Free Executive Summary

Complementary and Alternative Medicine in the United States

Committee on the Use of Complementary and Alternative Medicine by the American Public

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Integration of complementary and alternative medicine therapies (CAM) with conventional medicine is occurring in hospitals and physicians offices,health maintenance organizations (HMOs) are covering CAM therapies,insurance coverage for CAM is increasing, and integrative medicine centersand clinics are being established, many with close ties to medical schoolsand teaching hospitals. In determining what care to provide, the goalshould be comprehensive care that uses the best scientific evidence availableregarding benefits and harm,encourages a focus on healing,recognizesthe importance of compassion and caring,emphasizes the centrality of relationship-based care, encourages patients to share in decision making about therapeutic options, and promotes choices in care that can includecomplementary therapies where appropriate. Hazards

It outlines areas of research in convention and CAM therapies, ways ofintegrating these therapies, development of curriculum that provides furthereducation to health professionals, and an amendment of the Dietary Supplement Health and Education Act to improve quality, accurate labeling,research into use of supplements, incentives for privately funded research into their efficacy, and consumer protection against all potential

Nauseous approaches to delivering integrative medicine have evolved.Complementary and Alternative Medicine in the United States identifies anurgent need for health systems research that focuses on identifying the elementsof these models, the outcomes of care delivered in these models,and whether these models are cost-effective when compared to conventionalpractice settings.

Executive Summary

Americans' use of complementary and alternative medicine (CAM)—approaches such as chiropractic or acupuncture—is widespread. More than a third of American adults report using some form of CAM, with total visits to CAM providers each year now exceeding those to primary-care physicians. An estimated 15 million adults take herbal remedies or high-dose vitamins along with prescription drugs. It all adds up to annual out-of-pocket costs for CAM that are estimated to exceed $27 billion.

Friends confer with friends about CAM remedies for specific problems, CAM-related stories appear frequently in the print and broadcast media, and the Internet is replete with CAM information. Many hospitals, managed care plans, and conventional practitioners are incorporating CAM therapies into their practices, and schools of medicine, nursing, and pharmacy are beginning to teach about CAM.

CAM's influence is substantial yet much remains unknown about these therapies, particularly with regard to scientific studies that might convincingly demonstrate the value of individual therapies. Against this background the National Center for Complementary and Alternative Medicine (NCCAM), 15 other centers and institutes of the National Institutes of Health (NIH), and the Agency for Healthcare Research and Quality commissioned the Institute of Medicine (IOM) to convene a committee that would

- Describe the use of CAM therapies by the American public and provide a comprehensive overview, to the extent that data are available, of

the therapies in widespread use, the populations that use them, and what is known about how they are provided.

- Identify major scientific, policy, and practice issues related to CAM research and to the translation of validated therapies into conventional medical practice.
- Develop conceptual models or frameworks to guide public- and private-sector decisionmaking as research and practice communities increasingly conduct research on CAM, translate the research findings into practice, and address the barriers that may impede such translation.

TOWARD COMMON RESEARCH GROUND

Decisions about the use of specific CAM therapies should primarily depend on whether they have been shown to be safe and effective. But this is easier said than done, as there are extremes of belief about what counts as evidence. For some individuals, evidence limited to their own experience or knowledge is all that is necessary as proof that a CAM therapy is successful; for others, *no* amount of evidence is sufficient. This report will please neither of those extremes.

There are unproven ideas of all kinds, stemming from CAM and conventional medicine alike, and the committee believes that the same principles and standards of evidence should apply regardless of a treatment's origin. Study results may then move useful therapies from unproven ideas into evidence-based practice.

The goal should be the provision of comprehensive care that respects contributions from all sources. Such care requires decisions based on the results of scientific inquiry, which in turn can lead to new information that results in improvements in patient care.

This report's core message is therefore as follows: **The committee recommends that the same principles and standards of evidence of treatment effectiveness apply to all treatments, whether currently labeled as conventional medicine or CAM. Implementing this recommendation requires that investigators use and develop as necessary common methods, measures, and standards for the generation and interpretation of evidence necessary for making decisions about the use of CAM and conventional therapies.**

The committee acknowledges that the characteristics of some CAM therapies—such as variable practitioner approaches, customized treatments, "bundles" (combinations) of treatments, and hard-to-measure outcomes—are difficult to incorporate into treatment-effectiveness studies. These characteristics are not unique to CAM, but they are more frequently found in CAM than in conventional therapies. The effects of mass-produced, essentially identical prescription drugs, for example, are somewhat easier to

study than those of Chinese herbal medicines tailored to the needs of individual patients.

