National Center for Complementary and Alternative Medicine

Strategic Plan 2005–2009

Draft for Public Comment

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Executive Summary

Introduction

In February 2004, the National Center for Complementary and Alternative Medicine (NCCAM) celebrated its fifth anniversary as 1 of 27 institutes and centers at the National Institutes of Health (NIH). As stated in the law (P.L. 105-277) establishing NCCAM in FY 1999, its purposes for "the conduct and support of basic and applied research…research training, and other programs with respect to identifying, investigating, and validating complementary and alternative treatment, diagnostic and prevention modalities, disciplines and systems."

With that legal mandate in place, NCCAM moved quickly to develop its first 5-year strategic plan for 2001–2005, *Expanding Horizons of Healthcare.* Guided by input from the public and from complementary and alternative medicine (CAM) and conventional professional communities, the plan outlined a set of broad goals and objectives in four strategic areas: investing in research, training CAM investigators, expanding outreach, and facilitating integration, while pledging a commitment to practice responsible stewardship.

As the fifth anniversary of the Center and the plan approached, NCCAM initiated steps to develop a new strategic plan. The process again entailed seeking advice from NCCAM's stakeholder groups, who were provided with background material and analyses of the first plan (described in Part I: "Five Years of History, Lessons, and Challenges"). NCCAM's second 5-year strategic plan has used the lessons learned in meeting the challenges of the first plan to refine future directions—most importantly, to set priorities in all strategic areas—while affirming the original mission and vision statements.

Our Mission

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

Our Vision

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

Priority Setting

NCCAM's intent in managing its portfolio in the future is to concentrate on efforts likely to yield the greatest impact on the health and well-being of the public, using the following set of **master health goals** as important, but not exclusive, selection criteria:

- Enhance physical and mental health and wellness
- Manage pain and other symptoms, disabilities, and functional impairment
- Have a significant impact on a specific disease or disorder
- Prevent disease and empower the public to take responsibility for their health
- Reduce selected health problems of specific populations

Toward those goals, NCCAM also defines as high priority the need to increase basic research, and in particular, to work toward elucidating mechanisms of action underlying CAM practices. Indeed, the plan states as a guiding principle that, "In the absence of the science base or resources to enable studies of *why* a particular CAM practice works, investigators should first attempt to establish that it does indeed work. This is in keeping with the importance of supplying consumers with the reliable information they need to make informed decisions on their health care."

The Short and Long View. The new plan presents priority goals and objectives in the areas of research, research training, outreach, and governance, projected over the short and long term. There is some overlap—objectives that are common to several areas—and many aims are clearly very ambitious. NCCAM does not expect to achieve all its objectives in the next 5 years; some will be completed, while others will only have started. By establishing these aims as NCCAM's priorities, however, NCCAM is informing the public that these are the directions in which it wants to move. These priorities will be widely publicized and regularly updated to reflect research advances, new needs, and opportunities. To facilitate NCCAM's efforts, the Center will again look to its partners at the NIH and beyond for collaborations for the mutual benefit of shared resources and intellectual expertise in many areas of common interest. In addition, NCCAM is encouraging its stakeholders to aid the Center in building resources—tools, technologies, equipment, models, databases and the like—as well as recruiting the diverse intellectual capital needed to conduct CAM research.

Investing in Research

The major investment of NCCAM's budget is the support and conduct of research, so Strategic Area 1, *Investing in Research*, represents the largest set of goals and objectives in the plan. NCCAM now supports some 300 ongoing research projects—five times the level supported in the Center's first year—with grantees publishing widely in major peer-reviewed journals. Much of this research is clinically oriented, including studies of herbal/botanical products, acupuncture, Reiki, chiropractic manipulation, and a variety of mind-body practices. The new plan specifies eight sets of research goals, organized by the four principal CAM domains and whole medical systems, and the three areas of health services research, international health research, and ethical, legal, and social implications of CAM research and integrated medicine. The latter is a newly articulated area of research investment for NCCAM, based on the acknowledgment that integrating proven CAM practices with mainstream medicine is a desired outcome of CAM research, but with the realization that such integration, and even the conduct of CAM research itself, is restrained by a number of ethical, legal, and social issues that must be addressed.

The eight research areas are not represented equally across NCCAM's investment portfolio. The domain of biologically based practices has dominated NCCAM's research portfolio and will continue to do so in the future. High priority for NCCAM investment has also been assigned now to mind-body medicine. Not only do these two domains encompass a broad range of CAM practices in widespread use, but at least for some practices, there is a considerable research base on which to build, trained investigators to do the work, and well-defined hypotheses that can be tested. Ultimately NCCAM would like to see progress in all eight research areas, and it is with that aim in mind that each has been presented with its complement of goals and objectives.

A number of goals and objectives presented are a direct reflection of lessons learned over the past 5 years, such as the need for better quality control of the herbal/botanical products studied and the importance of conducting research to identify optimal doses and target populations before investing in large clinical trials. Without these preliminary studies, there is a risk that clinical trials could prematurely conclude that a CAM approach is ineffective.

Goals

Following is the list of the goals specified for the strategic areas of investing in **research, research training, outreach, and governance** in NCCAM's second strategic plan. The goals in the research area are organized according to the four CAM domains and whole medical systems and three areas of health services research, international health research, and ethical, legal, and social implications of CAM research and integrated medicine. Note that goals stating a broad aim, such as "verify and define the composition of botanicals," are not intended to apply to the universe of all botanicals, but to selected

products or practices of importance to CAM research because of the need to explore safety and efficacy/benefits and risks to the public.

Investing in Research

Mind-Body Medicine

Goal 1: Identify the common and specific features of widely used mind-body medicine practices.

Goal 2: Discover means of enhancing and accelerating the healing process beyond the effects provided by conventional medicine.

Goal 3: Explore the value of CAM therapies to reduce the burden of stress-related chronic illnesses.

Goal 4: Explore the value of CAM therapies to enhance resilience, coping, and wellness.

Goal 5: Identify the features of spirituality that may confer health benefits.

Biologically Based Practices

Goal 1: Verify and define the composition of botanicals.

Goal 2: Determine the mechanisms underlying the biological actions of selected CAM products and diets.

Goal 3: Determine the pharmaceutical and pharmacokinetic properties of selected CAM products.

Goal 4: Ensure the safety of selected CAM products and practices.

Goal 5: Establish the efficacy of selected biologically based practices to maintain health, prevent disease, and treat conditions of public health importance.

Manipulative and Body-Based Practices

Goal 1: Elucidate mechanisms of action operative in manipulative and body-based practices.

Goal 2: Determine the disorders and states of wellness for which selected manipulative and body-based practices may offer meaningful benefits and

specify the optimal circumstances under which the chosen manipulative and body-based practices are performed.

Goal 3: Study manipulative and body-based practices to determine their potential therapeutic or wellness benefits.

Goal 4: Determine the extent to which patient expectations prior to treatment and satisfaction following manipulative and body-based practices are related to objectively measured biological endpoints.

Energy Medicine

Goal 1: Apply in studies of energy medicine the same standards used in designing experiments in physics, chemistry, and other scientific disciplines.

Goal 2: Accelerate progress in understanding the source and biological effects of putative energy fields.

Goal 3: Enhance understanding of what transpires in the course of energy healer-patient interactions.

Whole Medical Systems

Goal 1: Acquire a richer understanding of CAM whole medical systems and how they operate within their indigenous and dispersed settings.

Goal 2: Document the benefits of some CAM whole systems treatments for selected health conditions.

Goal 3: Elucidate mechanisms underlying successful multimodal treatments used in CAM whole medical systems.

International Health Research

Goal 1: Advance understanding of traditional/indigenous medical systems through international collaborative studies.

Goal 2: Contribute to the preservation of irreplaceable and valuable traditional/indigenous CAM knowledge and resources.

Goal 3: Enhance understanding of processes that enable the integration of safe and effective CAM interventions with non-CAM interventions abroad and in the United States.

Health Services Research

Goal 1: Determine how CAM services affect the health care marketplace.

Goal 2: Enhance the design of CAM clinical studies and trials by adding instruments to collect health services research data.

Goal 3: Explore models of organized health care delivery that integrate CAM with conventional care.

Ethical, Legal, and Social Implications of CAM Research and Integrated Medicine

Goal 1: Enhance understanding of the social, cultural, and economic factors relating to the use of CAM.

Goal 2: Describe the framework needed to enable the creation of integrated, multidisciplinary research teams.

Goal 3: Encourage the creation of integrated research environments and practice communities.

Goal 4: Define and address ethical and legal issues related to the conduct of CAM clinical trials domestically and internationally.

Training CAM Investigators

NCCAM has succeeded in attracting many conventional investigators to CAM research but not enough CAM-trained professionals. The Center is currently completing an external evaluation of its research training and career development programs to suggest new, more effective approaches for enlisting CAM professionals in research endeavors. The development of mutually beneficial partnerships between CAM and conventional training institutions is one strategy that is showing promise.

Goal 1: Tailor a portfolio of research training programs reflective of the evolving needs of CAM research.

Goal 2: Continue to foster a research culture and the necessary resources to enable both CAM-trained and conventionally trained individuals to build successful careers in CAM research.

Expanding Outreach

From the outset, NCCAM recognized the importance of communicating CAM research findings to the public and practitioners to help them make better-informed choices. The Center operates an information clearinghouse, partners with the National Library of Medicine to maintain and update CAM on PubMed (www.nlm.nih.gov/nccam/camonpubmed.html), and provides an award-winning Web site (www.nccam.nih.gov), rich in information and resources to serve the public, health care providers, and investigators.

Goal 1: Help the public and health care professionals make informed health care decisions about CAM.

Goal 2: Enrich the pool of multidisciplinary CAM researchers.

Advancing Our Organization

Goal 1: Promote organizational growth.

Goal 2: Encourage and empower NCCAM's staff.

Goal 3: Optimize effective management of the public's investment in CAM research.

A Message from the Director

Congress established the National Center for Complementary and Alternative Medicine at the National Institutes of Health to bring scientific rigor to studies of what we have come to call "CAM." Indeed, this was a challenging mandate, given all that CAM encompasses—from acupuncture to Ayurvedic medicine, healing touch to homeopathy, massage to meditation—and more.

NCCAM accepted the challenge of building a comprehensive CAM research enterprise aware that it was entering a field fraught with controversy. After 5 years we can feel proud that the Center has done much to assure CAM critics and cheerleaders alike that our interests are their interests—and the public's interests—to establish the evidence that a CAM practice works for the purposes that it was designed for and is safe to use—and if not, why not. We stated these principles firmly in the Center's first 5-year strategic plan, *Expanding Horizons of Healthcare*, published in September 2000. The title of the plan was an expression of our hope that bringing sound science to the study of CAM would yield dividends—new therapies to benefit health, prevent disease, bring symptom relief, and enhance the quality of life. But the document made clear that there would be no equivocation in the face of negative findings. The evidence would speak for itself, even more loudly than any number of anecdotes or advertisements.

At the outset, we built a significant communications program for the public and professional groups as an integral part of the Center's operations. This outreach effort, along with the all-important needs of building the research base, training research investigators, and facilitating integration—looking forward to a time when CAM and conventional practitioners could work side-by-side in integrated health care programs—formed the four pillars of the Center's first strategic plan. Each of these four strategic areas specified goals to strive for and objectives to pursue.

Nearing the end of the first plan's timeframe, we initiated activities to inform and shape a second strategic plan, one that would take stock of all that happened in the start-up years and move on from there. As with the earlier plan, we sought advice from multiple audiences. We provided these groups with extensive background material on NCCAM's programs and budget, the results of several formal and informal evaluations, highlights of research and training over the years, and other data.

Part I of this document summarizes this background material to provide an overview of the Center's first 5 years. Importantly, it contains an appraisal of how NCCAM has measured up to the goals and objectives in the earlier plan, what lessons we learned, and what broad challenges remain.

This first section sets the stage for Part II, the new strategic plan itself, designed to guide NCCAM through the second half of its first decade: 2005 to 2009—and beyond, given that many of the goals and objectives are far-reaching. At the same time we have set

priorities in defining these goals. We want to limit investments to areas that appear the most promising, while remaining open to more high-risk ventures. In so doing, the plan aims to make the most prudent use of resources by a staff pledged to good governance. While we recognize there are practical limitations concerning what can be achieved in 5 years or more, there are no limits to the vision of the Center. The will to expand horizons of health care for the public, using advances from CAM research remains foremost, as does the dedication to explore CAM in the context of the most rigorous science.

Stephen E. Straus, M.D.

September 2004

Part I. Five Years of History, Lessons, and Challenges

The law (P.L. 105-277) creating the National Center for Complementary and Alternative Medicine in October 1998 (FY 1999) states that the Center's purposes are for "the conduct and support of basic and applied research…research training, and other programs with respect to identifying, investigating, and validating complementary and alternative treatment, diagnostic, and prevention modalities, disciplines and systems." The Center was the successor to the National Institutes of Health Office of Alternative Medicine (OAM), which had been established in 1991. The impetus for OAM had come from congressional leaders who recognized the growing popularity of complementary and alternative medicine and wanted NIH to bring its scientific expertise "to more adequately explore unconventional medical practices." OAM held a series of workshops to develop baseline information about the field and was able to initiate research studies by collaborating with and providing funds to other components of NIH.

OAM resources and authorities were limited, however, prompting Congress to create a *Center*. Elevation to Center status enabled NCCAM to take its place as 1 of now 27 relatively independent NIH institutes and centers (ICs), able to support an extramural research program through grantmaking authority—which NIH offices lack. The move was accompanied by a boost in the budget from $19.5 million for OAM in FY 1998 to $50 million for NCCAM in FY 1999.

Early Days

Recruitment immediately began for a Director for the new Center, resulting in the appointment of Stephen E. Straus, M.D., in October 1999. Dr. Straus is board-certified in internal medicine and infectious diseases and has had a distinguished career as an investigator at NIH in the National Institute of Allergy and Infectious Diseases, most recently as Chief of its Laboratory of Clinical Investigation (see Appendix II). With its new Director in place, NCCAM set about building an organizational structure and initiating strategic planning activities to guide Center activities.

Since the time of Dr. Straus's appointment, NCCAM staff has grown from 16 to over 90 individuals. The current structure and organization of the Center reflect a commitment to fulfill the mission, vision, goals, and objectives articulated in NCCAM's first 5-year strategic plan 2001–2005, *Expanding Horizons of Healthcare*. The plan, produced with widespread input from public and professional communities, was designed in part to allay the fears of CAM enthusiasts and skeptics by assuring them that the Center would neither condemn nor condone CAM, but was dedicated to the highest standards of rigorous science. In this context it would pursue goals and objectives in four strategic areas*: Investing in Research, Training CAM Investigators, Expanding Outreach,* and

Facilitating Integration. NCCAM's second 5-year strategic plan is both a response to how NCCAM has measured up in relation to the earlier plan and a statement of how the Center has refined its directions and priorities.

Defining the Scope of Research

NCCAM began by defining CAM as practices that are unproven by science and not presently considered an integral part of conventional medicine (also referred to as *biomedicine*, or *mainstream* or *allopathic* medicine). The definition of CAM acknowledges the dynamic nature of CAM, implying that as CAM practices are proven safe and effective, they will be integrated with mainstream health care. Within this definition, NCCAM groups CAM practices into four domains:

- Mind-body medicine, including meditation, yoga, the placebo effect, and actions associated with spirituality (such as prayer for one's health)

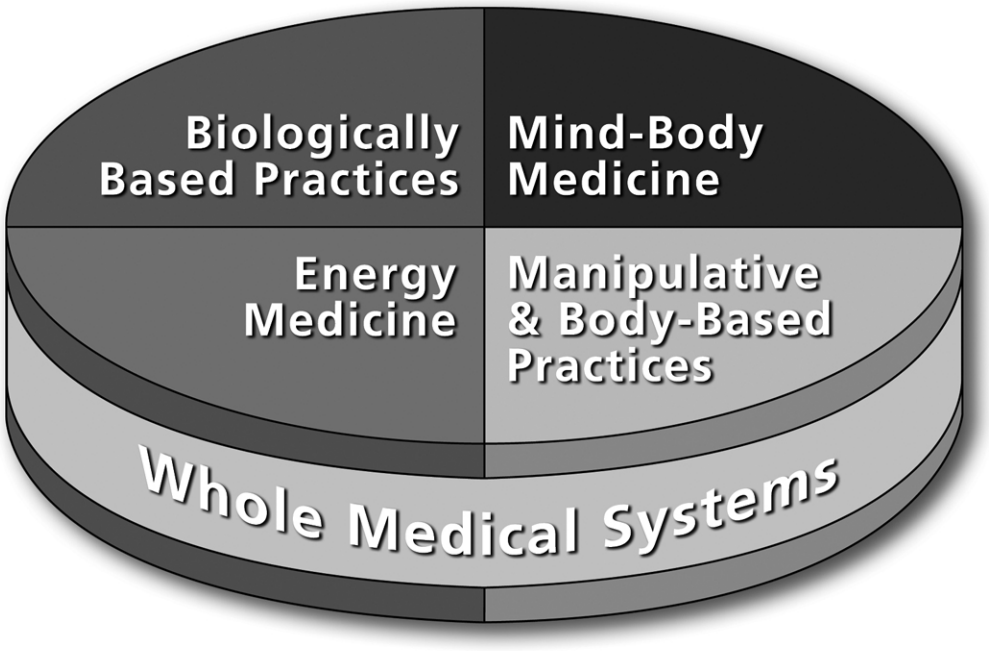
- Biologically based practices, largely the use of herbal or botanical products; selected compounds such as vitamins, minerals, and other molecules assumed to have therapeutic value; probiotics, strains of bacteria thought to be benign and to have healthful effects; and selected strict dietary regimens, purported to improve health and well-being

- Manipulative and body-based practices, exemplified by chiropractic and osteopathic manipulation and massage

- Energy medicine, involving the use of verifiable energy fields, such as electromagnetic radiation and sound, as well as biofields presumed to convey healing energies from master practitioner to patient

In addition, NCCAM studies **whole medical systems**, such as Indian Ayurvedic medicine, traditional Chinese medicine, and homeopathy. In the earlier plan, these systems constituted a fifth domain called "alternative medical systems." But since whole medical systems employ practices drawn from the four domains described above, it is more appropriate to place these systems in a class by themselves, as shown in *Figure 1*.

