

ALTERNATIVE MEDICINES

HEARING
BEFORE A
SUBCOMMITTEE OF THE
COMMITTEE ON APPROPRIATIONS
UNITED STATES SENATE
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SECOND SESSION

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CONTENTS

	Page
Opening statement of Senator Arlen Specter	1
Opening statement of Senator Tom Harkin	2
Opening statement of Senator Jon Kyl	4
Statement of Stephen Straus, M.D., Director, National Center for Com- plementary and Alternative Medicine	5
Prepared statement	6
Prepared statement of Peter G. Kaufmann	9
Statement of Andrew Weil, M.D., Director, Program in Integrative Medicine ..	16
Prepared statement	18
Statement of Mary Jo Kreitzer, Ph.D., Director, Spirituality and Healing, Katherine J. Kensford Center for Nursing Leadership	24
Prepared statement	25
Statement of Herbert Benson, M.D., President, Mind/Body Medical Institute, Associate Professor of Medicine, Harvard Medical School	33
Prepared statement	40
Summary statement of James Cassidy	34
Prepared statement	35
Summary statement of Kristen Magnacca	36
Prepared statement	37
Statement of Dean Ornish, M.D., Founder and President, Preventive Medicine Research Institute	50
Prepared statement	53
Statement of Walter Czapliewicz	57
Prepared statement	59

ALTERNATIVE MEDICINES

TUESDAY, MARCH 28, 2000

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN
SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:29 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.
Present: Senators Specter, Kyl, Harkin, and Murray.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The hour of 9:30 having arrived, we will begin this hearing of the Appropriations Subcommittee for Labor, Health, Human Services and Education. And today we have a very interesting hearing on what is called alternative or complementary or supplementary medicine.

There have been over the decades and centuries a great many treatments outside of the established medical profession, which seem to have worked. And they are now being incorporated in an expanding body of medical care in the United States.

Acupuncture is an ancient Chinese treatment once considered alternative but proven to be a method for treating pain the past couple of decades. Reserpine was the first drug treatment for high blood pressure, derived from a traditional Indian herbal medicine.

Digitalis, an English drug, an important plant-based product used for the treatment of heart disease from the flower foxglove. It was discovered in England, it is said, by the witch of Shropshire. Quinine, used by Native Americans to treat fevers of malaria from the bark of the cinchona tree.

In the past several years, there has been a marked trend toward the trend of alternative or supplementary medicine. I was frankly surprised to see the statistic that 42 percent of United States health care consumers spent \$27 billion on alternative supplementary medical treatments. I am not so surprised about the \$27 billion. Those figures are hard to comprehend. But for 42 percent of Americans to be into this form of treatment is very, very extraordinary, I think.

My colleague, Senator Tom Harkin, who should be joining us shortly, has been a leader in the field of stimulating alternative, supplementary or complementary medicine. And with my backing in 1992, we persuaded the Office of the National Institutes of Health to establish the Office of Alternative Medicine.

In 1998, the Office of Alternative Medicine was elevated to the National Center for Complementary and Alternative Medicine. We have been working to provide increased funding in these areas. And, in 1999, NIH awarded five mind/body center grants at \$2 million each for a total of \$10 million.

One of our distinguished witnesses today is Dr. Herbert Benson, who has pioneered in the field of mind/body. After reading one of his books many years ago, I called him and sought his advice.

Many people are yet to recognize the connection of mind/body, but I can attest personally to severe back problems I got after I lost an election in 1973. I have not had back problems since, and I have not lost an election since. I do not know if David Hume would say there is a causal connection, or if it would stand a demur or get to a jury on causality. But that is a field of tremendous importance, and we are trying to stimulate research and study in the field.

Dr. Andrew Weil was in Philadelphia recently. Senator Jon Kyl is about to introduce Dr. Weil. Senator Kyl came into the anteroom and proudly told me about Dr. Weil being an Arizonan. I asked Senator Kyl if he knew Dr. Weil was born in Philadelphia. I forget Senator Kyl's answer, but we had 1,200 people come out to listen to Dr. Weil the other night, and it was quite an outpouring.

We have Dr. Dean Ornish, the founder and director of Preventive Medicine Research Institute. Friends of mine, the Rubens, proclaimed Dr. Ornish's genius many years ago. So we have really an extraordinary group to supplement Dr. Stephen Straus, the director of the National Center for Complementary and Alternative Medicine.

There is a great deal more which could be said about what we are trying to do to stimulate the National Institutes of Health in running tests. We have anecdotal results, but it is important that these medicines, that these alternative procedures be thoroughly tested in the scientific context. And candidly, it has been a little hard to bring NIH along on that field, but a very powerful advocate on the subject is Senator Tom Harkin, my distinguished ranking member.

When the Democrats control the Senate, Tom chairs the subcommittee. I like it better when the Republicans control the Senate, so I can get to chair the subcommittee.

But we work as partners. There is no Democratic or Republican way to deal with health care or education or worker safety. And I learned a long time ago that if you want to get something done in Washington, you have to cross party lines.

So before yielding to Senator Kyl, I will call on our distinguished ranking member, Senator Tom Harkin.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Thank you very much, Mr. Chairman. Quite frankly, there are times when I am glad you are chairing. I mean, there are times when I wish I was chairing. So it kind of balances out once in a while. When you get into contentious issues sometimes, it is nice when you have to take the lead on some of those things.

Senator SPECTER. You mean the blame.

Senator HARKIN. Right. Exactly.

But I really want to thank you for holding this hearing. And we have a very distinguished panel of witnesses today. Mr. Chairman, both you and I share a very deep interest in the field of complementary and alternative medicine. We have discussed it personally many times.

My basic belief is that we need to take advantage of every possible method of keeping people healthy. And we cannot approach health care with biases that limit potential breakthroughs, either conventional or alternative.

I believe our health care system will be strengthened, if we bring together the best of both. And as American consumers demand freedom to choose the health care they use, they need and expect reliable information on these treatments.

That is why I pushed so hard. And you and I, Mr. Chairman, have made some important progress in the last decade. In 1991—that is when I was chairing—we worked to establish the Office of Alternative Medicine at NIH to make sure that quality research—

Senator SPECTER. Before you arrived, Senator Harkin, I gave you credit for the leadership of getting it started.

Senator HARKIN. Well, then we changed, and you have continued it. So I appreciate that very much.

But we got it established. And in 1998, again with you as chairing, we worked together to make that office into a center for complimentary and alternative medicine. The center can now make its own decisions regarding which studies to fund, allowing those with the greatest expertise and alternative therapy research to decide the direction of research in their own field.

I have met with the center's director, Dr. Stephen Straus, who is here today. I am very optimistic about some of the things the center is doing.

We took another step forward last year, when we included funding, Mr. Chairman, to create the White House Commission on Complementary and Alternative Medicine Policy. That commission, which was just announced a couple of weeks ago, is to give us recommendations on how to catch public policy up to the consumer interest in and use of these therapies. This commission will look at whether training of health professionals in complementary and alternative method therapies is adequate, should Federal higher education loans be available to those studying in CAM fields, is credentialing and licensing of CAM providers adequate, should health plans cover more CAM therapies.

These are just a few of the critical questions the commission will explore. Unfortunately, the commissioners have yet to be appointed, but I am hoping that that will happen very shortly.

So, Mr. Chairman, we have a number of leaders and innovators in health care with us today. Each of them has done great work, I think, both in complementary and alternative medicine, but also in bringing the two fields of traditional medicine and complementary and alternative medicine together.

Sometimes I wonder which is traditional. Sometimes the complementary and alternative medicine fields have been more traditional, if you go back a couple thousand years, than the so-called

traditional methodologies that we have been using for the last, say, century.

So I look forward to their statements. I look forward to their advice, as we continue our joint efforts in this area. Thank you.

Senator SPECTER. Thank you very much, Senator Harkin.

I would like now to turn to Senator Kyl.

The floor is yours, Senator Kyl.

OPENING STATEMENT OF SENATOR JON KYL

Senator KYL. Thank you very much, Mr. Chairman. I appreciate the opportunity to introduce Dr. Weil, even though he will not be the first person to testify here. You and I serve on another committee, and I have to chair that committee at a meeting beginning at 10:00 o'clock.

Incidentally, I note that there are many people born in Philadelphia who now live in Arizona. And we are happy for that.

Senator SPECTER. Iowa, too.

Senator KYL. But I know on the whole you would rather be in Philadelphia.

In any event, I appreciate the chance to say a few words about Dr. Weil here. He is the director of the Program in Integrative Medicine at the University of Arizona College of Medicine. He received his A.B. degree in biology from Harvard and an M.D. from Harvard Medical School. And the University of Arizona, which is my alma mater, Dr. Weil teaches alternative medicine, mind/body interactions and medical botany.

As you know, integrative medicine refers to an approach that incorporates conventional and alternative therapies into the practice of medicine. The University of Arizona's program of integrative medicine is a national leader in the development of the practice of integrative medicine.

In 1997, under Dr. Weil's leadership, the University began the Nation's first post-graduate training program in integrative medicine and pioneered a continuing integrative medical education project. In a few months, the program will initiate the Nation's first integrative medicine distance learning courses.

These courses will use technology to bring integrative medicine education to physicians and nurse practitioners all across the world.

Dr. Weil is also the founder of the Foundation for Integrative Medicine, a national organization dedicated to gaining widespread acceptance of the value of the integrative approach to health care. He is author of eight books, including two international bestsellers. His eighth book, *Eating Well for Optimum Health*, is currently number one on the New York Times' Bestseller List.

He was named by Time Magazine as one of the Nation's most influential people in 1997, incidently the year that the Program for Integrative Medicine was founded. Dr. Weil has noted evolutions in the practice of medicine and patients' increasing dissatisfaction with what is seen as a cold and impersonal medical system sometimes.

So I am very pleased to welcome Dr. Weil to testify before this subcommittee on this timely subject, and compliment you, Mr. Chairman, for conducting this hearing.

Senator SPECTER. Thank you very much, Senator Kyl.

STATEMENT OF STEPHEN STRAUS, M.D., DIRECTOR, NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

ACCOMPANIED BY PETER KAUFMANN, PH.D., LEADER OF THE BEHAVIORAL MEDICINE RESEARCH GROUP, NATIONAL HEART, LUNG AND BLOOD INSTITUTE, NATIONAL INSTITUTES OF HEALTH

Senator SPECTER. Our first witness is Dr. Stephen Straus, first director for the National Center for Complementary and Alternative Medicine. An intramural scientist at NIH for 23 years, he is most widely known for his pioneering research on chronic fatigue syndrome.

He has had extensive clinical research experience with Lyme disease, chronic hepatitis B, HIV/AIDS. Medical degree from Columbia, bachelor's degree from MIT.

He is accompanied by Dr. Peter Kaufmann, acting director of the Office of Behavioral and Social Sciences Research, a leader in the field of behavioral medicine research group of the National Heart, Lung and Blood Institute. Ph.D. from the University of Chicago, a master's and bachelors from Loyola.

Thank you for joining us, Dr. Straus and Dr. Kaufmann. As is our custom, there is a 5-minute green light which will go on. And if that is observed, it will leave us the maximum amount of time for dialogues, questions and answers.

So, Dr. Straus, the floor is yours.

Dr. STRAUS. Thank you, Mr. Chairman. Good morning, Senator Harkin, members of the committee. It is a pleasure to appear before you in my capacity as NCCAM's first director, to summarize very briefly our current work with particular emphasis on the areas of mind/body medicine training and integrative medicine.

As you so eloquently stated in your introductory remarks, the American people have a growing interest in complementary and alternative medicine. And they are relying on these many modalities with the hope and the expectation that they will sustain and improve their health. Our task at NCCAM is to provide the scientific support to help guide the American public; information that the public so greatly deserves.

I will illustrate for you very briefly with two panels to your right both the challenges and the opportunities afforded by complementary and alternative medicine. This first panel summarizes an important study published a few months ago using St. John's Wort for treatment of depression. The improvement in depression shown in green afforded by St. John's Wort was comparable to that afforded by a classic tricyclic antidepressant, Imipramine, and both superior to placebo.

But while active, the next panel shows that botanicals like St. John's Wort have hidden and unforeseen consequences. Here my colleagues at the NIH have studied the effects of St. John's Wort on the body's handling of one of our most important HIV drugs, in this instance, Indinavir. In the green are the normal blood levels of Indinavir that are achieved. But when St. John's Wort is added to the regimen, it speeds the clearance of that drug from the blood, to levels that are sub-optimal for AIDS therapy.

So while there is increased use of complementary and alternative medical tools, if they are to be active, they must have actions on the body. And we must study both the efficacy and the safety of these various modalities. Complementary and alternative medicine encompasses a very broad portfolio of opportunities that we are attempting to address with important guidance of our many stakeholders and our advisors.

Among the many disciplines is the area of mind/body medicine, part of which overlaps with the field of complementary and alternative medicine in the instance in which the modalities are not yet proven or yet well integrated into medical care.

Among our portfolio of studies in mind/body medicine are eight current projects that we are funding, including projects at the Maharishi University in Iowa and at Dr. Weil's home institution at the University of Arizona in Tucson, which I had the pleasure of visiting in February.

Our approach to studies of mind/body medicine will be like the broader field of complementary and alternative medicine, applying the most rigorous scientific tools to provide the American public definitive answers. I believe that the results of our research efforts will over time lead to the successful integration of safe and effective practices into mainstream medicine. Medicine, after all, is a constantly evolving field. And our research portfolio will provide definitive information.

Our important, newly announced initiative to fund studies of both factors that promote and prevent effective integration of practices will help as well. And recall, as you mentioned, that CAM is a new scientific discipline. And we have the important charge to build a cadre of competent investigators to lead this science forward.

We have announced within the past 4 months our ability to fund the full panoply of pre-doctoral and post-doctoral training and curriculum development initiatives for CAM investigators.

PREPARED STATEMENTS

We are funding intramural and extramural centers in CAM, including Dr. Weil's Center. And ultimately, their efforts coupled with those of our own other centers will be translated for the public through effective communication. An informed public will adopt the best therapies and reject those that are unproven or unsafe.

Thank you, Mr. Chairman. I would be happy to answer any questions you have.

[The statements follows:]

PREPARED STATEMENT OF STEPHEN E. STRAUS

Mr. Chairman and Members of the Committee: I appreciate the opportunity to appear before you today to address the subcommittee's interests in complementary and alternative medicine (CAM), training of CAM researchers, NCCAM's plans for facilitating integration of CAM modalities with conventional health care, and our support of mind-body research.

Accompanying me is Dr. Peter Kaufmann, Acting Director of the NIH Office of Behavioral and Social Science Research (OBSSR). He will be pleased to respond to any questions you may have regarding the overall NIH portfolio of research on behavioral and mind-body research supported across the NIH Institutes and Centers.

My presence here today, and moreover, NCCAM's very existence, reflects the growing public interest in complementary and alternative medicine (or CAM, as we

call it), and the belief that various CAM therapies may play a role in improved public health. Approximately 42 percent of U.S. healthcare consumers spent \$27 billion on CAM therapies in 1997. In recognition of this growing consumer trend, Congress in 1998 elevated the NIH Office of Alternative Medicine (OAM), expanded its mandate, creating the NCCAM, and affording it administrative authority to design and manage its own research portfolio. The Congress has continued to reflect the growing interest in CAM by further increasing funding for the Center in fiscal year 2000 to \$68.4 million. We are indeed appreciative of this support.

As the NCCAM's first permanent director, I am excited by the challenge put before me. As CAM use by the American people has steadily increased, many have asked whether reports of success with these treatments are valid. A number of practices, once considered unorthodox, have proven safe and effective and assimilated seamlessly into current medical practice. Acupuncture is routinely applied to manage chronic pain and nausea associated with chemotherapy. Some of our most important drugs—digitalis, vincristine, and taxol—are of botanical origin. Practices such as meditation and support groups are now accepted as important allies in our fight against disease and disability.

In the absence of definitive evidence of effectiveness, however, alternative practices may impart untoward consequences. It is critical that untested but widely used CAM treatments be rigorously evaluated for safety and efficacy. Likewise, promising new approaches worthy of more intensive study must be identified. I am energized by this challenge to help provide the American public the guidance it seeks.

NCCAM's strategy for taking on this challenge is different from that used by other NIH Institutes and Centers (ICs). While the research of other ICs is usually driven by basic scientific discoveries, NCCAM has chosen to focus most heavily on definitive clinical trials of widely utilized modalities that, from evidence-based reviews, appear to be the most promising. Compelling and rigorous data and not just anecdotes must be provided to the public, and we must educate conventional medical practitioners about the panoply of effective CAM practices, so they can be integrated into patient care.

Accordingly, the NCCAM is developing a strategic plan to ensure that these responsibilities are consistent with our continued growth, development and research directions. Five strategic areas have been identified as: Investing in research; training CAM investigators; expanding outreach; facilitating integration; and practicing responsible stewardship.

ST. JOHN'S WORT—OPPORTUNITIES AND CHALLENGES

Already, NCCAM has developed a diverse research portfolio in partnership with the other NIH Institutes and Centers. Among these are some of the largest, and certainly the most definitive Phase III clinical trials ever undertaken for a range of CAM therapies. Allow me to highlight one of these studies to illustrate both the promises and the challenges presented by CAM therapies.

Extracts of St. John's wort, a widely distributed flowering plant, have become quite popular as a treatment for depression. In fact, by some accounts, it is the number one selling nutritional supplement. Because of this intense interest, NCCAM, the National Institute of Mental Health, and the NIH Office of Dietary Supplements are collaborating on a study of the safety and effectiveness of St. John's wort for the treatment of depression. While that study is now nearing completion, those of other groups have underscored our interest in learning more about this botanical.

A recent report in *The British Medical Journal*, for example, showed that St. John's wort is more effective than placebo in treatment of depression, and perhaps as effective as an older generation anti-depressant drug Imipramine. NCCAM's study, which is considerably larger than the European trial, compares St. John's wort with placebo and with Zoloft, currently one of the most commonly used anti-depressants. However, the therapeutic promise of St. John's wort and of botanical products like it, is accompanied by risks that the public has largely ignored. An NIH study published February 12th in the *Lancet* found that St. John's wort, when taken together with the important HIV protease-inhibiting drug, Indinavir, increased the rate at which Indinavir was eliminated from the bloodstream, to the extent that blood levels fell below the desired level for effective AIDS treatment. Interestingly, other studies have suggested that St. John's wort has a similar effect on cyclosporin A, a drug used to prevent the rejection of transplanted organs. The use of St. John's wort may also increase an individual's sensitivity to exposure to the sun.

As these studies demonstrate, the dearth of credible scientific evidence on CAM practices provides unprecedented opportunity for determining the safety and efficacy

of CAM modalities. Included in our already very broad research agenda are studies of mind-body medicine.

NCCAM'S MIND-BODY RESEARCH

Mind-body medicine encompasses a spectrum of behavioral, biomedical, social, and spiritual components of our makeup that interact on a continuing basis in health and disease. This broad discipline overlaps partially with the NCCAM mission. The CAM community does not consider it a priority for NCCAM to study mind-body approaches that have a well-documented theoretical and evidence base such as patient education, biofeedback, and cognitive-behavioral approaches that are all addressed extensively by the other ICs working in concert with OBSSR. On the other hand, the types of projects NCCAM supported are rigorous studies of mind-body modalities involving: (1) still undocumented CAM techniques; (2) modalities for which there is little evidence in the conventional medical research community; and (3) unorthodox uses for otherwise conventionally-accepted mind-body techniques, such as hypnosis.

In keeping with this approach, the NCCAM portfolio already contains studies on:

- efficacy of relaxation/guided imagery and chamomile tea for treating bowel disorders in children;
- self-hypnosis, acupuncture, and osteopathic manipulation for children with cerebral palsy;
- palliative benefits of hatha yoga on cognitive and behavioral changes associated with aging and neurological disorders in multiple sclerosis patients and in the healthy elderly;
- reducing hypertension and other cardiovascular disease (CVD) risk factors through meditation;
- a combination of relaxation training, hypnosis, and guided imagery employed during radiologic procedures to reduce the need for intravenous drugs and improve patient safety;
- improvement in well-being and immune function as a result of self-transcendence in members of a breast cancer support group;
- biofeedback and yoga to treat asthma; and
- Tai Chi, compared to western exercise, in preventing frailty in the elderly.

One key aspect of mind-body research involves studies of the “placebo effect.” Later this year, NCCAM, in collaboration with NIDDK and other ICs, will convene a trans-NIH conference on this subject. Goals of the conference include providing a scholarly assessment of the state of the field; identifying areas for which there is scant research, but considerable opportunity; and recommending a research agenda to move the field forward, in particular projects to be pursued by interested ICs through individual or joint initiatives with NCCAM. Elucidating the nature of the placebo effect will help us better harness the healing power of the mind.

INTEGRATIVE MEDICINE, RESEARCH TRAINING, AND COMMUNICATIONS

Medicine is an ever evolving discipline. It integrates or rejects approaches based on scientific evidence. The results of rigorous research in CAM, including studies of mind-body medicine, will enhance the successful integration of safe and effective modalities into mainstream medical practice. NCCAM initiated a series of specific activities to facilitate this. On December 13, 1999, NCCAM solicited applications to foster incorporation of CAM information into the curricula of medical and allied health schools and continuing medical education programs. Also, the NCCAM must educate eager medical students about CAM so that they may knowledgeably guide their patients toward safe and effective CAM applications. In addition, we must work to overcome the reluctance of conventional physicians to consider validated CAM therapies and to assimilate proven ones into their practice. To this end, on December 13, 1999, the Center established a Clinical Research Curriculum Award (CRCA) to attract talented individuals to CAM research and to provide them with the critical skills that are needed. NCCAM also plans to solicit applications for applied research focusing on identifying barriers to the use of CAM modalities by conventional physicians; developing strategies to incorporate validated CAM interventions into standard medical practice; and evaluating the effects of this incorporation.

Integrative medicine is also a key goal of NCCAM's planned Intramural Research Program and a component of NCCAM's Specialized Research Centers. Each of the Specialized Research Centers focuses on one of several areas, including pediatrics, addiction, cardiovascular disease (CVD), minority aging and CVD, aging, neurological disorders, craniofacial health, arthritis, and chiropractic medicine. In addition to these nine Centers, NCCAM and the NIH Office of Dietary Supplements jointly established two Dietary Supplements Research Centers to advance the science of botanicals, including issues of their composition, safety, and biological ac-

tion. Another request for Center grant applications focusing on asthma and cancer was released for fiscal year 2000. This, coupled with our anticipated solicitation of one more botanical center in fiscal year 2000, will likely bring our total number of NCCAM-supported centers to as many as 15. Research training is conducted by these Centers, in part to advance our goals in integrative medicine, but also to assist us in building a cadre of skilled CAM investigators. Some of NCCAM's Centers spend as much as ten percent of their budget on training. In this regard, in two weeks I will be addressing the Deans of all U.S. medical schools on the subject of NCCAM's research and research training agenda.

