

# IMPACTS OF STRESS MANAGEMENT IN REVERSING HEART DISEASE

---

---

## HEARING

BEFORE A

SUBCOMMITTEE OF THE  
COMMITTEE ON APPROPRIATIONS  
UNITED STATES SENATE  
ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

---

### SPECIAL HEARING

MAY 16, 2002—WASHINGTON, DC

---

Printed for the use of the Committee on Appropriations



Available via the World Wide Web: <http://www.access.gpo.gov/congress/senate>

---

U.S. GOVERNMENT PRINTING OFFICE

81-061 PDF

WASHINGTON : 2002

---

For sale by the Superintendent of Documents, U.S. Government Printing Office  
Internet: [bookstore.gpo.gov](http://bookstore.gpo.gov) Phone: toll free (866) 512-1800; DC area (202) 512-1800  
Fax: (202) 512-2250 Mail: Stop SSOP, Washington, DC 20402-0001

COMMITTEE ON APPROPRIATIONS

ROBERT C. BYRD, West Virginia, *Chairman*

DANIEL K. INOUE, Hawaii	TED STEVENS, Alaska
ERNEST F. HOLLINGS, South Carolina	THAD COCHRAN, Mississippi
PATRICK J. LEAHY, Vermont	ARLEN SPECTER, Pennsylvania
TOM HARKIN, Iowa	PETE V. DOMENICI, New Mexico
BARBARA A. MIKULSKI, Maryland	CHRISTOPHER S. BOND, Missouri
HARRY REID, Nevada	MITCH McCONNELL, Kentucky
HERB KOHL, Wisconsin	CONRAD BURNS, Montana
PATTY MURRAY, Washington	RICHARD C. SHELBY, Alabama
BYRON L. DORGAN, North Dakota	JUDD GREGG, New Hampshire
DIANNE FEINSTEIN, California	ROBERT F. BENNETT, Utah
RICHARD J. DURBIN, Illinois	BEN NIGHTHORSE CAMPBELL, Colorado
TIM JOHNSON, South Dakota	LARRY CRAIG, Idaho
MARY L. LANDRIEU, Louisiana	KAY BAILEY HUTCHISON, Texas
JACK REED, Rhode Island	MIKE DEWINE, Ohio

TERRENCE E. SAUVAIN, *Staff Director*  
CHARLES KIEFFER, *Deputy Staff Director*  
STEVEN J. CORTESE, *Minority Staff Director*  
LISA SUTHERLAND, *Minority Deputy Staff Director*

---

SUBCOMMITTEE ON DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND  
EDUCATION, AND RELATED AGENCIES

TOM HARKIN, Iowa, *Chairman*

ERNEST F. HOLLINGS, South Carolina	ARLEN SPECTER, Pennsylvania
DANIEL K. INOUE, Hawaii	THAD COCHRAN, Mississippi
HARRY REID, Nevada	JUDD GREGG, New Hampshire
HERB KOHL, Wisconsin	LARRY CRAIG, Idaho
PATTY MURRAY, Washington	KAY BAILEY HUTCHISON, Texas
MARY L. LANDRIEU, Louisiana	TED STEVENS, Alaska
ROBERT C. BYRD, West Virginia	MIKE DEWINE, Ohio

*Professional Staff*

ELLEN MURRAY  
JIM SOURWINE  
MARK LAISCH  
ADRIENNE HALLETT  
ERIK FATEMI  
BETILOU TAYLOR (*Minority*)  
MARY DIETRICH (*Minority*)  
SUDIP SHRIKANT PARIKH (*Minority*)  
CANDICE ROGERS (*Minority*)

*Administrative Support*  
CAROLE GEAGLEY

## CONTENTS

---

	Page
Opening statement of Senator Arlen Specter .....	1
Statement of Peter G. Kaufmann, Ph.D., Behavioral Medicine Scientific Research Group Leader, Clinical Applications and Prevention Program, Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute, National Institutes of Health, Department of Health and Human Services .....	2
Prepared statement .....	4
Statement of David B. Abrams, Ph.D., professor of psychiatry and human behavior, Brown Medical Center .....	6
Prepared statement .....	8
Statement of Herbert Benson, M.D., president, Mind/Body Medical Institute, professor of medicine, Harvard Medical School .....	9
Prepared statement .....	11
Statement of Harvey Eisenberg, M.D., director, HealthView Center for Preventive Medicine .....	14
Prepared statement .....	16
Statement of Dr. Dean Ornish, founder, president, and director, Preventive Medicine Research Institute in Sausalito, CA, clinical professor of medicine at the University of California, San Francisco, a founder of UCSF'S Osher Center for Integrative Medicine .....	19
Prepared statement .....	23
Statement of Karen Matthews, Ph.D., director, Cardiovascular Behavioral Medical Research Training Program, University of Pittsburgh School of Medicine .....	32
Prepared statement .....	35
Statement of Colonel Marina Vernalis, MC, USA, D.O., Medical Director, Cardiac Risk Prevention Center, Walter Reed Army Medical Center .....	38
Prepared statement .....	40



## IMPACTS OF STRESS MANAGEMENT IN REVERSING HEART DISEASE

---

THURSDAY, MAY 16, 2002

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

The subcommittee met at 9:25 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Arlen Specter presiding.  
Present: Senator Specter.

### OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. We will now proceed with this hearing on the impacts of stress management in reversing heart disease for the Subcommittee on Labor, Health and Human Services, and Education, of the Appropriations Committee. We have an extraordinary collection of talent here today for this very important subject.

Our subcommittee has held numerous hearings in the 22 years I have been here on a wide variety of subjects, but we have not taken a look at the issue of stress management. Senator Harkin, who is now the chairman—I chaired the committee for 6½ years until last June—and I work very closely together. We have almost doubled the NIH budget for example, and we will complete the doubling this year. We have worked with the CDC holding many hearings on diet, and many hearings on cholesterol. A wide variety of subjects, but never on stress management.

From my own personnel experience, I have come to appreciate the value of stress management and I am very pleased that we have been able to assemble this extraordinary group of scientists for this very important subject. Sometimes the importance of the subject grows in inverse proportion to the number of television cameras here. I am glad there is one television camera here, but I am more interested in finding out what the hard facts are, and I think this will attract a lot of attention as we move through the process.

Almost every day in Washington is a complicated day. This day is somewhat more complicated. The Reagans are receiving a Congressional Medal of Honor today, so the President decided to come and meet with Republican Senators before that. On my own agenda, there is a Pennsylvania judge up for confirmation, a very critical proceeding for the Court of Appeals. We are having an executive session at 10 a.m., and I will have to excuse myself for a few

minutes. I may be gone only 5 minutes or I may have to be gone longer, depending on what happens. It may be put over until next week, which I think will be the case, but I wanted to mention that.

I'm prepared to come back and spend as much time as we need on this subject. The panelists are all invited to lunch, and 100 percent have accepted, for which I'm glad. However, if we have to skip lunch for the hearing, lunch takes second place, and all the rest of my activities with the Republican caucus will take second place as well in order to take the time to hear the experts. I know people have come long distances and I am very grateful for that.

**STATEMENT OF PETER G. KAUFMANN, Ph.D., BEHAVIORAL MEDICINE SCIENTIFIC RESEARCH GROUP LEADER, CLINICAL APPLICATIONS AND PREVENTION PROGRAM, DIVISION OF EPIDEMIOLOGY AND CLINICAL APPLICATIONS, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Senator SPECTER. The protocol of the committee is to hear first from Dr. Peter G. Kaufmann. Dr. Kaufmann is the Acting Director of the Office of Behavioral and Social Science Research at NIH. He serves as leader of the Behavioral Medicine Research Group at the National Heart, Lung, and Blood Institute. He has a master's and bachelor's from Loyola, and a Ph.D. from the University of Chicago. Our protocol dictates that we hear from him first. So Dr. Kaufmann, we welcome you.

