

**COMPLEMENTARY AND ALTERNATIVE MEDICINE
IN GOVERNMENT-FUNDED HEALTH PROGRAMS**

HEARING

BEFORE THE

**COMMITTEE ON
GOVERNMENT REFORM**

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

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COMPLEMENTARY AND ALTERNATIVE MEDICINE IN GOVERNMENT-FUNDED HEALTH PROGRAMS

WEDNESDAY, FEBRUARY 24, 1999

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 10:18 a.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Present: Representatives Burton, Gilman, Morella, Davis, Sanford, Hutchinson, Biggert, Chenoweth, Waxman, Maloney, Norton, Kucinich, and Blagojevich.

Staff present: Kevin Binger, staff director; Daniel R. Moll, deputy staff director; Beth Clay, professional staff member; David Kass, deputy counsel and parliamentarian; John Williams, deputy press secretary; Carla J. Martin, chief clerk; Lisa Smith Arafune, deputy chief clerk; Jackie Moran, legislative aide; Phil Schiliro, minority staff director; Phil Barnett, minority chief counsel; Kristin Amerling, Jon Bouker, and Sarah Despres, minority counsels; Karen Lightfoot, minority professional staff member; Ellen Rayner, minority chief clerk; Courtney Cook and Earley Green, minority staff assistants; and Barbara Wentworth, minority research assistant.

Mr. BURTON. The committee will come to order.

We have a Republican conference going on at this time and we'll probably have Members coming in and out. I was going to wait on them, but because we have a number of witnesses that have time constraints, I thought we would go ahead and get started.

A quorum being present, the committee will be called to order. I ask unanimous consent that all Members and witnesses written opening statements be included in the record and without objection, so ordered.

Today, we continue our inquiry into American's access to complementary and alternative medicine. Alternative medicine continues to increase in popularity and use in the United States. A 1997 survey in the *Journal of the American Medical Association* revealed that over 42 percent of Americans used at least 1 of 16 alternative therapies during the previous year.

Last year, we looked primarily at the research area. We focused on the ability of seriously ill patients to get access to FDA-approved clinical trials in alternative medicine. This may be a relatively

small percentage of the overall population, but it is one that is desperately in need of our help.

There are millions of Americans who are suffering from terminal or crippling diseases. For many of them, conventional treatments like chemotherapy do not work, or may be fatal themselves. For these people, alternative drugs and therapies are the only ray of hope that they have. I believe in my heart that we have an obligation to those people to invest the money that's needed into research and clinical trials to find out which treatments work and which ones do not. I believe that if someone is seriously ill and wants to try an experimental drug that safety has been established, the Federal Government has no business in blocking them. After all, it's their life.

I have a special interest in this area because of how my own family has been affected in just the last few years by cancer. Last September and October, I lost both my mother and my father to lung cancer. My wife struggled through breast cancer 5 years ago, and thanks to an experimental alternative cancer treatment, she has been in remission for 5 years. One of the things that has really troubled me over the past 5 years is this experimental program which has been so effective in helping my wife. The Food and Drug Administration, because of technicalities, tried to close the program down. I had about 70 women calling me who were crying on the phone and very upset because the last ray of hope they had was Dr. Springer's alternative therapy which stimulated the immune system. We had to literally have a real hard talk with the Food and Drug Administration because they were not going to relent.

Fortunately, they did review the situation, the problem was solved and the program has been ongoing. So those 70-some women who are in this experimental program are still happy and they are doing well, but it is unfortunate that you have to fight for a program like that when so many lives depend on it.

I'd be willing to bet that every member of this committee has lost a family member to cancer, heart disease, or some other serious illness. There is not anyone in this room whose family has not been touched by cancer, heart disease or some other devastating disease.

Last year, we began looking at the level of funding for alternative medicine cancer research through the National Institutes of Health. We learned that less than \$20 million of the \$2.7 billion that is the budget for the National Cancer Institute, was devoted to research in alternative medicine. This is less than 1 percent of their total budget, and I think that's deplorable.

This year, we are expanding our investigation to include patient access to alternative medicine through Government-funded health programs. Between 25 and 40 percent of Americans receive at least part of their health care through federally funded programs. This includes our active-duty military, veterans, and their families. It also includes Americans who receive medical care through Medicare, Medicaid, public health clinics, and Indian Health Services.

Are research results translating into access to alternative treatments by the average American? Well, the Health Care Financing Administration estimates that national health care expenditures for the United States will double by the year 2007 to exceed \$2.13 trillion. Almost \$1 trillion of those estimated dollars will be public

funds. It is imperative that the Government reduce these healthcare costs while working to improve the health and well being of the American people, and that's where alternative therapy comes in.

With the epidemic-level increases of chronic conditions such as heart disease, obesity, diabetes, arthritis, asthma, and depression, as well as the high percentages of cancers such as lung cancer, breast cancer, prostate cancer, colon cancer, and melanoma, we have to be aggressive and open-minded in looking for additional options in medical care. We have to find effective and efficient ways to treat chronic and debilitating illnesses. We have to find better ways to treat pain. We have to find ways to reduce the use of antibiotics. We just read the last week that many strains of viruses are becoming resistant to antibiotics, and so there has to be alternatives looked at very, very thoroughly. We have to find better ways to treat pain. We also need to better care for the terminally ill. We need to integrate the wisdom of the ages with the knowledge of this century and move forward into the next millennium expediently.

I remember when I was a State legislator, I had about 300 or 400 cancer patients who had been adjudged terminally ill come down to the Indiana State Legislature when we were debating an issue called Laetrile, and I know that's a very controversial issue. But many of those people had been helped because they had used alternative therapies and many had used Laetrile with some success. And the thing that frustrated me the most was the whole determination of those who opposed Laetrile as well as any alternative therapy. And the way they just ignored these people who were terminally ill, and it seemed to me at the time and it seems to me today that if somebody is adjudged terminally ill, they ought to be able to do anything they wish to try to save their life. After all, hope is one of the major ingredients in keeping people going. And when you take away that hope and just say go home and die, that's just what they are going to do.

Since a substantial portion of our population receives their healthcare through these agencies, it's important to look at the level of integration of complementary and alternative medicine in these programs. We've heard the cry here in this chamber of "Show me the science" in hearings of this committee as the mantra of why alternative medicine should not be used. Caution is important. Good scientific data is important, and thousand of years of safe and effective use of alternatives are also important.

We will hear today from two esteemed physician researchers. Both Dr. Ornish and Dr. Berman have conducted clinical trials in alternative medicine. Each hold teaching positions at highly respected U.S. medical schools. Each has published in peer-reviewed journals. Each has extensive experience and expertise in their fields, and we'll hear that there is good scientific research in alternative medicine and an ever-increasing amount of that reported in peer-reviewed medical journals.

We'll also hear from the Department of Health and Human Services, the Federal Government's principal agency for protecting the health of all Americans. The Department of Health and Human Services is responsible for providing essential human services, es-

pecially for those who are least able to help themselves. Among these services is the Medicare program, the Nation's largest health insurer. Many of these services are provided at the local level by State or county agencies or through the private sector grantees.

For many Americans, especially those on Medicare and Medicaid, the denial of coverage is a restriction of access and in some cases, ultimately is a death sentence. The Department of Veterans Affairs provides benefits and services to the country's veterans. This is a population of over 25 million. They also provide care for approximately 44 million family members. Given the increased demand by patients to have access to alternative therapies, in April 1998, the Veterans Administration initiated a survey to determine the level of alternative medicine availability and to assess what, if any, alternative therapies should be offered with the Department. That report was due out in December 1998 and it has still not been released and we're going to find out why.

The Department of Defense provides health care to its active-duty service members and active-duty dependants, retirees and their dependants, and survivors of deceased members and former spouses. There's an increasing number of healthcare providers within the Defense Department that have specialized training in complementary and alternative therapies.

Today, we have one of the foremost actresses, Jane Seymour, with us and she will present testimony regarding her experiences in integrating natural healing approaches into her life. Ms. Seymour has had numerous experiences with alternative medicines that have helped her family. She will talk about her father's cancer experience and her experiences of integrating herbs, homeopathy, and other complementary methods with conventional medicines.

Dr. Brian Berman is the Director of the NIH-funded Complementary Medicine Program at the University of Maryland in Baltimore. Dr. Berman has been a long-time advisor to the Federal Government on alternative medicine and he has conducted clinical research in acupuncture, mind-body and relaxation techniques, and coordinates the complementary medicine field group of the Cochrane Collaboration.

We are in a time of change in this country. Healthcare is important to all of us. How can we, as a Government, provide quality and effective care and not increase costs to the point of crippling our system? Complementary and alternative medicine may be a large part of the answer. As I have said before, we've heard the mantra "Show me the science" and we are moving to do that today. We will show that there is already scientific data to validate the effectiveness of several complementary and alternative therapies. We have moved to a point of looking at broader availability to our armed-services families and their veterans, and to those who rely on the Federal Government for part or all of their health care. It is time that we assume and assure that scientifically validated healthcare moves out of the ivory towers of research community and into the lives of the American people.

We look forward to hearing from today's witnesses. There has been a great desire by many patients, healthcare providers, associations, and researchers to speak to the committee on this topic. And we're not able to bring them all in today, but we will hold the

record open until March 10 to allow for written submissions to be included in the record. And I want to thank all of our guests for being here today. I really appreciate it. I know it takes a lot of time out of your busy schedule and we really, really appreciate that.

I'll now turn to Mr. Waxman, our ranking minority member, who just arrived for an opening statement.

[The prepared statement of Hon. Dan Burton follows:]

**OPENING STATEMENT
CHAIRMAN DAN BURTON
COMMITTEE ON GOVERNMENT REFORM**

**Opening the Mainstream to Complementary and Alternative Medicine:
How Much Integration is Really Taking Place?**

Wednesday, February 24, 1998

10:00 AM

Room 2154, Rayburn House Office Building

Good morning. Today we continue our inquiry into American's access to Complementary and Alternative Medicine. Alternative medicine continues to increase in popularity and use in the United States. A 1997 survey in the *Journal of the American Medical Association* revealed that over 42% of Americans used at least 1 of 16 alternative therapies during the previous year.

Last year we looked primarily at the research arena. We focused on the ability of seriously ill patients to get access to FDA-approved clinical trials in alternative medicine. This may be a relatively small percentage of the overall population. But it is one that desperately needs our help.

There are millions of Americans who are suffering from terminal or crippling diseases. For many of them, conventional treatments like chemotherapy do not work – or may be fatal themselves. For these people, alternative drugs and therapies are the only ray of hope they have. I believe in my heart that we have an obligation to those people to invest the money into research and clinical trials to find out which treatments work and which ones do not. I believe that if someone is seriously ill and wants to try an experimental drug that's safety has been established, the Federal Government has no business blocking them.

I have a special interest in this area because of how my own family has been affected by cancer. Last year, I lost my Mother and my Stepfather to lung cancer. My wife struggled through breast cancer, and thanks to an experimental alternative cancer treatment, she has been in remission for five years. I would be willing to bet that every Member of this Committee has lost a family member to cancer, heart disease, or another serious disease. There is not anyone in this room whose family has not been touched by cancer, heart disease, or other devastating disease at some time or other.

Last year we also began looking at the level of funding for alternative medicine cancer research through the National Institutes of Health (NIH). We learned that less than \$20 million of the \$2.7 billion budget of the National Cancer Institute was devoted to research in alternative medicine. This is less than one percent of their total budget.

This year, we are expanding our investigation to include patient access to alternative medicine through Government-funded health programs. Between 25 and 40 percent of Americans receive at least part of their health care through Federally funded programs. This includes our active duty military, veterans and their families. It also includes Americans who receive medical care through Medicare, Medicaid, public health clinics, and Indian Health Services.

Have Federal agencies that provide health care begun integrating complementary and alternative therapies? Are research results translating into access to alternative treatments by the average American?

The Health Care Financing Administration estimates that national health care expenditures for the United States will double by the year 2007 to exceed \$2.13 trillion. Almost \$1 trillion of those estimated dollars will be public funds.¹ It is imperative that the Government reduce these health costs while working to improve the health and well being of the American people.

With the epidemic-level increases of chronic conditions such as heart disease, obesity, diabetes, arthritis, asthma, and depression; as well as the high percentages of cancers such as lung cancer, breast cancer, prostate cancer, colon cancer, and melanoma; we have to be aggressive and open-minded in looking for additional options in medical care. We have to find effective and efficient ways to treat chronic and debilitating illnesses. We have to find better ways to treat pain. We have to find ways to reduce the use of antibiotics. We also need to better care for the terminally ill. We need to integrate the wisdom of the ages with the knowledge of this century and move forward into the new millennium expediently.

It is also important to include consideration for cultural diversity and personal beliefs in our health care system. Americans have clearly shown they want a holistic or whole person approach to medicine. Increasingly it is understood how important a person's mind and attitude are to healing. A person has to have hope. They have to have a positive outlook and inner peace. This is one of the strengths of many alternative systems of medicine – attention to the whole being.

The Federal Government provides health care primarily through three Departments – the Department of Health and Human Services (HHS), the Department of Defense (DOD), and the Department of Veterans Affairs (VA). Since a substantial portion of our population receives their health care through these agencies, it is important to look at the level of integration of complementary and alternative medicine in these programs.

We have heard the cry of “Show me the Science!” in hearings of this committee as the mantra of why alternative medicine should not be used. Caution is important. Good scientific data is important. And thousands of years of safe and effective use is also important.

We will hear today from two esteemed physician researchers. Both Dr. Ornish and Dr. Berman have conducted clinical trials in alternative medicine. Each hold teaching positions at highly respected US medical schools. Each has published in peer-reviewed journals. Each has extensive experience and expertise in their fields. We will hear that there is good scientific research in alternative medicine and an ever-increasing amount reported in peer-reviewed medical journals.

Every agency that is responsible for determining access to or coverage for a medical treatment considers cost, scientific evidence, patient preference, and the “first do no harm” philosophy. Our health care delivery paradigm is shifting dramatically. Medicine is moving back from a disease-centered approach to a patient-centered approach. This is not unlike what has been so fabulously displayed in the movie *Patch Adams*, where Patch Adam's vision of compassion and caring in medicine brings joy and improved health to his patients.

¹ Smith S, Freeland M, Heffler S, et al, The Next Ten Years of Health Spending: What Does the Future Hold?, Health Affairs, vol 17,1998:5: 128-140.

Alternative therapies are often lower in cost than conventional treatments. In chronic conditions where conventional medicine does not meet with great success, some alternative treatments may be more effective. Botanical products often have few adverse effects when used wisely. Many conventional drugs, even when used as directed, have serious and painful side effects. Botanical products also are considerably less expensive than their drug counterparts.

Additionally, there are many complementary therapies that can be used together with conventional treatments to enhance and improve outcomes. Acupuncture has been shown to be an effective treatment for nausea for chemotherapy patients and pregnant women, and for dental pain patients. Music, aromatherapy, meditation, massage, and guided imagery have all been shown to be good complements for pain management and stress. Foods, vitamins and herbs can also be used to improve health.

We will hear testimony from the Department of Health and Human Services -- the Federal Government's principal agency for protecting the health of all Americans. The Department of Health and Human Services is responsible for providing essential human services, especially for those who are least able to help themselves. Among these services is the Medicare program. Medicare is the nation's largest health insurer. Many of these services are provided at the local level by state or county agencies, or through private sector grantees.

Organizations and individuals within HHS have approached complementary and alternative medicine with varying levels of enthusiasm and trepidation. For example, the NIH Clinical Center has long been progressive in extending availability of complementary therapies to its patients. For years, the Clinical Center has had a physician on call to provide acupuncture to patients with intractable pain. Also, patients and family members have access to music therapy chairs and mats for stress and pain relief through the Rehabilitation Department. The Indian Health Services has implemented several programs to include or make available Native American Medicine. The Bureau of Primary Health Care held a conference almost two years ago to initiate a discussion in making alternative medicine available in public health clinics. However, little has happened since the conference.

For many Americans, especially those on Medicare and Medicaid, the denial of coverage is a restriction of access. Is HHS moving forward with making complementary and alternative therapies available? Dr. Ornish will talk to us today about a safe and effective lifestyle modification program that reverses heart disease.

The Department of Veterans Affairs provides benefits and services to the country's veterans. This is a population of over 25 million. They also provide care for approximately 44 million family members. Given the increased demand by patients to have access to alternative therapies, in April 1998, the Veterans Administration initiated a survey to determine the level of alternative medicine availability and to assess what, if any, CAM therapies should be offered within the Department. That report was due out in December 1998. It still has not been released.

Last year, the VA employee's magazine, *Vanguard*, ran a story featuring a few examples of alternative medicine practices available within the VA.² These included numerous art therapies, tai chi, meditation, humor therapy, spiritual care, massage therapy, and cranial-sacral therapy, among others. The article stated that within the VA, alternative medical practices may be used for treatment if they meet certain criteria. The alternative practice or technique must do no harm, be accepted by the patient, and reflect the interest of the practitioner. The practitioner also must be trained or certified in the technique and obtain privileges to practice that technique, and the practice or technique must have some level of acceptance as an "alternative."

What is the status of the survey? What did the Veterans Administration learn from the survey? What therapies will be provided system-wide? Is there a plan to increase availability of specific therapies? Is the Veterans Administration interacting with the National Center for Complementary and Alternative Medicine at the NIH or its extramural research centers on potential cooperative clinical trials and practice-based research networks? Should the Department of Health and Human Services and the Defense Department conduct similar surveys?

The Department of Defense provides health care to its active duty service members and active duty dependants, retirees and their dependants, and survivors of deceased members and former spouses. TRICARE is a new initiative to coordinate the efforts of the service's medical facilities. The Department of Defense has been mandated by Congress to conduct two alternative medicine demonstration projects – a Chiropractic Health Care Demonstration Program³ and the Ornish Lifestyle Modification Program⁴.

There is an increasing number of health care providers within the Defense Department that have specialized training in complementary and alternative therapies. Military physicians when assigned to military hospitals develop their Scopes of Practice based on their specific training and the comfort level of the hospital administration with allowing CAM. Walter Reed Army Hospital and Andrews Air Force Base Hospital each have physician acupuncturists on staff. However, these physicians do not focus entirely on acupuncture, nor is there a policy within the new managed care environment to allow referrals. Are there other projects ongoing or in development that will provide access to appropriate CAM therapies through DOD?

It should be noted that the military medical school in Bethesda, Maryland, the Uniformed Services University of the Health Sciences is fortunate to have former Office of Alternative (OAM) Medicine Director, Dr. Wayne Jonas and others with specialized complementary and alternative medicine training on faculty. The school was a co-sponsor with the OAM several years ago of a landmark conference looking at complementary and alternative medicine training in medical and nursing schools. I hope that they will continue to take the lead with other US medical schools in the expansion of medical school training to include complementary and alternative therapies.

² <http://www.va.gov/vanguard/altmed>, Vanguard Magazine, Washington, DC

³ THE CHCDP was initiated through the National Defense Authorization Act for FY 1995.

⁴ The Ornish Lifestyle Demonstration Program was initiated through the Omnibus Spending Bill of FY 1999.

It has been shown that medical students and physicians alike are extremely interested in this topic. Their patients are also asking their advice. We need to equip our medical personnel with adequate tools and knowledge to serve their patients.

Actress Jane Seymour will present testimony today regarding her experiences in integrating natural healing approaches into her life. Ms. Seymour has had numerous experiences with alternative medicines that have helped her family. She will talk about her father's cancer experience and her experiences of integrating herbs, homeopathy, and other complementary methods with conventional medicines.

Dr. Brian Berman is the Director the NIH-Funded Complementary Medicine Program at the University of Maryland in Baltimore, Maryland. Dr. Berman has been a long-time advisor to the Federal Government on alternative medicine. He has conducted clinical research in acupuncture, mind-body and relaxation techniques, and coordinates the complementary medicine field group of the Cochrane Collaboration. Dr. Berman also co-edited *Alternative Medicine: Expanding Medical Horizons, A Report to the NIH on the Status of Alternative Medicine in the United States*.

We are in a time of change in this country. Health care is important to all of us. How can we as a Government provide quality and effective care and not increase costs to the point of crippling our system? Complementary and alternative medicine may be part of the answer. We've heard the mantra, "Show Me the Science!" and we are moving to do that today. We will show that there is already scientific data to validate the effectiveness of several complementary and alternative therapies. We have moved to a point of looking at broader availability to our armed service families and veterans. And to those who rely on the Federal Government for part or all of their health care. It is time that we assure that scientifically validated health care moves out of the ivory towers of the research community and into the lives of the American public.

We look forward to hearing from today's witnesses. There has been a great desire by many patients, health care providers, associations, and researchers to speak to the Committee on this topic. We were not able to bring them all in today. But, we will hold the Record open until March 10 to allow for written submissions to be included in the Hearing Record.

Mr. WAXMAN. Thank you very much, Mr. Chairman.

There is no denying the growing popularity of alternative medicines. They constitute a rising proportion of our healthcare expenditures. The number and diversity of alternative products and services in the healthcare marketplace are increasing dramatically.

Today's hearing is focused on the right questions about alternative medicines. It is important that we seek information about therapies that can help improve our well being and to encourage access to safe and effective treatments. At the same time, we must promote thorough testing and review of therapies to prevent unnecessary harm and expense to consumers.

I believe that a quote from a recent editorial in the Journal of the American Medical Association provides the appropriate framework for today's discussion. The Journal of the American Medical Association recently wrote "there is no alternative medicine. There is only scientifically proven evidence-based medicine supported by solid data or unproven medicine for which scientific evidence is lacking." This is the test to which we must hold alternative medicine. Medicine of any kind must undergo the crucible of scientific investigation from clinical trials to publications in reputable peer-reviewed journals before it can gain a place in routine practice. We must place our trust in credible evidence and not mere speculation, or tradition, or popularity when we decide how best to care for the sick.

The Federal Government and others have invested millions into research on alternative medicines. Some research has had promising results. For example, the Journal of the American Medical Association recently reported on a preliminary study indicating that yoga stretching can relieve some symptoms of carpal tunnel syndrome.

On the other hand, other therapies have proven ineffective or dangerous. For example in 1997, the deaths of three cancer patients were linked to a Manassas physician who had been treating them by injecting them with concentrated aloe vera, a treatment that is not approved by the Food and Drug Administration. Patients reportedly had learned about this physician's treatment through the internet, word of mouth, or an aloe vera supplier.

In highlighting ongoing research, examples of scientifically validated forms of alternative medicine and positive personal experiences with alternative treatments, today's witnesses will help sift through the positive and the negative aspects of this area of medicine.

I join my colleagues in welcoming the witnesses here today and I just want to comment on the fact that we have a change of the list of witnesses and their order which we were never advised of until the very last minute. Not only were we not advised, but the Government witnesses—and it would have been helpful for them to know when they were to appear—were suddenly put on a third panel. And, I think for the record, I want to point out that we ought to be courteous to all of the witnesses try to accommodate them and also discuss with our colleagues, if we are going to have collegial hearings, how we're trying to treat the witnesses so we can get the opportunity to hear from them and not have them mistreated by having the schedules changed on them.

Thank you very much, Mr. Chairman. I do appreciate the hearing. I think the hearing is a worthwhile one and I will try to be here as much as possible, but I certainly will review the record for those witnesses where I am not present in the room because of conflict of schedule.

Mr. BURTON. Thank you, Mr. Waxman.

Let me just say that wherever possible, we always have our agency and administration officials testify first. We do have some time constraints which are a little unusual today. So, for that reason we've changed our panel structure around a little bit. So if that inconvenienced you, we apologize for that.

Mr. Hutchinson, do you have anything you would like to say?

Mr. HUTCHINSON. Thank you, Mr. Chairman.

I'm just delighted to participate in this hearing. I thank you for conducting this and I look forward to the testimony. And so in the interest of hearing the testimony, I yield back the balance of my time.

Mr. BURTON. Are you saying the chairman talked too long? Is that what you're saying? [Laughter.]

Mr. HUTCHINSON. I would never say that, Mr. Chairman.

Mr. Kucinich.

Mr. KUCINICH. Thank you very much, Mr. Chairman, Mr. Waxman, fellow committee members, and members of the panel. I appreciate the opportunity to participate in this hearing on complementary and alternative medicine. I applaud the chairman's willingness to address this issue and I thank him for providing us with this forum.

As a witness to the theories and practice of alternative medicine, I support the committee's efforts concerning this issue. With this in mind I look forward to exploring opportunities that will advance medical care and expand the treatment options afforded to today's doctors.

I think that all of us in Congress are fully aware that our healthcare system is on the verge of radical change. The direction that we are going remains to be seen, but with rising costs, with more and more Americans not having access to adequate healthcare, and with more and more Americans questioning whether they have any availability to healthcare, I think there is becoming a greater and greater interest in alternative methods.

This, in no way, is an attempt to denigrate allopathic practice because I think that, at a minimum, many allopathic practitioners would agree that alternative healthcare methods and therapies are a proper adjunctive theory. I have great respect for allopathic practice, but at the same time, I think that you will find that allopathic practitioners who are candid will admit that there are limitations to their own practice.

I think that we are fully aware that the United States enjoys some of the most advanced health care in the world, but yet we are unable to provide relief for a number of common ailments. The current standards of practice occasionally fail to recognize that medicine is an ancient art that encompasses all methods of healing. Somewhere along the road to advance medicine we sometimes forget that there are methods of treating those who need help. It's time to help widen the vision of modern medical doctrine and ex-

plore alternative medicine. We have to let go of the fear that alternative medical practices will replace and endanger standards and instead embrace the idea that any method that is proven a safe form of treatment ought to be available to the people.

American citizens have a right to health care and as Members of Congress, we have a duty to ensure that they have every available proven treatment option. Complementary and alternative medical care encompasses numerous forms of studies and tested procedures and practices and it is gaining support from mainstream medicine. Unfortunately, there is some unwillingness to support its practice and research. We must ensure nonprejudicial disbursement of research funds to all disciplines of medicine, including alternative medicine. We must utilize this research not only to educate practitioners and the public, but to provide them with access to proven methods of alternative medicine.

I hope these hearings will broaden our understanding of alternative medicine; will expose and end any bias that may exist within our current system of medical doctrine. All citizens deserve access to safe and proven methods of medical care and I thank the chairman and the panel for expanding our understanding of medicine that some would deem, unfortunately, the alternative.

Finally, Mr. Chairman, these hearings present a wonderful opportunity. We have to think creatively about healthcare; to think dynamically; to draw new worlds toward us using a higher consciousness of the potential we have within us to make this a better world. I think that we need to urge Government officials to keep an open mind on alternative therapies. Anyone who is watching or listening knows that once an individual has experienced a profound shift in his or her health as the result of a new approach toward health care, it is important that the story of the miracle of an individual's transformation be available to study, certainly, and also to share.

So, I welcome Ms. Seymour and the other witnesses and I thank you for participating in these hearings.

Thank you.

[The prepared statements of Hon. Joe Scarborough and Hon. Bernard Sanders follow:]

DAY BURTON, INDIANA
CHAIRMAN

ONE HUNDRED SIXTH CONGRESS

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HENRY A. WAXMAN, CALIFORNIA
RANKING MINORITY MEMBER

Congress of the United States
House of Representatives

COMMITTEE ON GOVERNMENT REFORM
2157 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6143
Majority (202) 225-5074
Minority (202) 225-5051

Opening Statement

Joe Scarborough (R-FL)

Committee on Government Reform

Hearing

**"Opening the Mainstream to Complementary and Alternative Medicine:
How Much Integration is Really Taking Place?"**

February 24, 1999

10:00 AM

**2154 Rayburn House Office Building
Washington, D.C.**

Introduction

I am pleased today that we continue our investigation into complementary and alternative medicine. As has been reported in the Harvard survey in the *Journal of the American Medical Association*, more than 40 percent of Americans used at least 1 of 16 alternative therapies during the previous year. This is up dramatically from the 1990 survey.

Are all Americans gaining access to these therapies and practitioners? Or, does alternative medicine remain available only to the middle and upper economic tiers? An increasing number of private insurance companies are beginning to include acupuncture and chiropractics as options as well as a few other alternative medical treatments. This is progress, even though with some this has only been a token coverage. And for chiropractors, the advent of managed care has actually dramatically reduced patient access. Forty insurance companies now reimburse for the Ornish Lifestyle Modification Program. Dr. Ornish will present his research today and talk about his four year quest with the Department of Health and Human Services to expand access to this life-saving program to Medicare recipients.

For those who seek complementary or alternative treatments because conventional medical care does not meet their needs, or for whom personal belief systems direct them toward more natural, less intrusive approaches, is the lack of coverage forcing financial hardships on families in order to pay for treatments out of pocket? We begin to address this topic today by looking first at what we as a Government provide to those who receive their health care through Federal programs.

My home district in Florida is largely a military and veteran population. Are these folks gaining access to those alternative treatments that have stood the test of good scientific rigor? Are we moving to integrate appropriate therapies into our military and veteran health delivery systems?

Research in Complementary and Alternative Medicine

The *Journal of the American Medical Association* recently published a systematic review of saw palmetto extracts for the treatment of Benign Prostatic Hyperplasia (BPH). This review was authored by researchers at the Minneapolis VA. Saw Palmetto has been used as far back as the 1700s by the Seminole Indians. It also is used extensively in Europe, more so than prescription medications to treat noncancerous prostate enlargement. BPH is one of the most common medical conditions in older men. As many as 40 percent of men 70 years and older have lower urinary tract symptoms consistent with BPH. In the US, treatment for BPH exceeds \$2 billion in costs, accounts for 1.7 million physician office visits, and results in more than 300,000 prostatectomies annually.

The evidence of the review of the literature indicates that saw palmetto improves urologic symptoms and flow measures. Compared with the prescription drug, finasteride, (Proscar), saw palmetto produces similar improvement in urinary tract symptoms and urinary flow and was associated with fewer adverse treatment events including impotence. Is this something that is

being integrated into our Government programs either through treatment recommendations or by providing product through the military pharmacies?

In November 1997, the National Institutes of Health held a Consensus Development Conference to review the scientific evidence in acupuncture. This non-Federal, non-advocate panel made the following statement: "There is clear evidence that needle acupuncture is efficacious for adult postoperative and chemotherapy nausea and vomiting and probably for the nausea of pregnancy. Much of the research is on various pain problems. There is evidence of efficacy for postoperative dental pain. There are reasonable studies (although sometimes only single studies) showing relief of pain with acupuncture on diverse pain conditions such as menstrual cramps, tennis elbow, and fibromyalgia. This suggests that acupuncture may have a more general effect on pain. However, there are also studies that do not find efficacy for acupuncture in pain. There is evidence that acupuncture does not demonstrate efficacy for cessation of smoking and may not be efficacious for some other conditions. Although many other conditions have received some attention in the literature and, in fact, the research suggests some exciting potential areas for the use of acupuncture, the quality or quantity of the research evidence is not sufficient to provide firm evidence of efficacy at this time."

Additionally, there is a considerable body of international literature on the risks and benefits of acupuncture, and the World Health Organization lists a variety of medical conditions that may benefit from the use of acupuncture or moxibustion. Such applications include prevention and treatment of nausea and vomiting; treatment of pain and addictions to alcohol,

tobacco, and other drugs; treatment of pulmonary problems such as asthma and bronchitis; and rehabilitation from neurological damage such as that caused by stroke.

Does DOD and VA make acupuncture available for any of these conditions? Can someone receiving treatment through a Public Health Clinic get acupuncture for any of these conditions? Are we adding licensed acupuncturists and physician acupuncturists to the staff of Government-funded facilities?

In October 1995, the NIH held a Technology Assessment Conference, a similar process to the Consensus Conference. This conference reviewed the science on the integration of behavioral and relaxation approaches into the treatment of chronic pain and insomnia. The panel stated, "A number of well-defined behavioral and relaxation interventions now exist and are effective in the treatment of chronic pain and insomnia. The panel found strong evidence for the use of relaxation techniques in reducing chronic pain in a variety of medical conditions as well as strong evidence for the use of hypnosis in alleviating pain associated with cancer. The evidence was moderate for the effectiveness of cognitive-behavioral techniques and biofeedback in relieving chronic pain. Regarding insomnia, behavioral techniques, particularly relaxation and biofeedback, produce improvements in some aspects of sleep, but it is questionable whether the magnitude of the improvement in sleep onset and total sleep time is clinically significant."

Have these techniques been integrated into Government-funded programs? We often hear in the press about the under treatment of pain in this country. The NIH consensus and technology assessment review process is the most prestigious and rigorous review in the medical

research community. In two separate NIH reviews, alternative treatments for pain have been validated and yet, today the average American will not have access to these treatments unless they have the money to pay for it. The NIH Clinical Center makes acupuncture available to patients with intractable pain and has for over five years, but Medicare does not provide coverage. It is time for this to change.

Health Care Costs

The Health Care Financing Administration estimates that national health expenditures for the United States will double by 2007 to exceed \$2.13 trillion. Complementary and alternative therapies may be useful options in reducing health care costs. One of the basic tenets of many of these therapies is the focus on wellness and prevention. Can we keep our population healthier longer through programs like Dr. Ornish's?

One of the leading reasons people visit a physician is stress. Can we as a nation focus on stress reduction through alternatives such as guided imagery, meditation, music therapy, aromatherapy, yoga, and moderate physical exercises such as walking? Can we learn as a nation to use our foods as healing tools?

Along with being a tourist state, Florida is probably best known as a great place for retirement. Not all retirees in Florida are the affluent who can afford to winter on our beautiful beaches and retirement communities and return to their homes in the north during the humid Florida summers. Just as in other states, many of Florida's seniors live on social security and

modest retirement incomes and rely on Medicare to pay for their health care. Every penny counts. Are these senior citizens suffering from arthritis pain that we can relieve from alternative treatments? Dr. Berman will testify about his clinical research in osteoarthritis of the knee. This is something that many elderly Floridians suffer with. If we have an effective treatment for this, then we most certainly should seriously work to provide access to it.

Research

Florida is home to several alternative medicine researchers including Dr. Tiffany Field of the Touch Research Institute (TRI) at the University of Miami Medical School. Dr. Field and her colleagues have studied the effects of massage therapy at all stages of life, from newborns to senior citizens. From these studies TRI has shown touch therapy to have many beneficial effects on human well-being. For example, massage therapy has been shown to: facilitate weight-gain in preterm infants, alter EEG in the direction of heightened awareness, positively alter the immune system, reduce pain, reduce stress hormones, and alleviate depressive symptoms.

The Upledger Institute of Palm Beach Gardens, Florida was founded in 1985 by osteopathic physician and surgeon John E. Upledger to support the work of Cranio Sacral Therapy (CST), a gentle hands-on method of evaluating and enhancing the function of the craniosacral system. CST has been used in the treatment of post-traumatic stress disorder, depression, temporomandibular joint syndrome, headache, and other pain related disorders.

Florida is home to numerous DOD and VA health centers which are excellent facilities for conducting clinical trials and outcomes research on complementary and alternative treatments. Are these facilities in contact with the National Center for Complementary and Alternative Medicine at the NIH and developing cooperative research projects where we can further our scientific understanding while providing access to care?

Conclusion

The Committee is dedicated to ensuring that all Americans have access to good health care. It is important that we encourage the integration of complementary and alternative medicine into the mainstream as research indicates safety, effectiveness, cost-savings, and patient preference. HHS, DOD, and VA should be leading the way of health care delivery. Just as we as a nation no longer tolerate prejudices based on race, religion, creed, or country of origin; institutional biases or prejudices against complementary and alternative treatments that are based on traditional healing systems of other cultures should become a thing of the past. It is time for our Government agencies to be open minded and progressive in expanding access to complementary and alternative medicine.