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

NCCAM sponsors national meetings, consensus conferences, and workshops. As outreach to research and medical professionals, CAM practitioners, and the health care consuming public, NCCAM has initiated a series of town meetings. The first of this series was held on March 15 in Boston, in conjunction with the Center for Alternative Medicine Research and Education of Beth Israel Deaconess Medical Center. Over 500 attendees heard presentations on the importance of CAM research. Many substantive issues were raised in the public forum portion of the program. The opportunity for dialog at the local level is important for us, not only for disseminating key research findings, but also for the public to provide perspective and help us shape our overall research strategy.

CONCLUSION

In closing, I would like to share with the Subcommittee my vision of where I expect complementary and alternative medicine to be in the years to come. I am confident that NCCAM's leadership will stimulate both the conventional and CAM communities to conduct compelling scientific research. Several therapeutic and preventative modalities currently deemed elements of CAM will prove effective. Based on rigorous evidence, these interventions will be integrated into conventional medical education and practice, and the term "complementary and alternative medicine" will be superseded by the concept of "integrative medicine." The field of integrative medicine will be seen as providing novel insights and tools for human health, and not as a source of tension that insinuates itself between and among practitioners of the healing arts and their patients. Modalities found to be unsafe or ineffective will be rejected readily by a well-informed public.

I would be pleased to answer your questions on NCCAM's activities and plans.

PREPARED STATEMENT OF PETER G. KAUFMANN

Mr. Chairman, I am pleased to submit the following statement on the role of the Office of Behavioral and Social Sciences Research (OBSSR) in fostering behavioral and social sciences research at the National Institutes of Health (NIH) as background information for the Subcommittee.

OBSSR GUIDING PHILOSOPHY

In 1993 the U.S. Congress created the Office of Behavioral and Social Sciences Research (OBSSR) in the Office of the Director, NIH, in recognition of the key role that behavioral and social factors often play in illness and health. The guiding philosophy of OBSSR is that scientific advances in the understanding, treatment, and

prevention of disease will be accelerated by greater attention to behavioral and social factors and their interaction with biomedical variables. Currently, NIH supports approximately \$1.6 billion in behavioral and social sciences research. (See attached funding table.)

MISSION AND RESPONSIBILITIES

The mission of the OBSSR is to stimulate behavioral and social sciences research throughout NIH and to incorporate these areas of research more fully into others of the NIH health research enterprise. The major responsibilities of the office and its director are:

- to provide leadership and direction in the development, refinement, and implementation of a trans-NIH plan to increase the scope of and support for behavioral and social sciences research;
- to inform and advise the director of NIH and other key officials of trends and developments having significant bearing on the missions of the NIH, Department of Health and Human Services, and other Federal agencies;
- to serve as the principal NIH spokesperson regarding research on the importance of behavioral, social, and lifestyle factors in the initiation, treatment, and prevention of disease; and to advise and consult on these topics with NIH scientists and others within and outside the Federal Government;
- to develop a standard definition of “behavioral and social sciences research,” assess the current levels of NIH support for this research, and develop an overall strategy for the expansion and incorporation of these disciplines across NIH institutes and centers;
- to promote cross-cutting, interdisciplinary research, and to incorporate a bio-behavioral perspective into research on the promotion of good health, and the prevention, treatment, and cure of diseases;
- to develop initiatives designed to stimulate research in the behavioral and social sciences;
- to ensure that findings from behavioral and social sciences research are disseminated to the public;
- to sponsor seminars, symposia, workshops, and conferences at the NIH and at national and international scientific meetings on state-of-the-art behavioral and social sciences research.

MIND/BODY RESEARCH

One example of the kind of behavioral and social sciences research that OBSSR promotes across all of the institutes and centers is mind/body research. Funding for mind/body research is significant and broad at NIH. Fourteen institutes and centers estimate that they will fund a total of approximately \$125.3 million in mind/body research in fiscal year 2001. Approximately 50 percent of OBSSR’s budget is specifically designated for mind/body research. A breakdown of that funding by institute and center follows.

FUNDING FOR MIND/BODY RESEARCH AT NIH

[In millions of dollars]

Participating	Fiscal year—		
	1999 actual	2000 estimate	2001 estimate
NCI	10.9	12.0	13.1
NHLBI	19.5	21.7	22.9
NIDCR	2.3	2.6	2.8
NINDS	1.6	1.8	1.8
NICHD	13.2	15.1	15.9
NIEHS	1.1	1.1	1.2
NIA	4.4	5.1	5.3
NIAMS	3.2	3.6	3.8
NIMH	5.7	6.5	6.9
NIAAA	32.5	33.9	33.2
NINR	1.0	1.1	1.6
NCRR	4.2	5.3	5.6
NCCAM	0.5	0.6	0.7

FUNDING FOR MIND/BODY RESEARCH AT NIH—Continued

[In millions of dollars]

Participating	Fiscal year—		
	1999 actual	2000 estimate	2001 estimate
OD	10.0	10.1	10.6
NIH ¹	110.0	120.6	125.3

¹ May not add due to rounding.

EXAMPLES OF MIND/BODY RESEARCH

Mind/body research encompasses behavioral, social and biomedical research on the interrelationships among cognition, emotion, biological functioning, and physical health. In recent years, we have made significant advances in the field of mind/body research. Provided below are examples of studies that exemplify the influence of psychological, behavioral, and social processes on all levels of biological functioning and health.

- For more than 10 years, the National Institute of Mental Health has funded research that examines the psychological and physiological effects of a group psychotherapy intervention for women with metastatic breast cancer. There is evidence that this treatment enhances coping and social support, reduces mood disturbance and pain, and may extend survival time. This work is now expanding to assess the physiological basis of psychosocial effects on cancer survival. It will evaluate whether lower cortisol levels and higher immune activity, especially natural killer cell cytotoxicity, will result from group psychotherapy and will predict longer survival.
- Research funded by the National Institute of Dental and Craniofacial Research is examining how stress affects the ability to heal. Care givers for those stricken with Alzheimer disease and students taking academic examinations are groups who clearly experience stress. Studies show that skin wounds in Alzheimer's care givers heal at a rate 25 percent slower than those who are not under chronic stress. Students taking final exams took 40 percent longer to heal than when they were not under the pressure of exams.
- An ongoing investigation at the National Institute of Mental Health is studying the link between social environment, psychological states (positive and negative affect, personal control, self-esteem) and vulnerability to upper respiratory infections. This research previously demonstrated that stress increases susceptibility to upper respiratory infection while the support of larger social networks decrease susceptibility. The current study will attempt to identify causal pathways (psychological, health practice and biological) linking stress, social network size, and disease susceptibility.
- An ongoing study at the National Cancer Institute is seeking to assess the effect of a stress reduction intervention program on the quality of life and immunologic function of women diagnosed with breast cancer. The study will use a well established and cost effective stress reduction technique known as Mindfulness-based Stress Reduction (MBSR) as the intervention method. MBSR has been previously shown to be effective in improving the ability to cope with stress and to promote psychological and physical well being. The effect of MBSR on women with breast cancer has never been studied. The investigators will test whether MBSR will produce greater improvement in psychological, social, and somatic functioning in the group receiving this intervention, compared to the group that does not. The investigators will also test whether MBSR will produce enhanced immune functioning.
- A study that examines the relationship between stress, immune function, and HIV disease progression in African American women in rural South Florida is supported by the National Institute of Mental Health. Previous work has demonstrated that stress is predictive of early HIV progression and that this mind-body interaction may be mediated by the impact of stress on key parameters of cellular immunity. Current research employs repeated measures to (1) establish a definite relationship between stress and HIV progression; (2) begin to determine whether important changes in host defense (killer cell levels and their functional activity) correlate with stress associated changes in clinical status; (3) determine if alterations in glucocorticoid function correlate with changes in immune/disease status. The results of these investigations will enhance the pos-

sibility of understanding causal mechanisms in stress and immune based illness at physiological cellular and molecular levels.

- The National Heart, Lung and Blood Institute is examining the pathways through which mental stress influences heart function in health and illness. The primary objectives are to evaluate the relative importance of psychological, neurological, and cardiovascular factors in precipitating heart attacks. Coronary heart disease patients as well as normal individuals are being studied through mental stress testing, mood and affect, personality variables, biochemical variables, and autonomic nervous system function. This study is one of the most comprehensive studies of mind-body interactions in cardiovascular health, and spawned a collaborative study of mental stress as a foreboding factor for cardiac events.
- The largest randomized clinical trial ever undertaken in the field of mind-body medicine examines whether treating depression and enhancing social support facilitates recovery from heart attack. This seven-year study is funded by the National Heart, Lung, and Blood Institute and has enrolled nearly 2,500 heart patients from nine centers nationwide.
- A project examining the mechanisms by which hypertension impairs intellectual function is supported by the National Heart, Lung, and Blood Institute. Positron Emission Tomography (PET) functional brain imaging permits scientists to test the hypothesis that hypertension impairs cerebral blood flow response. With the advent of ultrasound measurements, investigators can also test a second hypothesis that atherosclerosis of the carotid arteries influences intellectual function.

CONGRESSIONAL INTEREST IN MIND/BODY RESEARCH

In fiscal year 1999 OBSSR received \$10 million from Congress to establish five mind/body research centers. An RFA to fund five centers was issued in January 1999. OBSSR received 18 applications in response to the RFA. Following initial peer and secondary council reviews, NIH awarded five Specialized Centers Grants (P50) at approximately \$2 million (total costs) each in September 1999 to the University of Michigan, University of Pittsburgh Medical Center/Carnegie Mellon, University of Miami, University of Wisconsin and Ohio State University. NCI, NHLBI, NICHD, NIMH, and, NIDCR are administering the awards. The Centers support both basic research and clinical applications focusing on the influence of beliefs, attitudes and values on physical health; the determinants or antecedents of health-related beliefs, attitudes, and values; and stress management approaches to disease prevention and treatment. It will take about two years before the first results from the research supported through these Centers will be available.

The Center Directors and leaders of their research projects will be meeting with NIH staff on May 1–2, 2000 in the first of their annual meetings. The goal of this meeting is to familiarize each other with their research goals and projects and to explore avenues of coordination and cooperation.

Actual and projected funding for the Mind/Body Centers is as follows:

Institute	Fiscal year—				
	1999 actual	2000 estimate	2001 estimate	2002 estimate	2003 estimate
NCI	\$2,015,187	\$2,046,384	\$2,101,822	\$2,158,930	\$2,217,094
NHLBI	2,000,002	2,143,982	2,202,180	2,089,273	2,050,320
NICHD	1,999,100	2,038,179	2,059,895	1,968,479	1,825,140
NIDCR	1,995,569	1,956,068	1,972,841	2,037,693	2,089,959
NIMH	2,005,331	1,937,560	1,995,695	2,026,417	2,035,356

CONCLUSION

Mind/body research has a long and significant history of support at 14 institutes and centers at the NIH. OBSSR, an office whose mandate is to encourage additional funding and coordinate trans-NIH initiatives in mind/body medicine, is ideally located for this purpose in the Office of the Director. With broad funding support across the institutes and centers, and an office that serves as a central coordinating locus, mind/body research at NIH is in an excellent position to continue to flourish.

Thank you for your interest in the role of OBSSR in fostering mind/body approaches to health and healing at NIH.

Senator SPECTER. Thank you very much, Dr. Straus. I noted your comments about grants to Iowa and Arizona. Was it inadvertent that Pennsylvania was not mentioned?

Dr. STRAUS. Actually, Pennsylvania receives the largest funding of any State to this time, largely through the very important clinical trial chaired out of the University of Pittsburgh, a 5-year study of ginkgo biloba for prevention of dementia in otherwise healthy aging Americans.

Senator SPECTER. Well, I am very glad to have those facts on the record.

Dr. Straus, there has been considerable resistance to complementary alternative integrated medicine by the established medical profession. Do you see an easing of that resistance? And what do you think can be done to give a push to these alternative, complementary integrated approaches, which have established themselves with some substantial degree of reliability.

Dr. STRAUS. That is a very important question, Senator. The very fact that I accepted the offer to chair this center is an indication that the mainstream scientific community now appreciates that there are terrific challenges and opportunities. And with your help and that of the American people, we now have the independence and the resources to apply well-proven scientific principles to address complementary and alternative medical practices, the same way we do all other new ideas in medicine.

It is true that mainstream medicine has, to some extent, resisted some of these new ideas, but medicine has always been an evolving discipline. As you mentioned in your introductory remarks, there are practices today that were once considered quite alternative. Early in this century, radiation therapy was considered extreme.

Senator SPECTER. Let me interrupt you, Doctor—

Dr. STRAUS. Yes, sir.

Senator SPECTER [continuing]. Perhaps to go on to another question, because time is very limited. When you talk about the funding, Senator Harkin and I have taken the lead with this subcommittee in providing the funding.

Mind/body medicine was funded for the first time in 1998 at \$55 million. Now it is up to more than \$125 million. Complementary and alternative medicine was at a \$42 million level in 1997. Now it is almost four times that, a little over \$160 million.

And while you have to make the ultimate judgments, we are very concerned about the need for training for medical and other health care professionals in integrative medicine and incorporating integrative medicine into medical school curricula. In order to do that, there is going to have to be a push from your agency. I know Dr. Weil has a keen interest and has pointed out that issue.

Let me hear of your plans to move in that direction.

Dr. STRAUS. Certainly. First of all, we are currently funding some of Dr. Weil's fellows.

Senator SPECTER. But how about the medical training and the medical school curricula?

Dr. STRAUS. We announced a few months ago an intent to fund what is known as a CAM education project grant. We expect \$1.5 million of funding this first year. That will fund education of young individuals to become CAM investigators at all the allied health

professional schools, including nursing, dental, medical and osteopathic.

We also announced and intend to fund clinical research curriculum awards. We expect a seven-fold increase this year over last year in our funding for training and career development of CAM investigators.

Senator SPECTER. Dr. Straus, the issue of mind/body has been recognized to a substantial extent but is still looked upon with some skepticism by many. And there is the aspect of spiritual counseling, the prayer, so to speak, on the impact on physical ailments.

We would be interested in your evaluation of the efficacy of the mind/body approach and your suggestions as to what can be done to better educate the public on the facts on this issue.

Dr. STRAUS. Many parts of mind/body medicine have been very well integrated already, cognitive behavioral therapies and hypnosis and biofeedback and many exercise regimes. There is only a small part of mind/body medicine that is not embraced well by the other NIH institutes and centers. And we are conducting studies of spirituality and yoga and the like.

I think the best approach is to continue to address the opportunities of mind/body medicine across all the disciplines and fields within the NIH.

Senator SPECTER. Would you amplify what you mean by "addressing spirituality"?

Dr. STRAUS. We are funding studies of the use of spirituality in healing processes. I addressed a workshop on religion and spirituality—

Senator SPECTER. Religion and spirituality?

Dr. STRAUS. Yes—this past November. And we look forward to receiving applications to conduct additional such studies.

Senator SPECTER. Do you see any conflict whatsoever or potential conflict on spirituality and religion in a mind/body funding by the Federal Government?

Dr. STRAUS. Not when we are asking scientific questions; it is beneficial ultimately to the American public.

Senator SPECTER. So the issue as to approach is an individual one, if the individual chooses something spiritual or religious. And NIH is studying the physical impact in a scientific context.

Dr. STRAUS. Yes.

Senator SPECTER. So you do not see a conflict.

Dr. STRAUS. I do not.

Senator SPECTER. Senator Harkin.

Senator HARKIN. Thank you very much, Mr. Chairman.

Dr. Straus, again, I want to compliment you on your early leadership of the National Center. I believe it is doing some very important work and seemingly headed in the right direction. I want to clear up a couple of things here.

First of all, we just heard the chairman state that out of all of NIH, there is about \$160 million this year for some kind of complementary and alternative medicine. I want to point out that the National Center gets about \$67 million this year.

That is less than $\frac{1}{2}$ of 1 percent of the total funding for the entire NIH. I want to make that clear. Less than $\frac{1}{2}$ of 1 percent of

the total funding for NIH goes to the National Center for Complementary and Alternative Medicine.

If you throw in what the National Cancer Institute and all the others are doing here to get up to the \$160 million, that is still less than 1 percent of the total funding for NIH that goes to complementary and alternative medicine. And yet over half of the American people every year spend more money out of pocket for complementary and alternative medicine care and visits than they do in going to the so-called traditional method group.

And so I have been hearing reports in the press and stuff about how much money we are spending here. But in keeping with where the American people are going and what they want and what they are doing, it is woefully inadequate in terms of taking a look at the promising therapies and to really take a look at what is happening with a lot of the nutraceuticals that people are taking today.

So I wanted to clear that up. It may sound like a lot of money, but in the scheme of things, less than 1 percent of the total funding for NIH goes for this. Now having said that, I see all these different branches of NIH, all the different institutes spending this money.

For example, the National Cancer Institute lists \$38.4 million they are spending this year on complementary and alternative medicine.

My question to you, Dr. Straus, is: Do you have a good handle on what they are doing? And how closely are you coordinating with the National Cancer Institute to find out just what they are spending their money on?

Dr. STRAUS. Your comments are very cogent, Senator. Shortly after assuming the position of director, I met with the director of the National Cancer Institute to discuss this very issue.

And he assured me of very broad support for his office for complementary and alternative medicine, whose director, Dr. Jeff White, and I meet at least on a monthly basis. We are developing public information and website information together.

We are cosponsoring a major study of shark cartilage for the treatment of lung cancer and many other initiatives. They are conducting additional studies using green tea as well for cancer prevention.

Senator HARKIN. But when they do these studies, when NCI does it, how do they peer review them? Do they do them through your office, or do they peer review them in their own?

Dr. STRAUS. Applications to the NIH, as you know, go to the Center for Scientific Review. And they are reviewed in the normal study sections. In the instance of a shark cartilage study, or shall I say the green tea study, it would go to a cancer therapy study section. Our peer review group reviews applications that we in NCCAM call for specifically.

Senator HARKIN. Say that last again.

Dr. STRAUS. NCCAM's own peer review group reviews applications that we have called for specifically.

Senator HARKIN. I understand that. That is why we set that up.

Dr. STRAUS. Yes, sir.

Senator HARKIN. How confident are you that the peer review process for all these other institutes spending what they say they

are spending—and I am not certain. I tell you, I want everyone to know that I have some real questions about this, about just what they are spending their money on and listing it as complementary and alternative medicine. And I intend to pursue this further with the directors of each of the institutes.

I am just wondering about the peer review process. I have been through this a long time.

Dr. STRAUS. Yes, sir.

Senator HARKIN. And I know what that is like. And that is why we insisted that for NCAM the peer review process involve practitioners of complementary and alternative medicine.

I have said before, would you ever have a peer group to peer review a request, a research request, for some kind of a cancer chemotherapy, and that peer review did not contain one oncologist? What if they were just all podiatrists? I mean, that is what we are getting into.

And if in fact we are looking at complementary and alternative medicine, some of those people ought to be on that peer review committee.

Dr. STRAUS. If I may respond, my staff sees listings of every application that comes to the NIH. I am confident that we have an opportunity to fund them, even if other institutes do not. And in addition, the review panels often request our recommendations for practitioners who have expertise in those particular areas to join the standing review panel. So that does happen, Senator.

Senator HARKIN. One last thing. The statute that we passed that set up the center requires a full-time liaison from every institute to your center. Has that been established?

Dr. STRAUS. Yes, sir. I chair a trans-agency committee on complementary and alternative medicine. We are meeting again in another several days. I have addressed them this past fall.

Senator HARKIN. Good. That is very encouraging.

Dr. STRAUS. Thank you, sir.

Senator SPECTER. Thank you very much, Senator Harkin.

Thank you very much, Dr. Straus and Dr. Kaufman.

Dr. Kaufman is here to answer questions. And if there were more time, we would have had some questions. But we do thank you very much for coming. And as is customary, the agenda is so full, but we will be talking to both of you later. Thank you.

Dr. STRAUS. Thank you. I look forward to it.

STATEMENT OF ANDREW WEIL, M.D., DIRECTOR, PROGRAM IN INTEGRATIVE MEDICINE

Senator SPECTER. Let us turn now to our second panel, Dr. Andrew Weil and Dr. Mary Jo Kreitzer.

As previously announced, Dr. Weil is the director of the Program in Integrative Medicine at the University of Arizona College of Medicine where he teaches alternative medicine, mind/body interactions, and medical botany.

He is the founder of the Foundation for Integrative Medicine and has written and lectured extensively on alternative medicine, medicinal plants, and the redesign of medical education. Medical degree from Harvard Medical School and a bachelor's degree from Harvard University.

And in the interest of full disclosure, which is always a good idea, Dr. Weil and Senator Kyl and I came through the back room for the benefit of television. There is a documentary in process on Dr. Weil. Maybe it is on Senator Kyl. I am not sure. But that was why we entered in that manner. And there is no demonstration of favoritism to any witness. There may be a little favoritism to television, but not witnesses.

Dr. Weil, you are claimed by at least two States, Arizona and Pennsylvania. And Pennsylvania has priority. Thank you for joining us. And we look forward to your testimony.

Dr. WEIL. Thank you, Senator Specter, Senator Harkin. Thank you for inviting me here to testify.

I would also like to acknowledge your strong leadership in this area of working to provide the American public with a better form of medicine. And I would also like to say I am very happy to appear with distinguished colleagues in this field this morning.

The vast numbers of patients who are seeking care outside of conventional medicine represent a crisis of confidence with American medicine today. I travel around this country very frequently and speak in many different venues and interact with many different kinds of patients. I think I have a clear sense of what people are looking for in their visits to doctors today.

They want doctors who have time to explain to them in language they can understand the nature of their problems, who will not just promote drugs and surgery as the only way of doing treatment, doctors who are at least minimally aware of nutritional influences on health and can answer intelligently questions about uses of dietary supplements, a source of great confusion to the public today.

They want doctors who are sensitive to mind/body interactions and are willing to look at patients as more than just physical bodies. They want doctors who will not laugh at them if they bring up questions about Chinese medicine or homeopathy or other forms of treatment that are not taught in American medical schools.

I think those are very reasonable requests. But the fact is that that is not how we are training physicians today. So there is a widening gulf between what patients expect from their doctors and what they are getting. And in their frustration, they are going elsewhere.

I think most of these people, if given their first choice, would go to a medically trained person, to a medical doctor, a doctor of osteopathic medicine, who was open minded and able to guide them through the maze of conflicting treatment options out there. That clearly would be people's first choice.

So it seems to me that the fundamental problem is medical education. The way we are training doctors today does not meet the needs of the public. Now there is an argument that you will hear from some academicians that changes in medical education must be guided by science and research, not by consumerism. But I think in this case consumers are indicating severe failings in medical education.

The fact that medical education in this country does not include basic information about nutrition and how many kinds of disease can be influenced by making dietary change is inexcusable.

The fact that our country does not train physicians in the use of botanicals or that teach them differences between whole plant products and isolated chemicals from plants is inexcusable and puts us, by the way, at a great disadvantage in the world, where other countries like Japan and Germany are way ahead of us in this area.