We have a standing committee rule of 5 minutes. It will not be enforced. But after the presentations, there will be extensive dialogue. I would not be so presumptuous as to say questions, but extensive dialog. Dr. Kaufmann, the floor is yours.

Dr. KAUFMANN. Thank you, Mr. Chairman, and good morning to everyone. Just one small correction; I'm no longer the acting director of the Office of Behavioral and Social Science Research, although I still am leader of the Behavioral Medicine Scientific Research Group at the National Heart, Lung, and Blood Institute.

Senator SPECTER. Then I have to find a new chief clerk for my subcommittee. Anybody interested in the job?

Go ahead, Dr. Kaufmann.

Dr. KAUFMANN. I certainly welcome the opportunity to represent the National Heart, Lung, and Blood Institute, or the NHLBI, at this special hearing concerning the subcommittee's interest in the role of stress management in reversing heart disease.

My purpose today is to give a brief overview of the state of knowledge in this area. For many years the NHLBI has supported a vigorous program of research on behavioral and psychosocial impact of cardiovascular diseases, including projects conducted by members of this distinguished panel which is here today. As a result, in addition to the lifestyle risk factors of smoking, physical inactivity, obesity, diet and socioeconomic status, we know much more about the importance of psychosocial factors such as depression, social support, hostility, and mental stress.

For example, laboratory data obtained from heart patients showed that mental stress and emotions such as anger could cause myocardial ischemia, or reduced blood flow to the heart. Patients who respond to mental stress with myocardial ischemia are called "mental-stress-positive." The large study funded by NHLBI re-

cently showed that heart patients who are mental-stress-positive in the laboratory were also more likely to have ischemia in everyday life and are more likely to die over the subsequent 5 years.

This data adds to similar findings from studies at Duke, at Yale, and at the Uniformed Services University of the Health Sciences, and suggests that stress management interventions might improve the clinical status of these patients. Definitive evidence that stress management is effective, however, must come from randomized clinical trials, especially trials that involve an actual infarction as a primary outcome, which is considered to be the gold standard. Stress management has not been tested at this level.

Furthermore, it is generally acknowledged that the results of completed trials are hard to analyze, in part because they combine stress management with other rehabilitation strategies, and therefore it is difficult to disaggregate the relative contributions, and for other weaknesses of the clinical trial design as well.

Clinical trials conducted by different teams usually involve different strategies and targets, such as psychosocial characteristics, making it difficult to compare the results. Keeping in mind these limitations, we do note that a recent review of a variety of treatment strategies and randomized trials concluded that patients derive significant benefit when psychosocial interventions are added to usual medical care.

One preliminary study funded by the Institute and conducted at Duke University offered some of the best evidence that a stress management program may reduce the rate of second heart attack and the need for revascularization. Benefits may persist for 5 years, and the study has shown that medical expenditures may also be reduced. These promising results are now being tested in a larger study, also funded by this Institute.

The question of whether stress management can reverse heart disease is of considerable interest. Atherosclerosis is a common condition involving deposition of cholesterol, structural changes in the arterial wall, inflammation and calcification. Aggressive lowering of blood cholesterol levels with lipid lowering drugs can slow progressive atherosclerosis and improve vascular function and blood flow to the heart, and reduce heart attacks.

A small number of clinical trials involving intensive dietary modification have shown similar success. One of these, Dr. Ornish's heart trial, included stress management along with diet. It is not possible to know to what extent stress management contributed to the observed results.

It is also informative to consider that stress management has had only limited success in reducing blood pressure, a condition for which it has been examined much more thoroughly than for atherosclerosis. This suggests that developing effective stress management interventions for coronary heart disease patients will require sustained efforts.

In conclusion, what can we do today? We believe that a well designed clinical trial is needed to evaluate the potential of stress management in cardiac rehabilitation. However, because peak stress can trigger cardiac events, and initial results conclude that a trial seems promising, it is also prudent to include stress management in cardiac rehabilitation programs for patients who want

the intervention. To do so would improve quality of life and promote lifestyle changes.

PREPARED STATEMENT

In addition, reducing high fat diets, smoking, sedentariness and overweight reduces cardiac risks substantially. Attention to these lifestyle factors will benefit the public health.

So I thank you and I will be pleased to answer your questions.  
[The statement follows:]

PREPARED STATEMENT OF DR. PETER KAUFMAN

Mr. Chairman and Members of the Committee: I welcome the opportunity to appear before you on behalf of the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health to address the Subcommittee's interest in the role of stress management in reversing heart disease.

The NHLBI has, for many years, supported a vigorous program of research on behavioral factors that contribute to the development, treatment, and prevention of disease. Results from that research make it clear that several modifiable behavioral and psychosocial factors do play a significant role. The influence of stress should be considered in the context of these other risk factors, which include behaviors such as smoking, physical inactivity, diets high in fat and low in fruits and vegetables, and combinations of these risk factors that lead to overweight and obesity. Cumulatively, clinical research on the effects of interventions to alter these behaviors (i.e., to stop smoking, increase physical activity, improve diet, and reduce body weight) has shown that these lifestyle changes can be expected to reduce cardiovascular risk significantly.

Research has also revealed associations between several psychosocial factors and heart disease. The factors include chronic stress, depression, inadequate social support, anxiety, hostility, and socioeconomic status. Each has been associated with increased risk of heart disease in epidemiological studies, and the results of laboratory investigations have described several biological pathways through which psychosocial factors are thought to influence cardiovascular function and contribute to cardiovascular pathology.

As we consider the potential role of stress management in reversing heart disease, it is informative to assess the status of evidence linking psychological stress with cardiovascular risk. To address this issue, the NHLBI has supported a program of research that includes basic science, epidemiological studies, laboratory investigations, and clinical trials.

It is well known that exercise tolerance tests are useful in diagnosing coronary heart disease by revealing whether exercise results in myocardial ischemia (reduced blood flow to the heart). Similarly, studies of patients subjected to controlled mental stress in a clinical laboratory show unambiguously that mental stress can cause myocardial ischemia and that negative emotions such as anger can have similar effects. Patients who respond to mental stress with myocardial ischemia are called "mental-stress-positive." Data from a large NHLBI-initiated study, the Psychophysiological Investigations of Myocardial Ischemia, showed that heart patients who are mental-stress-positive during clinical stress testing also are more likely to experience myocardial ischemia in the course of everyday life. More important, data from this study published last month show that patients who were mental-stress-positive were more likely to die during the 5 years after mental stress testing than other patients. This finding confirms and extends the evidence from three previous studies conducted at Duke University, Yale University, and the Uniformed Services University of the Health Sciences, which showed that mental-stress-positive patients are at increased risk of various cardiac events, including unstable angina, repeat heart attacks, and need for coronary revascularization.

However, definitive evidence that stress management approaches can influence the course of heart disease must come from randomized, controlled clinical trials that track progression of disease, reduction of new heart attacks, or increased longevity as a result of stress management interventions. Among these, clinical trials that involve death as the primary outcome are the gold standard, and no stress management trials to date have been conducted at this level. Furthermore, although the NHLBI and others have funded a number of clinical trials involving stress management either as a stand-alone intervention or as a component of a broader program of lifestyle change, it is generally acknowledged in the published scientific literature that their results can be regarded only as preliminary. There are several

methodological reasons for this, including the fact that combining stress management interventions with other behavioral or rehabilitation strategies makes it difficult to disaggregate their relative contributions to observed outcomes. Clinical trials conducted by different teams involve interventions differing in intensity or duration and may target different psychosocial characteristics, making it difficult to compare their results. Nonetheless, a recent review of a variety of treatment strategies in randomized clinical trials showed that patients derive significant benefits when psychosocial interventions are added to usual medical care.

