiveness of chiropractic for chronic pelvic pain (Phase I clinical trial);
- Effectiveness of chiropractic relative to conservative medical care for sciatica and neck pain;
- Effects of spinal manipulation on immune function;
- Utility of joint end-play assessment (palpation);
- Effect of spinal manipulation on muscle excitability;
- Effect of vertebral loads on sympathetic nerve regulation; and
- Facet capsule biomechanics.

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BOTANICAL CENTERS

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

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

UCLA Center for Dietary Supplements Research on Botanicals (CDSRB) (David Heber, MD, PhD, University of California, Los Angeles) — The UCLA Center fosters interdisciplinary research to develop systematic evaluation of the safety and efficacy of botanical dietary supplements. The CDSRB is:

- Determining the effects of putative active ingredients (lovastatin in Chinese Red Yeast Rice, EGCG in Green Tea, Hypericin in St. John's wort) compared to the combination of compounds (Monacolin, Catechins, Hyperforin/Hypericin) that naturally occur in these botanicals;
- Examining the specific immune-enhancing actions of Echinacea;
- Establishing a screening assay for plant estrogens;
- Developing information on the bioavailability of flavonoids; and
- Assessing the inhibitory effects of soy isoflavones compared to genistein on prostate cancer growth.

RESEARCH TRAINING

POSTDOCTORAL FELLOWSHIPS

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

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

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

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CAREER DEVELOPMENT AWARDS

Mentored Research Scientist Development Award — (provides support of a scientist, committed to research, in need of both advanced research training and additional experience)

Raymond G. Devries, PhD, St. Olaf College
An Ethnographic Study of Institutional Review Boards — This Mentored Research Scientist Development Award in Research Ethics focuses on describing the social influences on Institutional Review Boards (IRBs) and the decisions they generate. The research has two aims: (1) to promote the development of the applicant as a scholar in the ethics of research on human subjects and (2) to address the behavior and effectiveness of IRBs.

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

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

INSTITUTIONAL TRAINING GRANTS

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

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

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

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

UCLA/RAND Health Services Research Training Program — (Ronald M. Anderson, PhD., *Cofunded by the Agency for Healthcare Research and Quality [AHRQ]*) — NCCAM provides funds for one postdoctoral trainee, working in the area of chiropractic research, to complete the two-year master's degree program in the Department of Epidemiology in the UCLA School of Public Health.

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APPENDIX V

NCCAM OUTREACH ACTIVITIES

NCCAM Clearinghouse P.O. Box 7923, Gaithersburg, MD 20898, Phone: 888-644-6226, Fax: 301-464-3616 — The NCCAM Clearinghouse disseminates information to the public and healthcare providers about the NCCAM's programs and research findings through CAM fact sheets, information packages, publications, and a quarterly newsletter distributed to 6,000 public subscribers. During the first 10 months of FY 1999, the Clearinghouse received more than 18,000 requests for information, distributed more than 37,000 copies of publications, and made nearly 13,000 referrals to other NIH organizations, NCCAM's research centers, other governing agencies, or CAM organizations.

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

Combined Health Information Database (CHID) (http://chid.nih.gov) — In February 1999, NCCAM joined CHID, a cooperative effort of several Federal agencies organized to consolidate information related to health and disease contained in individual government databases within a single database. CHID also contains some health information materials not available in other government databases. Currently, CHID contains approximately 1,000 records covering the spectrum of CAM assembled by the NCCAM Clearinghouse or that are publicly available elsewhere.

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

Conferences — The Center sponsors conferences in areas of CAM practice and research, for example:

- *Placebo and Nocebo Effects: Developing a Research Agenda,* December 1996
- *Complementary and Alternative Medicine in Chronic Liver Disease,* August 22–24, 1999, with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the Office of Dietary Supplements (ODS), NIH, and the American Association of Naturopathic Physicians.
- *The Science of the Placebo: Toward an Interdisciplinary Research Agenda,* November 19– 21, 2000, A trans-NIH/DHHS conference.

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APPENDIX VI

EVIDENCE-BASED REVIEWS

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

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

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

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

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

The Cochrane Field Groups work in collaboration with approximately 50 Cochrane Research Groups (CRGs), arranged by disease specialty, to carry out systematic reviews related to their disease specialty. The CRG with which the Field works is determined by the research question. For example, examining whether massage is effective in increasing the weight of low birth weight infants is being done in collaboration with the Neonatal CRG, whereas exploring whether homeopathy is effective for asthma is being done in collaboration with the Airways CRG. Since formation of the CM Field, staff have produced the Cochrane Registry of Randomized Controlled Trials in Complementary Medicine. As of March 2000 the registry holdings include approximately 4,700 RCTs, 5,400 possible RCTs, 204 systematic reviews, and 1,812 hard copy reports in the archive. The registry is available in the Cochrane Library Controlled Clinical Trials Registry (CCTR).

NIH Consensus Development and Technology Assessment Conferences — NCCAM supports NIH consensus conferences on CAM-related areas through the Office of Medical Applications of Research at the NIH. *Integration of Behavioral and Relaxation Approaches Into the Treatment of Chronic Pain and Insomnia*, a technology assessment conference held in October 1995, was cosponsored with nine NIH components.[4] *Acupuncture: An NIH Consensus Development Conference* was held in 1997 to review the efficacy of acupuncture in therapeutic and preventive medicine, jointly sponsored with eight components of the NIH. [5]

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APPENDIX VII

NCCAM Cancer Advisory Panel for Complementary and Alternative Medicine 1999

CHAIR

HAWKINS, Michael, MD
Washington Cancer Institute
Washington Hospital Center
Washington, D.C. 20010

MEMBERS

CHOYKE, Peter L., MD
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APPENDIX VIII

STRATEGIC PLANNING PROCESS

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

NCCAM's Strategic Plan has also been shaped at each stage of the process by input from the Center's broad range of stakeholders. Evolving drafts have been reviewed by NCCAM staff, members of the National Advisory Council on Complementary and Alternative Medicine, senior officials at NIH, and opinion leaders within the conventional and CAM communities. The public-at-large and the broad research community also were afforded the opportunity to help shape the final report. Indeed, this document was modified to reflect the thoughtful comments contributed by over 200 individuals and organizations who, representing the diversity of our stakeholders, reviewed the penultimate draft during the six-week period it was posted on NCCAM's Web site.[6]

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

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APPENDIX IX

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ENDNOTES

1 The term *conventional medicine* refers to medicine as practiced by holders of MD (medical doctor) or DO (doctor of osteopathy) degrees and their allied health professionals, who may also practice complementary and alternative medicine.

2 Readers interested in obtaining additional information are referred to the NCCAM Clearinghouse (http://nccam.nih.gov/nccam/fcp/clearinghouse, P.O. Box 7923, Gaithersburg, MD 20898, Phone: 888-644-6226, Fax: 301-495-4957).

3 As of October 1, 1999.

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

5 Office of Medical Applications of Research; Office of Research on Women's Health; National Cancer Institute; National Heart, Lung, and Blood Institute; National Institute of Allergy and Infectious Diseases; National Institute of Arthitis and Musculoskeletal and Skin Diseases; National Institute of Dental and Craniofacial Disorders; and National Institute on Drug Abuse.

6 Many respondents contributed comments related to policy issues, such as licensing, insurance, and regulation. Such issues are not within the purview of NCCAM's mission. These comments have been transmitted to the White House Commission on Complementary and Alternative Medicine Policy, which has been constituted specifically to make recommendations on these matters.

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Public Health Service
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