What we are trying to do at the Program in Integrative Medicine is to develop new models of medical education. The fellowship training that we do provides an excuse for developing curriculum in these areas that are now missing from conventional medical education that will be there when medical schools open to this possibility.

And by the way, I think there is increasingly openness within the schools. Some key schools, such as the University of California, San Francisco, Stanford, Duke University, among others, the University of Minnesota, have indicated willingness to move in this direction. Jefferson Medical College, as you know, has started a strong initiative in this area as well.

But these programs are fledgling programs. They are struggling. They need support. And without Federal direction and guidance, there is a real danger that they are going to fail. With due respect to Dr. Straus, the National Center for Complementary and Alternative Medicine provides no mechanisms for funding of these efforts. We are not in the business of training researchers. That is one aspect of what we do.

But the only money that NCAM says is available is for training of researchers in complementary and alternative medicine. That is not the issue here. The issue is where is the money to support curriculum development, to develop new models of training physicians that can meet the needs of consumers today?

PREPARED STATEMENT

At the moment, we see no mechanisms for getting that kind of support from the Federal Government. And if it is not going to come from the National Center for Complementary and Alternative Medicine, I would make a plea to this subcommittee to think about ways of designing other structures through which Federal funds can come to support an effort that is clearly needed.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF ANDREW WEIL

Mr. Chairman, Senator Harkin, and members of the Subcommittee, thank you for inviting me to testify this morning. For many, many years, I have been personally and professionally engaged in the very issue under consideration by the Subcommittee this morning. I am encouraged by the level of interest Congress has shown in behavioral, alternative, and mind-body medicine.

I would be remiss if I did not recognize the hard work Chairman Specter and Senator Harkin put into the fiscal year 2000 Labor, Health and Human Services, and Education bill. In strong and certain language, the Subcommittee recognized the importance of training physicians in integrative medicine. This language underscores our responsibility to meet the needs of the rapidly growing number of consumers who are demanding a more healing-oriented system of healthcare.

Recent data indicate that nearly 50 percent of all U.S. healthcare consumers have sought alternative medicine in some capacity, creating the expectation that physicians should be knowledgeably guiding their patients through a course of treatment that is right for them. We can do this by ensuring that physicians and other

healthcare providers have access to appropriate levels of education and training in the valuable relationship between alternative and conventional medicine. This is the spirit of integrative medicine—maximizing the body’s innate potential for self-healing by weaving alternative approaches into mainstream medicine.

With consumers’ growing interest in a more integrative approach to healthcare and Congress’ intent to fund integrative medicine education and training programs, allow me to share the unique and specific work we are doing at the University of Arizona to develop a model which best responds to these expectations.

The University of Arizona Program in Integrative Medicine was established in 1996 with seven objectives:

- (1) Establish integrative medicine as a new direction within academic medicine, not as a new specialty;
- (2) Develop a new model of medical education and curricula for use by other medical institutions;
- (3) Train physicians, pharmacists, nurses and other healthcare providers in the theory and practice of integrative medicine;
- (4) Challenge physicians and other healthcare providers to commit to their own health and healing;
- (5) Develop integrative medicine clinics as models for clinical education, patient care, and outcomes research;
- (6) Research theories and methods of integrative medicine including effectiveness of new models of medical education; and
- (7) Produce leaders who will establish similar programs at other academic institutions and set policy and direction for healthcare in the 21st century.

The mission of the Program in Integrative Medicine is to foster the redesign of medical education to incorporate the philosophy of integrative medicine. The Program developed a core curriculum which is adapted for its various educational components: the Fellowship in Integrative Medicine, the Associate Fellowship in Integrative Medicine (the “distance learning” model for clinicians), Continuing Professional Education (CPE), pre-medical and medical education, and education of healthcare professionals.

It is important to note that this curriculum does not represent a linear process. Rather, curriculum components are interwoven to form an educational program that provides students, physicians and other healthcare professionals with a comprehensive education depicting the philosophies, principles and practices that are central to integrative medicine.

Philosophical Foundations.—The most fundamental distinction of integrative medicine is to shift the orientation of medicine from disease to healing. This requires students to closely examine their attitudes, not only with respect to medicine but also the manner in which they view the world. Courses include healing oriented medicine, the philosophy of science, medicine and culture, the art of medicine and research education.

Lifestyle Practices.—A basic principle of integrative medicine is that the manner in which we live clearly affects our health and disease. Lifestyle practices and prevention are central to this approach. This component of the curriculum focuses on the basic aspects of life and health that are addressed in the care of patients as well as practitioners of integrative medicine. Courses include spirituality and medicine, mind/body medicine, nutrition, and physical activity.

Therapeutic Systems and Modalities.—This component explores a variety of modalities and therapeutic systems. The history, theories, appropriate applications and scientific evidence are presented for each system and modality. Physicians, healthcare professionals and students learn the techniques for some of these therapeutic modalities. More frequently, by presenting the theories and appropriate applications for these systems and modalities, those persons participating in the Program learn when and to whom they should refer their patients for the best treatment strategy individualized for their care. Courses include botanical medicine, manual medicine, Chinese medicine, homeopathy, energy medicine, guided imagery and hypnotherapy.

The coursework described above, while often taught experientially, is content-oriented. The following are more process-oriented, and are not, therefore, broken down into specific courses.

Personal Development and Reflection.—Approaches involved in the practice of integrative medicine require practitioners to commit to their own process of self-exploration and personal development. The current methods used to educate medical students often result in the underdevelopment or degradation of these processes, and often translate into sub-optimal interactions with patients. This component of the curriculum is focused on methods for relaxation and self-examination of the

healthcare professional. Included are such practices as meditation, personal reflection and group process.

Clinical Integration.—The process of integrating philosophically different systems of medicine into one comprehensive treatment plan for each patient is one of the most central features of the practice of integrative medicine. The goal is to teach the art of integration, not simply the strengths and weaknesses of alternative practices.

In the absence of physicians or other healthcare providers who are educated and practiced in the art of integration, patients are torn between the instructions they receive from their conventional physicians, alternative care providers, health food clerks, the Internet, and their families in making their own medical decisions. Healthcare providers must be skilled in understanding when and how to incorporate alternative approaches and to counsel patients against useless or fraudulent practices. This component also focuses on the integration of such philosophies and approaches into the practitioners' own personal and professional life.

Furthering the Field/Implementation.—This curriculum component is designed to help physicians and other practitioners put into practice what they have learned. There is strong focus on physicians as leaders functioning as agents of social change. Content areas include practical skills such as public speaking, business planning and management skills; social-political aspects of integrative medicine; medicine and law; and related ethical issues. For clinicians in practice, the emphasis is placed in putting this education into action within their clinical settings.

This core curriculum serves as the blueprint from which specific curricula are designed to meet the needs of the various educational components of the Program in Integrative Medicine.

THE FELLOWSHIP IN INTEGRATIVE MEDICINE

The Fellowship is a two-year, intensive program, incorporating didactic instruction, direct research and clinical experience, which is available to MDs and DOs who have completed residencies in primary care specialties. The objective of the Fellowship is to produce leaders in integrative medicine: individuals who will go on to other universities and healthcare institutions to establish similar programs and set policy and direction for healthcare in the 21st century; in other words, to "train the trainers."

A comprehensive, intensive course of study of the principles, theories and practices of integrative medicine is available to a relatively limited number of competitively selected, board-certified physicians. Such physicians, at the end of the Fellowship Program, are qualified to institute parallel programs in integrative medicine in medical and health professions institutions throughout the United States.

Of the first graduating class of Fellows in Integrative Medicine in the United States, which graduated in June 1999, three have received appointments to develop programs in integrative medicine at Northwestern University-Evanston, Beth Israel Medical Center and East Tennessee State University College of Medicine. The fourth graduate remained with the University of Arizona Program in Integrative Medicine to lead the CPE portion of the Program and, more recently, to serve as a resource to other medical and health professions institutions that are seeking to develop programs in integrative medicine.

In addition to the basic research education, Fellows regularly attend journal groups, during which time they review and learn to critically evaluate published studies in complementary and alternative medicine. The didactic instruction Fellows receive early in the program prepares them to develop and conduct direct research during the later part of the initial year and the second year of the Fellowship. This research is conducted under the guidance of their chosen research mentor, who is conducting research in the Program.

ASSOCIATE FELLOWSHIP IN INTEGRATIVE MEDICINE

The Associate Fellowship is an Internet-based distance-learning program to provide physicians throughout the country the opportunity to learn integrative medicine. The Associate Fellowship is the newest component of the Program, and will begin the education of Associate Fellows in the fall of 2000. The Associate Fellowship will consist of approximately 1,000 hours of study over a two-year period and will include Internet-based study, real-world assignments and three one-week sessions at the Program in Integrative Medicine at the University of Arizona Health Sciences Center in Tucson.

Internet technology was selected as the primary instructional medium in that it provides a "real-time," interactive learning forum that is highly appropriate for problem-based learning. Because integrative medicine is a rapidly developing field,

this format allows faculty and participants to keep up to date easily by responding to new information and discoveries.

During their three on-site training sessions in Tucson, Associate Fellows will meet the faculty of the Program in Integrative Medicine, learn mind-body skills such as meditation and guided imagery, participate in case conferences and learn strategies for sustained personal/professional development and leadership activities in their respective home communities.

The first enrollment in August 2000 will be limited to 40 participants. As of March 2000, more than 80 applications had been received for the first enrollment. Of the 40 who were selected, five are international applicants, 11 are from rural areas, 32 serve a combination of urban and rural environments, and 18 are from academic institutions. The applicants are evenly divided between males and females. Due to the demand and the large applicant pool, consideration is being given to adding a second class of Associate Fellows soon after the first begins. Subsequently, 50 participants will be enrolled at each intake. The Associate Fellowship will have at least two intakes of physicians by 2003.

Once the Associate Fellowship is established, efforts of the faculty and staff of the Associate Fellowship Program will be focused on adapting the core curriculum to the specific educational requirements of other healthcare professionals, such as nurses, physician assistants and pharmacists. With the knowledge gained utilizing the distance learning format, physicians and other healthcare professionals will be prepared to establish programs in integrative medicine in their home institutions.

CONTINUING PROFESSIONAL EDUCATION IN INTEGRATIVE MEDICINE

The Department of Continuing Professional Education (CPE) encompasses Continuing Medical Education (CME) for physicians, Continuing Education (CE) for nurses and pharmacists and educational programs for healthcare professionals. The purpose of the CPE Program is to introduce healthcare professionals and academicians to the philosophy, basic principles and clinical application of integrative medicine.

Participants evaluate the CME and CE curricula at the time these courses are conducted and courses are continuously modified to be consistent with the needs of physicians and healthcare professionals, while ensuring that the principles and practices of integrative medicine are accurately represented.

The CPE program differs from the Associate Fellowship in that it provides education to a wide range of healthcare professionals. To date, more than 4,500 individuals including physicians, nurses, pharmacists, social workers, massage therapists, psychotherapists, students and others have enrolled in one or more of the courses offered by the Program in Integrative Medicine's CPE program. A total of 2,489 individuals have received Continuing Education credits: 1,335 physicians; 798 nurses, nurse practitioners and physician assistants; and 125 pharmacists.

The Program plans to expand the opportunities for the education and training of nurses in integrative medicine. During the initial year of this expansion, the Fellowship curriculum will be modified to meet the specific needs of nurse practitioners and physician assistants. Research requirements will be identical to that of the Fellowship program for physicians. As is the case for physicians' Fellowship program, nurse practitioners who complete the two year program will be prepared to develop and implement curricula in integrative medicine within nursing education throughout the country.

MEDICAL SCHOOL EDUCATION

The Program in Integrative Medicine currently participates in and/or presents one required course and two elective courses at the University of Arizona College of Medicine.

I teach an interdepartmental, required course that is part of the basic science curriculum. The course gives students an understanding of the psycho-social and emotional aspects of clinical medicine by exploring the biological, environmental, social and psychological factors that influence a person as a patient. Some of the topics covered are the doctor-patient relationship, major health problems for children and adults, substance abuse, issues in human sexuality, coping with chronic illness, healthcare and the elderly, death and dying, ethical issues in medicine and legal aspects of medical care. Four two-hour lectures are dedicated to fundamentals in integrative medicine.

The Program also conducts two elective courses. The goals are to enable the students and residents to become familiar with the range of available alternatives to allopathic medicine, to be able to evaluate these systems of treatment critically, and to learn whether any elements of them may complement orthodox approaches.

One of the electives is a patient care course in which participants spend half the time in the Integrative Medicine Clinic with a Fellow and attending physician, observing patients and recommending treatments. During the other half of the rotation, students and residents are placed with alternative practitioners in southern Arizona (naturopaths, homeopaths, body workers, etc.) to observe their techniques. This approach provides the students with a broad exposure to the integration of allopathic and alternative modalities in very different settings.

The Program also is designing an elective for the fall semester of 2000. The course will allow students to explore the role of their own lives in their patients' lives and in the healing relationship. Based on the principles of integrative medicine, the course is the first of its kind to be offered in the College of Medicine at the University of Arizona.

UNDERGRADUATE EDUCATION

Currently, faculty and Fellows of the Program in Integrative Medicine lead discussions at the undergraduate level to teach basic principles of integrative medicine and discuss the implications for their professions and their lives.

For example, the University of Arizona Department of Molecular and Cellular Biology and the Program in Integrative Medicine are collaborating on the design of a web-based, interactive learning environment that will enable undergraduate students to use integrative medicine as a vehicle for exploring the philosophy of science and medicine. This module will play a pivotal role in the professional development of students entering the health professions by introducing them to the philosophy and practices of integrative medicine and illustrating how these practices can be related to their careers. This learning module will reach approximately 1,000 students per year in University of Arizona's Introductory Biology course, and will be disseminated to peer institutions nationwide.

CLINICAL PRACTICE OF INTEGRATIVE MEDICINE

The Clinical Practice of Integrative Medicine was designed to meet the challenge of shifting the orientation from one of disease to one of healing. The goal of this approach is to teach the art of integration, not simply the strengths and weaknesses of alternative practices or new protocols. The Integrative Medicine Clinic is a place to begin this discourse.

The clinical practice component, like the research component, is directly linked to the core curriculum. Emphasis is on establishing rapport with patients; obtaining patient histories that include the emotional, psychological, and spiritual aspects of patients' lives; listening carefully; assessing patients' belief systems; and presenting treatments in ways that increase the likelihood of successful outcomes.

During the initial one-hour visit, the Fellows interview and examine their patients and address any problems that require immediate intervention. They then present each patient in an interdisciplinary patient conference. At this conference, I am joined by clinicians representing various systems of medicine including Oriental medicine, homeopathy, mind-body medicine, osteopathy, pharmacy, nursing, nutrition, naturopathy, and spirituality. In this forum, Fellows develop an understanding of the different systems of medicine and recognize the appropriate applications for these systems to create an optimal integrative treatment plan. These plans are individualized and often include a combination of alternative and conventional treatments.

Interestingly, it has been the experience of the clinicians and Fellows of the Program in Integrative Medicine that the number of botanicals and supplements patients have self-prescribed prior to their visit to the Clinic are often reduced in the treatment plan established by the Fellow and contributing clinicians.

After the initial visit, the patient then returns to the Integrative Medicine Clinic for a discussion of the treatment options with the Fellow, and may also be scheduled for an evaluation in the clinic by an alternative practitioner together with the Fellow. The Fellow then has the opportunity to observe their patient undergoing evaluation and then treatment through an entirely different system from the one in which they are trained. This results in a much deeper understanding of alternative systems and their application.

RESEARCH IN INTEGRATIVE MEDICINE

Research in Integrative Medicine is designed to enable students and healthcare professionals to master critical thinking about research, including how to assess existing research and evaluate its validity and significance, how to formulate critical research questions, and how to design experiments and methodologies that effectively address these questions.

In addition to didactic coursework defined in the core curriculum, direct research experience is a requirement of the Fellowship Program. The direct research experience is currently focused on physicians in the second year of the Fellowship Program. Fellows may choose either to work on an existing project under the direction of the faculty member, or to work with a faculty member to develop a research project that is consistent with the goals and objectives of the Program's educational, research and clinical components.

There are currently 10 Fellows in the Program in Integrative Medicine, four of whom are in their second year. Of these four, one Fellow has secured funding for an independent research project, two are in the process of applying for funding to conduct independent research and one is participating in active research projects in the Program in Integrative Medicine. Four of the first-year Fellows are developing research projects. Two others are supported by a \$5,000,000 five-year NIH grant to establish and support a Pediatric Center for Complementary and Alternative Medicine (CAM) at the University of Arizona.

FORWARDING THE FIELD OF INTEGRATIVE MEDICINE

One of the Program in Integrative Medicine's highest priorities is to forward this field and facilitate implementation of integrative medicine into educational curricula nationally. The intent is to change premedical and pre-health education, pre-doctoral and postdoctoral medical education and nursing education, and to reach out to other healthcare professions such as pharmacy. The Program has and will continue to take a leadership role in identifying and working with academic institutions interested in integrating the Program's educational and clinical models into their systems.

As you recall, in the fiscal year 2000 Labor, Health and Human Services, and Education Appropriations bill, this subcommittee urged the National Center for Complementary and Alternative Medicine (NCCAM) to give priority consideration toward funding integrative medicine education and training. The language stated:

"The Committee urges NCCAM to give priority to the funding of post-graduate training of physicians in integrative medicine. In particular, the Committee encourages study of strategies for integrating complementary and alternative medicine into the traditional premedical, predoctoral, and postdoctoral medical education curricula. The Committee encourages NCCAM to give consideration to funding programs at academic institutions which offer postgraduate fellowships for physicians in integrative medicine, continuing education in integrative medicine for other health professionals, and distance learning models in complementary and alternative medicine for doctors and other health professionals throughout the country."

As I hope has been made clear, the Program in Integrative Medicine has developed a model standard for integrative medicine education and training. We believe that this model best meets the intent articulated by the subcommittee last year. Yet, approximately six months after we submitted a proposal in this regard, NCCAM has been reluctant to consider it.

Mr. Chairman, we appreciate that the NIH institutes and centers are largely research entities, and we recognize the critical need to fund research into complementary and alternative medicine applications. But if we are not able to provide relevant education and training for our healthcare workforce, the result will be nothing more than giving consumers the authority to practice medicine.

Consumers must rely on their physicians, nurses, pharmacists, and other healthcare professionals to make informed decisions on the course of treatment that is right for them. Considering the widespread interest in this field, the frustrations of physicians who have not been exposed to these modalities and the overwhelming demand of physicians for training in integrative medicine, we have a responsibility to provide more than just research into the efficacy of CAM applications. That is only half of the equation.

Federal funding will enable the Program to refine this comprehensive curricula in integrative medicine for premedical, medical, and postdoctoral medical education. Further, it will provide increased capacity for the Program to train national leaders in the field, physicians and other healthcare professionals, research the effectiveness of new models of medical and clinical education, and facilitate the integration of standardized curricula at other academic institutions.

The University of Arizona Program in Integrative Medicine therefore requests that the fiscal year 2001 appropriation for NCCAM include \$2 million specifically for an Education Program Grant to achieve this clinical education and training objective. Such an appropriation would clearly reaffirm the position taken by this Sub-

committee a year ago, when you asked NCCAM to make clinical education in integrative medicine a priority.

Mr. Chairman, we are disappointed that our proposal to NCCAM has not been considered more formally. Further, we are concerned that NCCAM has refused to respond to Congress' request to prioritize integrative medicine education and training. But we have a responsibility to our nation's physicians and their patients, and are committed to pursuing other avenues for funding which I would be happy to discuss with you and your staff.

Thank you for giving me the opportunity to testify this morning. I would be glad to answer your questions.

STATEMENT OF MARY JO KREITZER, PH.D., DIRECTOR, SPIRITUALITY AND HEALING, KATHERINE J. KENSFORD CENTER FOR NURSING LEADERSHIP

Senator SPECTER. Thank you very much, Dr. Weil.

We will come back for dialogue questions and answers after we hear from Dr. Mary Jo Kreitzer, director of Spirituality and Healing at the University of Minnesota. She received her Ph.D. from Minnesota, master's from the University of Iowa, and bachelor's from Augustana.

Thank you for joining us, Dr. Kreitzer. We look forward to your testimony.

Dr. KREITZER. Thank you, Chairman Specter and members of the subcommittee. I am the director of the Center for Spirituality and Healing at the University of Minnesota where I lead a team of physicians, nurses, chaplains and faculty representing many disciplines, including psychology, music, kinesiology, food science and nutrition and social work.

And our charge at the university is to integrate complementary care, spirituality and culturally based healing practices into the work and life of the university.

Our mission grew out of a planning process that included consumers, third-party payers, State legislators, biomedical and complementary practitioners, as well as representatives of health systems. A copy of our planning document will be appended to my written testimony.

Our mission at the center is three-fold: the generation and dissemination of research, the education of health professionals, and the development and evaluation of care models that offer integrative medicine. In many universities across the country, as Dr. Weil has described, there are attempts being made to develop programs to integrate integrative care. But I have to tell you that teaching is often limited to lectures offered within an optional or shadow curriculum.

At the University of Minnesota, we have brought integrative medicine out of the shadows. Our medical students, for example, get exposed to integrative medicine literally during their first week of medical school. Our goal is that they learn from the very beginning that there are multiple perspectives and world views, and biomedicine represents but one of those perspectives.

The transformation that many of us are talking about in health care today goes well beyond substituting an herb for a prescription or over-the-counter drug. It is clearly a mandate for broader access to an array of healing traditions, care that is attentive to the whole person, the body, mind and spirit, as well as support for self care, personal responsibility. People want to make choices about their health and healing.

And I think it is very critical that this be understood. Because in the old model of health care, education of physicians was sufficient. It was both necessary and sufficient.

Physicians were the gatekeepers to care, and consumers the passive recipients who did what they were told to do, at least some of the time. We now know from Eisenberg studies and others that more visits are made to complementary and alternative practitioners than to primary care physicians.

My argument today is that education of physicians is still necessary, but it is not sufficient, that the agenda for education needs to address education of both the next generation of health care providers, as well as the hundreds of thousands of practicing health professionals. Thus, it needs to incorporate undergraduate, graduate and post-graduate training.

Dr. Weil has articulated the need for physician education. But I am here to tell you that there is also a compelling need for education of nurses, along with professionals such as pharmacists, dentists and public health practitioners.

Nurses represent the largest group of health professionals in the world and are in direct contact with consumers. Thus, they are in a very key position to both educate consumers, as well as to coordinate and integrate care.

Much of what is often called integrative medicine has been within the domain of nursing for centuries. And this is a time when nursing is reclaiming, reaffirming and expanding its focus on complementary therapies to better serve the public.

Education of health professionals can also no longer occur in isolation from one another. The reality is that if we expect people to function as a team, we need to do a better job of educating them as a team, interdisciplinary education.