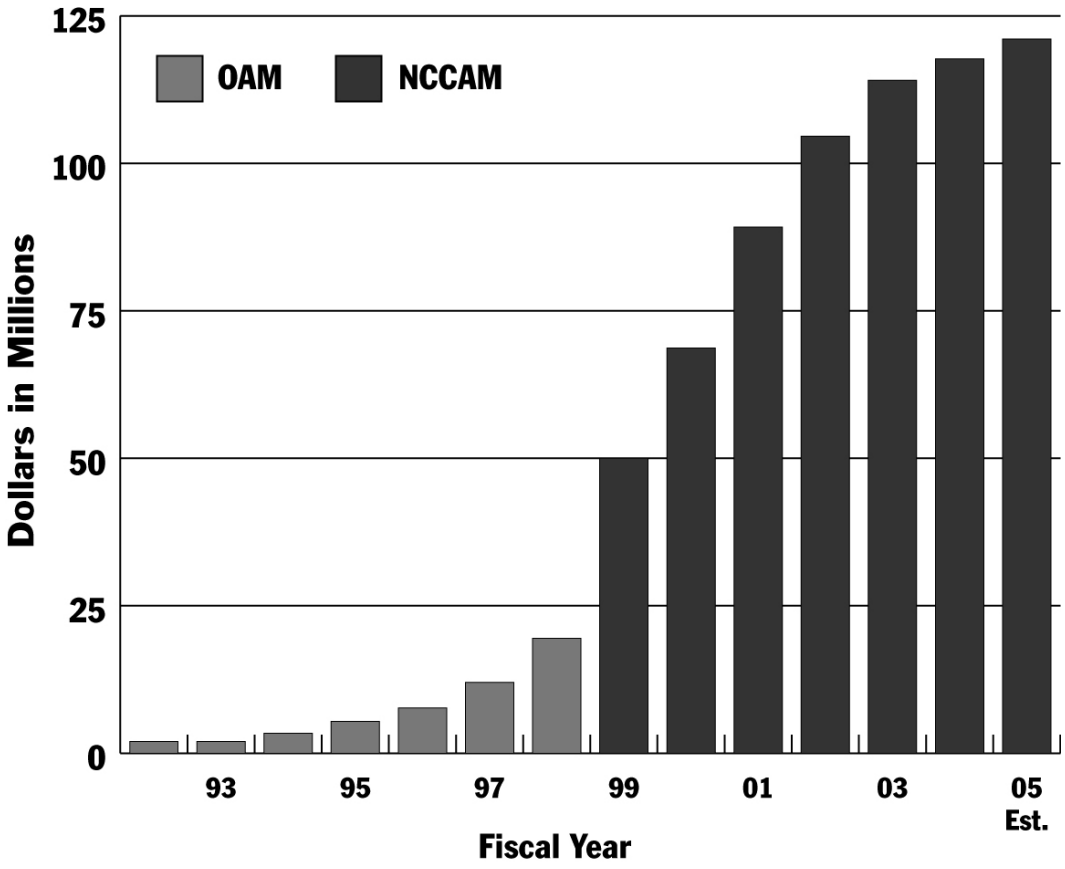
Figure 1. **Common CAM Practices**



Funding CAM Research

The Center's budget[1] continued to grow substantially after the initial $50 million appropriation, more than doubling to reach $104.6 million in FY 2002. Recent increases have been more modest, however, reflecting a general trend across NIH. The NCCAM FY 2004 budget of $117.8 million is 3 percent over FY 2003 and 0.4 percent of the total NIH budget of $27.8 billion for FY 2004 (*Figure 2).*

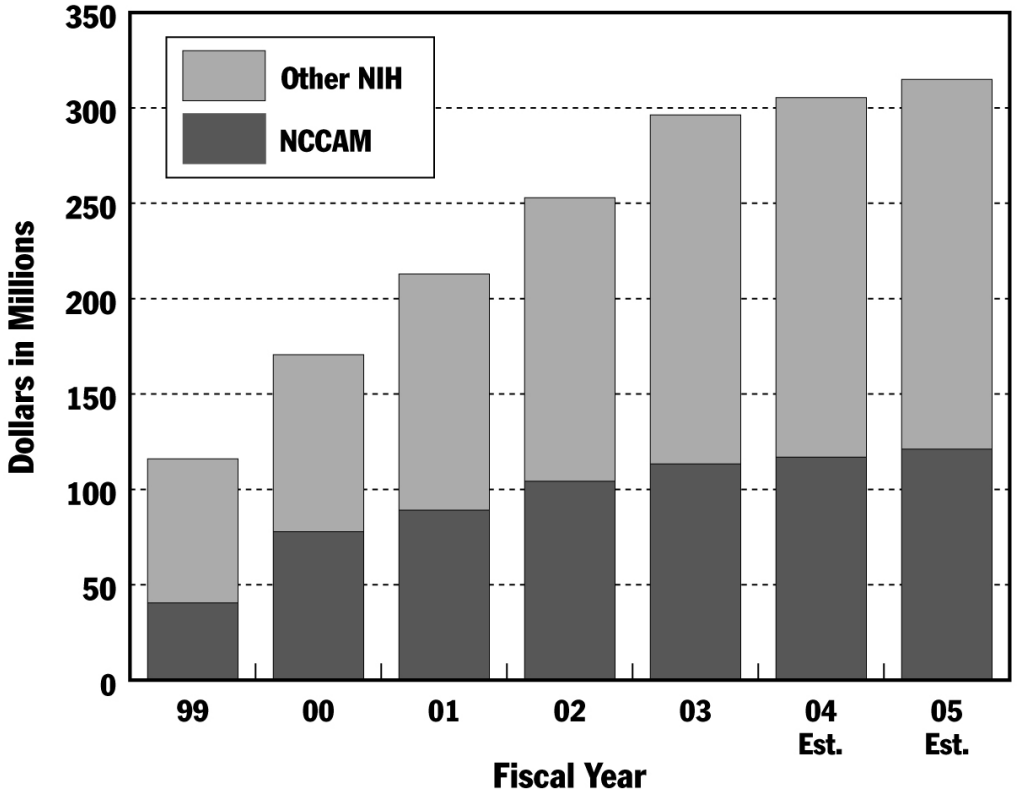
Figure 2. **NCCAM Appropriations History**



[1] There are slight variations in NCCAM budget figures in historic series and in various line items in the budget. These result from changes in accounting procedures or later revisions/corrections. They do not affect the overview of NCCAM's budget and the ways it is distributed as presented in this document.

In addition to NCCAM, other NIH components also fund CAM research, both independently and increasingly in partnership with NCCAM. Total NIH funding for CAM in FY 2004 is projected to be $305 million (*Figure 3*). At present, NCCAM is collaborating with 19 other ICs and the NIH Office of the Director on studies of CAM interventions for conditions either directly related to the missions of the other ICs, such as cancer, mental illness, and heart disease, or that involve health problems that are trans-NIH in nature, such as obesity, HIV/AIDS, and women's health.

Figure 3. **NIH and NCCAM Spending on CAM**



Operating in a collaborative and cofunding mode is very much NIH policy today, not only because of the perceived benefits of sharing resources and expertise across ICs, but also in light of NIH's Roadmap for Medical Research, meant to chart the course of medical research for the 21st century. The Roadmap, an initiative of NIH Director Elias A. Zerhouni, M.D., puts great emphasis on building interdisciplinary teams to advance medical progress and on reengineering clinical research to develop new partnerships—themes that are already a part of NCCAM's approach.

The Research Portfolio

NCCAM's ability to build partnerships across NIH reflects the broad purposes for which complementary and alternative medicine practices are used. Thus, the research and training projects that NCCAM supports cover a wide range, enabling the portfolio to be displayed across a number of important dimensions.

By Health Conditions

Research on the use of CAM in relation to cancer dominates NCCAM funding by categories of diseases or disorders. The next highest categories are mental health and pain research, followed by investments targeting a number of other major health conditions (*Figure 4).*

Figure 4. **NCCAM Research and Training Portfolio**
Distribution by Health Condition

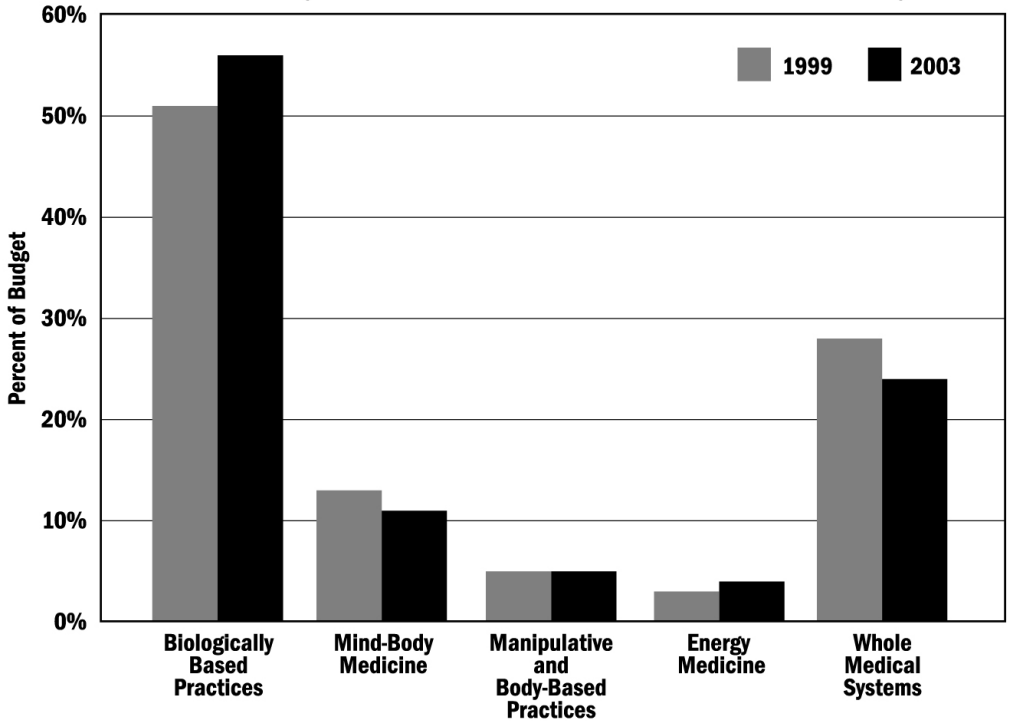
Health Condition	Dollars (in thousands)	Health Condition	Dollars (in thousands)
Cancer	15,433	Digestive	3,855
Mental Health	13,760	AIDS/HIV	2,700
Pain	13,590	Diabetes	2,217
Endocrine	11,931	Dental/Oral	2,097
Cardiovascular	10,409	Lung	1,737
Infectious Diseases	6,566	Obesity	1,176
Urologic	5,746	Immunology/Allergy	386

The conditions in the list are not mutually exclusive nor exhaustive of all categories of science NCCAM supports. For example, AIDS research is listed independently but is also included under Infectious Diseases.

By CAM Domains and Whole Medical Systems

Interestingly, the proportions spent for each of the four CAM domains and whole medical systems has remained relatively stable since NCCAM's founding (*Figure 5)*. Studies of biologically based practices, mostly herbal medicines, and whole medical systems research still dominate the portfolio.

Figure 5. **NCCAM Research and Training Portfolio**
Distribution by CAM Domain and Whole Medical Systems



By Gender

NCCAM research in relation to women's health has shown significant increases, from $14.8 million in FY 1999 to $30.4 million in FY 2003. The emphasis on women's health research correlates with their greater use of CAM practices, particularly in middle age, as revealed by the Study of Women Across the Nation, which NCCAM cofunds with the National Institute on Aging and other ICs. The outcomes of the Women's Health Initiative, which documented significant risks of prolonged hormone therapy, further stimulated NCCAM's investment in women's health. For example, the Center currently supports multiple studies looking at the potential of plant-based estrogens to relieve menopausal symptoms and for other health benefits.

By Vulnerable Populations

NCCAM participates in the NIH-wide initiative to reduce or eliminate health disparities among America's vulnerable populations, particularly racial and ethnic minorities. NCCAM is focusing on diseases like asthma, which are more prevalent in minorities, as

well as studying why and how ethnic and racial minority populations use CAM. Funding for health disparities research has risen from $3.9 million in FY 2000 to $11.5 million in FY 2003.

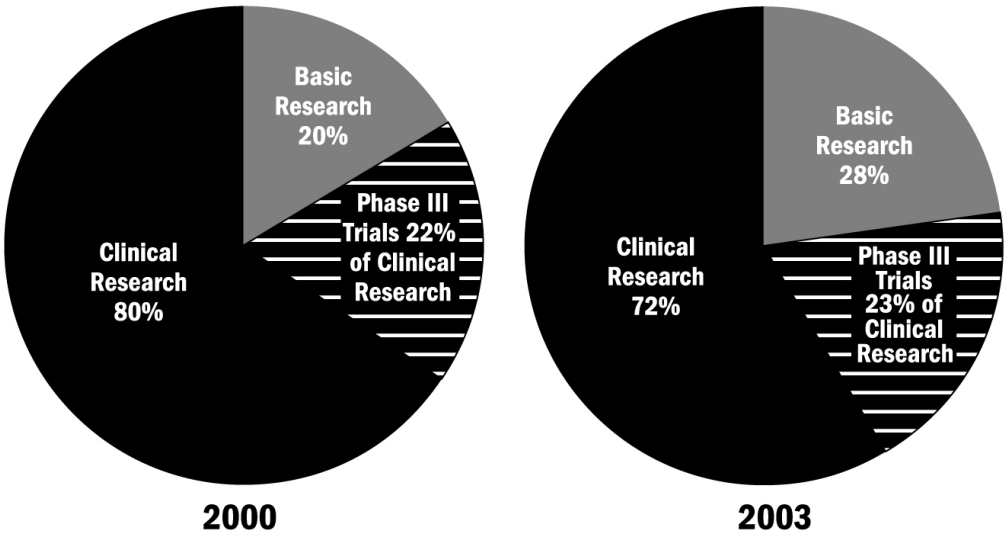
By Life Stage

Many CAM therapies are used to relieve symptoms as well as cure or prevent age-related diseases—or at least prevent the progression of diseases such as arthritis, heart disease, cancer, and degenerative neurological diseases, including the dementias. NCCAM funding for age-related CAM studies has shown a steady climb from $3.1 million in FY 1999 to $45.9 million in FY 2003.

The Balance of Basic and Clinical Research

NCCAM differs from other NIH components in the higher investment it makes in clinical research, a commitment the Center deemed essential in order to test the safety and efficacy of CAM products and procedures already in use by many Americans. While clinical research accounts for about a third of funding across NIH, NCCAM's clinical investments have been as high as 80 percent. But by putting increasing emphasis on basic research and preclinical studies, NCCAM's clinical investments are falling more in line with the norm at NIH (*Figure 6*).

Figure 6. **NCCAM Research and Training Portfolio**
Distribution by Type of Research



At the same time, the number of patients enrolled in NCCAM-supported clinical trials has been growing from a mere handful in FY 1999 to nearly 11,000 in FY 2002. Fifty-five

percent of these participants were enrolled in phase III trials, allowing the Center to reach enrollment totals to support rigorous statistical analysis. NCCAM's policy of pursuing collaborations with its NIH partners has been a particularly critical factor enabling support of a number of these complex and costly trials (*Figure 7*).

Figure 7. **NCCAM Phase III Clinical Trials**

Therapy	Condition	Co-Sponsors
Acupuncture*	Osteoarthritis	NIAMS
Glucosamine - Chondroitin	Osteoarthritis	NIAMS
Shark Cartilage	Lung Cancer	NCI
Vitamin E - Selenium	Prostate Cancer	NCI
St. John's Wort*	Major Depression	NIMH/ODS
St. John's Wort	Minor Depression	NIMH/ODS
EDTA Chelation Therapy	Coronary Artery Disease	NHLBI
Saw Palmetto - African Plum	Benign Prostate Hypertrophy	NIDDK/ODS
Ginkgo Biloba	Dementia	NIA/NHLBI/NINDS
Vitamin E	Down Syndrome	NICHD/NIA
Creatine	Amyotrophic Lateral Sclerosis	

*Study completed.
NIAMS, National Institute of Arthritis and Musculoskeletal and Skin Diseases; NCI, National Cancer Institute; NIMH, National Institute of Mental Health; ODS, NIH Office of Dietary Supplements; NHLBI, National Heart, Lung, and Blood Institute; NIDDK, National Institute of Diabetes and Digestive and Kidney Diseases; NINDS, National Institute of Neurological Disorders and Stroke; NICHD, National Institute of Child Health and Human Development; NIA, National Institute on Aging.

Prevention Priorities

A common reason people use CAM is to preserve health and quality of life. Accordingly, NCCAM's research portfolio includes funding to prevent major causes of morbidity and mortality. For example, the phase III trial of glucosamine is, in essence, a prevention trial intended not only to learn if glucosamine can relieve the pain and debility of degenerative arthritis of the knee, but also whether it can preserve joint cartilage and prevent disease progression. Similarly, the study of saw palmetto aims not only to improve urinary symptoms in men with enlarged prostates, but also to prevent the need for prostate surgery. And the EDTA (ethylenediamine tetra-acetic acid) chelation therapy trial aims to prevent heart attacks and death in people with preexisting heart disease.

The Role of Intramural Research

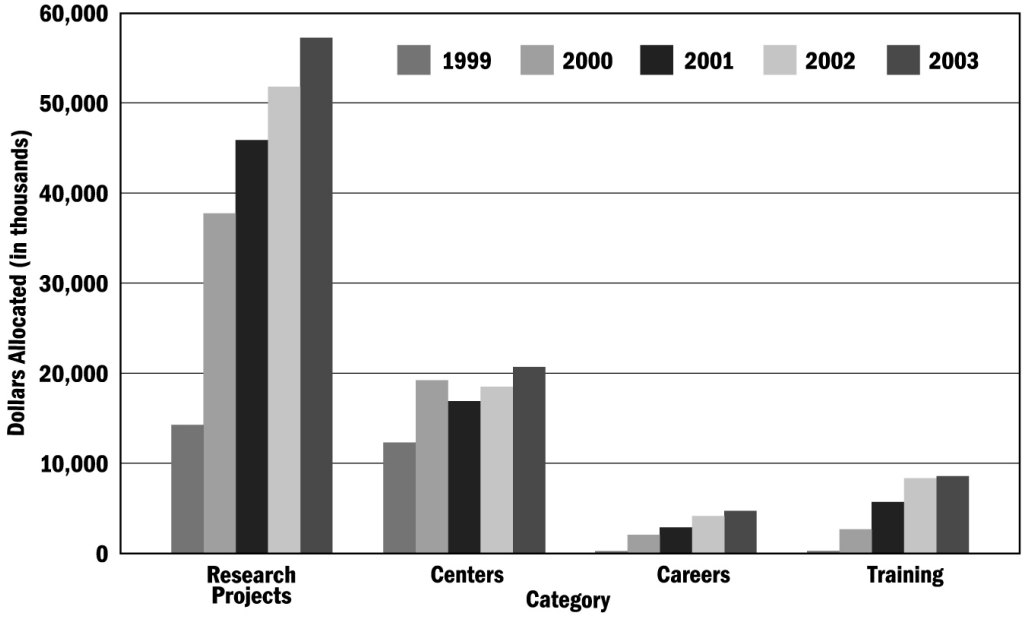
Soon after achieving Center status, NCCAM initiated steps to develop an intramural research program where staff scientists could conduct research and research training on the NIH campus—home to over 4,000 scientists conducting cutting-edge research. In this way NCCAM could capitalize on a resource-rich environment and cultivate cross-NIH collaborations. Today, NCCAM's Division of Intramural Research, currently funded at 4 percent of the Center's budget, focuses on research related to endocrine system factors associated with stressors of aging, such as depression, cognitive decline, pain, frailty, and sleep disorders. The Division partners extensively with other scientists both within and beyond NIH. At present, its Laboratory of Clinical Investigation has extensive collaborations with NIH scientists in studies of cancer, depression, hypertension, diabetes, obesity, and arthritis.

Research and Training Programs

NCCAM uses a broad array of NIH funding methods[2] to support its extramural research program, including research centers, individual investigator-initiated research project grants, and research training and career development programs (*Figure 8*). Research centers are employed at NIH as a means of bringing multidisciplinary teams of investigators together to implement research projects on a common theme, train new investigators, and, in general, hope for the kind of synergy that can advance research when scientists with different perspectives share ideas. In its early years, NCCAM expanded a developing centers program that Congress had urged OAM to establish, seeing the value of centers not only to advance science, but also as a means of giving visibility to CAM research, attracting new investigators, and building research infrastructure.

[2] Visit http://nccam.nih.gov/research.types/index.htm for a description of types of NCCAM grants (award mechanisms).

Figure 8. **NCCAM Research and Training Portfolio**
Distribution by Program



The distribution of NCCAM's investment by broad program area illustrates the early emphasis on centers and the subsequent shift over the last 5 years toward individual research projects, research training, and career development programs.