Testimony of Congressman Bernie Sanders (I-VT)**Committee on Government Reform Hearing on Complementary and Alternative Medicine
in Government-Funded Health Programs****February 24, 1999**

I would like to thank Chairman Burton for calling this hearing today on the federal government's use and coverage of complementary and alternative medicine. Those of us who are supporters of alternative treatments have been pleased to see that the Veterans Administration and the Defense Department are taking steps to ensure that the millions of Americans who want to utilize these services can do so. However, more needs to be done. I also think the Department of Health and Human Services should also try to ensure that our nation's Medicare and Medicaid beneficiaries - including seniors, disabled individuals, and low-income individuals - have access to complementary and alternative therapies.

Additionally, I would like this committee to investigate in the future how extensive our federal employees' coverage is for alternative therapies. According to the Office of Personnel Management, the Federal Employees Health Benefit Program neither mandates coverage for complementary and alternative therapies nor discourages its participating plans from offering them. OPM states that some therapies, such as biofeedback, acupuncture, and chiropractic care are covered under some FEHB plans. However, we should work to expand this coverage to our federal employees. In fact, I intend to offer legislation that would provide for greater coverage of complementary and alternative treatments for our federal employees.

I would also like to welcome all our witnesses, and especially Dr. Dean Ornish, whose groundbreaking work with his heart-healthy plan has saved many, many lives. He has been a pioneer in the field of complementary and alternative medicine and I am pleased he could join us today.

Alternative medicine is becoming more well-known, prominent, and widespread as Americans realize the benefits of these treatments. In recent years, more Americans are using these treatments. The Office of Alternative Medicine at NIH was recently elevated to the Center for Complementary and Alternative Medicine. And the Journal of the American Medical Association published a major study in November 1998 on alternative medicine. The study found that visits to alternative practitioners rose 47 percent since 1990; that 46 percent of survey respondents visited an alternative practitioner, up from 36 percent in 1990; and that Americans made 629 million visits to alternative medicine practitioners in 1997 as compared to 386 million visits to primary care doctors.

We cannot ignore these figures. More Americans are taking advantage of alternative therapies and we need to ensure that they have access to them. We can begin by ensuring that federal employees and others receiving federal benefits, such as veterans and Medicare beneficiaries, can use complementary and alternative treatments.

Over 3 million veterans receive care at the VA medical facilities. Due to demand from veterans, the VA conducted a study of what kinds of complementary and alternative therapies the VA should offer its patients. While the results of that study are not yet complete, we know that alternative medicine is being practiced at the VA in certain sites right now. Some VA Medical Centers are offering acupuncture, meditation, hypnosis, and massage therapy.

Currently, the VA can offer alternative therapies if they meet certain criteria. They must be accepted by the patient, do no harm, have a trained or certified practitioner, and the practice or technique must have some level of acceptance as an "alternative." I think these are extremely reasonable criteria and would hope that the VA will expand its treatment options and services at even more VA Medical Centers.

More of our veterans need to take advantage of these therapies. For example, the Dean Ornish Program is a lifestyle modification program that includes a low-fat diet and moderate exercise as a heart-healthy, less intrusive alternative to angioplasty or bypass surgery. Many veterans would benefit greatly from this program, and especially those who smoke, have high blood pressure, or who have other heart conditions. I hope that the VA will look into covering Dr. Ornish's program, which has been found to not only save lives, but also save money. The program costs \$6,000, but as some insurance companies have noted, it costs much less than the cost of angioplasty, which runs about \$18,000, or a heart bypass, which can cost \$40,000 and up. If our veterans participated in this program, the federal government would also save this money.

Last year, I was pleased to hear that the Defense Department in fact did receive funding for two military hospitals to cover the Dr. Ornish program, one in Pennsylvania and one in the D.C. area. I hope that Congress can encourage the Veterans Administration to provide this same benefit to our veterans this year.

With regard to the Department of Health and Human Services' coverage of alternative therapies, I think more needs to be done. With over 38 million Medicare beneficiaries and 33 million Medicaid beneficiaries under HHS's wing, we should encourage HHS to allow these individuals to have access to, and coverage of, complementary and alternative therapies. We know that lack of coverage can make these treatments out of reach for individuals who are low-income. We have seen this with other medical services needed by low-income Americans. For example, many seniors, about 35 percent, have no prescription drug coverage. Thus, they are forced to pay out-of-pocket for these drugs. Since 37 percent of seniors live on less than \$10,000 a year, they will skip taking their medications or not fill their prescriptions at all because they cannot afford them. I am sure that many seniors and low-income individuals would like to benefit from alternative therapies for chronic conditions, but cannot afford to pay for these services out-of-pocket. Having Medicare and Medicaid cover alternative therapies would improve the lives of our seniors and likely save the government money in the long run.

Some alternative medicine treatments particularly are beneficial to seniors. For example, naturopathy relies on herbs, diet, homeopathy, massage, and other natural treatments to treat many disorders, including cancer. We should give seniors the option to take part in this practice while they are enduring a painful cancer therapy. And chelation therapy, which injects patients with a prescription medication known as EDTA, is used to treat health problems like hardening of the arteries and Alzheimer's. Chelation helps the body get rid of metals such as lead and mercury. However, a course of treatment can cost between \$2,000 and \$4,000, which is out of range for most seniors who could benefit.

I hope that HHS will look into covering these therapies for seniors and I would like to offer to work with Chairman Burton and Members of the Committee to encourage the inclusion and coverage of complementary and alternative treatments under Medicare. Specifically, I would like to work with the Chairman and Members to draft a letter to the Medicare Commission asking them to consider covering alternative therapies.

Overall, I am pleased that some federal agencies are covering some complementary and alternative treatments, but I think much more work needs to be done. I look forward to working with my colleagues on this issue.

Mr. BURTON. Thank you, Mr. Kucinich.

Well, we now finally are at the stage where we hear from our witnesses and the first witness, Ms. Seymour, would you come forward and sit in this chair right here in the middle, and if you would like to have anybody with you, that's fine.

First of all, before you start your statement, let me just say how much we appreciate you being here. I especially appreciate you being here because I am one of your biggest fans. I watched you in East of Eden and I thought you did extremely well in that, and I saw you in "Somewhere in Time," which is a very romantic movie. I saw your picture on the wall in that movie theatre and just swooned. So I just want you to know you have a big fan here in the chairman and—

Ms. SEYMOUR. Thank you.

Mr. BURTON [continuing]. Although we usually limit testimony to 5 minutes, you can have all the time you want.

Ms. Seymour.

STATEMENT OF JANE SEYMOUR, ACTRESS

Ms. SEYMOUR. Thank you very much, Chairman Burton, and thank you all for giving me this opportunity. This is, obviously, very unusual for me and something I am very excited to be a part of.

My first experience with alternative medicine involved my father, Mr. John Frankenberg, a fellow of the Royal College of Obstetricians and Gynecologists in England. He specialized in infertility and prided himself in being a good doctor, with extraordinary results in his field, greatly due to the time he would spend listening to his patients. When he himself was diagnosed with lung and bone cancer and treated with radiation, his oncologist told him that that was it. He had no more options.

Distressed and desperate to find an answer, I found the Virginia Livingston Clinic in San Diego, a complementary medicine program which was heavily criticized by mainstream medicine. I offered this option to my father not believing that he would accept. However, after reading their brochure he did.

On his arrival in California, he was frail, gray, and lifeless. Not the man I had always known, but rather a man who appeared nearly dead, both physically as well as spiritually. After only 1 week there undergoing complementary medicine therapies and antibiotics, he regained his strength and his spirit. He decided to visit Sea World. He walked out of this wheelchair to look more closely at the exhibit. He was healthy looking and happy and we were all, including his oncologist, dumbfounded.

Many months later, he died of complications including heart problems, but he had a much longer life than predicted and, without question, a higher quality of life. He visited the opera 2 days before his death. He was happy and comfortable until the end. Before he died, I spoke with him asking if he had any regrets in his life. And he said that his strongest regret was his not knowing more about alternative medicine as he felt he could have been a better doctor with that knowledge to complement his own.

Since then, my sister Anne, who is with me today, has trained as a homeopath in England. I have seen her help many people. One

was a woman with fibroid tumors declared unable to conceive and told she needed surgery. Anne treated her homeopathically, and she has just delivered a healthy child and the doctors found no fibroids present in her body. When alternative medicine finally arrives, how many surgeries like this will be prevented?

My nephew with chronic Eczema has found relief at last with homeopathy instead of steroids. My sister, Sally, had a brain aneurysm and after surgery was given Arnica for the swelling with the permission of her brain surgeon who admitted he didn't really understand what Arnica was. He was then astounded, as were all the nurses, who determined her swelling to be one-tenth that of the other patients who had received the identical surgery that day.

In my own life, I've used high-quality herbs, vitamins, and homeopathy. During my 16-hour a day, 5 day-a-week job on Dr. Quinn, I rarely got sick. Indeed, even pregnant with twins at 45, I was able to support my immune system with this regime and not miss a single day of work.

I have recommended remedies to friends for headaches and flu symptoms with amazing success, even to the non-believers. My children, both teens and babies, routinely use alternative medicine first. More often than not, it has solved their problems. My pediatrician suggested homeopathy to avoid the excessive use of antibiotics. One of my twins did so well with this that he was antibiotic-free for over 6 months when all around him were suffering from the flu.

Recently, both twins with ear infections received antibiotics due to the severity of the case, but also took a series of other therapies like herbal medicine to support their immune systems. They sailed through this as if they were never sick and needed far less antibiotics rounds. It was amazing.

Another friend with chronic migraines would vomit uncontrollably and lie in a fetal position crying for help. Medicine prescribed for her did little. Only Codeine gave her some pain relief and sleep. The following day, she consulted a naturopathic medicine practitioner who after the session gave her a single remedy. She felt better within a half an hour and has remained pain and headache free ever since.

About 9 years ago, I almost died of anaphalatic shock from an injection of Cephliosporin prescribed for bronchitis. Needless to say since that close call, I've been more inclined to ask questions and seek options in my medical health. Do we all need a severe wake-up call? I have managed to avoid antibiotics on many occasions by catching early warning symptoms of viral infections using proven herbs such as echinacea, vitamins, and homeopathy.

Two years ago, I was very ill with Leptospirosis, a bacterial infection contracted while filming in a swamp. I was eternally grateful to have Tetracycline, which absolutely saved my life. I am also positive that by my abstaining in the past from antibiotics whenever possible and using complementary medicines, the antibiotic worked more effectively in that crisis.

The world of alternative medicine has become a major spark in my life and I am here to suggest the integration of western and alternative medicine within our medical establishments. It would be an injustice to deny America the information about and access to

alternative medicine, particularly as it has now been proven through laboratory and clinical research and has shown to be cost effective with 100 to 500 years of reproducible clinical results.

I am not standing here as a scientist, but as a concerned member of the public who has had the privilege to try these options which are supported by scientific evidence.

A recent article in JAMA estimated that there were 110,000 deaths annually from the use of medical drugs. It is the fourth cause of death in America. That is not to say that miracles have not been achieved with the use of prescription drugs, and I am not here to vilify western medicine. I am looking for inclusion, not exclusion. I propose every hospital in America include a complementary medicine department consisting of two or three licensed practitioners who direct the complement to unassisted treatments such as chemotherapy side effects and chronic, but not life-threatening, diseases. I propose the NIH stop withholding its billions of dollars in research funds from the implementation of natural medicines and protocols.

When I get sick, my children, or my friends, I want to know that "all" has been done to protect their health. Everything! I don't want to feel that I have to choose one medical system over the other. Each of us can benefit from a portfolio of medical choices and I want all the medical options available to me, to my family, and to you. There must be room for all remedies that bring health to the patient. Isn't this hearing about healing? Alternative no longer needs to mean one or the other. There should be no alternative other than the best health care known to man.

Thank you.

[The prepared statement of Ms. Seymour follows:]

Jane Seymour

**Testimony before the
House Committee on Government Reform
Hearing on Alternative Medicine**

February 24, 1999

My first experience with alternative medicine involved my father, John Frankenberg, a Fellow of the Royal College of Obstetricians and Gynecologists in England. He specialized in infertility and prided himself in being a good doctor, with extraordinary results in his field, greatly due to the time he would spend **listening** to his patients. When he himself was diagnosed with lung and bone cancer and treated with radiation, his oncologist told him that was it, he had – “no more options.” Distressed, and desperate to find an answer, I found the Virginia Livingston Clinic in San Diego – a complementary medicine program which was heavily criticized by mainstream medicine. I offered this option to my father not believing that he would accept. However, after reading their brochure, he did.

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The world of alternative medicine has become a major spark in my life, and I am here to suggest the integration of Western and Alternative medicine within our medical establishments. It would be an injustice to deny America the information about and access to alternative medicine, particularly as it has now been proven through laboratory and clinical research and has been shown to be cost effective with 100 to 500 years of reproducible clinical results.

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Mr. BURTON. Thank you very much, Ms. Seymour. That was a very, very enlightening statement. We are going to ask you some questions now.

Ms. SEYMOUR. OK.

Mr. BURTON. You didn't think you were going to get off scott free, did you? [Laughter.]

I'd like to know a little bit more about your father's situation. Do you know what kind of therapy they provided for him when he became deathly ill with cancer and they gave up hope?

Ms. SEYMOUR. I have the data here somewhere that I can show you. He had a number of therapies, but the main ones were intravenous vitamin C, which many people have poo-pooed, which I now believe is done all over the country. And a special vaccine made that was also at that time not allowed. In fact, he was very fortunate to get it. I believe the vaccine is now being used elsewhere in the country routinely for cancer. He also had an enormous amount of emotional counselling, which I think was a very large factor, too.

In his case, of course, the cancer was not caught early enough for him to go into remission. However, I think the point I am trying to make here is that he was given the quality of life, a comfort, and a sense of living until the end which I think that every one who goes through cancer should be entitled to, and especially if that exists.

And I think one of the reasons I am here today is because he was an eminent surgeon who did not necessarily believe or know anything about alternative medicine before. The fact that his only regret in life was that he didn't get to know more about these options until just before he died is really one of the reasons I am here today. I meet an enormous number of medical practitioners who really believe that there are holes in what they are doing and that there really is a great need for alternative medicine as a complement to what they are doing, particularly as you mentioned, in cancer.

I have three friends who just went through breast cancer. All three of whom were told at one point by their oncologist that their white blood cells were at a level that they, basically, were going to die. There was nothing more that could be done for them. And they all said, "well, what do you mean? What do we do now?" And their oncologists said, "well, there is nothing we can do now. We are finished. This is it. We've done our best. That's all we can do." And my friends said "well, are we supposed to walk out of door and die?" And their oncologists said, "well, we don't like to put it that way, but there is nothing more that we actually can do."

In all three cases, they found alternative medicine and, in fact in all three cases, it was Chinese herbal medicine that brought back their immune system. All three of them are incredibly healthy. All in remission and all of them would swear by alternative medicine, and that is another reason I am here.

Mr. BURTON. Those are very impressive stories and it is not unlike the situation that my wife went through 5 years ago. They gave her less than a 50-percent chance to live 5 years and she just celebrated her 5th year and she is very healthy.

So, I'd like to make just one more comment along the lines of your father. He was a doctor and he was not enthralled with alter-

native therapies until he became ill. For those who are from HHS and FDA, I hope you listen to this story.

We had a Governor in Indiana who was deaf on alternative therapies and he supported the AMA's position right down the line. And I fought with him when I was a legislator and he was Governor over some of these alternative therapies. His wife became ill with cancer and he went and used every alternative therapy he could possibly use to save her life and I do not fault him for that. The only thing that bothered me was that that is the way it ought to be for everybody. And he later became the head of HHS, incidentally.

You mentioned in your testimony that you use alternative treatments in your children. How do you decide what is safe for your children?

Ms. SEYMOUR. My pediatrician is actually the person who started me out on this. She is a regular M.D. She does not practice any alternative medicine. Her name is Dr. Lisa Stern, a prominent pediatrician in Los Angeles. She said to me that the use of antibiotics for small children was not safe to do on a regular basis. That they were trying to find other options and she suggested that I consult a homeopath. I consulted Dr. Asa Hershoff in Los Angeles with my twins and we've been using homeopathic and herbal remedies for them really pretty much since they were born. We use, obviously, things like chamomile for teething; Arnica for bumps and bruises; pulsatile for flu. They really are incredibly healthy considering both of them were on heart monitors. Both of them were born early; 6 weeks early and being twins, you know, they are not as resistant usually as other children to infections that are around them because they had low birth weights.

I generally will go to the pediatrician first and then I will take them to the homeopath and we'd look at what the options are and, invariably, we'd try homeopathy for at least a couple of days. Usually it works and, therefore, we don't end up having to use the antibiotics.

Mr. BURTON. Let me just ask one more question here. What would you say right now to mothers all across America about the use of antibiotics? You just talked about that. I presume you would just tell them to be very careful; not to use them unless it is absolutely necessary. I mean, how do you judge that and what would you say to them?

Ms. SEYMOUR. I think you go to your regular medical practitioner and I personally believe you also have a homeopath or someone like that, a naturopathic doctor that you can consult. As a mother—for me, I would check their ears and make sure there is no major ear infections or problems that way. And most pediatricians will now agree and say that antibiotics should be used very sparingly in small children and they are very happy to have alternative means to try first.

Mr. BURTON. Thank you. Mr. Waxman.

Mr. WAXMAN. Thank you very much, Mr. Chairman, and Ms. Seymour. We are delighted to have you here and I appreciate your testimony.

I think the important point that I get from what you had to say is that we don't want one medicine here and another medicine

there. We want the best healthcare possible for all of our people. And that means that everybody has to be open-minded enough to reevaluate information, and if new information comes out, we ought to accept it. I gather your father had a feeling that as a medical person, he wasn't open to some of these alternatives because he had been trained in a particular way and didn't think about some of these other things that were being suggested.

Is that a correct statement?

Ms. SEYMOUR. Yes, I think the temperature has changed in America today. I think people are aware now that they can take health into their own hands and that preventive medicine is probably a very important part of their lives. I think people are very aware of how diet, nutrition, health, exercise, and all kinds of protocols can really help them.

My father discovered rather late in life that this is an area he wished he had known more about.

Mr. WAXMAN. Well, I'm not a scientist, but as a lay person and a consumer, I want to be able to have more of a say over what my family has in terms of healthcare and what decisions they would make and I would make about whatever medicine that I may or may not decide to pursue. But I also want the doctors to be open to other—we call them alternatives—but other indications of good health care.

To me, one of the shocking things is that how little in medical schools they teach doctors about nutrition. Even though now we are learning so much more about the value of nutrition. Dr. Ornish will be testifying and I know his long record in this area.

It's important that we not look at medicine as one sort or another science—good science to me ought to be open to alternatives and then those alternatives ought to be tested and accepted wisdom ought to be retested as well so that we try to get the best that we can for all of our people.

Have you had any obstacles or members of your family encountered any difficulties in trying to get access to these different remedies or different alternative practitioners?

Ms. SEYMOUR. I have had no difficulty whatsoever. There are—you know, we were talking about studies. There are 3,000 blind and double studies, you know, done worldwide on the effects of herbal medicine and these studies comes from countries like Germany, Japan, France, and England. So there are studies that can be evaluated and I think it is rather remarkable that we accept their studies on making fair Mercedes or a German car and that is acceptable to us, but we disregard what the Germans have to say about homeopathy and they are really, probably, the foremost in the world in this area.

I, obviously, have had no problem in finding help. No, and none of my friends. I would like to see the general public be able to have this. My sister just brought with me a very interesting report from England—from a part of England which is close to a house that I own where the National Health did a study to see the cost effectiveness and how it would affect the general public in terms of health. And they took half of that area of the National Health. They gave them regular medicine and the other half they used homeopathy and natural medicine and the results were astounding.

The patient's response were as that 90 percent of them were very happy with the alternative medicine. Far less of them came back for repeated visits to the doctor afterwards and the cost was so much less to the National Health. So in England, they are taking this very seriously.

Mr. WAXMAN. And we should take it seriously here. There is no question that if we can prevent disease, we are far better off. And I'm encouraged by the amount of attention I see in the press about encouraging people to exercise; watch their diet; to take care of themselves; and to understand the value of nutrition. This is, it seems to me, the direction that we ought to go as we learn more information.

I am going to ask you one other question. Do you have any suggestions on how the Government can help individuals obtain access to alternative treatments that are safe and effective?

Ms. SEYMOUR. I think that it would be very useful to have a panel of maybe 200 to 300 practitioners that is decided within alternative medicine—as you know, there is 40 or 50 different forms of it—that they should decide who this panel is. And they should be the people who should monitor amongst themselves as to who is actually doing the right alternative medicine and who isn't. And I would like to see in the hospitals when you go to an oncologist, when you go to a hospital for cancer and you are offered chemotherapy, that someone talks to you about how you can support your immune system while you are going through this.

It is very cost effective. In fact, I think you will find less people becoming sick if we educate them in what they can do with alternative therapies as a complement to, of course, the brilliant remedies that we do have in allopathic medicine.

Mr. WAXMAN. I agree with you and—

Ms. SEYMOUR. Thank you. I'm glad you do. [Laughter.]

Mr. WAXMAN. I was pleased that you mentioned the point about spirituality because I think that is very important in how people address their ailments because we don't know why, but we do know that those who have an optimistic view of the world often are able to heal themselves.

Ms. SEYMOUR. It is called holistic medicine because wellness is about the whole being. I personally have discovered that homeopathy and Chinese herbs do work for me and for everyone around me with remarkable results. So I do hope that money will be spent to enable this to be shared with the rest of the population.

Thank you.

Mr. BURTON. Thank you, Mr. Waxman.

Mr. Gilman.

Mr. GILMAN. Thank you, Mr. Chairman.

I want to commend you for bringing on this important issue before our committee. The hearing should help to stress the need for alternative and complementary treatments into the mainstream of health care and provide patients with a variety of treatment options. And I'm pleased that Dean Ornish is here to tell us about how he's attacked the problems with regard to heart situations.

And I want to thank Ms. Seymour for coming with her examples of how homeopathic treatment has helped her. How did you find the homeopathic physician that you needed? Were they listed prop-

erly among physicians or were you just referred by another patient?

Ms. SEYMOUR. No, they are listed. They are quite easy to find. In fact, there is a brilliant thing called the Alternative Medicine Digest which is a phenomenal book that will tell you where you can find any practitioner and how all the different methods work. But homeopathy is quite easy to find all over the world.

Mr. GILMAN. One of the things I've found, Mr. Chairman, is that there is so little education on pharmaceutical agendas at the medical schools and I'm just wondering whether alternative medicine has reached the training in the medical schools.

Would you know that Ms. Seymour?

Ms. SEYMOUR. I do know that my homeopath teaches, I think—is it at UCLA? Yes, he teaches at UCLA and I just recently, 2 nights ago, spoke to one of the top doctors at UCLA, Dr. Becker, who said that they were about to instigate a program there investigating the use of alternative medicine as a complement to what they were doing.

Mr. GILMAN. And maybe Dr. Ornish, in his testimony, can tell us a little bit more about the kind of training that exists in our Nation on alternative medicines.

Studies have found, Mr. Chairman, that more than 40 percent of all of our people try alternative and complementary medical treatments, seeking out the advice of physicians with regard to these treatments. Many who have suffered through the agonizing effects of traditional cancer treatment, such as chemotherapy and radiation. We all know some of those examples are now turning more and more to complementary and alternative treatments like herbal therapy, meditation, and nutritional therapy.

In a bill I introduced several years ago—and I'll keep introducing it until we get some place—is a preventive medicine to make certain we do more in prevention that can save us more dollars on the cure if we apply prevention appropriately. And I'm pleased that more and more nutritional advice is finding its way into our medical system.

In our Nation, it is some sort of a stigma when we talk about alternative medicine, and as a result, funding alternative studies has been difficult for physicians and researchers. Significant achievements are being made, though, in the cures for cancer that are occurring overseas and in Europe and Asia. I think it is long overdue that our Nation works together with its foreign counterparts, sharing information, sharing strategies and treatments, and to provide our Nation with easy access to those treatments.

Some patients in our Nation have the ability to travel overseas to receive alternative treatments, and we continually hear about how they go to great lengths to try to find some proper remedy. But all Americans should be afforded that opportunity to access all forms of treatments, both traditional and alternative. We should pool our resources to create affordable, beneficial alternatives, to establish treatments in an alternative form, from which all of our patients can benefit.

So, Mr. Chairman, I thank you for focusing attention on the studies that have shown that these alternative complementary treatments create positive results. It is our hope that, with hear-

ings such as this, these treatments will be integrated into our healthcare system.

I thank our panelists, Ms. Seymour and Dr. Ornish, for coming before us.

Thank you, Mr. Chairman.

Mr. BURTON. Thank you, Mr. Gilman. Mr. Kucinich.

Mr. KUCINICH. Thank you again, Mr. Chairman. I want to again state for the record that I think that the Chair is performing a very valuable public service, as is Mrs. Seymour for her participation. This is a subject that we are only beginning to get into on a national level, and Congress has a great ability here to coordinate a lot of knowledge. Again, it needs to be said that Mr. Burton is doing something here that is important for the country. I think that he should be supported in his efforts. That is why I am here.

I also think that there is something about alternative medicine which is uniquely symmetrical with democracy and democratic tradition. We in this country believe in individual responsibility. Alternative medicine certainly does that. Would you agree, Ms. Seymour?

Ms. SEYMOUR. Absolutely.

Mr. KUCINICH. What would be your view as to how those who you love and your family have had more control over their own lives by being able to seek alternative therapies?

Ms. SEYMOUR. Well, for example, it was pointed out to me the other day that mammograms, which are routinely done on women, are now shown to be causing cancer unnecessarily. There are other ways of discovering the breast health with thermography and ultrasound used together, and then the mammogram used to bolster that, to make sure that the symptoms are discovered.

There are other options in so many different areas. I think the whole feeling of wellness, the whole concept of holistic medicine is to want to be healthy and to want to be in a well state, rather than constantly patching one's self up with bandaids that will take away symptoms. Somebody once described homeopathy to me as, if you drove a car and the oil light went on to tell you that something was wrong with your oil, you could have that light removed or you could actually go to the garage and find out what part of your car, what part of the oil system is not working. I think this is what we are talking about in alternative medicine, that if we become in tune with our health, then we may not get to such severe cases so often.

Mr. KUCINICH. Would you say that is self-empowering?

Ms. SEYMOUR. Yes, I think there's a lot of things we can do for ourselves, and we can empower people to take care of their own health. Rather than bandaiding it with things that take away symptoms, I think they can listen to their bodies and probably hear the symptoms and be able to notify the doctors as to what is really happening in their bodies.

Mr. KUCINICH. I think, Mr. Chairman, in conclusion, one of the values of this hearing, and hearing from Ms. Seymour and other witnesses, is that we start to shift our view of how health is defined. One could almost ask at the beginning of this hearing, alternative to what? Because as we broaden our knowledge of

healthcare, more things that appeared at one time to be on the fringe or alternative suddenly become part of the mainstream.

Ms. SEYMOUR. I think also a huge issue today for all of us is the support of the immune system. We never really thought of the immune system until we had viruses and AIDS and hepatitis C, which I believe is to be the next huge problem we have here. I think we all have a responsibility to ourselves and to our families to keep ourselves in as good health as we can, so that we are able, our bodies are able to withstand these viruses.

Mr. KUCINICH. Mr. Chairman—

Mr. BURTON. If the gentleman will yield to me just for one comment—years ago, when I was in the Indiana General Assembly and we were working on the laetrile bill, I called Dr. Linus Pauling—and I am sure you have all heard of him. He won two Nobel Prizes. I think one was for cancer research or scientific research. I was talking to him about laetrile, and he interrupted me in mid-sentence and said, “Well, that does have some promising qualities to it,” he said, “but the thing that I am convinced is going to save a lot of lives and prevent heart attacks and cancer is megadoses of vitamin C.” More and more people today are agreeing with what Dr. Linus Pauling said, and this was about 20 years ago.

I might add that he lived to be 92 years old and didn’t have cancer or heart trouble.

So thank you very much for yielding, Mr. Kucinich.

Mr. KUCINICH. Just in conclusion, so that we can move on here, what comes from any study of holistic medicine is an understanding that healthcare is a profoundly personal matter. In line with what I indicated previously about a symmetry with democratic tradition and personal responsibility, we learn, as we explore alternative practice, that there is something, a process that begins inside of each of us.

Mr. Waxman referred to the potential for spiritual considerations in that. Belief systems, faith, and hope are all part of that process that, in effect, happens before we meet that outside world, which offers us a variety of choices. So I think that as we look at this, the many options which are available to us begin, first, with our own decision to be open-minded in approaching the possibilities of better healthcare, which begin with ourselves.

Ms. SEYMOUR. Yes, we don’t want to be statistics. We want to be considered as human beings, as people. You are very right; if you believe that you are going to be well and that you can be healthy, an enormous amount can be done. The mind can override enormous symptoms.

Mr. KUCINICH. Thank you again.

Ms. SEYMOUR. Thank you.

Mr. BURTON. Thank you, Mr. Kucinich. Mrs. Morella.

Mrs. MORELLA. Thank you, Mr. Chairman. Again, this is a very informative hearing. Ms. Seymour, it is a delight to have you here. You are a role model. So, therefore, what you say has a tremendous effect on attitudes.

I just guess I want to try to synopsise your feeling, and that is that attitude is altitude; as we approach something, attitude is critically important; that balance is important and openness. For instance, I think the American public has reached the point where

we are skeptical. We just don't know what to believe. One day we hear about St. John's Wort or something that is going to take the place of the antidepressants. We hear about other possible medications or herbs that could be used for arthritis. From one day to the next week, we find that there are differences in approaches. So our confidence is kind of eroded. We just don't know what to believe.

I guess what you are saying is you have got to continue to use mammograms, using that just as an example, since you mentioned it; you have got to continue to have co-rectal examinations, but at the same time you should be open to the totality or the homeopathy. Is this correct?

Ms. SEYMOUR. To some degree. There are other options to mammograms. I think the point I am saying is, rather than the routine mammograms that we blithely all take without considering the cost to ourselves healthwise in terms of the radiation and the fact that it could cause cancer, there are other ways of doing this which are far more cost-effective, which are thermography. I tried it the other day, and it is amazing how they can discover what is wrong with different parts of your body and accurate they were. I had a blind test done on me because I didn't believe in it. Sure enough, we called up my internist and my dentist, and the findings were absolutely agreed up. So there are other ways of detecting disease like that, without necessarily hurting the human being.

So I guess it should be investigated anyway.

Mrs. MORELLA. It is an openness, that we look to the various facets, the various aspects. I just don't want people to think that they can't go off and get these examinations regularly, or that they should not be part of their routine.

Ms. SEYMOUR. No, but I do think that it would be nice if we could spend some of those billions of dollars on looking at thermography. There are only 30 people practicing that in this country right now, whereas there are thousands in Europe, where they are doing this very successfully. This would also be a wonderful option for people in Third World countries, where they could really detect what was wrong with patients very inexpensively, very quickly. A lot of people could be helped.

Mrs. MORELLA. I want to thank you. Also, I want to thank you, Mr. Chairman, for the articles that you have given us all, too, that I think are very uplifting in terms of the number of opportunities that are open with regard to alternative medicine. Thank you. Thank you, Mr. Chairman.

Mr. BURTON. Would you yield to me just real quickly?

Mrs. MORELLA. Indeed, yes.

Mr. BURTON. I don't have the exact figure in front of me, but I think \$20 million is being used for alternative therapies and alternative therapy research by the departments of health in our country, and \$2.3 billion is being used for conventional medicine. I think one of the things that we need to do, and I hope we are stressing today, is giving more funds for the alternative therapy research and complementary research, instead of just going ahead with the conventional approach that we are taking.

We had a doctor named Dr. Barry Marshall. Dr. Barry Marshall came up with a theory that stomach ulcers were not caused by nerves; they were caused by a bacteria. Well, conventional wisdom

in the medical profession for years and years and years and years was that it was caused by nerves. They said that bacteria could not live in the acidity of your stomach. Well, he did some research and found that it could. He gave a speech—I think it was in Belgium—about this and he was laughed off the stage, literally. He then went home and drank the bacteria, became deathly ill, and cured himself with a combination of bismuth and some antibiotics.

But the point is, there are billions of people in this country that are suffering from stomach ailments that can be cured because of his research. But he was ignored, not unlike what Pasteur was, for a long time. He proved that the bacteria does live in the stomach, and this alternative therapy research that he did alone is going to save thousands, maybe millions, of lives and millions of people from this kind of pain.

That is why I think, and I hope, these hearings that we are going to continue to have will point out the fact to the National Institutes of Health, to FDA, and everybody else, that we need to have more funds used for research into alternative therapies. Because if we do that, we are going to find, like Ms. Seymour has said, that there are alternatives out there that are not as dangerous that are going to help humanity.

I thank the gentlelady for yielding.

Mrs. MORELLA. Thank you. NIH is in my district, and I know that they are moving ahead with alternative medicine.

I just wanted to point out there is no one panacea. So we need to look at the entirety, and not just one little facet of it.

Ms. SEYMOUR. Yes, if I may quickly add—I didn't know if I had time in my 5-minute speech, but we see incredible results with acne, which a lot of people suffer from acne and adult acne. Homeopathy can cure this within 4 days—it is amazing—without the use of injections and steroids and antibiotics and birth control pills and Accutane, which, of course, is very bad for women.

There are options also with migraines and things like these. These are huge issues for the American public that can be helped very inexpensively and very quickly without any adverse effects.

Mr. BURTON. Thank you, Mrs. Morella. Ms. Norton, do you have any questions?

Ms. NORTON. Thank you, Mr. Chairman. Mr. Chairman, I think these hearings are very important, and I appreciate that you have called them.

And I appreciate your last statement about research, because in a very real sense oppositional thinking about alternative medicine and traditional medicine is very unhealthy, is not good for your health. Hearings like this I think are important for the way in which they—for particularly the notion of what is necessary in order to have an informed public.

Ms. Seymour, I think we are very fortunate that you have been willing to come forward. By your own high profile, you raise the profile of this very important subject.

Our country is abysmally behind on coming to grips with alternative medicine. It is hard for me to criticize my country in this regard when I realize what it has done in traditional medicine; that in a real sense it is like being ahead in soccer, and I think you neglect the other sports. We are so ahead on what we have

given to the world in everything from AIDS to—that we let this slide. We are only now coming to grips with it.

I have read books that—I must tell you, the only books that convince me about anything are books that have been written by people trained in medicine who have something to compare it with.

I have a question about the way we go about this. I have to confess that, without scientific evidence, I have myself often been very open to alternative suggestions about what to do, and, anecdotally, have found some of them to be effective. I am more inclined to insist upon the scientific medicine when it comes to traditional medicine than I am to alternative medicine. That is proper, because what the public kind of reads in the newspaper, in the magazines, gets absorbed as what kind of alternative medicine should be done.

That is why what the chairman said about research is no less important for alternative medicine than it is for any other kind of medicine—I want to just take issue with your notion, for example, about mammograms. Some of us who are women in this Congress have had a hell of a time getting women to be sufficiently unafraid to get mammograms because of all this stuff about radiation; that the whole notion that anybody without research would say, “Well, I think I am going to wait until thermo-something”—look, all the scientific evidence now tells us that there is not radiation danger, and that if there is, it pales beside the danger of not getting a mammogram.

It is very important that there be research into alternative methods. I would support that. But, again, the public really is just left out there now. Whatever comes through the microphones, including what we say here today, becomes what you ought to go out and do. That is not the case with traditional medicine, because there has been some regulation.

I associate alternative medicine as well with preventative medicine. That is one of the reasons why I am a great supporter of it. I applaud what NIH is doing. I don’t think it is enough, and I think it came too late, but I think it is important to do.

I don’t agree that more training is necessary in order for doctors to do this. I have a young doctor. Young doctors who keep up with good medicine will prescribe alternative medicine. If you go to a doctor who does not know anything about alternative medicine, you ought not go to that doctor, because if she is reading in the literature, she ought to know what is effective and not effective. I don’t think people should listen to anybody except a doctor or a scientist about what is effective or not effective, although I applaud the notion of doing what I do. As an intelligent consumer, if you all don’t know yet, and nobody tells me that this is harmful to me, well, I am going to do what I think is good for my health. That does not stand in the place of research.