We have initiated at the University of Minnesota a graduate minor in complementary therapies and healing practices that grew out of a significant demand from students currently enrolled in graduate programs, as well as professionals throughout the State.

This spring, we will be requesting from the National Institutes of Health funding to expand this program to include certificate programs, as well as distance learning options.

The transformation of health care being called for today clearly requires funding for both education, as well as research. The need for research is very clear, and I think it is well understood.

PREPARED STATEMENT

But if we want to see the findings from research integrated into practice and changes made in how care is delivered, then we also need to invest, and invest significantly, in education of health professionals.

Thank you very much.
[The statement follows:]

PREPARED STATEMENT OF MARY JO KREITZER

Mr. Chairman, and Members of the Subcommittee: I am the director of the Center for Spirituality and Healing at the University of Minnesota where I lead an interdisciplinary team that includes physicians, nurses, chaplains and faculty from many disciplines, including pharmacy, psychology, music, kinesiology, food science and nutrition, and social work. Our charge is to integrate complementary care, spirituality

and culturally based healing practices into the work and life of the University. Our mission grew out of a University-community planning process that included consumers, third-party payers, State legislators, biomedical and complementary practitioners, and representatives of health systems. After a comprehensive review of trends and issues, a clear mandate emerged—that the University should become a national leader and model in integrative medicine. The University-appointed task force produced a report entitled “Transforming Health Care: Integrating Complementary, Cross-Cultural and Spiritual Care” that has been distributed across the country. It is appended to my written testimony.

Our mission as a Center is threefold: the generation and dissemination of research, the education of healthcare professionals, and the development and evaluation of care models that truly integrate complementary, biomedical and culturally based approaches to healing.

In many universities across the country, where attempts are being made to develop programs in integrative care, teaching is limited to elective courses or to lectures offered within an optional shadow curriculum. It is our belief at the University of Minnesota that for integrative medicine to be legitimized, it needs to come out of the shadows. It needs to be integrated into education, research, and patient care. For example, our medical school students are exposed to integrative medicine during their very first week of medical school. The goal is to ensure that, from the very start of their training, they learn that there are multiple perspectives and worldviews of healing, and that biomedicine represents but one. Before they begin medical school, they are required to read Anne Fadiman’s *When the Spirit Catches You, You Fall Down* a highly regarded work that describes the experiences of a Hmong child with epilepsy caught in a medical system that does not understand her culture and that disregards culturally based values. Competencies in integrative medicine are also being woven into the 4-year, undergraduate primary-care curriculum within the medical school.

I come to Washington today with the full support of the University president, senior vice president for the Academic Health Center and the deans of medicine, nursing and pharmacy to seek support for increased funding of education as well as research in integrative medicine.

The transformation of healthcare called for today goes well beyond substituting an herb for a prescription or over-the-counter drug. It is a mandate

- for increased access to a broader array of healing traditions.
- for care that is attentive to the whole personbody, mind, and spirit.
- for support for self-care, in other words, consumers assuming increased personal responsibility for their health and wellness.

It is critical that this be understood. In the old model of healthcare, educating physicians was both necessary and sufficient. Physicians were the gatekeepers to care and consumers the passive recipients. We now know from the Eisenberg studies and others, that more visits are made to complementary and alternative practitioners than to primary care physicians. The education of physicians is still necessary—but it is not sufficient.

The agenda for education in integrative medicine needs to address the education of both the next generation of healthcare providers as well as the hundreds of thousands of presently practicing healthcare providers.

Looking first at the next generation of health care providers: The need for physician education has been well articulated. I am here to tell you that there is also a compelling need for funding the education of nurses, as well as other health professionals, such as pharmacists, dentists, nutritionists and public health practitioners. Nurses represent the largest group of healthcare professionals in the country—indeed the world. Survey after survey documents that nurses are among the most trusted of healthcare professionals, are in direct contact with consumers of healthcare, and are in a key position to both educate consumers and to facilitate and coordinate care that integrates biomedical and complementary approaches to healing. While much of what is now being called integrative medicine includes approaches to care and healing that have been within the domain of nursing for centuries, there is a need for nursing curriculum to reclaim and to reaffirm this heritage and to assure that nurses are well prepared to serve the public.

Similarly, there is a significant need to integrate complementary and alternative medicine (CAM) content into pharmacy education. In many drug stores and supermarkets across the country, herbs and nutritional supplements are being sold in the absence of pharmaceutical care practitioners who are prepared to inquire about herbal use and to engage patients in frank, empathetic, and knowledgeable discussions about their use of all medications and supplements. Ignoring herbal products does not discourage their use; it simply means that consumers will self-medicate

without seeing these products as part of an overall medication regime. This makes medication management extremely difficult.

The education of health professionals can no longer occur in isolation from one another. The reality is that if we expect people to function as a team, a community of healers, we need to do a better job of interdisciplinary education at undergraduate, graduate and post-graduate levels. At the University of Minnesota, we have initiated an interdisciplinary graduate minor in complementary therapies and healing practices. This program grew out of a significant demand for education from both students enrolled in University graduate programs and practicing health professionals. This Spring, we will be requesting funding from the National Institutes of Health to expand this program to include certificate programs and distance learning options. NIH funding has also been requested for a clinical research fellowship program to train CAM researchers. The program is being developed by Richard Grimm, MD, Director of the Berman Center for Clinical Outcomes, in collaboration with the University of Minnesota and Northwestern Health Sciences University.

Second, while training the next generation of healthcare providers is essential, I cannot emphasize enough the importance of also educating presently practicing healthcare professionals. Post-graduate continuing education courses offer an opportunity to teach highly relevant, specialty-based content to large groups of practicing healthcare professionals. Over the next two months at the University of Minnesota, our faculty will be teaching at an annual family practice review, a cardiac arrhythmia conference, a diabetes conference, an annual primary care conference, and a continuing education program on liver and pancreatic disease. We face a tidal wave of demand and can accommodate but a fraction of the requests we receive for education.

The transformation of healthcare called for today requires funding for both education and research. The need for research is well understood. However, to move beyond the generation of research to the dissemination of research and to changes in practice will require investment in education. We need funding to develop undergraduate, graduate, and post-graduate educational programs, as well as funding to train faculty who teach in academic training programs across the country.

Senator SPECTER. Thank you very much, Dr. Kreitzer.

Senator HARKIN.

Senator HARKIN. Thank you very much. I just want to pick up one thing Dr. Kreitzer just said. I am informed that there is a national drugstore chain—I might as well say it, CVS—that has now put out a document that publishes drug interactions with nutraceuticals like St. John's Wort now so that people can look that up now.

So they have now started including other things other than just prescription drugs. So I think that is a step. You mentioned about educating pharmacists. I was reading your statement here. So as I understand it, that is one drug chain that has taken the lead.

Dr. Weil, I want to thank you personally. I have read a number of your books, obviously. But you published a CD sometime ago on healing. And to anyone who has not heard it, I am not shilling for Dr. Weil or anything like that, I want you to know, but I have listened to it. And I must tell you, it is just an amazing thing how it can put you in the deepest kind of relaxation mode, especially after a stressful day or a stressful week.

My wife also has a fairly stressful job. She is in the private sector. She was watching me put my headphones on and listen to this one time and got curious about it. And so she was kind of questioning it. So I had her try it. It was just amazing, absolutely amazing. If you have a stressful week and you want to get the weekend off right, that is what I do.

So I want to thank you for it, because it has just done a lot for me personally.

I also want to say one other thing, Dr. Kreitzer. The University of Iowa Medical School has opened a clinic. I do not know if you

are familiar with it. But when a patient comes in, that patient is thoroughly looked at and given options as to just what type of procedure and process the patient wants to go to.

And instead of gearing that patient first to the traditional prescription drug, invasive type of medicine, they are asked if they would like to try and go through complementary and alternative-type practices first. It is an interesting approach. And this is at the University of Iowa Medical School.

So these things I see happening around the country. And I think a lot of it has happened since the Office of Alternative Medicine started in 1991. More and more medical schools are moving in that direction. So I am very intrigued by what you are doing north of us in Minnesota.

I just would ask both of you, and I want to ask Dr. Ornish the same question, what direction do we go in now? We are going to be—I think we are going to get more money for the center. You have heard me talk about the different things that are happening at NIH. What is the next step? What should we be thinking about here?

Dr. WEIL. Senator, again, I cannot say too strongly that I would like you to be thinking about how we can change medical education. I see this as fundamental to everything.

For example, there is tremendous economic incentive at the moment for clinics facing bankruptcy or HMOs in very competitive markets to offer complementary holistic services in response to this consumer demand. But where are the practitioners going to come from to direct these programs, if our medical schools are not training people in this way?

If we want to see more and better research in mind/body medicine or in botanical medicine, it is not going to happen until we graduate people from an educational system that makes them see the importance of mind/body interactions or the importance of botanicals and differences from isolated chemicals.

So I see that as really the root problem. That is the fundamental thing that has to change.

Senator HARKIN. Dr. Kreitzer.

Dr. KREITZER. Senator Harkin, there are two areas that I think funding is critical. One is to fund some programs, educational programs, that can become national models, that can be demonstration projects that can be replicated in other institutions. As Dr. Weil mentioned, there are many places around the country that are trying to do this, but attempts are fledgling, the very early stages.

The other area where I think we need funding is to really evaluate what is going to work in terms of integrative care, models of care delivery. I am familiar with the University of Iowa, having graduated there with my master's degree in nursing.

And I have kept in contact with my colleagues there. We are establishing a similar clinic at the University of Minnesota. But I think we do not know yet what are going to be the most successful factors in those clinics to target success.

Senator HARKIN. The one thing we want to hear from you—I am going to obviously ask Dean Ornish this, also—and that is, what do we do in terms of nutrition? It seems to me that starting with kids in high school, grade school, with the school lunch program,

school breakfast program, I do not know that we have really done enough in this country to integrate nutrition with medicine and to start early on to get kids to understand what health care is about in terms of what they eat.

If you have a thought—

Dr. WEIL. Senator, I think that is an understatement. The total instruction that I got in nutrition in 4 years at Harvard Medical School and a year of internship was 20 minutes, which were grudgingly allowed to a dietician in one hospital I worked at in Boston to tell us about special diets we could order for patients. That has not changed significantly since I have been out of medical school.

There are now 20 percent of schools that say they teach nutrition. But when I look at what they teach, it is mostly biochemistry. It is not the kind of information that enables doctors to answer questions like, "Should I eat butter or should I eat margarine," or "Is olive oil safe or is it not," or "Is it okay to take Beta-Carotene in isolated form?" Doctors do not know the answers to those questions unless they make an effort to go out and learn them.

And by the way, one of the immediately obvious consequences of the lack of sophistication about the medical profession in this area is the utterly abysmal food that is served in hospitals in this country, which should be a national disgrace. And that includes the cafeterias in leading academic medical centers, where doctors, nurses, medical students and house officers eat. I think we have a long way to go here.

And we do not need more research. This is not an area in which we need to train researchers. We need to change the medical curriculum. We need to develop a practical, workable curriculum in nutritional medicine that can be made foundational. To regard this as alternative or complementary would be foolish.

Dr. KREITZER. Senator Harkin, we are beginning to offer courses like Andrew Weil has described at the University of Minnesota. Being a land grant institution, we also have the advantage of having a college of agriculture on our campus, as well as an academic health center.

And we are working very hard to establish close bridges to connect the whole issue of landscape sustainability with human health sustainability, another important area for investigation.

Senator SPECTER. Thank you, Senator Harkin.

Before turning to Senator Murray, let me recognize Mr. Leo Verneti, vice president of the Inner Harmony Wellness Center, Clock Summit, PA, who is here traveling with Dr. Weil.

Now, Senator Murray.

Senator MURRAY. Well, thank you very much, Mr. Chairman. Thank you for having this hearing. I think that this is an issue that we really do need to focus on.

And certainly consumers are looking more and more at alternative care, because they want to take control of their own lives and make choices for themselves that work well for them. And they are looking to a medical profession that, as you have correctly stated, has not been trained to give them the information they need.

As a result, they look for information in wrong places. So I think it does behoove us to do the right thing, to provide people with good information.

Dr. Weil, you were talking about medical education and what doctors receive. It seems to me that the mentality has been in our medical schools to treat diseases rather than preventive medicine. And alternative medicine often focuses on prevention. Is that whole philosophical issue what we really need to address?

Dr. WEIL. Sure. I think that—this is, I think, why it is a bit wrong to emphasize complementary and alternative medicine, because those terms suggest a focus on modalities. It is giving doctors other tools to put in their black bags. That is not what we should be focusing on.

What we need is a shift in perspective in the way that doctors are trained toward an emphasis on healing and on prevention, toward looking at new scientific models in which some of these unexplainable therapies might be explainable, towards a re-emphasis of the doctor-patient relationship, toward a new way of interpreting placebo responses, that rather than seeing these as nuisances, they are really central to the practice of the medicine.

They are healing responses. And if you can get the maximal placebo response with a minimal intervention, that is the best kind of medicine that you can do.

So I think we have a chance now, because of economic factors, to really make a shift in perspective, which would be enormously beneficial to the enterprise of medicine and certainly to the public. And it would be a shame if we just get focused narrowly on studying particular modalities out there.

Senator MURRAY. And it also goes directly to health care insurance and how medical needs are funded. If you have a disease, you are taken care of. If you go in and try to find out what to do because your mother had rheumatoid arthritis, what can I do now to make sure that I do not suffer those kinds of things.

Dr. WEIL. Exactly.

Senator MURRAY. It is not covered.

Dr. WEIL. Exactly. I also think it would be a tragedy if integrative medicine becomes medicine of the affluent because insurers do not reimburse for it. So I think there is an urgent need to look at that. This should be medicine that is available to everybody.

Senator MURRAY. All right. I had one other question, and it is a concern I have in general medicine that women are often excluded from trials. And certain conditions and diseases that affect women in particular are left out. How do we make sure that as we go down this road, women's conditions and diseases are not excluded?

Dr. WEIL. I could not agree with you more. One interesting historical observation: In 1810 Samuel Hahnemann, the inventor of homeopathy wrote a textbook of medical principles of how to study drugs. One of his principles was that drugs should be tested equally on men and women in case there are differences in gender.

I mean, that is a basic common sense principle that we have ignored.

Senator MURRAY. Right. Dr. Kreitzer, do you have any additional comments?

Dr. KREITZER. Senator Murray, I only had one additional comment, and that is that there is the opportunity in teaching prevent-

ative medicine to also begin teaching health professional students and medical students about self-care practices.

And that, too, has been a long neglected area in the education of health professionals. And I think until we begin teaching people how to integrate this into their own life, it will be hard for that to be translated to care of patients and families.

Dr. WEIL. May I? I think that is an excellent point. I feel that doctors and other health professionals should be role models. They should be models of health, because the best way to teach is by example.

I think one of the black marks against the way that we train health professionals currently is that it almost guarantees that people will come out of that system with unhealthy lifestyles.

Senator MURRAY. And Senator Harkin, I would agree with you that we need to do a better job of teaching our kids about nutrition. But we have to teach their parents, too, which many parents are severely lacking in any kind of knowledge on that.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Murray.

Dr. Weil, your work has certainly popularized integrative medicine, which I know is the term you prefer. We would be interested to hear from you your own personal experience as to how the response has grown. As I commented earlier, you were in Philadelphia a couple of weeks ago, and you drew a crowd of some 1,200 people to hear you speak with a substantial admission price. And you have been at this for some time. Could you tell us what the crowds were like when you started, what they were like when you finished your second book and your fifth book and your eighth book?

Dr. WEIL. Well, they were not very big back in the 1970s, when I started writing about this. And I think in the eighties what I saw was that there was a growing response from consumers, but essentially no response from academic medicine. And what I have seen, especially in the past 2 years, and I think especially in the past year, is increasing numbers of people in academic medicine who come and are interested, and I am invited to talk in venues about changes in medical education.

Dr. Kreitzer and I are involved in an initiative that I think is most interesting, a consortium of deans of medical schools, who have indicated interest in this direction, to at least open the dialogue about how we could begin to bring this into medical curricula.

Senator SPECTER. When you talk about consumers, let me interject this additional question. As I said at the outset, I was really surprised to find that 42 percent of Americans who get health care are looking to integrated alternative and complementary medicine at \$27 billion a year.

Now, when the consumers start to pay attention, then the Congress pays even more attention, because consumers vote. And there is a certain lag between what the consumers are doing, what the Congress recognizes, and even a greater lag, perhaps, as to what the established medical profession is willing to undertake.

I am impressed with what you have to say about the need for more education in the field. What concretely would you like to see done to stimulate medical education in integrative medicine?

Dr. WEIL. I would like to see funding made available to programs like we have at our two universities, which are beginning the process of developing curriculum and developing new models for training for physicians.

Senator SPECTER. Well, you already have the programs. How about funding for schools that do not have the programs?

Dr. WEIL. I am all for that. And what we would like to do is develop models that can be replicated around the country.

Senator SPECTER. Dr. Kreitzer, you comment that you have had this educational approach for some time. Have you had it long enough for your doctors to have graduated, who have a feel for complementary alternative integrative medicine to see if they have taken the gospel from the classroom to the practitioner's office?

Dr. KREITZER. No, Senator Specter. We are quite early in our process. Our medical students this fall will be the first medical students for whom we have developed a 4-year curriculum to integrate integrative medicine into medical school.

And I think while both Dr. Weil's program and my program are established programs, the funding needs are very, very critical. I think both programs receive very minimal support from our respective institutions internally. And so we really rely very much on grants, philanthropy, other sources of support.

Senator SPECTER. Dr. Weil, I am not sure that it is your most profound statement today among many, but your comment about hospital food is certainly 100 percent consensus getter. And your comment about food in the cafeterias at places where the operators ought to know better. Now the big question for you is: What is the cafeteria like at your place?

Dr. WEIL. We have—of all the radical things that we have been able to accomplish out there, bringing energy healers in to work with our physicians, beginning to teach elements of quantum and chaos theory to physicians, we have not made an inch of progress in getting the food improved in the university cafeteria. And—

Senator SPECTER. How do you expect to change America, if you cannot change your own cafeteria?

Dr. WEIL. I think that comes from my other area of work, that is, raising the awareness of consumers to the point that they get angry enough to bring pressure on institutions and the big food service companies to make some changes here.

Senator SPECTER. Give TV a sound bite, Dr. Weil, 17 seconds or less. What is your prescription for Americans on diet?

Dr. WEIL. To eat less refined and processed food of all kinds, more whole and natural foods. I think that is the best thing that we could do. The growth of fast food in this country and throughout the world is a disaster for our health.

Senator SPECTER. Is it practical to eat five fruits every day?

Dr. WEIL. It is absolutely practical to eat five fruits every day.

Senator SPECTER. How many do you eat? Let us get personal.

Dr. WEIL. Well, it varies. When I am on a book tour, that is not fair.

But I had a big plate of melon this morning.

Senator SPECTER. My red light is on.
Senator Harkin.

Senator HARKIN. I do not have any follow-ups. I appreciate all that you are doing out there. And I think we are making some great progress.

American people—you see, I think people by and large, if they just sort of listen to their own bodies and think about what is happening to them, and if they have information, can make pretty darn good judgments about what is best for themselves. They just need the information. They need the support to enable them to make those kinds of decisions.

Right now they are geared to only one decision-making route. And one of the purposes, hopefully, of this hearing, what you are doing and what we are trying to do through NCAM, is to again give people that power, the power that people need themselves to decide for themselves what is best.

And while people may make mistakes, doctors make mistakes, too. And I think, I still think—I will just say it one more time for emphasis—if people have the knowledge and they have the education and they have the pathways, if they were given the time to listen to themselves and their own bodies, they will make the best decisions for themselves.

Senator SPECTER. Thank you very much, Senator Harkin.

Thank you, Dr. Weil and Dr. Kreitzer. We know you have other commitments. We really appreciate your being here.

Dr. WEIL. Thank you.

**STATEMENT OF HERBERT BENSON, M.D., PRESIDENT, MIND/BODY
MEDICAL INSTITUTE, ASSOCIATE PROFESSOR OF MEDICINE,
HARVARD MEDICAL SCHOOL**

ACCOMPANIED BY:

JAMES M. CASSIDY

KRISTEN MAGNACCA

Senator SPECTER. We would like to turn now to panel three, Dr. Herbert Benson and Mr. James Cassidy and Ms. Kristen Magnacca.

Dr. Benson is a founding president of the Mind/Body Medical Institute at Harvard Medical School, where he is associate professor of medicine, also chief of the Division of Behavioral Medicine at the Beth Israel Deaconess Medical Center, a graduate of Wesleyan University at Harvard Medical School, author or co-author of 150 scientific publications and 5 books. And as I said earlier, someone whose writings I had read and had consulted sometime ago.

Dr. Benson, you have two of your patients with you. And you have a demonstration of the protocol and procedures of yours.

Dr. BENSON. Thank you, Senator Specter, Senator Harkin, members of the committee. It is a delight to be here testifying before the committee. And I am wondering, because of the time, whether I might change the order a bit and start off with our two patients and then go on to an explanation of what was occurring.

Senator SPECTER. Dr. Benson, your option.

Dr. BENSON. Thank you.

Mr. Cassidy.

SUMMARY STATEMENT OF JAMES M. CASSIDY

Mr. CASSIDY. Thank you, Dr. Benson.

Thank you, Senator Specter and Senator Harkin. It is a pleasure to be down here from Boston, MA, this morning, where it is raining cats and dogs.

I wanted to tell you that I am a patient of the Cardiac Wellness Program at the Beth Israel Deaconess Hospital. And what you are looking at is one of the success stories, I hope. So what you see is what you get. And I am going to give you a brief statement of my time of 1 year with the Cardiac Wellness Program, which started just a year ago.

In May of 1990 at the age of 64, I had major open heart surgery, a four-way artery bypass at the Deaconess Hospital, Boston, MA, covered by medical insurance at a cost of approximately \$100,000, and that was back in the year 1990. After successful surgery and recuperation, I wandered through the next 8 years without any particular motivation to stay well.

Despite my cardiologist's warnings to keep my weight down, a sensible diet plan and exercise, I continued to put on weight and to generally get out of condition. For example, difficulty in breathing, some angina pain, susceptible to colds and other illnesses, and of course asking for major trouble.

My salvation came in the mail on January 1999 when my medical insurance company—that is GIC. That is the Group Insurance Commission in Boston—offered to cover my entire cost in the Cardiac Rehabilitation Program offered by the Beth Israel Deaconess Medical Center in Boston, MA.

Since I had retired from full-time employment, I decided to make a New Year's resolution and to devote the year 1999 to the program and to see what would happen.

Senator SPECTER. The child is—you can stay.

Ms. MAGNACCA. I am sorry.

Senator SPECTER. Come on back. You are fine.

Go ahead, Mr. Cassidy. You can handle it.

Dr. BENSON. The witness is an ex-radio announcer. So I think he could handle this.

Mr. CASSIDY. I know the hearing is glad to see a baby in here.