But while randomized controlled trials (RCTs) remain the "gold standard" of evidence for treatment efficacy, other study designs can be used to provide information about effectiveness when RCTs cannot be done or when their results may not be generalizable to the real world of CAM practice. These innovative designs include:

- *Preference RCTs*: trials that include randomized and non-randomized arms, which then permit comparisons between patients who chose a particular treatment and those who were randomly assigned to it
- *Observational and cohort studies*, which involve the identification of patients who are eligible for study and who may receive a specified treatment, but are not randomly assigned to the specified treatment as part of the study
- *Case-control studies*, which involve identifying patients who have good or bad outcomes, then "working back" to find aspects of treatment associated with those different outcomes
- *Studies of bundles of therapies*: analyses of the effectiveness, as a whole, of particular packages of treatments
- *Studies that specifically incorporate, measure, or account for placebo or expectation effects*: patients' hopes, emotional states, energies, and other self-healing processes are not considered extraneous but are included as part of the therapy's main "mechanisms of action"
- *Attribute-treatment interaction analyses*: a way of accounting for differences in effectiveness outcomes among patients within a study and among different studies of varying design

Given limited available funding, prioritization is necessary regarding which CAM therapies to evaluate. The following criteria could be used to help make this determination:

- A biologically plausible mechanism exists for the intervention, but the science base on which plausibility is judged is a work in progress.
- Research could plausibly lead to the discovery of biological mechanisms of disease or treatment effect.
- The condition is highly prevalent (e.g., diabetes mellitus).
- The condition causes a heavy burden of suffering.
- The potential benefit is great.
- Some evidence that the intervention is effective already exists.
- Some evidence exists that there are safety concerns.

- The research design is feasible, and research will likely yield an unambiguous result.
- The target condition or the intervention is important enough to have been detected by existing population-surveillance mechanisms.

A therapy should not be excluded from consideration because it does not meet any one particular criterion—say, biological plausibility. However, the absence of such a mechanism will inevitably raise the level of skepticism about the potential effectiveness of the treatment (whether conventional or CAM). Moreover, the amount of basic research needed to justify funding for clinical studies of the treatment, and the level of evidence from those studies that is needed to consider the treatment as "established," will both increase under such circumstances.

A NEW POSITION ON DIETARY SUPPLEMENTS

The committee has taken a similarly pragmatic approach to dietary supplements, which have become a prominent part of American popular health culture but continue to present unique regulatory, safety, and efficacy challenges.

Under the Dietary Supplement Health and Education Act of 1994—the capstone, thus far, of herbal-medicine regulation—the Food and Drug Administration (FDA) was authorized to establish good-manufacturing-practice regulations specific to dietary supplements. But the Act did not subject supplements to the same safety precautions that apply to prescription and over-the-counter medications. Instead, it designated that supplements be regulated like foods, a crucial distinction that exempted manufacturers from conducting premarket safety and efficacy testing. Similarly, FDA's regulatory-approval process—which would be standard operating procedure if supplements had been classified as drugs—was eliminated, thereby limiting the agency to a reactive, postmarketing role.

The committee is concerned about the quality of dietary supplements in the United States. Product reliability is low, and because patent protection is not available for natural substances there is little incentive for manufacturers to invest resources in improving product standardization. Yet reliable and standardized supplements are needed not only for consumer protection but also for research on safety and efficacy. Without consistent products, research is extremely difficult to conduct or generalize. And without high-quality research, medical practitioners cannot make evidence-based recommendations to help guide patients.