Now I have a question to ask you, because I found your testimony very balanced. For example, you report in your testimony 110 deaths annually from the use of medical drugs. Well, you know, we can get to the point where somebody is going to report, because there are no controls, because there is no good information about deaths from alternative medicine. We are already getting those kinds of reports.

The question for society for alternative medicine is the same question society had when it had to decide whether or not you ought to have x rays for your teeth or whether you ought to listen to these people that say that, if you do, something will happen; you will float into the universe.

You have to intelligently decide whether or not there has been sufficient investigation, and there is no way for the public to know now. Thus, the public does what I do. Look, if you say a megadose of A, B, C vitamin will help me feel better in some way, well, fine, let me do this because nobody told me it will kill me. So I am going to use a megadose. It is not very good, Eleanor, but that is what I do.

Now in your testimony you also said something very important here. You said, "I am not here to vilify western medicine; I am looking for inclusion, not exclusion." And that is where our country has failed—exclusion of alternative medicine.

I would like to ask you whether or not—I noted that in your breast cancer example these three women who used alternative medicine had found that the doctors had said to them, "There is nothing more we can do for you." Now, of course, there are women all over America, and these stories are beginning to come out, for whom something can be done, who believe that this kind of traditional medicine or that kind of traditional medicine for breast cancer isn't what they should do. So they are more likely to go into some alternative which has not been scientifically shown.

I am asking you whether or not you would feel more comfortable if there were far more—if our country engaged in a regime of greatly increased controlled studies, so that the public could make informed decisions, instead of anecdotal decisions, about what is best for their health.

Ms. SEYMOUR. There are studies, conclusive studies in—

Ms. NORTON. I am not talking about where there are studies. I am talking about where there are not studies.

Ms. SEYMOUR. We should make studies, yes, and I would like that. I think this is what we are asking for today. Let's appropriate some of those funds and get onto it right away, and have those tests done, maybe even blind testing, the way they did it in England.

Ms. NORTON. It must be blind testing.

Ms. SEYMOUR. Do it in the hospitals, and allow the people to have it, rather than waiting another 20 years and then find out that what they were doing for 500 years did work.

I am certainly not saying that mammograms shouldn't be done, and I am certainly not saying that in breast cancer you should not have chemotherapy. What I am saying, and what I testified—and I am sorry if I was misunderstood—is that we are talking about inclusion here. We are talking about doing chemo alongside Chinese herbal medicine, which will help the patient to survive not only the cancer, but the chemotherapy. We have seen countless stories of people where this has worked.

I guess while we are eventually, however this happens in government, appropriating those funds, so we can investigate these and find out who the true practitioners are, what the real scientific data, and everyone gets happy about it. Meanwhile, Americans are

trying these things. You, indeed, yourself are trying these things. You, indeed, are sort of admitting that they do work for you.

Ms. NORTON. Absolutely do.

Ms. SEYMOUR. Absolutely.

Ms. NORTON. I want to make sure that I am not having an effect in my mind rather than in my mind.

Ms. SEYMOUR. Well, the other people are the doctors, and they will tell you, but, from what I have been told in my data, maybe one or two people, if that, died last year from homeopathy, from side effects of homeopathy. It is almost impossible to die from a side effect from those forms of alternative medicine, whereas it is very easy and has been scientifically proven that over 110,000 people died last year from adverse drug reactions. These are not people who took drugs without being told by the doctors. These were people who were specifically designated to take those drugs for those specific things, and at the time it seemed to be appropriate for them to take those things.

Ms. NORTON. Thank you, Mr. Chairman.

Mr. BURTON. Ms. Chenoweth.

Mrs. CHENOWETH. Thank you, Mr. Chairman.

Mrs. Seymour, I can't tell you how very pleased I am that you are here today.

John Kennedy, back in the 1960's, who was not the President of my party, but I am deeply grateful to him for raising the awareness of how important exercise is in our life. And perhaps you will help supplement how important it is that we control our own health and stay ahead of the power curve in terms of boosting our immune systems and staying healthy. You may very well be one who will take us on into the next century in boosting the public awareness that we need alternative forms of medicine.

You, like I, we are both very busy women. We shake a lot of hands, and we see a lot of people. We fly on a lot of airplanes. We are exposed to a lot of things. I find it interesting, Mrs. Seymour, that I am 61, and my 30-something-year-old staff have to follow me out to Idaho and back for a weekend and take 2 days to recover. [Laughter.]

Now the only difference is that I believe in homeopathy and I take massive doses of vitamin C. The reason I did, after having worked for physicians for 18 years and really appreciating all that they do for their patients and the love they have for their patients, and how much they give—nevertheless, there was such an entire freeze-out of other alternative forms of medicine from the status quo institutional form of medicine, that when someone suggested to me, when I had a very severe case of Manieres disease, that I see a naturopath, I thought they were crazy. Finally, when the physician suggested surgery in the head for a shunt to relieve the symptoms of the Manieres disease, I finally went to a naturopath, who took a hair analysis and put me on zinc. The symptoms disappeared.

I went out of obligation to the naturopath because of the deep respect I had for the person who just begged me to do it. Now not everybody can have a miracle cure like that, but it certainly made me realize alternative forms of medicine are so important to us being able to stay healthy and not ever have to, hopefully, expend

a lot of money as we reach the final years of our life, which I don't expect will be for quite a while for me, but I intend to stay healthy.

Thank you very, very much for your contribution. It is deeply appreciated.

I want to share with you the fact that there was a recent decision in the 10th circuit court of appeals involving two litigants, Dirk Pearson and Sandy Shaw, who challenged the FDA on the first amendment rights for people involved in homeopathy to be able to talk about the results of their alternative medicine. The court agreed with them that it is a first amendment right. In fact, the court bifurcated the decision and said, we will deal first with the constitutional issue of first amendment rights, and then we will come down after with a decision on the Administrative Procedures Act. That was significant in the way the court did that. The court, obviously, felt very compelled about first amendment rights in this issue. I was thrilled to see the way the court dealt with it. If you haven't seen that case, I recommend it to you.

I think that it is important, Mrs. Seymour, that the government, the Congress recognize the importance of alternative form of medicine. I think that we need to support it in research. But, looking down the pike, if we give government money for supporting research, I want to make sure that those first amendment rights are guarded, and that government does not exert undue control, to the point that, again, we lose control of our own ability to stay healthy.

Thank you so much for what you are doing, and thank you very much for being here.

Ms. SEYMOUR. Thank you.

Mr. BURTON. Thank you, Ms. Chenoweth. Ms. Norton has an introduction, I think, real briefly here.

Ms. NORTON. I thank you, Mr. Chairman, for allowing me to introduce some youngsters who I am very glad have gotten to hear this.

I do want to say to Ms. Chenoweth that the reason that the young people who travel back are so much more tired than you may be the same reason that you don't look 61. [Laughter.]

Good genes.

Mrs. CHENOWETH. Very good genes.

Ms. NORTON. Mr. Chairman, I am pleased that the youngsters from the Knolle Elementary School had an opportunity to sit in. They are part of a program that I run for D.C. youngsters, who, after all, live in the District, called D.C. Students in the Capital. I want to welcome them. I will take them out in the hall now to say a few words to them.

Thank you, Mr. Chairman.

Mr. BURTON. Thank you, Ms. Norton, and welcome to you, students. It is nice that you are here learning more about your government.

Mr. Davis.

Mr. DAVIS. Thank you very much.

I know it has been a long morning for you, Ms. Seymour, but thank you very much, because I think what you have to say is very important. Sometimes somebody of your stature coming up here and saying it just wakes everybody up to something we have been hearing anecdotally for some time.

My wife is an OB/GYN. She was a tenured professor of obstetrics and gynecology, but I think she would agree with everything that you have said today.

I don't think there is any reason we can't, up here in Congress, direct some money for the complementary medicine departments or courses in the medical schools, so at least doctors will have some exposure to this. Right now they don't seem to get it. In fact, conventional medicine, there is almost a push on against some of this.

Your coming up here and speaking about it, and opening up that a lot of us have anecdotal information, I think helps that a lot.

The key here is that Washington and Congress, and even the medical establishment, doesn't always know best. We are dealing in some very changing areas where we are learning new things every day. We want to enable consumers to make their best choice. We best do that by the kind of things that you have outlined here—giving them the full gamut of information, so they can make intelligent choices, and letting our doctors and medical community, NIH, and others do some exploration to see why some of these things seem to work; that it is not necessarily in somebody's head if it is working medi-physically as well.

So you have done a great job. I appreciate your being here, and I hope that we can followup legislatively to some of that. I know it has been a long morning. I won't use all my time. But thank you very much.

Ms. SEYMOUR. Thank you.

Mr. BURTON. Thank you, Mr. Davis. Ms. Biggert.

Ms. BIGGERT. Thank you, Mr. Chairman.

Mrs. Seymour, I was in Bolivia over our break on another issue, but we had the opportunity to stop by a museum, which was a museum of preventative medicine by the natives, Indians, of Bolivia. It was quite interesting to see the bottles of herbs and the way that they addressed—by looking at animals and the organs, how they would determine whether somebody had that illness.

I wondered if that really is a part of homeopathic medicine. Has there been any movement to categorize what is used in, well, Native American or other countries, the types of medicines that they use that has been of help to us?

Ms. SEYMOUR. Well, I think, obviously, the people to ask about homeopathy are here today. You should address them on that issue.

I always found it amusing, when I was playing Dr. Quinn, that digitalis is what the Native Americans suggested as one of the herbs that she used. Then, of course, the Native Americans had herbs which, of course, are now used in synthesized form in our regular medicines today.

So, yes, very much, I think these are things that we should look into. I mean, we all now take echinacea, a large number of the population. Not very long ago, everyone said "echinacea what?" What is this stuff? As he said, Linus Pauling and vitamin C, and I am sure Bolivia has a lot of things to offer us and I am sure there are experts here who can answer you exactly on that.

Ms. BIGGERT. Thank you, Mr. Chairman.

Mr. BURTON. Thank you.

We now have a vote on. So what I think we will do is we will have the committee break, go down and vote, and come back. As soon as we return—and I apologize to the second panel—we will have the second panel come forward.

Dr. Ornish, I understand you have limited time. You have time constraints. So we will have you testify first and see how we are going on time. Then, at around noon, we have food and refreshments back there for the panelists. So we will break around noon, and then we will come back and finish right after we have lunch.

Ms. Seymour, you have been a lovely witness. We really appreciate your being here. If you can stay around later, fine. If not, we will see you later on today.

Ms. SEYMOUR. Thank you.

Mr. BURTON. Thank you very much.

We stand in recess to the fall of the gavel.

[Recess.]

Mr. BURTON. Because of Dean Ornish's time constraints, I would like to go ahead and get started with his testimony. Then we will break shortly after that for about 20–25 minutes, so everybody can get a bite to eat. Then we will come back and finish with the second panel.

Would the second panel come forward.

So, Dean Ornish, welcome. We really appreciate your being here. I have read a great deal about you. Since we want to save some time and get you on your way in a timely fashion, we will go ahead and let you testify now.

STATEMENT OF DEAN ORNISH, M.D., PRESIDENT AND DIRECTOR, PREVENTIVE MEDICINE RESEARCH INSTITUTE, AND CLINICAL PROFESSOR OF MEDICINE, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, CA

Dr. ORNISH. Well, thank you, Mr. Chairman. I don't know how much time you want, but I am available until 10 after 1, just so you know.

Mr. Chairman, members of the committee, Ms. Clay, thank you very much for the opportunity to be here today. My name is Dean Ornish. I am a physician. I am founder, president, and director of the nonprofit Preventive Medicine Research Institute and a clinical professor of medicine at the University of California, San Francisco, School of Medicine, where I am also one of the founders of the new Osher Center for Integrative Medicine there.

The theme of all of my work is simple, and that is, if we don't treat the underlying cause of a problem, any problem—in this case, heart disease—that more often than not, the same problem comes back again. We get a new set of problems or side effects that we hadn't counted, or on a social and health policy level we are often faced with painful choices.

Whenever I lecture, I often start by showing a cartoon of doctors mopping up the floor around a sink that is overflowing, and nobody is turning off the faucet—a little like ignoring the oil indicator light on the car that Ms. Seymour was talking about.

During the past 22 years, my colleagues and I have conducted a series of clinical trials demonstrating for the first time that the progression of even severe coronary heart disease often is actually

reversible by making comprehensive changes in diet and lifestyle. These include a low-fat vegetarian diet, moderate exercise, stopping smoking, a variety of stress management techniques, including stretching and breathing and meditation exercises, and a lot of emphasis on psycho-social and emotional support.

This was a radical idea when I began my first study 22 years ago. It has now become mainstream—the idea that heart disease is often reversible. It has become generally accepted by most cardiologists.

In my testimony and in my research I am going to focus on heart disease, but I think it is also a much bigger issue. It is an example of how powerful changes in diet and lifestyle can be. We often think it has to be a new drug or a new laser or a new surgical technique, or something really high-tech and expensive to be powerful. We often have a hard time believing that these simple choices that we make in our lives every day can make such a powerful difference, but they do.

In the research that my colleagues and I have done, we have used these very high-tech, state-of-the-art measures to prove the power of these very ancient and low-tech, and low-cost interventions.

Within a few weeks after making these changes, the patients in these studies showed a 91 percent reduction in the frequency of chest pain. Most of them became essentially pain-free, including those who had been unable to work or even walk across the street without getting severe chest pain. Within a month, we found that those patients not only felt better, but in most cases they were better in ways we could actually measure. We found that the blood flow to the heart improved. We found that the ability of the heart to pump blood was better. After a year, we found that even severely blocked arteries began to become measurably less blocked, became improved, in 82 percent of the patients.

These research findings were published in the most respected peer review medical journals, including the *Journal of the AMA*, 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 NIH. Although it is very difficult to get funding to do this kind of work, and early on, when I began doing it, it was a bit of a catch-22, because it was thought impossible to reverse heart disease. So it was hard to get funding from the government and from the conventional major foundations. Without the funding, we couldn't show it was feasible. And since they didn't think it was feasible, they didn't want to fund it. And then they said, well, where's the evidence to show that we should fund it? It becomes a self-fulfilling prophecy.

I might add, by the way, that in order to get the studies underway, we said, let's just raise the money as we go along and hope that we can do it. As we began to get more data showing it was working, initially financed by just individuals who thought this was an interesting idea, over time we later got major foundation and much later NIH support.

In our latest report, which was published in the December 16, 1998 issue of the *Journal of the AMA*, we found that these patients

were able to stay with it for 5 years, not just for 1, and, on average, they showed even more reversal of heart disease after 5 years than they did after 1 year.

In contrast, the patients who were in the comparison or control group, who were making more moderate changes, got worse after 1 year, and even worse after 5 years. So moderate changes don't go far enough even to stop heart disease from getting worse. But the good news is that, if people are willing to make bigger changes, they can stop and in most cases even reverse it.

We also found that the incidence of cardiac events, like heart attacks and strokes and operations, was 2½ times lower in the patients who made these lifestyle changes than in the control group.

There has been strong interest in the general public as well, as Ms. Seymour has alluded to. A 1-hour documentary of our work was broadcast on NOVA, the PBS science series, and was featured in Bill Moyers' series, "Healing in the Mind."

I think these research findings have particular significance for older Americans and the Medicare population. One of the most meaningful findings was that the older patients who made lifestyle changes in our research improved as much as the younger ones. When I began doing this work, I thought that the younger patients with milder disease would be more likely to show reversal, but I was wrong. The major determinant of improvement wasn't how old or how sick they were; it was how much they changed. In fact, the oldest patient, who is now 83, showed more reversal than anyone.

This is, I think, a very hopeful message for people in the Medicare population, because it says, since the risk of bypass surgery and angioplasty increase with age, that the benefits of changing lifestyle occur at any age, I think that this has particular benefit for older Americans and offers many of them new hope and new choices that they didn't have before.

I think these findings have particular significance also for women. This is by far the leading cause of death in women, especially in the Medicare population. They have less access to conventional treatments like bypass surgery and angioplasty. I spoke for the Surgeon General's Conference a couple of years ago on this very issue. When women do get operated on, they don't do as well as men. They have higher rates of mortality and morbidity following a bypass or an angioplasty. So that is the bad news.

But the good news: Women seem to be able to reverse heart disease easier than men can, whether through diet and lifestyle or even through lipid-lowering drug therapy. If you give a woman estrogen to lower the risk of heart disease, you raise their risk of breast cancer. But if you change lifestyle to lower the risk of heart disease, you lower the risk of breast cancer and osteoporosis. Here again, when you treat the cause, you don't have to make these painful choices that often occur when we literally or figuratively just bypass the problem without also treating the cause.

The next research question, once we demonstrated that heart disease was reversible, and that became generally accepted, was: How practical is this? People said, well, sure, you can reverse heart disease, but you live in California; they will do anything there; no one else can do this. So we began training hospitals around the country.

As you know, there has been bipartisan interest in finding ways of controlling healthcare costs without compromising the quality of care. Many people are concerned that the managed care approach is simply shortening hospital stays and shifting to outpatient surgery and forcing doctors to see more and more patients in less and less time, while compromising the quality of care, because, here again, they are not treating the cause. It is frustrating for physicians, and it is frustrating for patients as well.

Beginning 5 years ago, my colleagues and I established the Multi-Center Lifestyle Demonstration Project, a nonprofit institute. We wanted to find out: How practical is this? Can we train other health professionals in other parts of the country to do this? Can they motivate their patients to the same degree that we did? Can this be not only a medically effective, but also a cost-effective alternative to things like bypass surgery and angioplasty?

In the past, lifestyle changes have been viewed as prevention, but we are showing they can also be an alternative treatment. I went to insurance companies and I said, "Would you pay for these kinds of interventions?"

They said, "No, we don't pay for diet and lifestyle."

"Why not?"

"We don't pay for that because that is prevention. We don't pay for prevention."

"What is wrong with prevention?"

"Twenty to thirty percent of people change companies every year. It may take years to see the benefits. So why should we spend our money today for some future benefit that may occur years later, when chances are some other company will get it?"

And I said, "It is the right thing to do." That wasn't persuasive enough. So I said, "It is not just prevention. It can be an alternative treatment. For every patient, every man or woman, who chooses to change lifestyle rather than, say, undergoing bypass surgery, you save \$50,000 immediately—real dollars today, not just theoretical dollars years later."

They replied, "That sounds great in theory. We don't think people can do it. So it is too hard to change lifestyles. So if we pay for your program, most patients who can't follow it, we will end up paying for their bypasses anyway. Now our costs have gone up rather than down."

So the missing links really were the data on adherence. Then not only the immediate savings, but also the long-term savings can occur because so many bypasses and angioplasties clog up after just a few months or a few years; 40 to 50 percent of angioplastied arteries clog up again within just 4 to 6 months.

There is potentially a lot of money to be saved. In 1994, over \$15 billion in the United States was spent just on those two operations. So that even if only 20 or 30 percent of the people were willing to make these changes, it is a savings of billions of dollars per year—real dollars today, because it is a direct alternative to these treatments.

So we have trained a diverse selection of hospitals—Alegeon Emmanuel Center in Omaha, and Mercy Medical Center in Omaha, Beth Israel Medical Center in New York, Mercy Hospital in Iowa, Broward General Hospital in Ft. Lauderdale—a whole list of them

that are in my written testimony. Also, High Mark, which is western Pennsylvania Blue Cross/Blue Shield is both providing the program as well as covering it. Over 40 other insurance companies are covering this program as a defined program at the sites that we have trained.

We have been approved by the Technology Assessment Committees of Blue Cross and of Blue Shield of California separately two separate times, and found to be reimbursable and noninvestigational.

What we found, which we published in the American Journal of Cardiology 3 months ago, was that 77 percent of men and women who were eligible for bypass surgery were able to avoid it by changing lifestyle, by going on our program.

Mutual of Omaha, which was the first insurance company to cover this program, calculated savings almost \$30,000 per patient immediately. These patients reported reductions in chest pain or angina comparable to what you can get with bypass surgery or angioplasty, but without the costs and the risks of going through that.

Now what about Medicare? Over half a million Americans die annual from coronary heart disease, making it by far the leading cause of death in both men and women. As I mentioned, \$15.6 billion was spent in 1994, more than for any other surgical procedure. Not everybody is interested in changing lifestyle, but a lot of people are, and billions could be saved if people changed.

But, as you said in your opening remarks, Mr. Chairman, for many Americans the denial of coverage is the denial of access. Surgery is covered; angioplasty is covered, but lifestyle changes are not.

Because of the success of our research and demonstration projects, we asked HCFA, the Health Care Financing Administration, to consider providing coverage for this program, or ones like it, if they had the evidence to prove that they were. I really believe that this can help provide a new model for lowering Medicare costs without compromising the quality of care or access to care. It is a new model that is more caring and more compassionate and more cost-effective and competent, because we are treating the cause; we don't have to have these painful choices.

This approach empowers the individual. It can immediately and substantially reduce healthcare costs by billions of dollars, while improving the quality of care, rather than limiting access to it. It offers the information and tools that allow individuals to be individually responsible, personally responsible, for their own healthcare choices and decisions, and it provides access to quality, compassionate, and competent, affordable healthcare to those who most need it.

Now, without going into the details—and I am happy to elaborate in the question-and-answer period—I first began meeting with officials from HCFA in June 1994, almost 5 years ago, and I have had many, many meetings and conversations with them since then. Then, as now, the concern was that, if we start to pay for anything other than surgical procedures, and so on, if we start to pay for anything that is, “alternative” medicine, then a Pandora's box would be opened. In other words, anyone who had any kind of al-

ternative medicine program would say, well, you are covering this program; why don't you cover ours? Or, even in a more limited way, people who had one for treating heart disease would say that. I understand this concern. It is a valid one.

In the first meeting almost 5 years ago with people from HCFA, I was accompanied by the medical director at that time with Mutual of Omaha. He said,

We have the same concerns and here is how we dealt with it: We only pay for programs that have scientific data to support them, whether they are traditional or nontraditional approaches. And this right now is the only lifestyle intervention that has scientific data from randomized control trials showing that it can reverse heart disease. So we paid for it. And when other people develop those data or they have programs that are similar enough, we will pay for those, too.

I appreciate very much the leadership of Honorable Nancy-Ann Min DeParle and her colleagues, Dr. Jeff Kans, Dr. Bob Berenson, Dr. John Whyte, and others at HCFA. After going back and forth with them for years now, during which a variety of different options have been considered, including a demonstration project, I am respectfully requesting that HCFA now make a decision to cover this program for selective patients.

Another demonstration project would, in effect, duplicate largely what we have already done and what we have already published in peer review journals. It would cost millions of dollars. It would take years before a coverage decision could be made, and I think the time is right to do it now because Americans can benefit from this.

Coverage can be limited to those people who are choosing this program as a direct alternative to a bypass or angioplasty, because these are the patients for whom the cost savings are the most dramatic and the most immediate. It, also, can reduce the likelihood of fraud and abuse because you have to get a letter from your doctor saying that this person is sick enough to need a bypass. You have present test data from angiography and other tests showing that this person really is qualified to have a bypass or angioplasty. Because the program is difficult, people who aren't interested in changing lifestyle to this degree aren't going to do it, and they self-select, which is good. Because the real question is not, how many Americans are willing to change; the real question, if I were at HCFA, would be, how likely is it, if we pay for someone, that they are likely to succeed? If they self-select for people who are likely to succeed, that is OK. That is part of the reason why we found that almost 80 percent of people were able to avoid these operations.

Then my colleagues and I would be happy to work with an outside group. I am meeting in 10 days with the heads of the American College of Cardiology at their annual scientific meeting in New Orleans to say, you could be a credentialing group to certify who has the scientific evidence—not just as anyone who has the evidence to support that their program works. That can meet HCFA's understandable need for credentialing of programs, to make the program available to the people who most need it.

In response to an earlier request from Bruce Vladeck, Honorable DeParle's predecessor, Dr. Claude Lenfant, the Director of the Heart, Lung, and Blood Institute at NIH, evaluated this program,

found it to be safe—actually, had to go through a process saying it was safe for older Americans to walk and meditate and quit smoking and eat vegetables, but we have been through that process.

We also have strong bipartisan letters of support from some of the most conservative Republicans, some of the most liberal Democrats, and everyone in between. I think this committee is an example of how this is a basic need that affects all Americans. This is an area we can all come together, I think at a time when our country really needs that kind of bipartisan support.

We have support from some of the country's most eminent medical authorities: Dr. Alexander Leaf, who was the chief of medicine at Harvard; Dr. Christine Cassel, who is the immediate past president of the American Board of Internal Medicine in the American College of Physicians; Dr. Marion Nestle, the chairman of nutrition at NYU, and so on.

We also appreciate very much a recent appropriation from Congress to the Department of Defense to make this program available at the Walter Reed Army Medical Center. I am very grateful to Dr. James Simbol, who is the president of the Uniformed Services University, and Dr. John Mazzuchi, in the Office of the Secretary of Defense, who are here this morning.

Because if heart disease can be reversed, not only can it save money in the military, but the implications for prevention are even greater. As we have talked about, we focused on heart disease as a model, but I think the same kind of lifestyle interventions can reduce the likelihood of diabetes, hypertension, obesity, breast cancer, prostate cancer, and colon cancer.

I am directing a study now, in collaboration with Dr. William Fair from Memorial Sloan-Kettering Cancer Center, who has been the chief of urology there, and Dr. Peter Carroll, the chairman of urology at UCSF, to see whether the progression of prostate cancer might be stopped or reversed. It is the first randomized control trial to look at that. Our preliminary data are very encouraging, and if it is true for prostate cancer, chances are it may be true for breast cancer as well.

A recent editorial by the editors of the *New England Journal of Medicine* last year said, "There can't be two kinds of medicine, conventional and alternative." This is very similar to what was said earlier about the *JAMA* editorial.

There is only medicine that has been adequately tested and medicine that has not; medicine that works and medicine that may or 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.

Now this program, our lifestyle program, has been tested rigorously. It has been found to be safe and effective. It works. So, therefore, I respectfully submit that it should be covered by Medicare for selective heart patients as an alternative to a bypass or angioplasty.

Everyone benefits. Patients have access to new choices that empower the individual. Health professionals have new options to serve their patients. Medicare does something innovative to lower healthcare costs without compromising the quality of care, and

Congress can demonstrate bipartisan leadership in an area that is important to so many Americans.

I appreciate very much the opportunity to be here today. I would be delighted to answer any questions you may have.

[The prepared statement of Dr. Ornish follows:]

Preventive Medicine Research Institute

A non-profit public institute dedicated to research, education, and service

Dean Ornish, M.D.
Founder, President & Director
Preventive Medicine Research Institute
Clinical Professor of Medicine
School of Medicine, University of California, San Francisco
900 Bridgeway, Suite 1, Sausalito, California 94965
phone: 415/332-2525 x222; FAX: 415/332-5730
e-mail: DeanOrnish@aol.com

Testimony of Dean Ornish, M.D.

Committee on Government Reform
Congress of the United States
House of Representatives

Hearing:

“Opening the Mainstream to Complementary and Alternative Medicine:
How Much Integration is Really Taking Place?
An Inquiry into Access to Complementary and Alternative Medicine in
Government-Funded Programs”

February 24, 1999
2154 Rayburn House Office Building
Washington, D.C.

INTRODUCTION AND BACKGROUND

Mr. Chairman, members of the Committee, thank you very much for the opportunity to be here today. My name is Dean Ornish, M.D. I am Founder, President, and Director 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 a founder of the new Osher Center for Integrative Medicine at UCSF.

The theme of all of my work is simple: if we do not treat the underlying causes of a problem—in this case, heart disease—then the same problem may recur, new problems may emerge, or we may be faced with painful choices. Whenever I lecture, I often show a cartoon of doctors mopping up the floor around an overflowing sink without also turning off the faucet.

During the past 22 years, my colleagues and I have conducted a series of 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, low-cholesterol diet, stress management techniques, moderate exercise, smoking cessation, and psychosocial support. This was a radical idea when I began my first study; now, it has become mainstream and is generally accepted as true by most cardiologists and scientists.

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% of the 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.

THE LIFESTYLE HEART TRIAL

In our latest report, published in the December 16, 1998, issue of the *Journal of the American Medical Association*, we found that most of the study participants were able to maintain comprehensive lifestyle changes for 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 most physicians (i.e., a 30% fat diet) worsened after one year and their coronary arteries became even more clogged after five years. 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. There has been strong interest in this research in the general public as well. 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 I began the research, I believed that the younger patients with milder disease would be more likely to show regression, but I was 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 83) 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 even easier 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?

As you know, 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. Despite the great expense of bypass surgery and angioplasty, up to one-half of bypass grafts reocclude after only five to seven years, and 30-50% of angioplastied arteries restenose after only four to six months— an example of mopping up the floor around the overflowing sink without also turning off the faucet. When this occurs, then coronary bypass surgery or coronary angioplasty is often repeated, thereby incurring additional costs.

Through our non-profit research institute (PMRI), we trained a diverse selection of hospitals around the country. The initial sites were Alegant Immanuel Medical Center/Alegant Heart Institute, Omaha, NB; Alegant Bergen Mercy Medical Center, Omaha, NB; Beth Israel Medical Center, New York, NY; Mercy Hospital Medical Center/Iowa Heart Center, Des Moines, IA; Broward General Medical Center, Fort Lauderdale, FL; Palmetto Richland Memorial Hospital, Columbia SC; Mt. Diablo Medical Center, Concord, CA; Beth Israel Deaconess Medical Center/Harvard Medical School, Boston, MA; Scripps Hospitals and Clinics, La Jolla, CA. Additional program sites included the School of Medicine, University of California, San Francisco; California Pacific Medical Center, San Francisco; Franciscan Health System of the Ohio Valley, Cincinnati Ohio; Swedish American Health System, Rockford, IL; and Swedish Medical Center/First Hill, Seattle, WA.

Also, Highmark Blue Cross/Blue Shield of Western Pennsylvania was the first insurer to both cover and to provide this program to its members. Over 40 other insurance companies are covering this approach as a defined program at the sites we have trained. The Technology Assessment Committees of both Blue Cross of California and, separately, Blue Shield of California have evaluated this program and determined it to be reimbursable and non-investigational.

In brief, we found that 77% of people who were eligible for bypass surgery or angioplasty were able to avoid it safely by making comprehensive lifestyle changes in the hospitals we trained. Mutual of Omaha calculated an immediate savings of \$29,529 per patient. These 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 operation by making comprehensive lifestyle changes after surgery.

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 1994 at a combined cost of approximately \$15.6 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 disease need 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 to consider providing 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, 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.

I first met with officials from HCFA on June 9, 1994, almost five years ago, and many times since then. Then, as now, concern was expressed that if HCFA were to cover an "alternative medicine" program, then a "Pandora's Box" would be opened. In other words, if HCFA covered this program, then everyone who had any kind of alternative medicine program would demand coverage. Or, even in a more limited way, everyone who had an alternative program for treating coronary heart disease would demand coverage from HCFA.

I understand this concern. In the first meeting with HCFA in 1994, I was accompanied by the medical director of Mutual of Omaha. In response to this issue, he replied that Mutual of Omaha made a decision to provide coverage for this program because it has the scientific data from many years of randomized controlled trials demonstrating safety and efficacy. If other programs develop this scientific evidence of safety and efficacy, then Mutual of Omaha would consider providing coverage for those programs as well. Other insurance companies that are providing coverage for this program in the sites we have trained have expressed similar ideas.

I appreciate very much the leadership and vision of Hon. Nancy-Ann Min DeParle at HCFA. After going back and forth with HCFA for several years during which a variety of options have been considered (including a demonstration project), I am respectfully requesting that HCFA now make a decision to cover this program for selected patients. Another demonstration project would largely duplicate the demonstration project that we have already conducted, it would cost millions of dollars, and it would delay this program for several more years to Americans who may benefit from it.

Coverage from HCFA could be limited to people who are choosing this program of comprehensive lifestyle changes as a direct alternative to bypass surgery or angioplasty. These are the patients in whom the cost savings are the most dramatic and immediate, and it would be the easiest group in which to prevent fraud or abuse. My colleagues and I would be happy to work with an outside group (e.g., the American College of Cardiology) that could provide certification for any comprehensive lifestyle program that has sufficient scientific evidence of medical effectiveness and cost effectiveness to justify coverage. This certification could be offered on a non-exclusive basis and would meet HCFA's understandable need for credentialing of programs to avoid fraud and abuse, thereby making the program available to the people who most need it.

In response to an earlier request from Hon. DeParle's predecessor, Bruce Vladeck, Dr. Claude Lenfant (Director, National Heart, Lung, and Blood Institute, National Institutes of Health) evaluated this program and found it to be safe for Americans in the Medicare population.

Also, bipartisan letters of support were written from President Clinton, former Speaker Gingrich, and ten other U.S. Senators (Republican and Democrat), as well as AARP executive director Horace Deets, former Surgeon General C. Everett Koop, and other medical authorities including Christine Cassel, M.D. (Professor and Chairman, Department of Geriatrics and Adult Development, The Mount Sinai Medical Center, Immediate Past President, American College of Physicians, Chair, American Board of Internal Medicine), Alexander Leaf, M.D. (Jackson Professor of Clinical Medicine, Emeritus, Chairman, Department of Medicine, Emeritus, Chairman, Department of Preventive Medicine & Clinical Epidemiology, Emeritus, Harvard Medical School and Massachusetts General Hospital), Marion Nestle, Ph.D. (Professor and Chair, Department of Nutrition and Food Studies, New York University), and others.

We appreciate very much a recent appropriation from the Department of Defense to make this comprehensive lifestyle change program available at the Walter Reed Army Medical Center and elsewhere. If heart disease can be reversed, then the implications for prevention are even more important. Increasing evidence links a low-fat plant-based diet with a lower incidence of diabetes, hypertension, obesity, and cancers of the prostate, breast, and colon.

A recent editorial by 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." This program has been tested rigorously and was found to be reasonably safe and effective. It works. Therefore, I respectfully submit that it should be covered by Medicare for selected heart patients as an alternative to bypass surgery or angioplasty.

Everyone benefits: patients have access to new choices, health professionals have new options to serve their patients, Medicare offers an innovative approach to lowering health care costs without compromising the quality of care, and Congress can demonstrate bipartisan leadership in an area that is important to so many Americans.

Thank you very much for this opportunity to be here today. My colleagues and I are very grateful for your interest in our work.

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Mr. BURTON. Thank you, Dr. Ornish.

Now HCFA has been unresponsive to your request, is that correct?

Dr. ORNISH. No, sir, I wouldn't put it quite like that. I think Honorable DeParle has been very responsive, and I have great admiration and appreciation for what she and her colleagues are doing.

But I think that to make this a covered benefit will require congressional statutory authority because it currently isn't. They don't cover, just like many insurance companies didn't cover, lifestyle interventions.

Mr. BURTON. I wasn't aware of that. So, without congressional authority, they can't expand the funding for this kind of a program?

Dr. ORNISH. Well, these are things we don't learn much about in medical school, so I am not sure.

Mr. BURTON. I will have to check into that. I will tell my staff to check into that, but we will try to contact the people at HCFA and HHS to see if we can have a dialog about that. We may have some people from those agencies here today; I think we do back there. I will be happy to talk to them about that as well.

Dr. ORNISH. Thank you.

Mr. BURTON. I have a number of my colleagues and friends who have had bypass surgery and have had angioplasty, and it is depressing and surprising for me to hear you say that, within 4 to 6 months after angioplasty, the arteries can once again close up.

Dr. ORNISH. Yes, in 30 to 50 percent of the cases.

Mr. BURTON. In 30 to 50 percent of the cases?