Senator SPECTER. When I was sworn in as an assistant district attorney, my 20-month-old son rushed to the front of the courtroom. So I am very sympathetic here.

Mr. CASSIDY. Thank you, Senator.

I had previously entered several short-time programs, but did not stay committed. I was very motivated to succeed in this wellness program, as the long-term goals of the program kept me focused on practical goals as I followed every directive throughout the entire year.

The expert staff were instrumental in guiding and motivating each class through weekly sessions of moderate exercise, relaxation response sessions, proper nutrition that you could live with, and interrelationship dialogue, all designed to motivate similar cardiac patients in group therapy. I think this group dialogue we had was most important to keep us motivated.

As I saw and felt improvements in my own health, appearance and general activity on life, I slowly changed my whole attitude, became less stressful, less negative, ate sensibly and lost weight as I entered into a new lifestyle.

The program is designed for slackers and procrastinators, such as myself. I actually looked forward to each weekly session with the staff and the patients, who had now become my friends as we discussed mutual concerns. Do not forget, we are all involved in cardiac programs, so we had something in common.

The motivation continued at home during the week with daily recitations of the relaxation response. We had tapes of beautiful, soothing surf, music, wonderful music. This is relaxing and really helps you. And breathing, important to breathe. So we had daily exercise and nutritional and sensible meals.

There is a lot of interesting and delicious low calorie and no fat food out there. And this is what I am still on. But yet, I am not suffering from it at all. It is wonderful.

My medical record speaks for itself as to my health improvements. I have lost 50 pounds, my cholesterol is down 40 points into a very safe level, normal blood pressure, waist is minus 7 inches and still counting. I am feeling healthier, more alive and ready to take on new challenges, as I am now really enjoying my golden years with a good quality of—

Senator SPECTER. Dr. Benson, you are up to 5 minutes of your allotted 10. Now you are the master of ceremonies here, but I wanted to give you—

Mr. CASSIDY. I will go very quickly. I will just wind up here.

I do a lot of work in this mind/body thing by local caring groups in the church, senior citizen and so forth. Today at 74 years I continue my new healthier lifestyle. I want to say to you all that it is not all severe penance, sack cloth and ashes. We are allowed to celebrate special events, but moderation is the watch word.

PREPARED STATEMENT

For instance, a week ago, Friday, March 17, I went out with my wife and enjoyed my traditional corn beef and cabbage dinner and a lot of Irish music. But I did not end up with a gallon of Irish green beer, but rather black coffee and a clear head.

Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF JAMES CASSIDY

In May of 1990, at the age of 64, I had major open-heart surgery, a four-way artery bypass at the Deaconess Hospital, Boston, MA. covered by medical insurance company at a cost of approximately \$100,000.

After successful surgery and recuperation, I wandered through the next eight years without any particular motivation to stay well. Despite my cardiologist's warnings to keep my weight down, a sensible diet plan and exercise, I continued to put on weight and to generally get out of condition—difficulty in breathing, some angina pain, susceptible to colds and other illnesses and of course asking for trouble.

My salvation came in the mail on January, 1999 when my medical insurance company (GIC) Group Insurance Commission offered to cover my costs in the Cardiac Rehabilitation Program offered by the Beth Israel Deaconess Medical Center, Boston, MA.

Since I had retired from full time employment, I decided to make a New Year's resolution and to devote the year 1999 to the program and to see what would happen.

I had previously entered several short-term programs but did not stay committed. I was very motivated to succeed in this wellness program as the long-term goals of the program itself kept me focused on practical goals as I followed every directive throughout the year. The expert staff were instrumental in guiding and motivating each class through weekly sessions of moderate exercise, relaxation-response sessions, proper nutrition that you could live with and interrelationship dialogue all designed to motivate similar cardiac patients in group therapy.

As I saw and felt improvements in my own health, appearance and general attitude on life, I slowly changed my whole attitude, became less stressful, less negative, ate sensibly and lost weight as I entered into a new life style.

The program is designed for slackers and procrastinators such as myself. I actually looked forward to each weekly session with the staff and the patients who had now become my friends as we discussed mutual concerns.

The motivation continued at home during the week with daily elicitation of the relaxation response (tapes of soothing surf, etc.), daily exercise and nutritional and sensible meals (there's a lot of interesting and delicious low calorie, no fat food out there).

My medical record speaks for itself as to my health improvement: weight—lost 50 lbs., cholesterol—down 40 points into a very safe level, normal blood pressure, waist—minus 7 inches and counting.

I'm feeling healthier, more alive and ready to take on new challenges as I am now really enjoying my golden years with a good quality of life, ready to turn over the vegetable garden and enjoy the ever increasing grandchildren, birthday parties, and computers, too.

Mind, body, spirit—the stress reduction and spirituality aspect was important to improved health and manifested in my increased volunteering for many local caring activities in my church, Senior Citizen Center (Medical Transportation, Friendly visitors, Senior Sports), local American Legion Post and as an artist in local Artists' Associations.

Today at 74 years I continue my new healthier lifestyle. I want to say to you all that it's not all severe penance, sackcloth and ashes—we are allowed to celebrate special events—but moderation is the watchword. For instance, a week ago Friday, March 17th, I went out with my wife and enjoyed my traditional corned beef & cabbage dinner and Irish music—but I didn't end up with a gallon of Irish green beer, but rather black coffee and a clear head. And as usual, the next day I went to my YMCA working off those few extra calories and feeling great.

Senator SPECTER. I thank you, Mr. Cassidy.
Do you want to turn now to Ms. Magnacca?
Dr. BENSON. Please.

SUMMARY STATEMENT OF KRISTEN MAGNACCA

Senator SPECTER. Ms. Magnacca is from Upton, MA, author of *Girlfriend to Girlfriend*, a fertility companion. She is here today to discuss her treatment experience at Harvard University's Mind/Body Clinic. And we thank the child on her lap, who ought to be a party to this. So welcome to both of you and your husband, who appears to be your husband.

Ms. MAGNACCA. Yes.

Senator SPECTER. He nods, but I do not want be too presumptive. And we will turn the time clock on again. Thank you.

Ms. MAGNACCA. Thank you. Good morning. In 1997 I arrived at the Mind/Body Clinic for Women's Health a shattered woman. For 3 years my husband Mark and I had been trying to have a baby. We began the journey through infertility, and our lives revolved around our childlessness. While praying to God for a baby and strength, we began high-tech fertility treatments. A year later, we thought our prayers had been answered when I became pregnant.

As I wondered if our baby would have his father's soulful eyes or possibly my strawberry blond hair, our lives were crushed. I was faced with an atopic pregnancy, a life-threatening medical emergency, and lost the baby. Due to surgical complications, I was left

incontinent. I experienced a physical, emotional and spiritual crisis and fell into a depression.

For months my husband watched as my anger at my body, my anger at myself, my anger at him and my intense anger at God for taking our child was slowly killing me. With our marriage deteriorating, my husband began calling the Mind/Body Infertility Clinic daily in hopes of getting into the program. We both needed help.

I arrived at the first orientation class dragging my anger and pain with me. I was not convinced I wanted to be there. But as I listened to what the program offered, my anger began to melt, and I felt relief. I had found a group of compassionate experts, who knew what we were going through and could provide guidance. Mark and I dove into the program. With each class, I began to heal.

As my spirit and old self reappeared, everything improved.

My husband turned to me one day and said, "Kristen, I have so missed the sound of your laughter. It is so wonderful to hear it again." I had not realized how long it had been since I felt joy.

The tools I learned from the mind/body program, including how to elicit the relaxation response, allowed me to reconnect with my spirit and God. I felt as though my mind, body and soul were through the crisis period, and I found myself once again.

It would be impossible for me to describe in words how I felt when I discovered I was pregnant during the course, especially when we had been told that I would never be able to have a baby naturally. For 9 months, my husband Mark and I joyfully awaited the birth of our child.

On September 21, 1998, at 7:46 a.m., the miracle happened. I gave birth to a healthy baby boy, our son, Nicholas Armand Magnacca. He arrived with his father's soulful brown eyes and my strawberry blond hair, a 7 pounds, 7 ounce bundle of true miracle.

PREPARED STATEMENT

I believe with all my heart that without the intervention and life skills that we learned through the Mind/Body Clinic, our son would not be with us today. I urge you to give your full support to this endeavor so that other women may have access to this incredible care and experience that I received from the Mind/Body Institution.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF KRISTEN MAGNACCA

Good morning, my name is Kristen Magnacca. In 1997 I arrived at the Beth Israel Deaconess Medical Center's Mind/Body Center for Women's Health a shattered woman.

For three years my husband Mark and I had tried unsuccessfully to conceive a child. We were unexpectedly thrust into the world of infertility treatment; our life revolved around our childlessness.

We obtained the best medical intervention and progressed along the road of assisted reproductive technologies, namely IUI's, or Intrauterine Insemination. Being raised in a devout Catholic family, I prayed to God, asking him to send me a baby and provide me with strength.

It was determined that both my husband and I needed to have surgery to help correct our conditions. Following our surgeries, I completed three cycles of daily blood monitoring and ultrasounds culminating with medical instruction regarding nightly hormone injections.

Our third cycle resulted in a low positive pregnancy test. We watched while holding our breath that the hormone level would rise, and it did. I will forever remember the words that came from my doctor: "Kristen, for the very first time in your life you may consider yourself pregnant!"

As I wondered if our baby would have his father's soulful eyes or possibly his great grandfather's strawberry blond hair, I began to bleed. It was determined that this was an ectopic pregnancy, a life-threatening situation. The embryo had implanted itself outside of my uterus and as a result of this my body began trying to expel the pregnancy. I was rushed by ambulance to the hospital in serious condition with extensive internal bleeding. My pregnancy could not continue.

Due to surgical complications, I was left incontinent. We were also informed that due to problems from the ectopic pregnancy, the likelihood of a conceiving normally was non-existent. We would have to progress to in vitro fertilization, bypassing my tubes all together. I felt as though my body had failed me, I had no emotional strength left and that God had abandoned me. I rapidly fell into a depression and lost my will to go on. All at once I was experiencing a spiritual, physical and emotional crisis.

For months, my husband watched as my anger at my body, my anger at him and my intense anger at God for taking our child was slowly killing me.

With our marriage deteriorating, my husband began calling the Mind/Body Infertility Clinic daily in hopes of becoming participants. A close friend of ours had attended the clinic and thought that it would be beneficial given our circumstances. The class that was beginning in a few weeks' time was full. But through my husband's persistence and the clinic's compassion, we were allowed to join that group.

We both needed intervention, and agreed to experience this course together in hopes of learning strategies to deal with our situation and life. If a baby would come of this experience, that would be glorious, but that was a secondary goal.

I arrived at the first orientation class dragging my anger and pain with me. Then Dr. Ali Domar spoke. "We are not going to talk about how bad infertility is, we all know that it is, we are going to give you strategies to deal with your situation and life." As I broke down in tears, feeling her unconditional understanding, my anger began to melt.

Mark and I dove into the exercises, listening to the relaxation response tape before going to sleep, checking in with each other and questioning if we had elicited the relaxation response through "mini's."

Waves of stress released themselves from my body, and my focus began to return. Little by little I could see glimpses of my old self reappearing.

The awareness that eliciting the relaxation response brought was life altering. I remember driving my Jeep to a doctor's appointment where we were about to discuss my next set of infertility options. As I looked down at my hands on my steering wheel, I realized that my knuckles were white from my unconscious grip on the wheel.

A few weeks prior I would not even noticed my state, and would not have known to elicit the relaxation response through a "mini." I visualized the warmth of a flowing stream of water entering through my head, washing away my unacknowledged stress. I was able to change my state in an instant by relying on the skills I had developed through the clinic.

With each class I instilled the recommended changes. I began to eat a better diet and take nightly walks with my husband. On one of our walks my husband and I shared a moment of laughter. In the middle of the street he stopped and hugged me, saying, "Kristen, I have missed the sound of your laughter, it's so wonderful to hear that again." I hadn't realized how long it had been since I had felt joy.

Our marriage was on the mend; our communication had greatly improved. But most importantly, I allowed myself to be, in the quietness of my being.

My new awareness didn't end with my physical self. I began to reconnect with my spirit and God through the quietude of the relaxation response. In the quiet I could start to rebuild my relationship with my Creator.

As the weeks passed, I felt as though my mind, body and soul were through the crisis period and I could begin to move back into a more balanced state.

The focus of my life had been our childlessness for what seemed a lifetime. Through the strategy of "mindfulness" I could now focus on being in a restaurant with my husband instead focusing on the couple next to us with their infant. I still longed for our child, but I re-framed my life experience to "mind" how fortunate I was to be out with my husband and to have someone else cook me dinner!

We decided to postpone our first cycle of in vitro fertilization (IVF) and instead focus on our marriage and our new skills.

I began to come to terms with our fertility challenges. I finally accepted the fact that our child would have to be conceived in a room filled with medical experts, not within an intimate moment alone with my husband.

However, despite what the doctors said, we discovered that I was pregnant, the natural way, two months after becoming participants at the Mind/Body Clinic. My mind, body and soul fell into alignment through the specific strategies the clinic taught, allowing for this unbelievable occurrence to take place.

On September 21, 1998 at 7:46 am, what the conventional medical establishment said was impossible, happened. I gave birth to our son, Nicolas Armand Magnacca. He arrived with his father's soulful eyes and my grandfather's strawberry blonde hair; a 7lb, 7oz bundle of true miracle.

Without the intervention and life altering skills that we learned through the mind/body clinic, I believe that our son would not be with us today.

Senator SPECTER. Well, that is very impressive, Ms. Magnacca. Thank you very much.

Dr. Benson, you said you were going to bring two witnesses. It looks like you brought three. So we will have to give you a little extra time.

Dr. BENSON. All right. I will cut down on my testimony.

It is projected that spending on health care is likely to double—

Senator SPECTER. Dr. Benson, we turned the clock back on. So you have the full 5 minutes.

Dr. BENSON. Thank you.

Senator Specter, Senator Harkin, it is projected that spending on health care is likely to double to \$2.1 trillion by the year 2007. That is a trillion dollars more than we are now spending. I propose that mind/body medicine holds great promise for the health care of the Nation and for reducing its cost.

Consider for a moment that I was testifying about a new drug, and the scientific evidence indicated that this new drug could successfully treat a wide variety of prevalent medical conditions, conditions that lead to 60 to 90 percent of visits to health care professionals.

Furthermore, consider that this drug could also prevent these conditions from occurring and recurring and that it was safe and without dangerous side effects. And consider that the new drug was demonstrated to decrease visits to physicians by as much as 50 percent and that this decrease could lead to annual cost savings of more than \$54 billion.

The discovery of such a drug would be front page news and immediately embraced. Scientific evidence now exists that mind/body belief-related, spirituality-related therapies can now produce such clinical and economic benefits.

Health and well-being are best conceptualized by the analogy of a three-legged stool. One leg is pharmaceuticals, a second leg is surgery and procedures, a third leg is self-care. Health and well-being are balanced and optimal when all three legs of the stool are in place.

Self-care consists of health behaviors for which the patients themselves are responsible and includes mind/body approaches—that is, the relaxation response—the belief, the spirituality of the patient, and stress management, as well as including a profound influence on both nutrition and exercise.

A most essential feature of this self-care leg is the relaxation response. Two steps are necessary to elicit it. The first is a repetition.

A repetition can be a word, a sound, a phrase, a prayer, or even repetitive muscular activity. The second is to disregard other thoughts when they come to mind with the return to the repetition.

When a relaxation response is elicited, there are profound physiologic changes, decreased metabolism, decreased heart rate, decreased breathing, decreased muscle blood flow, brain waves slow. And recently published data show that there are distinct brain wave mapping changes, FMRI changes, that occur.

These changes are directly opposite to those of stress. And please remember that stress leads to over 60 percent of visits to health care professionals.

To elicit the relaxation response, a person may choose any repetitive focus. But to combine its healing powers with the profound healing powers of belief and to ensure that the patient will adhere to the practice, the focus should be one in which the patient believes. It may be secular, or it may be religious.

The Mind/Body Medical Institute has created clinical programs that offer a fully balanced three-legged stool and has established 12 affiliates throughout the United States to disseminate them. The programs can effectively treat the disorders that are caused or exacerbated by stress. These include hypertension, cardiac rhythm irregularities, many forms of chronic pain, insomnia, infertility and the symptoms of cancer of the symptoms of AIDS.

These programs can reduce visits to HMOs by up to 50 percent. And as noted above, such decreased visits could lead to cost savings of over \$54 billion per year. The full integration of mind/body belief, spirituality related medicine is completely compatible with existing health care. Mind/body medicine responsibly fulfills the needs of our patients who want therapies, as you were pointing out, Senator Harkin, that enhance traditional medicine and do so in a scientifically established, safe and cost-savings fashion.

PREPARED STATEMENT

In conclusion, I propose that in addition to increased NIH funding for mind/body medicine, that the Health Care Financing Administration establish large demonstration projects to definitely test the clinical efficacy of mind/body belief, spirituality related interventions and to assess their cost savings.

These projects should start with medical conditions that are prevalent and expensive, such as the prevention and treatment of coronary artery disease, the treatment of chronic pain, and the treatment of women's disorders that include infertility.

Thank you for having me.

[The statement follows:]

PREPARED STATEMENT OF HERBERT BENSON

I'm delighted to be called to testify on mind-body medical interactions, their clinical applications and the need for their reimbursement.

Before I start my testimony, let me say a few words about the Mind/Body Medical Institute and the work I have been doing at the Harvard Medical School and its affiliated hospitals for the last thirty years. The Mind/Body Medical Institute is dedicated to performing research and to conducting teaching and training of health care professionals in mind-body and belief-related approaches and transmitting this information to the general public. The Institute is now in its twelfth year of existence. I occupy the Mind/Body Medical Institute Chair at the Harvard Medical School as an associate professor of medicine.

It is projected that spending on healthcare is likely to double to \$2.1 trillion by the year 2007 (Smith, et al., 1998). That's a trillion dollars more than we are spending now. Managed care savings have about run their course. What's driving this surge in costs? It is expensive prescription drugs, enthusiasm for new medical technology and greater freedom to visit medical specialists whenever patients desire to do so. Imaginative and responsible approaches to healthcare are needed. I propose that mind-body medicine, with its self-care and belief-related approaches, holds great promise for the nation's health and cost of healthcare (Friedman, et al., 1995).

Consider for a moment that I were here today discussing a new drug and the scientific evidence indicated that this new drug could successfully treat a very wide variety of prevalent medical conditions—conditions that lead to 60 to 90 percent of visits to physicians. Furthermore, consider that it could also prevent these conditions from occurring and recurring, and was safe, without dangerous side effects. And, consider that the new drug was demonstrated to decrease visits to doctors by as much as 50 percent and that this decrease could lead to annual cost savings of more than \$54 billion (Benson, 1996). The discovery of such a drug would be front-page news and immediately embraced. Such scientifically validated mind-body belief-related therapies have been shown to produce such clinical and economic benefits, but as yet have not been so received.

My testimony will be evidence-based; the data I will present will be scientific findings that have been published in peer-reviewed journals. Some of these data were evaluated and supported at a 1995 NIH Technology Assessment Conference

I will cover the following categories: stress and the fight-or-flight response; the relaxation response; the placebo effect—the importance of belief in healing; the three-legged stool—the importance of balanced self-care; and the need for large demonstration projects to definitively assess the efficacy of mind-body medicine.

STRESS AND THE FIGHT-OR-FLIGHT RESPONSE

Stress contributes to many of the medical conditions confronted by healthcare practitioners. In fact, when the reasons for patients' visits to physicians are examined, between 60 to 90 percent of visits to physicians are related to stress and other psychosocial factors (Cummings, VandenBos, 1981; Kroenke, Mangelsdorff, 1989). Current pharmaceutical and surgical approaches cannot adequately treat stress-related illness. Mind-body approaches including the relaxation response, nutrition and exercise, cognitive restructuring and the beliefs of patients have been demonstrated to successfully treat such disorders. To better understand mind-body treatments it is best to first understand the physiology of the stress and the fight-or-flight response.

Stress is defined as the perception of threat or danger that requires behavioral change. It results in increased metabolism, increased heart rate, increased blood pressure, increased rate of breathing and increased blood flow to the muscles. These internal physiologic changes prepare us to fight or run away and thus the stress reaction has been named the "fight-or-flight" response. The fight-or-flight response was first described by the Harvard physiologist, Dr. Walter B. Cannon (1941) earlier in this century. It is mediated by increased release of catecholamines—epinephrine and norepinephrine (adrenalin and noradrenalin)—into the blood stream. The fight-or-flight response occurs automatically when one experiences stress, without requiring the use of a technique.

THE RELAXATION RESPONSE

Building on the work of Swiss Nobel laureate Dr. Walter R. Hess, my colleagues and I more than 25 years ago described a physiological response that is the opposite of the fight-or-flight response (Benson, 1975). It results in decreased metabolism, decreased heart rate, decreased blood pressure, and decreased rate of breathing, as well as slower brain waves (Wallace, Benson, Wilson, 1971). We labeled this reaction the "relaxation response" (Benson, Beary, Carol, 1974). Most recently, Lazar et al used functional magnetic response imaging to establish that when the relaxation response is elicited there is activation in the brain of areas that control the autonomic nervous system—the areas that control, for example, metabolism, heart and breathing rates and blood pressure (Lazar et al, 2000, in press).

Two steps are necessary to elicit the relaxation response. They are: (1) the repetition of a word, a sound, a prayer, a phrase, or muscular activity (2) the passive disregard of everyday thoughts that come to mind and a return to the repetition.

One can choose any focus, but to enhance the benefits of the relaxation response with the healing effects of belief and to help ensure that a person will adhere to the routine, the focus should be one in which a person believes: if religious, a prayer

could be chosen; if not, a secular focus. Regardless of the techniques or focus that one selects, the relaxation response will be evoked if one uses the two basic steps.

There is no "Benson technique" for eliciting the relaxation response. In fact, my colleagues and I offer people a smorgasbord of techniques and focus words.

The following are focus words, phrases, and prayers that are frequently used:

Secular Focus Words:

"One"

"Ocean"

"Love"

"Peace"

"Calm"

"Relax"

Religious Focus Words or Prayers:

Christian (Protestant and Catholic):

"Our Father who art in heaven,"

"The Lord is my shepherd"

Catholic:

"Hail, Mary, full of grace,"

"Lord Jesus Christ, have mercy on me"

Jewish:

"Sh'ma Yisroel,"

"Shalom,"

"Echod," "The Lord is my shepherd"

Islamic: "Insha'allah"

Hindu: "Om"

Adherence to the two steps evokes the relaxation response. The following is a generic technique:

Step 1. Pick a focus word or short phrase that's firmly rooted in your belief system.

Step 2. Sit quietly in a comfortable position.

Step 3. Close your eyes.

Step 4. Relax your muscles.

Step 5. Breathe slowly and naturally, and as you do, repeat your focus word, phrase, or prayer silently to yourself as you exhale.