Therefore **the committee recommends that the U.S. Congress and federal agencies, in consultation with industry, research scientists, consumers, and other stakeholders, amend the Dietary Supplement Health and Educa-**

tion Act of 1994 and the current regulatory scheme for dietary supplements, with emphasis on strengthening:

- **Seed-to-shelf quality-control** (based on standards for each step of the manufacturing process—from planting to growth, harvest, extraction, and screening for impurities),
- **Accuracy and comprehensiveness in labeling and other disclosures,**
- **Enforcement efforts against inaccurate and misleading claims,**
- **Research into how consumers use supplements,**
- **Incentives for privately funded research into the efficacies of products and brands, and**
- **Consumer protection against all potential hazards.**

FILLING THE GAPS

Evidence of the safety and efficacy of individual CAM treatments is essential, but it represents just one facet of the research that is needed. For example, there is a paucity of clinical research that compares CAM therapies with each other or with conventional interventions. Very little research has been done on the cost-effectiveness of CAM. And although there is great opportunity for scientific discovery in the study of CAM treatments, it is an opportunity largely missed.

Such investigations are hindered by shortages of established scientists engaged in CAM research, which tends to involve subject matter beyond the conventional scientist's knowledge base. CAM also needs a cadre of new junior researchers. While major U.S. health-sciences campuses have long offered training in basic and clinical research for conventional medicine, the challenge is to induce these schools to embrace CAM research as well. One approach might be to add specific CAM content to conventional-medicine postdoctoral training programs.

Furthermore, CAM research will benefit from the contributions of more than one discipline. In addition to providers who have specialized knowledge of CAM treatments and methodologists who can address the challenges inherent in CAM study design, investigators with backgrounds in fields such as psychology, sociology, anthropology, economics, genetics, pharmacology, neuroscience, health services, and health policy can make important contributions. Interdisciplinary teams, grouped into "critical masses" at various locations, will be favorably positioned to probe the many factors that influence individuals to use CAM treatments and that determine the outcomes of those treatments.

Research on CAM is inextricably linked to practice. CAM therapies are already in widespread use today; it is reasonable to attempt to evaluate the outcomes of that use, and in the practice setting one can focus on research

that answers questions about how therapies function in the "real world" where patients vary, often have a number of health problems, and are using multiple therapies. Practice-based research addresses real world practice issues and facilitates adoption of practice changes that are based on research results.

To address these gaps, **the committee recommends that the National Institutes of Health (NIH) and other public agencies provide the support necessary to:**

- **develop and implement a sentinel surveillance system** (composed of selected sites able to collect and report data on patterns of use of CAM and conventional medicine); **practice-based research networks** (defined by the Agency for Healthcare Research and Quality as "a group of ambulatory practices devoted principally to the primary care of patients, affiliated with each other [and often with an academic or professional organization] in order to investigate questions related to community-based practice"); **and CAM research centers to facilitate the work of the networks** (by collecting and analyzing information from national surveys, identifying important questions, designing studies, coordinating data collection and analysis, and providing training in research and other areas).
- **include questions relevant to CAM on federally funded health care surveys (e.g., the National Health Interview Survey) and in ongoing longitudinal cohort studies (e.g., the Nurses' Health Study and Framingham Heart Study).**
- **implement periodic comprehensive, representative national surveys to assess the changes in prevalence, patterns, perceptions, and costs of therapy use (both CAM and conventional), with oversampling of ethnic minorities.**

INTEGRATING CAM AND CONVENTIONAL MEDICINE

Even as CAM and conventional medicine each maintain their identities, traditions, and practitioners, integration of CAM and conventional medicine is occuring in many settings. Hospitals are offering CAM therapies, a growing number of physicians are using them in their private practices, integrative-medicine centers (many with close ties to medical schools and teaching hospitals) are being established, and health maintenance organizations and insurance companies are covering CAM.

Cancer treatment centers in particular often use CAM therapies in combination with conventional approaches. For example, the Memorial Sloan-Kettering Cancer Center has developed an Integrative Medicine Service that offers music therapy, massage, reflexology, and mind-body thera-

pies. As the Website of the Dana Farber Cancer Institute's own Zakim Center for Integrated Therapies explains, "When patients integrate these therapies into their medical and surgical care, they are creating a more comprehensive treatment plan and helping their own bodies to regain health and vitality."

In response to the growing recognition of CAM therapies by conventional-medicine practitioners for their patients' care, the Federation of State Medical Boards of the United States has developed *Model Guidelines for the Use of Complementary and Alternative Therapies in Medical Practice*.