One carefully conducted clinical trial, although relatively small and preliminary, offers some of the best evidence that stress management may be beneficial for patients with coronary heart disease. The study, funded by the NHLBI and conducted at Duke University, showed that patients who participated in a 4-month stress management intervention program experienced a significantly lower rate of recurrent heart attacks, need for revascularization, and death during the ensuing 3 years, compared with patients who did not receive the intervention. In addition, the data showed that patients who were at highest risk because they experienced many episodes of myocardial ischemia in daily life benefitted substantially from stress management: the number of ischemic episodes was reduced greatly, suggesting that it may be possible to identify patients who are most likely to benefit from such interventions. Earlier this year, the study provided an update of its results, which showed that the benefits of stress management tended to be sustained over a 5-year period, albeit at a reduced level. It also showed that stress management can be economically viable, as the medical expenditures of patients in the stress management group were significantly lower than expenses of patients receiving usual care.

As mentioned previously, this and other studies have several limitations, including small sample size, reliance on relatively “soft” clinical outcome measures, and partial randomization. Nonetheless, the extensive data collected for these patients on mental-stress-related cardiovascular function in the clinical laboratory as well as in daily life have provided the necessary foundation to undertake a trial involving a larger number of patients, which is under way today. Two hundred and ten patients with documented coronary heart disease will undergo comprehensive biomedical and psychosocial evaluation, followed by random assignment to usual care, aerobic exercise, or a stress management intervention. The study will provide new insights into the clinical benefits of exercise and stress management, as well as add to our knowledge of the biological pathways through which stress affects heart function.

The question of whether “reversal of heart disease” is feasible has been a subject of considerable interest and research. Atherosclerosis in coronary arteries is a complex condition involving deposition of cholesterol, structural changes in the lining of the arterial wall, inflammation, and calcification, which together affect vascular structure and function. Aggressive lowering of blood cholesterol levels results in beneficial changes in many of these aspects—vascular function and blood flow are improved, with an associated decrease in the risk of coronary events. However, reversal or regression in the sense of returning to a disease-free state does not occur. Numerous research studies have shown the benefits of lipid-lowering drugs on coronary artery function. Moreover, a small number of clinical trials involving lipid-lowering via intensive dietary modification have shown similar success. One of these, the Lifestyle Heart Trial, included stress management as part of the intervention. Its author, Dr. Dean Ornish, is here today. While intensive risk factor modification through lifestyle changes has shown some success in stabilizing coronary function and reducing cardiovascular risk, it is not possible to know to what extent stress management contributes to the observed results.

To assess the present status of stress management interventions generally, it is also informative to examine the results of studies in individuals with high blood pressure, a very well-established risk factor for coronary heart disease. The NHLBI has supported a series of clinical trials in this area, which has been one of the most intensive targets of investigation for stress management. The most definitive review article on this subject was written by David Eisenberg, who reviewed more than 800 studies and selected 26 that met scientific standards for evidence-based medicine. The results of the analysis, involving 1,264 patients, showed that blood pressure was reduced by only 2.8 mm Hg systolic and 1.3 mm Hg diastolic, results which were not significantly different from changes observed in patients assigned to control or “sham” therapies. Similar conclusions were drawn by Podszus and Grote, who later published a review of a more narrowly defined set of stress management studies. One of the larger stress management studies was conducted within the NHLBI-initiated Trials of Hypertension Prevention, involving 562 individuals with blood pressures initially in the high-normal range, which found no statistically sig-

nificant differences between treatment and control conditions after an 18-month intervention program.

Some of the studies published since completion of these reviews have shown beneficial effects, but their size is too small to change the general conclusions of the earlier review by Dr. Eisenberg. The status of knowledge concerning the effects of stress management on blood pressure reduction, a condition that has been studied more extensively than atherosclerosis, suggests that developing effective stress management interventions for coronary heart disease patients will require continued efforts and perseverance.

In conclusion, what can we do today? We believe that definitive evidence of beneficial effects of stress management on progression of heart disease is not currently available. However, because the evidence of acute effects of stress on cardiac events is well-established, and because the results of the initial clinical trials of stress management interventions for patients with established coronary disease appear promising, it seems prudent to integrate stress management approaches with cardiac rehabilitation programs for patients who want to avail themselves of these interventions. Doing so may improve quality of life and promote lifestyle changes as well as adherence to medical regimens. We do know with certainty that altering several other behavioral risk factors, namely high-fat diets, smoking, sedentariness, and overweight, can play a very substantial role in reducing heart disease. Attention to these areas would benefit the public health.

I would be pleased to answer your questions on this subject.

Senator SPECTER. Thank you very much, Dr. Kaufmann. I have already reinstated my chief clerk because she provided a document from the National Institutes of Health dated May 1, 2002, at 2:06 p.m., which lists you as Acting Associate Director of Behavioral and Social Sciences. So, I guess I won't question that. You don't have to answer that, you have a right to remain silent. It's just I'm impressed by the precision, May 1 at 2:06 p.m.

What additional funding will be necessary for NIH above \$23 billion to update these résumés?

Dr. KAUFMANN. Yes, that is impressive indeed, Mr. Chairman.

Senator SPECTER. I would appreciate it if you will stay where you're seated, Dr. Kaufmann, and we're going to call the other witnesses up so that the interaction, I think, will be preferable to my questioning you alone on behalf of a number of views.

So, if Dr. Abrams, Dr. Benson, Dr. Eisenberg, Dr. Ornish, Dr. Vernalis, and Dr. Matthews would step forward, we will proceed.

**STATEMENT OF DAVID B. ABRAMS, Ph.D., PROFESSOR OF PSYCHIATRY AND HUMAN BEHAVIOR, BROWN MEDICAL CENTER**

Senator SPECTER. We have moved here in alphabetical order because it is not possible to give appropriate recognition, except on some grander basis such as alphabetical order.

Dr. David Abrams is our first witness, a professor of psychiatry and human behavior at Brown Medical School and founding director of the Centers for Behavioral Preventive Medicine at the Miriam Hospital. He has had a distinguished career in South Africa until the United States was lucky enough to have him settle in Rhode Island. A Ph.D. in clinical psychology from Rutgers University. Dr. Abrams made an earlier trip to Washington to consult with the subcommittee and help us provide the basis for this hearing, and we're very pleased to have you here today, Dr. Abrams, and we look forward to your testimony.

Dr. ABRAMS. Thank you, Mr. Chairman.

We have been hearing good news. We now know that people can take action to slow the progression of heart disease and even reverse it. In the past 30 years, cardiac deaths have decreased dra-

matically, in part due to new medical advances, but changes in smoking and eating behavior have played a major role as well.

Stress is one psychosocial factor that has been linked to the development of heart disease. Stress may be a separate risk factor for heart disease, or it may increase the severity of other risk factors such as smoking and diet. Acute stress can precipitate cardiac problems. Stress can also interfere with both providers' and patients' ability to adhere to medical recommendations.

It is hard to separate out the effects of stress alone on heart disease. Usually stress management is combined with other lifestyle and medical components in a total package to reduce heart disease. If we're going to prevent heart disease in the first place, we must target people throughout their entire life span. This means giving everyone in the country messages and behavioral help with changing their behavior.