Step 6. Assume a passive attitude. Don't worry about how well you're doing. When other thoughts come to mind, simply say to yourself, "Oh, well," and gently return to the repetition.

Step 7. Continue for ten to twenty minutes.

Step 8. Do not stand immediately. Continue sitting quietly for a minute or so, allowing other thoughts to return. Then open your eyes and sit for another minute before rising.

Step 9. Practice this technique once or twice daily.

With this generic technique, you could sit quietly in a comfortable position, close your eyes, and relax your muscles. However, you can also elicit the relaxation response with your eyes open; kneeling; standing and swaying; or adopting the lotus position.

You can also jog and elicit the relaxation response, paying attention to the cadence of your feet on the pavement "left, right, left, right" and when other thoughts come into mind simply say, "Oh, well," and return to "left, right, left, right." Of course you must keep your eyes open!

Our research conducted at the Harvard Medical School as well as that of others has documented that relaxation-response approaches, generally used in combination with nutrition, exercise, and stress management interventions, result in alleviation of stress-related medical disorders. In fact, to the extent that stress causes or exacerbates any condition, mind-body approaches that invariably include the relaxation response have proven to be effective. Because of this scientifically documented efficacy, a physiological basis for many millennia-old mind-body belief-related approaches has been established and a great deal of initial professional skepticism has been overcome.

It is essential to understand that regular elicitation of the relaxation response results in long-term physiologic changes that counteract the harmful effects of stress throughout the day, not only when the relaxation response is being brought forth (Hoffman, et al, 1982). These mind-body approaches have been reported to be effective in the treatment of disorders that include hypertension (Stuart, et al, 1987), cardiac arrhythmias (Benson, Alexander, Feldman, 1975), chronic pain (Caudill, et al., 1991), insomnia (Jacobs, et al, 1993; Jacobs et al, 1996), anxiety and mild and moderate depression (Benson et al., 1978), premenstrual syndrome (Goodale, Domar, Benson, 1990), and infertility (Domar, Seibel, Benson, 1990).

As a result of the evidence-based data, the relaxation response is becoming a part of mainstream medicine. Approximately 60 percent of US medical schools now teach the therapeutic use of relaxation-response techniques (Friedman, Zuttermeister, Benson, 1993). They are recommended therapy in standard medical textbooks and a majority of family practitioners now use them in their practices.

The Mind/Body Medical Institute created mind-body group clinical programs that are built upon such evidence-based medicine. The groups are conducted by multi-disciplinary teams comprised of physicians, psychologists, nurses, nutritionists, exercise physiologists, social workers and/or clergy. The components of the treatment are:

- elicitation of the relaxation response, the physical state of deep rest that changes the physical and emotional responses to stress (e.g., decrease in heart rate, blood pressure, and muscle tension). The relaxation response may be elicited by secular or religious techniques. The patient makes a choice that will adhere to his or her belief system.
- cognitive-behavioral strategies to enhance coping skills
- exercise/activity programs
- nutrition management

Medications are monitored and may be adjusted. This is done in consultation with the patients' physicians.

The program goals are to:

- bring about a reduction in symptoms
- develop an understanding of the disease or symptom process
- regain a sense of control and well-being
- modify factors or situations—such as lifestyle, diet, stress, or physical tension—that contribute to symptoms

The mind-body medical clinic programs available include:

- Medical Symptom Reduction for general stress-related physical symptoms such as headache, GI disorder, palpitations, fatigue
- Infertility
- HIV +/AIDS
- Cancer
- Chronic Pain/Chronic Fatigue Syndrome
- Insomnia
- Chemotherapy and Radiation Therapy (one session)
- Pre-medical, Surgical or Radiological Procedures (one session)
- Cardiac Wellness Programs for patients with hypertension, lipid disorders, diabetes, arrhythmias and/or heart disease
- Perimenopause/Menopause

The mind-body medical clinical program visits include:

- one initial assessment
- nine to thirteen 2 hour weekly visits depending on the program
- one discharge assessment

THE PLACEBO EFFECT AND THE IMPORTANCE OF BELIEF IN HEALING

The importance of mind-body interactions in healing is also profoundly evidenced by the beliefs of the patient. The effects of belief have been called the “placebo effect.” Throughout history, medicine and healing have relied heavily on non-specific factors such as the placebo effect (Benson and Friedman, 1996). In other words, what patients believe, think and feel can have profound effects on the body and physicians and other healers have historically appreciated the effects of both positive and negative emotions.

However, modern medicine has largely disregarded and ridiculed the importance of the placebo effect by using such statements as, “It’s all in your head,” “It’s just the placebo effect,” or “It’s a dummy pill.” These pejorative terms arose gradually over a period of decades as specific remedies for specific illnesses were developed and the reliance on what is now called non-specific healing factors—the placebo effect—diminished. Because the specific therapies were and are, so dramatically effective, they became the sole treatments utilized.

Specific treatments such as insulin, antibiotics and cataract surgery are truly awe-inspiring. The result was that mind-body approaches were largely forgotten and pushed aside as the wondrous modern pharmaceuticals and surgeries and procedures advanced. Rather than using a combination of specific and non-specific, belief-related therapies to promote healing, modern medicine has come to value and to rely exclusively on the specific effects of pharmacological and procedural interventions. It ignores the healing powers of belief.

The pioneering work of Beecher (1955) established that in patients with conditions of pain, cough, drug-induced mood changes, headaches, seasickness, and the common cold, the placebo effect was effective in 35 percent of the cases. Since these early findings, the placebo effect has been documented to be effective in 50 to 90 percent of diseases that include bronchial asthma, duodenal ulcer, angina pectoris, and herpes simplex (Benson and Friedman, 1996; Benson, 1996).

The placebo effect is dependent on three sets of beliefs: (1) the beliefs of the patient; (2) the beliefs of the healthcare provider (the healer); and (3) the beliefs that ensue from the relationship between the healthcare provider and the patient.

A study of Japanese students who were allergic to the wax of a lacquer tree, which produces a rash similar to that of poison ivy, provides one demonstration of the power of the belief of patient (Ikemi and Nakagawa, 1962). The students were first blindfolded and then told that one of their arms would be stroked with lacquer tree leaves, and that their other arm would be stroked with chestnut tree leaves, to which they were not allergic. However, the researchers switched the leaves. The skin that the subjects believed to have been brushed with the lacquer leaves, but that was actually stroked with chestnut tree leaves, developed a rash. The skin that had actual contact with the leaves of the lacquer tree, but that was believed to have been stroked with the chestnut tree leaves, did not react.

A study of treatments for angina pectoris provides an example of how beliefs of the healthcare practitioner can affect disease (Benson and McCallie, 1979). A number of therapies for angina pectoris have been used throughout the decades that are now known to have no therapeutic value. These include vitamin E and bizarre internal mammary artery surgeries. When they were used and believed in by physicians, they had a dramatic effect. They were found to be 70 to 90 percent effective in relieving the pain of angina pectoris. Not only would the pain disappear, but the patients' electrocardiograms and exercise tolerance would improve. However, when these therapies were later invalidated and no longer believed in by physicians, their effectiveness dropped to 30 percent or lower.

The beliefs that ensue from the relationship between physicians and patients are the third component of the placebo effect. A study by researchers at the Massachusetts General Hospital (Egbert, et al., 1964) compared two matched groups of patients who were to undergo similar operations. The doctors responsible for their anesthesia visited both groups of patients, but interacted with them quite differently. They made only cursory remarks to patients in one group, but treated the other group with warm and sympathetic attention, detailing the steps of the operation and describing the pain they would experience. The patients who received the friendlier more supportive visits were discharged from the hospital an average of 2.7 days sooner and asked for half the amount of pain-alleviating medication than patients in the other group.

Some insight into the possible brain mechanisms for the placebo effect is provided in a study conducted by Dr. Steven Kosslyn (Kosslyn, et al., 1993). He and his colleagues examined how the brain processes information, both real and imagined. Subjects were asked to look at a grid with a letter printed on it. As they did so, a PET Scan was used to determine what areas of the brain were active in seeing the grid and the letter. The subjects were then asked to look at the same grid without the letter on it, but asked to visualize the letter in their mind's eye. The PET scan was then repeated. The same area of the brain was stimulated in both situations. In other words, from the brain's perspective the visualization of a scene is similar to actually seeing the scene.

This process helps to explain the placebo effect. All of our thoughts, actions, and memories, represent the activation of specific brain connections. Pain in an arm or leg is represented as activation of specific brain areas. There are memories in our brains of pain. There are also memories of being without pains. There are also brain connections for having a skin rash and of being without a skin rash. Thus, belief in a sugar pill or an inactive therapy can result in activating the brain connections to "remember" what it is to be without the pain or the rash. The pain or rash can be thus alleviated. In other words, thoughts can activate brain connections that can result in physical healing.

The biased words "placebo effect" should be discarded and changed to "remembered wellness." Remembered wellness is what explains this powerful mind-body belief reaction and the words, remembered wellness, have a positive connotation.

Placebos are not the only way to evoke remembered wellness. Consider the most profound belief Americans share. Ninety-five percent of the U.S. population believe in God (Gallup, 1990). Research by different investigators working in different locations throughout the United States have repeatedly demonstrated a connection amongst religious beliefs and greater well-being, better quality of life, and lower rates of depression, anxiety and substance abuse (Koenig, 1998). Religious beliefs

and practices have been associated with decreased mortality and enhanced physical health (Koenig, et al, 1997; 1998). They are also associated with a lower use of expensive health services (Koenig, Larson, 1998). Recently, such research has appeared in respected medical journals and has begun to influence both the education of physicians and the practice of medicine (Marwick, 1995; Levin et al., 1997).

The effects of the relaxation response should not be confused with remembered wellness (the placebo effect). The relaxation response is a specific, proven mind-body intervention. The measurable, predictable, and reproducible changes of the relaxation response will occur when you follow the two specific steps—belief is not essential. It is like penicillin—it will work whether believed in or not.

THE THREE-LEGGED STOOL AND THE IMPORTANCE OF BALANCED SELF-CARE

Health and well being and the incorporation of mind-body therapies in medical care are best conceptualized in terms of an analogy of a three-legged stool (Benson and Friedman, 1996; Benson, 1996). One leg is pharmaceuticals, the second is surgery and procedures, and the third leg is self-care. Self-care consists of health habits and behaviors for which patients themselves can be responsible. Specifically, self-care includes the relaxation response, beliefs, stress management, nutrition and exercise. Health and well-being are balanced and optimal when all three legs of the stool are in place. Of course, attention to nutrition and exercise has been recognized for centuries. In contrast, the scientific documentation of mind-body interactions has only recently been presented.

For more than a hundred years medicine has relied almost exclusively on the first two legs of the stool: pharmaceuticals and surgery. Without the support of the third leg through mind-body and belief-related approaches, the treatment of many medical conditions is unbalanced and inadequate. Patients receive less than optimal clinical care and the care they receive is more costly.

Mind-body medicine is different from what is called alternative and complementary medicine. Mind-body medicine is evidence-based whereas alternative medicine is not. If alternative medicine were evidence-based, it would no longer be alternative. Secondly, alternative medicine is akin to the first two legs of the three-legged stool—there is little difference between an herb and a pharmaceutical or between acupuncture and surgery. They are both given to or conducted on the patient. In contrast, self-care is performed by the patient. Finally, alternative medicine is cost additive whereas self-care saves money.

One example of how mind-body group programs can reduce costs was shown through a study conducted at the Harvard Community Health Plan (Hellman, et al., 1990). Two group mind-body interventions that evoke the relaxation response were compared among high-utilizing primary care patients who experienced physical symptoms which had psychosocial components. The symptoms included palpitations, shortness of breath, gastrointestinal complaints, headaches, and sleeplessness. Both interventions offered patients educational materials, relaxation-response training, and awareness training, and both included cognitive restructuring. These groups were compared with a randomized control group that received only information about stress management, not the actual interventions. Six months after treatment only the patients in the mind-body groups reported less physical and psychological discomfort and averaged about 50 percent fewer visits to the health plan than the patients in the control group. The estimated net savings to the HMO above the cost of the intervention for the mind-body patients was \$85 per participant in the first 6 months.

Chronic pain and insomnia are two other examples of the successful integration into mainstream medicine of mind-body interventions (NIH Technology Assessment Panel on Integration of Behavioral and Relaxation Approaches Into the Treatment of Chronic Pain and Insomnia, 1996). Millions of Americans are in chronic pain, which by definition, is pain that cannot be eliminated, but must be managed. Chronic pain sufferers, motivated both by medical and emotional factors, often become frequent users of the medical system. The treatment of chronic pain becomes extremely costly and frustrating for patients and healthcare providers. In one study, clinic usage was assessed among chronic pain patients at an HMO who participated in an outpatient mind-body group program, of which the relaxation response was an integral part (Caudill, et al., 1991). In addition to decreases in the severity of pain as well as in anxiety, depression and anger, there was a 36 percent reduction in clinic visits among program participants for over two years following the intervention as compared to their clinic usage prior to the intervention. In the 109 patients studied, the decreased visits projected to estimated net savings of \$12,000 for the first year following treatment and \$24,000 for the second year.

Another example of how these same mind-body group interventions can result in better medical care and reduce medical costs is in the treatment of another extremely common disorder, insomnia (NIH Technology Assessment Panel on Integration of Behavioral and Relaxation Approaches Into the Treatment of chronic Pain and Insomnia, 1996). Approximately 35 percent of the adult population experiences insomnia. Half of these insomniacs consider it a serious problem. Billions of dollars are spent each year on sleeping medications, making insomnia an extremely expensive condition. In fact, the direct costs to the nation are approximately \$15.4 billion yearly and the actual costs in terms of reduced quality of life, lowered productivity and increased morbidity are astronomical. Although frequently employed, sleeping pills are not effective in the long term. The shortcomings of such drug therapy, along with recognition of the role of behavioral features of insomnia, prompted the development of mind-body behavioral interventions for this condition. Researchers at our laboratories at the Mind/Body Medical Institute studied the efficacy of a multifactorial behavioral intervention for insomnia that included relaxation-response training. Compared to controls, those subjects who received behavioral and relaxation-response treatment showed significantly more improvement in sleep patterns. On average, before treatment it took patients 78 minutes to fall asleep. After treatment, it took 19 minutes. Patients who received behavioral and relaxation response treatment became indistinguishable from normal sleepers. In fact, the 75 percent reduction in sleep-onset latency observed in the treated group is the highest ever reported in the literature (Jacobs, G.D. et al, 1993; Jacobs, Benson, Friedman, 1996).

It is also important to remember that the research on mind-body, behavioral therapies in the treatment of both chronic pain and insomnia were reviewed in 1995 at a NIH Technology and Assessment Conference. The planning committee chairman was my late friend and colleague Dr. Richard Friedman. Dr. Julius Richmond, former Surgeon General of the United States Public Health Service and Assistant Secretary for Health of the Department of Health and Human Services under President Carter, was the chair of the independent panel (before he became a trustee of the Mind/Body Medical Institute) that reviewed the evidence. Dr. Richmond stated in a press conference that it was "imperative" that these interventions be integrated into routine medical care.

As I noted earlier, if medical care continues to be based only on two legs, it is estimated that the costs for this care will double in the next decade (Smith, et al., 1998). Mind-body programs are scientifically proven strategies that can be thoroughly integrated with pharmaceuticals and surgery and procedures and, they offer cost savings. I've also noted that 60 to 90 percent of physician office visits are related to stress-related conditions. To estimate the monies that could be saved per year by the application of mind-body therapies, I used 75 percent as an average. I estimated that half of these doctor office visits—or 37.5 percent—could be eliminated with a greater use of mind-body approaches. Using 1994 statistics, there were approximately 670,000 practicing physicians in the United States who reported an average of 74.2 patient visits per doctor per week, for a total of 3,858.4 office visits per doctor that year. Each visit for an established patient cost an average of \$56.2. Thus, the average cost per year was $670,000 \times 3,858.4 \times \$56.2 = \$145.3$ billion. By reducing these visits by 37.5 percent, the cost savings would be \$54.5 billion, for one year alone (Benson, 1996).

The full integration of mind/body, self-care medicine is completely compatible with existing healthcare approaches. The integration is important not only for better health and well-being, but also for a more economically-feasible healthcare system. Mind-body medicine responsibly fulfills the needs of our people who want therapies that enhance and complement traditional medicine and that do so in a scientifically-established, safe, and cost-savings fashion. Mind-body and belief-related interventions hold such promise that they should be further researched, advocated and utilized for the health and well-being of the people of our nation.

PROPOSED DEMONSTRATION PROJECTS

I propose that the Health Care Financing Administration establish large demonstration projects to definitively test the clinical efficacy of mind-body and belief-related interventions and to assess the cost-savings afforded by such approaches. These projects should start with medical conditions that are prevalent and expensive, such as, the prevention and treatment of coronary artery disease; the treatment of chronic pain; and the treatment of women's disorders including infertility.

Senator SPECTER. Dr. Benson, thank you very much for that testimony and for bringing Ms. Magnacca and Mr. Cassidy here today. Very informational and really very helpful.

As noted earlier, but worth repeating, the mind/body medicine funding started in 1998 at \$54.9 million and is now in excess of \$125 million. And we would be interested in knowing your personal response, since you began to press mind/body as one of the national/international experts. I have commented about a back problem, which I developed after losing an election in 1973.

And I was skeptical at the time that there was any connection. And since, I have come to believe that there was a causal connection.

But there is, I think fairly stated, a great deal of skepticism among most people about the mind/body connection. When you talk about a cure for cancer and you talk about beliefs, would you amplify how in a medical context—and you are a distinguished cardiologist—that works? How does the work range from mind to belief to body on something as difficult as cancer?

Dr. BENSON. To the best of my knowledge, there is no evidence that stress or mind/body reactions either cause or can reverse cancer. But what we are effective in doing is changing the symptomatology that a patient recognizes or experiences when they have cancer. If a woman learns she has breast cancer, she is no longer Jane Smith. She is Jane Smith, breast cancer patient. And frequently, the symptoms come not from the cancer itself, but from the knowledge of being a different person and the stress of having to adjust to it. It is those symptoms we can effectively treat.

However, Senator, there are many conditions that are directly affected by stress.

Senator SPECTER. Such as?

Dr. BENSON. For example, tension headaches. Many forms of hypertension are directly related to stress.

Senator SPECTER. How about back pain?

Dr. BENSON. Back pain. Pain indeed is often a memory of a pain itself that stress can exacerbate. If you can turn off that memory by a belief system, by remembering what it was to be without the pain, remembering wellness, if you will, remembered wellness is our term to describe the placebo effect, it is a way of dissociating the pain and forgetting the pain and, in many cases, the pain can be alleviated.

Insomnia, for example, affects 60 million Americans. Our clinics are now having published results which are showing a 75-percent cure rate of insomnia, which has a cost to the Nation of literally hundreds of billions of dollars a year because of the problems of insomnia.

Senator SPECTER. Dr. Benson, what has been the public's reaction to the mind/body approach? What differences have you noted since you began your career? I would be interested in when that was when you started to develop your approach to mind/body and how it has expanded and become better accepted.

Dr. BENSON. My career dates back to my fellowship at Harvard Medical School in the department of physiology. And that—actually, it goes further back. It goes back to my very training at Harvard Medical School. Mind/body was unaccepted as a discipline at

the time. In fact, when I started studying stress, I was told I was throwing away, in effect, a promising career to do so.

The change has been spectacular. The acceptance by mind/body is now widespread. There is a marked gender difference in understanding mind/body. For women, there is no issue in understanding that mind has a profound influence on body. Men often need a disease condition to be convinced that that reaction is there.

I think because of the fact that the scientific data have now established this, the establishment itself is now widely accepting mind/body as a direction to go.

Senator SPECTER. Are the HMOs funding the medical treatments related to mind/body? Have you persuaded HMOs about that \$54 billion figure?

Dr. BENSON. Yes, Senator, it is a major issue, but I am proud to say in Massachusetts our programs are largely covered by HMOs. It is our goal to extend this nationally now. And therein lies the issue. Namely, we are training health care professionals and people from HMOs themselves. But the fact is that they often do not change their billing practices.

Ninety-nine percent of physicians believe that belief can heal, and religious belief can heal. Ninety-four percent of HMO executives believe the same. Yet only 10 percent of HMO executives have instituted such plans into their own practices. The data are there.

As I pointed out, this is an intervention that can effectively treat 60 to 90 percent of visits to physicians. A change must occur. And the way people recognize that disease comes not only, or disease need only be treated by the first two legs of the three-legged stool, namely pharmaceuticals, herbs or acupuncture and surgery.

These are procedures done to people. What we are talking about is what people can do for themselves. There is a profound desire for people to do this. We recognize that and get these services paid for.

Senator SPECTER. Thank you very much, Dr. Benson.

Senator Harkin.

Senator HARKIN. Thank you very much, Dr. Benson, for being here and bringing these two witnesses, who—

Senator SPECTER. Three witnesses.

Senator HARKIN. Three witnesses. Thank you, Mr. Chairman. That is why you are chairman. You recognize those things.

Because I believe what you just told, both you, Mr. Cassidy and Ms. Magnacca, really, I think, illustrate the efficacy of different approaches to healing and well-being.

I agree with you, Dr. Benson, that in the realm of well-being, that we have given short shrift to what you say should be discarded as the placebo effect. I agree with you. That word ought to be discarded. I do not think it has a place. It is a pejorative type of a term. And we ought to get rid of it, because the mind does have a lot to do with how we are and what we do and how we feel and our well-being.

So everything you have done in all your research, I think, points to that. You and I are both on the advisory committee of a group called the inter-faith coalition for spiritual counseling and healing. And again, I believe these types of groups can add a lot to our health care system in America.

I might disagree with you a little bit, a couple of percentage points here, when you say mind/body medicine is different from what we call alternative and complementary medicine. Mind/body medicine is evidenced based, whereas alternative medicine is not. If alternative medicine were evidenced based, it would no longer be alternative. You say that alternative medicine is akin to the first two legs of this three-legged stool. Finally, alternative medicine is cost additive, where self-care saves money.

Well, that is kind of where I depart a little bit there from you. I think that a lot of alternative medicine has been evidenced based. But we have a different paradigm in how we look at the evidence for medical care in this country. Acupuncture, for example, has been well known for years to alleviate pain.

I am not going to bore you with the whole story of my brother and acupuncture and watching medical doctors watch an acupuncturist relieve his pain, when he was dying of cancer. But it has been evidenced based. The evidence is there, but we have not looked at it.

So I think a lot of alternative and complementary medicine has been quite adequately evidenced based, just not in our frame of reference. That is all.

Second, I do not think that complementary alternative medicine is cost additive. I think it can replace a lot of the traditional forms of medicine that we are now doing. Take St. John's Wort, for example. If St. John's Wort—I think it is proving to be quite an acceptable regime for depression. And it is a lot more inexpensive, for example, than taking the pharmaceutical drugs for depression.