Other tools are also needed to aid conventional practitioners' decisionmaking about offering or recommending CAM, where patients might be referred, and what organizational structures are most appropriate for the delivery of integrated care. The committee believes that the overarching rubric for guiding the development of these tools should be the goal of providing comprehensive care that is safe, effective, interdisciplinary, and collaborative; is based on the best scientific evidence available; recognizes the importance of compassion and caring; and encourages patients to share in the choices of therapeutic options.

Studies show that patients frequently do not limit themselves to a single modality of care—they do not see CAM and conventional medicine as being mutually exclusive—and this pattern will probably continue and may even expand as evidence of therapies' effectiveness accumulates. Therefore it is important to understand how CAM and conventional medical treatments (and providers) interact with each other and to study models of how the two kinds of treatments can be provided in coordinated ways.

In that spirit, there is an urgent need for health systems research that focuses on identifying the elements of these integrative-medicine models, their outcomes, and whether they are cost-effective when compared to conventional practice.

The committee recommends that NIH and other public and private agencies sponsor research to compare:

- **the outcomes and costs of combinations of CAM and conventional medical treatments and models that deliver such care**
- **models of care delivery involving CAM practitioners alone, both CAM and conventional medical practitioners, and conventional practitioners alone. Outcome measures should include reproducibility, safety, cost-effectiveness, and research capacity**

Additionally, **the committee recommends that the Secretary of the U.S. Department of Health and Human Services and the Secretary of the U.S. Department of Veterans Affairs support research on integrated medical**

care delivery, as well as the development of a research infrastructure within such organizations and clinical training programs to expand the number of providers able to work in integrated care.

The pursuit of such goals requires examination of the ethics of medicine, both in the provision of personal health services and the profession's advocacy for public health. Medicine is continuously shaped by larger social, cultural, and political forces, and the integration of CAM therapies is another juncture in this evolutionary process.

The ethical principles that guide conventional biomedical research should also be applied to CAM research. Legal and ethical issues often arise and sometimes conflict with use of CAM therapies because the decision facing a conventional practitioner or institution may engender a conflict between medical paternalism (the desire to protect patients from foolish or ill-informed, though voluntary decisions) and patient autonomy. The Model Guidelines noted above seek to establish greater balance between physician and patient preferences. In addition, a number of legal rules—including state licensure laws, precedents regarding malpractice liability and professional discipline, state and federal food and drug laws, and statutes on health care fraud—protect patients by enhancing quality assurance, offering enhanced access to therapies, and honoring medical pluralism in creating models of integrative care.

Without rejecting what has been of great value and service in the past, it is important that these ethical and legal norms be brought under critical scrutiny and evolve along with medicine's expanding knowledge base and the larger aims and meanings of medical practice. The integration of CAM therapies with conventional medicine requires that practitioners and researchers be open to diverse interpretations of health and healing, to finding innovative ways of obtaining evidence, and to expanding the medical knowledge base.

EDUCATING FOR IMPROVED CARE

Essential to conventional and CAM practitioners alike is education about the others' field. Conventional professionals in particular need enough CAM-related training, the committee believes, so that they can counsel patients in a manner consistent with high-quality comprehensive care. Therefore **the committee recommends that health profession schools (e.g., schools of medicine, nursing, pharmacy, and allied health) incorporate sufficient information about CAM into the standard curriculum at the undergraduate, graduate, and postgraduate levels to enable licensed professionals to competently advise their patients about CAM.**

Because the content and organization of an education initiative on CAM will vary from institution to institution, depending on the objectives of each program, there is no consensus on what should be taught and how to fit it into an already crowded set of courses. At Brown University School of Medicine, for example, the program includes didactic sessions in acupuncture, chiropractic, and massage therapy and an elective clinical experience; and variations exist at many of the other leading schools. Some of these initiatives have been aided by NCCAM's education projects, which aim to develop new ways of incorporating CAM into health-professional curricula and training programs.

CAM practitioners, for their part, need training that will enable them to participate as full partners and leaders in research so that studies may accurately reflect how CAM therapies are practiced. But many CAM institutions do not have an infrastructure for research or the financial resources to develop them. Training in research has not traditionally been part of CAM curricula, nor for the most part have practitioners' careers been dependent on publishing research findings. CAM institutions focus primarily on training for practice.