We do not fully appreciate the power of changing behavior in the entire population. Small changes can result in huge reductions in the absolute numbers of those with disease burden, but this takes many years to see. Tens of thousands fewer deaths from lung cancer in men are due to the decrease in tobacco use over the last 30 years. Significant reductions in cardiovascular disease, cancer, and associated Medicaid savings have been noted in the state of California as a direct result of their decade long aggressive antismoking campaign.

Population-wide changes in health do not capture the headlines as much as an announcement of an artificial heart or death due to defective tires in Ford Explorers, but over 160,000 deaths from heart disease and stroke, and 170,000 from lung cancer, would be averted if nobody smoked.

For those who already have heart disease, we must also focus on preventing a second cardiac event and improving quality of life. In cardiac rehabilitation programs, the benefit of combined behavioral and medical approach is compelling. A summary of 37 studies found that stress management combined with life style change programs produced a 54 percent reduction in cardiac death, and improvements in life style as well.

Cardiac rehabilitation is highly cost effective but only 15 percent of eligible patients participate each year. Many programs do not implement the stress, diet and life development components very well.

So you see, there is some good news and bad news. Thousands more lives would be saved and quality of life improved if we could only put our research findings into practice. We must look at our opportunities at many levels, health services, physician and patient behavior. Public health and medical care delivery is weakest in prevention. Our recent awareness of gaps in public health raised by the threat of bioterrorism has brought the need for a stronger infrastructure into sharp focus.

We need to increase the Nation's capacity to address both bioterrorism, as well as health promotion and disease prevention. Both may protect and save millions of lives. We need research that would inform us how to rapidly translate our science into practice. If we can reach all relevant target audiences with best practices, our sci-

entific discoveries will yield an enormous return on the investment in NIH.

Continued progress depends on multidisciplinary research that focuses on both fundamental science as well as its translation into practice and policy. Dissemination of research findings to other disciplines will be greatly accelerated by the integration of biomedical methods with behavioral and public health expertise.

We can detect those at risk for heart disease with simple tests such as for cholesterol and lifestyle habits. As diagnostic tests and imaging technology improves, we will need to address these new challenges and opportunities raised by improved screening, early detection, and the ability to track the progression of disease in its early stages.

We can increase the availability of treatments through interactive computer programs in the home and other communication technologies. Tracking disease progression can help to motivate people to change their lifestyle and then see the progress they are making.

#### PREPARED STATEMENT

In summary, the scientific foundations of prevention and treatment of heart disease are supported by clinical practice guidelines. Combined medical lifestyle and stress management can make a measurable impact on preventing or reversing the progression of heart disease. The impact is most dramatic if we begin as early as possible in the disease process. This is echoed in the Hippocratic oath which states, I will prevent disease wherever I can, for prevention is preferable to cure. Thank you.

[The statement follows:]

#### PREPARED STATEMENT OF DR. DAVID B. ABRAMS

##### WHAT IS THE IMPACT OF STRESS MANAGEMENT ON REVERSING HEART DISEASE?

My name is Dr. David Abrams. I am professor and director of the Centers for Behavioral and Preventive Medicine at Brown Medical School. I am also President of the Society of Behavioral Medicine, the largest organization of researchers and practitioners dedicated to integrating behavioral and biomedical science.

We've been hearing GOOD NEWS:

We now know that people can take action to slow the progression of heart disease and even reverse it. In the past 30 years, cardiac deaths have decreased dramatically in part due to medical advances. But changes in smoking and eating behavior have played a major role as well.

Stress is one psychosocial factor that has been linked to the development of heart disease. Stress may be a separate risk factor for heart disease, or it may increase the severity of other risk factors such as smoking and diet. Acute stress can precipitate cardiac problems. Stress can also interfere with providers' and patients' ability to adhere to medical guidelines.

It is hard to separate out the effects of stress alone on heart disease. Usually stress management is combined with other lifestyle and medical components to reduce heart disease.

If we are going to prevent heart disease in the first place, we must target people throughout their entire lifespan starting at a young age. This means giving everyone in the country messages and help with changing their behavior.

We do not fully appreciate the power of changing behavior in the entire population. Small changes can result in huge reductions in the absolute numbers of those with disease burden. But this takes many years to see. Tens of thousands fewer deaths from lung cancer in men are due to decreasing tobacco use over the last 30 years. Significant reductions in cardiovascular disease, cancer, and associated Medicaid savings have been noted in the State of California as a direct result of their decade long aggressive anti-smoking campaign.

Population wide changes in health do not capture the headlines as much as an announcement of a new artificial heart or deaths due to defective tires on Ford explorers. Over 160,000 deaths from heart disease and stroke and 170,000 from lung cancer would be averted if nobody used tobacco.

For those who already have heart disease, we must also focus on preventing a second cardiac event and quality of life. In cardiac rehabilitation programs, the benefits of combined behavioral and medical approaches are compelling. A summary of 37 studies found that stress-management and lifestyle change programs produced a 34 percent reduction in cardiac death and improvements in lifestyle as well.

Cardiac rehabilitation is highly cost-effective, but only 15 percent of eligible patients participate each year. Many programs do not implement the stress, diet and lifestyle components very well.

So you see there is good news and bad news. Thousands more lives would be saved and quality of life improved if we only could put our research findings into practice. We must look at opportunities at many levels-health services, physician and patient behavior.

Public health and medical care delivery is weakest in prevention. Our recent awareness of gaps in public health, raised by the threat of bio-terrorism, has brought the need for a stronger infrastructure into sharp focus. We need to increase the nation's capacity to address both bio-terrorism as well as health promotion and disease prevention. Both may protect and save millions of lives.

We need research that will inform us how to rapidly translate our science into practice. If we can reach all relevant target audiences with best practices, our scientific discoveries will yield an enormous return on the investment in NIH.

Continued progress depends on multidisciplinary research that focuses on both fundamental science and its translation into practice and policy. Dissemination of research findings to other disciplines will be greatly accelerated by the integration of biomedical methods with behavioral and public health expertise.

We can detect those at high risk for heart disease with simple tests such as for cholesterol and lifestyle habits. As diagnostic tests and imaging technology improves, we will need to address the new challenges and opportunities raised by improved screening, early detection, and our ability to track the progression of disease in its early stages.

We can increase the availability of treatments through interactive computer programs at home and other communications technologies. Tracking disease progression can also help to motivate people to change their lifestyle and see the progress they are making.

In summary, the scientific foundations of prevention and treatment of heart disease are supported by authoritative clinical practice guidelines. Combined medical, lifestyle and stress management can make a measurable impact on preventing or reversing progression of heart disease. The impact is most dramatic if we begin as early as possible in the disease process. This is echoed in the Hippocratic Oath, which states, "I will prevent disease whenever I can, for prevention is preferable to cure."

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

Senator SPECTER. Thank you very much, Dr. Abrams. Our next witness is Dr. Herbert Benson, founding president of the Mind/Body Medical Institute at Harvard Medical School, where he is the associate professor of medicine. He is chief of the division of behavioral medicine at the Beth Israel Deaconess Medical Center. He is a graduate of Wesleyan and Harvard Medical School, and author or co-author of 6 books and over 150 scientific publications.

Dr. Benson has testified before this subcommittee on a number of occasions, has counseled this subcommittee, and has been the recipient of grants. It is hard to find a sufficiently extraneous adjective for his advocacy on meditation, including treating Arlen Specter with some limited success. Dr. Benson, thank you for joining us today.

Dr. BENSON. Thank you, Senator. It's a delight to be here and I'm thankful for this opportunity to testify on the impact of stress

management on reversing heart disease. Stress contributes to many medical conditions that are treated by healthcare professionals. In fact, over 60 percent of patient visits to healthcare professionals are related to stress and psychosocial factors.