So I just want to tell you, because those words leaped out at me. And I hope that perhaps, since you are a friend of mine, we might discuss this later on.

Dr. BENSON. Fair enough. May I respond briefly now?

Senator HARKIN. Sure. Sure.

Dr. BENSON. With respect to evidenced based, the question I have is that there is no—let me state that I do believe that alternative medicines help a great many people. Clearly there are testimonies and there are studies to this effect.

The question I have, is it really the alternative medicine working or might not it be the belief in the alternative medicine that is working?

And I will not deny that many of our routine medicine may work, not because of their inherent pharmaceutical, but because of the belief in that pharmaceutical. What I am trying to emphasize is the extraordinary power of belief that we in medicine have ridiculed for more than 100 years. Yet the placebo effect that I now would like to call remembered wellness is effective in 50 to 90 percent of diseases that include angina pectoris, asthmas, skin rashes, rheumatoid arthritis, congestive failure.

I think alternative medicine should be explored. I wholly agree with that. But let us control and that we not ascribe to the alternative medicine what is truly the—may be the belief in the alternative medicine.

Senator HARKIN. I guess my response is, what difference does it make? I mean, if someone is taking an herbal remedy and it helps them and they feel better and they are healthier—I mean, I have

talked to people who have taken Chinese herbs that get rid of asthma, for example. Now you might say it does not, but they believe it does. So what?

Dr. BENSON. I thoroughly agree with that, Senator, but what it does do is diminish the knowledge and the use of what our true power is; that is our power of belief. As humans, we have come to believe that something done to us, be it an herb or a pharmaceutical, is more powerful than what we can do for ourselves.

And I will not deny the power of our pharmaceuticals, our surgery, our herbs and what have you. What I am trying to emphasize is what may be the underlying power in many of these therapies, and that is our belief system. And for many the most powerful belief system may well be belief in spirituality.

Senator HARKIN. Well, obviously from my comments earlier, I agree with you on that. It is just that I also feel that in many ways, whether it is herbal supplements, vitamins, for example, we know what effect vitamin E has on people and vitamin C, for example. I mean, this is not just clearly in one's mind. It has to do with the physiological reactions in your body that the vitamins help and minerals help.

We know what nutrition, for example, does. We could get back into that again. This is not entirely in your mind. It has something to do with what the physiological reactions in your body are. So it is not just mind.

Dr. BENSON. I agree with that, Senator. But what we often deny is the mind component. I am not saying it is all mind. Of course the vitamin could well help. But let us also pay due attention to how belief may enhance the inherent properties of the vitamin. That is why I am arguing so for a three-legged stool.

If we simply argue that herbs and vitamins and pharmaceuticals are one leg, surgery and procedures, acupuncture and massage are another, those are done to you. What I would like to emphasize is the due respect and research to support what we can do for ourselves. And in that component, belief is a vital part.

Senator SPECTER. The Chair finds you two men in agreement.

Senator HARKIN. I think we are pretty much in agreement.

Dr. BENSON. I think we are, too.

Senator SPECTER. Thank you very much, Dr. Benson, Ms. Magnacca and Mr. Cassidy. We really appreciate your coming here. And I think that your views, Dr. Benson, are very important for America's health. And I think they are catching on. And perhaps this hearing will give a little extra boost. Thank you.

STATEMENT OF DEAN ORNISH, M.D., FOUNDER AND PRESIDENT, PREVENTIVE MEDICINE RESEARCH INSTITUTE

Senator SPECTER. We now turn to our fourth panel, Dr. Dean Ornish and Mr. Walter Czapliwicz.

Dr. Ornish is the founder, president and director of the Preventive Medicine Research Institute in Sausalito, California, clinical professor of medicine at the University of California, San Francisco, and founder of Osher Center for Integrative Medicine, written extensively about how comprehensive lifestyle changes can reverse coronary heart disease, medical degree from Baylor College and bachelor's degree from the University of Texas.

Welcome, Dr. Ornish, and the floor is yours.

Dr. ORNISH. Thank you. Mr. Chairman, Senator Harkin, distinguished colleagues, thank you very much for the privilege of being here today. I just want to begin by acknowledging your leadership in bringing funding and in bringing science to this area, which I am deeply grateful for.

I believe that the medicine of the 21st century should integrate the best of allopathic, mind/body medicine and complementary medicine. Our work is a model of the scientifically based approach that may be helpful in building bridges between these. In our research, my colleagues and I use the latest in high-tech, state-of-the-art medical technology to prove the power of these ancient and low-tech and low cost interventions.

We have conducted a series of scientific studies demonstrating that the progression of even severe heart disease can often be reversed without drugs or surgery. Our program includes a very low fat, plant-based, whole foods diet, stress management techniques, modern exercise, smoking cessation and psycho-social support.

The idea that heart disease might be reversible was a radical concept when I first began doing studies in this area 23 years ago. But that idea has now become mainstream. And we have published our findings in leading peer reviewed medical and scientific medical journals.

The improvement in quality of life for these patients is dramatic. We found a 91-percent reduction in the amount of chest pain. Most of them became pain-free within weeks. But they not only felt better, in most cases they were better in ways we could actually measure. They showed even more reversal of heart disease after 5 years than after 1 year. And we found that they had two-and-a-half times fewer heart attacks, bypasses, angioplasties and other things.

I think these findings are giving many people new hope and new choices that they did not have before, as Mr. Czaplewicz will later discuss. In contrast, the patients in the control group, who were making the more conventional changes, like a 30-percent fat diet, got worse and worse over time, rather than better and better.

I think these findings have particular significance for women, because heart disease is by far the leading cause of death in women. Women have less access to angioplasty and bypass surgery than men do. When they do get operated on, they have higher morbidity and mortality than men. But the good news is that women seem to be able to reverse heart disease even easier than men simply through making diet and lifestyle changes.

We found that our program is not only medically effective, but also cost effective in the diverse selection of hospitals and other sites around the country, including ones in Iowa and Pennsylvania. Seventy-seven percent of people who were eligible for bypass surgery or angioplasty were able to safely avoid it simply by changing diet and lifestyle with an immediate savings of almost \$30,000 per patient.

We also found that the older patients improved as much as the younger ones, which is not what I thought we would find. And we found that since the risk of surgery increases with age, but the benefits of lifestyle changes occur at any age, you can argue that this a particular benefit in those in the Medicare population.

Over 40 insurance companies are covering our program in the sites that we have trained. And also, a high mark, Blue Cross/Blue Shield of Pennsylvania was the first insurer to both provide and cover the program to its members.

We also found that several people who had such severe heart disease that they were waiting for a heart transplant were able to get off the heart transplant list because they improved so much, which saves an average of almost \$300,000 a patient, not to mention the suffering that comes from having to go through that.

Also, Congress, including Senator Stevens and other members of this committee, appropriated funds via the Department of Defense for us to train at the Walter Reed Army Medical Center and the Bethesda National Naval Medical Center in our program. So finally we can now order people to meditate and eat healthy.

We appreciate that HCFA finally agreed to move forward with the demonstration project of our work, to determine the effectiveness of our program in the medical population, thereby making it available to Americans who most need it, regardless of their ability to pay. And I want to again acknowledge Senators Specter and Harkin for their support of that.

We believe that this can provide a new model for lowering Medicare costs without compromising the quality of care or access to care by addressing the underlying causes of why people get sick, rather than just literally or figuratively bypassing them.

A few years ago, we began conducting the first randomized trial to see if prostate cancer could be reversed by a similar program. And our preliminary data are very encouraging. We are finding that PSA levels are going down in the experimental group, and they are going up in the control group in direct relation to their adherence.

I believe in the power of science to help sort out conflicting claims, to distinguish what works from what does not and for whom and under what circumstances. And as you both indicated, the question is not should Americans be using alternative medicine, they already are, but with adequate information scientifically to make informed and intelligent choices.

I applaud Congress, and particularly the two of you, for its role in establishing the NIH Center for Complementary and Alternative Medicine and the NIH Office of Behavioral and Social Sciences Research. But, Senator Harkin, as you pointed out, the budgets are still only a half percent of the overall NIH budget.

And therefore, I respectfully request Congress to consider substantial increases in funding for rigorous scientific research into the efficacy of various approaches in complementary and alternative medicine and mind/body medicine, such as those described by Dr. Weil, Dr. Benson and others.

PREPARED STATEMENT

Whatever is learned will be of great interest. So please encourage HCFA to cover alternative medicine and mind/body programs, if they have demonstrated safety and medical efficacy in randomized control trials published in peer review journals. Anecdotal evidence is important, but it is not sufficient.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF DEAN ORNISH

INTRODUCTION AND BACKGROUND

Mr. Chairman, members of the Committee, distinguished colleagues, thank you very much for the privilege of being here today. My name is Dean Ornish, M.D. I am the founder and president of the non-profit Preventive Medicine Research Institute and Clinical Professor of Medicine at the School of Medicine, University of California, San Francisco (UCSF), where I am also one of the founders of the new Osher Center for Integrative Medicine at UCSF. Also, I was recently appointed to the Presidential White House Commission on Complementary and Alternative Medicine Policy.

For the past 23 years, my colleagues and I at the non-profit Preventive Medicine Research Institute have conducted a series of scientific studies and randomized clinical trials demonstrating, for the first time, that the progression of even severe coronary heart disease often can be reversed by making comprehensive changes in diet and lifestyle, without coronary bypass surgery, angioplasty, or a lifetime of cholesterol-lowering drugs. These lifestyle changes include a very low-fat, plant-based, whole foods diet, stress management techniques, moderate exercise, smoking cessation, and psychosocial support. We published our findings in the leading peer-reviewed medical and scientific journals.

Our work is a model of a scientifically-based approach that may be helpful to others in building bridges between the alternative and conventional medical communities. The idea that heart disease might be reversible was a radical concept when we began our first study; now, it has become mainstream and is generally accepted as true by most cardiologists and scientists.

I am a scientist as well as a clinician because I believe in the power of science to help sort out conflicting claims and to distinguish fact from fancy, what sounds plausible from what is real, what works and what doesn't, for whom, and under what circumstances. Indeed, that is the whole point of science: as Tom Cruise playing Jerry Maguire might say if he were a scientist, "Show me the data!" The peer-reviewed scientific process is about people challenging each other to demonstrate scientific evidence, not just their opinions or beliefs, to support their position. Not everything that counts can be counted, and not everything meaningful is measurable, but much is.

Nowhere are there more conflicting claims than in the area of complementary or alternative medicine. The question is not, "Should Americans seek out alternative medicine practitioners," because they already are. Although there is relatively little hard scientific evidence proving the value of most alternative medicine approaches, several studies have revealed that as much money is spent out of pocket for complementary or alternative medicine than for traditional physician services. In most cases, these decisions are being made with inadequate scientific information to make informed and intelligent choices.

Therefore, I respectfully request the Committee on Appropriations of the U.S. Senate to consider substantial increases in funding for rigorous scientific research into the efficacy of various approaches in complementary and mind/body medicine such as those offered by Dr. Benson, Dr. Weil, and others. Whatever is learned will be of great interest. Those approaches that are found to be safe and effective should be covered by Medicare and other third-party payers so that these methods can be more widely available to other Americans who may benefit from them. Scientific studies that find other approaches to be ineffective or unsafe will be of great value in helping to protect the American people as well as Medicare from fraud and abuse. Anecdotal evidence is not sufficient.

I applaud Congress for establishing the Office of Alternative Medicine and elevating its status and funding to the NIH National Center for Complementary and Alternative Medicine. However, their budget is still only a small fraction of the overall NIH budget. Although at least 50 percent of the determinants of our health are our behaviors such as diet and lifestyle, only 1.4 percent of the national health expenditures and only 7 percent of the NIH budget is devoted to these areas.

The editors of *The New England Journal of Medicine* (1998;339(12), p. 839-841) stated, "There cannot be two kinds of medicine—conventional and alternative. There is only medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work. Once a treatment has been tested rigorously, it no longer matters whether it was considered alternative at the outset. If it is found to be reasonably safe and effective, it will be accepted." But this presumes that funding is available to for rigorous testing.

Although research in alternative and mind/body medicine is so important, it is very difficult to obtain funding to do these studies. In my experience, it is often a catch-22: there is a presumption at the NIH and among many funding agencies that these approaches have little value, so they are reluctant to fund studies to determine their effectiveness, yet one cannot assess their effectiveness without funding to do the research. Thus, it is important to increase funding and support for the National Center for Complementary and Alternative Medicine and to encourage the rest of the NIH to conduct rigorous research in these areas. The presumption that unstudied approaches have no value is itself unscientific until these approaches are scientifically studied and tested.

The medicine of the 21st century should integrate the best of traditional allopathic medicine and complementary or alternative medicine. Our research has demonstrated that this integrated approach is both medically effective and cost effective.

We tend to think of advances in medicine as a new drug, a new surgical technique, a laser, something high-tech and expensive. We often have a hard time believing that the simple choices that we make each day in our lives—what we eat, how we respond to stress, whether or not we smoke, how much we exercise, and the quality of our social relationships—can make such a powerful difference in our health and well-being, even in our survival, but they often do.

When we treat these underlying causes of diet and lifestyle, we find that the body often has a remarkable capacity to begin healing itself, and much more quickly than had once been thought possible. On the other hand, if we just literally bypass the problem with surgery or figuratively with drugs without also addressing these underlying causes, then the same problem may recur, new problems may emerge, or we may be faced with painful choices—like mopping up the floor around an overflowing sink without also turning off the faucet.

For example, one-third to one-half of angioplastied arteries restenose (clog up) again after only four to six months, and up to one-half of bypass grafts reocclude within only a few years. When this occurs, then coronary bypass surgery or coronary angioplasty is often repeated, thereby incurring additional costs. Yet over \$20 billion were spent in the United States last year just on these two operations, many of which could be avoided by making comprehensive changes in diet and lifestyle.

In our research, we use the latest high-tech, expensive, state-of-the-art medical technologies such as computer-analyzed quantitative coronary arteriography and cardiac PET scans to prove the power of ancient, low-tech, and inexpensive alternative and mind/body interventions. Below is a summary of some of our scientific studies:

CAN LIFESTYLE CHANGES REVERSE HEART DISEASE?

We began conducting research in 1977 to determine if coronary heart disease is reversible by making intensive changes in diet and lifestyle. Within a few weeks after making comprehensive lifestyle changes, the patients in our research reported a 91 percent average reduction in the frequency of angina. Most of the patients became essentially pain-free, including those who had been unable to work or engage in daily activities due to severe chest pain. Within a month, we measured increased blood flow to the heart and improvements in the heart's ability to pump. And within a year, even severely blocked coronary arteries began to improve in 82 percent of the patients. The improvement in quality of life was dramatic for most of these patients.

These research findings were published in the most well-respected peer-reviewed medical journals, including the *Journal of the American Medical Association*, *The Lancet*, *Circulation*, *The American Journal of Cardiology*, and others. This research was funded in part by the National Heart, Lung, and Blood Institute of the National Institutes of Health.

We found that most of the study participants were able to maintain comprehensive lifestyle changes for at least five years. On average, they demonstrated even more reversal of heart disease after five years than after one year. In contrast, the patients in the comparison group who made only the moderate lifestyle changes recommended by many physicians and agencies (i.e., a 30 percent fat diet) worsened after one year and their coronary arteries became even more clogged after five years.

Thus, instead of getting worse and worse, these patients who made comprehensive lifestyle changes on average got better and better. Also, we found that the incidence of cardiac events (e.g., heart attacks, strokes, bypass surgery, and angioplasty) was 2.5 times lower in the group that made comprehensive lifestyle changes after five

years. A one-hour documentary of this work was broadcast on NOVA, the PBS science series, and was featured on Bill Moyers' PBS series, *Healing & The Mind*.

These research findings have particular significance for Americans in the Medicare population. One of the most meaningful findings in our research was that the older patients improved as much as the younger ones. When we began the research, we believed that the younger patients with milder disease would be more likely to show regression, but we were wrong. Instead, the primary determinant of change in their coronary artery disease was neither age nor disease severity but adherence to the recommended changes in diet and lifestyle. No matter how old they were, on average, the more people changed their diet and lifestyle, the more they improved. Indeed, the oldest patient in our study (now 86) showed more reversal than anyone. This is a very hopeful message for Medicare patients, since the risks of bypass surgery and angioplasty increase with age, but the benefits of comprehensive lifestyle changes may occur at any age.

These findings also have particular significance for women. Heart disease is, by far, the leading cause of death in women in the Medicare population. Women have less access to bypass surgery and angioplasty. When women undergo these operations, they have higher morbidity and mortality rates than men. However, women seem to be able to reverse heart disease more easily than men when they make comprehensive lifestyle changes.

MULTICENTER LIFESTYLE DEMONSTRATION PROJECT

The next research question was: how practical and cost-effective is this lifestyle program?

There is bipartisan interest in finding ways to control health care costs without compromising the quality of care. Many people are concerned that the managed care approaches of shortening hospital stays, shifting from inpatient to outpatient surgery, forcing doctors to see more and more patients in less and less time, etc., may compromise the quality of care because they do not address the lifestyle factors that often lead to illnesses like coronary heart disease.

Beginning five years ago, my colleagues and I established the Multicenter Lifestyle Demonstration Project. It was designed to determine (a) if we could train other teams of health professionals in diverse regions of the country to motivate their patients to follow this lifestyle program; (b) if this program may be an equivalently safe and effective alternative to bypass surgery and angioplasty in selected patients with severe but stable coronary artery disease; and (c) the resulting cost savings. In other words, can some patients avoid bypass surgery and angioplasty by making comprehensive lifestyle changes at lower cost without increasing cardiac morbidity and mortality?

In the past, lifestyle changes have been viewed only as prevention, increasing costs in the short run for a possible savings years later. Now, this program is offered as a scientifically-proven alternative treatment to many patients who otherwise were eligible for coronary artery bypass surgery or angioplasty, thereby resulting in an immediate and substantial cost savings.

For every patient who chooses this lifestyle program rather than undergoing bypass surgery or angioplasty, thousands of dollars are immediately saved that otherwise would have been spent; much more when complications occur. (Of course, this does not include sparing the patient the trauma of undergoing cardiac surgery.) Also, providing lifestyle changes as a direct alternative for patients who otherwise would receive coronary bypass surgery or coronary angioplasty may result in significant long-term cost savings.

Through our non-profit research institute (PMRI), we trained a diverse selection of hospitals around the country. Also, Highmark Blue Cross Blue Shield of Western Pennsylvania was the first insurer to both cover and to provide this program to its members, now at three different sites, including Windber Hospital in Johnstown, PA. Mutual of Omaha was the first insurance company to cover this program in 1993. Over 40 other insurance companies are covering this approach as a defined program either for all qualified members or on a case by case basis at the sites we have trained.

In brief, we found that 77 percent of people who were eligible for bypass surgery or angioplasty were able to avoid it safely by making comprehensive diet and lifestyle changes in the hospitals we trained. Mutual of Omaha calculated an immediate savings of almost \$30,000 per patient. Patients reported reductions in angina comparable to what can be achieved with bypass surgery or angioplasty without the costs or risks of surgery. These findings were published in the *American Journal of Cardiology* in November 1998. We also found that patients who needed bypass surgery or angioplasty were able to reduce the likelihood of needing another oper-

ation by making comprehensive lifestyle changes after surgery. Since then, of the 300 heart patients at Highmark Blue Cross Blue Shield who are in the program, none has suffered a heart attack, stroke, or required bypass surgery, only one patient underwent angioplasty, and none has died.

Several patients with such severe heart disease that they were waiting on the heart transplant list for a donor heart (due to ischemic cardiomyopathies) improved sufficiently that they were able to get off the heart transplant list. This improvement was not only clinically but also objectively verified by cardiac PET scans and/or echocardiograms. Avoiding a heart transplant saves more than \$300,000 per patient as well as significant physical and emotional trauma.

In summary, we found that we were able to train other health professionals to motivate their patients to make and maintain comprehensive lifestyle changes to a larger degree than have ever been reported in a real-world environment. These lifestyle changes resulted in cost savings that were immediate and dramatic in most of these patients. These findings are giving many people new hope and new choices.

MEDICARE

Over 500,000 Americans die annually from coronary artery disease, making it the leading cause of death in this country. Approximately 500,000 coronary artery bypass operations and approximately 600,000 coronary angioplasties were performed in the United States in 1998 at a combined cost of over \$20 billion, more than for any other surgical procedure. Much of this expense is paid for by Medicare. Not everyone is interested in changing lifestyle, and some people with extremely severe and unstable disease may benefit from surgery, but billions of dollars per year could be saved immediately if only some of the people who were eligible for bypass surgery or angioplasty were able to avoid it by making comprehensive lifestyle changes instead.

Unfortunately, for many Americans on Medicare, the denial of coverage is the denial of access. Because of the success of our research and demonstration projects, we asked the Health Care Financing Administration (HCFA) to provide coverage for this program. We believe that this can help provide a new model for lowering Medicare costs without compromising the quality of care or access to care. In short, a model that is caring and compassionate as well as cost-effective and competent.

This approach empowers the individual, may immediately and substantially reduce health care costs while improving the quality of care, and offers the information and tools that allow individuals to be responsible for their own health care choices and decisions. It provides access to quality, compassionate, and affordable health care to those who most need it.

Because of the success of our Multicenter Lifestyle Demonstration Project, HCFA conducted their own internal peer review of our program. Recently, HCFA agreed to move forward with a demonstration project to determine the medical effectiveness of our program in the Medicare population. If they validate the cost savings that we have already shown in the Multicenter Lifestyle Demonstration Project, then they may decide to cover this program as a defined benefit for all Medicare beneficiaries. If this happens, then most other insurance companies may do the same, thereby making the program available to the people who most need it.

Medicare coverage also affects medical training and education. If we demonstrate the cost-effectiveness of our program in the Medicare population, we will provide a new model for lowering Medicare costs without compromising the quality of care or access to care. This demonstration project is about to begin in the sites we have trained.

Also, Congress appropriated funds via the Department of Defense for us to train the Walter Reed Army Medical Center and the Bethesda National Naval Medical Center in our program for reversing heart disease. The program at Walter Reed is scheduled to begin operation next month.

CAN PROSTATE CANCER BE SLOWED, STOPPED, OR REVERSED BY CHANGING LIFESTYLE?

Three years ago, we began conducting the first randomized controlled trial to determine if prostate cancer may be affected by making comprehensive changes in diet and lifestyle, without surgery, radiation, or drug (hormonal) treatments.

The scientific evidence from animal studies, epidemiological studies, and anecdotal case reports in humans is very similar to the way it was with respect to coronary heart disease when my colleagues and I began conducting research in this area over twenty years ago. For example, the incidence of clinically significant prostate cancer (as well as heart disease, breast cancer, and colon cancer) is much lower in parts of the world that eat a predominantly low-fat, whole foods, plant-based diet.

Subgroups of people in the U.S. who eat this diet also have much lower rates of prostate cancer and breast cancer than those eating a typical American diet.