Strategic partnerships between CAM institutions, NIH, and health-sciences universities would help foster development of the necessary infrastructure; and NCCAM has already begun funding such partnerships. In addition, lessons can be learned from other fields, such as geriatrics and HIV/AIDS research, which have gone through processes relevant to CAM's current need to develop qualified researchers. In geriatrics, for instance, the establishment of centers of excellence at major academic health centers, foundation support for the development of curricula and partnerships, and continuing-education mechanisms such as summer institutes illustrate the importance of using multiple strategies to create an environment in which new science has been able to flourish.

The committee recommends that federal and state agencies, and private and corporate foundations, alone and in partnership, create models in research training for CAM practitioners.

Furthermore, both CAM research and the quality of CAM treatment would be fostered by the development of practice guidelines—what a 1992 IOM report defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." Key to guideline development is the participation of those who will be most directly affected. This means that CAM practitioners, possibly through their own professional organizations, should formulate guidelines for their own therapies.

The committee recommends that national professional organizations for all CAM disciplines ensure the presence of training standards and develop practice guidelines. Health care professional licensing boards and

accrediting and certifying agencies (for both CAM and conventional medicine) should set competency standards in the appropriate use of both conventional medicine and CAM therapies, consistent with practitioners' scope of practice and standards of referral across health professions.

KNOWNS AND UNKNOWNS ABOUT CAM USE

Prevalence estimates for CAM use range from 30 percent to 62 percent of U.S. adults, depending on the definition of CAM. Women are more likely than men to seek CAM therapies, use appears to increase as education level increases, and there are varying patterns of use by race. Adults who undergo CAM therapies usually draw on more than one type, and they tend to do so in combination with conventional medical care—though a majority do not disclose the CAM use to their physicians, thereby incurring the risk, for example, of potential interactions between prescription drugs and CAM-related herbs. Studies of specific illnesses have documented the popularity of CAM for health problems that lack definitive cures, have unpredictable courses and prognoses, and are associated with substantial pain, discomfort, or medicinal side effects.

Existing surveys tell us little, however, about how CAM treatment is initiated (Does the patient unilaterally decide to use a therapy? Does a CAM or a conventional provider recommend the therapy?), and we have scant data about how the American public makes decisions about accessing CAM options. While there is an extensive literature on adherence to conventional treatment, there are virtually no data available on adherence to CAM treatment. This is an important issue given that any therapy, even if efficacious, may place users at risk of harm, or cause them to experience little or no effect, when used in the wrong way. Similarly, we have virtually no information about the extent to which the use of a CAM therapy may interfere with compliance in the use of conventional therapies, how people's self-administration of CAM therapies changes over time, and the factors that influence such change.

Moreover, there is little research on the public's perceptions of information as alternatively credible, marginal, or spurious; how people understand such information in terms of risks and benefits; and what they expect their providers to tell them. Because the few small studies that have occurred suggest that considerable misinformation is dispensed by vendors and on the Web, a closer monitoring of Websites, enhanced enforcement of the Dietary Supplement Health and Education Act as well as of Federal Trade Commission regulations, and the creation of a user-friendly authoritative Website on CAM modalities are needed.

As a means of remedying the dearth of information noted above, **the committee recommends that the National Institutes of Health and other**

public or private agencies sponsor quantitative and qualitative research to examine:

- **The social and cultural dimensions of illness experiences, health care-seeking processes and preferences, and practitioner-patient interactions;**
- **How often users of CAM, including patients and providers, adhere to treatment instructions and guidelines;**
- **The effects of CAM on wellness and disease-prevention;**
- **How the American public accesses and evaluates information about CAM modalities;**
- **Adverse events associated with CAM therapies and interactions between CAM and conventional treatments.**

Further, **the committee recommends that the National Library of Medicine and other federal agencies develop criteria to assess the quality and reliability of information about CAM.**

We are in the midst of an exciting time of discovery, when evidence-based approaches to health bring opportunities for incorporating the best from all sources of care, be they conventional medicine or CAM. Our challenge is to keep an open mind and to regard each treatment possibility with an appropriate degree of skepticism. Only then will we be able to ensure that we are making informed and reasoned decisions.