Stress is defined as the perception of or threat of, but perception of a threat or danger that requires behavioral change. Not all stress is deleterious; in fact, a certain amount of stress is beneficial. As stress increases, so does performance and efficiency, but only to a point. More stress decreases performance and efficiency, and could be injurious to health.

Stress increases metabolism, heart rate, blood pressure and rate of breathing. These internal physiological changes have been labeled the fight or flight response. This response is mediated by the release of epinephrine, norepinephrine, adrenalin, noradrenalin, if you will, into the blood stream. The mean effect of these hormones is influenced by nitric oxide, which can correctly counteract epinephrine, but nitric oxide like stress can be both beneficial and harmful depending on its concentration.

The relaxation response is a physiologic reaction opposite to that of stress. Relaxation response is characterized by decreased metabolism, heart rate, blood pressure and rate of breathing, as well as slower brain waves and specifically altered changes within the brain itself when it's being elicited. It is also believed that the relaxation response is directly related to increased beneficial nitric oxide activity.

Two steps are necessary to elicit the relaxation response. They are, first, the repetition of a word, sound, prayer or phrase, or muscular activity. Second, there should be a passive disregard of everyday thoughts that come to mind and a return to the repetition. There are many different behavioral techniques that elicit the relaxation response. They include for example, meditation, tai chi, chi gong, repetitive exercise, yoga, and also repetitive prayer.

Relaxation response approaches are useful in the treatment of angina pectoris and other manifestations of coronary artery disease. For example, relaxation response techniques decrease premature ventricular contractions in ischemic heart disease. Further, long-term yoga has been reported to reduce coronary atherosclerosis on coronary angiogram, and to improve symptomatic status, including reduction of angina pectoris and a decrease in the need for revascularization procedures, and an increase in exercise capacity.

There are also improvements in cardiac risk factor profile including reductions in body weight, reductions in serum cholesterol, LDH, triglyceride levels, and an increase in HDL. Additionally, tai chi training has been reported to facilitate better cardiorespiratory outcome and cardiac functioning following coronary artery bypass surgery. Relaxation response has also been shown to enhance the physical and psychological status of patients after rehabilitation following myocardial infarction. Relaxation response therapy has also been shown to improve long-term cardiovascular prognosis in coronary artery disease as it decreases future ischemic events such as fatal myocardial infarction.

## PREPARED STATEMENT

In summary, stress plays a major role in cardiovascular disease. On a molecular basis, these disorders appear to be connected to nitric oxide pathways and a balance of the various molecular signaling pathways that may be a crucial step in achieving better health outcomes. Such a balance may be stabilized or facilitated by the use of relaxation response techniques since they counteract stress, lower epinephrine activity, in the action, we believe, of ameliorating restriction of nitric oxide pathways. In fact, relaxation response techniques have been shown to be of use in the treatment of hypertension, cardiac arrhythmias, angina pectoris and other manifestations of coronary artery disease.

Of course, more research is necessary into not only the fundamental molecular aspects of stress and its alleviation, but also its clinical applications. Again, I thank you for the opportunity to testify here today.

[The statement follows:]

## PREPARED STATEMENT OF DR. HERBERT BENSON

I'm pleased to be called upon to testify on the impact of stress management on reversing heart disease.

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

## STRESS AND THE FIGHT-OR-FLIGHT RESPONSE

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

Stress is defined as the perception of threat or danger that requires behavioral change. Not all stress is deleterious. In fact, a certain amount of stress is beneficial. As stress increases, so do performance and efficiency, but only to a point. More stress decreases performance and efficiency and can be injurious to health.

Stress 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. Walter B. Cannon (1941), the Harvard Medical School physiologist, described the fight-or-flight response in the last century. It occurs automatically when one experiences stress, without requiring the use of a technique.

The fight-or-flight response is mediated by increased release of catecholamines—epinephrine and norepinephrine (adrenalin and noradrenalin)—into the blood stream. The impact of these hormones is influenced by nitric oxide, a so-called autoregulatory, signaling molecule. It can directly counteract norepinephrine. Thus, nitric oxide can directly affect the manifestations of stress, but like stress, nitric oxide can be both beneficial and harmful depending upon its concentration. A proper balance is necessary (Stefano et al, 2001, Esch et al—in press).

## STRESS AND THE HEART AND CIRCULATION

Stress can have major effects on the heart and circulation. It leads to increased blood pressure, heart rate and increased clotting. It directly influences hypertension, heart attacks, angina pectoris, and cardiac arrhythmias. The influence of stress is dependent upon its amount, its acute or chronic nature, the patient's predisposition to stress and the patient's genetic make-up. Like stress, nitric oxide, as noted above, is a double-edged sword. A small amount of so-called constitutive nitric oxide is beneficial whereas larger amounts of so-called inducible nitric oxide can be detrimental (Stefano et al, 2001, Esch et al—in press).

## 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). Lazar et al used functional magnetic response imaging to establish that when the relaxation response is elicited there is activation in the brain of areas that control the autonomic nervous system, the areas that control, for example, metabolism, heart and breathing rates and blood pressure (Lazar et al, 2000). Recently, Stefano et al (2001) have proposed that the relaxation response actions are directly related to increased constitutive nitric oxide activity.

Two steps are necessary to elicit the relaxation response. (Benson, 1996) They are: (1) the repetition of a word, a sound, a prayer, a phrase, or muscular activity and (2) the passive disregard of everyday thoughts that come to mind and a return to the repetition.

There are many approaches and techniques that elicit the relaxation response. They include: repetitive prayer, meditation, tai chi, chi gong, repetitive exercise and yoga. (Benson, 1999)

One can choose any focus, but to enhance the benefits of the relaxation response with the healing effects of belief and to help ensure that a person will adhere to the routine, the focus should be one in which a person believes: if religious, a prayer could be chosen; if not, a secular focus. Regardless of the techniques or focus that one selects, the relaxation response will be evoked if one uses the two basic steps.

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

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

Secular Focus Words:

"One"  
 "Ocean"  
 "Love"  
 "Peace"  
 "Calm"  
 "Relax"

Religious Focus Words or Prayers:

Christian (Protestant and Catholic): "Our Father who art in heaven," "The Lord is my shepherd"

Catholic: "Hail, Mary, full of grace," "Lord Jesus Christ, have mercy on me"

Jewish: "Sh'ma Yisroel," "Shalom," "Echod," "The Lord is my shepherd"

Islamic: "Insha'allah"

Hindu: "Om"

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

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

Step 2. Sit quietly in a comfortable position.

Step 3. Close your eyes.

Step 4. Relax your muscles.

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

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

Step 7. Continue for ten to twenty minutes.

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

Step 9. Practice this technique once or twice daily.

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

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

#### THE RELAXATION RESPONSE AND HEART DISEASE

Our research conducted at the Harvard Medical School as well as that of others has documented that relaxation-response approaches, sometimes used in combination with nutrition, exercise, and stress management interventions, result in alleviation of stress-related heart disorders. Because of this scientifically documented efficacy, a physiological basis for many millennia-old mind-body belief-related approaches has been established.

As a result of the evidence-based data, the relaxation response is becoming a part of mainstream medicine. Approximately 60 percent of U.S. 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.

It is essential to understand that regular elicitation of the relaxation response results in long-term physiologic changes that counteract the harmful effects of stress throughout the day, not only when the relaxation response is being brought forth (Hoffman, et al, 1982). These mind-body approaches have been reported to be effective in the treatment of disorders such as hypertension (Stuart, et al, 1987, Linden and Chambers, 1994) and cardiac arrhythmias (Benson, Alexander, Feldman, 1975).