Dr. ORNISH. Yes, sir.

Mr. BURTON. Is that widely known? I was not aware of that.

Dr. ORNISH. Well, there is a lot that isn't widely known. This is widely known within the medical profession. But, you know, it goes even further than that, sir.

Mr. BURTON. If it is fairly wide known in the medical profession, why is that not communicated to patients and the public, because I don't think it has been? Angioplasty, at least the people that I have talked to that have had it, is seen as a panacea. Obviously, they ask them to have dietary changes, and so forth, to try to keep it from coming back, and they take an aspirin and all that sort of thing.

But the fact is, I don't think anybody I have ever talked to that has had angioplasty knows that there is a good chance it will reoccur within a short period of time.

Dr. ORNISH. Well, that is the problem, getting the information out, and that is part of why I write books and give lectures and things, and why I appreciate the chance to be here today.

But if you actually look at all the scientific data, if we talk about we want evidence-based, randomized, double-blind—or not double-blind, but placebo-controlled studies. There have been three major randomized trials of bypass surgery, and in every one of them they found that bypass surgery prolongs life or prevents heart attacks in only about 2 percent of people. Those are the most severe diseases.

Mr. BURTON. Only in 2 percent of the people.

Dr. ORNISH. Two point one percent, to be exact. These are people with left main coronary artery disease and poor left articular function.

No study has ever even been conducted that compares angioplasty with just drug therapy to see whether it prolongs life or prevents heart attacks. So for the vast majority of Americans who get operated on for these two operations, for which billions of dollars are spent every year, there is no evidence that it prolongs their life or prevents heart attacks. What it does do is relieve their chest pain or their angina. So it has value. But we found in all of our studies a greater than 90 percent reduction in angina or chest pain within weeks when people make bigger changes in diet and lifestyle than most doctors recommend.

Mr. BURTON. Within weeks, you say?

Dr. ORNISH. Within weeks.

Mr. BURTON. Usually, when people go in and they are diagnosed with arteries that are closed or almost completely closed, the doctors prescribe surgery or angioplasty within a very, very short period of time.

Dr. ORNISH. Yes, sir.

Mr. BURTON. The danger is, somebody says, I have been diagnosed with 90 percent closure in one artery and 100 percent in another, and the doctor says, if we don't act pretty quickly, you are going to have a heart attack. The fear factor is very great.

Dr. ORNISH. That is correct.

Mr. BURTON. For them to talk to somebody like you, who says, if you change your diet and change your lifestyle, in 4 to 6 weeks things will get better—they worry about being around in 4 to 6 weeks.

Dr. ORNISH. That is right.

Mr. BURTON. So how does a person who goes in, they say you have got closed arteries; you run the risk of a heart attack—how does he get that information, when his doctor says you have to have surgery; you have to have angioplasty?

Dr. ORNISH. Well, it is a very important question. Let me respond on two levels. The first is, how do you get the information out? And the other is, what does the medical science show us? In terms of how to get the information out, I think you change reimbursement, you change medical practice, and you change medical education. I used to think that good science was sufficient, and I was naive. I think good science is important, but generally sufficient to motivate lasting changes in physician behavior. I think we have to change reimbursement. And I want to make it clear, most doctors are motivated by service, but if you are trained to do these things and you get reimbursed to do these things, then that is what people do.

So if Medicare were to cover this, it would have implications that go far beyond this. It would change medical education as well as medical practice.

Now it turns out that the 90 percent lesions are not as dangerous as the 30 percent ones. That is the conventional thinking now among some of the leaders in the field, like Dr. Valentine Fuster at Harvard, and so on. It seems a little counterintuitive because you think that, the more blocked it is, the greater the danger. The

more blocked it is, the more likely it is to cause chest pain. But it is actually the more mild lesions, the 30 to 40 percent, that are more likely to cause heart attacks because they are more unstable.

Now no one is going to bypass the 30 percent blockage, and yet, those are the ones that may be the most dangerous. But when a person changes diet and lifestyle to the degree that we do, or even when they go on cholesterol-lowering drug therapy, the endothelium, the lining of the artery, stabilizes, and the risk of a heart attack goes down dramatically.

Most patients don't know that the surgery is unlikely to prolong their life, unless they are unstable, which is a separate category, which most patients are not, or they are the 2.1 percent of patients. For most patients, the surgery is not going to prolong their life or prevent a heart attack. They don't know that, if they were willing to change their lifestyle, they could accomplish the same reduction in angina.

Mr. BURTON. Let me ask you two quick questions.

Dr. ORNISH. Yes, sir.

Mr. BURTON. If a person who normally would have a very small chance of survival, like you said, it is not going to change their life-and-death situation if they have the heart surgery or the angioplasty. If they have the heart surgery or if they took the alternative therapy, do you have any studies or any figures that show how long their lives would be extended, or do you have any kind of an average?

Dr. ORNISH. Yes, sir. We found, in the study that came out in the Journal of the American Medical Association 2 months ago in December 1998, there were 2½ times fewer cardiac events in people who changed their lifestyle compared to the control group that made more moderate changes. So people not only feel better, but in most cases they are better.

We used quantitative arteriography to measure the blockages. We used cardiac PET scans, positron emission tomography, to measure blood flow to the heart. The state-of-the-art showed these patients got better and better over time.

Now not everybody wants to change lifestyle. I don't even tell my own patients to change. But I do believe in freedom of choice. I think it is a very American idea. For those people who don't want to change, I find a good surgeon or a good interventional cardiologist or I put them on drugs. But for that subset of patients who are willing and who are motivated to change—and that subset is a lot bigger when people really know what the facts are—I think it would be nice to give them the freedom of choice, too, by covering programs like this.

Mr. BURTON. Thank you.

Ms. Norton, do you have any questions?

Ms. NORTON. Yes, Mr. Chairman. This hearing is very well-structured, Mr. Chairman, I think, because we are going to get to questions of representatives of the Federal Government to establish responsibility here. I am glad we heard of your own testimony beforehand, Dr. Ornish. I think it is very valuable testimony, precisely because you are a credentialed and experienced physician.

Dr. ORNISH. Thank you.

Ms. NORTON. The balance that you bring to the table is very important, particularly as we try to play catch-up, it seems to me, on making available these approaches. What you have spoken about is hard to call an alternative approach because it is also a preventive approach.

Dr. ORNISH. Yes.

Ms. NORTON. It is what most fascinates me about homeopathic medicine. I appreciate the full information you have given us. For example, the chairman asked an important question: Well, how in the world, if 30 to 50 percent close back up again, as it were, but you indicate that they do bring some relief. Obviously, a physician wants to bring some relief to the chest pains. So he wants to do whatever he can; he wants to do it quickly. So he has something that works and he hopes that the next thing will work. I want to ask a question about that.

I do believe what you say about, well, let those who will; most people won't. Well, let's do it for those who will. I do think there is a very strong case to be made, since I do believe—and here you are talking about what we do have evidence about—that these changes, if you are willing to make them—can both prevent heart disease and help retard it once you have had a heart attack.

This morning there was a report—I heard it on the National Public Radio; it was a very informative report—about autopsies that were done on young men. I think it was young men from the Korean War. Now they have done all of the studies.

Dr. ORNISH. Yes, ma'am.

Ms. NORTON. It was quite amazing. Essentially, it is not about old fogies like me. It is about how young people like my legislative assistants are getting their arteries all clogged up, as I speak—

Dr. ORNISH. Yes.

Ms. NORTON [continuing]. And won't pay any attention to it until they get to be middle age, and then they have found that these people in their twenties are showing signs, significant signs, of heart disease. By the time they got as old as 35, they just had it. Nobody even thinks about heart disease at those ages.

Two questions: One is, if this information is available, so that physicians, who also don't concentrate on young people, in part, because they don't go to the doctor, if physicians look to young people as a way of dealing with heart disease, a runaway problem in this society, won't this, in turn, get us to the point that you want to get, which is the change in the lifestyle will become more automatic?

I ask this question because young people became environmentalists when it took old people, who had been so used to being wasteful, to understand it. So they became teachers, as it were, for older people.

Is there a way, now that we know that heart disease it not simply a disease of middle and old age, to get to where you want to get simply by changing our focus from the pool that has been the target to a younger pool, in which case some of the problems get prevented and the others, it seems to me, we are able to deal with in a lifestyle you indicate. I would like to hear you discuss how this might be done, if it could be done, if it would be effective. Second, how it might be done, given the fact that young people not only be-

lieve they are immortal, but have no reason to seek the help of physicians, for the most part?

Dr. ORNISH. Well, Ms. Norton, I appreciate so much the question. You are absolutely right; studies have shown that American soldiers killed in Korea, Vietnam, the Persian Gulf, even at the age of 19, had significant plaque in their coronary arteries. A study done by Dr. Gerald Berenson in Louisiana found that children who died in accidents, that half of them had severe plaque, and all of them had blockages in their aortas. So this is a problem that begins in childhood and progresses over a period of decades. So you are quite right; that is where we have to begin.

Now the old joke is, if I change my lifestyle, if I eat this way, am I going to live longer or is it just going to seem longer? You know, that is what a lot of young people think, that lifestyle changes—

Ms. NORTON. Either will do.

Dr. ORNISH. Pardon me?

Ms. NORTON. Either will do at this point. [Laughter.]

Dr. ORNISH. Well, there is this myth that the good life is eating a high-fat diet and getting drunk and using cocaine and smoking and getting under a lot of stress, and that it is boring to have a healthy lifestyle. Part of what I have learned is that telling a young person they are going to live to be 86 instead of 85 does not motivate them. In fact, it hardly motivates people who are 85—[laughter]—because people want to feel better.

The paradox I have found is that it is actually easier to make big changes than to make small ones. That is why I began changing when I was 19, growing up in Texas, eating meat a lot, because I found I felt better. I had more energy. I could think more clearly.

Now you know Viagra came out last year at the same time the Nobel Prize was awarded to the doctors who discovered a compound called nitric oxide, which dilates blood vessels. One of the things that happens when people change their diet is that their sexual function often improves, particularly in older men, because it is not just your heart that gets more blood flow. People find that they think more clearly. They have more energy. Now, as a scientist, those are harder things to measure than arteries in coronary blood vessels getting better, but from the motivational standpoint, one of the most effective anti-smoking ads was not “smoking causes cancer,” but “do you want to taste like you have been licking an ashtray when someone kisses you?” It puts it into the here and now.

That is what younger people really respond to, changes that affect their quality of life in the short run. We doctors like to talk about risk factor reduction and prevention, but most young people find that boring. I have found that we need to talk about changes in lifestyle that improve the quality of your life very quickly. That is what happens when you make changes. I think it is never too early to begin making these changes, and it is never too late to begin making them.

Ms. NORTON. Thank you. Thank you, Mr. Chairman.

Mr. BURTON. Thank you. Thank you, Doctor.

Mrs. Chenoweth.

Mrs. CHENOWETH. Thank you, Mr. Chairman.

Dr. Ornish, I was fascinated as you gave your testimony because you almost gave it word for word with rarely looking at your notes. [Laughter.]

Interesting observation.

I wanted to ask you, it seems that the dog in the manger seems to be the insurance companies. You said it better than I did. You were more politically correct. You said, once reimbursements get in line, then the rest of the policy will follow. I couldn't agree with you more.

On page 4 of your testimony, you mention that 77 percent of the patients who were candidates for bypass surgery or angioplasty responded very positively to your recommendations or those types of recommendations, and that Mutual of Omaha said that it saved \$30,000 per patient.

Dr. ORNISH. Immediately.

Mrs. CHENOWETH. Immediately. These guys look at the bottom line—why aren't they responding to this? What is wrong? That startled me.

Dr. ORNISH. Well, they are responding. That is why 40 insurance companies are now covering this program in the hospitals that we have trained. But if HCFA, if Medicare were to cover this, then most of the other insurance companies would follow suit. That is really the Rosetta Stone. That is where the leverage point is. That is where the opportunity for change is the greatest.

If we can focus on the area where the cost savings were the most immediate and the most dramatic, then I am hoping it will be a much smaller step for them to see that there is value in paying for preventive services as well. But let's start in an area that I think is where the cost savings can really be shown the most quickly and the most dramatically. That is why we focused on that area, but it is by no means limited to that in terms of the benefits.

Mrs. CHENOWETH. I have been frustrated because other alternative forms of medicine, such as the practice of chiropractic and naturopathy, and so forth, there seems to be so much manipulation in terms of what will be paid for and what won't be paid for, and what takes certain approvals, and so forth. So I hoping that shortly we will see people working together—MD's working in consultation with other people who have an expertise in an area that they could offer great advice. That is my hope.

In following up with the chairman's comments, this 77 percent figure fascinated me. Doctor, does that mean that 23 percent of the people would be eligible and would need bypass or angioplastic surgery because they were the unstable candidate, those that may not live for the next week or so?

Dr. ORNISH. The patients, for whatever reason, 23 percent ended up getting operated on during that 3-year period. It was a 1-year program. We followed them for 3 years.

Now an interesting fact is that, because the cost differential between a bypass and paying for lifestyle intervention is so great—it is, say, maybe \$50,000 for a bypass and, say, \$7,000 for a year of lifestyle training—if we just delayed surgery for a year and a half, and then 100 percent of people failed, the interest saved on that \$50,000 would more than cover the cost of a lifestyle program. We have certainly done a lot better than that.

So from an economic, hard-dollars standpoint, this makes sense. I would love to see coming out of these hearings two things. One has already been discussed, which is increased funding for research. I am a scientist. That is what I do. I have great appreciation for the value of science to help sort out what works and what doesn't work, and for whom and under what circumstances, so we can cut through a lot of the hype and say, what really is the science here?

The other thing that I would like to come out of this is that there are a few so-called alternative approaches, like what we have done, that have been proven to work, that are both medically effective and cost-effective. Let's now take them to the level of reimbursement, which is where change really can happen. Then I think you will find it will affect medical education, as well as medical practice, as well as medical research.

Mrs. CHENOWETH. Thank you, Doctor.

Mr. BURTON. We are going to break for lunch for about 20–25 minutes because I can hear people's stomachs growling, and we have some food for the panelists along with some refreshments.

But I would like to end up by asking you just one really hard question.

Dr. ORNISH. Yes, sir.

Mr. BURTON. Do you believe, as a scientist and a doctor, that there is resistance from some areas of government and medicine because of the profit that is to be made by pharmaceutical companies and the medical profession in performing these types of operations and prescribing these types of medicines?

Dr. ORNISH. Well, time for lunch. [Laughter.]

Mr. BURTON. I don't want to take too much time, but this is very serious, because there has been some suspicion among some of us in Congress that people who work at the Food and Drug Administration and at Health and Human Services have been influenced unduly by pharmaceutical companies, for instance. Many of them have been paid fees for some forms of research. They have put on boards by some of the pharmaceutical companies, and that tie kind of concerns us, because what we want, as Members of the Congress, is the best quality of healthcare, whatever it is, for the American people. That emanates, in part, from the pharmaceutical companies and the research they do, but it also emanates from holistic approaches. So I am concerned that maybe our health agencies in the Federal Government might be unduly influenced, and that is why I would like to have your opinion about that.

Dr. ORNISH. Well, let me put it in a slightly different context. I think most doctors are genuinely interested in doing what is best for their patients. I believe the vast majority of doctors are generally interested in service. But, at the same time, having been trained very conventional—you know, I went to medical school at Baylor and did my course surgery medical surgical rotation with Michael DeBakey, the eminent heart surgeon. I did my post-graduate training at Harvard and Mass. General, and I am at UCSF now.

I understand that training process, and I also understand how hard it is to be a doctor these days, when you are getting squeezed from all sides. If managed care says you have to see a new patient

every 7 minutes, even if you are interested in nutrition or dealing with the psychosocial and the emotional and spiritual dimensions of health and well-being, you don't have time to do it. In 7 minutes, you don't have time to talk to about the problems with the marriage or the problems at work or the problems with the kids on drugs, whatever it happens to be. You, basically, have time to listen to the heart and lungs. You write a prescription for a cholesterol-lowering drug. You are on to the next patient.

It is profoundly unsatisfying for most physicians and for most patients. Most physicians, according to the latest surveys, which I am sure you have seen, wouldn't recommend medicine as a career for their sons or daughters because it is not fun.

Now we are trying to say, look, if you treat the cause of the problem, if we change reimbursement, we offer different approaches. Of course, there is an economic incentive the way things are set up now, but why can't there be an economic incentive to do things differently. We always have the money to pay the \$50,000 for a bypass. Why not the \$7,000 for a year of lifestyle training, which is a whole team of people, not just a physician, but a dietician, an exercise physiologist, a stress management instructor, a psychologist, and so on, to deal with the cause of the problem?

If we can make it economically reimbursable, then we change those other incentives. Some patients do need surgery. Some patients do benefit from drugs. But I think we also need to include these other approaches which are of permanent benefit, which can really empower the individual and make such a huge difference in both their quality of lives and in their survival.

Mr. BURTON. Thank you, Dr. Ornish. That was a great statement, and it had some real political overtones. Have you thought about entering politics? [Laughter.]

Dr. ORNISH. Well, I am trying to build bridges here.

Mr. BURTON. Yes, I know you are, and I appreciate that.

We have some people from HCFA here, don't we? Do we not? Don't we have somebody from the Department here? Can you come back and have lunch with us? I would like for Dr. Ornish and you and I to talk a little bit.

OK, I think we will break now for about a half an hour and have a little bite to eat. You have to leave at 10 after 1?

Dr. ORNISH. Yes, sir, but I just want to say, in closing, how grateful I am to you for organizing these hearings and for the opportunity to be here today.

Mr. BURTON. Thank you, Doctor.

We will reconvene in about 30 minutes.

[Recess.]

Mr. BURTON. We will reconvene.

We will have other Members, I believe, coming back here shortly. They are running all over the place because there's a number of hearings going on today. So I apologize for the people coming in and out.

But I would like to have Dr. Brian Berman of the University of Maryland and Mr. Ollie Johnson and his lovely wife, Barbara, come forward. We will have your testimony now.

I appreciate very much your patience and hope you did get something to eat. We normally don't provide that service, but today we did.

Why don't we start with Dr. Berman? Dr. Berman, do you want to start and give us an opening statement? If you want to, you can submit your statement for the record, and then summarize.

STATEMENTS OF BRIAN BERMAN, M.D., ASSOCIATE PROFESSOR AND DIRECTOR, PROGRAM FOR COMPLEMENTARY MEDICINE, UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE, BALTIMORE, MD; AND OLLIE AND BARBARA JOHNSON, DEAN ORNISH LIFESTYLE PATIENT AND SPOUSE, COLUMBIA, SC

Dr. BERMAN. Thank you very much. Mr. Chairman, members of the committee, I am extremely honored to be here today and given the opportunity to provide testimony to the Committee on Government Reform.

I am a board-certified family physician and pain management specialist, and I am also trained in acupuncture and homeopathy at the Royal London Homeopathic Hospital. I went on to look at some of these therapies and incorporate those into my practice because I was frustrated that I didn't have all the answers for my patients—excellent training for acute care, trauma, but not for a lot of the chronic diseases that we see every day.

I have been practicing integrated medicine for the past 17 years. I am also associate professor at the University of Maryland School of Medicine and director of the complementary medicine program there, and principal investigator on the National Institute of Health-funded Center for Alternative Medicine Pain Research and Evaluation, as well as CAM research grants from the NIH and the Department of Defense. So I have been asked to present today from the three perspectives as a clinician, as a researcher, and as an advisor to the government for the past 6 or so years.

Our center was started in 1991, and we really started it because of some of the remarks that were made today. Back then, I really felt that these types of therapies weren't going to be brought into the mainstream of medicine unless there was a proven scientific base to these therapies. So we started back then, in a time when there was a great deal of public interest, but the medical community's interest was low, if not hostile. As we all know, and it has been said today by you, there has been a great sea of change over the past 7 or 8 years. It has gone from 3 in 10 to 4 in 10 Americans using these therapies, and worldwide 75 percent of the world uses these forms of therapy as their primary form of healthcare. In this country, we see that there has been an increase in expenditures to \$21 billion just for the providers' side, and another \$13 billion for the other out-of-pocket expenses of herbs, vitamins, books, and so forth.

What has also changed over this period of time has been the government's support, and that started really with the opening of the Office of Alternative Medicine at the NIH in 1992, through the support of Senator Harkin and others. Thanks to the efforts of this Congress, now it has become a center with increased autonomy, increased budget, which has brought the much-needed funding or the

start of the much-needed funding to an area that does not have access to the deep pockets of an industry, the sort of research and development industry, of a pharmaceutical industry that we have with modern medicine.

So I became involved with the Office of Alternative Medicine at its start through chairing the Ad Hoc Advisory Committee, the consensus meetings in Chantilly and then the report for the NIH "Alternative Medicine: Expanding Medical Horizons Report," and as an advisory council member. Over these years, I have seen tremendous progress in the field. One has been the Office of Alternative Medicine's funding 11 centers of research, and that has started the infrastructure. Over the past 2 days, I was at meetings of the principal investigators, and the excitement to see people representing the field of cancer, heart disease, pediatrics, pain, many areas, women's health, and having from 7 to 10 projects, really getting out information that the Congress and the public really wanted to see.

Pilot projects have been funded, and now definitive studies in several promising areas are underway, such as osteoarthritis or acupuncture in the use of osteoarthritis in the elderly, St. John's Wort clinical trial, and some of these definitive studies that we have all been wanting to see happen.

At the University of Maryland we focus on the area of pain, and particularly the modalities of acupuncture and mind/body therapies. I would like to use these right now as an example of the progress that has been made in some areas of complementary medicine, and then give a picture of where they stand as regards the government policy.

We at our place are building a mosaic of information, of evidence, basic science information, looking at how does acupuncture actually work, studies ongoing there; randomized controlled trials. Is acupuncture and mind/body therapy safe, effective for acute pain conditions such as post-operative dental pain, as well as chronic pain problems like osteoarthritis in the elderly, lower back pain, fibromyalgia? Also, what is going on in the actual clinical setting, tracking the outcomes and the real-life experience of patients?

We are also collecting and evaluating the existing literature. One of the criticisms of complementary medicine, as we heard alluded to today, is the general lack of scientific evidence. We have found and collected over 11,000 citations in complementary medicine and pain alone. The difficulty, in part, has been finding this literature, that it is in either foreign journals or nonmainstream journals.

So our investigations to date, they paint the picture that acupuncture and mind/body therapies, part of which we heard earlier by Dean Ornish, mind/body therapies and acupuncture have great potential, whether alone or as adjunct to therapies, for many of the pain problems. More research is needed to complete this picture and fill in the gaps.

While this research is important and the building block for practicing evidence-based healthcare, how is it being brought into the public arena, where it can be useful in setting clinical guidelines and affecting healthcare policy? Some of the things that have occurred—back in 1994, the NIH and the FDA held a joint conference looking at acupuncture. The outcome of that meeting was that they

determined there was enough evidence to say that acupuncture was no longer going to be listed as an experimental device.

The NIH Acupuncture Consensus Conference was held in 1997. The outcome there was they found there was sufficient evidence to expand its use into conventional medicine and to conduct future studies. They listed a whole range of conditions, from addiction, to asthma, to pain conditions, where there was fairly good evidence.

There was also a Technology Assessment Conference in Mind/Body Therapies for Pain and Insomnia, held through the National Institutes of Health, for which I was a panel member. There the findings were that there was strong evidence for treating a wide range of chronic pain conditions.

Both conferences recommended these therapies be covered by healthcare payers. This is far from the reality today. So the recurring theme of coverage comes up. Insurers and healthcare companies, they put them on today sometimes as additional riders or reduced rates. Over the 7-year increase in patients usage that we saw from those surveys, there wasn't any change in the coverage.

What about the government-funded healthcare programs? I would like to just give you a quick story about one of my patients. Before I came here, last week when I was preparing for this testimony, one of my patients, an elderly gentleman with chronic back pain, whose insurance is Medicare, called me, and he said, "I won't be able to come for treatment any longer." Now he had tried all the conventional treatments for his chronic back pain without success. He came to me. We treated him with acupuncture. Maryland has acupuncture licensing laws. I am licensed in the State of Maryland to practice acupuncture. He benefited greatly over the course of about 4 months' time. Now he has to come back and say, it is not going to be covered, so he has to go back to the treatment which he had before, physical therapy, which really didn't benefit him. And as a side, there isn't much in the way of strong evidence to show the efficacy of physical therapy for chronic back pain.

At the end of the day, who is being served by this? Certainly, not the patient, who now has to give up an effective treatment for him, and certainly not Medicare. I think it is time to start considering complementary and alternative medicine as viable healthcare options in our healthcare system.

So how do we do this? With over 200 modalities under this broad umbrella "complementary medicine," it could seem an overwhelming task to know what information there is, which treatments merit consideration based on solid evidence. At our university, part of our program, one of our main efforts has been in gathering the best information and trying to disseminate that.

Part of that effort is through the Cochrane Collaboration, which is an international organization dedicated to evaluating all medical therapies. So we are coordinating this international field for complementary medicine as part of the Cochrane Collaboration, and through these efforts, there now exists a specialized registry of randomized controlled trials that is available worldwide of about 4,000 clinical studies and another 4,000 we are considering.

We and others worldwide are involved with reviewing this evidence with a systemic review and then drawing conclusions that can help guide clinical decisions and future research. There have

been 164 of these reviews completed, and it is this type of information that can help guide the integration of complementary medicine into the mainstream.

So, in conclusion Mr. Chairman, I offer the following: We need continued proactive funding by the government. Most complementary alternative medicine therapies are not patentable, and therefore, of little interest to industry. We need to continue to investigate the safety, efficacy, cost-effectiveness, and use the full range of methodologies from randomized controlled trials to basic sciences to health services research.

No. 2, we need quality information that is succinct and evidence-based made available to the public, to researchers, payers, and policymakers.

No. 3, based on this research and quality information, we need to make complementary therapy more accessible, especially to those with little disposable income. I think this can be accomplished, one, through coverage, through Medicaid/Medicare, and, two, through setting up demonstration programs at places like the VA system, military medicine, the Bureau of Primary Health Care.

Then, last is setting up the President's commission. There was language to set up the President's commission. I think we should go forward with that. I think that will help us facilitate other government agencies become involved in this field.

I think the continued interest and support of your committee and other government programs will help ensure that ours and future generations benefit from the availability of effective healthcare approaches, regardless of whether they are labeled alternative, complementary, or conventional.

Thank you very much.

[The prepared statement of Dr. Berman follows:]



UNIVERSITY OF MARYLAND
SCHOOL OF MEDICINE

COMPLEMENTARY MEDICINE PROGRAM

Testimony of
Brian Berman, M.D.
Associate Professor of Family Medicine
University of Maryland School of Medicine

to the Committee on Government Reform
Congress of the United States

February 24, 1999

**Opening the Mainstream to Complementary and Alternative Medicine:
How Much Integration is Really Taking Place?
An Inquiry into Access to Complementary and Alternative Medicine in
Government-Funded Programs**

Patient Appointments:
University Physicians Clinic
James L. Kerman Hospital
2200 Kerman Drive
Baltimore, Maryland 21207-6697
410 448-6722
FAX: 410 448-1873

Academic Research & Education Office:
Kerman Hospital Mainstem
2200 Kerman Drive
Baltimore, Maryland 21207-6697
410 448-6871
FAX: 410 448-6875
TDD: 410 328-9603

Mr. Chairman and members of the Committee, I am extremely honored to be given the opportunity to provide testimony to the Committee on Government Reform.

I am a board certified family practitioner and pain management specialist, and Director of the University of Maryland School of Medicine Complementary Medicine Program. In addition, I am Principal Investigator of the National Institutes of Health (NIH)-funded Center for Alternative Medicine Pain Research and Evaluation. I have been asked to present to you my perspective on complementary and alternative medicine (CAM) both as a clinician, a researcher, and an advisor to the government. I hope this will throw light on the important role the government can and must play in supporting investigation of this field and in offering the American public valid choices in their healthcare.

As a family practitioner I started to investigate therapies outside of the mainstream in a quest to find other answers and options for my patients. I was frustrated at the shortcomings of my Western medical training, which, although unsurpassed for treating acute disease and trauma, did not help many of my patients who suffered from complex, chronic illnesses. After a number of years abroad, training in such alternative therapies as acupuncture and homeopathy and practicing an integrative approach to medicine, I felt far more fulfilled in my role as physician and healer, but simultaneously was becoming more ostracized by my medical colleagues. It was the vision and support of Sir Maurice Laing and the Laing Foundation of Great Britain that allowed me to return to the US in 1991 and begin a program of research in CAM at the University of Maryland. At that time, while the people of America and Britain were very involved with using alternative therapies, awareness and openness to CAM among the medical establishment was low, if not hostile.

Much has changed over the intervening eight years. First, the public's interest in and use of CAM therapies has changed. It has substantially increased. Whereas in 1990, 3 in 10 Americans used at least one form of CAM, now 4 in every 10 use CAM - a 25% increase. Over the same time period, expenditures for CAM professional services increased by 45% to a staggering \$21 billion per year. Unchanged is the equally staggering fact that over half of this expenditure is being paid out-of-pocket. What has also changed is interest in CAM in our country's medical schools, hospitals, managed care companies and insurance companies. Most U.S. medical schools now include a course on CAM in their curricula, many hospitals now have or are contemplating offering CAM services, and an increasing number of managed care and insurance companies are offering CAM programs or benefits. The government's commitment to investigate CAM has also changed. As I am sure you are all aware, an Office of Alternative Medicine was established in the NIH in 1992. Funding for this program has increased substantially each year and, thanks to the efforts of this Congress, the Office has recently been elevated to Center status in the NIH. This initiative has led to many positive developments. Primarily, it has brought sorely needed research funding to a field that does not have access to the deep pockets of an industry's research and development department, as is the case with modern medicine and the pharmaceutical industry.

I became involved with the Office of Alternative Medicine at its start. I was honored to be invited to chair the initial ad-hoc advisory group for the Office and the consensus meetings held in Chantilly, VA where experts in all forms of CAM were invited to participate in mapping the field. We subsequently produced a report to the NIH entitled "Alternative Medicine: Expanding Medical Horizons" which grouped the therapies into general categories, explained their philosophical basis and clinical method and application, gave an overview of the current state-of-the-science, and made recommendations for future directions for research. At times the process was fraught with emotion and conflict, since many CAM practitioners felt they had long been ignored and spurned by the establishment. Ultimately, the result was constructive with agreement being reached on the need for rigorous investigation as well as better regulation and monitoring of the CAM professions by their practitioners. Much progress has been made in both of these areas.

The NIH Office of Alternative Medicine has funded research centers in 11 academic centers around the country as well as putting seed funding into developmental studies. This has laid the foundation for the funding of definitive studies in areas that appear particularly promising. At our own center at the University of Maryland we have concentrated on the area of pain. A great deal of our research to-date has centered around acupuncture and mind/body therapies and I would like to use these two areas as examples of the progress being made in some CAM areas and give a picture of where they stand as regards government health care policy.

Our research team has been looking at building a mosaic of evidence in acupuncture and mind/body therapies. We have been conducting basic science studies looking at how acupuncture works and fielding large randomized controlled trials - considered "the gold standard" in research methodologies - focusing on whether acupuncture and mind/body therapies are effective and safe in the treatment of acute pain problems, such as post-operative dental pain, and chronic problems, such as osteoarthritis in the elderly and low back pain. We have also been collecting and evaluating all the evidence that exists already. It is interesting to note that although one of the criticisms of CAM in general is its lack of scientific evidence, we have collected over 11,000 citations related to CAM and pain alone. Up to this point, it has been difficult to evaluate the state-of-the-science in CAM because a lot of the literature has been difficult to obtain, either because it is printed in non-mainstream or in foreign journals. In the case of acupuncture and mind/body therapies, our team continues to be focused on synthesizing and systematically reviewing this literature in the areas of our research studies. Our investigations to-date paint a picture of acupuncture and mind/body therapies as having great potential, either alone or as adjuncts to standard care, in helping many pain problems. More research is still needed, however, to complete the picture and to fill in the many gaps in our knowledge.

While all this research is important and is the building block for the practice of evidence-based medicine, how has it been brought out into the public arena where it can be useful in setting clinical guidelines and effecting health care policy? In the case of acupuncture, the NIH and the Federal Drug Administration co-sponsored a conference in 1994 featuring the testimony of many acupuncture experts and researchers. The outcome of the conference was the removal of the

classification of acupuncture needles as "experimental devices". In 1997 the NIH then organized a consensus development conference - a well-established format used by the NIH to evaluate promising but controversial areas of medicine - focused on acupuncture. Once again, researchers such as myself, were called upon to present the evidence in our areas of expertise to a panel of scientists and clinicians. Based on careful consideration of this evidence the panel found promising results have emerged, for example, for the efficacy of acupuncture in adult post-operative and chemotherapy induced nausea and vomiting and in post-operative dental pain. Furthermore, acupuncture may be useful as an adjunct treatment or an acceptable alternative or be included in a comprehensive management program for addiction, stroke rehabilitation, headache, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, and asthma.

Over this same time period, the NIH organized another technology assessment conference, this time on mind/body therapies in the treatment of pain and insomnia. I was part of the panel asked to judge the evidence. Our findings included that there was strong evidence for relaxation techniques in treating chronic pain and hypnosis in relieving cancer-associated pain, and moderately strong evidence for a number of techniques such as hypnosis, cognitive behavioral techniques and biofeedback in treating a wide range of chronic pain disorders.

Both conferences recommended that these therapies be covered by health care payers. Nonetheless, this remains far from being a reality in our country today. I mentioned earlier the huge amounts of money being paid yearly by Americans for CAM treatment and would like to emphasize again that over half of this they are paying out-of-pocket. While insurers and managed care companies are seeing the large market in CAM, any coverage they are offering at this time is usually in the form of additional riders and/or negotiated reduced rates. And what of government-funded healthcare programs? I would like to tell you the story of a local Baltimore man who has been coming to me as a patient, an elderly gentleman whose health care is covered by Medicare. He came to me with severe back pain for which he had already tried many conventional treatments and found no relief. I am licensed to practice acupuncture in the State of Maryland, one of many states that now has licensing requirements for both physicians and lay acupuncturists, and it was this form of treatment I have been using with this patient for his back pain. Just last week as I was preparing this presentation, I received a telephone call from the same man informing me he would have to cease coming to me for treatment. The reason for this is that Medicare would not cover his acupuncture treatment. He was greatly distressed. Acupuncture had been alleviating his back pain and now he is faced with returning to physical therapy, the treatment Medicare will cover but that was not helping him for his problem. As an aside, I would like to add that the scientific evidence for physical therapy treatment of chronic low back pain is not strong. Does denying this patient coverage for acupuncture really make sense for this patient, or indeed for Medicare? The options both are faced with are continuing with therapies that have not worked for him and in the long run incurring even more distress and expense, especially if he has to resort to back surgery at an approximate cost of \$15,000. This patient had had seven acupuncture treatments from me at a cost of \$75 a session and had experienced considerable relief.

It is time to start considering complementary and alternative therapies as viable options in our health care system. I would like to encourage the government to continue to support much needed investigation of this field but to now take into consideration the findings that are coming out of the very worthwhile endeavors it and others have already sponsored. In addition, the work of researchers internationally should be considered. This is not an impossible task. As vast as the field of CAM is, encompassing well over 200 modalities, it could indeed seem a daunting task to know what information there is and which therapies merit consideration based on solid evidence. I would like to draw your attention, however, to the work of the Cochrane Collaboration which is an international volunteer organization dedicated to evaluating all medical therapies. At the University of Maryland we are responsible for coordinating the section, or field, on complementary medicine. As part of our NIH funding we have been able to help support the network of people involved in collecting and systematically reviewing all the scientific evidence on CAM. Thanks to these efforts, there are now over 4,000 randomized controlled trials on all of CAM in the Cochrane database and 4,000 more trials being screened for inclusion. This database is available to investigators worldwide and we and others are involved in the task I mentioned earlier of pooling all the evidence in a particular area (for example, acupuncture for chronic pain), reviewing it for scientific rigor, and drawing conclusions that can help guide clinical decisions and future research. At present 164 such reviews have been completed. It is synthesized, evidence-based information such as this that can guide thoughtful integration of CAM into the mainstream.