This study is being conducted in collaboration with Peter Carroll, M.D. (Chairman, Department of Urology, UCSF School of Medicine) and William Fair, M.D. (Professor and recent Chairman of Urology, Memorial Sloan-Kettering Cancer Center in New York). Patients with biopsy-proven prostate cancer who have elected to undergo "watchful waiting" (i.e., no treatment) are randomly assigned to an experimental group that is asked to make comprehensive diet and lifestyle changes or to a control group that is not. Both groups are studied and compared.

Because of these epidemiological, animal, and anecdotal human data, I am encouraged by the possibility of being able to determine if the progression of prostate cancer may be modified in humans. If we are successful in demonstrating that we may affect the progression of prostate cancer, the implications for helping to prevent prostate cancer may be of equal importance. Also, these findings may extend to some other forms of cancer, including breast cancer and colon cancer, both of which have been linked to diets high in fat and animal protein. We have the opportunity to determine the effects of diet and comprehensive lifestyle changes on prostate cancer without confounding variables, a study that would not be ethically possible in breast cancer, colon cancer, or related illnesses. Whatever we show, the data will be of wide interest.

In our study, patients are tested with PSA levels and free PSA levels twice at baseline and again every three months thereafter for one year. Additional tests include MRI and MR spectroscopy scans of the prostate to determine tumor size and activity. These are performed at baseline and after one year.

While it would be premature and unwise to draw any definitive conclusions from a study that is still in progress, our preliminary data are encouraging. Dr. Carroll and I presented our interim findings at scientific meeting organized by the National Cancer Institute in Baltimore in August and at the CapCURE annual scientific session in October 1999. We found that PSA levels are decreasing in the experimental group and increasing in the control group. Also, the degree of adherence to the lifestyle program was directly correlated with changes in PSA.

In summary, our experience provides a model for taking alternative medicine mind/body interventions into the mainstream. First, conduct rigorous scientific studies published in peer-reviewed medical and scientific journals to evaluate medical effectiveness and to understand mechanisms of healing. Then, conduct studies to demonstrate cost effectiveness. Finally, obtain coverage from third party payers and Medicare to make this program available to those who may benefit from it.

I would be grateful if Congress would increase the support of research in alternative medicine and mind/body interventions and encourage the Health Care Financing Administration to cover alternative medicine and mind/body programs that have demonstrated medical effectiveness in randomized controlled trials published in peer-reviewed medical journals. In particular, please consider increasing the budgets of the NIH National Center for Complementary and Alternative Medicine, the NIH Office of Behavioral and Social Sciences Research, and related governmental agencies.

Thank you very much for the opportunity to share these thoughts with you today.

Senator SPECTER. Thank you very much, Dr. Ornish.

STATEMENT OF WALTER CZAPLIEWICZ

Senator SPECTER. We will now turn to Mr. Walter Czapliwicz, assistant general manager for Bidwell Food Services in Pittsburgh, here today to discuss his participation in "The Dean Ornish Program for Reversing Heart Disease."

Regrettably, I am going to have to excuse myself at this point. I am due on the Senate floor. We are debating an amendment which I am an original co-sponsor. I want to thank you for coming, gentlemen. And I think we are moving forward on this very important subject. And this today's hearing, I think, is a big help.

My distinguished colleague, Senator Harkin, has agreed to chair for the remaining time, which is relatively brief.

Thank you.

Mr. CZAPLIEWICZ. Thank you, Senator.

Good morning. My name is Walt Czapliwicz, and I am 44 years old and a resident of Pittsburgh, PA. About 11 weeks ago, I became a participant in the Dr. Dean Ornish Program for Reversing Heart Disease offered by Highmark Blue Cross/Blue Shield.

I came to the program with a medical history of hypertension and coronary heart disease. In fact, before I joined the Ornish Program, I had three heart attacks. The first one was on Christmas Day in 1996. I had two more heart attacks in the following year. And I had bypass surgery in October of 1997.

I seemed to be doing well for about 2 years. Then in the fall of 1999 I started experiencing chest pain again. The bypass was clogging up again. The pain became more and more frequent. So I was taking nitroglycerine pills several times a week. I would get pain after walking, after meals or during times of stress. I could tell by how I felt that I knew I was going to have a fourth heart attack and need more bypass surgery soon.

As the new year approached, I saw a story in the newspaper about Dr. Ornish's program. I asked my cardiologist for his thoughts, and he recommended it. I started the program 10 weeks ago. Right from the start, I followed it 100 percent. Within the first 10 days, my chest pain diminished greatly. And it was completely gone after 6 weeks. In fact, I have not had any chest pain since then.

I have lost 34 pounds in the past 10 weeks, even though I am eating more food and more frequently than before, so I do not feel deprived or hungry. Because the food is low in fat, it is also low in calories. When I started the program, my stress test was abnormal.

After only 6 weeks, it came back negative. And after just 9 weeks in the program, my resting blood pressure went from 160 over 80 to 128 over 72. My cholesterol is also much lower, overall from 193 to 114. And my triglycerides have decreased from 316 to 103.

All four of the program's components, diet, exercise, stress management and group support, have been a true blessing to me. The results I have experienced in the first weeks alone made me even more committed to the program. I am fortunate to live in an area where my health insurance company, Highmark Blue Cross/Blue Shield, had the vision to make this program a reality.

In 1997 Highmark became the first health insurer in the country to both provide and pay for the Ornish Program for their customers. My experience with the program and the Highmark staff has been nothing but positive. Many of the participants are over age 65. In fact, I was the youngest in my group.

But as we all know, heart disease can strike any of us, young and old alike. The older participants in the program are doing as well as the younger ones.

We share group meals, exercise sessions and, perhaps most importantly, our life experiences, all of which created a close-knit group working toward a common goal, good health. I manage stress so much better than before.

The nutrition portion of the program also has contributed to my improved health status and more positive attitude. The diet consists primarily of fruits, vegetables, grains, beans, non-fat dairy egg whites, and no added oils, which make the diet about 10 percent

fat. I also was advised to take some vitamins and fish oil supplements.

I manage a catering company, so this was a big change in my diet at first. But now I like it. The recipes in the program from appetizers to desserts are delicious, nutritious and easy to prepare. And I feel so much better. It is worth it.

The program's supervision is also very comforting. We are guided through the program sessions by some very skilled professionals, including a medical director, registered dieticians, exercise physiologists, stress management instructors, behavior health clinicians, and nurse case managers. All participants remain under the care and control of their own physicians, who receive regular progress reports and copies of all tests.

In closing, I would like to reiterate my dramatic improvements in the Dr. Dean Ornish Program. This program reflects a commitment to offering innovative solutions that truly improve one's health. The program treats the underlying causes of heart disease, not just the symptoms, and may spare patients from surgery and, most importantly, improve their quality of life.

PREPARED STATEMENT

I think that just about everyone would benefit from a program like this, whether or not they had heart disease. And I hope the Government can find ways to make programs like this more widely available. Thanks to this program, I feel like I am 35 again. I feel better, look better, and I am healthier than I have been in years.

Coming into the program, I knew I was going to have another heart attack and need bypass surgery soon. But now I do not. And now I do not have to endure the pain and fear. And I truly believe this program saved my life.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF WALTER CZAPLIEWICZ

Good morning. My name is Walter Czaplewicz. I'm 44 years old and a resident of Pittsburgh, Pennsylvania. About 11 weeks ago, I became a participant in the Dr. Dean Ornish Program For Reversing Heart Disease offered by Highmark Blue Cross Blue Shield.

I came to the program with a medical history of hypertension and coronary heart disease. In fact, before I joined the Ornish program, I had three heart attacks. The first one was on Christmas day in 1996. I had two more heart attacks in the following year. I had bypass surgery in October of 1997.

I seemed to be doing well for about two years. Then, in the Fall of 1999, I started experiencing chest pain again. The bypasses were clogging up again. The pain became more and more frequent, so I was taking nitroglycerine pills several times a week. I would get pain after walking, after meals, or during times of stress.

I could tell by how I felt that I knew I was going to have a fourth heart attack and need more bypass surgery soon.

As the New Year approached, I saw a story in the newspaper about Dr. Ornish's Program. I asked my cardiologist, Dr. Bryan Donahoe, for his thoughts, and he recommended it. I started the program 10 weeks ago; right from the start, I followed it 100 percent.

Within the first ten days, my chest pain diminished greatly, and it was completely gone after six weeks! In fact, I haven't had any chest pain since then. I've lost 34 pounds in the past 10 weeks even though I'm eating more food and more frequently than before, so I don't feel deprived or hungry. Because the food is low in fat, it's also low in calories.

When I started the program, my stress test was abnormal; after only six weeks, it came back negative. And, after just nine weeks of the program, my resting blood pressure went from 160/80 to 128/72. My cholesterol is also much lower.

All four of the program's components diet, exercise, stress management, and group support have been a true blessing to me. The results I've experienced in the first weeks alone made me even more committed to the program.

I am fortunate to live in an area where my health insurance company, Highmark Blue Cross Blue Shield, had the vision to make this program a reality. In 1997, Highmark became the first health insurer in the country to both provide and pay for the Ornish program for their customers.

My experience with the program and the Highmark staff has been nothing but positive. Many of the participants are over age 65. In fact, I was the youngest in my group. But, as we all know, heart disease can strike any of us, young and old alike. The older participants in the program are doing as well as the younger ones.

We share group meals, exercise sessions, and, perhaps most importantly, our life experiences all of which created a close-knit group working toward a common goal: good health. I manage stress so much better than before.

The nutrition portion of the program also has contributed to my improved health status and more positive attitude. The diet consists primarily of fruits, vegetables, grains, beans, non-fat dairy egg whites and no added oils, which makes the diet about 10 percent fat. I also was advised to take some vitamins and fish oil supplements.

I manage a catering company, so this was a big change in my diet at first, but now I like it. The recipes in the program from appetizers to desserts are delicious, nutritious, and easy to prepare. And I feel so much better, it's worth it.

The program supervision is also very comforting. We are guided through the program sessions by some very skilled professionals including a medical director, registered dietitians, exercise physiologists, stress management instructors, behavioral health clinicians, and nurse case managers.

All participants remain under the care and control of their own physicians, who receive regular progress reports and copies of all tests.

In closing, I'd like to reiterate my dramatic improvements in the Dr. Dean Ornish Program. This program reflects a commitment to offering innovative solutions that truly improve one's health. The program treats the underlying causes of heart disease not just the symptoms and may spare patients from surgery and, most importantly, improve their quality of life.

I think that just about everyone would benefit from a program like this, whether or not they had heart disease. I hope the government can find ways to make programs like this more widely available.

Thanks to this program, I feel like I'm 35 again. I feel better, look better, and am healthier than I have been in years. Coming into the program, I knew I was going to have a heart attack and need more bypass surgery soon, but now I don't. Now, I don't have to endure the pain and fear. I truly believe this program saved my life.

Senator HARKIN [presiding]. Thank you very much. Pronounce your last name, so I do not mispronounce it.

Mr. CZAPLIEWICZ. Czapliewicz.

Senator HARKIN. Thank you very much for that testimony, Mr. Czapliewicz.

And thank you, Dr. Ornish, for being here and for all the great work that you do. I have a couple three questions. First of all, I remember I visited—I was in New York, I think, at the Einstein Medical Center back in 1993, just—

Dr. ORNISH. Beth Israel, I think.

Senator HARKIN. Maybe it was Beth Israel. I forget exactly where I was, but Beth Israel. It was about 1993, just about the time when a couple insurance companies were starting to provide coverage. So I visited some of your patients in New York at that time and was just astounded at the progress that they had made. And every single one of them was like Mr. Czapliewicz. They were just overjoyed at what had happened to them.

Well, that was in 1993. This is 7 years later. Now you say some other insurance companies are now starting to cover this, right? You have how many—there is more than just a couple.

Dr. ORNISH. There are about 40 altogether. And recently, Medicare agreed to move forward on its demonstration project. But it is a slow process.

Senator HARKIN. Now Medicare is not doing anything in this, though, right?

Dr. ORNISH. Well, you know, we tend to think of advanced in medicine as a new drug or a new surgical technique or new laser or something really high tech and expensive. And insurance companies often have a hard time believing that the simple choices that we make in our lives every day, you know, like what we eat and how we respond to stress and so on, can make such a powerful difference.

But as you say, Mr. Czaplewicz, the stories that you have heard, I mean, I see this over and over and over again. It is frustrating to me that there is not more coverage for something that is not only the right thing to do, but can save them so much money.

Senator HARKIN. Absolutely. And make them feel better. I guess I just want to make a point here for the record again, that—and for the people of the press who are here. If someone who is on Medicare goes in for bypass surgery, Medicare pays for it.

Dr. ORNISH. That is right.

Senator HARKIN. If someone with the same situation wants to go into your program, will Medicare pay for it?

Dr. ORNISH. No, sir. Well, actually they will now, because they just agreed to do a demonstration.

Senator HARKIN. Well, that is only in a demonstration mode.

Dr. ORNISH. But not as a defined benefit. No, sir. And it is unfortunate, because we have already shown that it can save an average of \$30,000. These are—you know, traditionally insurance companies have been reluctant to pay for alternative medicine or mind/body interventions, in part because they say these are prevention.

It may take 5 years to see the benefit. By then, they have changed companies. So why should we spend our money for some future benefit that, chances are, someone else is going to get.

And we said this is not just prevention, it is an alternative treatment. And for every man or woman who would have undergone bypass surgery who can avoid it, you save \$30,000 immediately. You know, real dollars today, not just theoretical dollars years later. Their skepticism was, well, you know, people cannot change, it is too hard, so we will end up paying for the bypass anyway.

Well, we have shown in a demonstration project, and we have now trained over 20 sites, that almost 80 percent of the people were able to avoid the surgery. It has taken us 6 years going back and forth with the Health Care Financing Administration just to get to the point where we are finally ready to begin a demonstration project. Even so though this is something that is in the best interest of everyone, the American people, HCFA can do something innovative.

And, you know, as you know, traditional approaches to saving money are really frustrating Americans, shortening hospital stays, shifting to outpatient surgery, forcing doctors to see more and more

patients in less and less time. None of those really address the more fundamental causes of why people get sick. And that is one of the reasons why people are going to alternative practitioners, because they spend time with people, and they listen to them, and they do not rush them out.

So what we are trying to do is to create a new model that is more caring and more compassionate, whereby treating the underlying causes instead of just bypassing them, you know, literally or figuratively, it saves money, as well as being the right thing to do.

And as Dr. Benson says, it empowers people with information, rather than just doing things to them, which, you know, half or the angioplasties clog up within just 4 to 6 months, and up to half of the bypasses within just a few years. And we spent \$20 billion last year just on those two operations.

These kind of approaches go way beyond heart diseases. We focused on that as a model for how powerful these changes can be. And nothing would please me more than if Congress could, you know pass legislation so that the Health Care Financing Administration can make this available. Because if they cover it, everyone will cover it.

And in the final analysis, we doctors do what we get paid to do. And we get trained to do what we get paid to do. So no single effect that Congress could do would make a bigger difference in medical practice and medical education than passing legislation encouraging the Health Care Financing Administration to cover these kinds of interventions.

Senator HARKIN. We have been on them for some time, because it is evidence based now. Honestly, I wish I knew why they were dragging their feet so much. I guess it is just part of a larger question. We have the evidence of the efficacy of your approach.

Dr. ORNISH. Yes.

Senator HARKIN. Why is it taking so long for it to be accepted in normal practice? Why are we not integrating these into current practices?

Dr. ORNISH. Well, Senator, I have asked myself that question a long time, because I have been doing this work for 23 years. And I used to think that if we just did good science and the science was well accepted, that would change medical practice.

But I was naive. It is not enough to have good science. I am the scientist. I believe in the power of science. I am continuing to do science. I think science can really help people sort out what is truth from what is not.

But it is more than science that is required. It is reimbursement. And as I say, if we change reimbursement, we change medical practice, and we change medical education. It is very difficult for entrenched bureaucracies to do things that are innovative, because there is always a risk associated with it.

But I think that, here again, if Congress legislated HCFA with the authority and the requirement to begin doing not only demonstrations like what we are doing, but covering those programs that have the science, nothing will make a faster and more powerful difference in the American people. And it would save billions of dollars a year.

Senator HARKIN. I think one of the problems we have is that, like Mr. Czapliewicz, when you entered the program, you had supervision, you had a support group, you had all of that around you. I think for a lot of people out there they just do not have that.

People say, yes, I would like to change my lifestyle, I would like to change it. But they have to have support. They have had a whole lifetime of eating fat foods and terrible diets and not exercising. And somehow they need the kind of integration into a group that you had. But people do not have that. So the only thing they have left is to go in and have bypass surgery.

Dr. ORNISH. Well, that is why we are trying to create new models in medicine that are more caring and compassionate that are also more cost effective and competent. And, you know, if I went into an insurance company or Medicare and said, we want to create places for people to learn to create community and open their hearts to each other, they would show me the door.

But if we can show them PET scans and the angiograms and the specthalium and the rate—the—showing these people are getting better, and for every dollar they spend they are saving several more—it also allows us to address not only things like diet and exercise, which are so important, but the kind of things that Dr. Benson writes so eloquently about, the psycho-social, the emotional and the spiritual dimensions as well.

Senator HARKIN. Just a couple other things. We have to close up here. Your study on prostate cancer, is the—I was trying to read through your statement there. But is this based on more use of soy-based products?

Dr. ORNISH. It is a soy-based project, too.

Senator HARKIN. And isoflavins and things like that?

Dr. ORNISH. Yes, sir. It includes that. But it is also a program very similar to what we found can reverse heart disease. And it is being funded in part by the Department of Defense through its appropriation and also through foundations like Captor and others.

It is a multi-factorial interventions, because I think we are at a place with respect to prostate cancer very similar to where we were with heart disease 23 years ago. If you look at the animal data, the epidemiological data.

You know, like in China they have a fraction, 120 times less prostate cancer than we have here. But when they begin to eat here and live like us, they begin to die like us, not only heart disease, but prostate, breast, colon cancer, all kinds of other diseases.

And so I think that we are taking men who have biopsy-proven cancer, who have decided not to be treated conventionally, randomly divided them into two groups. Half of them go through our program, half of them do not. And we compare them.

We are doing this in collaboration with Memorial Sloan-Kettering Cancer Center in New York and at UCSF. And we are finding that it seems to be making a difference. And I think that if it is true for prostate cancer, it will likely be true for breast and colon cancer as well.

Senator HARKIN. How about the step previous, before you have biopsy-proven prostate cancer, as a preventative measure?

Dr. ORNISH. Well, clearly, we focused on areas where people are sick, to try to show that if you can reverse disease, clearly you can

prevent it. It may take years to wait for the heart attack that does not come or the prostate cancer that does not come.

But if you can take somebody who is already sick and turn that around, then clearly it works to prevent it even better.

In particular with heart disease, that is important because, you know, a third of people first find out they have a heart problem when they die from it, which of course is not a good way to find out. And so prevention is what we really need to be talking about.

You mentioned earlier about teaching our children how to eat more healthfully. I think that is really where it has to begin. But here again, it really comes down to Congress.

Your leadership, Senator, and Senator Specter's leadership in setting up the Center for Alternative Medicine, the National CCAM, is making a huge difference. But if we can now take the next step and get legislation passed, it could be a quantum breakthrough.

Senator HARKIN. Well, I would like to have some more of your thoughts on the legislation. You are mostly talking about reimbursement is what you are talking about, I guess, right?

Dr. ORNISH. Well, again, reimbursement is the single most important factor in medical practice and medical education. Even Dr. Weil talked about the difficulties they are having. And, you know, he is very prominent. So we need to provide—it is like, you know, what Willy Sutton said, if we can show where the money is, I think that the other things will follow. Not at the expense of the science.

And here again, I would like to see two things, in summary. More money for research in this area to get the science, to help people sort things out. You know, one of the catch-22's is that it is very hard to get funding to do these studies, because they do not think it is worth doing. And without the funding, you cannot show it is worth doing. And if they do not think it is worth doing, they do not want to fund it.

So funding to support this, to do good science, and legislation to encourage Medicare to cover programs like this and like Dr. Benson's and others, because if these are covered, doctors will do it. And until then, it will remain on the fringes of medical practice, no matter how good the science is.

Senator HARKIN. Lastly, on a personal note, talking about diets and nutrition, I have prided myself on having a good diet and good nutrition program for myself and for my wife. But our two daughters grew up, and they always cooked our meals. That was part of the deal.

When they were in high school, they had to cook dinner for us. Right? We got our own breakfast. And so we had a good regimen.

Well, they are both gone now. So my wife works and I work. I get home late. She gets home late. Put something in the microwave and just read the ingredients on this stuff.

Dr. ORNISH. I know.

Senator HARKIN. They are awful. So I have gone to health food stores and places to look for more—fast food is wrong. What do you call it?

Dr. ORNISH. Convenience.

Senator HARKIN. Convenience foods that are quick, that you can eat. Now it seems to me that somebody has to start making better

foods in convenience packages that are more healthy than what we are finding. I mean, they are either loaded with fat or the sodium level is out of this world.

I am just wondering. You are on top of all this. Is there anything going on that would provide more convenience foods that are in accordance with the diets that you and others have outlined?

Dr. ORNISH. Well, as a matter of fact, I have worked with ConAgro to develop a line of foods—I have consulted with them—that fit these guidelines, to try to make it easier for people to eat this way. As a scientist, I am trying to do the best research I can. But as an educator, I am trying to get this out to people who can benefit from it.

But the great thing about America is supply and demand. And as people become more educated about the power of these changes in diet and lifestyle, as we get more coverage to make these kinds of things available, then consumers will begin demanding that. And then manufacturers will begin making them available.

Senator HARKIN. Well, I hope so. There is a dearth of good products out there right now for people that need to eat in a hurry.

Dr. ORNISH. I agree. I am also working with Web MD, an Internet provider, to get this information out worldwide to people who can benefit from it. There is a globalization of illness that is occurring around the world, as people begin to copy our fast foods and so on.

But we can use that same technology to get information to people that can heal them, as opposed to causing them to become sick.

Senator HARKIN. OK. Well, thank you very much, Dr. Ornish and Mr. Czapliewicz, Dr. Benson, Dr. Straus, whoever else is left here.

Thank you all very much. It has been a very interesting and very good hearing.

Dr. ORNISH. Thank you, Senator. I am very grateful.

Senator HARKIN. Again, I want to compliment Dr. Straus and his leadership at NCAM and look forward to doing some more things in the future in terms of what you have talked about here, reimbursement and—I also want to look at some of the provisions in mind/body health that we might be able to move ahead on, too.

So thank you all very much for all of your leadership in this area. You are truly making a big difference out there. Thank you, all.

Dr. ORNISH. Thank you, Senator. So are you.

CONCLUSION OF HEARING

Senator HARKIN. Thank you all very much for being here, that concludes the hearing. The subcommittee will stand in recess subject to the call of the Chair.

[Whereupon, at 11:26 a.m., Tuesday, March 28, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]