Note that centers funded as "program project grants" are classified as research project grants for official budgeting purposes, but they are counted here as centers. Grouping activities in this way allows the data to be presented in a more meaningful way for analysis.

The First Strategic Plan: Lessons Learned and Challenges Ahead

This overview of NCCAM's first 5 years would be remiss were it not to include an appraisal of how well the Center has met the goals and objectives of the first strategic plan—including the lessons learned and ***key remedies undertaken (highlighted with bold italics)***. What follows is a brief summary of how well NCCAM has measured up.

Investing in Research

Two of the four goals articulated in this area in the first strategic plan—**create an NCCAM intramural research program** and **establish a global NCCAM research enterprise**—have been achieved. As indicated earlier, NCCAM now has its own intramural program, and an Office of International Health Research was created to develop grant programs fostering international collaborative research and training.

The two other research goals in the plan were more general—**stimulate the submission of high-quality applications by both CAM and conventional investigators** and **expand the scope of the NCCAM extramural research portfolio and participation by research**

subjects. Substantial progress has been made toward both goals—as witness the fact that NCCAM now supports over 300 ongoing research projects—a quintupling over the level in FY 1999—and has expanded opportunities for research through the creation of new focused organizational units such as the Office of Special Populations and the Office of International Health Research. That NCCAM-supported scientists have been productive is indicated by their record of publication. NCCAM staff have made substantial contributions to the literature,[3] and since 1999, the number of CAM papers published in scientific journals by NCCAM grantees has risen dramatically, from 55 in 1999 to roughly 1,000 in 2004.[4] As an example, NCCAM grantees have contributed significantly to the literature in such high-impact journals as the *Proceedings of the National Academy of Sciences, New England Journal of Medicine, Journal of the American Medical Association,* and *Annals of Internal Medicine*. Table 1 summarizes a number of key research findings.

[3] Visit http://nccam.nih.gov/research/intramural/bibliography.htm

[4] Data from NCCAM Grantee Publications Database. Accessed at http://nccam.nih.gov/cgi-bin/bibliography.cgi on August 18, 2004.

Table 1. Research Highlights

- An NCCAM, National Institute of Mental Health, and NIH Office of Dietary Supplements study showed that St. John's wort was no more effective than placebo or sertraline for treatment of major depression of moderate severity; an ongoing three-center study is assessing its value in treating minor depression.[5]
- Multiple herbal preparations alter the expression and activity of the hepatic CYP450 enzymes and thus the serum levels of many common drugs.[6,7,8,9,10]
- Formal analyses found that herbal products differ widely in content and may be contaminated by drugs or heavy metals.[11]
- An NCCAM, National Institute on Aging, and National Heart, Lung, and Blood Institute study of *Ginkgo biloba* is the largest randomized, placebo-controlled trial of an herbal medicine ever conducted and among the largest ever to seek a way to prevent age-related dementia.[12,13,14] While awaiting completion of this historic study, we have begun to define mechanisms.
- Acupuncture is increasingly being integrated with mainstream methods of pain control. NCCAM's studies using brain imaging are providing some understanding of the neurobiological actions of traditional needling practices and further illuminating the nerve cells, pathways, and areas of the brain involved in the perception of pain.[15,16]
- Analyses of products used to treat menopausal symptoms indicate that those containing red clover, hops, and chasteberry show significant estrogen activity. Questions of safety and efficacy remain.[17]
- NCCAM- and NIH Office of Dietary Supplements-funded analyses, conducted by the Agency for Healthcare Research and Quality's RAND Southern California Evidence-Based Practice Center, provided key data used by the U.S. Food and Drug Administration (FDA) to ban the sale of ephedra for weight loss and enhanced athletic performance.

[5] Hypericum Depression Trial Study Group. Effect of Hypericum perforatum (St. John's wort) in major depressive disorder: a randomized controlled trial. *Journal of the American Medical Association.* 2003;290(11):1500-1504.

[6] Markowitz J, Donovan J, DeVane CL, et al. Effect of St John's wort on drug metabolism by induction of cytochrome P450 3A4 enzyme. *Journal of the American Medical Association.* 2003;290(11):1500-1504.

[7] Markowitz JS, DeVane CL, Chavin KD, et al. Effects of garlic (Allium sativum L.) supplementation on cytochrome P450 2D6 and 3A4 activity in healthy volunteers. *Clinical Pharmacology and Therapeutics*. 2003;74(2):170-177.

[8] Donovan JL, DeVane CL, Chavin KD, et al. Siberian ginseng (Eleutheroccus senticosus) Effects on CYP2D6 and CYP3A4 activity in normal volunteers. *Drug Metabolism and Disposition: The Biological Fate of Chemicals*. 2003;31(5):519-522.

[9] Wadsworth T, Poonyagariyagorn H, Sullivan, E, et al. In vivo effect of PC-SPES on prostate growth and hepatic CYP3A expression in rats. *The Journal of Pharmacology and Experimental Therapeutics*. 2003;306(1):187-194.

[10] Chang TKH, Chen J, Benetton SA. In vitro effect of standardized Ginseng extracts and individual ginsenosides on the catalytic activity of human CYP1A1, CYP1A2, and CYP1B1. *Drug Metabolism and Disposition: The Biological Fate of Chemicals*. 2002;30(4):378-384.

[11] Harkey MR, Henderson GL, Gershwin ME, et al. Variability in commercial ginseng products: an analysis of 25 preparations. *American Journal of Clinical Nutrition*. 2001;73(6);1101-1106.

[12] Luo Y, Smith J, Paramasivan V, et al. Inhibition of amyloid-beta aggregation and caspase-3 activation by the Ginkgo biloba extract EGb761. *Proceedings of the National Academies of Science* 2002;99(19):12197-12202.

Clinical Research Issues. The path of CAM research has not always been as smooth as the Center would have liked, however, particularly with regard to conducting clinical studies. Initially, NCCAM invested in large clinical trials to determine the safety and efficacy of popular CAM practices—as Congress had urged. In the process, however, NCCAM encountered a series of problems, learned a number of important lessons, and developed approaches to resolve them.

To begin with, and to some extent continuing today, NCCAM found itself in the center of a debate concerning whether it is fair to apply accepted mainstream research methodologies to tests of complementary and alternative medicine, the argument being that such approaches force CAM practices, many of which have been used since ancient times, to adhere to an unreasonably high standard of proof. NCCAM agrees that the gold standard of the double-blind, placebo-controlled clinical trial is neither appropriate nor feasible for all CAM therapies, but it is also not an appropriate design for all conventional therapies. For example, the use of surgical procedures or behavioral approaches such as psychotherapy are interventions that cannot easily be blinded. These are among issues that have been debated in numerous scholarly articles, along with discussions of the ethical criteria that should be applied in determining whether a proposed clinical trial should be conducted in the first place.[18] From both ethical and methodological perspectives, NCCAM believes firmly that CAM research should not be privileged, but be subjected to the same ethical criteria and methodological standards as are applied in conventional research. While certain classes of interventions can be challenging to study—in both CAM and conventional medicine—existing methodologies usually suffice to allow fair and credible, yet rigorous, tests of CAM therapies.

That said, NCCAM has also faced a number of problems with regard to the particular intervention to be tested in a CAM clinical trial. First, it was assumed that traditional wisdom and data from prior studies dictated the right dose, product, and patient population.

Lessons Learned. Only through subsequent analysis did it become apparent that there is rarely a consensus among CAM experts on the optimal product, dose, or intended users. Unfortunately, to make less-than-optimal choices with regard to any of these variables in a trial runs the risk of seeing the trial fail—and the CAM therapy

[13] Smith JJ, Burdick AJ, Golik P, et al. Anti-apoptotic properties of Ginkgo biloba extract EGb761 in differentiated PC12 cells. *Cellular and Molecular Biology.* 2002;48(6):699-707.

[14]Wu Z, Smith J, Paramasivan V, et al. Ginkgo biloba extract EGb761 increases stress resistance and extends life span of *Caenorhabditis elegans*. *Cellular and Molecular Biology*. 2002;48(6):725-731.

[15] Langevin HM, Churchill DL, Fox JR, et al. Biomechanical response to acupuncture needling in humans. *Journal of Applied Physiology*. 2001;91(6):2471-2478.

[16] Langevin HM, Churchill DL, Cipolla MJ. Mechanical signaling through connective tissue: a mechanism for the therapeutic effect of acupuncture. *FASEB Journal: Official Publication of the Federation of American Societies for Experimental Biology*. 2001;15(12):2275-2282.

[17] Liu J, Burdette JE, Xu H, et al. Evaluation of extracts of plant extracts for the potential treatment of menopausal symptoms. *Journal of Agricultural Chemistry*. 2001; 49(5):2472-2479.

[18] An example is Miller FG, Emanuel EJ, Rosenstein DL, et al. Ethical issues concerning research in complementary and alternative medicine. *Journal of the American Medical Association.* 2004; 291(5):599-604.

dismissed—not because of a lack of merit, but because the wrong dose was chosen for the wrong set of patients.

To avoid these problems NCCAM resolved, with the advice of its Council members and consultants, to place greater emphasis on phase I trials (to test product safety and establish optimal dosage and route of administration) and phase II trials (to test efficacy), regarding them as essential if NCCAM is to evaluate CAM therapies under the best possible circumstances. Should the results of these early phase studies be promising and the decision to mount a phase III trial be made, NCCAM will also ensure that experts with a range of viewpoints are included on the steering committee planning the trial, in order to reach consensus on what constitutes a fair test of the CAM therapy in question.

A second issue arose in connection with biologically based practices, such as herbal and botanical compounds, which were frequently the focus of NCCAM's initial clinical trials. These products, sold as dietary supplements, are subject to less stringent controls over purity and manufacturing processes under the guidelines of the Dietary Supplement Health and Education Act of 1994 than would be the case had the products gone through the level of substantial study and regulatory review required for the marketing of a drug.

Lessons Learned. As a result, NCCAM found that off-the-shelf dietary supplement products could be contaminated with unwanted ingredients. As well, the concentration of active ingredients could vary widely.

NCCAM now requires that CAM products be characterized before they are studied and that only research-grade materials be used in clinical trials. To help investigators, NCCAM has begun to submit samples of the reagents they are using to contract facilities for independent testing. Plans are also under way to fund a resource to perform analyses appropriate to the products under study, including stability, bioavailability, pharmacokinetics, and drug interactions.

Lastly, NCCAM experienced delays in implementing clinical trials due to the lengthy reviews of trial protocols. Before an NIH-sponsored clinical trial can be conducted, the purpose of the trial, its protocol, and other material relating to the trial, such as the content of informed consent forms, must be approved by an independent Institutional Review Board (IRB), whose members also perform oversight during the course of the conduct of the trial itself.

Lessons Learned. NCCAM found that IRB members were sometimes unfamiliar with CAM and uncomfortable with the body of background data, and so might opt to disapprove a proposed trial. IRB members have also raised questions about the ethics of testing products where potential risks or benefits were unknown, or where products lack formal analyses of their composition, mode of action, and safety in human subjects.

NCCAM has created an Office of Clinical and Regulatory Affairs, which conducts oversight on all phases of clinical trial design, implementation, and analysis. In addition, NCCAM staff has met with FDA officials to offer perspectives on the promulgation of guidelines on botanical

investigational new drugs and with national leaders in IRBs and bioethics to develop a framework to facilitate protocol review.

Research Centers Issues. A research centers program was initiated by OAM in 1994, and NCCAM inherited and began to build upon a large portfolio of exploratory centers. By late 1999, more than half of NCCAM's extramural research budget was committed to centers focusing on a wide range of areas for which CAM practices are sought: addiction, aging and women's health, arthritis, botanicals, cancer, cardiovascular disease, chiropractic, craniofacial health, minority aging and cardiovascular disease, neurological disorders, and pediatrics.

This early emphasis on centers allowed NCCAM to cultivate research, resources, and new investigators at a time when NCCAM was newly established and just beginning to build its research program.

Lesson Learned. By 2002, it was clear that NCCAM's centers were achieving only a mixed record of scientific productivity.

To address the issue, NCCAM convened an expert panel, which advised a more flexible approach to funding CAM centers. NCCAM followed this advice and has begun to fund centers structured as program project grants for investigators with proven research records, exploratory centers that require collaboration between investigators at CAM institutions and research-intensive universities, and planning grants for collaborative centers in which U.S. institutions are paired with a foreign CAM institution. A second expert panel advised on the future of NCCAM's botanical research centers, recommending that the next generation of centers increasingly focus on the safety and efficacy of botanicals for human use.

Training CAM Investigators

When Congress established NCCAM, it authorized the Center to use the existing NIH research training and career development award mechanisms to ensure that there would be an ample pool of both CAM and conventional investigators to carry out NCCAM's research mission. NCCAM followed suit, and in addition, funded educational grants to CAM and conventional schools to increase mutual knowledge and understanding. Again, NCCAM cast its net widely in efforts to recruit and retain new investigators. The Center also drew investigators into the field by offering loan-repayment programs and by opening CAM research to conventional researchers through recruiting them to collaborate in clinical trials and other programs conducted at selected research centers. NCCAM's intramural program has also played its part in funding fellowship programs through the NIH visiting scientist program, intramural research training awards, and postbaccalaureate programs.

These efforts have been successful in increasing the numbers of conventional investigators engaged in CAM research. While many of these grantees have long records of dedicated engagement in CAM activities, few possess CAM degrees. The majority hold traditional M.D., Ph.D., or joint M.D.-Ph.D. degrees. The Center has not been able to meet, as well as it wished, the goals set for enlisting *CAM-trained* professionals in research efforts. Efforts to increase the number of underrepresented minorities in CAM research have also been problematic.

Lessons Learned. In retrospect, it appears that the goal of building a cadre of CAM professionals engaged in CAM research may be a more long-term process than initially thought. Because the traditional focus of CAM schools has been on education for practice—that is, to train students to be proficient in a particular CAM system or practice, following time-honored traditions and precepts taught by experts—undertaking research training has required many CAM institutions to adopt a wholly new approach. And not only does research training require courses and curricula, it also requires resources: successful investigators who can serve as role models, well-equipped laboratories and libraries, support structures, and personnel. Even as CAM institutions demonstrate their interest in conducting CAM research, the lack of materiel and mentors remains a daunting challenge. Much the same can be said about conventional settings, however. CAM research remains somewhat novel and successful research training in CAM requires access to the full range of institutional resources.

With these observations in mind, NCCAM engaged a panel of experts to independently reflect on NCCAM's current approach to CAM research training and career development and how the Center might increase the impact of its investments. In particular, the panel was asked to consider issues such as how NCCAM can best target its research training resources and use the most effective approaches for preparing particular groups of researchers, such as CAM practitioners and underrepresented minorities.

Expanding Outreach

In the public law establishing NCCAM was the importance of disseminating information on the safety and efficacy of CAM products and practices. The two goals for outreach in the first strategic plan spoke to this mission: **enhance NCCAM's capacity to provide information to consumers, practitioners, and investigators** and **establish an effective dialogue with CAM stakeholders**.

Early on, NCCAM leadership saw that it was vital to establish a robust Office of Communications and Public Liaison if NCCAM were to succeed in becoming recognized as *the* authoritative source of CAM information in America. Beyond the Office, outreach responsibilities extend throughout the entire NCCAM organization. As a result, the Center's extensive communications enterprise has reached out to the public and professional audiences directly—through fact sheets, alerts and advisories of immediate import, quarterly newsletters, monthly updates, an information clearinghouse, the NCCAM Web site, chat rooms, lectures and presentations—and indirectly—through media contacts that have led to featured radio, TV, and print stories. Professional audiences (as well as the public) are further served by the listing of CAM publications on PubMed, an online list of publications by NCCAM grantees, and NCCAM's presence and presentations at professional meetings. Many of these occasions are opportunities for dialogue. In addition, NCCAM meets regularly with stakeholder groups such as patient advocacy groups.

Lessons Learned. One of the challenges in outreach and communications is the relatively low recognition of NIH in general and NCCAM specifically. Its stakeholders are forced to sort through myriad and conflicting messages about CAM. Some already have very strong feelings about CAM, both positive and negative. NCCAM's role is to communicate objectively, providing the best, most accurate evidence-based information. Unfortunately, much of the research to support evidence-based information is inconclusive, nonexistent, not rigorous, or still underway.

NCCAM is still learning how best to convey research findings that conflict with popular beliefs and marketing claims.

By employing the same rigor in its public pronouncements as it does in the support and conduct of CAM research and training, NCCAM has succeeded in gaining the trust of its disparate stakeholders. NCCAM is seeking partners among other Government and non-Government agencies to reach wider audiences and increase dialogues with constituents to keep alert to issues and concerns of the public as they occur.

Facilitating Integration

NCCAM has stated that it would "work to facilitate a more integrated practice of medicine" establishing two goals in this fourth strategic area: **facilitate development of health education curricula that respect and incorporate insights and opportunities afforded by safe and effective CAM and conventional practices** and **facilitate coupling of effective CAM and conventional practices within a coordinated, interdisciplinary health care delivery system**. Toward these goals NCCAM has awarded a number of education project grants to enrich CAM-related curricula in conventional professional schools and has begun an initiative to strengthen research curricula in schools that train CAM practitioners.

Lessons Learned. It is now evident that the ideal of a health care system in the United States in which integrated teams of practitioners draw upon both conventional and proven CAM therapies in providing health care must be preceded by a careful examination and resolution of many ethical, legal, and social issues, especially ones that fall well beyond the purview of NIH. Just as these issues have arisen in the conduct of CAM research, they also arise in the context of the feasibility of integrating CAM practices into the overall health care delivery system in America. Among the concerns are legal issues pertaining to the wide variation in state licensing and credentialing of CAM practitioners, safety concerns about CAM practices and products that are only loosely regulated or not regulated at all, and questions of insurance liability and third-party payers—all in the context of a changing social and cultural climate in which the public is receptive to therapies whose safety and efficacy are yet to be proven.

In order to benefit from the nation's best thinking with regard to a number of questions that have arisen with regard to integration of complementary and alternative medicine, NCCAM, joined with 16 NIH partners and the Agency for Healthcare Research and Quality (AHRQ), engaged the Institute of Medicine of the National Academies in a comprehensive study. Accordingly, the Institute of Medicine charged a panel of experts to address a range of CAM science, policy, and practice issues. They were asked to describe the use of CAM therapies by the American public, providing a comprehensive overview—to the extent that the data are available—of the therapies in widespread use, the populations who use them, and how they are provided. They were also asked to identify the major scientific, policy, and practice issues related to CAM research and the translation of validated therapies into conventional practice. Finally, they have developed conceptual models or frameworks to guide public- and private-sector decisionmaking as research and practice communities confront the challenges of

conducting research on CAM, translating research findings into practice, and addressing the distinct policy and practice barriers inherent in that translation.

NCCAM's second strategic plan has made facilitating integration an overarching part of the Center's vision. Attaining that vision will depend in large part on the fruits of NCCAMs' efforts in each of the other three strategic areas: investing in research, training CAM investigators, and expanding outreach. In addition, the new plan is adding to its research portfolio a section on the ethical, legal, and social issues with regard to CAM research and integrated medicine, highlighting the issues and proposing goals and objectives.

Broader Challenges

Defining CAM. At its outset, NCCAM deliberately chose an evolving definition of CAM in terms of practices "unproven and not presently considered an integral part of conventional medicine." However, this poses a continual challenge in terms of determining the boundaries of what is - or is not - CAM. While most will agree that homeopathy is CAM, there is an ongoing debate whether lifestyle changes that already are gaining broad acceptance constitute CAM. Botanicals are CAM; but what about their single most active ingredients? If NCCAM's horizons extend to what everyone will agree is CAM, it could drain energy and resources into studies with more limited potential for success. To avoid the problem that would be created by too restrictive a definition of CAM, NCCAM has deliberately focused on studies *that have greater potential for success and benefit to public health*, wherever the study might lie in relation to some definitions of CAM. For example, in the current effort to combat obesity in America, NCCAM has subjected a popular low-carbohydrate diet to controlled trials, even though some have argued that this lifestyle change through diet should not be categorized as CAM.