In conclusion, Mr. Chairman, I would like to offer you the following. First, we need continued pro-active funding of CAM research by the government. Other than nutraceuticals and botanicals, most CAM therapies are not patentable and therefore are of little interest to industry money. These are exactly the therapies that people are using. In order to ascertain which therapies are safe and effective over the short term but also over an extended period, the types of research supported should range from randomized controlled trials to basic science studies to health services research. Second, in an age of information overload - especially, in the case of CAM, poor quality, unsubstantiated information - we need access to succinct, high-quality information based on scientific fact. Finally, based on this research and quality information, we need to make CAM more accessible, in particular to those people who lack the disposable income to seek it out privately. This could be made possible through coverage of proven CAM therapies by Medicare and Medicaid and the support of demonstration projects in federal programs such as the Veteran Administration Hospitals and the Bureau of Primary Health Care. The continued interest and support of your committee and other government programs will help ensure that ours and future generations benefit from the availability of effective health care approaches, regardless of whether they are labeled conventional, complementary or alternative.

Mr. BURTON. I have some questions, but we will go ahead and hear the other panelists, and I will ask you about those in just a moment.

Mrs. Johnson, ladies before gentlemen.

Ms. BARBARA JOHNSON. Thank you.

Mr. BURTON. Would you pull the microphone pretty close? Thank you very much.

Ms. BARBARA JOHNSON. Mr. Chairman, members of the committee, thank you for the kind invitation to allow me to testify at this hearing today. My name is Barbara Johnson, and I have been my family's caregiver for 42 years. I appreciate the opportunity to share with you mine and Ollie's journey to the Dr. Dean Ornish's Program for Heart Disease Reversal.

In 1987, my husband, Ollie Johnson, was diagnosed with heart disease. He had a heart catheterization at Richland Memorial Hospital in Columbia, SC, which showed that he had a 70 percent blockage in one artery and a 90 percent blockage in another. His doctor did not think that he was a candidate for any kind of surgery, so he prescribed medication for him. All of the medication was provided by the pharmacy at Moncrief Army Hospital at Ft. Jackson, SC, since Ollie is retired from the Air Force.

At my insistence, the doctor also provided a way for Ollie to go to the cardiac rehab program at the University of South Carolina. On my own, I bought cookbooks which were recommended by the American Heart Association, because we didn't really get any nutritional information from the doctor, and started cooking, "heart healthy." We stopped eating beef and ate chicken, pork, and fish. We stuck to this regimen for several years. He exercised periodically by walking 3 to 5 miles a week.

In 1991, I began to see Dr. Dean Ornish on various talk shows and became intrigued with his program. I bought his book, "Dr. Dean Ornish's Program for Reversing Heart Disease," and knew that the program would work for us.

When Ollie had his next regularly scheduled appointment with his cardiologist, we mentioned the book and program to him, and expressed a keen interest in trying it. The doctor quickly dismissed us and said, "You can't do that program. It's too harsh." I did not believe this, but was powerless against his suggestion. So for the next 4 years, we followed the American Heart Association diet with a 30 percent fat intake.

By June 1995, when Ollie had his yearly checkup, it was discovered that his heart disease had gotten worse, and now a third artery had significant blockage. Knowing that the Dean Ornish program would stop the progression of the disease, I asked the doctor what did we need to do to stop the disease from getting any worse. By this time, the Richland Memorial Hospital offered the program. The doctor said that the only way that he knew of to get the disease to stop was to enroll in the Ornish program. So I asked him to please get us in the next class, and he did.

We started the program in July 1995. For the first 3 months, we were required to go to the hospital 3 nights a week for lectures, exercise, stress management, and supper. This is how we learned to live the program.

At one point, our family members were invited to the hospital and they were given information on the program. Their questions were answered, and we all had a meal together. This event was invaluable to us because it emphasized the value of staying with the program and how family support was so important.

I do not have heart disease, but I entered the program to support my husband and to ensure his success. In our home we eat and live the Ornish lifestyle. When we started the program in July, we were told that Ollie's insurance, Blue Cross/Blue Shield, would not pay for our participation. We had to pay \$5,000 for Ollie and \$1,000 for me. We paid \$3,000 down and were given 2 years to pay off the remaining \$3,000. We paid a monthly payment to the hospital.

During the first year in the program, we faithfully stayed in compliance with all of the dietary, exercise, and stress management requirements. We filled out program compliance sheets daily and mailed them to the hospital monthly. We actually filled out these forms for 3 years. The first year was a year of learning—learning how to cook so that meals were tasty and satisfying.

We also had to give ourselves time to adjust to the new lifestyle. Travel and eating out were challenges that we were up to and slowly but surely mastered. During the first 2½ years, whenever we traveled, we took an electric cooler and a two-burner stove and all of our food with us. If we couldn't find a restaurant to serve us, we would cook in our hotel room. We made this fun and never saw it as a hardship.

After 3 years, I am very good at preparing our meals and we are both energetic and healthy. Ollie walks 15 to 20 miles a week and lifts weights three times a week. I walk 30 to 35 miles a week, work out at the gym on weight machines three times a week, and take an aerobics class twice a week. And by the way, I am in training for the Cooper River Bridge Race.

Another plus of this program is that our food bill has gone down dramatically. When you do not have to buy meat, you realize a substantial savings at the grocery store.

When Ollie had the thallium stress test and blood work after 1 year, his test results were so favorable that his doctor took him off the Procardia and reduced the Tenormin from 50 milligrams to 25 milligrams daily, and the doctor tells us on the side that he doesn't really think Ollie needs the Tenormin, but he is scared to take him off of it.

Eliminating the Procardia amounted to a savings of \$40 a month to the U.S. Army. The current cost of Tenormin is less than 1 cent per day. Every thallium stress test that he has had since then has been more favorable each year.

The hospital had been sending Ollie's medical test results and our compliance sheets to the insurance provider. After we had paid on the remaining \$3,000 for 13 months, the insurance company paid off the balance. The insurance provider currently pays for some patients to participate in the program. However, when we entered the program, the insurance provider would only pay if the participant had previously had a heart attack, bypass surgery, angioplasty, or stints.

We are fortunate and grateful that the Dr. Dean Ornish program is available in Columbia. In July 1995, Columbia was one of only

seven locations in the United States. However, there is a need for this program to be available throughout the United States. I believe that participation in this program has eliminated the potential of my husband having a heart attack or bypass or some other kind of invasive measure. I wholeheartedly recommend that this, the Dean Ornish program, be authorized under Medicare.

I thank you for your attention, and I will be glad to answer any questions.

[The prepared statement of Mrs. Johnson follows:]

Testimony of

**Barbara J. Johnson
Columbia, South Carolina**

**Before the Committee on Government Reform
US House of Representatives
Hearing**

**“Opening the Mainstream to Complementary and Alternative Medicine:
How Much Integration is Really Taking Place?”**

**A Family Caregiver's Experience Leading to
Participation in the
Dr. Dean Ornish's Program to Reverse Heart Disease**

**February 24, 1999
2154 Rayburn House Office Building
Washington, D.C.**

Mr. Chairman, members of the Committee, my name is Barbara Johnson. I have been my family's caregiver for 42 years. I appreciate the opportunity to share with you my husband's journey to the Dr. Dean Ornish Heart Disease Reversal Program.

In 1987, my husband, Ollie Johnson, was diagnosed with heart disease. He had a heart catheterization at Richland Memorial Hospital in Columbia, S.C. which showed that he had a 70% blockage in one artery and a 90% blockage in another. His doctor did not think that he was a candidate for any kind of surgery, so he prescribed medication for him. All of the medication was provided by the pharmacy at Moncrief Army Hospital at Fort Jackson, S.C.; my husband is retired from the United States Air Force. At my insistence, the doctor also provided a way for Ollie to go to the Cardiac Rehab Program at the University of South Carolina.

On my own, I bought cookbooks which were recommended by the American Heart Association and started cooking heart healthy. We stopped eating beef and ate chicken, pork and fish. We stuck to this regimen for several years. He exercised periodically by walking three to five miles a week.

In 1991, I began to see Dr. Dean Ornish on various talk shows and became intrigued with his program. I bought his book "Dr. Dean Ornish's Program for Reversing Heart Disease" and knew that the program would work for us. When Ollie had his next regularly scheduled appointment with his cardiologist, we mentioned the book and program to him and expressed a keen interest in trying it. The doctor quickly dismissed us when he said, "You can't do that program; it is too harsh." I did not believe this but was powerless against his suggestion. So for the next four years, we followed the American Heart Association diet with a 30% fat intake.

By June of 1995, when Ollie had his yearly check-up, it was discovered that his heart disease had gotten worse and now a third artery had significant blockage. Knowing that the Dean Ornish Program would stop the progression of the disease, I asked the doctor what did we need to do to stop the disease from getting any worse. By this time the Richland Memorial Hospital offered the program. The doctor said that the only way that he knew of to get the

disease to stop was to enroll in the Ornish Program. So I asked him to please get us in the next class. He referred us to the very next class.

We started the program in July 1995. For the first three months, we were required to go to the hospital three nights a week for lectures, exercise, stress management and supper. This is how we learned to live with the program. At one point family members were invited to the hospital and they were given information on the program, their questions were answered and we all had a meal together. This event was invaluable to us because it emphasized the importance of staying with the program and how family support was so important. I do not have heart disease but I entered the program to support my husband and to insure his success. In our home we eat and live the Ornish lifestyle. When we started the program in July we were told that Ollie's insurance, Blue Cross Blue Shield, would not pay for our participation. We had to pay \$5,000 for Ollie and \$1,000 for me. We paid \$3,000 down and were given two years to pay off the remaining \$3,000. We paid a monthly payment to the hospital.

During the first year in the program we faithfully stayed in compliance with all of the dietary, exercise, and stress management requirements. We filled out program compliance sheets daily and mailed them to the hospital monthly. We actually filled out the forms for three years.

The first year was a year of learning. Learning how to cook so that meals were tasty and satisfying. We also had to give ourselves time to adjust to the new lifestyle. Travel and eating-out were challenges that we were up to and slowly but surely mastered. During the first two and one-half years, whenever we traveled we took an electric cooler and a two-burner stove and all our food with us. If we couldn't find a restaurant to serve us we'd cook in our hotel room. We made this fun and never saw it as a hardship.

After three years, I'm very good at preparing our meals and we're both energetic and healthy. Ollie walks 15 to 20 miles a week and lifts weights three times a week. I walk 30 to 35 miles a week, work out at the gym on weight machines three times a week and take an aerobic

class twice a week. Another plus of this program is that our food bill has gone down dramatically. When you do not have to buy meat you realize a substantial saving at the grocery store.

When Ollie had the thallium stress test and blood work after one year his test results were so favorable that his doctor took him off of the procardia and reduced the tenormim from 50mg to 25mg daily. Eliminating the procardia amounted to a saving of \$40.00 per month to the U.S. Army. The current cost of Tenormin is less than one cent (.01) per day. Every thallium stress test that he has had since then has been more favorable each year.

The hospital had been sending Ollie's medical test results and our compliance sheets to our insurance provider. After we had paid on the remaining \$3,000 for 13 months, the insurance company paid off our balance. This insurance provider currently pays for some patients to participate in the program. However, when we entered the program, the insurance provider would only pay for participants who had previously had a heart attack, by-pass surgery, angioplasty or stents.

We are fortunate and grateful that the Dr. Dean Ornish Program is available in Columbia. In July 1995, Columbia was one of only seven locations in the United States. However, there is a need for this program to be available throughout the USA. I believe that participation in this program has eliminated the potential of my husband having a heart attack, by-pass or some other kind of invasive measures. I wholeheartedly recommend that this, the Dean Ornish Program, be authorized under Medicare. I thank you for your attention and Ollie will share with you his experience as a patient.

Mr. BURTON. Mr. Johnson, would you care to comment?

Mr. OLLIE JOHNSON. Thank you, Mr. Chairman. I'm Ollie Johnson, and I am the patient here. I appreciate the opportunity to share with you my experiences overcoming my heart disease and also my thoughts as a taxpayer.

It is very sobering when one is told, "You are going to have a heart attack." I was told that by my cardiologist, and later by a nurse while I was in the cardiac rehab. unit at the University of South Carolina. Fortunately, at this time in my life I feel very certain that it is not going to happen.

My initial attempt to seek treatment in 1987 was at the Moncrief Army Hospital at Ft. Jackson. I was seen by a clinical nurse who administered an at-rest EKG. There were no visible symptoms since I was not put under stress. Consequently, I was told that I had no problem.

We were not satisfied with this diagnosis, and subsequently, saw my current cardiologist, who at that time diagnosed blockage after a more thorough examination and verification by cardiac catheterization. After completing the cardiac rehabilitation in 1987 and changing my lifestyle, the possibility of a heart episode still remained. When I started the Dean Ornish program to reverse heart disease in 1995, initial tests showed that my heart disease had progressed, but simply at a slower pace.

After the first 6 months in the Ornish program, tests showed a significant lowering of my cholesterol levels, favorable levels of my HDL, LDL, and triglycerides. This was viewed by the Heart Center staff as the environment in which reversal takes place.

After 1 year, the progression of my disease completely stopped. After the second year, there was evidence that the area served by the blockage was getting more blood. After the third year, even more blood flow was noted. In addition, my ischemia had disappeared.

My cardiologist commented that, if you didn't know that I had heart disease, he could not tell from my electrocardiogram stress test. I feel confident that my disease is being cured, and that I will not require a catastrophic heart procedure. I am healthy and energetic. I walk 15 to 20 miles a week. I meditate for 1 hour 4 to 6 days each week, and I adhere to the Ornish diet.

My wife and I are involved in our community. I do part-time consulting work. We travel, occasionally visit and enjoy our grandchildren, and enjoy our lifestyles.

I would be remiss if I did not thank the many people who have helped save my life. Dr. Dean Ornish, who invented and developed this program, and weathered the rocky road to get this program widely accepted; the Heart Center at Palmetto Richland Memorial Hospital for making this program available in South Carolina; the medical directors, Drs. Don Sanders and Joe Collins; my cardiologist, Dr. Stephen Humphrey; the wonderful staff at the Heart Center: Susan Bevron, who coordinated the Ornish program when we entered it; Colleen Wracker, a nutrition specialist who patiently taught us how to eat Ornish and answered all of our many questions; Brent Schell, our stress management specialist, and Jean Humphrey, our group support volunteer—and last, but by no means least, my wife, Barbara Johnson, who determined long be-

fore I knew that this was the program that would save my life. She is my advocate, my cook, my motivator, my caregiver, and she is the mother of my children. I am truly blessed, and I am grateful for this program.

I just want to share with you as a taxpayer that I feel very strongly that when the government invests in the health and well-being of its citizens, there should be specific outcomes. The program should have a favorable impact on the society that it serves. It should be cost-effective, and it should be measurable.

I believe that the Dr. Dean Ornish Lifestyle Program meets these outcomes. I am healthier. There is evidence that my blockage is regressing, and I am avoiding a catastrophic bypass procedure cost of about \$45,000 to me and my insurance carrier.

I have some data from the South Carolina Budget and Control Board, Office of Research and Statistics. These figures show cardiac procedures, angioplasty and bypass, and their average costs for the period October 1997 through September 1998. There were 6,587 procedures at a cost of more than \$228 million. If one-fourth of that population had early access to, and embraced, the Dean Ornish Heart Disease Reversal Program, there was a potential savings of more than \$57 million in medical costs within South Carolina; and, 1,646 people might have avoided catastrophic invasive procedures.

I would certainly urge this distinguished panel to support Medicare coverage of this program. I thank you for allowing me to participate. I will answer any of your questions.

[The prepared statement of Mr. Johnson follows:]

Testimony of

**Ollie L. Johnson
Columbia, South Carolina**

**Before the Committee on Government Reform
US House of Representatives
Hearing**

**“Opening the Mainstream to Complementary and Alternative Medicine:
How Much Integration is Really Taking Place?”**

A Patient's Experience and Taxpayer's Perspective

**February 24, 1999
2154 Rayburn House Office Building
Washington, D.C.**

Mr. Chairman, members of the Committee, I am Ollie Johnson, the patient. I wish to share with you my experiences overcoming my heart disease, and offer my thoughts as a taxpayer.

It is very sobering when one is told "you are going to have a heart attack." I was told that by my cardiologist and later by a nurse, while in cardiac rehabilitation at the University of South Carolina. Fortunately, at this time in my life, I am certain that it will not happen.

My initial attempt to seek treatment in 1987, was at Moncrief Army Hospital, Fort Jackson, S.C. I was seen by a Clinical Nurse who administered an at-rest EKG. There were no visible symptoms, since I was not put under stress. Consequently, I was told that I had no problem. We were not satisfied with this diagnosis and subsequently saw my current cardiologist, who at that time diagnosed blockage, after a more thorough examination and verification by cardiac catheterization.

After completing cardiac rehabilitation in 1987 and changing my lifestyle, the possibility of a heart episode still remained. When I started the Dr. Dean Ornish Program to Reverse Heart Disease in 1995, initial tests showed that my heart disease had progressed but at a slower pace. After the first six months into the Ornish Program, tests showed a significant lowering of my cholesterol levels, favorable levels of my HDL, LDL and triglycerides. This was viewed by the Heart Center staff as the environment in which reversal takes place.

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I feel confident that my disease is being cured. And, that I will not require a catastrophic heart procedure. I am healthy and energetic. I walk 15-20 miles a week, I meditate for one hour

4-6 days each week, and I adhere to the Ornish diet. My wife and I are involved in our community. I do part-time consultant work; we travel, occasionally visit with and enjoy our grandchildren and enjoy active lifestyles.

I would be remiss if I did not thank the many people who have helped save my life: Dr. Dean Ornish, who invented this program and weathered the rocky road to get this program widely accepted. He is a true hero. Palmetto Richland Memorial Hospital, The Heart Center, for making this program available in South Carolina. Medical Directors, Drs. Donald Saunders and Joseph Hollins; my Cardiologist, Dr. Stephen Humphrey. The wonderful staff at the Heart Center: Susan Beverung, RN, who coordinated the Ornish program; Collene Wracker, RD, Nutrition Specialist, who patiently taught us how to "eat ornish" and answered all of our many questions. Brent Schell, our Stress Management Specialist and Jean Humphrey, our Group Support volunteer. And, last but by no means least, my wife, Barbara Johnson, who determined long before I knew, that this was the program that would save my life. She is my advocate, cook, motivator, caregiver and mother of my children. I am truly blessed and I am grateful.

As a taxpayer, I feel strongly that when the Government invests in the health and well being of its citizens, there should be specific outcomes. The program should have a favorable impact, it should be cost effective, and it should be measurable. I believe the Dr. Dean Ornish's Lifestyle Program meets these outcomes. I am healthier. There is evidence that my blockage is regressing and I am avoiding catastrophic bypass procedures of about \$45,000 cost to my insurance carriers. I have included data from the State of South Carolina Budget and Control Board, Office of Research and Statistics. These figures show cardiac procedures (angioplasty, and by-pass) and their average costs, for the period October 1997 through September 1998. There were 6,587 procedures at a cost of \$228,600,377. If one-fourth of that population had early access to and embraced the Dr. Dean Ornish's Heart Disease Reversal Program, there was the potential savings of \$57,157,092 in medical costs in South Carolina. And, 1,646 people, might have avoided catastrophic invasive procedures. I urge this distinguished Committee to support Medicare coverage of this program Thank you.

Attachment

OCTOBER 1997 - SEPTEMBER 1998
SOUTH CAROLINA INPATIENT DISCHARGES AND AVERAGE CHARGES
FOR SELECT PROCEDURES

| <u>PROCEDURE</u> | <u>CASES</u> | <u>AVE. CHG.</u> |
|---------------------|--------------|------------------|
| BALLOON ANGIOPLASTY | 1905 | \$18,407 |
| *CABG W CARD CATH | 2788 | \$45,948 |
| CABG W/O CARD CATH | 1894 | \$34,547 |

*CABG - Coronary Bypass
CARD - Cardiac
CATH - Catheterization

Average charge excludes charges 2 standard deviations
above and below the state's average charge

Source: South Carolina State
Budget and Control Board
Office of Research and Statistics
Rembert C. Dennis Building
1000 Assembly Street
Columbia, South Carolina 29201-3117
Phone: (803) 734-3818
Fax: (803) 734-7804

Mr. BURTON. Thank you, Mr. Johnson. Your wife must be an extraordinary woman, as well as a good cook.

Mr. OLLIE JOHNSON. Yes, she is.

Mr. BURTON. Mr. Sanford ought to be very proud of you as constituents, because you make a very strong case, and you are examples of what people ought to do to make sure their lifestyles are enhanced. So congratulations.

Let me just ask you a couple of questions, and then I will yield to Mr. Sanford.

What is your cholesterol level now?

Mr. OLLIE JOHNSON. 196 or 195.

Mr. BURTON. Is that right, below 200?

Mr. OLLIE JOHNSON. Oh, yes, it has been down to 170, but I had some tests last week and it was about 195 or 190, somewhere in there.

Mr. BURTON. Your LDL and HDL are at acceptable levels as well?

Mr. OLLIE JOHNSON. They are all in acceptable levels, yes.

Mr. BURTON. What were they before? Do you recall?

Mr. OLLIE JOHNSON. I don't know because I didn't pay too much attention to it until I got them, and when I first was checked, it was 3 or 4 months into the program; they had all just kind of gotten into compliance.

Mr. BURTON. What about your blood pressure? Is it pretty good?

Mr. OLLIE JOHNSON. Yes, my blood pressure—they have to sort of wake me up.

Mr. BURTON. 120 over 80 or—

Mr. OLLIE JOHNSON. Yes, it is usually somewhere at 120 over 80, 78.

Mr. BURTON. But it was higher than that when you first started taking Tenormin, I guess?

Mr. OLLIE JOHNSON. Yes. Yes, it was higher than that. But I haven't had a problem in 3½ years.

Mr. BURTON. Did you take Zocor or any of the cholesterol-controlling drugs at any time?

Mr. OLLIE JOHNSON. No. I took Procardia that dilutes your blood vessels. They took me off that medication and they reduced my Tenormin from 50 milligrams to 25 milligrams. Right now I am taking 25 milligrams of Tenormin and a baby aspirin, and I take a multiple vitamin.

Mr. BURTON. But the doctor really doesn't even think you need those; it is just a precaution?

Mr. OLLIE JOHNSON. That is correct. He doesn't really think I need that, but he won't take me off of it.

Mr. BURTON. OK, very good. Well, I can tell you right now that we are going to be having meetings with Dean Ornish and people at HCFA. I have already talked to some of the people over there about that. It sounds like to me that there is not a lot of opposition over at Health and Human Services and HCFA to the Ornish program. The problem, I guess, it looks like to me, is that we need some legislation to enable them to approve this program being paid for by the Medicare system. If we can get HCFA and Health and Human Services, FDA, and everybody onboard, then it seems to me we ought to be able to get the Congress to go along with that. We

should be able to get that done. So maybe your wish and Dr. Ornish's wishes, will be realized before too long. Anyhow, we are going to be meeting with them in the not-too-distant future.

I would like to ask Dr. Berman a couple of questions about the acupuncture. You said in your testimony that—I may be paraphrasing what you said—but, because it is not profitable, a lot of the companies are not interested in this, or a lot of the providers are not interested in this. Maybe you could clarify that. I might have—

Dr. BERMAN. I think what I was saying was that a lot of these therapies or complementary alternative medicines are not patentable. So because there is no patent, there is no great incentive for a drug company to put the amount of money that it takes to go through the steps to have it. So, therefore, they don't really get evaluated and taken to that sort of stage from people's observations—yes, it seems to work anecdotally—all the way through to the clinical trials that we need.

I was more talking about that research dollars are really needed, and it is not going to come from—a lot of our research is from the drug industry, and that is where a lot of the dollars come from.

Mr. BURTON. Do you think that some of the opposition to the procedures that you provide comes from pharmaceutical companies because there is no real profit incentive?

Dr. BERMAN. We are back to that question again.

Mr. BURTON. Well, you know, I ask that question, and I asked it of Dean Ornish, and the reason I ask it is because it is very important that we get that out in the open. That is not something you can hide behind, because if agencies of the Federal Government are being controlled, in part even, by pharmaceutical companies, because they invest large amounts of moneys in research, and they are afraid their research dollars are going to go down the tube because somebody finds bark off a tree that is going to cure cancer, instead of their product, then if they have that kind of influence, it is unseemingly.

I think in the process—and I am going to go off on a little tirade here—I think in the process of getting alternative therapies accepted, we may have to, as a government, figure out some way to protect pharmaceutical companies against making great investments in scientific research, and then have something come along that didn't cost anything that knocks their research out of the box, and there is maybe \$2 or \$3 billion that has gone down the tubes.

I am sympathetic to the problem that they face. If they patent something, they go through all the research; they come up with a compound that works, and then somebody comes up with something that is homeopathic that works just as well, but doesn't cost anything. So they are out all that money. So I am sympathetic to that.

But, at the same time, I think we need to know in the Congress if pharmaceutical companies, if medical facilities in this country are using their influence to keep a lid on alternative therapies, so that they can still make the almighty dollar.

Dr. BERMAN. I think that does exist. I think we would have to say straight that there is a great profit motive, and it is not there for many of these therapies. So while some of them are now—quite

a few of the big pharmaceutical companies are starting to look at this field, they are coming along with a big net to see where is the market, and beginning to start their own lines of vitamins and minerals, and have not yet gone the other way to say, let's put in the research dollars, because of these concerns: Where is that patent going to be, and their payout at the end of the line.

Mr. BURTON. Well, perhaps we can wade through that and figure out some way to be able to encourage them, so that they can make money and still get to the final conclusion we all want.

Let me ask you a little bit about acupuncture, because I am not that familiar with it. How does it work on joints and pain? If you use acupuncture, for instance, if you have knee problems or tennis elbow or shoulder problems or back problems, does it give long-lasting relief or is it just a temporary thing, like aspirin or acetaminophen or something?

Dr. BERMAN. What we have found is that it generally, in the beginning, the treatments are maybe—if somebody has a chronic problem—if it is an acute problem, often it lasts. But if it is a chronic disease, let's say, like somebody with osteoarthritis of the knees, and they have had this for many, many years. Initially, you may find that the treatments last for just a couple of days, and then as you go along, if this treatment is working for this particular patient, they tend to last longer and longer, and there is more of a carryover effect. From some of our studies, it has lasted sort of for 12 weeks before we saw any decrease in the effects from the treatment.

Mr. BURTON. Does it ever provide a complete cure or is it just like some kind of pharmaceutical that would provide a cure for a short period of time, and you have to take it again?

Dr. BERMAN. Well, in the traditional way of looking at it, they would say the cure might be that you come in once a season eventually, and it has to do with not just your local knee pain, but your general health. Whether or not it can—it really depends on which problem. I mean, I have seen it cure tennis elbow quite effectively and some problems of chronic headaches.

But something where it is really—looking at osteoarthritis, part of the joint is gone, and they are waiting to have joint replacement, it is not going to regenerate that joint. There is some evidence that glucosamine and some of the other compounds might have some effect there, but for acupuncture you are not going to regenerate it, but you will decrease the inflammation around that joint. You will decrease the pain, and you will increase the quality of life, so that the person is really perhaps able to not have the surgery or avoid having the surgery.

Mr. BURTON. Very good.

Mr. Sanford.

Mr. SANFORD. I guess I would ask this of my fellow South Carolinians. We grew up not only in the Sunbelt, but in the stroke belt as well. Growing up where we did, I have a particular love of fried chicken, country fried steak, fried okra. My hope that is, as you look at the Ornish program, a part of it is what you eat; a part of it what you do in terms of exercise, and a part of it, I suppose, is what you think with meditation, and maybe there are other elements in terms of herbs.

How much of it is the nutrition part? Can I skip out on the nutrition part and still be OK, or, no, it is all three?

Mr. OLLIE JOHNSON. It is all of them. We asked that question. It is like we can only have one drink a day. I asked, could I save them up until Saturday? They said, no, you can't. [Laughter.]

But the food part, we don't eat meat; we don't eat seafood. We go to a restaurant and we talk to the cook or we say, "Look, can you fix up the meal?" They will say, "We can fix you a vegetarian meal." But if they are going to put "fat-back" into it, we have a problem there. So we actually just leave.

Mr. SANFORD. So is it equal, a third, a third, a third, or is it really more relying on what you eat than anything else?

Mr. OLLIE JOHNSON. No, sir. I don't know that they have an answer for that, because we never got one that is one-fourth exercise, one-fourth meditation, one-fourth diet, and one-fourth group support. I don't believe they have any evidence to say which is the most influential. We have not at this point. So we do all of it. We do all of it, and it is working.

Mr. SANFORD. What would you say to folks that say—detractors, in essence, of alternative medicine who say, wait a minute, the Federal Government can only fund so many things. This is not magic. I know that fried okra probably isn't the best thing in the world for me, but I grew up eating it; I love eating it.

In other words, since it is not magic, since I know it is not good for me, therefore, you could have figured this out earlier. What shouldn't government involvement be reserved for the very end of things? In other words, what would you say to a detractor that said, only so many dollars; save it for the end because people, if they are really disciplined, could be doing this stuff without having government involved in a program of Dean Ornish or others?

Mr. OLLIE JOHNSON. Well, I think the evidence of it, good or bad, is the cost in South Carolina right now, \$228 million, just last year alone. All of those people—I didn't have any figures on what their ages were, but I would suspect that they are maybe older people. I sort of crossed that bridge. I have a lot of friends who still eat Kentucky Fried Chicken, or "KFC" now—we don't say, "fried" anymore. [Laughter.]

And we don't perceive it as being a hard thing. It is really very difficult to convince another person that this is a good way that is not so bad. Most of my friends do not eat Ornish, and they know I eat Ornish. We go to a restaurant, and I may end up eating a salad, but that is it. Every now and then, when they say, "Your weight, you look pretty good," I say, "Well, it is part of the program that I am in." They will ask me a few more questions. I know that they are eating better. They probably gave up the double hamburgers and stuff like that, and they are eating more turkey, because they see me every day and they believe that something is happening with that guy; he is a better person because I know he is meditating. He is a little bit better to get along with.

So I don't criticize their lifestyle. I am willing to tell them about mine.

Mr. SANFORD. Right.

Mr. OLLIE JOHNSON. I have had that question, "Well, I can't do that because I am enjoying this lifestyle," but we are both at the concert or the theater, you see.

Mr. SANFORD. I would ask the question, I suppose, to Mr. Berman, unless you want to throw in your thoughts. That is, how would you guard against quackery, though? In other words, if you open up government to doing a lot of other things, surely, there would be a lot of folks that maybe—AMA has pretty strict guidelines. How you have an AMA-like control over who does or doesn't do acupuncture or herbal remedy?

Dr. BERMAN. There is a lot of efforts in that way. There is certification. You look at certification, regulation, licensing, education, experience, and there are the acupuncturists, the chiropractors, massage therapists, they do have national—and many of the States have their own regulations. So you would go look at that. I think that is very important.

You could set up many things. You could set up looking at the adverse reactions of many of these therapies, so you could look at what goes on with them adversely. And you would also continue to do the research, so you could separate out what doesn't work and discard those, and then keep in the ones that do work.

So I think there are many ways that we could really improve, both from a conventional as well as a complementary medicine side, to separate out the quackery.

Mr. SANFORD. Mr. Chairman, thank you.

Mr. BURTON. Thank you. I would just like to say, Mr. Sanford, that we had Dean Ornish in earlier, and, of course, I think you were in other committee meetings or something. I hope that you and some of the other members will take advantage of an invitation Dean Ornish made, and that was that he said he would be willing to come back from San Francisco to meet with a number of Congressmen to tell them about his specific program, and if you are interested, get you on it, because it has had substantial results.

In addition to that, they have scientific research in his program that backs up, in Dean Ornish's case, what these people have said here today, that it does eliminate in many cases, but certainly reduces the necessity for heart surgery and bypass surgery and also angioplasty. They estimated that it would save \$30,000 to \$35,000 for each case. When you put a pencil to that, if we could get Health and Human Service, HCFA, and all the health agencies to incorporate this into Medicare, it would probably save billions of dollars for the Medicare program that could be well used elsewhere. It is one of the things that I know that you will want to work with us, and I will talk to you about that.

Let me just thank you very much. I am going to have to find out, Mrs. Johnson, what you cook that tastes so good that doesn't have cholesterol in it. [Laughter.]

Maybe I can get you to come to Indiana and teach me and my family. But, anyhow, I am just teasing you.

Thank you very much for being here, and I am sorry you had to wait so long. We will take to heart what you said. We are going to meet with Dean Ornish. What you are requesting is going to be looked into very thoroughly and, hopefully, we will get some results on it. So thank you very much.

Thank you, Dr. Berman. We are going to check into the acupuncture. I may be talking to you about acupuncture myself.

Dr. BERMAN. OK.

Mr. BURTON. Why don't we have the next panel come forward? We will get started with the next panel.

We are going to have a vote coming up here right now.

The next panel is Dr. Kamerow, Dr. Holohan, and Dr. Mazzuchi.

Dr. Kamerow, we talked earlier today. You know, Dr. Kamerow, I only wish the Army had as nice of uniforms as you guys. I was in the Army and our uniforms never could measure up to you or the Marines.

Why don't we start with Dr. Kamerow, since we will just go from left to right? Did I mention everybody or did I leave someone out?

Mr. MAZZUCHI. Dr. Zimble is here with me, sir. He is the president of the Uniformed Services University of the Health Sciences.

Mr. BURTON. Oh, Doctor, well, I apologize for that. OK.

Dr. Kamerow.

STATEMENTS OF DOUGLAS KAMEROW, M.D., DIRECTOR, CENTER FOR HEALTH CARE TECHNOLOGY, AGENCY FOR HEALTH CARE POLICY RESEARCH, DEPARTMENT OF HEALTH AND HUMAN SERVICES; THOMAS V. HOLOHAN, M.D., CHIEF, PATIENT CARE SERVICES OFFICER, VETERANS HEALTH ADMINISTRATION; JOHN F. MAZZUCHI, DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS, CLINICAL AND PROGRAM POLICY, DEPARTMENT OF DEFENSE; AND JIM ZIMBLE, M.D., PRESIDENT OF THE UNIFORMED SERVICES UNIVERSITY FOR THE HEALTH SCIENCES

Dr. KAMEROW. Thank you, Mr. Chairman, members of the committee. I am Dr. Douglas Kamerow, testifying on behalf of the Department of Health and Human Services. Our Department, HHS, has a number of roles related to complementary and alternative medicine. NIH, the National Institutes of Health, facilitates research into new health therapies that may someday be options for the treatment of illnesses. FDA, the Food and Drug Administration, is responsible for approving new medical devices or drugs that are safe and effective in the treatment and prevention of disease.

I work in another public health service agency, the Agency for Health Care Policy and Research, AHCPR. Unlike my colleagues on the panel here today, we at AHCPR neither deliver care nor regulate care. Our mission is to access the evidence for what works and what does not work in healthcare.

We support and conduct research that improves the quality, the outcomes, and the appropriate use of healthcare services. We provide the scientific foundation that is necessary for informed healthcare decisions. We want those decisions, which are being made every day by patients, by clinicians, by purchasers, healthcare system leaders, and policymakers, to be based on solid evidence about what works, when it works, and for whom it works.

The study of complementary and alternative medicine is squarely within AHCPR's mission. While we have done some work in this area, we have really just begun to look at it. Let me tell you a lit-

tle, about 3 minutes' worth, of what it is that we have done and what we are doing.