Relaxation response techniques have also been demonstrated to be helpful in the treatment and prevention of atherosclerosis and endothelial dysfunction. For example, Transcendental Meditation has been shown to reduce oxidative stress and lower serum levels of lipid peroxides, thereby reducing the risk of developing atherosclerosis (Schneider et al, 1998). Relaxation response approaches are also useful in the treatment of angina pectoris and other manifestations of coronary artery disease (Benson et al, 1975, Linden et al, 1994, Manchanda, et al 2000, Cunningham et al, 2000). For example, the relaxation response techniques decrease premature ventricular contractions in stable ischemic heart disease. Further, long-term yoga has been reported to reduce coronary atherosclerosis on coronary angiogram and to improve symptomatic status including reduction of angina pectoris, a decrease in the need of revascularization procedures and an increase in exercise capacity. There are also improvements in the cardiac risk factor profile including a reduction in body weight, serum total cholesterol, LDL, triglyceride levels and an increase in HDL (Mahajan et al, 1999, Manchanda et al, 2000). Additionally, tai chi training has been reported to facilitate better cardiorespiratory outcome and cardiac function following coronary artery bypass surgery (Lan et al, 1999.) The relaxation response has been shown to enhance the physical and psychological status of patients after rehabilitation following myocardial infarction (van Dixhoorn et al, 1990). Relaxation response therapy also has been shown to improve long-term cardiovascular prognosis in coronary artery disease as it decreases future ischemic events such as fatal myocardial infarction (Patel et al, 1985).

In summary, stress plays a major role in cardiovascular diseases. On a molecular basis, these disorders appear to be connected with nitric oxide pathways and a balance of the various molecular signaling pathways may be a crucial step in achieving better health outcomes. Such a balance may be stabilized or facilitated by the use of relaxation response techniques since they counteract stress and norepinephrine activity through the activation of ameliorating, constitutive, nitric oxide pathways. In fact, relaxation response techniques have been shown to be of use in the treatment of hypertension, cardiac arrhythmias, angina pectoris and other manifestations of coronary artery disease.

Further research is needed to better understand these findings and their clinical applications.

**STATEMENT OF HARVEY EISENBERG, M.D., DIRECTOR, HEALTHVIEW  
CENTER FOR PREVENTIVE MEDICINE**

Senator SPECTER. Thank you very much, Dr. Benson. Our next witness is Dr. Harvey Eisenberg, founder of the HealthView Center for Preventive Medicine in California. A pioneer in the field of interventional radiology and medical imaging, he is also the inventor of the angio CAT technology. He served as professor of radiologic sciences at UCLA, Harvard, and Stanford. He served as a medical consultant to many businesses over 35 years, including working as medical director at Raytheon and Acac Labs. He has a bachelor's degree from the University of Pennsylvania, an M.D. from Thomas Jefferson University, and is a native of Philadelphia.

I had an opportunity to visit with Dr. Eisenberg in Newport Beach. We see the display here of the original body scan, and it is quite a process. We look forward to your testimony, Dr. Eisenberg.

Dr. EISENBERG. Thank you, Senator Specter. Technology as integration of behavioral and metabolic medicine plays an essential role in enabling the capabilities that we consider to be essential to achieving a paradigm shift to preventive or proactive medicine. There is no area that this applies to more profoundly than coronary artery disease, where we now see great opportunities to improve our treatment approaches.

Advancing these technologies will be critical to fulfilling this opportunity. I am using visual demonstrations here on the screen to show, these are the factors we consider to be the essential ones in basically preventive medicine. We need to get earlier and more accurate diagnosis of the disease. We need to get into actually achieving behavioral changes, and we are doing this now visually through self visualization, which is a very motivating process, and translates into a very educational process that we will demonstrate here in a moment.

People in general think that a disease advances in their body, that they go downhill in reaction to that disease process, and that their body will in the early stage give them a warning that there is a problem. This is true of infectious diseases, but it isn't true of pretty much all of the diseases that take us down in life, that change our life outcomes or the quality of life. These diseases, like arteriosclerosis, Alzheimer's, emphysema, and cancer, are usually present for 20, 25, 30, 40 years before the actual symptoms occur, because the body has great compensation mechanisms that keep them in the asymptomatic state. Even cancers are generally present for much longer periods of time than people realize before the symptoms will occur.

We practice medicine out here on this downward slope, but 90 percent of the disease is really back here in the asymptomatic stage. So we spend our training dealing with symptomatic events when in fact the real opportunity, we believe, is to get into the disease at a much earlier stage.

Now to do that, you first need to do the early diagnosis. We rely upon something like a physical exam to achieve that, but the physical exam in many studies that we've known about, showed that it really doesn't accomplish this very well, and it's routine for us to see patients who have advanced heart disease or masses the size

of grapefruits or even larger in the body, and who just passed their annual physical exams, and this has not been a sufficient answer.

In areas like cancer, there is no screening test for most of the cancers that we have and the screening tests that we have that are good, like mammography, still have a 12 to 20 percent miss rate, and others like colonoscopy, many people avoid because of the invasiveness.

In heart attacks the stress test that we rely upon will only really pick up the late stage disease. And this is very significant because we now know that about 85 percent of heart attacks are caused by smaller plaques that suddenly rupture to cause sudden death, much more so than the larger plaques. And so, those will not show up with symptoms or with stress tests and we need to get in and find these. It is very common for us to see patients with extensive coronary artery disease that have no symptoms or are physically fit and who have just passed their stress test.

So the first thing is to be able to identify the disease process at an earlier stage, and to that end we have for 23 years now been using a technique which we helped develop called calcium screening or heart scanning, which has now evolved new a much broader concept of a full body scan for early detection, and it has taken us back significantly in our diagnosis capability. We are developing a new technology with the support of Department of Defense funding and backing of senators like Dr. Stevens, Ted Stevens, who has seen the importance of this, and Senator Inouye, and this is helping us get to a much greater level of very early detection.

The body scan looks something like this. It's a very visual process and we use this visual process to take the patient on this virtual body tour. We are really showing them the internal organ structures in very graphic ways and it's a very powerful process. We get into the heart and lungs in great detail right down to the cellular level of the air nodules. In plaque disease we can take it to a much earlier detection capability than our current screening tests, and very often see extensive disease that even an angiogram has missed.

The plaques look like this. The patient gets to see the actual plaque structure and it's very powerful for them to self visualize this, and in fact we need to train on how to present this information so it's not frightening but is in fact turned into a motivational process, which is essential to the process.

So after finding the disease, you now have the bigger challenge, and that's to take patients who are asymptomatic and convince them that they have to make major behavioral changes in their lives. So this indeed is a very difficult proposition, which we are in fact having significant success in about 87 percent of patients, by showing them the visuals; the cell visualization is very motivating. It translates into what we call teachable modes, where we want to know how to deal with the diseases that we almost invariably find, and certainly that includes in many patients the heart problems, and then it becomes a tracking process.

And the tracking is very essential. This is a patient, for example, who had passed his stress test, had extensive disease, actually needed bypass, but at six months after bypass, still passing his stress test without any symptoms, we see a 130 percent increase

in his plaques with the normal heart regimen. Over the next 10 years we got him into a program much like the Northern State program where we were able to slow this growth rate down to about 5 to 7 percent from 150 growth rate.

In another patient, like one of my relatives with a very bad family history of heart disease, at the age of 57 had normal stress tests and no symptoms, we were able to take her plaques and in a 6-month period get an almost 50 percent volumetric reversal, as visualized by our technique which visualizes a portion of the plaque and seems to correlate well with how patients follow programs in terms of getting active reversal.