Complementary and Alternative Medicine

IN THE UNITED STATES

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by the American Public
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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

"Knowing is not enough; we must apply.
Willing is not enough; we must do."
—Goethe

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Preface

Complementary and alternative medicine (CAM) therapies, by whatever name they are called, have existed from antiquity. Recognition of the widespread use of CAM by the people of the United States has given new emphasis to the need to better understand the effects of these treatments from the perspective of personal and public health. To provide a rational, effective, efficient, and personally satisfactory health care system, it is important and useful to know who is using CAM therapies and why, how the public obtains information about CAM and how credible that information is, why many users of CAM do not inform their physicians about such use, just what CAM is, and whether these therapies are safe and effective.

It is only relatively recently, however, that there has been a serious general interest in the United States in investigating and evaluating these therapies. In 1992 the U.S. Congress established the Office of Alternative Medicine (OAM) within the National Institutes of Health (NIH) to begin to develop a baseline of information on CAM use in the United States. In 1999 the Congress elevated OAM to the National Center for Complementary and Alternative Medicine and appropriated $48.9 million to carry out work directly related to CAM. Other institutes of NIH and other federal agencies also engaged in the effort and by 2003, 19 institutes and centers within NIH were collectively spending $315.5 million on CAM-related research and other activities.

This report was commissioned in September 2002, when 16 NIH institutes, centers, and offices plus the Agency for Healthcare Research and Quality asked the Institute of Medicine to convene a study committee to explore scientific, policy, and practice questions that arise from the signifi-

cant and increasing use of CAM therapies by the American public. Specifically, this study was asked to

1. Describe the use of CAM therapies by the American public and provide a comprehensive overview, to the extent that data are available, of the therapies in widespread use, the populations that use them, and what is known about how they are provided.
2. Identify the major scientific, policy, and practice issues related to CAM research and to the translation of validated therapies into conventional medical practice.
3. Develop conceptual models or frameworks to guide public- and private-sector decision making 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.

Furthermore, the committee was asked to explore several issues, including

- the methodological difficulties in the conduct of rigorous research on CAM therapies and how these relate to issues in regulation and practice, with exploration of the options that can be used to address the difficulties identified.
- the shortage of highly skilled practitioners who are able to participate in scientific inquiry that meets NIH guidelines and who have access to the institutions where such research is conducted.
- the shortage of receptive, integrated research environments and the barriers to developing multidisciplinary teams that include CAM and conventional medical practitioners.
- the availability of standardized and well-characterized materials and practices to be studied and incorporated, when appropriate, into practice.
- the existing decision-making models used to determine whether or not to incorporate new therapies and practices into conventional medicine, including evidence thresholds.
- the applicability of these decision-making models to CAM therapies and practices; that is, do they form good precedents for decisions relating to regulation, accreditation, or integration of CAM therapies?
- identification and analysis of successful approaches to the incorporation of CAM into health professions education.
- the impact of current regulations and legislation on CAM research and integration.

Committee membership was chosen to represent the most salient perspectives and competences, since there was no possibility that all or even most of the interest groups could be represented. Members included providers of CAM and conventional health care as well as analysts, observers, and managers of CAM and conventional health care systems. To ensure effective input from CAM providers, the committee established a working liaison group composed of 35 leaders of CAM and conventional medical disciplines and held a number of formal and informal interchanges with these groups.

The committee proceeded to educate and inform itself through a systematic review of the extensive relevant literature, a series of expert presentations, discussions, and public comments in open meetings, and focused interchange and deliberation in committee meetings. The work of the committee was especially informed by discussions and a paper on experimental design written for the committee by Naihua Duan, Joel Braslow, Alison Hamilton Brown, Ted J. Kaptchuk, and Louise E. Tallen. The agendas and participants in the public meetings are listed in Appendix G.

As described more extensively in Chapter 1 of the report, the committee deliberated at length concerning whether and how to define CAM most usefully for the purpose of this report. All proposed definitions were imprecise, ambiguous, or otherwise subject to misinterpretation. Judging that a definition was necessary, for the purposes of this report the committee adopted the definition stated on page 19. Several important caveats need to be understood to interpret correctly the committee's meaning of statements concerning CAM in this report. The definition is necessarily imprecise and nonlimiting since it is based in part on the implied intended purpose of the practitioner and the user (i.e., improvement of health outcomes) and in part on exclusion from a category (the dominant health care system) that itself is not precisely defined and that changes substantially over time.