Resource Realities. NCCAM is able to support only a small fraction of all applications it receives. Indeed, this percentage is among the lowest of any NIH component (14 percent in FY 2003). This can have serious consequences for CAM research. Applicants may become discouraged and go elsewhere, and NCCAM will not be able to pursue all the opportunities that should arise from successful exploratory studies.

These constraints make priority setting even more essential. The timing of the current strategic planning process, with the aim of setting priorities within and among strategic areas, is therefore especially opportune.

Part II. NCCAM Strategic Plan 2005–2009

Five years ago NCCAM assumed responsibilities as an NIH Center with grantmaking authority, urged by Congress to advance the science of complementary and alternative medicine, train research investigators, and inform the public on matters of CAM safety and efficacy. The Center embarked on this mission in the hope that NCCAM research would yield ways to enhance the health and well-being of the public. We stated our commitment toward that end in principles we again articulate in our mission and vision statements.

Our Mission

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

NCCAM will strive to develop a cadre of both conventional and CAM-trained professionals to conduct CAM research and encourage their working together in multidisciplinary teams to facilitate CAM research.

Our Vision

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

NCCAM is committed to studies to establish the safety and efficacy of particular CAM practices, guided by the imperative to inform the public of what CAM practices work—and alternatively—what practices do not work. It is especially important that NCCAM be recognized as an authoritative voice in advising the public, given the rise of consumer interest in health and a growing sense of personal responsibility and the need to take charge of one's own health.

A New Agenda

Our first strategic plan elaborated on general approaches for **investing in research, training CAM investigators, expanding outreach, and facilitating integration,** with ambitious goals and objectives—but without indicating explicitly what we would do. We wanted to keep our options open, encourage researchers to enter the field, and observe

which research directions appeared to be the most fruitful. We also pledged our commitment to good governance, articulated in a section called **practicing responsible stewardship.**

Now, with 5 years of experience we are poised to refine our efforts. Our second strategic plan retains the research, training, and outreach areas of the first plan and adds a section under research: ethical, legal, and social implications of CAM research and integrated medicine**.** Hindsight has taught us that all three of these original strategic areas are necessary to the integration of CAM with conventional medicine, but there are complex ethical, legal, and social issues that must be addressed to overcome barriers to the conduct of CAM research and to enable the desired integration.

Our new agenda has benefited not only from the lessons we have learned, but also from the extensive advice provided by experts (listed in Appendix IV) and discussions we have held with staff and outside groups. (The process is described in Appendix III.)

Priority Setting

The new plan is noteworthy in its emphasis on priority setting. Our advisory groups urged us, and we agree, that we need to manage our research portfolio in ways that are likely to yield the greatest impact on the health and well-being of the public. Accordingly, we have identified a set of **master health goals** as important, but not exclusive, criteria in setting priorities:

- Enhance physical and mental health and wellness
- Manage pain and other symptoms, disabilities, and functional impairment
- Have a significant impact on a specific disease or disorder
- Prevent disease and empower the public to take responsibility for their health
- Reduce selected health problems of specific populations

Toward those goals, we also see as high priority the need **to increase basic research, and in particular, to work toward elucidating mechanisms of action underlying CAM practices.**

The Short and Long View. Our new plan presents priority goals and objectives in research, training, outreach, and in the area of governance, indicating what we hope to accomplish in the short and long term. There is some overlap—objectives that are common to several areas—and our aims are very ambitious. We know we will not be able to achieve all our objectives in the next 5 years; rather, it is our hope to have completed a number of key objectives while initiating the others. Thus, by defining our priorities, we are telling ourselves—and the world—that these are the directions in which

we want to move. We will publicize these priorities widely, aware that as research proceeds and new opportunities or needs emerge, we will need to refine and update them.

Operating Principles

The research that NCCAM conducts and supports overlaps the mission and goals of every other component of NIH, enabling us to capitalize on these shared interests and leverage both intellectual and financial resources. Not only does this make good sense, but it also has become a high priority for NCCAM. Thus, the Center will continue to look to partnerships at NIH in the future and work to build links beyond NIH to other Government agencies and to NCCAM's many stakeholder groups.

The Strategic Areas

NCCAM's major investment is the support and conduct of research, so Strategic Area 1, *Investing in Research*, represents the largest set of goals and objectives in the plan, embodying eight areas of research. These are organized according to the four principal CAM domains and whole medical systems (see the descriptions on page 14 and also in the glossary, Appendix V)—and three areas on health services research—international health research; ethical, legal, and social implications of CAM research; and integrated medicine.

These eight areas are not represented equally across our portfolio of investments. The domain of biologically based practices has dominated NCCAM's research portfolio and will continue to do so in the future. We now assign high priority to mind-body medicine, so that our investments in this area will grow substantively in the coming years. Not only do these two domains encompass a broad range of CAM practices in widespread use, but also at least for some practices, there is a considerable research base on which to build, trained investigators to do the work, and well-defined hypotheses that can be tested. Ultimately NCCAM would like to see progress in all eight research areas, and it is with that aim in mind that each has been presented with its complement of goals and objectives.

Priority goals and objectives are also presented for *Training CAM Investigators* and *Expanding Outreach.* Advisors and staff contributed significantly to the development of the research agendas that follow. (See Appendix IV for the working group rosters and Appendix III for a description of the planning process.)

Investing in Research

Two guiding principles emerged in the course of generating the agenda for the CAM research areas that follow:

- In the absence of the science base or resources to enable studies of *why* a particular CAM practice works, investigators should first attempt to establish that it does indeed work. This is in keeping with the importance of supplying consumers with the reliable information they need to make informed decisions on their health care. In some cases mechanistic studies (why a practice works) may proceed in parallel with studies to determine if it does work (efficacy).

- When there is evidence that a specific CAM practice works, it is a high priority to study why it works.

Building Resources

Also emergent as a dominant theme is the need to enrich the tools and technology supporting the science base for CAM and to diversify the pool of investigators. The result is a set of generic resource requirements, listed below. The discrete technologies needed and the range of interdisciplinary scientific expertise relevant to each area in the plan are enumerated prior to the goals and objectives for that area.

While these resources are instrumental to the pursuit of particular goals, NCCAM is limited in the extent to which we ourselves can develop them. We therefore encourage our stakeholders and partners to make investments here as valuable contributions to the research enterprise:

- New or improved tools, methodologies, technologies, and models for the conduct of research

- Better metrics in basic and translational research as well as standardized protocols and outcome measures for clinical studies

- Databases of CAM research studies and repositories of selected research materials accessible to qualified investigators elsewhere

- A scientific workforce that reflects the full range of expertise needed in CAM research

Mind-Body Medicine

Of all CAM domains, the most widely practiced is mind-body medicine, which involves the interplay of mind, brain, other body systems, and behavior. Research in this domain encompasses basic studies on how the mind and body interact and communicate, epidemiological studies of the key psychological characteristics and health of a given population, and clinical studies of the how mind-body interactions affect health and

disease. Examples of clinical interventions that may be deemed CAM in some instances are certain **lifestyle behaviors**, such as tai chi chuan exercise; **meditative strategies**, such as yoga and mindfulness meditation; **psychological strategies,** such as stress management approaches; and **spiritual practices**, commonly prayer, for the prevention and treatment of disease and the enhancement of health and well-being.

As with a variety of CAM practices, many mind-body techniques are ancient. Some remain intrinsic to Eastern systems of healing. In the West, they formed a part of the Greek and Roman tradition of medicine, which survived at least through the 17th century. At that time, nascent discoveries in science, along with the separation of mind and body (and soul) espoused by Descartes, ushered in an era of dualism. In time, wave after wave of discovery would lead to a partitioning of the body—seeing it in terms of ever smaller units—systems, organs, cells, and finally molecules of DNA, whose functioning in living organisms could be reduced to the fundamental laws of physics and chemistry. The success of this reductionist approach in biology has led to its dominance in Western medical science. Nevertheless, the very advances in technology that enabled descriptions of the body's discrete organs and systems and their activities began to reveal connections. Pioneers like Walter Cannon[19] and Hans Selye[20] pointed to the effects of stress on the body, for example, which were later more fully described in terms of pathways connecting the brain with the pituitary and adrenal glands.

Today, there is evidence that patients faced with chronic and even terminal illnesses—particularly conditions like heart disease and cancer—can learn and employ a variety of mind-body practices to achieve a level of symptom relief and a better quality of life, and in some cases, improvements in health outcomes. Importantly, the clinical reports of these effects are supported by a growing body of basic research, much of it in the neurosciences, psychoneuroimmunology, and behavioral medicine. These studies are aimed at elucidating the underlying mechanisms of action, using a variety of biochemical markers and physiological measures, as well as advances in brain imaging technology.

Such tools have been used to document the ability of people skilled in yoga or various forms of mindfulness meditation to lower their heart rate and blood pressure.[21] Mindfulness meditation has also been shown to improve antibody response to a flu vaccine, with the magnitude of measured brain activity in the meditative state predictive of the level of immune response.[22] Innovative monitoring strategies have established that specific psychological characteristics like optimism and positive affect are linked to faster recovery following heart transplant surgery and to greater longevity.[23,24] These latter

[19] Cannon WB. *The Wisdom of the Body*. New York, NY: Norton; 1932.

[20] Selye H. *The Stress of Life*. New York, NY: McGraw-Hill; 1956.

[21] Schmidt T, Wijga A, Von Zur Muhle A, et al. Changes in cardiovascular risk factors and hormones during a comprehensive residential three month kriya yoga training and vegetarian nutrition. *Acta Physiologica Scandinavica. Supplementum*. 1997;640:158-162.

[22] Davidson RJ, Kabat-Zinn J, Schumacher J, et al. Alterations in brain and immune function produced by mindfulness meditation. *Psychosomatic Medicine*. 2003;65(4):564-570.

[23]Danner DD, Snowdon DA, Friesen WV. Positive emotions in early life and longevity: findings from the nun study. *Journal of Personality and Social Psychology*. 2001;80(5):804-813.

investigations have underscored the apparent value of resilience and positive emotions to health and well-being.

Pain research has been useful in exploring the placebo effect. In one experiment volunteers were first subjected to a painful stimulus and then told that an "analgesic" cream (actually a placebo) would be applied to the skin at the pain site. When a pain stimulus of the same intensity as the original one was then applied to the skin, many subjects reported significantly less pain.[25]

Similar manipulations of expectations in patients taking prescription drugs for chronic diseases have shown that they, too, can be conditioned, so that following an initial dosage of a drug at typical therapeutic levels, a subsequent administration of a subtherapeutic dose or even a placebo can result in sizable physiological effects—such as the release of dopamine in the brains of Parkinson's disease patients.[26]

This growing body of physiological evidence is helping to shatter the long-held cultural belief in the West that mind and body are separate, especially since these studies are occurring at a time when the very leaders of reductionist biology are pointing to a need to move to an integrative approach in order to understand how complex systems work. Indeed, the potential is there for safe and effective mind-body practices to add to the repertoire of conventional medicine—particularly with respect to managing chronic illness and associated symptoms, enhancing resilience and coping to promote health, and fostering wellness. NCCAM aims to play a prominent role in this important area and is assigning it a high priority. We encourage researchers to pursue new knowledge and understanding of mind-body medicine, using all the high-tech tools and techniques available.

Resources Needed

- Rigorous measures of key individual differences in psychosocial and cultural characteristics, environmental context, emotional and psychological states, and spirituality
- Standardized protocols for brain imaging
- Validated and more reliable surrogate markers of brain states, correlated with brain imaging
- A research community that includes geneticists, immunologists, endocrinologists, neuroscientists, psychologists, social scientists, brain imaging specialists, cell

[24] Scheier MF, Matthews KA, Owens JF, et al. Optimism and rehospitalization after coronary artery bypass graft surgery. *Archives of Internal Medicine.* 1999;159(8):829-835.

[25] Benedetti F, Arduino C, Amanzio M. Somatotopic activation of opioid systems by target-directed expectations of analgesia. *Journal of Neuroscience.* 1999;19(9):3639-3648.

[26] Fuente-Fernández R, Ruth TJ, Sossi V, et al. Expectation and dopamine release: mechanism of the placebo effect in Parkinson's disease. *Science.* 2001;293(5532);1164-1166.

biologists, physiologists, clinicians, and specialists in the diseases and modalities under study

Goal 1: Identify the common and specific features of widely used mind-body medicine practices.

Objective 1. Characterize meditative interventions such as yoga, relaxation, mindfulness-based meditation, and Transcendental Meditation, looking for specific commonalities in the procedures and in subsequent changes in the brain, and in emotional, psychological, and physiological measures, in relation to the generation of positive health outcomes.

Objective 2. Elucidate emotional and psychological mechanisms that link the most efficacious features common to these modalities with meaningful clinical and physiological outcomes.

Objective 3. Elucidate neurological, endocrine, autonomic, and immunological mechanisms responsible for linking the most efficacious features common to these modalities with meaningful clinical and physiological outcomes.

Goal 2: Discover means of enhancing and accelerating the healing process beyond the effects provided by conventional medicine.

Objective 1. Investigate the potential enhanced efficacy of a range of mind-body intervention strategies (e.g., meditation, relaxation) when used alone or as complements to mainstream therapeutic interventions.

Objective 2. Test interventions of the built environment (e.g., the use of light, music, color, architectural modifications) that complement the positive effects of conventional interventions on healing and recovery times, with the important additional aim of understanding how these environmental enhancements may affect the healing process and promote wellness.

Objective 3. Determine the ability of mind-body factors that underlie the placebo effect to enhance proven treatments, and characterize the important dose and time parameters as well as features of the health care provider and patient encounter that are associated with the placebo effect.

Goal 3: Explore the value of CAM therapies to reduce the burden of stress-related chronic illnesses.

Objective 1. Study the effects of maintained negative mental states (e.g., stress, depression, anxiety) on the function and structure of the brain, and on the function of the autonomic, endocrine, and immune systems.

Objective 2. Study the role of stress-related changes in physiology in contributing to the initiation, development, and symptoms of specific conditions, such as gastrointestinal disorders, autoimmune diseases, asthma, and sleep disorders.

Objective 3. Determine, among the range of mind-body practices, which, if any, practices can be individualized to reduce stress in specific patients with stress-related chronic diseases.

Goal 4: Explore the value of CAM therapies to enhance resilience, coping, and wellness.

Objective 1. Characterize biological correlates of positive affect and well-being.

Objective 2. Investigate the effects of resilience, coping, forgiveness, and positive emotions on health and well-being.

Goal 5: Identify the features of spirituality that may confer health benefits.

Objective 1. Conduct research to identify commonalities in physiology in spiritually oriented individuals and when feasible ascertain how these relate to clinically meaningful outcomes (e.g., relief of pain).

Objective 2. Elucidate the mechanisms that link common features of a spiritual orientation with favorable health outcomes.

Biologically Based Practices

The use of substances from the living world as a source of healing remedies—as well as a means of altering moods or mental states or to simply feel good—is as old as humanity. Indeed, there is evidence that our close kin among the primates also use materials from their natural environment in self-treatment. Today, what are called biologically based practices encompass the use of a wide range of products, including complex herbs and botanicals, animal extracts, selected bacteria used in pre- and probiotic formulations, whole diets reputed to be healthful, and so-called "functional" foods that may provide a health benefit beyond basic nutrition, such as soy. Other biologically based practices include use of bioactive compounds (e.g., flavonoids, carotenoids, lutein); or vitamins and minerals, fatty acids, and amino acids, which have been purified or synthesized as simpler compounds.

Botanical substances, most notably herbal products marketed as dietary supplements, are among the most popular CAM therapies in America. Many people believe that because these products are "natural," or have been in use in some parts of the world for generations, they must be safe. In fact, few have been subject to large-scale studies of safety and efficacy. Indeed, because of their widespread use, the Center felt obliged to move quickly to multicenter phase III clinical trials to gather data on the safety and efficacy of popular herbal remedies, basing the tests initially on the products commercially available and the dosages recommended for the intended population of

consumers. As it turned out, conducting research to determine the true value of any of these products in terms of their intended purposes and audiences has proven challenging.

It is the reality of the regulations under which dietary supplements are marketed in America[27] that some products are used virtually unprocessed; and others are extracts, perhaps mixed with other chemicals, or in other ways represent varying degrees of complexity in the formulation. Given their intrinsic complexity and the added variability due to formulation, it is especially difficult to determine the nature of the active ingredient(s) of these products, establish dosage levels, determine mechanisms of action, and weigh risks against benefits. Until the FDA finalizes its guidance on good manufacturing practices for dietary supplements, manufacturers are required only to follow the good manufacturing practices regulations for foods. Thus many products on the market vary widely in the actual contents of the product on the label. Many even fail to meet standards of purity and could be contaminated or adulterated with prescription drugs or toxic substances. Further, even with well-characterized products and quality control production standards in place, it is evident that care must be taken to establish dosages and appropriate populations to avoid the risk of false-negative findings.

A Balanced Portfolio. Based on our experience, as well as what we have learned from listening to experts, NCCAM has determined a course to follow for future studies of biologically based products. Our goal is to achieve a balanced portfolio that will include research on products at all levels of complexity. We will implement an orderly procedure for progressing from smaller to larger studies and ultimately to multicenter controlled clinical trials. The CAM product in question must be well characterized and meet reasonable standards of uniformity and purity before proceeding to phase I trials (to establish safety and dosage levels) and phase II trials (for efficacy). Studies of simpler single-chemical products may progress through the phases of clinical studies more rapidly than investigations of complex botanical mixtures. Preclinical *in vitro* and animal studies will assume growing importance to define the products, their pharmacological properties, their biological targets, and mechanisms of action. In some cases, based on historical evidence, phase II dose-ranging studies of products may be conducted in parallel with studies of their underlying mechanisms. Large phase III randomized controlled clinical trials will only be undertaken following a consideration of formal preclinical and earlier phase clinical study results, the public health significance of the approach, and feasibility.

NCCAM's investment in a number of other biologically based practices, such as probiotics and popular CAM diets, has been less substantial than for dietary supplements but remains important. The inherent complexity of diets, many of which are embedded in cultural approaches and individualized, makes their study a challenge. But here again, we will adhere to rigorous standards.

[27] Dietary Supplemental Health and Education Act of 1994. Public Law 103-417. Accessed at http://www.fda.gov/opacom/laws/dshea.html on August 18, 2004.

Resources Needed

- Resources to analyze and standardize products and ensure they are contaminant-free. When feasible, products should be standardized on more than one marker.

- Publicly available databases on product quality and of translated texts and ancient manuscripts.

- A repository of selected research reference materials (e.g., test compounds, serum, tissue) to be analyzed in the future when more sophisticated methods become available and active markers are identified.

- Access to resources to enable application of state-of-the-art technologies and approaches (e.g., metabolomics, proteomics, genomics, microarrays, mass spectrometry, nuclear magnetic resonance).

- Interdisciplinary teams of researchers with a broad range of relevant expertise that include biochemists, pharmacologists, pharmacognosists, cell and molecular biologists, geneticists, genomicists, nutritionists, and CAM and conventional clinical researchers.

Goal 1: Verify and define the composition of botanicals.

Objective 1. Use state-of-the-art analytic tools and methods to identify key ingredients of selected products and their concentrations and verify that they meet acceptable analytical profile criteria.

Objective 2. Use state-of-the-art analytic tools and methods to verify that products are not contaminated or adulterated.

Goal 2: Determine the mechanisms underlying the biological actions of selected CAM products and diets.