Unfortunately, my cousin thought this was so wonderful that she celebrated for a year and then grew the plaques right back. And this emphasizes the essential working program, which focuses on, one, the ability to reverse disease, and the need to keep it up. Patients need to sustain process.

Smokers, we have a very effective result in getting them to stop smoking by showing them cell visualization of the tremendous destruction that's always present in an active smoker.

#### PREPARED STATEMENT

So, what we need is to advance these technologies, including the kind that we are developing that will take us up diagnostically, and also the information technologies that Dr. Abrams referred to. These are the essential tools that we need to continue to develop. There is no test today or combination of tests that actually lets us see the heart plaque, its volume, its composition, its effect on blood flow, and its propensity to rupture. We don't have that today, and that is what we need and that's what's in development.

Thank you very much for this opportunity.

[The statement follows:]

#### PREPARED STATEMENT OF DR. HARVEY EISENBERG

A consensus opinion of our national healthcare debates of the nineties was the necessity for a paradigm shift in healthcare from our emphasis on symptomatic (late stage) disease diagnosis and management to the proactive diagnosis and management of earlier asymptomatic disease. This is consistent with the Hippocratic Oath which states "I will prevent disease whenever I can, for prevention is preferable to cure." In most diseases the body's compensation mechanisms or reserves keep us asymptomatic while disease progresses, often for many years. This is true of the most prevalent diseases that affect the length and quality of life. Arteriosclerosis, the cause of heart attacks, strokes and some hypertension starts in childhood and 25-40 years later unpredictably causes sudden death or disability without warning in most patients. Alzheimer's is present for 25-30 years before the devastating symptoms that will afflict 1 of 5 patients over 80 in a steadily aging population. Cancers are usually present for years before symptoms. Emphysema takes massive lung destruction before symptoms. The degenerative spine diseases that dramatically affect our quality of life in later years start in the twenties. We currently spend the great bulk of our healthcare dollars (trillions), in the crisis management of the late stage effects of disease. There is increasing evidence that the courses of all of these diseases and many others are substantially modifiable, no matter what the genetic drive, through early detection and advances in biomedical and behavioral sciences. Advances in these areas continue to yield improved treatment, which under ideal circumstances can prevent, cure, modify or even reverse disease. These opportunities require advancement of technologies already in development as part of a program entitled "Reengineering Healthcare" that we presented to congress in 1994. This proposes near term technology driven solutions to many of our nations most pressing and costly problems in healthcare delivery. The several elements include:

- Paradigm shift from reactive to proactive medicine
- Compacting the diagnostic process
- Improved therapy planning
  - Better information
  - Routine simulation
- Improved therapy performance
  - Micro-invasive, precision
  - Interactive computer/image guidance
- New doctor bag
  - Information access
  - A.I. driven decision making-updated knowledge
  - Portable Dx and Rx
- Telepresent home health care
  - Education
  - Dx
  - Rx

Our organization has been evolving technologies and early disease management capabilities in a program entitled HealthView™ that integrate our advances in imaging and informatics technologies with programs in behavioral and metabolic medicine to enable what we perceive to be the key components in achieving the paradigm shift to earlier disease management and preventive medicine. These include:

- Earlier and more accurate diagnosis
- Motivating patients to behavioral changing and taking responsibility for their own healthcare initiatives through graphic self-visualization
- Advanced and continuing graphic patient education and empowerment
- Tracking asymptomatic disease for corrective diagnosis, treatment, and preventive maintenance

The above applications are pervasive and transcend current medical capabilities and practices. For example the answer to cancer is probably as simple as finding it very early, and removing or destroying it with a variety of precisely guided minimally invasive therapies, predominantly outpatient. Unfortunately there are currently no screening tests for most cancers. Even the most successful tests like mammography still have a 12–30 percent miss rate. Many women still avoid it because it hurts, as most people avoid screening endoscopies (colonoscopy, gastroscopy, bronchoscopy). Blood testing has produced little beyond the prostatic serum antigen (PSA), which is still fairly non-specific and often generates unnecessary biopsies. The annual physical exam often misses tumors the size of grapefruits or even larger.

In coronary artery disease, the single largest cause of premature death, disability and economic burden, current screening tests only can identify late stage flow obstructing disease (over 60–70 percent blockage), when its been shown that 85 percent of heart attacks result from the sudden rupturing and arterial blockage from plaque whose size is below this level. Heart attack risk appears related more to the numbers and composition of plaque than to their size, and also to plaque biologic activity and rapidity of growth. In fact there currently is no single test or combination of tests, including invasive coronary angiography, that can accurately identify plaque size, composition, numbers, or propensity to rupture. This translates to a current inability to accurately predict risk of heart attack or to accurately track plaque growth and metabolism to assess results of plaque regression therapies. Over the past 23 years we have been involved in developing a non-invasive CT heart scan that sees a portion of the plaque (Calcium). This test approximates the numbers of plaques, generally sees them much earlier than stress tests, and has provided the first non-invasive plaque tracking capability. This has proven valuable in patient management but still falls far short of the above necessary goals. We gradually evolved this technology into a full 3-D CT torso scan and introduced the concept of the CT screening “body scan” in 1997. We integrated this scan with proprietary new information technologies and behavioral medicine programs into a full disease management program called HealthView™. In applying HealthView™ to over 30,000 patients, we have found it to be lifesaving on an almost daily basis, routinely diagnosing early cancer and life threatening heart disease in asymptomatic patients that passed routine screenings. Over 400 physicians scanned considered it a major advance. 98 percent of all patients, including physicians, recommend it to family and friends. While the statistics of behavioral medicine suggest that only 10–15 percent of patients make the lifestyle changes recommended by their physician, our latest data is showing the full HealthView™ program resulted in 87 percent of patients making immediate behavioral and lifestyle changes, including stopping smoking. This is largely achieved through graphic self-visualization of emerging pathology as displayed in a physician guided 3D virtual body tour. This information when prop-

erly presented with specially trained techniques achieves motivation and creates “teachable moments” of empowering education. While such programs are moving us in the right direction, they still fall short of the desired goals.

In order to accomplish these goals and several other elements of the “Re-engineering Healthcare” program we have been developing a core technology called Volume AngioCAT™ (VAC) with DOD funding. VAC is a foundation for numerous programs of considerable pervasive impact to healthcare delivery, and to the DOD, including military healthcare, battlefield trauma care, baggage and ordnance scanning, non-destructive testing, safety testing, simulation and modeling for numerous applications.

The VAC is designed to non-invasively provide for the first time comprehensive fused imaging of the anatomy, physiology and biochemistry (molecular function), of the entire body. This will be accomplished within a few seconds to minutes in 3-D and near real-time 4-D, and at resolutions and speeds that are orders of magnitude greater than the current state of the art. VAC has been designed to create a full body scan, including the brain, that advances the current “body scan” from a screening exam to a comprehensive and definitive diagnosis. This should yield very low false negative results or the false positive results that generate the need for additional unnecessary studies that occurs with all screening techniques, and which generate questions about cost effectiveness. VAC is expected to provide for the first time a complete analysis of cardiovascular disease and arterial plaque including the full size of plaques, their numbers, composition, effect on blood flow and heart muscle performance, and information about the likelihood of plaque rupture. This is expected to be a new powerful tool for the very early and later stage management of cardiovascular disease, including accurate risk assessment, improved therapy planning, guidance, tracking, and results. VAC is also being designed to look for cancer in several different ways simultaneously with resolutions capable of detection down to a 1–2 millimeter level throughout the entire body, a size almost certain to result in cure. This capability should provide a major advance in defeating cancer. Its applications will span a broad range of other diseases such as Alzheimer’s, emphysema, diabetes, degenerative diseases, and congenital diseases. Altogether those represent the most prevalent and deadly diseases affecting mankind.