First, we are working to provide accurate statistics about the use of complementary and alternative medicine in the United States. One of our surveys, the Medical Expenditure Panel Survey, has collected information on persons who consult with complementary and alternative medicine providers. This is the largest available survey of persons who have used alternative care, and when we release results, they will provide the most accurate estimates yet about the use of complementary and alternative care providers.

Second, we supported a number of early studies on the effectiveness and cost-effectiveness of alternative therapies for treatment of low back pain, including chiropractic, acupuncture, and spinal manipulation. We have also evaluated patient satisfaction with their care compared to patients treated with conventional therapies.

Third, we are working closely with our colleagues at NIH, at the National Center for Complementary and Alternative Medicine, to co-sponsor two studies on acupuncture: one looking at the effectiveness of acupuncture on back pain and, second, in treating depression during pregnancy.

Fourth and finally, we are helping to document and synthesize the scientific and clinical evidence that supports complementary and alternative medicine. In 1997, we established 12 evidence-based practice centers around North America to systematically analyze important clinical topics. Let me give you one example.

I am a family physician. A patient recently asked me about using garlic preparations to help reduce his blood pressure and his cholesterol. I was frustrated because there really was nowhere I could turn for reliable information about this substance, which is commonly used in this country and abroad. I am pleased to say that now we at AHCPR have commissioned what we call an evidence report on garlic. One of our EPCs will scour the world's literature about it, systematically review that research, and authoritatively tell us what is known about what works and what doesn't work about garlic.

In addition to this report, we are also reviewing other complementary and alternative medicine topics for future reports, and we are discussing further collaboration with our colleagues at NIH.

Now AHCPR is a small agency, and therefore our investment in this area only scratches the surface. What is needed to create the scientific foundation for CAM, for complementary and alternative medicine? We need to develop better, more reliable methods for studying and evaluating these therapies, and much more research is needed on their effectiveness and outcomes. We need to increase the available data on their use, and we need to know how patients feel about the care they receive and why.

We at AHCPR believe that the best evaluation of medical care is one that measures the impact on the outcomes that patients care about and what they care about most. The bottom line is that all of us—doctors, other health professionals, patients, health systems, and payers—need evidence. We need to know what works and for

whom. It is our job at AHCPR to provide this evidence. These efforts will allow us to identify complementary and alternative therapies that improve health, improve health care, and enhance the quality of life of our patients.

Thank you.

[The prepared statement of Dr. Kamerow follows:]

Testimony of

Douglas B. Kamerow, M.D., M.P.H.

Assistant Surgeon General
Director, Center for Practice and Technology Assessment
Agency for Health Care Policy and Research
U.S. Department of Health and Human Services

Before the

Committee on Government Reform and Oversight

February 24, 1999

The Department of Health and Human Services has a variety of roles related to alternative medicine. The National Institutes of Health facilitate research into new therapies that may someday be future options for the treatment of illnesses. The Food and Drug Administration is responsible for approving new medical devices or drugs that are safe and effective in the treatment of diseases and other maladies.

The mission of the Agency for Health Care Policy and Research (AHCPR), where I work, is to support and conduct research that improves the quality, outcomes and appropriate use of health care services. Our research provides the scientific foundation that is necessary for informed health care decisions. We want the decisions that are made by patients and clinicians, purchasers, health care system leaders, and policymakers to be based on solid evidence about what works, when and for whom.

Throughout the Department of Health and Human Services, there is a central standard that drives decision making on alternative medicine. Before we approve new or different treatments, they must be proven both safe and effective. FDA does not approve drugs or devices that are not proven safe and effective. Medicare and Medicaid do not reimburse the cost of treatment unless it is proven safe and effective.

I serve as Director of AHCPR's Center for Practice and Technology Assessment, where we sponsor and conduct evaluations that provide the evidence of the impact on health care services. This evidence is then translated into the information that makes us all more informed health care decision-makers.

The study of complementary and alternative medicine falls solidly under AHCPR's mission. This is an area where the scientific foundation is inadequate at best. While we have a wealth of data documenting the growth in the popularity of alternative care, we don't have details on who these patients are and what services they are using. We don't know which alternatives treatments work, which don't work, and which can cause harm to the patients who use them. This research is particularly critical as the availability of complementary and alternative therapies increases and their popularity grows.

AHCPR has been supporting research on complementary and alternative medicine since we were created in 1989. Our early research in this area has focused on the effectiveness and cost-effectiveness of alternative therapies, including chiropractic, acupuncture, and manual therapy, for the treatment of low back pain. It also evaluated patients' satisfaction with their care as compared with patients treated more conventionally.

We also are working closely with the National Center for Complementary and Alternative Medicine at NIH to improve the methodology for studying alternative therapies. This partnership has greatly enhanced our ability to support health services research on alternative medicine as well as supporting conventional clinical trials through the NIH institutes. Currently, we are cosponsoring two studies on acupuncture. The first will evaluate its effectiveness to treat back pain; the second, its effectiveness in treating depression during pregnancy.

These studies will give us valuable information on the clinical situations in which

acupuncture works. But they will also help us in another way. One of the contributions AHCPR can make is to advance the methods that researchers can use to evaluate the effectiveness of health care. Our collaborations in the evaluation of alternative and complementary medicine are designed not only to answer today's questions about effectiveness, but also to develop better and more reliable approaches for evaluating complementary and alternative medicine for years to come.

For example, AHCPR is cosponsoring a conference with NIH in late 1999 to develop strategies that address common challenges faced by researchers as they study the effectiveness of complementary and alternative therapies. This is our second joint conference. In 1996, a meeting we cosponsored on how insurers make coverage decisions for complementary and alternative medicine made it very clear that decision makers have few data sources to guide their decisions.

Let me be more specific with examples of how we are building the capacity to study alternative medicine. AHCPR has undertaken a two-part effort to build new sources of data. First, we are using our Medical Expenditure Panel Survey (MEPS) to collect information on persons who consulted with a complementary and alternative medicine provider during 1996.

This survey represents 21,500 individuals and 9,500 households. It will provide the largest national sample of persons who have used alternative care, and will provide the most accurate estimates yet of the use of complementary and alternative care providers.

The second part of our investment in data is support for a national alternative medicine ambulatory care survey conducted by the Group Health Cooperative of Puget Sound. The primary goal of this survey is to provide a comprehensive description of alternative providers' practices. Providers being surveyed are acupuncturists, chiropractors, massage therapists and naturopaths. This survey, modeled on a current survey of ambulatory medical care, will provide unprecedented information on the content of care for some of the most common alternative and complementary providers.

We also are helping establish the scientific, clinical evidence for complementary and alternative treatments. In 1997, we established 12 Evidence-based Practice Centers (EPCs) to develop evidence reports and technology assessments on clinical topics that are common, expensive, and/or are significant for the Medicare and Medicaid populations. Under this initiative, we are currently evaluating the use of garlic and silybum marianum in the treatment of certain diseases and conditions. We also are reviewing a number of complementary and alternative medicine topics for future reports, and we are discussing further collaborations with NIH's Center for Complementary and Alternative Medicine.

AHCPR is a small agency, and therefore our investment in this area only scratches the surface of what is needed to create the scientific foundation for complementary and alternative medicine. We need to develop better, more reliable methods for studying and evaluating these therapies, and much research is needed on their effectiveness and outcomes. We need to increase the available data on their use and we need to know how patients feel about the care

they receive and why. The best evaluation of medical care is one that measures its impact on the outcomes that patients care about the most.

These efforts will allow us to identify complementary and alternative therapies that improve health and health care and enhance patients' quality of life. We also may learn lessons that will help us in our work to improve the delivery of conventional health care services.

Thank you.

Mr. BURTON. Thank you, Doctor.

We have 5 minutes before this vote expires. So I apologize to the panelists. I mean, how would you like to live this life where you run back and forth? The only good thing about it—

Dr. KAMEROW. Exercise.

Mr. BURTON [continuing]. Is exercise, yes. We will be back in 5 or 10 minutes.

[Recess.]

Mr. BURTON. We will reconvene.

Thank you, Dr. Kamerow, for your testimony.

We will hear from Dr. Mazzuchi now.

Mr. MAZZUCHI. Yes, thank you, Mr. Chairman. I will just highlight some pieces of my testimony for you, in the interest of time.

Mr. BURTON. Thank you, Doctor.

Mr. MAZZUCHI. One of the questions that you had asked that I cover in my testimony, and I have covered it in some detail in the written testimony, deals with a chiropractic demonstration program that the Department of Defense is operating in response to the Defense Authorization Act of 1995. We now have 13 sites. We use two different models: a patient choice model and a managed care model. In addition to those 13 sites, we have 3 comparison-sites where we also ask similar questions to patients who are undergoing care, but from traditional providers, and not the chiropractic providers. The data-gathering phase of that will continue through September 30, 1999, and then we will report to Congress, which we are required to do by the act, which requires us to report on both the feasibility and the advisability of adopting the chiropractic care into the military health system.

We don't have enough data for me to give you the answer to that yet, but I can say, from the information that we have gathered, that the patients who are receiving chiropractic care are quite pleased with that care.

In my opinion, one of the most beneficial aspects of complementary and alternative medicine is that these therapies tend to focus on self-care and stress a balance in living. We in the DOD continue to initiate and implement programs that recognize that personal health behaviors are extremely important in reducing the incidence and severity of disease, injury, and disability.

The first step in any comprehensive healthcare plan to promote a healthy lifestyle is to evaluate current health status. The Health Enrollment Evaluation Assessment Review [HEAR], is an age-appropriate tool that surveys the general health status of each of our beneficiaries. The HEAR gathers information on current health status, family medical history, currency of immunizations, prevention screenings, mental health, use of alcohol and drugs, et cetera, and has become a very important instrument to us as we look at lifestyle, so that we can initiate prevention programs that meet the needs of our population both individually and our population as a whole.

Let me address the fact that you asked about training of our DOD providers. Overall, there are many elements of CAM offered in DOD facilities throughout our Department. Our physicians have been trained in acupuncture techniques. They have been appro-

priately credentialed and now treat patients with acupuncture in DOD facilities.

For example, selected providers at both Walter Reed Army Medical Center and Andrews Air Force Base, both here in Washington, at the Family Practice Clinic, treat patients who have chronic pain with acupuncture.

Another example: a radiation oncologist assigned to Edwards Air Force Base conducts an acupuncture practice every morning in his practice and has accommodated about 1,200 visits for the treatment of pain, smoking cessation, and obesity.

Many of our hospitals and clinics offer stress management programs that include relaxation training, visualization, breathing techniques, exercise information, and cognitive therapies. Our psychology clinics within the Department offer biofeedback and other behavioral modification services. Some mental health professionals and other staff use meditation techniques with our patients. T'ai Chi, for instance, is used by some of our facilities as a routine for relaxation therapy.

Many therapies considered to be complementary or alternative have not been adopted as mainstream medicine because of the current lack of evidence for their scientific support for their efficacy and safety. We are held accountable to a particular standard for the services we cover outside of our medical treatment facilities.

And just so that you understand, we have a military health system that involves not only the MTFs, or the medical treatment facilities, that we ourselves run and operate, but we also have a managed care program as well as the standard CHAMPUS program, which is a piece of that program, that offers care outside of our facilities.

So what we can cover on the outside is governed by a standard that requires us to show the cost-effectiveness and scientific efficacy and safety of those products. Inside the house, we do have our physician community who are trained in many CAM techniques. They do actually provide those techniques within our healthcare system, but we do not pay for them outside of our system.

To uphold our accountability, we have regulations and program policies that restrict covered benefits. However, the DOD will follow very carefully the research done through institutions such as the Office of Alternative Medicine within the National Institutes of Health, the Uniformed Services University of the Health Sciences, and programs of other medical schools, such as the one we heard about at the University of Maryland's Complementary Medicine Center, for answers to the questions that CAM therapies pose to us.

Many of our beneficiaries are interested in complementary and alternative medicine, and our providers realize that within each person there is the natural recuperative power that is the key to all healing, and that taking charge of one's own health and well-being, both physically, mentally, emotionally, and spiritually, is within the grasp of each of us.

Moreover, the Department does not restrict the practice of providers who are knowledgeable, willing, and able to provide alternative medicine therapies to their patients. The spectrum of CAM, however, is broad, involving many things, and the truth is that

there is no one single definition that can clearly define what is alternative medicine. Moreover, the line between what is alternative medicine and mainstream therapy is not consistently clear in the minds of patients and providers alike.

We remain a society that is built upon science and depended upon science to solve many of the problems that we, as well as our future generations, will be facing. As therapies which are currently considered complementary or alternative are tested and shown to be safe, efficacious, and cost-effective, they will be integrated into the DOD health system.

Dr. Zimble is with me here today. He is the president of the Uniformed Services University and is here to talk about two particular aspects that you asked in your program, mainly, medical school training, since he operates our military medical school, as well as the Dean Ornish Demonstration Project, which funds were just transferred this week, so we can move on with that—if Dr. Zimble would like to do that.

Dr. ZIMBLE. Mr. Chairman, I want to thank you very much for allowing me to be a strap-hanger with Dr. Mazzuchi. I have learned a great deal here today about the sense of this committee and, also, some of the great contributions that are being toward the integration more and more into mainstream medicine.

We have started at the Armed Services University interest in CAM in 1994, when we began seminars for the complementary and alternative medicine. We have had about 64 seminars since that time in 1994.

Also, in 1996, we had what I consider to be a really good beginning in getting involvement of other medical schools and schools of nursing into an interest in CAM. We held a 3-day Consensus Conference with representation from about 33 different institutions, looking at various aspects of all types of alternative/complementary medicine, including workshops by many of the practitioners.

Now we are beginning an elective 4th-year curriculum to teach complementary medicine and then alternative medicine. We have about 13 research projects, protocols, currently underway within our school of basic sciences and clinical sciences that deal with various aspects of complementary medicine. Now we want to do more of this, and, as I listen to the Ornish that is described, I have a great deal of difficulty in accepting this as an alternative medicine. I think this is mainstream medicine that is currently underfunded and under-recognized.

As the evidence accrues, we need to learn how to integrate that into the practice of medicine. We try to teach that to our students. By the way, one out of every five physicians in on active duty today is a graduate of your Uniformed Services University. So we are a growing enterprise, and we are part of the academic health center of the military health system.

I am very pleased that the first Director of the Office of Alternative Medicine, Dr. Wayne Jonus, is now a member of our facility. He is a lieutenant colonel, family medicine physician in our Department of Family Medicine. I was very pleased when Mr. Waxman

quoted him from his editorial in the November 11th Journal of the American Medical Association.

I have a full statement that is included in the written report to you, and I stand by to answer any questions you might have.

[The prepared statement of Drs. Mazzuchi and Zimble follows:]

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Military Health System

**Statement on Availability of Complementary and Alternative
Therapies for Department of Defense (DoD) Beneficiaries**

By

John F. Mazzuchi, Ph.D.

**Deputy Assistant Secretary of Defense for Health
Affairs**

Clinical and Programs Policy

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U.S. House of Representatives**

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Introduction

Mr. Chairman, Distinguished members of the Committee, thank you for the opportunity to testify before this special hearing on the availability of complementary and alternative therapies available to DoD beneficiaries.

Let me begin by offering an overview of DoD policy with regard to complementary and alternative medicine (CAM), then discussing areas of specific activity within DoD. Our mission within Health Affairs is two-fold. With respect to military readiness, the Military Health System (MHS) provides medical and preventive health services and support to the United States Armed Forces military operations. Peace-time health care provides continuous medical and preventive services and support to members of the Services, their family members, and survivors, retired members and their families and all others entitled to Department of Defense health care. The MHS strives to provide care of the highest quality for our uniformed men and women and their families because that is what they expect. That is what they deserve. That is what they need in order to deploy all over the world with minds focused on the mission, confident that their families will be taken care of with medical care that is second to none. With this in mind let me say that the Department of Defense is open to and encourages the use of CAM therapies in treating our beneficiaries when science, through reviewed outcomes based research, has shown those therapies to be safe, efficacious, and cost effective.

Chiropractic Health Care Demonstration Project

Chiropractic therapy is one such non-traditional approach to patient care presently being tested in the MHS. Established in 1885 by Daniel David Palmer, chiropractic theory suggests that partial dislocation or subluxation of vertebrae interferes with normal transmission of nerve impulses, causing disorders in parts of the body remote from the spine. By manipulating the spine and soft tissues, pressure on nerves is relieved and thus the cause of the ailment is removed. Chiropractors consider their approach to be a conservative approach to healing because it requires a minimum of intervention; uses neither drugs nor surgery; and supports wellness through hygiene, nutrition, and patient education. Although it is not main stream medical therapy, chiropractic therapy has increased in popularity over the years, and has become a covered treatment with some medical insurance carriers.

The Chiropractic Health Care Demonstration Program (CHCDP) was implemented in response to the National Defense Authorization Act for Fiscal Year 1995 which directed the Secretary of Defense to establish a "demonstration program to evaluate the feasibility and advisability of providing chiropractic care through the medical care facilities of the Armed forces." The Act further required that the Secretary "designate not less than 10 major military medical treatment facilities " and provide contract chiropractors for these facilities. The Department of Defense was directed to enter into contractual agreements with sufficient numbers of chiropractors to provide care at the designated sites throughout the period of the demonstration.

The DoD has set up thirteen test sites for the demonstration program at various medical centers and clinics around the country under three models. Six of the demonstration sites are set up under the Patient Choice Model at which patients are given a choice of receiving chiropractic or traditional treatment for their neuromusculoskeletal conditions. Those locations are Ft. Carson, Jacksonville Naval Air Station (NAS), Scott Air Force Base (AFB), Walter Reed Army Medical Center, Bethesda National Naval Medical Center, and Wilford Hall Medical Center. There are seven demonstration sites that utilize the Primary Care Manager Model. Under this model, patients with neuromusculoskeletal conditions of the spine may be referred for chiropractic treatment by their primary care manager (PCM). Those sites are Ft. Benning, Ft. Jackson, Ft. Sill, Camp Lejeune, Camp Pendleton, Offutt AFB, and Travis AFB. Three other sites, Ft. Stewart, Pensacola NAS, and Andrews AFB are involved in the demonstration as Comparison sites where chiropractic care is not offered, but data is collected on similar patients and in the same manner.

The CHCDP is available to active duty personnel, their family members, retirees, and their family members. Participants are offered an optional Patient Screening Checklist, a Patient Acknowledgment Form that provides documentation that they are well informed about the CHCDP and that they consent to participate. Participants also complete a Patient Initial Visit Survey, and another Patient Four-Week Follow-Up Survey. These surveys provide information on the patient's status and the extent to which their condition has changed over the course of the previous four-week period. This survey also provides information concerning satisfaction with the care received. Similar surveys are given to the medical personnel, traditional providers and chiropractors, with follow-up surveys re-administered yearly during the demonstration period.

The goal of the CHCDP evaluation is to answer the basic questions regarding feasibility and advisability posed by the Congress in mandating a demonstration of chiropractic care in military medical facilities. To answer the feasibility question we need to carefully consider the resource, policy, and procedural questions that this program explores. The objective and subjective measures of patient, provider, and institutional behavior are all factors to consider in determining the feasibility and consequently the advisability of offering chiropractic therapy to beneficiaries as a routine benefit. The project receives oversight by an Oversight Advisory Committee composed of DoD Health Affairs and TRICARE Management Activity, the Surgeons General of the Army, Navy, and Air Force, the General Accounting Office, the Foundation for Chiropractic Education and Research, the Federation of Chiropractic Licensing Boards, the Association of Chiropractic colleges, the Congress of Chiropractic State Associations, and the Council on Chiropractic Education.

Since the program is ongoing, it would be inappropriate for me to offer conclusions at this time. However, in general, chiropractic patients have consistently rated their satisfaction with the program as very positive. As of January 30, 1999, the program has collected 24,868 initial surveys: 12,668 from chiropractic participants and 3,803 from traditional participants. A total of 8,818 four-week follow-up surveys have been received; 5,870 from chiropractic participants and 1,261 from traditional participants. Data collection will continue through September 30, 1999, with a final report due to Congress on May 1, 2000.

Wellness and Disease Prevention

One of the beneficial aspects of complementary and alternative medicine is that the therapies tend to focus on self-care and prevention. They stress a balance in living. The DoD continues to initiate and implement programs that recognize that personal health behaviors are extremely important in reducing the incidence and severity of disease, injury, and disability. The first step in any comprehensive health plan to promote a healthy lifestyle is to assess current health status. The Health Enrollment/Evaluation Assessment Review (HEAR) is an age-appropriate tool that surveys the general health status of each beneficiary. The HEAR queries current health status, family medical history, currency of immunizations, currency of prevention screenings such as pap smears, mammograms, testicular exams, rectal exams, level of activity, cholesterol

screening, hypertension history level of stress and coping mechanisms, number of medications currently in use, tobacco use status, alcohol use status, pediatric lead screening, and basic mental health screening. Information from this survey provides important individual and population health data and medical status to primary care providers and others tasked to meet the health and medical treatment needs of all our beneficiaries. Information from the HEAR alerts primary care providers to the identification of chronic disease, the need for preventive care, the need for case management and disease management, and the need for health education and counseling. Our goal is to help our beneficiaries attain and maintain the best health status possible.

The Department of Defense issued policy in November 1996 and March 1998 to implement "Put Prevention into Practice" (PPIP) within the Military Health System. PPIP is a national campaign developed by the Office for Disease Prevention and Health Promotion, Department of Health and Human Services, to improve the health of the United States' population through prevention of premature death, disease, and disability. MHS implementation of PPIP supports the transformation of healthcare delivery focus from disease and injury treatment to overall disease/injury prevention and health. PPIP provides a sound, practical methodology for clinicians to adapt preventive care into all aspects of their practices. It promotes teamwork in its delivery and involves everyone: the patient, the clinic/office staff, and the clinician. It provides research-proven tools to facilitate the delivery of preventive interventions, and stresses that every clinical visit by a patient should be used as an opportunity for preventive care.

The DoD has endorsed the goals of the "Healthy People 2000" initiative. Healthy People features 334 health related goals and objectives in 22 priority areas under three general categories, portions of which should be included with every clinical encounter.

Health Promotion deals with physical activity, nutrition, tobacco use, alcohol and drug use, family planning, mental health and mental disorders, violent and abusive behavior, education and community based programs.

Health Protection deals with unintentional injuries, occupational health and safety, environmental safety, and oral health.

Preventive Service deals with maternal and infant health, heart disease and stroke, cancer, diabetes and chronic disabling conditions; HIV/AIDS, sexually transmitted diseases, immunizations and infectious diseases, and clinical preventive service.

This system-wide education, training and counseling program is continually practiced and reinforced, and stresses the fact that some diseases are preventable by vigilance and individual effort. Additionally, even when disease is not preventable, it can often be detected and treated in its early stages through screening and intervention programs. Prevention results in longer, healthier lives for the individual, a more fit and ready fighting force, and can decrease demands on health care resources in the DoD.

The promotion of certain nutritional supplements for routine use is an example of how prevention has become a theme within the MHS. For many years obstetric and family medicine providers have stressed the need for a minimum of 0.4 mg of folic acid per day to prevent neural tube birth defects such as spina bifida and anencephaly, and decrease the risk of occlusive cardiovascular disease by lowering plasma homocysteine levels in adults. On January 23rd, 1998 DoD formalized that practice into a formal policy memorandum issued to all the Services. The policy stated that "a folic acid-containing supplement should be offered/dispensed to all active-duty recruits, both male and female, during basic training. A daily supplement should continue to be strongly encouraged as well as a diet rich in folates and folic acid. Primary care managers, women's health care providers, and health promotion educators should advise all adult MHS beneficiaries of the protective benefits of folic acid. We should encourage diets rich in fruits, vegetables and grains, and the regular consumption of a folic acid-containing supplement."

Uniformed Services University of the Health Sciences

Dr. Zimble will discuss the role of the Uniformed Services University of the Health Sciences (USUHS) regarding CAM as well as address the Dean Ornish Demonstration projects.

In 1994 the Department of Preventive Medicine and Biometrics sponsored the establishment of a Complementary and Alternative Medicine Seminar series at the USUHS. Since then over 56 CAM seminars have been

presented, many of which were funded and approved for graduate and CME credit.

In 1996, sponsorship for the seminars was transferred to the Department of Family Medicine. In the last fiscal year six CAM lectures were provided on the following subjects: The Bond Between Chiropractic Medicine and the Physician, Manifesto for a New Medicine; Your Guide to Healing Partnerships and the Wise Use of Alternative Therapies, Complementary and Alternative Medicine: What Is It? How Can We Evaluate It? Alternative Medicine: An Evidence-based Approach, and Pain Management and Acupuncture.

Thus far in 1999, a lecture entitled Traditional, Alternative and Complementary Healing Practices in Substance Abuse Treatment was given on February 2nd, and a lecture on Alternative and Complementary Medicine in Managed Care is scheduled for April 15th. Medical student training has been enriched by experiential clinics that have been held for the 1st and 2nd year medical students and a CAM elective has been proposed for 4th year students.

The visibility and profile of CAM within the University has been enhanced by the recent assignment of LTC (Dr.) Wayne Jonas to the University's Family Medicine Department. Dr. Jonas is the former Director of the Office of Alternative Medicine, National Institutes of Health. He is complemented by Dr. Joseph Kaczmarczyk, MPH, USPHS who is Senior Advisor on Integrative Medicine and Alternative Health Practices for the Bureau of Primary Health Care, Health Resources and Services Administration. He has volunteered to be the faculty advisor for the creation of an official USUHS student CAM Special Interest Group and the faculty lead for a USUHS 4th year elective.

Significant CAM research is being undertaken at the USUHS. Approximately twelve active protocols are underway in topics such as 1) Stress, Heart Disease and Stress Reduction, 2) Weight Loss and Maintenance, 3) Pediatric Parent Decision Making, 4) Nutrition and Exercise Benefits on Operational Performance, 5) Efficacy of Yogurt in Reducing GI Infection.

An exciting protocol carrying forward Dr. Dean Ornish's Lifestyle Demonstration Project is currently being established by a member of the

Internal Medicine Department faculty at Walter Reed Army Medical Center (WRAMC). The Lifestyle Demonstration Project provided evidence that comprehensive lifestyle changes that include a low-fat vegetarian diet, moderate aerobic exercise, stress management techniques, smoking cessation, and group support meetings can significantly retard or reverse the progression of coronary atherosclerotic lesions in selected heart patients. These studies have shown that a reduction in serum cholesterol results in reduced chest pain, increased functional capacity, improved blood flow to the heart and elevated psychosocial status.

In FY 1999, Congress provided \$2.5M to support research on non-invasive treatments for coronary artery (and prostate) disease. These funds will be used to support a multi-center effort investigating the efficacy of intensive lifestyle modifications in improving the clinical status of patients with moderate to severe coronary heart disease (and in patients with prostate cancer who have elected not to undergo conventional treatment). The lifestyle modification program includes a low-fat vegetarian diet, moderate aerobic exercise, stress management techniques, smoking cessation, and group support meetings.

Program management and administrative support will be accomplished by the USU and the Henry M. Jackson Foundation for the Advancement of Military Medicine. This multi-center effort will be conducted at WRAMC; Windber Medical Center (WMC), Windber, Pennsylvania; and the non-profit Preventive Medicine Research Institute (PMRI), Sausalito, California. Studies at WRAMC will focus on both coronary and prostate disease patients, studies at WMC will be concerned only with coronary disease patients, and studies at PMRI will be concerned only with prostate disease patients. WRAMC is a major DoD Medical Center drawing patients from the large urban, metropolitan area of Washington, DC. There is a significant patient population seen for both coronary and prostate disease, with patients being both active duty and retired military, as well as their dependents. WMC provides a complementary group of patients, principally retired military with a small active duty population, living in a remote, rural setting with a significant difference in lifestyle from the patient population at WRAMC. PMRI is a well-established non-profit private research organization, the recognized leader in investigating the effect of lifestyle changes on prostate cancer, and uniquely capable of performing research studies in this area.

Graduate Medical Training

Some of our medical residency programs have begun to make CAM a core curriculum. The Family Practice Residency Program at Andrews AFB will have a mandatory curriculum on CAM starting next year. Clinical hypnosis and relaxation therapy techniques have been a part of that curriculum for many years. Training is also offered in biofeedback technique at Andrews AFB.

Hospitals and Clinics

Overall, various elements of CAM are offered in selected facilities throughout DoD. There is no set program or standardized therapy offered. Some of our physicians have been trained in acupuncture techniques through their own interest. After being appropriately credentialed by their MTFs, they are allowed to treat patients with acupuncture. Selected providers at WRAMC and the Andrews AFB Family Practice Clinic treat patients who have chronic pain with acupuncture. In another example, a radiation oncologist assigned at Edwards AFB conducts an acupuncture practice every morning and has accommodated about 1200 visits. He focuses on referrals from the family practice and surgery departments and reports a high success rate with the use of acupuncture in treating pain, allergies, smoking cessation, and obesity. He has also spoken at DoD conferences such as a DoD Breast Cancer Meeting this past year. Other CAM therapies, such as therapeutic touch are available at the National Naval Medical Center at Bethesda by specific providers.

Most of the hospitals and clinics offer stress management programs that include relaxation training, visualization, breathing techniques, exercise information, and cognitive techniques. The psychology clinics within the DoD often offer biofeedback and other behavioral medicine services. Some mental health professionals and other staff use meditation with patients. A provider in San Diego teaches patients to incorporate T'ai Chi into their daily routine for relaxation therapy. Naval Medical Center Portsmouth recently started a nurse-run alternative pain treatment program as part of the pain clinic.

Conclusion

Many therapies considered to be complementary or alternative have not been accepted as mainstream medicine due to the lack of scientific

evidence to support their effectiveness or safety. The MHS is held accountable by all Americans for the medical care it provides for Service members and their families. To uphold that accountability we have regulations and program policies that restrict benefits (i.e. TRICARE/CHAMPUS Policy Manual 6010.47) to “those devices, treatments, or procedures for which the safety and efficacy have been proven to be comparable or superior to conventional therapies. Any device, medical treatment, or procedure whose safety and efficacy has not been established is unproven.” The DoD will follow closely the research done through reputable institutions such as the Office of Alternative Medicine within the National Institutes of Health, USUHS, and programs at other medical schools such as the Program for Complementary Medicine through the University of Maryland School of Medicine for answers to the questions that CAM therapies pose.

Many of our beneficiaries are interested in complementary and alternative medicine. Our providers realize that within each of us there is a natural recuperative power that is the key to all healing, and that taking charge of one’s health and well-being, physically, mentally, emotionally and spiritually is within the grasp of each individual. Moreover, the Department does not restrict the practice of providers who are knowledgeable, willing and able to provide alternative medical therapies for their patients. However, the spectrum of CAM is broad; folk medicine, herbal medicine, diet fads, homeopathy, faith healing, new age healing, chiropractic, acupuncture, naturopathy, massage, music, magnetic, and a host of other therapies. The truth is that one simple definition cannot describe all that is now considered “alternative medicine.” Moreover, like politics and religious beliefs, the line between alternative and mainstream therapy is not consistently clear in the minds of patients and providers alike. We remain a society that is built upon science and dependent upon science to solve many of the problems that we as well as future generations face. We are also a society that values the past, appreciates the foreign, and hopes for something new from both that can be used in the present. As therapies that are currently considered complementary or alternative are tested and shown to be safe, efficacious, and cost effective they will become the standard of care in the DoD.

This concludes my testimony. I will be pleased to answer your questions.

Mr. BURTON. Thank you. We will get back to questions in just a moment.

Dr. HOLOHAN.

Dr. HOLOHAN. Thank you, Mr. Chairman. I am glad to be sitting next to the president of USUHS, which has a superb faculty, I am told, as well.

First, permit me to note that Dr. Kizer, the Under Secretary for Health, yesterday sent letters to the committee Chair and ranking member in which he emphasized some points that we made in our written testimony, and complimented the committee for addressing this topic. A conflict in his schedule prevents him from being present to testify today.

Public interest in alternative medical practices is increasing, and there are likely many reasons for this, including dissatisfaction with limitations of conventional medicine, desire for treatment directed toward the whole person, distrust of drugs and side effects, and some understandable frustration in search for a cure on the part of patients afflicted with chronic or serious disorders.

Conventional medicine's interest is evidenced by the fact that an entire recent issue of the Journal of the American Medical Association was devoted to this topic. Of note, VA participated in one of the trials that was reported in that issue.

Alternative medicine is a very nonspecific term that has been used to describe a heterogeneous group of practices. While their underlying philosophies and the manner in which their agents and techniques are employed diverge from mainstream medical principles and practices, that separation is not distinct and absolute, as we shall later discuss and as has been mentioned several times by previous witnesses.

VA recently awarded a contract to evaluate alternative practices as they might apply to our system of healthcare in VA. At present, that report hasn't been completed, but we do, however, have some preliminary survey data regarding the state of alternative practices in VA facilities.

While knowledge and even awareness of alternative practices varied widely among providers and facilities, most of the 131 facilities surveyed provide some such treatments. These practices usually reflected the presence of a practitioner or practitioner advocates and managerial willingness to accept the implementation of those programs. Most of the facility management teams were reported as pragmatically oriented and described as having no biases for or against alternative treatments.

The main concerns VA personnel expressed related to the highly variable training and credentialing of practitioners, the lack of sound scientific evidence supporting the use of many alternative therapies, and uneasiness about the budgetary impact of alternative practice in an environment of constrained resources.

We note that many practices often considered as alternative have been or are also used by conventional medicine. For example, physical and manual treatment significantly overlap with modalities that are widely used in the current practice of physical medicine and rehabilitation. Many nutritional therapy models have counterparts in allopathic medicine, such as the use of hyperalimentation as an adjunct to conventional cancer treatment.

The mainstream medical literature contains numerous studies of vitamin supplementation, the use of zinc and antioxidants, among many others. Many drugs that are used by conventional practitioners are, in fact, botanical preparations which have been evaluated in clinical trials and approved for marketing by FDA. These include vincristine from the periwinkle plant, digitalis from foxglove, and taxol, which was originally extracted from the Pacific yew tree bark.

Moreover, mind/body interaction is not a phenomenon that is only recognized by alternative practitioners, as there is, in fact, a long history in medicine of appreciation of those mutual effects. A significant body of mainstream research has provided data that indicate the prognosis for coronary disease patients with depression is worse than for those without; that breast cancer patients who attended a support group had measurably better outcomes than those who did not, and that single male cancer patients had poorer prognoses than married patients.

Many similar findings are published, and currently, in VA we are developing a formal systemwide strategy to fully integrate mental health and medical services throughout our system of care, based upon our belief that all diseases or disorders exist within an individual who is the unit of the care.

At the same time, one cannot ignore alternative or unconventional care that may be extreme. There are a number of therapies whose advocates have proposed unreasonably optimistic claims and whose treatments have been ineffective and often harmful. Our written testimony provided specific examples of a number of such regimens.

Indeed, in the early 1980's, a committee chaired by the late Congressman Claude Pepper published a comprehensive, sobering, yet remarkable, report on the wide variety of ineffective treatments being sold to the public. We do not mean by imply that all unconventional treatments are ipso facto suspect. The critical point to be made is that the advocate of any treatment, conventional or unconventional, allopathic or homeopathic, surgical or psychological, has an ethical and moral obligation to provide high-quality evidence that satisfactorily demonstrates the treatment is effective, and that the benefit is clearly proportionate to the risk. This is true for conventional treatment, and it is true for alternative practices.

Claims that assert that scientific research standards are inappropriate or irrelevant to alternative practices are wrong. Science is not a belief system, but merely a disciplined method of investigation that enables one to test the hypothesis, and its applicability is virtually universal, we feel.

The scientific method is the only instrument that permits a mathematically sound statement of the probability that a particular cause will result in a specific effect. A casual and an unsystemic linkage of cause and effect is too often erroneous, and for those reasons, prudent clinicians are loathe to accept anecdotal evidence, a few cases, or subjective judgments as proof of efficacy.