Objective 1. Employ rigorous molecular, cellular, and biochemical techniques and approaches, including DNA microarray, proteomic, and other cutting-edge approaches in studies to determine mechanisms of action of CAM products.

Objective 2. Quantify biochemical and physiological changes induced by CAM products and popular CAM diets in animals and human subjects.

Objective 3. Examine whether complex chemical mixtures such as herbal products or combinations of herbal products provide greater safety and benefits in preclinical and early phase studies than single herbs or single chemical constituents of herbs.

Objective 4. Identify immunological and microflora changes associated with use of probiotics.

Goal 3: Determine the pharmaceutical and pharmacokinetic properties of selected CAM products.

Objective 1. Study the stability, dissolution, absorption, and metabolism of CAM products.

Objective 2. Define potential contributions of pharmacogenomics to variability in pharmacokinetics and drug interactions with botanical products.

Goal 4: Ensure the safety of selected CAM products and practices.

Objective 1. Measure safety and toxicity in all clinical studies by monitoring relevant parameters.

Objective 2. Define the optimal dose and schedule for CAM products through appropriate preclinical and early phase clinical studies. Exploit existing data sources for information relevant to adverse effects of biologically based practices.

Objective 3. Where appropriate, use placebo controls to verify which, if any, adverse reactions could be attributable to the CAM products and diets.

Objective 4. Characterize interactions between herbal products and conventional drugs and biologicals.

Goal 5: Establish the efficacy of selected biologically based practices to maintain health, prevent disease, and treat conditions of public health importance.

Objective 1. Using well-validated qualitative and quantitative methods—including randomized, placebo-controlled trial designs of herbal/botanical products, other compounds, probiotics, and diets, for which there is sufficient evidence to select optimal regimens, target populations and clinical endpoints—determine whether the given practice is effective and safe.

Manipulative and Body-Based Practices

Perhaps the best-known manipulative therapy in America is provided by Doctors of Chiropractic, who apply pressure to the joints of the spine (and other joints and muscles) to effect beneficial changes, including changes in the nervous system. According to the most recent national survey,[28] 7.5 percent of Americans had chiropractic treatment in 2002. Chiropractic adjustment, as well as massage (reported to have been used by 5 percent of the population in the same survey), osteopathic manipulation, and other manipulative and body-based practices are used primarily to relieve musculoskeletal problems—commonly low-back and neck pain. These literally hands-on treatments ("chiro" is from the Greek word for hand) are also used to manage other conditions, including other musculoskeletal pain conditions, asthma, stress, mental health problems,

[28] Barnes P, Powell-Griner E, McFann K, Nahin R. *Complementary and Alternative Medicine Use Among Adults: United States, 2002*. CDC Advance Data Report. 2004.

and to enhance the function of other body systems. Common to these approaches to healing is the belief that reducing stresses and improving alignment of the skeleton and its associated soft tissues will, because of the interrelatedness of all the body parts, elicit the body's innate ability to heal.

Some forms of massage are ancient and were incorporated into the traditional medical systems of Egypt, China, India, and other countries. Other manipulative approaches are more recent. Chiropractic and osteopathic medical systems were developed in the United States during the 19th century. Still other body-based practices gained popularity in mid-to-late 20th century America, including several named for their founding practitioners: Alexander technique, Feldenkrais method, Trager bodywork, and rolfing. The techniques and application sites of these and other manipulation and massage practices vary widely. For example, "craniosacral therapy" works on the plates of the skull; "reflexology" uses foot and sometimes hand massage applied to so-called reflex zones. (See Appendix V for a representative list of these therapies.)

The evidence that these approaches are efficacious, as determined by well-designed, randomized controlled clinical trials is incomplete. Reports in the literature primarily relate to chiropractic manipulation. Collectively, reports of animal studies, case studies, and numerous clinical trials of chiropractic manipulation suggest that spinal manipulation can alter the activity of nearby nerve cells that sense body position and muscle movements. In turn, these alterations may ultimately lead to observed changes in circulating levels of various neurochemicals and proteins that affect nervous system function. Whether this cascade is responsible for the reported clinical efficacy of chiropractic manipulation for back and neck pain is unknown.

Studies of massage-like stimulation in animals indicate that the treatment can stimulate the nervous system release of morphine-like chemicals (opioids) for the relief of pain.[29] These studies clearly invite further investigation, replication, and expansion for clues as to what may be happening physiologically, and—along with phase I trials for safety and establishment of optimal regimens, and phase II trials for efficacy—should precede and provide the rational basis for full-scale phase III clinical trials.

Resources Needed

- Application of advanced imaging techniques, such as positron emission tomography (PET) and functional magnetic resonance imaging (fMRI)

- Development and exploitation of better biomarkers and instruments to quantify disease symptoms and disability

- Development of *in vitro* and animal models to study manipulative techniques

[29] Lund I, Yu LC, Uvnas-Moberg K, et al. Repeated massage-like stimulation induces long-term effect of nociception; contribution of oxytocinergic mechanisms. *European Journal of Neuroscience*. 2002;16(2):330-338.

- Use of biomechanical principles, tools, and techniques to better measure forces on the body's soft and hard tissues

- Expertise from other fields to work in interdisciplinary teams including, biomechanical and tissue engineers, computer scientists, pain neuroscientists, imaging experts, geneticists, neuroendocrinologists, neurophysiologists, immunologists, manipulative and body-based practitioners, muscle physiologists, rheumatologists, and orthopedists

Goal 1: Elucidate mechanisms of action operative in manipulative and body-based practices.

Objective 1. Use the resources outlined to facilitate the design of research to determine the effects of manipulative and body-based practices. Begin with tissue studies and animal models and proceed to clinical research, using objective outcome measures (e.g., biomarkers of pain versus subjective patient ratings).

Objective 2. Conduct comparative studies of manipulative and body-based practices to determine commonalities and differences at the molecular, biomechanical, neurological, and clinical levels.

Objective 3. Characterize the biomechanics of manipulative and manual procedures.

Goal 2: Determine the disorders and states of wellness for which selected manipulative and body-based practices may offer meaningful benefits and specify the optimal circumstances under which the chosen manipulative and body-based practices are performed.

Objective 1. Use the findings from studies of the biomechanical and biological features of manipulative and body-based practices, and the existing body of clinical evidence to formulate optimal regimens (i.e., number, intensity, duration, and frequency of treatments) for each approach found to offer therapeutic or wellness benefits.

Objective 2. Use biomarkers and other tools to measure tissue strain and neurological, immunological, and endocrine responses to manipulative and body-based interventions to identify patient populations who would be most responsive to manipulative and body-based practices, noting diagnostic and genetic variability.

Goal 3: Study manipulative and body-based practices to determine their potential therapeutic or wellness benefits.

Objective 1. Conduct larger phase II and phase III trials if preliminary preclinical and small clinical studies of selected manipulative and body-based practices indicate significant benefits.

Objective 2. Incorporate into large trials measures of the costs and benefits of manipulative and body-based approaches relative to more conventional practices.

Goal 4: Determine the extent to which patient expectations prior to treatment and satisfaction following manipulative and body-based practices are related to objectively measured biological endpoints.

Objective 1. Compare outcomes of treatment on subjective reports (wellness, improved function) with validated physiological and psychosocial measures.

Energy Medicine

Energy medicine is based on the belief that all living things possess and emit energies, and can be affected by external energies. This is certainly true for a number of forms of energy—and verifiable by the various instruments that record electrocardiograms, electroencephalograms, and infrared (thermal) emissions. Indeed, a number of external and verifiable sources of energy that are in use now are known to aid diagnosis and treatment, including radiation therapy, magnetic resonance imaging, and cardiac pacemakers. Other external energies are reported to have therapeutic benefits, including electromagnetic fields and light therapy. However, the field of energy medicine also encompasses much more than these verifiable energies. There is an underlying belief in certain healing systems of a potent "life force" present in all living individuals, whose imbalance or attenuation leads to disease. This theory has led to the belief that vital energies can be reoriented or strengthened to promote or restore health. Examples of therapeutic modalities using life force energies are qi gong, therapeutic touch, Reiki, polarity, healing touch, and Johrei.

What makes the field of energy medicine problematic to study is the lack of measurability of these latter healing energies by the instruments and devices available in the physical sciences. Further, it is believed that such energies can operate both locally and nonlocally—over long distances in some cases. Thus, an individual deemed able to transmit energies to a patient—a healer—may not necessarily have to be in close proximity to the patient to restore health.

The use of the common term energy medicine to apply to the therapeutic use of both verifiable and nonverifiable forms of energy has contributed to some misunderstanding and lack of acceptance of the whole field by the scientific community. We will continue to use the traditional term energy medicine for this domain of CAM, with the understanding that alternative terms such as "information medicine" or "biofield" medicine may be preferred by some practitioners to describe certain of its approaches.

Resources Needed. The field of energy medicine research is in its infancy and is challenged by a major impediment to research: the inability to characterize—detect, describe, store, measure—the so-called healing energies or life forces. Failure of science to characterize such energies does not, of course, confirm that they do not exist. Indeed, the history of physics provides examples of successive discoveries of sources of energy and their "taming"—through the development of mathematical models for the laws that

govern them and through instrumentation to detect them. Accordingly, it is imperative to:

- Recruit multidisciplinary teams to investigate energy medicine: physicists, biophysicists, physical chemists, engineers, cell biologists, and both CAM and non-CAM clinicians and investigators.

Goal 1: Apply in studies of energy medicine the same standards used in designing experiments in physics, chemistry, and other scientific disciplines.

Objective 1. Develop preclinical models—cell, tissue, animal—to validate measuring devices and test the effects of verifiable energy sources.

Objective 2. Ensure that the methodology of clinical studies of energy medicine using verifiable sources conforms to standard procedures/protocols used in other clinical studies.

Goal 2: Accelerate progress in understanding the source and biological effects of putative energy fields.

Objective 1. Investigate currently available devices that are said to detect and quantify energy fields.

Objective 2. Study the biological effects of putative healing energy sources, with rigorous attention to regimen, dosages, controls, and objective outcome measures in cells, organ systems, and animals before undertaking clinical studies.

Goal 3: Enhance understanding of what transpires in the course of energy healer-patient interactions.

Objective 1. Study characteristics of practitioners as clues to the nature of the putative healing energies they may be transmitting to a subject.

Objective 2. Study the psychosocial aspects of healer-patient relationships to determine to what extent aspects of the placebo effect—expectation, belief, desire to please—contribute to outcomes.

Whole Medical Systems

Worldwide, about 80 percent of all people rely in part or exclusively for their health care on whole medical systems that are based on precepts and principles distinctly different from the conventional (allopathic) whole system of care that is standard in the United States and other developed countries. Many of these CAM medical systems are very old. *Traditional Chinese medicine* (TCM) in written form dates back to the third century B.C., and variations of it have spread to Korea, Southeast Asia, and Japan.[30] In TCM, health is

[30] Unschuld PU. *Medicine in China: A History of Ideas*. Berkley, CA: Berkley University Press; 1985.

seen to be a balance between two opposing forces: yin, the cold, slow, or passive principle; and yang, the hot, excited, and active principle.[31] Disease is the result of an imbalance between the forces that leads to the blocking of blood flow and "vital energy" (qi) along prescribed pathways in the body called meridians. Interventions, notably acupuncture, in which needles are inserted and agitated at specified points along the meridians, are designed to restore the flow of qi and blood. (*Qi gong*, a CAM procedure that uses movement, meditation, and breath control to enhance the flow of qi, is practiced by some religious groups in China, including Daoists and Buddhists; it overlaps with, and is considered a component of, secular TCM.[32])

Indian Ayurvedic ("the science of life") *medicine* is based on ancient Hindu concepts of the composition of human beings and involves practices of meditation and yoga that invoke body, mind, and spirit as well as the use of herbal preparations, cleansing procedures, and physical manipulations. Like Chinese medicine, Indian medicine sees disease as a disturbance in the natural harmony of body, mind, and spirit; and interventions are designed to restore that harmony.

Other healing systems can be found among tribal groups or indigenous communities, in North and South America, and in Africa, Asia, and the Pacific. Often these indigenous systems involve religious or spiritual beliefs in which diseases or disorders are considered the result of divine intervention, witchcraft, or a sign that the individual has committed some offense and is being punished. There is rich ground for exploration of the medical practices of these relatively isolated groups—especially gleaning information on their use of natural products to enhance or restore health—as well as for exploring the major alternative medical systems in use in the world today.

Two more recent CAM medical systems have their roots in Germany. *Homeopathy* is a system of medicine developed by Samuel Hahnemann in the 18th century. It is based on treating disease with vanishingly small doses of agents that in larger amounts would cause symptoms similar to those associated with the disease being treated.[33] Using an elaborate set of questions and clues, homeopathic physicians are expected to pay close attention to the individual characteristics of their patients, including their mental and emotional states, to identify the appropriate treatment.

Naturopathy is a system of medicine that postulates that the body has innate powers of healing. It is derived from many sources but most directly from hydrotherapy (the use of water to treat illness). In parallel with Chinese and Indian medicine, remedies are chosen to restore the body's natural balance or harmony. Early naturopaths in Germany predominantly proposed water cures and herbal remedies. Naturopathy today is considerably more eclectic, adding homeopathic medicine, chiropractic manipulation,

[31] Kaptchuk TJ. Acupuncture: theory, efficacy, and practice. *Annals of Internal Medicine*. 2002;136(5):374-383.

[32] Miura K. The revival of qi: qigong in contemporary China. In: Kohn L. *Taoist Meditation and Longevity Techniques*. Ann Arbor, MI: University of Michigan Press; 1989:331-362.

[33] Jonas WB, Kaptchuk TJ, Linde K. A critical overview of homeopathy. *Annals of Internal Medicine*. 2003;138(5):393-399.

diet, massage, and other interventions, as long as they are deemed "natural," as opposed to, for example, potent drugs.

All these systems are individualized and multimodal, meaning that the regimens are designed according to the perceived needs of each patient and employ various combinations of plant or animal extracts, physical manipulation, exercise, diet, and assorted mind-body practices, along with modalities unique to the system, such as Chinese acupuncture and moxibustion, or Indian techniques of breathing and meditation. Thus, research on whole medical systems overlaps all four domains in NCCAM's research portfolio. Some CAM whole medical systems also incorporate some conventional medical treatments in their systems, such as the use in naturopathic medicine of some drugs or vaccines. Thus, just as many Americans use CAM to complement, rather than as an alternative to, mainstream medicine, people using CAM systems as their primary source for health care may find that their providers complement the traditional healing approaches with conventional interventions.

To date, research on practices that are prevalent in these whole medical systems has tended to single out particular modalities in a system for study. This is particularly true for the herbal products, which has led to some interesting findings. For example, studies of *Artemesia annua*, a traditional Chinese herb used to treat fevers, led over the past two decades, to the development of semisynthetic artemisinin drugs for malaria based on an extract of the herb.

Acupuncture is often used by itself, but it is a part of TCM. Popular interest and a growing Western research emphasis on acupuncture began in the early 1970s with preparation for President Nixon's visit to China. *New York Times* reporter James Reston's story, of how he underwent emergency appendectomy surgery there, recounts his relief of postsurgical pain and discomfort as a result of the acupuncture needling treatment. A growing body of evidence suggests that acupuncture treatment effects changes in the peripheral and/or central nervous system that influence pain pathways and perhaps regulatory control over temperature and other involuntary functions. Moreover, there is reasonable evidence that acupuncture ameliorates nausea and dental pain, with more equivocal and contradictory evidence for efficacy in other types of pain, numbness, paralysis, movement disorders, and psychiatric conditions.

There have been other research studies exploring the efficacy of selected modalities of whole medical systems to treat health problems, such as the utility of yoga to treat insomnia or of practicing Chinese exercises (tai chi) to benefit Parkinson's disease, but there has been a growing sense that whole medical systems merit study in their totality. Not only are patients being treated in whole medical systems likely to be subject to a number of interventions, but their treatment will be individualized with additional advice on diet, exercise, lifestyle, and so on.

How To Study Whole Systems. Clearly this is not an easy matter. Conducting research on whole medical systems has been likened to comprehending an opera: it cannot be teased apart into this or that melodic line, chorus, plot progression, or climax, but seen as a whole, working synergistically together—orchestral harmonies, mythic plot, majestic

chorus, heroic characters—interacting seamlessly to create an esthetically rich and intellectually satisfying musical experience. Applying the same sweeping approach to the study of whole medical systems means, at the very least, engaging members of a multidisciplinary team. It may also mean observing the operations of a traditional system in the field—in India or China or other countries where the system is the standard for health care.

Resources Needed. The study of whole systems requires scientists who can apply high-tech resources and analytic tools as well as those who have skills in the conduct of clinical trials. In addition, research on whole medical systems needs to enlist scholars from other fields, including cell and molecular biologists, geneticists, CAM and conventional practitioners, behavioral and social scientists (including ethnographers and medical anthropologists), epidemiologists, and biostatisticians.

Goal 1: Acquire a richer understanding of CAM whole medical systems and how they operate within their indigenous and dispersed settings.

Objective 1. Determine how patients and providers using a whole medical system define health and diagnose, treat, or prevent diseases. This will entail studying the basic precepts and philosophy underlying the system.

Goal 2: Document the benefits of some CAM whole medical system treatments for selected health conditions.

Objective 1. Conduct outcome studies of multimodal treatments, using subjective, patient-oriented measures as well as objective outcome measures, including, where appropriate, the relative benefits, risks, and cost-effectiveness of the treatments for selected disorders.

Objective 2. Conduct randomized controlled clinical trials of multimodal therapies where there is evidence of efficacy from observational and earlier phase clinical studies.

Goal 3: Elucidate mechanisms underlying successful multimodal treatments used in CAM whole medical systems.

Objective 1. Undertake mechanistic studies of individual modalities used as parts of whole medical systems, and apply appropriate analyses to data from studies of multimodal treatments, to estimate the relative contributions each makes to the overall changes in health.

International Health Research

The Center's first strategic plan included a goal to "establish a global NCCAM research enterprise." This goal was further developed in a strategic planning document drawn up in 2002, *Expanding Global Horizons of Healthcare*.[34] The intent was to increase

[34] Visit nccam.nih.gov/about/plans/oihr/index.htm.

understanding of complementary and alternative medical systems throughout the world, study how certain practices may have evolved after introduction in the United States by successive waves of immigrants, and consider the potential of adopting those practices shown to be beneficial for use. Accordingly, a number of research and training programs were launched to foster international collaborative research, build research capacity at foreign sites, and enhance understanding of, and sensitivity to, the many ethical and social issues involved in conducting CAM research across diverse cultures.

These remain laudable goals. But the intervening years have heightened awareness of the pressing importance of NCCAM's attention to the explicit goal of advancing global health per se. AIDS, drug-resistant tuberculosis, and more recently severe acute respiratory syndrome (SARS) provided rude awakenings to the ever-present threat of new or reemerging diseases. Furthermore, data from the World Health Organization and others indicate that the most serious threats to future generations worldwide will include diabetes, hypertension and vascular disease, and depression—conditions for which many CAM practices and systems claim an important role.

Accordingly, NCCAM's plans for international health research include study of key complementary and alternative medical systems where they may best be observed—in their countries of origin—and determining the extent to which some of these systems and their discrete practices may add to the armamentarium of interventions to combat global health problems.

Resources Needed

- Increased capacity for international CAM research (e.g., modern facilities, well-trained researchers, and the ability to secure research funding)

- An international network of CAM research institutions in developed and developing countries that can collaborate to share knowledge and resources, advance CAM research methodology, and carry out specific studies

Goal 1: Advance understanding of traditional/indigenous medical systems through international collaborative studies.