The term *CAM*, as used in this report, encompasses a large, diverse, and changing set of "systems, modalities, and practices and their theories and beliefs." The diversity of practice within CAM is so great that there are few, if any, generalizations that apply equally to all systems, modalities, and practices defined as CAM. When the term CAM is used in this report, it is not intended to include all CAM practices equally but, rather, to refer to a substantial group of CAM practices.

The work of the committee began with the question, what do patients and health professionals need to know to make good decisions about the use of health care interventions, including CAM? Of primary importance in making decisions about whether to use specific CAM therapies is determining that they are safe and effective. There are extremes of belief about effectiveness; for some individuals, no other evidence than hearsay or their

own experience or knowledge is necessary to determine that a CAM therapy is effective. For others, no evidence of any quality or quantity is sufficient to prove CAM effective. This report will please neither of those extremes.

Recognizing that all scientific conclusions are tentative, the committee adopted proven and conventional standards of scientific evidence as the basis for judgments of the safety and effectiveness of both CAM and conventional medicine.

The widespread use of CAM has focused attention on the need to find answers to the numerous questions surrounding such use, questions such as who is using CAM therapies and why, how does the public obtain information about CAM and how credible is that information, why aren't users of CAM informing their physicians about such use, just what is CAM and are these therapies safe and effective?

A significant portion of this report is devoted to an examination and analysis of evidence: what it is, how we obtain it, and how it is used by various stakeholders to make decisions. Methodological challenges are examined, and innovative study designs are discussed. Existing evidence about the effectiveness of some CAM therapies is reviewed and gaps in our knowledge are identified. Input from the liaison panel was particularly important as the committee explored the issue of evidence and how we know what we know.

The report also addresses a number of issues related to the integration of CAM and conventional medicine, including how a therapy moves from a new idea to an accepted practice, a framework for advising patients about CAM, and approaches to integration. The committee concluded that the goal should be the provision of comprehensive medical care that is based on the best scientific evidence available regarding benefits and harm, that encourages patients to share in decision making about therapeutic options, and that promotes choices in care that can include CAM therapies, when appropriate. Our challenge was to eliminate parochial bias and to apply the best-available means of assessment of safety and effectiveness adapted to particular clinical circumstances of both CAM and conventional medicine. In this way we will be able to ensure that we are making informed, reasoned, and knowledge-based decisions about the safety, effectiveness, and use of CAM in health care.

On behalf of every member of the committee, I want to express our unbounded respect and appreciation for the wisdom, industry, and judgment that Lyla Hernandez put into this study. At many critical junctures she kept the committee on track; and she was regularly a source of important ideas, data, and experts. The study would not have been completed without her gracious perseverance. We also want to thank Kysa Christie,

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Stuart Bondurant, *Committee Chair*

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Throughout the past two years, the IOM Committee on the Use of Complementary and Alternative Medicine (CAM) by the American Public was fortunate to interact with many individuals interested in the role of CAM in the United States and willing to share their expertise, time and thoughts with the committee.

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Speakers at the five public meetings provided a broad overview of the field of CAM and its interaction with conventional medicine, as well as providing specific information about CAM. We would like to thank those speakers: Joseph Betz, Timothy Birdsall, Opher Caspi, Garrett Cuneo, Steven Dentali, George DeVries, Claude Gagnon, Harley Goldberg, James Gordon, Milton Hammerly, Aviad Haramati, William R. Hazzard, Dilip Jeste, Wayne Jonas, Mary Jo Kreitzer, Lee Lipsenthal, John Melnychuk, Will Morris, David Morrison, Donald Novey, Willo Pequegnat, Rowena Richter, Lawrence Smith, and Stephen E. Straus.

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Reviewers

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the NRC's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by Dan G. Blazer, J.P. Gibbons Professor of Psychiatry, Duke University Medical Center, and Henry W. Riecken, Professor of Behavioral Sciences, Emeritus, University of Pennsylvania. Appointed by the National Research Council and the Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

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