VA believes we have a serious responsibility to demand evidence of benefit and safety for treatments we provide to veteran patients, and we have invested considerable resources to that end. We also believe that opinion or beliefs do not constitute scientific evidence

and that anecdotes or small series studies represent the weakest forms of evidence and only serve to provide a hypothesis that can be tested in a well-designed trial.

While such positions are not in accord with the opinions of some in both the conventional and alternative medical fields, they are ratified by how most of us, tacitly or overtly, rely on the scientific method in our daily lives. When we step into an airplane, we are aware of our dependence upon the research and experimentation underlying the engineer's theories and upon the repeated testing of materials and design of the airframe, engines, and controls. We expect the Federal Aviation Administration to provide serious oversight of aircraft manufacture, and that design and construction will rely in the application of scientific investigation. We also expect that production will be accomplished by technical experts qualified by training and experience, and certified as competent by reliable and responsible authorities.

It is dangerous to assume that so-called natural or nonpharmaceutical products are by nature safe. In our written testimony, we noted the recent recall of a dietary supplement, gamma butyrolactone, or GBL, which has caused comas, seizures, cardiac and respiratory arrest, and death. Undoubtedly, most consumers made ill or killed by GBL assumed its production and sale implied at least some research demonstrating safety, if not effectiveness. Sadly, they were mistaken.

At present, there is a paucity of rigorous, reliable, and valid clinical trial data supporting many alternative interventions. Indeed, that was identified as a major concern of VA personnel in our contractors' survey. We believe that evidence is critical in our determination as to the role alternative medicine may play in the care of our patients. To that end, our research and development program will continue to fund scientifically meritorious investigator-initiated research related to alternative practice at all levels.

Inconsistent alternative provider credentialing, licensing, and regulation pose serious problems in the utilization of those practitioners and techniques. And, Mr. Chairman, you asked a question about this a minute ago of Dr. Berman. Acupuncturists are licensed in 35 States; massage therapists in 27; naturopaths in 4, and homeopaths in 14 States.

I did some surfing of the internet on naturopathy and found an internet site that provided naturopathy information—actually, two sites—that made a statement that, "Certified naturopaths may complete a 4-year program of study or they may be someone with nothing more than a diploma from a diploma mill or a correspondence school."

VA has set high standards for practitioner education, credentialing, and certification. All newly hired VA physicians must be licensed and board-certified. Advanced practice nurses must possess licensure, national certification, and a graduate degree; and registered nurses, licensure and a bachelor's degree. We believe that all providers in VA should meet appropriate comparable standards, irrespective of their practice focus.

In closing, VA is investigating alternative medicine practices and is presently gathering data to address the interest of our clinicians and the extent of alternative medicine use in our system. We ex-

pect to be reviewing information developed from the literature base for alternative practices, the appropriateness of employment for our population, and information on cost and cost-effectiveness.

VA expects that any treatment offered to veteran patients, whether conventional or alternative, and provided outside the context of a clinical trial, will be chosen on the basis of objective evidence sufficient to permit the conclusion that it is both safe and effective.

Thank you.

[The prepared statement of Dr. Holohan follows:]

**Statement of
Thomas V. Holohan, M.D., FACP
Chief, Patient Care Services
Veterans Health Administration
Department of Veterans Affairs
For
Committee on Government Reform
U. S. House of Representatives**

February 24, 1999

Public interest in, and use of, unconventional, complementary, or alternative medical practices (CAM) is increasing. Contemporary observers have offered many reasons for the phenomenon, including dissatisfaction with limitations of conventional medicine, desire for treatment directed toward the "whole person", distrust of drugs and side effects, and awareness of linkages between disease and emotional and lifestyle factors. Added to this is the understandable frustration and search for "cure" on the part of patients afflicted with chronic or serious disorders which have not responded well to available therapy. Other factors likely include the reduction in time physicians are able or willing to spend with individual patients, as productivity concerns in medical practice assume ever greater importance.

Several recent publications have indicated that up to \$27 billion are spent each year on CAM, and that a third of persons surveyed have used at least one modality that may be defined as "alternative". In 1993, the National Institutes of Health (NIH) established the Office of Alternative Medicine (OAM) to facilitate the evaluation of alternative therapies. OAM currently has an annual budget of \$50 million. Interest on the part of the conventional medical community is evidenced

by the fact that an entire recent issue of the Journal of the American Medical Association was devoted to CAM.

The heterogeneous treatments employed by the many schools of alternative practices cannot be encompassed within a single paradigm. When we refer to CAM, we are using a nonspecific term to describe a variable group of practices which include the use of botanical therapies, mind-body interactive approaches, nutritional interventions, various physical or manual therapies, some chemical entities or biologics which have not been evaluated by the Food and Drug Administration (FDA) on the bases of clinical trials, and similar modalities. Still others are rooted in cultural or religious belief systems that may be foreign to contemporary Western society. Their single commonality is that their underlying philosophies and the manner in which their agents and techniques are employed diverge from our mainstream medical principles and practices. However, that separation is not distinct and absolute, as we shall later discuss.

VA recently awarded a contract to survey alternative practices as they might apply to our system of healthcare. Elements of the report are to include: the current state of use and familiarity with alternative practice within our system; a review of VA's patient database and a literature-based assessment of the applicability of alternative practices to VA patients; an evaluation of the state of alternative practices in the private sector; and an appraisal of the cost-effectiveness of alternative practices. At present, the report has not been completed. We do, however, have some preliminary information regarding the state of alternative practices in VA facilities. While knowledge, and even awareness, of alternative practices varies widely among VA providers and facilities, most facilities provide some such treatments. These have generally included modalities such as acupuncture, dietary therapy, yoga, biofeedback, relaxation, music therapy, and Native American therapies (e.g., "sweat lodges"). These practices usually reflect the presence of practitioner advocates and managerial willingness to accept the implementation of those programs.

Preliminary data also show that most facility management teams were reported as pragmatically oriented, and described as having no biases for or against alternative treatments. The main concerns VA personnel expressed related to the highly variable training and credentialing of practitioners, the lack of sound scientific evidence supporting use of many alternative therapies, and uneasiness about the budgetary impact of alternative practice in an environment of constrained resources.

We would call the Committee's attention to the fact that many practices often considered as alternative medicine have been, or are, also used in "conventional" medicine. For example, physical and manual treatments (such as massage therapy) significantly overlap with modalities widely used in the current practice of physical medicine and rehabilitation. Many nutritional therapy models have counterparts in allopathic medicine, such as the use of hyperalimentation as an adjunct to conventional cancer treatment. In addition, the mainstream medical literature contains numerous studies of vitamin C supplementation, zinc for treatment of viral respiratory infections, and the use of vitamin E as an antioxidant, among many others. Many drugs widely used by conventional practitioners are, in fact, botanical preparations which have been evaluated in clinical trials and approved for marketing by FDA. These include vincristine (from the periwinkle plant), digitalis (foxglove), and taxol (originally extracted from Pacific Yew tree bark). Many metallic elements have been employed by conventional practitioners including cis-platinum (for cancer), mercury (syphilis), magnesium (eclampsia of pregnancy), and others. Indeed, maggots have been sometimes used in lieu of surgery to successfully treat putrefying wounds and remove dead tissue in certain infections, based on observations made in the First World War that maggot infested wounds rarely became gangrenous.

Moreover, the mind-body interaction is not a phenomenon only recognized by alternative practitioners. There is a long history in medicine of appreciation of those mutual effects. A significant body of mainstream research – both old and

new - has provided data that indicate the prognosis for coronary disease patients with depression is worse than for those without; that breast cancer patients who attend a support group have measurably better outcomes than those who do not; that single male cancer patients have worse prognoses than married patients; that cancer patients who are optimistic and who have stronger religious feelings tend to fare better than patients not so inclined. Indeed, it is no accident that the VA's Chaplains' Service is an integral part of our Office of Patient Care Services, and not attached to administrative programs. We see their ministry as part and parcel of clinical care. Further, we are currently developing a formal VA-wide strategy to fully integrate mental health and medical services throughout our system of care, based upon our belief that all diseases or disorders exist within an individual who is the unit of care, and that one treats a whole patient, not simply an organ system.

An additional example of the appreciation of mind-body interactions includes our growing understanding that the so-called placebo effect is real, and is potent. We know that patients often experience what they expect to experience. The Physician's Desk Reference (PDR) compendium of FDA-approved drug labeling includes data on adverse effects reported by patients during trials in which drugs were compared with placebo. For pilocarpine (used to treat salivary gland dysfunction), nine percent of patients given a placebo reported increased sweating, and eight percent reported headache. For diltiazem (used to treat hypertension), of the patients given placebo and not the active drug, five percent reported headache, three percent dizziness, and 2.3% had abnormalities of their electrocardiogram (versus 1.6% of those treated with the active drug). In controlled trials of interferon, nearly 20% of placebo-treated patients reported fever, and 15% malaise. Suggestion is powerful, as has repeatedly been demonstrated since the 19th century by hypnotherapy.

At the same time, one cannot ignore the portion of the spectrum of alternative or unconventional care that is truly extreme. There are a number of therapies

whose advocates have proposed unduly optimistic claims and whose treatments have been unequivocally demonstrated as ineffective and often harmful. Such treatments include immunoaugmentative therapy for cancer, offered in the Bahamas for many years. In this genre are also administrations of coffee enemas as cancer therapy, and the promotion and sale of laetrile, the latter having been legalized by the legislatures of 24 states despite the opposition of major medical professional societies, the NIH, FDA, and the American Cancer Society. Indeed, in the early 1980's, a committee chaired by the late Congressman Claude Pepper published a lengthy, sobering yet remarkable report on the wide variety of ineffective or fraudulent treatments being sold to the public. We do not mean to imply that all unconventional treatments are *ipso facto* suspect. The critical point to be made is that the advocate of any treatment, conventional or unconventional, allopathic or homeopathic, surgical or psychological, has an ethical and moral obligation to provide high quality, convincing evidence that satisfactorily demonstrates the treatment is effective and that the benefit is clearly proportionate to the risk. This meets the intent of the Kefauver Commission which in 1962 mandated that pharmaceuticals must be shown by their manufacturers to be effective for their intended purpose.

Claims asserting that scientific research standards are inappropriate or irrelevant to alternative practices are flawed. Science is neither an entity nor a belief system, but merely a disciplined method of investigation. It is a tool that enables one to formulate and then test a hypothesis; as such its applicability is virtually universal. For science, data rather than opinion are determinative. It is the only instrument that permits a mathematically sound statement of the probability that a particular cause will result in a specific effect. A casual and unsystematic linkage of cause and effect is too often erroneous in biological systems. For those reasons, prudent clinicians are loath to accept anecdotal evidence, a few cases, or subjective judgements as proof of efficacy.

Treatments should be offered patients only after there has been provided convincing evidence of effectiveness and acceptable adverse effects. This is no less true of conventional than of alternative practices. Ignoring this tenet does not serve patients well. During the 1960's an operation to prevent stroke by connecting the external carotid to the internal carotid artery (EC-IC bypass) was developed and widely applied based upon a number of reports of small series of patients. Because of the outspoken skepticism of some in the medical community, and despite the prestige of the advocates, the NIH sponsored an international, multicenter prospective randomized trial comparing the surgery with medical therapy. The results, published in 1985, demonstrated that not only did the procedure fail to prevent stroke, but also that operated patients died sooner and in greater proportion than did patients treated medically. Clinical research on pharmaceutical preparations is required by statute. Current federal law requires that the FDA approve drugs only on the basis of well-controlled clinical trials; similar requirements exist for some medical devices (those implanted or used for life-threatening conditions). There are no such standards for surgical procedures or for alternative medical therapies.

VA believes that we have a serious responsibility to demand evidence of benefit and safety for treatments we provide to veteran patients, and we have invested considerable resources to that end. We have recently established a Technology Recommendations Panel, to add to our Technology Assessment Program (a component of our Office of Research and Development), with the view of aiding such evaluations. We also believe that expert opinion or beliefs do not constitute scientific evidence; anecdotes, case reports, and studies of small series of patients represent the weakest forms of evidence and best serve to provide a hypothesis which may be tested in a well-designed clinical trial. While such positions are not in accord with the opinions of some in both the conventional and alternative medical fields, they are ratified by how most of us, tacitly or overtly, rely on the scientific method in our daily lives. When we step into an airplane, we are aware of our dependence upon the research and

experimentation underlying the engineers' theories, and upon the repeated testing of both the materials and the design of the airframe, engines, and controls. We expect the Federal Aviation Administration to provide serious oversight of aircraft manufacture, and that design and construction will not rely solely on opinions or beliefs but on the application of scientific investigation. Likewise, we expect items such as our automobile brakes and tires will be the products of materials research, carefully controlled testing, and standardized components and construction meeting standards of the Department of Transportation. In both of those venues, we also expect that the production will be accomplished by technical experts qualified by training and experience and certified as competent by reliable and responsible authorities.

It is dangerous to assume that so-called "natural" or non-pharmaceutical products are by nature safe. This month, the FDA required manufacturers to recall gamma butyrolactone (GBL), a dietary supplement widely sold in health food stores, gymnasiums, and over the Internet. Its primary commercial use is as a solvent in paint thinners and nail polish remover. Use of the product had caused comas, seizures, dramatic slowing of heart rates, respiratory arrest, and death. Those occurrences mimic those of a chemical banned in 1991, gamma hydroxybutyrate, which had been linked to deaths and use in "date rape" cases. However, after ingestion, GBL is converted in the body to the banned gamma hydroxybutyrate. The Council for Responsible Nutrition, a trade association representing supplement manufacturers, stated that GBL should never have been marketed because it had clearly been shown to be dangerous to humans and animals. Undoubtedly, most consumers made ill or killed by GBL assumed that its production and sale implied at least some research demonstrating safety, if not effectiveness. Sadly, they were mistaken.

At the present time, there exists a paucity of rigorous, reliable, and valid clinical trial data supporting many alternative interventions. Indeed, that was identified as a major concern of VA personnel in preliminary information received from our

contractor. We believe such evidence is critical in our determination as to the role CAM may play in the care of our patients. To that end, the VA research and development program will continue to fund scientifically meritorious investigator-initiated research related to alternative practices at all levels, from basic biomedical trials through multicenter clinical trials, and health services outcomes studies. We will continue to encourage health professionals to submit research proposals in their areas of interest and expertise, as well as support public and private sector collaborations to pursue research on high priority health care needs of veterans. Whenever appropriate, such collaborations will include alternative or unconventional medical practices.

Additionally, inconsistent CAM provider credentialing, licensing, and regulation pose serious problems in the utilization of those practitioners and techniques. Acupuncturists are licensed in 35 states; massage therapists are licensed in 27, naturopaths in 14, and homeopaths in four states. A naturopathy-related Internet site states that "Certified Naturopaths may complete a four-year program of study or they may be someone with nothing more than a diploma from a 'diploma mill' or a correspondence school." Similar problems undoubtedly exist for other alternative disciplines. VA has set high standards for practitioner training, education, credentialing, and certification. All newly hired VA physicians must be licensed and board certified; all advanced practice nurses must possess licensure and a graduate degree, and all registered nurses licensure and a Bachelor's degree. We believe that all providers in VA should meet appropriately equivalent and comparable standards, irrespective of their practice focus.

In closing, VA is investigating alternative medical practices, and is presently gathering data addressing the interest of our clinicians and extent of alternative medicine use in our system. We expect to be reviewing information developed from the literature base for alternative practices, the appropriateness of employment for our population, and information on cost and cost-effectiveness. VA expects that any treatment offered to veteran patients – conventional or

alternative – and provided outside the context of a clinical trial will be chosen upon the basis of objective evidence sufficient to permit the conclusion that it is both safe and effective.

Mr. BURTON. Thank you, Dr. Holohan.

Dr. Kamerow, why is it that, if there is a program like Dr. Ornish's that has substantial evidence that shows that it is effective in reducing conventional therapies, such as open heart surgery and—what is the balloon thing again—angioplasty, why is it that there is not some mechanism for the Department of Health and Human Services to contact Congress and suggest to us that we take legislative action that will enable you to put that under the Medicare program?

I guess the point I am trying to make is this: We are finding out today that most of the people here agree that that program has merit, is effective, and is going to save a lot of money in the area of reduced heart surgeries and angioplasties. If that is the case, we are finding out about it, and we are going to be getting together with you and others at the Department of HHS, along with the doctor, to figure out some way to provide the passage of legislation, so that you can put that into the Medicare program.

My question is, why is it, when something like this happens, do you have to wait for Congress to come to you and take the initiative? Wouldn't it be better, if you know that there is something that works, for you to tell people in Congress about it, so that we could start the wheels rolling that will enable you to incorporate it into your procedures?

Dr. KAMEROW. I think that is a good idea, Mr. Chairman. I will certainly check with the Health Care Financing Administration and suggest that to them.

I think that in this particular case it is only really recently—and I mean quite recently, such as the last several months—that there have been good randomized control studies in fairly large populations of the kinds of interventions that Dr. Ornish is talking about. It is a very intensive regimen—

Mr. BURTON. I understand.

Dr. KAMEROW [continuing]. And it has been done successfully in small numbers of people. My understanding is that the people at HCFA are looking at it closely and would be glad to talk to you about it.

Mr. BURTON. I understand it takes a lot of discipline.

I wish you would suggest to them—I know that the agencies are not supposed to lobby Members of Congress. However, I can tell you, as one Member of Congress and chairman of one committee, that I would not consider it lobbying if, for instance, the Department of HHS came to us and said, "Here is a procedure that will help people, reduce medical costs, and one that we could use in the Medicare program with great efficiency and effectiveness, if Congress would allow us to do it, but right now we are prohibited from doing it because there is a legislative prohibition against it."

Dr. KAMEROW. I will be glad to take that message—

Mr. BURTON. And, really, I don't think anybody would consider that lobbying—it is that you gave us some ideas or suggestions—and I certainly wouldn't. I wish you would tell them that over there, because there may be other things that we don't know about besides this program that might be very advantageous to the Medicare program, to HHS, and to the populace in general.

Dr. KAMEROW. I would be happy to do that.

Mr. BURTON. Let me ask you just a couple more questions. I know that you are pinch-hitting for the Secretary, since there is no one on her staff that covers alternative medicine. Do you think that it would be helpful for HHS to have an Associate Secretary for Complementary or Alternative Medicine?

Dr. KAMEROW. I think that the Department is working to coordinate these issues at multiple levels, and that they would be glad to consider those kinds of suggestions from you. As I said in the testimony, there certainly are a number of activities going on throughout the Department and a number of agencies. I think they are working together to try to coordinate them. The Director of NIH, Dr. Varmus, does have a committee that he convenes across the Public Health Service, with representatives from the different agencies, to talk about research in complementary and alternative medicine. So I think there are some mechanisms that are in place now to coordinate the different activities.

Mr. BURTON. I guess the question I am posing is—I am not talking about a person who is an advocate for alternative therapy, but someone who would constantly peruse the medical journals and check to see if there are new alternative ways that are coming on-line that have been proven effective that they could point out to the people who are in charge of HHS, who will be making decisions on whether or not to move into different areas or new areas that might help the population.

So you might throw that out to them, as well as some idea on how to keep Congress informed, as well as the upper echelons of HHS, on new therapies that may be coming along of an alternative nature.

Dr. KAMEROW. I would be happy to do that.

Mr. BURTON. In 1997, the NIH consensus panel, their consensus was that acupuncture was effective in the treatment of post-operative and chemotherapy nausea. Why is it that they are still not allowing acupuncture to be utilized through the Medicare program?

Dr. KAMEROW. My understanding about acupuncture and Medicare is that there is a national noncoverage statement and policy, and that, in light of the recent Consensus Conference and other evidence, that they are looking at this, and when they feel that the evidence is strong enough, that they will change that.

It is important to point out that evidence from one source, such as an NIH Consensus Conference, may not be all that is necessary. It may be the opinion of some experts, and HCFA often requires that there be the kinds of randomized control trials that Dr. Ornish talked about before they will cover interventions. But that is one kind of evidence, and they certainly are taking that under consideration.

Mr. BURTON. Well, I have some personal experience. My wife had chemotherapy. My mother and father, who both died last September and October, had chemotherapy. And I know the kinds of problems that you have when you take that after a period of time. You regurgitate. You have all kinds of complications. It just seems to me if acupuncture has been helpful—even though they took medication, they still had these kinds of problems. If acupuncture relieves those kinds of symptoms, and it has been proven to do so, as we believe it has, it seems to me that that ought to be some-

thing that is seriously considered. You might want to put some limitations on acupuncture until other things are proven, but if it is helping in those areas, I wish that you would at least talk to them about that and look into that.

Dr. KAMEROW. I certainly will.

Mr. BURTON. How much money has VA invested in alternative medicine research?

Dr. HOLOHAN. I will pass that question over to our representative from the Office of Research, Dr. Burris.

Mr. BURTON. Doctor, why don't you come over to the microphone, so that I can hear you?

Do you know how much they have spent?

Dr. BURRIS. In fiscal year 1998, there were over 100 individual research products in the area of complementary and alternative medicine being conducted in VA facilities. They were funded at approximately \$5.5 million by VA, and an additional over \$9 million from all other sources of funding combined, other Federal agencies as well as nonprofit organizations.

Mr. BURTON. So the total for VA as well as other Federal agencies was about \$14, \$15 million?

Dr. BURRIS. In fiscal year 1998, that is correct.

Mr. BURTON. What percentage of that would be the total expenditure for conventional healthcare therapies?

Dr. BURRIS. It would be a little less than 2 percent of the VA research budget for that fiscal year.

Mr. BURTON. As well as the other agencies you were talking about?

Dr. BURRIS. No, I don't know what the figure would be of the other agencies.

Mr. BURTON. OK. But it is about 2 percent?

Dr. BURRIS. Of the VA budget.

Mr. BURTON. In the area of cancer research, didn't you say that it was about 1 percent, that we are putting \$2.3 billion into conventional cancer research and about \$20 million into alternative therapies? So we are looking at somewhere between 1 and 2 percent for alternative therapies.

Is there any suggestion that VA or the Department of Defense or at HHS that we increase that percentage? Because some of these alternatives have been very, very effective. Dr. Mazzuchi?

Mr. MAZZUCHI. Well, there is a way of doing that, I think, without necessarily increasing the percentage. I wish I had better data for you, and I can get it for you. As part of the DOD's breast cancer research program, where the Congress has appropriated considerable amount of money to the Department for breast cancer research, some of those moneys are set aside for IDEA grants. I have forgotten what the IDEA acronym stands for, but, basically, it is research moneys given to researchers who do not have a proven track record in the business; they have not been in the business of cancer research, or who are looking at alternative therapies or new techniques. It is basically meant to stimulate research in areas from people who have not been in this area before and with ideas that are different from some of the more mainstream research ideas. I think that is a good way to go with alternative medical research, is that you open the door, not necessarily setting out a cer-

tain percentage, but you certainly encourage, as part of your overall grant, that some areas would be in places that were not—

Mr. BURTON. See, the concern I have is that to encourage is kind of a nebulous thing. If there are specific funds that are allocated for a project or an area, that money is going to be used for that specific area. If you do it any other way, then the money, in all probability, won't get to that.

Mr. MAZZUCHI. Our IDEA grants actually are a certain amount of money that is set aside. It is not really percentage, but I guess you could make it a percentage of the money.

Mr. BURTON. OK, what amount of money is set aside for that?

Mr. MAZZUCHI. I have to get the number for you. It is quite large. It is about a quarter of the research grants are done with IDEA grants. Now all the IDEA grants aren't alternative medicine. They are simply with people who have not done this kind of research in the main or are trying to attract both new scientists and new methodologies, which some of that would go into.

[The information referred to follows:]

The goal of the Breast Cancer Research Program is to promote innovative, integrated research on breast cancer. The intent of the IDEA research program is to stimulate and reward creative ideas that may be viewed as speculative, but with the potential for high payoff. This research may represent a new paradigm, challenge existing paradigms, or look at an existing problem from a new perspective. The FY 98 Breast Cancer Research Program was a strong advocate of innovative approaches including utilizing alternative medicine proposals.

FY 98 Breast Cancer Research Program

| | |
|---|--|
| Total Proposals Submitted | 1322 |
| Total IDEA proposals submitted | 808 (61% of total proposals) |
| Total Grants accepted | 410 (31%) |
| Total IDEA grants accepted | 231 (28%) |
| Funding | |
| 66% of total funding went to IDEA grants | \$71,927,000 |
| IDEA Grants | |
| Submitted and Identified by Researcher as Alternative Medicine | 14 Submitted 4 Funded (28%) @ \$1,000,000 |
| Submitted under Nutrition/Diet/Vitamin Category | 20 Submitted 7 Funded (35%) @ \$2.77 million |

Proposals and funding from previous years showed a similar distribution.

Mr. BURTON. Well, we know that in the area of HHS and cancer it was about 1 percent, and we know now that at VA it is about 2 percent. So that is a very, very small percentage of the overall spending. There is a growing sense in the country among people who are veterans, at the VA, people in the Defense Department, and the general population that alternative therapies are something that they really want to take a hard look at before they go with conventional therapies. So it seems to me that there ought to be more money spent in that area instead of just a mere pittance; 1 or 2 percent is not going to cut it.

Yes, sir?

Dr. ZIMBLE. Mr. Burton, I just wanted to mention, I overlooked one fairly important fact, and that is that, in the 1999 appropriation to the Department of Defense, \$2.5 million was appropriated to our university to support the Ornish program. We will be bringing that to Walter Reed Army Medical Center, which will be doing some work specifically for that.

Mr. BURTON. So you are very supportive of that program?

Dr. ZIMBLE. Oh, yes, sir.

Mr. BURTON. What I would like for you to do, if you would, for me—because we are going to be meeting with the people at the HHS about that program, and we are going to have Dr. Ornish come back from San Francisco to meet with us, to try to figure out some way to legislatively get that program online, so we can incorporate it into the Medicare program. If you are sympathetic toward that end with the VA and the Department of Defense, if you could send me a letter to that effect, I would sure like to have that, just saying that you think it has worked; it has been effective.

[The information referred to follows:]



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4799



March 1, 1999

Honorable Dan Burton
Chairman
Committee on Government Reform and Oversight
2157 Rayburn House Office Building
Washington, DC 20515-6143

Dear Representative Burton:

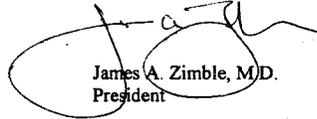
I am writing in response to your request during the Committee Hearing on "Opening the Mainstream to Complementary and Alternative Medicine", held on February 24, 1999.

The Uniformed Services University of the Health Sciences (USUHS) vigorously endorses the coronary and prostate disease reversal program developed by Dr. Dean Ornish, Director of the Preventive Medicine Research Institute. We recognize that this lifestyle change program is a valid alternative to such therapies for patients with coronary artery disease as bypass surgery, angioplasty, and/or a lifetime of cholesterol-lowering drugs. The success of the Ornish program in coronary disease reversal is well established in the peer-reviewed scientific literature, and his work on prostate disease reversal seems promising in the early stages of research.

The USUHS is currently working in a collaboration with Dr. Ornish which will enable patients under the care of the Military Treatment Facilities in the National Capital Area to have access to his lifestyle change program. We are assisted in this endeavor by the Henry M. Jackson Foundation for the Advancement of Military Medicine, which provides all necessary logistical and administrative support to ensure success of the program. The FY 1999 funding appropriation will enable us to establish a treatment test site at Walter Reed Army Medical Center in Washington, DC.

Please let me know if I can be of further assistance.

Sincerely,



James A. Zimble, M.D.
President

cc:

Honorable Henry A. Waxman
Ranking Minority Member

Assistant Secretary of Defense (Health Affairs)

President, Henry M. Jackson Foundation for the
Advancement of Military Medicine

Director, Preventive Medicine Research Institute

Mr. BURTON. Let me ask you one more question regarding the veterans. Is saw palmetto available to veterans? We understand that that has had a positive impact on prostate problems.

Dr. HOLOHAN. Frankly, Mr. Chairman, I don't know.

Mr. BURTON. Well, could somebody maybe check into that and let me know? Because that is one thing that there is some evidence that has been helpful in a number of prostate problems in men.

[The information referred to follows:]

Stars & Stripes, 1/4-17/99
The National Tribune

Saw Palmetto Takers Report Prostate Improvement

(Stars and Stripes)—Men taking saw palmetto extracts were nearly twice as likely to report improvements in prostate enlargement symptoms than men taking placebos, researchers led by Dr. Timothy Wilt of the Minneapolis VA Medical Center reported recently.

The herbal remedy popular for treating prostate problems works without the side effects of traditional drugs, researchers—adding that more tests are needed—told the Associated Press.

According to a report in the *Journal of the American Medical Association*, berries from the saw palmetto tree have been used to treat symptoms caused by the enlargement of the prostate gland as far back as the Seminole Indians in Florida in the 1700s.

Saw palmetto is used far more than prescription drugs in Europe to treat noncancerous prostate enlargement, but its chemical mechanism is unknown.

In the report, doctors reviewed 18 studies of saw palmetto use involving 2,939 patients with benign prostate enlargement, which causes difficulty urinating in many men over 50. The trials ranged from four to 48 weeks.

When compared with finasteride, a prostate-shrinking prescription drug marketed in the United States as Proscar, saw palmetto provided similar relief with fewer side effects, including impotence, the AP reported.

None of the studies compared saw palmetto with the most commonly used prostate drugs, a class called alpha blockers that relax prostate muscles and are marketed in the United States as Cardura, Flomax and Hytrin, the AP said.

"Our results should be viewed with caution," the authors were quoted as saying. Few studies reported their findings in standardized ways, most were brief and they involved varying doses and combinations of saw palmetto with other plant-based compounds.

"I tell my own patients that saw palmetto is harmless, that there's a suggestion that it may improve symptoms, but we don't really know with certainty," Dr. John McConnell, a spokesman for the American Urological Association, told the AP.

Mr. BURTON. You mentioned that the Defense Department will begin integrating alternative therapies when they have been tested and shown to be safe and cost-effective. Since acupuncture has been shown by an NIH consensus panel to be effective for post-operative and chemotherapy nausea, as well as dental pain, when will the Defense Department begin making acupuncture in certain cases available systemwide?

Mr. MAZZUCHI. We have begun the process to do that. Based on the Consensus Conference at NIH, we communicated that information to the office in Aurora, which is the benefits office, which tends to look at new technologies and does technology assessment with us. That office is looking at the literature right now, and is looking at perhaps doing some clinical trials to determine whether this should be a covered benefit. It is a process that takes between 1 and 2 years. We are about 8 or 9 months into that process now. My expectation is that, based on the literature we have seen so far, it looks fairly favorable that at least in some circumstances it would be covered. Now, as I have said, we do cover it inside the MTFs, our medical treatment facilities, like Walter Reed, and so forth. But in terms of being paid for, if you receive your care external to our military hospitals, that we still do not do, but that is where we are heading.

Mr. BURTON. Let me just make one more comment, and then we will let you folks go. I am sorry you had to wait all day. I really appreciate your patience.

One of the things that I believe Dr. Ornish mentioned was that they had a very difficult time—I think it was Dr. Ornish—they had a very difficult time getting the funds to get the body of evidence that was necessary to show that the program was effective. He said he had to go to private foundations to get the money, which was very difficult. He could not get any from the Federal Government, even though we now know, in retrospect, that the program does work and it does have real benefits.

Are any of the funds that you are allocated being used to look into these alternative therapies, so that people like Dr. Ornish can get the results that you require, so that they can be incorporated into your programs? Do you see what I am saying? I mean, if a very small percentage is dedicated for alternative therapy research, and somebody like Dr. Ornish comes up with a new procedure that is going to be very effective and save money and help save lives, and everything else, how can we allocate more of our resources so that they can get that kind of testing result finalized, so that you can have it for your review, and, ultimately, for getting the procedure into your practices and your policies? Did I make myself clear? Maybe I didn't.

Dr. ZIMBLE. At the Uniformed Services University, we work with a statutorily created 501(3)(c) foundation, the Henry M. Jackson Foundation for the Advancement of Military Medicine.

Mr. BURTON. Who puts the money into that? Is that a government funded—

Dr. ZIMBLE. That can come through government. It comes from both the private sector and can come from the government. The \$2.5 million I mentioned to you previously will go from me to the foundation. The foundation will give some of that to the Walter

Reed Army Medical Center. Some of that will go to Dr. Ornish for his preventive medicine research.

Mr. BURTON. I am not just talking about Dr. Ornish. I am talking about the other—

Dr. ZIMBLE. Right, but we can use that—that paradigm can be used for other methodologies.

Mr. BURTON. OK. So the Department of Defense, even though the funds are not high—

Dr. ZIMBLE. Right.

Mr. BURTON [continuing]. It is a very small amount—you do have a way of doing that. How about NIH and HHS?

Dr. KAMEROW. HHS has a number of mechanisms for either new investigators or small grants for novel ideas, sometimes more off-the-wall ideas, that they can use. I know that AHCPR, we have a small grants program for just those kinds of pilot programs or early research, where people can apply if they don't have the credentials that Dr. Ornish was talking about before to get funding for these kinds of projects.

Mr. BURTON. How do they make the judgment on who gets those grants?

Dr. KAMEROW. They are reviewed in study sections, which is typical.

Mr. BURTON. By whom?

Dr. KAMEROW. By peers. Peer review.

Mr. BURTON. Peer review, doctors. Are any of those doctors on any boards of any pharmaceutical companies, or have they ever been employees of any pharmaceutical companies?

Dr. KAMEROW. I believe that is a pretty—

Mr. BURTON. Broad question?

Dr. KAMEROW [continuing]. Pretty broad question. I am sure somewhere there is, but they are generally university and other researchers.

Mr. BURTON. Well, I think you know why I asked that question. There is a concern that, if an alternative therapy or alternative vitamin or drug, or whatever it might be, comes on the market, that there might be some impediments to them getting that approved or even getting a grant to have it tested thoroughly because of influence being exerted by people who have a vested interest.

Dr. KAMEROW. I think that this is an important point that you have made a couple of times during the hearing, and my response would be that I think it is through the government research where this kind of nonprofitable, if you will, research gets a chance, because the R&D that gets paid for by the drug companies won't pay for this kind of work. So really it is very important for us in the public sector to fund this research in the most impartial way possible.

Mr. BURTON. Toward that end, if we can be of any help at all, and if you think that there is any way, any of your agencies, that we could be of help, I wish you would let me know.

Dr. KAMEROW. I look forward to talking with you further about HHS and Dr. Ornish's program and some legislation that we might be able to put together, together, that might get that thing into the overall Medicare program.

Dr. KAMEROW. Yes, sir.

Mr. BURTON. Well, thank you very much for being here. I really appreciate it.

Thank you very much.

We stand adjourned.

[Whereupon, at 3:16 p.m., the committee was adjourned.]

[Additional information submitted for the hearing record follows:]

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PHONE 610-266-1433 FAX 610-264-2768

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3/2/99

Committee on Government Reform
The Honorable Dan Burton, Chairman
2157 Rayburn House Office Building
Washington, DC 20515-6143

Comments regarding the Full Committee hearing held Wednesday, February 24th, 1999 on "Opening the Mainstream to Complimentary and Alternative Medicine: How Much Integration is Really Taking Place?"

Honorable Congressman Dan Burton;

I had the privilege of attending the above Committee Hearing and was overall pleased by the committee's openness to understanding the interaction between the "Powers-that-be" in mainstream medicine, especially the Allopathic Hierarchy that has developed itself as the only institution of "science" in this country, and the "Alternative Medicine providers" with the widely varied minority view of medicine that is rapidly becoming the norm in this country.