Objective 1. Increase global CAM research, emphasizing research and training collaborations that link U.S. research-intensive institutions with foreign CAM institutions.

Objective 2. Enhance training in the conduct (design, methodology, implementation, analysis, and ethics) of CAM basic and clinical research for investigators and practitioners at foreign study sites, and enhance knowledge of international CAM practices by U.S. investigators and practitioners.

Objective 3. Conduct basic and clinical studies of promising CAM interventions for global health problems.

Objective 4. Conduct qualitative studies using interviews, survey instruments, and ethnographic/anthropological observations to probe how individuals (and families) in a given culture define and respond to illness and make decisions on treatment.

Goal 2: Contribute to the preservation of irreplaceable and valuable traditional/indigenous CAM knowledge and resources.

Objective 1. Foster international efforts to sustain biodiversity and protect the sources of natural products used in research, wherever it is conducted or wherever the interventions are used, through accepted principles of conservation and protection.

Objective 2. Enhance efforts to characterize and protect indigenous and traditional knowledge.

Objective 3. Foster fair sharing of the benefits of research through appropriate and creative approaches to the protection of intellectual property and benefit-sharing agreements.

Goal 3: Enhance understanding of processes that enable the integration of safe and effective CAM interventions with non-CAM interventions abroad and in the United States.

Objective 1. Study the ways in which other countries have successfully integrated Western practices and those of CAM whole medical systems.

Health Services Research

With the rise of consumer interest—and spending—for CAM products and services over the past few decades, investigators have been intrigued to discover the who, what, and why of CAM use. Such questions fall into the broad category of health services research, which explores the factors that influence people's access to and utilization of health care services; the nature, costs, and quality of that care; and ultimately the effects on their health and well-being. While surveys have been of varying size, scope, and methodology, they have been consistent in charting growth in the use of CAM by the American public over the past decade. The most recent and comprehensive survey was one in which NCCAM collaborated with the National Center for Health Statistics of the Centers for Disease Control and Prevention in developing a questionnaire to supplement the 2002 National Health Interview Survey.[35]

The Who. The survey, based on interviews with over 31,000 adults, indicated that 36 percent of Americans had used some form of CAM in the previous 12 months. The figure jumps to 62 percent if the definition of CAM includes the use of prayer specifically for health.

[35] Barnes P, Powell-Griner E, McFann K, Nahin R. *Complementary and Alternative Medicine Use Among Adults: United States, 2002*. CDC Advance Data Report. 2004.

The What. Of the 27 different CAM therapies listed in the questionnaire, mind-body interventions[36] were the most commonly used. Leading CAM interventions used included prayer for one's own health (43 percent), prayer by others for the respondent's health (24 percent), natural products (19 percent), deep breathing exercises (12 percent), meditation or chiropractic care (about 8 percent each), yoga (5 percent), and massage (5 percent). The five leading health problems for which respondents chose a CAM therapy were a back pain or problem, head or chest colds, a neck pain or problem, joint pain or stiffness, and anxiety or depression.

And Why. When asked why they used CAM, the majority said they thought that it would help in combination with conventional care. About a quarter used CAM because their regular health care provider had recommended it—while another fourth of users did so because they didn't think conventional treatments would help. Thirteen percent said that they used CAM because they thought conventional medicine was too expensive. In fact, many CAM therapies are paid for out of pocket. A 1997 study[37] estimated that between $36 billion and $47 billion was spent on CAM therapies, of which somewhere between $12.2 billion and $19. 6 billion represented out-of-pocket expenses paid to CAM providers—fees that exceeded the sums the public paid out-of-pocket for all hospitalizations that year, and half what they paid out-of-pocket for regular physician services.

Gaps To Be Filled. Data from the survey released in May 2004 will continue to be mined to provide further "big picture" details of the who, what, and why of CAM use. But there remain many health services research questions that will not be answered by large surveys and need to be addressed in specific studies. One would like to know, for example, for a proven CAM intervention, whether it is truly cost-effective compared with conventional treatments; what degree of risk may be involved; and whether there are long-term benefits for quality of life and well-being. Government agencies, such as the Center for Medicare and Medicaid Services and the AHRQ, have an interest in these questions as well, providing additional resources for health services research independently or in partnership with NCCAM. Should research findings favor the use of the CAM intervention, they could be instrumental in policy changes leading to insurance coverage as well as encouraging steps to integrate the CAM practice with mainstream medicine.

So far, rigorous CAM health services research in any of these areas has been sparse and at times has yielded contradictory results. For example, retrospective studies suggested that chiropractic therapies could reduce referral and treatment costs for low-back pain, while prospective studies suggested that CAM was an additional expense that did not substitute for conventional care.[38] CAM health services research in other areas—detailing

[36] The following practices were listed under mind-body therapies: biofeedback, meditation, guided imagery, progressive relaxation, deep-breathing exercises, hypnosis, yoga, tai chi, qi gong, prayer (prayed for own health, others ever prayed for your health, participate in a prayer group, healing ritual for own health).

[37] Eisenberg DM, Davis RB, Ettner SL, et al. Trends in alternative medicine use in the United States, 1990-1997. *Journal of the American Medical Association*.1998;280(18)1569-1575.

[38] White AR, Ernst, E. Economic analysis of complementary medicine: a systematic review. *Complementary Therapies in Medicine*. 2000;8(2):111-118.

which procedures are covered by third-party payers and why,[39,40,41] establishing whether CAM therapies truly enhance quality of life,[42,43] learning in general what CAM patients believe about CAM[44,45,46,47] and if they are satisfied with treatments[48,49,50]—have all been subject to study, but variations in the methods and instruments used as well as how CAM and quality of life were defined in them, make it difficult to generalize and indeed dictate that future NCCAM-supported health services research should be specific with respect to service and disease. Different services for different conditions may have varying implications for quality, cost, patients and populations, access, and organization of care.

Resources Needed

- Improved survey instruments (along with their performance characteristics) to measure quality of life, patient satisfaction, health care quality, and value of delivery of effective care in health care organizations

- Interdisciplinary teams that include health economists, epidemiologists, computer scientists and statisticians, social and behavioral scientists, CAM and conventional care providers, and clinical trialists

[39] Pelletier KR, Astin JA. Integration and reimbursement of complementary and alternative medicine by managed care and insurance providers: 2000 update and cohort. *Alternative Therapies in Health and Medicine*. 2002;8(1):38-39, 42, 44.

[40] Pelletier KR, Astin JA, Haskell WL. Current trends in the integration and reimbursement of complementary and alternative medicine by managed care organizations (MCOs) and insurance providers: 1998 update and cohort analysis. *American Journal of Health Promotion*.. 1999;14(2)125-133.

[41] Pelletier KR, Marie A, Krasner M, et al. Current trends in the integration and reimbursement of complementary and alternative medicine by managed care, insurance carriers, and hospital providers. *American Journal of Health Promotion*. 1997;12(2):112-122.

[42] Jacobsen PB, Meade CD, Stein KD, et al. Efficacy and costs of two forms of stress management training for cancer patients undergoing chemotherapy. *Journal of Clinical Oncology*. 2002;20(12):2851-2862.

[43] Targ EF, Levine EG. The efficacy of a mind-body-spirit group for women with breast cancer: a randomized controlled trial. *General Hospital Psychiatry*. 2002;24(4):238-248.

[44] Henderson JW, Donatelle RJ. Complementary and alternative medicine use by women after completion of allopathic treatment for breast cancer. *Alternative Therapies in Health and Medicine*. 2004;10(1):52-57.

[45] Williamson AT, Fletcher PC, Dawson KA. Complementary and alternative medicine: use in an older population. *Journal of Gerontological Nursing*. 2003;29(5):20-28.

[46] Duggan J, Peterson WS, Schutz J, et al. Use of complementary and alternative therapies in HIV-infected patients. *AIDS Patient Care and STDs*. 2001;15(3)159-167.

[47] Astin JA. Why patients use alternative medicine: results of a national study. *Journal of the American Medical Association*. 1998;279(19):1548-1553.

[48] Rao JK, Mihaliak K, Kroenke K, et al. Use of complementary therapies for arthritis among patients of rheumatologists. *Annals of Internal Medicine*. 1999;131(6):409-416.

[49] Coulter ID, Hurwitz EL, Adams AH, et al. Patients using chiropractors in North America: who are they, and why are they in chiropractic care? *Spine*. 2002;27(3):291-296.

[50] Baldwin ML, Cote P, Frank JW, et al. Cost-effectiveness studies of medical and chiropractic care for occupational low back pain; a critical review of the literature. *Spine Journal*. 2001;1(2):138-147.

Goal 1: Determine how CAM services affect the health care marketplace.

Objective 1. Conduct studies to discover if proven CAM services add to or replace the costs of conventional treatments; determine what effect integrating the CAM service with conventional care has on health care costs, and how patient cost-sharing affects utilization of CAM.

Goal 2: Enhance the design of CAM clinical studies and trials by adding instruments to collect health services research data.

Objective 1. Add validated quality-of-life components to large clinical studies of selected CAM therapies.

Objective 2. Use a variety of qualitative and quantitative methods, including randomized clinical trials, as a vehicle for collecting data on costs, cost offsets, and cost effectiveness.

Objective 3. Provide for careful monitoring and reporting of adverse effects within effectiveness trials.

Goal 3: Explore models of organized health care delivery that integrate CAM with conventional care.

Objective 1. Measure outcomes of integrated health care delivery models with respect to quality of care, cost, and access.

Ethical, Legal, and Social Implications of CAM Research and Integrated Medicine

A number of social, legal, and ethical issues impede a smooth pathway to conducting CAM research, training CAM investigators, expanding outreach, and facilitating integration. Indeed, these concerns pose sufficient challenges that NCCAM is augmenting its research portfolio by the addition of a research agenda specifically addressing the ethical, legal, and social implications of CAM research and integrated medicine. Examples of these issues have been raised elsewhere in the plan; they are briefly recapitulated here.

Social Issues. NCCAM was established after Americans began to spend billions of dollars every year for products and procedures marketed as natural and safe complements or alternatives to scientifically proven modalities—albeit with little research to support their use. NCCAM assumed the responsibility of doing studies needed to assure the public that the CAM therapies they were using were acceptable, or else to alert them to potential harm. Communicating this information effectively, without unduly alarming or antagonizing the public, demands an understanding and sensitivity to social and cultural variables. Yet, despite the abundance of survey data on CAM, information regarding who uses CAM and for what purposes, when, and why, is incomplete, as is information on the knowledge and attitudes of mainstream practitioners, educators, and others in a position to effect social and policy changes. In

this regard, it is not clear when and if patients using CAM therapies tell their conventional providers of their CAM use—or whether the conventional provider routinely asks. This lack of communication, for whatever reason, can have serious consequences resulting from interactions of CAM products and prescription drugs.

Studies of how and why the use of CAM has come into such prominence today are also limited. In 19th century America, a variety of alternative practices flourished in competition with what constituted orthodox (and often toxic) medicine, especially in its pregerm theory, preantiseptic heyday. In 1910, the publication of the Flexner report[51] changed all that, all but eliminating alternative schools and ushering in an era of professional medical education and practice in America based on an ever-evolving medical *science*—which came to dominate and continues to define mainstream medicine.

Subsequent gains in health and average lifespan in the 20th century from advances in medicine, as well as in sanitation and public health, have altered the patterns of health and disease in America. Growing numbers of mature adults in good health expect to live long and stay well. Many other Americans, who in spite of suffering from chronic diseases not easily treated by conventional medicine, also want to lead a good life with relief of symptoms. If a conventional cure or help with symptoms is not at hand, many may opt for alternative approaches, seeking comfort in the kinds of compassionate care in the individualized, less technological settings characteristic of many CAM therapies and therapists. Again the questions arise: Who chooses (or rejects) CAM? As complement? As alternative? For what reasons? What kinds of CAM? For what conditions? Answering these questions will not only advance understanding of the dynamics of social change in America, but also point the way to more effective means of presenting scientific findings from NCCAM research to guide the public and professional communities NCCAM serves in making decisions.

Legal and Ethical Issues in CAM Practice. Against the changing social and cultural climate in America today, a number of challenging legal issues have emerged. CAM practitioners and practices span a range of disciplines for which training, credentialing, and licensure vary from state to state, with few national credentialing and licensing bodies to determine qualifications for a particular CAM practice. There is further variability with respect to access to and reimbursement for CAM procedures by third-party payers. Until each of the professions has established clear standards of practice, it will be hard for many CAM practitioners to be credentialed and reimbursed.

Legal and Ethical Issues in CAM Research. Nor will it be possible for CAM practitioners, without credentialing, to participate as coinvestigators in NCCAM-supported research studies. This is one of several legal and ethical issues that have arisen with regard to conducting CAM research and clinical trials, both domestically and internationally. Another issue, encountered in connection with biologically based practices, concerns products sold as dietary supplements. Under the Dietary Supplement

[51] Flexner A. *Medical Education in the United States and Canada*. New York: Carnegie Foundation for the Advancement of Teaching; 1910. Flexner's study accelerated reforms in the standards, organization, and curriculums of U.S. medical schools.

Health and Education Act of 1994,[52] such products are subject to less stringent regulatory laws than prescription drugs. This has led to problems in research with regard to their characterization, standardization, and stability, including the potential for contamination with harmful substances. To counter these problems, NCCAM has taken steps to assure quality control of products used in research.

CAM clinical studies have also been subject to ethical questions and concerns that are impeding research. For example, IRB members who may be unfamiliar with CAM modalities may reject studies of products that lack formal analysis of their composition, mechanisms of action, and safety in humans, and question the ethical validity of testing any CAM procedure in the absence of known benefits or risks. More generally, ethical issues have been raised about the design of CAM clinical trials in terms of the adequacy of consent forms, use of placebo controls (here a major CAM issue is the difficulty in devising "sham" procedures for modalities such as mind-body interventions and manipulative procedures), potential for bias, and so on. These issues have been addressed in an article by Miller et al.,[53] which concluded that CAM clinical studies and trials can and should be conducted with the same degree of rigor as conventional clinical trials.

Given the international scope of complementary and alternative medicine, NCCAM must also address ethical issues that have emerged when industrialized countries conduct clinical trials in the developing world (home to many CAM whole medical systems). One concern focuses on what some believe to be an absolute requirement of uniform care—assuring that trial subjects in developing countries receive care equivalent to what would be received in the industrialized world. One could ask, for example, if it would be ethical for NCCAM to support a study in China of an unproven traditional Chinese medicine intervention that is widely accepted as "standard care" there, if there is an accepted mainstream standard of care in the United States.

NCCAM recognizes the importance of airing these collective ethical, legal, and social concerns and values the advice and guidance from experts. Toward that end, in 2002 NCCAM, joined by 16 NIH institutes and AHRQ, commissioned a study by the Institute of Medicine of the National Academies to address research and policy issues with regard to the ethical, legal, and social implications of CAM research and practice. The recommendations of the Institute of Medicine report will inform the Center's approaches to studies of the ethical, legal, and social implications of CAM that affect both its study and the potential for CAM approaches to be meaningfully integrated with mainstream health care practices in the United States.

Resources Needed

- Guidelines to assist IRBs in reviewing CAM clinical trial proposals

[52] Public Law 103-417. Accessed at http://www.fda.gov/opacom/laws/dshea.html on August 18, 2004.

[53] Miller FG, Emanuel, EJ, Rosenstein, DL, et al. Ethical issues concerning research in complementary and alternative medicine. *Journal of the American Medical Association*. 2004;291(5):599-604.

- Data on the training, licensing, accrediting, and credentialing of CAM practitioners state by state

- Strong professional guidelines for training and credentialing of CAM practitioners, and clear and consistent laws defining their scope of practice

- Input and participation from a diverse group of scholars, including ethicists, clinical trial researchers, biostatisticians, CAM and conventional researchers and practitioners, lawyers, insurers, representatives from other Government agencies, credentialing and licensing authorities, social and behavioral scientists, anthropologists, and cultural historians

Goal 1: Enhance understanding of the social, cultural, and economic factors relating to the use of CAM.

Objective 1. Use well-validated qualitative and quantitative social science instruments for assessing knowledge, attitudes, and beliefs held by the public and CAM and conventional practitioners with respect to the use of CAM products and practices.

Objective 2. Determine whether and how conventional practitioners introduce new CAM interventions into their practices, and examine the variables that affect their decisions.

Objective 3. Investigate how the knowledge, attitudes, and beliefs of consumers and health care providers (CAM and conventional) affect the nature, cost, and outcomes of health care services in the United States.

Objective 4. Develop a consensus definition of CAM for use in the design of survey instruments to enable comparisons of data among individual surveys.

Goal 2: Describe the framework needed to enable the creation of integrated, multidisciplinary research teams.

Objective 1. Study historical models to learn how academic health care and practice communities successfully integrated new disciplines such as psychology, social work, and many other allied professions into the research and health care delivery system.

Objective 2. Assess the barriers that prevent CAM and conventional practitioners from working together in practice.

Goal 3: Encourage the creation of integrated research environments and practice communities.

Objective 1. Identify the requirements needed to create and sustain academic medical institutions committed to integrated research, using the experience of institutions that have successfully forged multidisciplinary teams of researchers and allied health professionals.

Objective 2. Study how allied health professionals achieved credibility and acceptance as meritorious researchers and practitioners among their peers, and how institutions subsequently incorporated these members into multidisciplinary teams.

Objective 3. Use the knowledge obtained from studies of barriers to integration, as well as features of successful models, to develop demonstration projects of integration.

Goal 4: Define and address ethical and legal issues related to the conduct of CAM clinical trials domestically and internationally.

Objective 1. Examine ethical issues in the conduct of research in settings that rely heavily on traditional, indigenous health practices.

Objective 2. Develop model designs and protocols adhering to the highest standards of ethical criteria for CAM clinical trials conducted in the United States or abroad.

Objective 3. Identify barriers that impede IRB approval of CAM clinical trials.

Training CAM Investigators

The focus of Strategic Area 2 in NCCAM's first strategic plan was on research training, with the goal of **increasing the number, quality, and diversity of CAM investigators**—both conventional and CAM-trained professionals—able to conduct CAM research. Mindful of the diversity of the individuals attracted to CAM research, NCCAM chose to implement a variety of research training opportunities at predoctoral, postdoctoral, and faculty levels, through both individual and institutional awards. NCCAM also committed to a research training component when it established its intramural research program.

Five years' experience has yielded some successes: as NCCAM has grown, so too has the pool of established, conventional researchers—M.D., Ph.D., and M.D.-Ph.D.—who were drawn to and now conduct basic and clinical CAM research. At the same time, students, postdoctoral fellows, and junior faculty have received training in CAM research at sites around the country and in NCCAM's intramural laboratories. NCCAM's research training and career development programs have attracted both CAM practitioners and those from conventional backgrounds.

Still, CAM research could benefit from a more diverse workforce: relatively few of NCCAM's investigators hold CAM degrees or are from racial and ethnic groups underrepresented in medical research. Currently, NCCAM is striving to foster the long-term success of CAM practitioners undergoing research training and to improve recruiting underrepresented minorities to CAM research.

These are among the issues addressed by a panel of experts convened to conduct a formal review of NCCAM's training and career development programs as part of the

Center's ongoing evaluation activities. Their full report is expected to be released in early 2005. But because the evaluation process was coincident with plans to develop the second strategic plan, the panel of reviewers joined with the other experts convened into working groups to draft goals and priority recommendations for the Center in the next 5 years, and many of their findings and recommendations are included here.

Resources Needed. The absence of an established research infrastructure and of an adequate supply of mentors—and in some sites, the lack of an institutional culture recognizing the value and rewards of CAM research—are currently leading barriers to developing a strong cadre of CAM-trained investigators. Just as in other fields of science, adequate resources are a prerequisite to successful research training in CAM, whether it takes place in a CAM or conventional institution.

Goal 1: Tailor a portfolio of research training programs reflective of the evolving needs of CAM research.

Objective 1. Offer research training and career development opportunities for those from both CAM and conventional backgrounds and encourage skilled investigators to enter the field of CAM research.

Objective 2. Provide research training opportunities for individuals ranging in experience from predoctoral students to junior faculty, maintaining an emphasis on training at the postdoctoral level and beyond.

Objective 3. Invest in research training and career development in CAM-specific areas that other NIH institutes and centers are unlikely to support, as well as in conventional areas that are particularly relevant to CAM research.

Goal 2: Continue to foster a research culture and the necessary resources to enable both CAM- and conventionally trained individuals to build successful careers in CAM research.

Objective 1. Ensure that CAM research training and career development take place in settings where there is a critical mass of ongoing related research, infrastructure, and research mentors.

Objective 2. Foster CAM practitioners' exposure to, and understanding of, the biomedical research literature and evidence-based approaches to advancing science and health care.

Objective 3. Target selected research training awards for CAM practitioners.

Objective 4. Support career development awards for promising postdoctoral fellows to ease the transition from postdoctoral training in CAM research to independent research careers.

Objective 5. Capitalize on opportunities to draw underrepresented minorities into CAM research training.

Objective 6. Reinforce the importance of experienced mentors in CAM research training, by emphasizing programs that support midcareer investigators in research and mentorship roles.

Expanding Outreach

The Center recognized early on the importance of informing the public about CAM research results so they could make informed health care decisions. The subject matter of CAM presents unique challenges and opportunities. Unlike other areas of research, large segments of Americans are already using various complementary and alternative healing practices in the absence of rigorous scientific evidence of their safety and effectiveness. Further, there are very strong feelings about the study of CAM. Among NCCAM's many publics are CAM proponents who may regard NCCAM's research activities as an effort to disprove CAM; another group includes CAM opponents who consider NCCAM's research endeavors an endorsement of unproven medicine; and a vast general public who hear many conflicting messages about CAM, including the assumption that any product labeled as "natural" must be safe. Thus, the topic of CAM presents an environment of uncertainty for the public. Where can the public turn for reliable and accurate information? Who can they trust? In communicating its messages, NCCAM applies the same rigor in reporting and responsiveness to the public as NCCAM does in its very support and conduct of CAM research: It presents the facts—and acknowledges the limitations on what is known—about particular CAM procedures and products. NCCAM recognizes the power of collaboration in communication to the public and has begun partnering with like-minded consumer advocacy and health professional organizations to disseminate CAM information.

In outreach to the scientific community, the Center has recognized the necessity of recruiting seasoned conventional researchers who could bring their expertise and experience to address CAM-related research questions. Also key to the research process is outreach to CAM practitioners, who can lend their subject-matter expertise to enrich the research process. In addition, NCCAM reaches out to health professionals and students at conventional and CAM institutions, informing them of opportunities for funding of research, research training, and career development.

These measures have done much to establish NCCAM as the national voice for complementary and alternative medicine—among those who are aware of the Center—earning the respect of both CAM and conventional practitioners and the public. Nevertheless, many Americans are unaware of NCCAM and the research it supports. Because CAM practices are so diverse and used for so many conditions, NCCAM has strived to identify natural communications partners to enhance its outreach efforts.

Resources Needed

- Organizations with whom NCCAM can partner to extend its reach to wider audiences. Partnerships should be sought among patient and professional associations, NIH components and other Federal agencies, private foundations, community organizations, and other interested parties.

Goal 1: Help the public and health care professionals make informed health care decisions about CAM.

Objective 1. Conduct consumer research to assess stakeholder perceptions, barriers, opportunities, and unmet needs, using surveys, interviews, focus groups, and other means as appropriate and to evaluate the effectiveness of NCCAM communications.

Objective 2. Position NCCAM as an authoritative, trusted source of CAM information.

Objective 3. Continue to develop a coalition of outreach partners to expand the reach of critical CAM health information. Meet with key stakeholder groups to maintain a dialogue and solicit feedback on NCCAM's communication activities.

Objective 4. Communicate state-of-the-science CAM information through a multifaceted communications program that includes the media, public forums, the continued development of culturally sensitive health information materials, and an enhanced Internet presence.

Objective 5. Provide the public with critical assessment skills so they are better able to discern conflicting messages about CAM.

Goal 2: Enrich the pool of multidisciplinary CAM researchers.

Objective 1. Engage and recruit multidisciplinary researchers in the study of CAM by informing the research community of opportunities, publicizing research advances, attending and providing lectures at scientific meetings, and developing informational tools for prospective grantees.

Objective 2. Develop and implement an outreach strategy to attract minority researchers.

Objective 3. Work to facilitate research partnerships domestically and internationally.

Part III. Advancing Our Organization

Since NCCAM's founding in 1999, our staff has grown severalfold, and with that growth have come new challenges. With 5 years of experience, we learned many lessons and are examining how we have evolved, what our organizational culture is, and how we conduct our work. As a result, we are now poised to further advance the Center's goals and mission through better management of the public's investment in CAM research.

The goals and objectives described below outline ways in which NCCAM can build upon the strong foundation laid during its formative years.

Goal 1: Promote organizational growth.

Objective 1. Develop an organizational culture that values integrity and practices respect, teamwork, and open communications.

Objective 2. Clearly define the roles and responsibilities of each division and office.

Objective 3. Encourage dialogue among NCCAM staff members at all levels and across all organizational units; actively solicit, respond to, and reward staff input, as appropriate.

Objective 4. Enhance working relationships and develop trans-NCCAM work teams that value and utilize the perspectives and expertise of all staff members.

Objective 5. Promote diversity among NCCAM employees and enhance understanding and appreciation of cultural differences.

Objective 6. Share decisionmaking processes and knowledge at all levels of the organization.

Goal 2: Encourage and empower NCCAM's staff.

Objective 1. Clearly define the roles and responsibilities of each staff member.

Objective 2. Entrust staff members with the authority, accountability, and autonomy to fulfill their responsibilities effectively.

Objective 3. Clarify performance expectations, refine metrics for success, encourage creativity, and reward achievements.

Objective 4. Further develop staff expertise and encourage career development through mentoring, practical experience, and training.

Objective 5. Support quality-of-work life programs and initiatives.

Goal 3: Optimize effective management of the public's investment in CAM research.

Objective 1. Evaluate our programs and operations to further incorporate best practices and solidify management controls.

Objective 2. Develop standard operating procedures with input from all relevant staff members and widely communicate them to all those affected.

Objective 3. Seek opportunities to further leverage our resources through partnerships and collaborations to maximize the return on research investment.

Objective 4. Provide effective management tools, capitalizing on information technology.

Appendix I

Important Events in NCCAM's History

November 1991 – Public Law 102-170 provides $2 million to the National Institutes of Health to establish an office and advisory panel to recommend a research program that would investigate promising unconventional medical practices.

June 1993 – Public Law 103-43, the NIH Revitalization Act of 1993, establishes the Office of Alternative Medicine within the Office of the Director of NIH. The purpose of OAM is to facilitate the evaluation of alternative medical treatment modalities and to disseminate information to the public via an information clearinghouse.

October 1995 – A research centers program is established to provide a nationwide focus for interdisciplinary CAM research in academic institutions.

October 1996 – A public information clearinghouse is established.

November 1996 – OAM is designated a World Health Organization Collaborating Center in Traditional Medicine.

September 1997 – The first phase III clinical trial is funded, a study of St. John's wort for major depression. The trial is cosponsored by OAM, the National Institute of Mental Health, and the NIH Office of Dietary Supplements.

October 1998 – Public Law 105-277, the Omnibus Consolidated and Emergency Supplemental Appropriations Act, elevates the status and expands the mandate of OAM by authorizing the establishment of NCCAM. This act amends Title IV of the Public Health Service Act.

January 1999 – William R. Harlan, M.D., is appointed Acting Director of NCCAM.

February 1999 – The Secretary of Health and Human Services signs the organizational change memorandum creating NCCAM and making it the 25th independent component of NIH. The NCCAM Director is vested with broad decisionmaking authority, especially concerning financial and administrative management, and fiscal and review responsibility for grants and contracts.

May 1999 – NCCAM independently awards its first research project grant.

The NCCAM Trans-Agency CAM Coordinating Committee is established to foster the Center's collaboration across NIH, HHS, and other Federal agencies.

June 1999 – A Special Emphasis Panel is chartered to enable NCCAM to conduct peer review of mission-specific CAM applications.

August 1999 – The National Advisory Council for Complementary and Alternative Medicine is chartered.

September 1999 – NCCAM funds it first research training, fellowship, and career development awards.

October 1999 – The Secretary of Health and Human Services appoints Stephen E. Straus, M.D., as the first Director of NCCAM.

NCCAM and the NIH Office of Dietary Supplements establish the first Dietary Supplements Research Centers with an emphasis on botanicals.

September 2000 – NCCAM's first strategic plan is published, *Expanding Horizons of Healthcare: Five-Year Strategic Plan 2001–2005*.

February 2001 – NCCAM and the National Library of Medicine launch CAM on PubMed, a comprehensive Internet source of research-based information on CAM.

April 2001 – The Division of Intramural Research is established.

April 2002 – Results of NCCAM's first phase III clinical trial, of St. John's wort for major depression, are published.

June 2002 – NCCAM's first intramural study, of electroacupuncture to treat chemotherapy-induced nausea, is launched.

July 2002 – NCCAM initiates a new lecture series, "Distinguished Lectures in the Science of Complementary and Alternative Medicine."

October 2002 – NCCAM and 16 Federal cosponsors launch an Institute of Medicine study of the scientific and policy implications of the use of CAM by the American public.

February 2003 – Margaret A. Chesney, Ph.D., is appointed as NCCAM's first Deputy Director (see Appendix II).

September 2003 – As part of its restructured research centers program, NCCAM funds three types of centers: Centers of Excellence for CAM Research to support established researchers, Developmental Centers to partner CAM institutions and major research universities, and planning grants for International Centers on CAM Research to partner U.S. and international research teams.

February 2004 – NCCAM establishes an analytical resource center to assay and characterize dietary supplements.

Appendix II

Biosketches

Stephen E. Straus, M.D.

Stephen E. Straus, M.D., was appointed the first Director of the National Center for Complementary and Alternative Medicine in October 1999. An internationally recognized expert in clinical research and clinical trials, Dr. Straus is also Senior Investigator in the Laboratory of Clinical Investigation at the National Institute of Allergy and Infectious Diseases (NIAID). He has extensive basic and clinical research experience related to many conditions for which there are alternative or complementary remedies, including chronic fatigue syndrome, Lyme disease, HIV/AIDS, chronic hepatitis B virus, genital herpes infections, and chronic post-herpetic pain. Dr. Straus also has extensive background in investigations of the molecular biology, pathogenesis, treatment, and prevention of human viral infections and immunologic diseases. Among his accomplishments in these areas are his demonstration that acyclovir suppresses recurrent genital and oral herpes and his characterization of a previously unrecognized genetically determined disease, the autoimmune lymphoproliferative syndrome.

Dr. Straus began his academic training at the Massachusetts Institute of Technology, where in 1968 he obtained his Bachelor of Science degree in life sciences. In 1972, he received his medical degree from the Columbia University College of Physicians and Surgeons. Dr. Straus's career at the National Institutes of Health began in 1979, when he joined NIAID as a Senior Investigator. He is board-certified in internal medicine and infectious diseases.

His professional achievements have been recognized by many prestigious professional societies, including the Association of American Physicians and the American Society for Clinical Investigation, and by appointment to the editorial boards of several scholarly journals. He is the 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 HHS Secretary's Distinguished Service Award for drafting the blueprint to reinvigorate clinical research at NIH. Dr. Straus is a member of the Clinical Research Roundtable of the National Academies' Institute of Medicine and of the National Institutes of Health Steering Committee. He has published more than 375 research articles and edited several books.

Margaret A. Chesney, Ph.D.

Margaret A. Chesney, Ph.D., is Deputy Director of the National Center for Complementary and Alternative Medicine. She also serves as the Center's Director of the Division of Extramural Research and Training. While engaged in clinical research in behavioral medicine and health psychology, Dr. Chesney focused on the relationship between behavior and chronic illness; behavioral factors in clinical trials, including issues of recruitment, adherence, and retention; and the development and evaluation of behavioral treatments of health problems. Her research primarily targeted women's health concerns, cardiovascular disease, and HIV/AIDS.

Dr. Chesney received her undergraduate degree from Whitman College, Walla Walla, Washington. She obtained her master's and doctoral degrees in clinical psychology and counseling from Colorado State University, Fort Collins. Dr. Chesney completed postdoctoral fellowship training in the Department of Psychiatry at Temple University's School of Medicine, Philadelphia.

Before joining NCCAM in February 2003, Dr. Chesney was Professor of Medicine at the School of Medicine, University of California, San Francisco (UCSF). While at UCSF, she served as Co-Director of the Center for AIDS Prevention Studies; Associate Director of the California AIDS Research Center at UCSF; and Director of the Behavioral Medicine and Epidemiology Core of the UCSF Center for AIDS Research. In 2001 and 2002, Dr. Chesney also was a Visiting Scientist with the Office of Research on Women's Health in the Office of the Director of NIH.

Dr. Chesney is a past President of the Academy of Behavioral Medicine Research and of the American Psychosomatic Society, and President of the Division of Health Psychology of the American Psychological Association. Her awards include the Annual Award for Outstanding Contributions to the APA Division of Health Psychology in 1982 and 1986, the President's Award from the Academy of Behavioral Medicine Research in 1987, and the Charles C. Shepard Science Award from the Centers for Disease Control and Prevention in 1999. In 2000, Dr. Chesney was a Senior Fellow at the Center for the Advancement of Health in Washington, DC, supported by the Robert Wood Johnson and John D. and Catherine T. MacArthur Foundations. In 2001, she was elected to the Institute of Medicine of the National Academies.

Appendix III

The Strategic Planning Process

The strategic planning process proceeded in two phases. In phase I, NCCAM solicited advice and comments on its future activities from a broad range of stakeholders, each acting independently. The exercise began with insiders' views: an NCCAM staff retreat held on February 11, 2004. The Strategic Plan Advisory Panel met 2 days later and consisted of highly regarded CAM and non-CAM scientists, clinicians, public health advocates, academicians, editors, and administrators. (See Appendix IV.) The third and fourth groups included representatives of CAM disciplines, investigators, and members of the public who were invited to testify at two regional stakeholder forums. They spoke before listening panels composed of NCCAM senior staff and NCCAM Advisory Council members. The East Coast forum was held in Bethesda, Maryland, on March 22, followed on April 19 by a West Coast forum in Seattle. Additional public comments were elicited from NCCAM's Web site (nccam.nih.gov/about/plans/2005/index.htm).

Based on the various priority listings of research topics from the phase I meetings, we developed a list of **master health goals** (see page 33)—such as the seriousness of the health problems, needs of special populations, and use of CAM practices to prevent disease and promote health and wellness.

These were incorporated into the charge to the 10 working groups (see Appendix IV) constituting phase II of the strategic planning process. These groups were defined by the themes repeatedly emphasized by phase I participants.

- NCCAM was advised to dedicate five working groups to parallel the **four principal CAM domains and whole medical systems**, while the recognition that CAM is a global enterprise dictated a need for a working group on **international health research**. The admonition from advisors to study in more detail who uses CAM and how, when, and why, as well as to evaluate the cost-effectiveness of CAM practices, spurred the conviction that NCCAM should have a working group on **health services research**.

- **Outreach** and **research training** as subjects for working groups were obvious, since they were strategic areas in our first plan. Moreover, there was some urgency in the concerns voiced by many stakeholders about who is best able to conduct CAM research—and where. These concerns meshed with plans already in place to evaluate NCCAM research training and career development programs, and led to integrating evaluation into the charge of the Research Training Working Group.

- Issues raised by the phase I advisors also inspired the creation of a working group on the **ethical, legal, and social implications of CAM research and integrated medicine.**

Approximately 80 individuals participated as members of one or more of the 10 working groups. To ensure a broad perspective, each group was co-chaired by an outside expert and an NCCAM staff member. Members included representatives of both CAM and conventional research and practitioner communities, members of the National Advisory Council for Complementary and Alternative Medicine, and members of the phase I Strategic Plan Advisory Panel. Included were many distinguished researchers, new to CAM, who lent their expertise and experience in other areas toward solving problems related to CAM research, using the range of state-of-the-art approaches from molecular and cellular biology through population-based studies.

In addition to these 10 working groups, an internal working group with broad representation of NCCAM staff and an expert consultant provided recommendations for advancing the NCCAM organization. (See Appendix IV.)

The plan benefited from extensive preliminary review by working group members. It was discussed at the meeting of the National Advisory Council for Complementary and Alternative Medicine on September 10, 2004, and members of the public at large were offered the opportunity to provide comments via the NCCAM Web site. In addition, comments were specifically solicited from individuals instrumental in the initial formation and development of the Office of Alternative Medicine and NCCAM.