Those that have turned "medical science" into a theology have for the past number of decades continued to try and use the government to push a modern day inquisition on "alternative" views of medicine. Due to our country being a democracy and the public's ever growing cynicism of the "medical scientists" intentions and tactics, the "alternative medicine" practitioners have been able to allow the field to grow and to begin to show the fruit of their efforts. The advantage of this that it is becoming ever more evident that there is more to medicine than the medical scientific theocracy, while the disadvantage is that there is now a call to have the theocracy take over by incorporating aspects of alternative medicine while watering down the underpinnings that make it work well in order to decry its efficacy. This is what we must be concerned about. True scientific rigor is like gold and fears no forge. Unfortunately, the present day medical scientific rigor is biased and in many ways corrupted, with their requirement that alternative medicine be subjected to the "gold standard" of double blind studies while less than 10% of the drugs, modalities and surgeries they use meet that standard.

The goal of this discussion is not to belabor the present day medical theocracy, but to stimulate new processes for understanding how research and health care really works. Blinded studies can prove that something has been killed or at least that it has been relegated to less than symptomatic levels for a certain amount of time, usually despite whatever that patient is doing for themselves so that patient compliance requirements are minimal. Blinded studies are not effective in cases where there is individualization of treatment or where there are differing diagnostic techniques, with a good example of this being Oriental Medical diagnosis and treatment. The concept that it might be laughable and only shows either bias or ignorance in those that propose blinded studies be used for alternative medicine to be proven in every case.

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Perhaps the best way to provide data on individualized treatment is to simply provide large scale coverage for a number of promising alternative medicine prospects such as the Ornish program and for acupuncture and Oriental herbal medicine. This coverage being provided while putting a sunset clause of 10 years for reasonable proof, combined with clauses that research analysis and methodology be paid for that allows the treatment covered to be done by those competently trained in the work being done, and not merely present day medical physicians with little or no training and even less experience in such things. This may require that there be a ramp up of the development of alternative providers training in statistical methodology and research protocols, as well as a stimulation of interaction between alternative providers and conventional ones in both hospital and clinical settings. This can be done in 10 years with strict legislative oversight and deadlines for true scientific honesty and removal of bias in these studies and statistical research.

In looking through the testimony of the panels after the fact, combined with seeing the actual testimony, I would like to point out some interesting points for the committees perusal.

I had no real difficulties with the testimonies of Jane Seymour, Dean Ornish, or Brian Berman due to the clarity and, interestingly enough, the lack of bias in either direction relative to conventional or alternative medicine, with their information showing a true scientific curiosity towards medicine and healing.

With regards to the testimony of Douglas Kamerow, I would like to say that I hope the AHCPR lives up to his expectations with regards to complimentary and alternative therapies. The chief difficulty once again lies in developing an understanding of individualization of treatment with regards to research development, and the competency of the providers of treatment in that research. The National Center for Complimentary and Alternative Medicine at the NIH has actually been expanding its anti complimentary bias in the recent past by minimizing participation of alternative providers and researchers on the panel, even though this is directly requested in the document providing funds for the project.

There is also the idea of a modality of a field of medicine, such as acupuncture is to Oriental Medicine, being removed from the background that has been part of its development and its efficacy for hundreds if not thousands of years and being minimized into pigeonholes for specific ailments as if it were a drug with a fixed set of uses and not recognizing it as a homeostatic mechanism that provides much more, depending on the training and abilities of the practitioners. While it is nice to prove acupuncture is good for a specific set of symptoms, this demeans the profession and the field of medicine as if one were to say that Allopathic medicine is good only for car accident trauma. Provide alt med programs with hundreds of thousands of practitioners, hundreds of teaching hospitals and colleges, and billions of dollars for research and we will give complete answers similar to the ones given for allopathic therapies and drugs, but in the absence of those things, don't decry what we do as ineffective or worse. Dr. Kamerow's testimony in itself was not inflammatory and he seemed to be genuinely concerned that what is useful be used, but one could almost see the blinders of either bureaucratic or medical arrogance in the answers to some of the questions posed. We can only hope that this comes to his awareness as he continues to work with the Center for CAM so that his seeming bias doesn't interfere with his scientific integrity.

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With regards to the testimony of Thomas Holohan, I would like to start with his statement "The critical point to be made is that the advocate of any treatment, conventional or unconventional, allopathic or homeopathic, surgical or psychological, has an ethical and moral obligation to provide high quality, convincing evidence that satisfactorily demonstrates the treatment is effective and that the benefit is clearly proportionate to the risk. This meets the intent of the Kefauver Commission which in 1962 mandated that pharmaceuticals must be shown by their manufacturers to be effective for their intended purpose." This is a telling statement in that it compares the safety of homeopathics to that of pharmaceuticals relative to risk, while the only risk found to show for homeopathics is that of not undergoing proper allopathic treatment to avoid imminent injury or death, while pharmaceuticals have seriously injured hundreds of thousands of people a year when prescribed by physicians knowing what it is they are prescribing and after the studies and research have been done! (JAMA # 278, No15)

He also stated that "Science is neither an entity nor a belief system, but merely a disciplined method of investigation.", which in itself is a part of a belief system that believes that medical science is unbiased and cannot be corrupted by money and influence. We would all hope this would be true, but few are convinced of it being a reality in today's world. The fact remains that money will buy whatever answer your research requests to a large extent and having no money will only prove that what you have does not work, unless you do as Dean Ornish requested and have unbiased government funded studies done by those who have actual expertise in the processes being done. All this while patients die, and the truth is that there are almost no adverse effects in the Ornish program when done as specified! This is true of almost all "alternative medicine" when done by competently trained practitioners, and the fact that there are so few occurrences with all the non competently trained folk doing things is relative proof of its safety. Face it. The FDA is constantly looking for more tryptophan type occurrences, while the pharmaceutical Rome is burning.

Another example is Dr. Holohan's discussion of gamma butyrolactone (GBL), which is presently being vilified in most every state but in reality is being used by the public to their detriment only because the FDA removed GHB, the naturally occurring substance that GBL turns into in the body, from the market. People do die of GBL use, or perhaps it is better to say poorly made GBL use. GBL is indeed dangerous because it is made by the consumer themselves out of solvents and such, instead of purchasing pre-made GHB in vitamin or pharmaceutical labs as had been done for over 10 years with few problems. It seems that GHB had been growing in popularity too fast and that it was taking over a similar part of the market to tryptophan. The sleep deprived market. So it was vilified by the FDA as a "date rape drug" because if one takes too much, one falls into a deep sleep that one can't be awakened up from until a few hours later, to a point where it was starting to be used for minor surgery in people who reacted to other analgesic and sedative drugs. It is true that it can be used for date rape perhaps, if you can get the 9 or more grams (3 tsp) of the vile, terrible tasting stuff into someone. Remember being told that it was an odorless, odorless substance when legislators were being sold on making it illegal? They forgot to mention taste. By the way, you wake up refreshed too and it isn't patentable, so it will remain competitive and cheap. Don't you feel safer now that it is off the market?

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For Dr. Holoman to compare physics, metallurgy and chemical science to biological science is to oversimplify the subject. While there are some parallels, there is a world of difference between the living world and the physical sciences, and it is much easier to know what the physical properties of metals and brakes and tires than the Sputnik technological level of understanding we have of the body's biological processes today.

Dr. Holloman also states that the VA "has set high standards for practitioner training, education, credentialing, and certification", and also "all providers should meet appropriately equivalent and comparable standards, irrespective of their practice focus.", while having their anesthesiologists and other VA health practitioners treat pain without equivalency to the recognized national certification process. This is a concern of our profession because those exposed to acupuncture within the VA or the DOD may be getting substandard acupuncture care, which will affect our profession later should the patient, and the VA's research, not get the results of a fully trained Oriental Medicine acupuncturist.

Finally, in regards to the testimony of John F. Mazzuchi, there is only the above statement of a necessity of having those practicing acupuncture provide the level of an Oriental Medicine acupuncturist for their patients and for the DOD training program in acupuncture and possibly the development of herb research and teaching programs using the presently available minimum competency based training and examination model.

Thank you for providing the forum for discussion of alternative medicine practices relative to Federal departments and agencies. I hope that we can continue to participate and work with the committee to provide the public with the best possible future.

Sincerely



David Molony
Executive Director AAOM

“Mind/Body Interactions and Their Potential Clinical Applications”

by

Herbert Benson, M.D.

President, Mind/Body Medical Institute, Mind/Body Medical Institute Associate Professor of Medicine,
Harvard Medical School, Beth Israel Deaconess Medical Center, Boston, Massachusetts 02215

Submitted to the

United States Congress

Government Reform Committee

The Honorable Dan Burton, Chairman

February 24, 1999

Mind/Body Interactions and Their Potential Clinical Applications

Herbert Benson, M.D.

A recent study 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. According to this report, managed care savings have about run their course. What's driving this surge in costs? According to the report, 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 approaches holds great promise for the nation's health and cost of healthcare (Friedman, et al., 1995).

This 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 and the importance of belief in healing; the three-legged stool and the importance of self-care; and the proper use of mind/body therapies and the creation of mind/body medical centers.

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, and the beliefs of patients have been demonstrated to successfully treat stress-related 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 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 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. 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).

The fight-or-flight response occurs automatically when one experiences stress, without requiring the use of a technique. In contrast, two steps are usually required to elicit the relaxation response. They are: (1) the repetition of a word, sound, prayer, phrase or muscular activity and (2) when other, everyday thoughts intrude, there is a passive return to the repetition (Benson, 1975; Hoffman, et al, 1982). Many different methods can be used to bring forth the relaxation response including: progressive muscle relaxation, meditation, autogenic training, yoga, and repetitive physical exercise. In addition, many forms of prayer can also be used. These include repetitive prayers such as the rosary as in the Catholic tradition, centering prayers in Protestant religions and pre-davening prayers in Judaism. The specific method used usually reflects the beliefs of the person eliciting the relaxation response (Benson, 1984). The method may be secular or religious, and performed either at rest or during exercise.

Our research conducted at the Harvard Medical School and that of others has documented that relaxation-response based approaches generally used in combination with nutrition, exercise, and stress management interventions result in alleviation of many 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 approaches has been established and has overcome a great deal of initial professional skepticism.

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 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% 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 Placebo Effect and the Importance of Belief in Healing

The importance of mind/body interactions in healing is also profoundly evidenced by the placebo effect. Throughout history, medicine and healing has relied heavily on non-specific factors such as the placebo effect (Benson, Friedman, 1996). In other words, what patients believe, think and feel has profound effects on the body. 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 mind/body interactions such as 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 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 beliefs.

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% of the cases. Since these early findings, the placebo effect has been documented to be effective in 50 to 90% of diseases that include bronchial asthma, duodenal ulcer, angina pectoris, and herpes simplex (Benson, 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, 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 effect disease (Benson, 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 cobra venom, 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" probably should be discarded and changed to "remembered wellness." Remembered wellness is what explains this powerful mind/body 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 enhanced physical health (Koenig et al, 1997; 1998). They are also associated with a lower use of expensive health services (Koenig, Larson, in press). 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 proven, specific 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 or not you believe in it.

The Three-Legged Stool and the Importance of 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, 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 that promote health, 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 have 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 behavioral approaches, the treatment of many medical conditions is imbalanced and inadequate. Patients receive less than optimal clinical care and the care they receive is more costly.

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 therapies 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 emphasis on mind/body health. 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 dollars, for one year alone (Benson, 1996).

One example of how mind/body, behavioral interventions can reduce costs was shown through a study conducted at the Harvard Community Health Plan (Hellman, et al, 1990). Two group mind/body interventions 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. Six months after treatment only the patients in the mind/body groups reported less physical and psychological discomfort and averaged about 50% 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 behavioral medicine 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 behavioral medicine program, of which the relaxation response is 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 for over two years in the patients who participated in the behavioral medicine program as compared to their clinic usage prior to the intervention. In the 109 patients studied, the decreased visits projected to an 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 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 multifactor 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% 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.

The Proper Use of Mind/Body Therapies

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% of visits to physicians. Furthermore, consider that this new drug was safe and without dangerous side effects. It could also prevent these conditions from occurring and recurring. And, consider that the new drug was demonstrated to decrease visits to doctors by as much as 50% 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 therapies have been shown to produce such clinical and economic benefits, but as yet have not been so received.

Why, given results such as these, have mind/body therapies such as the relaxation response and those related to the beliefs of patients not been more effectively integrated into mainstream medicine? Barriers to integration include: 1) the lack of knowledge of the existing scientific data among healthcare providers, researchers in other fields, among patients and among policy makers in government and private industry; 2) a bias against mind/body interventions in medical care as being "soft" science; 3) inadequate insurance payments for these treatments; and 4) a bias against shifting away from the overwhelming use of pharmaceuticals as well as surgeries and procedures.

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 medicine holds such promise that it should be further researched, advocated and utilized for the health and well-being of the people of our nation.

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Testimony
to the
U.S. House of Representatives
Committee on Government Reform

"Opening the Mainstream to Complementary and Alternative Medicine:
How Much Integration is Really Taking Place?"

Dannion H. Brinkley
Chairman of the Board - Compassion in Action
Author

P.O. Box 1919
Aiken, South Carolina 29802

My name is Dannion Brinkley. I am the Chairman of the Board of a non-profit organization, Compassion in Action. I and like-minded souls formed this organization to recruit and train a cadre of hospice volunteers known as the Twilight Brigade. I feel very strongly that no one in this country should die alone and have worked tirelessly for over twenty years to recruit hospice volunteers as well as serving as a volunteer myself.

Chairman Burton, thank you very much for conducting the February 24 hearing on the integration of complementary and alternative medicine into Government-funded health programs. I was pleased to learn that you were receiving testimony from the delightful Jane Seymour, who has dazzled many of us with her stellar performances on the big and small screens. She has also sets an excellent example for mothers across America in how to be empowered to educate oneself about health care options for families. Studies have shown that it is typically the wife and mother who do health care research for families and who make the majority of these decisions. So, Ms. Seymour, along with Mrs. Johnson, from my own home state of South Carolina, have shown us that reading books and magazine articles, going to the library and asking friends and relatives as well as health care practitioners what our options are, can open up more health care options. Who better than "Medicine Woman" to start your new legislative year and series of alternative medicine hearings off with.

Dr. Dean Ornish has set a high goal for other cardiac researchers to match. He has worked for twenty years to show that a diagnosis of heart disease is not a prescription for major surgery and early death. He has done this through rigorous, high quality research that has been published in the best medical journals in the world. I was pleased that so many on the Committee agreed with you that it was time that Federal programs began providing this successful program to Americans on Medicare. I hope that the Department of Health and Human Services' Health Care Financing Administration will work quickly to implement this program. I was also pleased to learn that the Department of Defense will be making this available also. As a survivor of open-heart surgery, I can well attest that if it can be avoided, it should be.

It was extremely appropriate for you to also bring Dr. Brian Berman of the University of Maryland before the Committee to talk about the progress of alternative medicine research. Dr. Berman has blazed the trail for many, establishing a hospital clinic for complementary medicine, teaching medical students, developing research projects that merit National Institutes of Health funding, as well as serving as an advisor to the Federal government because of his expertise, experience, and balanced perspective.

It was refreshing to note that all three of the agencies that provide care are exploring ways to improve access to complementary and alternative medicine. The men and women of our armed forces should have access to these therapies as well as our veterans. I look forward to the publication of the Veterans Affairs Survey on Complementary and Alternative Medicine, and hope that it will signal a move to provide additional access to veterans. I have had many opportunities to visit with veterans and have taught many how to deal with intractable pain with music, massage, aromatherapy, and color therapy. I have also seen the phenomenal results of acupuncture on pain in the hospice environment. Just at the National Institutes of Health brings in Dr. Ming Tian to treat pain, every hospice in America should have the ability to do so. This will only happen if acupuncture is covered under Medicare, Medicaid, and offered through the VA.

I have a great deal of personal experience with integrating complementary and alternative medicine into a successful health regime for myself. I have been very fortunate over the last 22 years of my life, having survived electrocution from lightning in September 1975, suffering complete paralysis for a time and then slowly and painfully recovering the use of my body. In fact, my doctors did not believe I would survive and sent me home to die. I surprised them all, as I continue to do today, but was left with multiple health issues to deal with, including extreme back pain from contusions of the spine, which proved to be the reason I was introduced to alternative medical therapies. I have included chiropractic treatments in my health care regimen for over twenty years and as a result been relieved of pain and headaches that otherwise are debilitating. Nine years ago, after going into heart failure, I was required to have a heart valve replaced -- a result of the lightning injury and an inherited heart valve disorder. Since then, I have been required to take the anti-coagulant medication, Coumadin. I have learned what many

people fear, the long-term effects on the body of harsh pharmaceuticals. I am not complaining, my life is much better as a result of pharmaceutical interventions, but in order to stay alive and in order to have any quality of life, I was forced to find complements to my treatment protocol.

Over the years, I have tried many complementary and alternative therapies. In addition to chiropractic medicine, I have successfully used nutritional approaches and supplementation, meditation, Traditional Chinese Medicine including acupuncture, massage therapy, guided imagery, biofeedback, qi gong, aromatherapy and color and music therapy. I have a strong realization of the power of the mind to work in harmony with the body to heal and have had many personal experiences in which this was the case.

Eighteen months ago, as a result of an imbalance of my Coumadin, I suffered several cerebral subdural hematomas, and required brain surgery. I was not expected to live, and learned what pain really was. However, prior to and following my surgery, I spent many hours in a deep meditative state using headphones and music to block out hospital noises and assist in the relaxation and meditative process. As a result, I was able to take less pain medication. I also was fortunate to have many thousands of people offering prayers on my behalf and have gained understanding into the effect that prayer can have in someone's healing. Being in an Intensive Care Unit, I was not told that prayer vigils across the country and the world were taking place. But I felt that love, and I saw a healing aura of blue light in my room at various times.

Because of my personal experiences and because of the many people I come in contact with in my role as a hospice volunteer and as a motivational speaker at conferences where I have tried to share the message that we are spiritual beings having a human experience, I pay very close attention to what happens within the Halls of Congress. As Americans, we have gained a measure of freedom that few else in the world have achieved, and it is our responsibility to treasure, protect, and nurture it. Only through the combined actions of the people of this country with their legislative representatives can we move forward in improving the health and well-being of the inhabitants of this great land.

I have served as a hospice and nursing home volunteer for many years, having helped over 160 individuals, including veterans, and their families through those most difficult days of facing their own or a loved ones mortality and letting go of their fear of death. I have a deep commitment to help during this transitional time and have had much success in using complementary therapies in easing some of the stresses in the hospice environment, in particular, color and music therapy and aromatherapy. There is an increasing body of research evidence to show how these complementary therapies help reduce anxiety and stress in hospital, nursing home, and hospice environments. It suggest the Government Reform Committee investigate the advantages of complementary and alternative medicine in hospice or end of life care in both the private sector and for our veterans.

Medical doctors in this country do the best they can with the training they have received. They have been trained to be chemists. Please do not misunderstand, my life is better because of this chemistry. But, it is not all there is to healing. I have been one of the fortunate ones because I have been able to integrate complementary and alternative therapies with my conventional medicine and maybe more importantly because I have the comfort of my spiritual connectedness. This last stay in the hospital opened my eyes to the high level of fear that abounds within patients in the hospital setting, due to a lack of spiritual comfort. Doctors like Larry Dossey and David Larsen are working to change that. They are working to return spiritual tools to the health professions and hospitals. Prayer and spiritual healing are among those alternatives such as subtle energies that make the hierarchy of the Government research agencies like the National Institutes of Health very nervous. But they are among the most vital that we as a nation should not and cannot ignore just because they are difficult to explain. I hope that this Committee will conduct hearings to investigate the important aspects of spirituality and healing. I also hope that as a result of this hearing, that Government agencies will move to make more alternative therapies available to Americans who receive their health care in Government-funded programs. Our Public Health Clinics, military facilities, veteran's facilities, as well as the coverage provided under Medicare and Medicaid, need to expand to include these options.

I have been a strong supporter of the need for research in complementary and alternative therapies since the inception of the Office of Alternative Medicine. I participated in the early *ad hoc* meetings, the Chantilly meetings, as well as attending all but one of the meetings of the Alternative Medicine Program Advisory Council, that one being at the time of my brain surgery. I felt very fortunate that during this meeting, my long-time friends paused during this meeting in silence to send out prayers for my recovery. Today, I owe my recovery in part to these and the thousands of others who prayed for me.

This past October, the Office of Alternative Medicine was elevated to the Center for Complementary and Alternative Medicine. It will be very important for the Government Reform Committee to keep a close watch over this growing organization. It is very important that this new Center actually fund and conduct cutting edge research that will provide answers to Americans about what works and what does not, and under what circumstances. It has at times been very disappointing to see the amount of bureaucratic interference and red tape that slowed things down after these last seven years. It seemed at times that the leadership at the National Institutes of Health was impeding progress rather than nurturing it. I hope with the new Center status that the work will progress and that finally Americans will receive information about their options in complementary and alternative medicine.

Gentleman as we move into the next millennium and the rapid change of medicine in managed care we must look for ways to cut cost and deliver the finest healthcare at the lowest prices possible. I believe a combination of both conventional and complementary medicine is the future. I wish for all of you a clear conscious, an open mind and a dedicated heart for it is our families, our mother, our fathers, brothers, and sisters that are depending on you.

Dannion H. Brinkley

ALAN DUMOFF

Attorney at Law

Master of Social Work

Licensed in the District of Columbia and the State of Maryland

11140 Rockville Pike · Suite 600 · Rockville, MD 20852 · (301) 984-6551 · Fax: (301) 984-2215

BY FACSIMILE

ORIGINAL TO FOLLOW

March 10, 1999

S. Elizabeth Clay
United States House of Representatives
Committee on Government Reform
and Oversight
2157 Rayburn House Office Building
Washington, DC 20515

Re: Written submission for the record
Hearings on Integration of Complementary and Alternative Medicine

Dear Ms. Clay:

Please accept this submission to the record, which I write to address a few of the critical points regarding the integration of complementary and alternative medicine ("CAM") into mainstream medical use. As an attorney and consultant specializing in integrative medicine, I write on my own behalf about the experiences many of my clients have had, and seek to draw the attention of the Committee to the following four areas:

- The first issue regards Dr. Livingston, a pioneer in CAM approaches to care, who was mentioned by Jane Seymour at the hearing for the assistance she provided her father. HCFA excluded Dr. Livingston for the very practices that helped her father and many others, an appalling use of prosecutorial authority of which this Committee should be aware.
- Second, fraud and abuse and other claims and regulatory matters create serious barriers to the practice of integrative medicine and need to be modified.
- Third, as one of many examples of the difficulties physicians using CAM methods face, this comment provides a detailed example of a physician currently facing a medical board investigation because of his knowledgeable use of CAM methods in nearby Maryland.
- Four, research priorities need to include funding for the actual methods of integration, in addition to investigating particular CAM methods for particular ailments.

Committee on Government Reform and Oversight
 Written Statement of Alan Dumoff, J.D., M.S.W.
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Virginia Livingston, M.D. Exclusion by HCFA

Jane Seymour testified at the February 24 hearing that her father's received invaluable assistance for cancer from Virginia Livingston, M.D., a pioneering physician who I represented prior to her death is survived by a clinic in San Diego. The Committee should know that HCFA excluded Dr. Livingston from Medicare for the very practices that helped Mrs. Seymour's father and many others, an appalling use of prosecutorial power. HCFA excluded Dr. Livingston because some of her patients submitted Medicare claims against her instructions. In a decision chilling for the practice of promising CAM treatments, HCFA decided that the sanctions for "substandard" medicine could be applied against a physician practicing "nonstandard" medicine. When the dust settled, and the ALJ agreed that HCFA was improperly interpreting the statute, the transactional costs to the taxpayer and my client exceeded \$1 million. HCFA exacted this price because of a good faith difference of opinion about proper medical care. These transactional costs were so exorbitant in part because HCFA refused, even after the ALJ ruled against them, to reinstate Dr. Livingston. This is but one of many examples of activities in which the government actively opposes the delivery of CAM care.

Structural Barriers

The lack of reimbursement for many services of demonstrated efficacy is of course another overriding concern, but there are also numerous structural barriers within government that make integration quite difficult. Medical necessity determinations by conventional physicians in the context of Medicare and other insurance and managed care settings, restrictions on billing arrangements by CAM providers working with medical supervision, restrictions on laboratory testing by physicians and CAM practitioners, and restrictions on statements that can be made by practitioners about CAM methods are but a few of the many structural barriers that are making full integration by practitioners difficult as a pragmatic matter. Federal kick-back and anti-referral regulations are confusing and are a prime example of the way the government makes the collaboration patients need among practitioners very difficult. These are critical areas that the Committee's staff would do well to examine for the Committee.

Bruce Rind, M.D. - Medical Board Inquiry and Insurance Reimbursement

Medical physicians do face difficult consequences for the lack of comprehension about holistic and CAM care that pervades major medical insurers and medical boards. I write to provide some detail about one example that is instructive of the way the structure and inertia in our health care system make it difficult for holistic physicians to practice.

The Board of Physician Quality Assurance ("Board") in the State of Maryland is investigating Bruce Rind, M.D., for practices that have been questioned by Blue Cross Blue Shield of the National Capital Area ("BCBSNCA"). I represent Dr. Rind in this matter, and the issues regard a long-standing dispute between BCBSNCA which is unable to comprehend the value of Dr. Rind's

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integrative use of functional and other holistic approaches to care.

The Board in Maryland has evidenced some clarity and balance in addressing the integration of complementary and alternative medicine ("CAM") into medical practice. The report of the Commission on Complementary Medical Methods, issued in December of 1995, documented the position of the Board as historically allowing of the competent practice of complementary medicine as long as any needed informed consent forms are executed and the basis for the procedure is adequately documented. We do not yet know how the Board will respond to BCBSNCA's complaint, but the very fact that an insurance company with the influence of BCBSNCA would levy such a complaint is of concern, and has a chilling effect upon physicians who believe that putting their patients' best interests first often requires the use of CAM methods and holistic approaches to their patients. A large percentage of patients who see Dr. Rind have exhausted conventional medical options without success, and a fair portion of these find relief from the approaches used by Dr. Rind.

BCBSNCA conducted an audit of Dr. Rind's practice three years ago, completed in April of 1995. BCBSNCA concluded that Dr. Rind was practicing "experimental/investigational" medicine—the language BCBSNCA repeated to the Board—based upon BCBSNCA's inference that Dr. Rind was rendering services for environmental illness, or multiple chemical sensitivity ("MCS"), a diagnosis recognized in the CAM community but not within the mainstream biomedical community. This conclusion was based upon an exercise that, in our view, was a re-diagnosis of Dr. Rind's patients by BCBSNCA. Dr. Rind diagnosed the ten patients in the audit as suffering from various conditions, including "B6 deficiency syndrome, fatigue, arthralgia, magnesium deficiency, glucose intolerance, myalgia, muscle spasm and shortness of breath." Dr. Rind was surprised, as would be most physicians, to learn that such common diagnoses as glucose intolerance, myalgia, shortness of breath, and fatigue are actually environmental illnesses.

Dr. Rind did for the sake of a collegial effort to resolve the matter acknowledge and surrender as non-covered payments for three of the audited patients as having been diagnosed by other physicians as MCS. While some controversy does exist, such a diagnosis is valid and within the proper scope of a physician to make. MCS is recognized by numerous agencies as legitimate for disability purposes, including the Department of Education and the Department of Housing and Urban Development. MCS is an enforceable disability under the Americans with Disabilities Act. Many of the patients seeking care who present to Dr. Rind with a diagnosis of MCS have objective, abnormal laboratory findings. Given that there is documented dysfunction, Dr. Rind is obligated to treat these patients despite BCBSNCA's difficulty with the label "MCS." The concerns about physicians practicing "environmental medicine" expressed by the American College of Physicians has been diagnosis in the absence of objective findings and the use of neutralization therapy as a treatment. Neither of these occur in Dr. Rind's practice. While BCBSNCA may have the right to create an exclusion for MCS for payment not shared with doctor or patient until after the claims are submitted, BCBSNCA's complaint that such a diagnosis is improper is a flagrant misunderstanding of evolving medical practice.

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BCBSNCA's rediagnosis of Dr. Rind's patients certainly appears to be an effort to deny payment for what would rationally be considered appropriate services, based upon a belief that CAM efforts are not medically necessary or proper standard of care. Dr. Rind provided numerous CAM therapies to the ten audited patients, including bee venom therapy, dietary supplements, soft tissue mobilization, acupressure, EDTA chelation therapy, treatment with oral DHEA, oxidative (H₂O₂) therapy, Dr. Janet Travel's (whom I believe was John F. Kennedy's physician) 'dry needle technique,' and intravenous vitamin therapy, but he did not submit claims for these services as they were understood to be noncovered. All of these techniques are used for a wide variety of indications; for many of these treatments, environmental illness is not even an indication. Yet BCBSNCA determined that these patients were not being treated for the stated conditions but rather for environmental illness, or multiple chemical sensitivity ("MCS"), a condition excluded from coverage.

Because it is Dr. Rind's practice not to submit claims for CAM services, it is our belief that it was necessary for BCBSNCA to rediagnose Dr. Rind's patients in order to create a basis for nonpayment of covered services. With this complaint to the Board, BCBSNCA has evidently taken upon itself the further task of manufacturing cause to seek regulatory redress against physicians whose practices are unconventional. Were BCBSNCA to monitor Dr. Rind's outcomes rather than take this course, they might in fact understand their financial interest lies in supporting his practice.

A Research Priority - Clinical Methods of Integration

For integration to successfully proceed, we not only need to additional data charting the terrain of intervention efficacy, such as whether acupuncture is useful for carpal tunnel syndrome; we also need to understand clinical methods whereby clinical decisionmaking that includes diverse methods can best guide patient care. Given that a migraine patient may find relief from acupuncture, chiropractic, herbal medicine, or homeopathy to name a few, how can we cost-effectively help patients make decisions about treatment choices. Differential diagnosis when the decision trees of the various biomedical and CAM professions have roots in different forests is a science and art that we are only just beginning to learn how to accomplish. Creating a cost-effective integrative health care system requires investing in research dollars to learn how this can best be done.

My thanks to Chairman Dan Burton and to the Committee for this interest in the matter.

Sincerely,


Alan Dumoff

TESTIMONY**“Opening the Mainstream to Complementary and Alternative Medicine:
How Much Integration is Really Taking Place?”**

February 24, 1999
Mary R. Prunchak
For the Public Record
To the House Government Reform and Oversight Committee

I want to make the Committee aware of a case, which illustrates that access to alternative medicine can successfully treat complex, chronic health problems. None of the care that I describe was covered by my insurance and none of my son's health plan doctors have been particularly interested or have the time to investigate into what my family has chosen. I believe that my son has received the best care that his parents, doctors, health plans, private tutors, and school programs have had to offer. He's been lucky. He is in the sixth grade, receiving LD services for language arts.

The grim reality was that he finished the fourth grade with pneumonia, pleurisy, and asthma. His private tutor had given up, saying that he wasn't the right person to help Eric. His teachers had all met with me feeling that they were unable to make a difference for Eric, although he had learned a lot of information and was a sweet boy, who got along with his classmates. He just couldn't perform due to motor and perceptual challenges, and seemed lazy, lacked coordination and energy. The teachers felt he wasn't applying himself. A comprehensive report by Dr. Martha Bridge Denckla, MD at the Kennedy Krieger Institute in Baltimore had confirmed Eric's diagnosis of ADD to label his complex challenges.

We had tried two pharmaceutical drugs, Rytalin and Cylert. Rytalin caused immediate negative side effects and Cylert had had little effect and had caused Eric to stop eating and to alarm his doctors. He had also been on antibiotics most of his life, starting with treatment for meningitis at 2 and one half months. He had been taking allergy shots and used an inhaler more and more frequently. At that point, we took him off of Cylert and saw an immediate increase in appetite and a healthy weight gain, but Eric was still sick all of the time.

Then I met a neuronaturopathic geneticist/virologist, Dr. P Vincent Buyck, who teaches an approach to diagnosis and treatment which incorporates what he calls, "aggregate medicine and sciences."

In June of 1997, the doctor began analysis of my husband's and my urine as well as Eric's to examine down to the DNA/RNA level, and identify sources of Eric's complex problems. In August, 1997 we received the first round of raw, organic medicine for Eric. It turned out that Eric had inherited a virus, bacteria and the muscular dystrophy gene.

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During the first year, Eric continued to gain weight. He had more energy. He began breathing through his nose for the first time. Without allergy shots, he had no reactions (we do keep his inhaler handy in case he needs it.) He complained to me that he looks like he has makeup on. I explained that he has color in his cheeks now. I found him in the bathroom brushing his hair, on both sides with the same hand (something he'd never been able to do before.) He passed a spelling test for the first time and then got an A. We began to be able to read his writing.

My husband and I were pleased with Eric's health and with the progress. This is year two, and Dr. Buck is still treating Eric with a set of organic custom formulas that match his needs, even his DNA/RNA. After 18 months of treatment and steady improvement, Eric's teachers say that he is astounding them. He will turn 12 on April 7. Recently Eric came to me to say, “Mom, that medicine is really working. I no longer look at the classroom clock all day. Time goes by faster. When I read, I get involved in the book without being distracted by every little noise. I am using my best vocabulary in my writing now and my teachers are impressed with how well I am paraphrasing in social studies assignments.” I have noticed that he comes home and opens his backpack to start homework, sometimes without watching television or eating first. Yesterday, Eric's teacher called me after talking with his LD teacher. Both teachers are reporting incredible progress in Eric's ability to read, write, calculate, focus, create, discuss and maintain energy. They concur with me that there no longer seems to be a motivational deficit and that he is making slow progress with spelling, his biggest challenge at this point. The only medications that Eric takes are the ones developed for his set of problems by Dr. Buyck. These organic medications are not intended for a lifetime. No nutritional products have been used and no special diet has been followed. Eric's prognosis appears to be much brighter.

Some say to us that Eric is simply growing up. I realize children are particularly hard to evaluate because they do grow up; however, I am choosing to believe that his improvement is largely due to the fact that Eric is being treated. If Eric started taking Ritalin and he improved, doctors would attribute his improvement to the Ritalin, so why not organic, customized medication? He is making great progress and is transforming into a self confident, alert, motivated, creative student.

Dr. Buyck indicates that Eric's treatment is aimed at the virus, bacteria and fungal elements which have impaired the immune system and neurological communications, and the muscular dystrophy gene, which has been affecting Eric's ability to keep up physically and maintain energy. Viral, bacterial and fungal elements are leaving Eric, neural communication is being restored and genetic repair is occurring. Is this preposterous? I don't believe so, and I challenge you to consider the possibility that what Dr. Buyck is doing for Eric he and others could do for other children. I believe that

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“Opening the Mainstream to Complementary and Alternative Medicine: How Much Integration is Really Taking Place?”

customizing organic medications is a key and offers hope for our children, 8 million of whom are estimated to be on drugs like Ritalin, or thousands who struggle with chronic/degenerative diseases. I urge you to consider how you might establish research and assure access to such care in the future.

I have written to a doctor at NIH challenging him to consider research so that other children can be helped. I have been told that, although the information and documentation that I sent him was compelling, this wellknown researcher did not know what to do with my report. I can only assume that because there is no technology/pharmaceutical involved that there would be no money for research.

I can't begin to explain Neuronaturopathic Genetics and Virology in this testimony, or to provide information on Dr. Buyck's REONA Theory that explains how genetic repair is possible without extracting or injecting genes. I simply ask you to make this testimony public record as part of your current hearings and to invite Dr. Buyck to testify in the future. The curriculum of the National College of Complimentary Medicine and Sciences is attached for the record as well. I request that this curriculum be made part of the record.

Please consider how access to this type of treatment and access to medical training can be made possible now so that many, not a few, can benefit. I believe that this approach to care has the potential to save cost and improve outcomes and will do no harm.

Respectfully,

Mary R. Prunchak
4400 Jackson Place
Alexandria, VA 22309
(703) 360-7733