Appendix IV

NCCAM Advisors

Strategic Plan Advisory Panel

Strategic Planning Workshop Working Groups

- Mind-Body Medicine
- Biologically Based Practices
- Manipulative and Body-Based Practices
- Energy Medicine
- Whole Medical Systems
- International Health Research
- Health Services Research
- Research Training
- Outreach
- Ethical, Legal, and Social Implications of CAM Research and Integrated Practice
- NCCAM Stewardship Working Group

Strategic Plan Advisory Panel

Natcher Conference Center, NIH
February 13, 2004

CHAIRPERSON
Arthur Kleinman, M.D., M.A.
Chairperson, Department of Anthropology
Esther and Sidney Rabb Professor of Anthropology
Harvard University
Professor of Medical Anthropology and Professor of Psychiatry
Department of Social Medicine
Harvard Medical School
Cambridge, MA

MEMBERS
Shu Chien, M.D., Ph.D.
University Professor of Bioengineering and Medicine
Chairperson, Department of Bioengineering
University of California, San Diego
La Jolla, CA

Haile T. Debas, M.D.
Executive Director
Global Health Services
University of California, San Francisco
San Francisco, CA

Balz Frei, Ph.D.
Professor and Director
Department of Biochemistry and Biophysics
Linus Pauling Institute
Oregon State University
Corvallis, OR

Peggy Hamburg, M.D.
Vice President for Biological Programs
Nuclear Threat Initiative
Washington, DC

Ted J. Kaptchuk, O.M.D.
Assistant Professor of Medicine
HMS Osher Institute
Harvard Medical School
Boston, MA

Tieraona Low Dog, M.D.
Assistant Professor
Department of Family Medicine
Integrative Medicine Education Associates
University of New Mexico
Albuquerque, NM

George D. Lundberg, M.D.
Special Healthcare Advisor to the Chairman and CEO, WebMD
Santa Clara, CA

William Meeker, D.C., M.P.H.
Vice President
Palmer Center for Chiropractic Research
Davenport, IA

William (Bill) J. Mulvihill, M.Ed.
Senior Associate Athletic Director
University of Cincinnati
Cincinnati, OH

Herbert Pardes, M.D.
President and CEO
New York-Presbyterian Hospital
New York, NY

Robert Park, Ph.D.
Director of Public Information
American Physical Society
Washington, DC

Ralph Snyderman, M.D.
Chancellor for Health Affairs,
President/CEO
Duke University Health System
Duke University
Durham, NC

Allen M. Spiegel, M.D.
Director
National Institute of Diabetes
and Digestive and Kidney Diseases
National Institutes of Health
Bethesda, MD

Nora D. Volkow, M.D.
Director
National Institute on Drug Abuse
National Institutes of Health
Bethesda, MD

Robert E. Wittes, M.D.
Physician-in-Chief
Memorial Sloan-Kettering Cancer
Center
New York, NY

Strategic Planning Workshop
Mind-Body Medicine Working Group

Hunt Valley, Maryland
May 23-25, 2004

CO-CHAIRS

Margaret Chesney, Ph.D.
Deputy Director
Director, Division of Extramural Research and Training
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

Anne Harrington, Ph.D.
Professor for the History of Science
Harvard University
Cambridge, MA

REPORTER

Dale Birkle, Ph.D.
Scientific Review Administrator
Office of Scientific Review
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

MEMBERS

Vania Apkarian, Ph.D.
Associate Professor
Department of Physiology
Northwestern University Medical School
Chicago, IL

Fabrizio Benedetti, M.D.
Professor, Department of Neuroscience
University of Turin Medical School
Turin, Italy

Richard Lane, M.D., Ph.D.
Professor of Psychiatry, Psychology, and Neuroscience
University of Arizona
Tucson, AZ

Robert Nussenblatt, M.D.
Chief, Laboratory of Immunology
National Eye Institute
National Institutes of Health
Bethesda, MD

Thomas Pickering, M.D., D. Phil.
Professor of Medicine
Director, Behavioral Cardiovascular Health and Hypertension Program
Columbia Presbyterian Medical Center
New York, NY

Bruce Rabin, M.D., Ph.D.
Professor of Pathology and Psychiatry
University of Pittsburgh Medical Center
Medical Director, UPMC Healthy Lifestyle Program
Pittsburgh, PA

Bruce Rosen, M.D., Ph.D.
Director, Martinos Center for Biomedical Imaging
Massachusetts General Hospital
Charlestown, MA

Strategic Planning Workshop
Biologically Based Practices Working Group

Hunt Valley, Maryland
May 23-25, 2004

CO-CHAIRS

Marguerite Klein, M.S.
Program Officer
Division of Extramural Research and Training
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

Irwin Rosenberg, M.D.
Dean, Friedman School of Nutrition Science and Policy
Boston, MA

REPORTER

Jeanette Hosseini, Ph.D.
Scientific Review Administrator
Office of Scientific Review
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

MEMBERS

Andrew Avins, M.D., M.P.H.
Research Scientist
Northern California Kaiser-Permanente
Associate Professor
Departments of Medicine and Epidemiology and Biostatistics
University of California, San Francisco
Kentfield, CA

Yung-Chi (Tommy) Cheng, Ph.D.
Professor, Department of Pharmacology
Yale University School of Medicine
New Haven, CT

Paul Coates, Ph.D.
Director, Office of Dietary Supplements
National Institutes of Health
Bethesda, MD

Gordon Cragg, Ph.D.
Chief, Natural Products Branch
National Cancer Institute
National Institutes of Health
Frederick, MD

Adrian Dobs, M.D., M.H.S.
Professor, Department of Medicine
The Johns Hopkins School of Medicine
Baltimore, MD

Steven Kliewer, Ph.D.
Professor, Department of Molecular Biology and Pharmacology
University of Texas Southwestern Medical Center at Dallas
Dallas, TX

Eric Lien, Ph.D.
Professor Emeritus
Department of Pharmaceutical Sciences
University of Southern California
Los Angeles, CA

Tieraona Low Dog, M.D.
Clinical Assistant Professor
Department of Family and Community Medicine
University of New Mexico Medical School
Corrales, NM

Steven Zeisel, M.D., Ph.D.
Professor and Chairman, Department of Nutrition
School of Medicine
Associate Dean for Research
School of Public Health
University of North Carolina at Chapel Hill
Chapel Hill, NC

Strategic Planning Workshop
Manipulative and Body-Based Practices Working Group

Hunt Valley, Maryland
May 23-25, 2004

CO-CHAIRS

Daniel Cherkin, Ph.D.
Associate Director and Scientific Investigator
Group Health Cooperative Center for Health Studies
Professor of Family Medicine and Health Services
University of Washington
Seattle, WA

Richard Nahin, Ph.D., M.P.H.
Senior Advisor for Scientific Coordination and Outreach
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

REPORTER

Christine Goertz, D.C., Ph.D.
Director of Clinical Research
Samueli Institute for Information Biology
Alexandria, VA

MEMBERS

Boyd Bowden, D.O.
Orthopedic Surgeon
Member, Board of Directors
American Osteopathic Association
Columbus, OH

Vince Caiozzo, Ph.D.
Associate Professor
Departments of Orthopedics and Physiology and Biophysics
College of Medicine
University of California, Irvine
Irvine, CA

Leslie Crofford, M.D.
Associate Professor
Department of Internal Medicine-Rheumatology
University of Michigan Medical School
Ann Arbor, MI

Mark Grabiner, Ph.D.
Professor and Head
Department of Movement Sciences
University of Illinois at Chicago
Chicago, IL

Joel Greenspan, Ph.D.
Associate Professor
Department of Biomedical Sciences
Director, Research Center for Neuroendocrine Influences on Pain
University of Maryland at Baltimore
Baltimore College of Dental Surgery
Baltimore, MD

Janet Kahn, Ph.D., N.C.T.M.B.
Research Assistant Professor
Department of Psychiatry
University of Vermont
Burlington, VT

William Meeker, D.C., M.P.H.
Vice President for Research
Palmer Chiropractic University Foundation
Director
Palmer Center for Chiropractic Research
Davenport, IA

William Mulvihill, M.Ed.
Senior Associate Athletic Director
University of Cincinnati
Cincinnati, OH

John Triano, Ph.D., D.C.
Co-Director of Conservative Care
Director, Chiropractic Division
Texas Back Institute
Research Professor, Department of Engineering
University of Texas, Arlington
Plano, TX

Strategic Planning Workshop
Energy Medicine Working Group

Hunt Valley, Maryland
May 23-25, 2004

CO-CHAIRS

Joan E.B. Fox, Ph.D.
Research Scientist
Department of Molecular Cardiology
Director, Center for Integrative Medicine
The Cleveland Clinic Foundatioin
Cleveland, OH

Morgan Jackson, M.D., M.P.H.
Director, Office of Special Populations
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

Shan Wong, Ph.D.
Program Officer
Division of Extramural Research and Training
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

REPORTER

Carol Pontzer, Ph.D.
Scientific Review Administrator
Office of Scientific Review
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

MEMBERS

Steven Bolling, M.D.
Professor of Surgery
University of Michigan Medical School
Ann Arbor, MI

F. Edward Dudek, Ph.D.
Professor of Anatomy and Neurobiology
Department of Biomedical Sciences
Colorado State University
Fort Collins, CO

Clair Francomano, M.D.
Senior Investigator
Human Genetics and Integrative Medicine Section
Laboratory of Genetics
National Institute on Aging
National Institutes of Health
Baltimore, MD

Shin Lin, Ph.D.
Professor of Cell Biology, Physiology and Biomedical Engineering
University of California, Irvine
Director
International Alliance on Mind/Body Signaling and Energy Research
Irvine, CA

Robert Park, Ph.D.
Director of Public Information
American Physical Society
Washington, DC

Roderic Pettigrew, Ph.D., M.D.
Director, National Institute of
Biomedical Imaging and
Bioengineering
National Institutes of Health
Bethesda, MD

Gerald Pollack, Ph.D.
Professor, Department of
Bioengineering
University of Washington
Seattle, WA

Strategic Planning Workshop
Whole Medical Systems Working Group

Hunt Valley, Maryland
May 23-25, 2004

CO-CHAIRS

Martin Goldrosen, Ph.D.
Director, Office of Scientific Review
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

Ted Kaptchuk, O.M.D.
Assistant Professor of Medicine
Harvard Medical School
Boston, MA

REPORTER

Patrick Mansky, M.D.
Staff Clinician
Division of Intramural Research
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

MEMBERS

Mikel Aickin, Ph.D.
Senior Investigator
Helfgott Research Institute
National College of Natural Medicine
Center for Health Research
Kaiser-Permanente NW
Portland, OR

Thomas Csordas, Ph.D.
Professor of Anthropology and Religion
Chair, Department of Anthropology
Case Western Reserve University
Cleveland, OH

Haile Debas, M.D.
Executive Director
Global Health Sciences
University of California, San Francisco
San Francisco, CA

Wayne Jonas, M.D.
Director
Samueli Institute for Information Biology
Alexandria, VA

Bala Manyam, M.D.
Director
Plummer Movement Disorders Center
Professor, Department of Neurology
Scott and White Memorial Hospital and Clinic
Texas A&M College of Medicine
Temple, TX

Stephen Myers, Ph.D., B.Med., N.D.
Director
Australian Centre for Complementary Medicine Education and Research
Lismore, Australia

Jeff Sloan, Ph.D.
Director, Quality of Life Program
Department of Biostatistics
Mayo Clinic College of Medicine
Rochester, MN

Strategic Planning Workshop
International Health Research Working Group

Hunt Valley, Maryland
May 23-25, 2004

CO-CHAIRS

Haile Debas, M.D.
Executive Director
Global Health Sciences
University of California, San Francisco
San Francisco, CA

Jack Killen, M.D.
Director
Office of International Health Research
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

REPORTER

Barbara Sorkin, Ph.D.
Program Officer
Division of Extramural Research and Training
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

MEMBERS

Mikel Aickin, Ph.D.
Senior Investigator
Helfgott Research Institute
National College of Natural Medicine
Center for Health Research
Kaiser-Permanente NW
Portland, OR

Thomas Csordas, Ph.D.
Professor of Anthropology and Religion
Chair, Department of Anthropology
Case Western Reserve University
Cleveland, OH

Joseph Fins, M.D., F.A.C.P.
Chief, Division of Medical Ethics
Weill Medical College
Cornell University
New York, NY

Lorraine Fitzpatrick, M.D.
Director, Global Development
Amgen, Inc.
Thousand Oaks, CA

William Folk, Ph.D.
Associate Dean for Research and Professor of Biochemistry
University of Missouri-Columbia
School of Medicine
Columbia, MO

Dean Jamison, Ph.D.
Senior Fellow
Fogarty International Center
National Institutes of Health
Bethesda, MD

Wayne Jonas, M.D.
Director
Samueli Institute for Information Biology
Alexandria, VA

Ted Kaptchuk, O.M.D.
Assistant Professor of Medicine
Harvard Medical School
Boston, MA

Bala Manyam, M.D.
Director
Plummer Movement Disorders Center
Professor, Department of Neurology
Scott and White Memorial Hospital and Clinic
Texas A&M College of Medicine
Temple, TX

Stephen Myers, Ph.D., B.Med., N.D.
Director, Australian Centre for Complementary Medicine Education and Research
Lismore, Australia

Jeff Sloan, Ph.D.
Director, Quality of Life Program
Department of Biostatistics
Mayo Clinic College of Medicine
Rochester, MN

Strategic Planning Workshop
Health Services Working Group

Hunt Valley, Maryland
May 23-25, 2004

CO-CHAIRS

William Lafferty, M.D.
Associate Professor, Department of Health Services
School of Public Health and Community Medicine
University of Washington
Seattle, WA

Karen Kun, M.P.H., M.A.
Scientific Program Analyst
Aspen Systems Corporation
Rockville, MD

REPORTER

Heather Miller, Ph.D., M.F.S.
Senior Advisor for Women's Health
Division of Extramural Research and Training
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

MEMBERS

Samuel Bozzette, M.D., Ph.D.
Professor, Department of Medicine
University of California, San Diego
La Jolla, CA

Daniel Cherkin, Ph.D.
Associate Director and Scientific Investigator
Group Health Cooperative Center for Health Studies
Professor of Family Medicine and Health Services
University of Washington
Seattle, WA

Wilson Compton, M.D.
Director, Division of Epidemiology, Services and Prevention Research
National Institute on Drug Abuse
National Institutes of Health
Bethesda, MD

Kenneth Fink, M.D., M.G.A., M.P.H.
Director, Evidence-based Practice Centers Program
Agency for Healthcare Research and Quality
Rockville, MD

Kevin Frick, Ph.D.
Associate Professor
Departments of Health Policy and Management, Economics and Opthalmology
Bloomberg School of Public Health
The Johns Hopkins University
Baltimore, MD

Robert Fullilove, III, Ed.D.
Associate Dean, Community and Minority Affairs
Joseph L. Mailman School of Public Health
Columbia University
New York, NY

Richard Liebowitz, M.D.
Executive Medical Director
Duke Center for Living
Duke University Medical Center
Durham, NC

Laura Patton, M.D.
Clinical Director, CAM Services
Group Health Cooperative
Seattle, WA

Mary Ruggie, Ph.D.
Adjunct Professor of Public Policy
Kennedy School of Government
Harvard University
Cambridge, MA

Strategic Planning Workshop
Research Training Working Group

Hunt Valley, Maryland
May 23-25, 2004

CO-CHAIRS

Nancy Pearson, Ph.D.
Program Officer, Division of Extramural Research and Training
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

Jennifer Sutton, M.S.
Evaluation Officer
Office of Science Policy and Operations
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

Donald Wilson, M.D.
Dean and Vice President for Medical Affairs
University of Maryland
School of Medicine
Baltimore, MD

REPORTER

Ellen O'Donnell
Senior Science Writer
Office of Communications and Public Liaison
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

MEMBERS

Leslie Crofford, M.D.
Associate Professor
Department of Internal Medicine-Rheumatology
University of Michigan Medical School
Ann Arbor, MI

Charles Flexner, M.D.
Associate Professor, Medicine, Pharmacology and Molecular Sciences, and International Health
The Johns Hopkins School of Medicine
Baltimore, MD

Clair Francomano, M.D.
Senior Investigator
Human Genetics & Integrative Medicine Section
Laboratory of Genetics
National Institute on Aging
National Institutes of Health
Baltimore, MD

Heather Greenlee, N.D., M.P.H.
Postdoctoral Research Fellow
Department of Epidemiology
Mailman School of Public Health
Columbia University
New York, NY

Barbara Hamkalo, Ph.D.
Professor, Department of Molecular Biology and Biochemistry
University of California, Irvine
Irvine, CA

Charles Henderson, D.C., Ph.D.
Associate Professor, Neuroscience
Palmer Center for Chiropractic Research
Davenport, IA

Gail Ironson, M.D., Ph.D.
Professor of Psychology and Psychiatry
University of Miami
Coral Gables, FL

Walter Schaffer, Ph.D.
Acting Director
Office of Extramural Programs
National Institutes of Health
Bethesda, MD

Larry Walker, Ph.D.
Director, National Center for Natural Products Research
University of Mississippi
University, MS

Strategic Planning Workshop
Outreach Working Group

Hunt Valley, Maryland
May 23-25, 2004

CO-CHAIRS

Alyssa Cotler, M.P.H.
Communications Specialist
Office of Communications and Public Liaison
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

William Mulvihill, M.Ed.
Senior Associate Athletic Director
University of Cincinnati
Department of Athletics
Cincinnati, OH

REPORTER

Karla Ehrler
Correspondence Coordinator
Office of Communications and Public Liaison
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

MEMBERS

John Burklow
Associate Director for Communications
National Institutes of Health
Bethesda, MD

Lynne Camoosa
Assistant Director
Communications and Patient Information
American Society of Clinical Oncology
Alexandria, VA

Lynne Doner, M.A.
Independent Consultant/Social Marketing Counselor
Lynne Doner Consulting
Arlington, VA

Penny George, Psy.D.
President
George Family Foundation
Minneapolis, MN

George Lundberg, M.D.
Editor in Chief Emeritus, Medscape
Special Healthcare Advisor to the Chairman and CEO, WebMD
Los Gatos, CA

William Meeker, D.C., M.P.H.
Vice President for Research
Palmer Chiropractic University Foundation
Director, Palmer Center for Chiropractic Research
Davenport, IA

Carolyn Messner, D.S.W.
Director of Education and Training
CancerCare, Inc.
New York, NY

Gerald Pollack, Ph.D.
Professor
Department of Bioengineering
University of Washington
Seattle, WA

James Radack
Vice President
National Mental Health Association
Alexandria, VA

Chris Shreeve, M.A.
Senior Vice President - Health & Medical
Ogilvy Public Relations
Washington, DC

Kathleen Stephan, M.B.A.
Program Analyst
Office of Administrative Operations
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

Strategic Planning Workshop
Ethical, Legal, and Social Implications of CAM Research and Integrated Medicine Working Group

Hunt Valley, Maryland
May 23-25, 2004

CO-CHAIRS

Robert Fullilove, III, Ed.D.
Associate Dean, Community and Minority Affairs
Joseph L. Mailman School of Public Health
Columbia University
New York, NY

Jane Kinsel, Ph.D., M.B.A.
Associate Director for Science Policy and Operations
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

REPORTER

Catherine Law, M.T.S.C.
Science Writer, Office of Communications and Public Liaison
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, MD

MEMBERS

Joseph Fins, M.D., F.A.C.P.
Chief, Division of Medical Ethics
Weill Medical College
Cornell University
New York, NY

Lorraine Fitzpatrick, M.D.
Director, Global Development
Amgen, Inc.
Thousand Oaks, CA

Charles Henderson, D.C., Ph.D.
Associate Professor, Neuroscience
Palmer Center for Chiropractic Research
Davenport, IA

Dean Jamison, Ph.D.
Senior Fellow
Fogarty International Center
National Institutes of Health
Bethesda, MD

William Lafferty, M.D.
Associate Professor
Department of Health Services
School of Public Health and Community Medicine
University of Washington
Seattle, WA

Debra Lappin, J.D.
Senior Advisor
B&D Sagamore
Englewood, CO

George Lundberg, M.D.
Editor in Chief Emeritus, Medscape
Special Healthcare Advisor to the Chairman and CEO
WebMD
Los Gatos, CA

Laura Patton, M.D.
Clinical Director, CAM Services
Group Health Cooperative
Seattle, WA

Mary Ruggie, Ph.D.
Adjunct Professor of Public Policy
Kennedy School of Government
Harvard University
Cambridge, MA

Strategic Planning Workshop
NCCAM Stewardship Working Group

CHAIRPERSON
Camille Hoover, M.S.W.
Executive Officer

MEMBERS
Margaret Chesney, Ph.D.
Deputy Director
Director, Division of Extramural Research and Training

Carol Fitzpatrick
Committee Management Officer
Office of Science Policy and Operations

Deborah Jennings Cudjoe
Secretary
Office of the Director

Catherine Law, M.T.S.C.
Science Writer
Office of Communications and Public Liaison

Richard Nahin, Ph.D., M.P.H.
Office of the Director
Senior Advisor for Scientific Coordination and Research
Office of the Director

Ellen O'Donnell
Senior Science Writer
Office of Communications and Public Liaison

Charles Sabatos
Program Analyst
Office of Science Policy and Operations

Kathleen Stephan, M.B.A.
Program Analyst
Office of Administrative Operations

Shirley Villone
Program Advisor
Office of Administrative Operations

Appendix V

Glossary of Terms

Under Development

Appendix VI

Acronyms and Abbreviations

AHRQ	Agency for Healthcare Research and Quality
CAM	complementary and alternative medicine
D.C.	Doctor of Chiropractic
EDTA	ethylenediamine tetra-acetic acid
FDA	U.S. Food and Drug Administration
fMRI	functional magnetic resonance imaging
FY	fiscal year
HHS	U.S. Department of Health and Human Services
ICs	institutes and centers (within NIH)
IRB	Institutional Review Board
NCCAM	National Center for Complementary and Alternative Medicine
N.D.	Doctor of Naturopathic Medicine
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
OAM	Office of Alternative Medicine (within NIH; NCCAM's predecessor)
O.M.D.	Doctor of Oriental Medicine
PET	positron-emission tomography
PubMed	online list of publications maintained by the National Library of

	Medicine (within NIH)
TCM	traditional Chinese medicine