The VAC is also designed to dramatically compact the diagnostic process, potentially replacing nearly \$80k worth of testing with a single non-invasive \$1,500–\$2,000 test performed within seconds. Tests replaced will include all CT, most MRI, mammography, conventional x-rays, (chest, spine, etc.), nuclear medicine, (SPECT, PET), diagnostic angiography and cardiac catheterizations, and diagnostic endoscopies, (colonoscopy, gastroscopy, bronchoscopy). The use of diagnostic imaging and associated tests has been steadily increasing. As baby boomers are now turning 50 every 9 seconds and reaching the age of disease manifestation these costs will escalate prohibitively. The VAC seeks to provide a powerful solution to this impending financial crisis as well as a substantial advance in earlier diagnosis, more definitive diagnosis, and provide better therapy planning, guidance and results.

Additional funding is required for completion of the VAC prototype and to advance ongoing basic research to further enhance its performance capabilities. Funding is also needed to fulfill the many spin off opportunities for advanced simulation and modeling, precise image guided microsurgery, and automated diagnosis. These are enabled by the massive integrated near real time (4D) data sets that increase the data density from our current 200mb/exam to 5–10gb/exam, and require the powerful VAC computational and information handling systems. The VAC applications extend to advanced mobile rapid mass casualty care (battlefield, homeland), and to automated baggage and ordnance scanning.

Funding is also required to allow for advances in informatics and computer technologies that will allow for the creation of a sophisticated, yet cost efficient program that includes interactive disease and lifestyle management interventions tailored to the unique needs of each individual patient. Such interventions can be widely disseminated at modest unit cost once initial development is completed. This is the concept of mass customization, which leverages “high-tech” while retaining the crucial elements of “high touch”, (the trusting, caring doctor/patient relationship).

In addition, to advance the field as outlined above, we recommend a demonstration test with two phases. The first phase will focus on the development of an integrated diagnostic imaging and behavioral medicine cardiovascular risk reduction program. Initial evaluation will demonstrate feasibility and acceptability of the program, and will provide evidence of effectiveness (proof of concept phase). Success in Phase I will facilitate a second phase of more rigorous scientific evaluation via usual NIH mechanisms (i.e., the NIH investigator-initiated peer review grant process). Funding to develop the program and conduct initial evaluation is being sought through other (i.e., non-NIH) channels to jump-start the process.

Funding vehicles: My 37 years involvement in medical technology development as academician, consultant and medical directorships in the medical imaging and military industrial industries lead me to the following observations. It needs to be clearly understood by congress that medical technology development is unique in that it generally takes 15–20 years to develop a medical product, validate its clinical efficacy and achieve necessary third party reimbursement to get it to the public. This is completely unacceptable given the explosion of current technology opportunities to improve our national healthcare. In order to expedite this process it is recommended that funding be targeted to come from several sources, including DOD, NIH, and transportation. The DOD is the preferable funding source for technology R&D and productization, which is analogous to weaponry, and requires similar systems approach and similar information and communication technologies. The NIH is an academic culture insufficiently experienced in these areas and having a sub-optimal track record in medical technology/product development. The large medical manufactures are earnings driven and risk adverse, used to letting small entities break the envelope and buying them if successful at both product development and proving the market. This process adds many years to rapidly evolving technology opportunities. The venture capital community is intensely near term and high profit driven, adverse to risk research, and usually divorced from issues of social or national interests or long-term quality. The military industrial companies are heavily incentivized toward weaponry and don't understand the complex and diverse medical market.

One of the very few places that support the essential role of risk research in achieving real progress is DARPA, responsible for such breakthroughs as the Internet. Most of their funding goes to small companies in the true American spirit and foundation of entrepreneurship. DARPA has the proper culture for fast tracking R&D and has the knowledge base and experience to accomplish this. I have observed them to accomplish a great deal with very little medical budget in the brief period they were asked to do this in the late 90's. (Accompanying booklet) accomplishing technology advancement important to both battlefield and national healthcare. I recommend a considerable expansion of their budget to pursue medical technology advancement. They are also one of the few agencies capable of bringing the resources of the military industrial complex to the table. A natural combination with DARPA are military agencies for product development, such as the army's MEDCOM, which includes such entities as TATRC (Telemedicine and Advanced Technologies Research Command). This is currently where most research is going forward for telemedicine, breast and prostate cancer. MEDCOM's RDT&E budget should be greatly expanded in pursuit of rapid productization.

NIH excellent track record in the biomedical sciences make it well suited to guide development of imaging pharmaceuticals or molecular tracers. It's also well designed to conduct clinical trials arising from the myriad clinical applications of these new technologies, establish demonstration projects for clinical efficacy, outcomes analysis and cost effectiveness.

Department of transportation and homeland security offices need to recognize that many of their needed applications such are baggage scanning, chemical and bio-detection, and mass casualty handling are spinoffs of core technologies for medicine. They should participate in funding the development for their specific applications, which will provide a multiple use synergy and economy.

Thank you for the opportunity to present these programs and viewpoints.

Senator SPECTER. Thank you very much, Dr. Eisenberg. As I said earlier, I'm going to have to excuse myself for a few moments to go to the Judiciary Committee. The matter is likely to be held over, so I may be back very very briefly. If I have to stay there a while, I will return as soon as I can and we will proceed. We will take whatever time this discussion requires. So, we stand in recess for a few moments.

**STATEMENT OF DR. DEAN ORNISH, FOUNDER, PRESIDENT, AND DIRECTOR, PREVENTIVE MEDICINE RESEARCH INSTITUTE IN SAUSALITO, CA, CLINICAL PROFESSOR OF MEDICINE AT THE UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, A FOUNDER OF UCSF'S OSHER CENTER FOR INTEGRATIVE MEDICINE**

Senator SPECTER. The committee will reconvene. Our next witness is Dr. Dean Ornish, founder, president and director of the Pre-

ventive Medicine Research Institute in Sausalito, CA, clinical professor of medicine at the University of California, San Francisco, and a founder of UCSF's Osher Center for Integrative Medicine. He has written extensively about how comprehensive life style changes can reverse coronary heart disease. He received his MD from Baylor College of Medicine, and his bachelor's degree from the University of Texas at Austin.

Dr. Ornish has been very helpful as a consultant to the committee and I have had the opportunity to read two of his books. Somebody said his talk was difficult, and I responded that that was a vast understatement. I recently purchased some soy products and found some of them palatable. Soy is very good, but not even to have fish in a diet sounds very difficult, but I'm listening. You don't have to explain that now, Dr. Ornish. You may give us your regular testimony.

Dr. ORNISH. I will be happy to. Mr. Chairman, thank you for the privilege of being here today and I want to emphasize again that not everybody needs to make such strict changes in life style. What we all say about an ounce of prevention is really true. It takes one of the worst diseases and gives us the ability to reverse it, and I will talk about that.

I wasn't planning to show the slides but since Dr. Eisenberg came in with this plasma screen, I thought I'd take advantage of it. I really think all the work we have been doing in the last 25 years can be summarized in this cartoon, that is, our goal is not just turn off the faucet, I mean not just to mop up the floor but also to turn off the faucet, to treat the underlying causes of heart disease. And the idea is if you don't treat the cause, if you just do the bypass surgery or do an angioplasty, or medications, without also addressing the factors that really cause heart disease, more often than not the same problem comes back again, the bypass gets clogged up again, and we get a new set of problems or side effects.

We all know at the health policy level they have painful choices. As you know, we have 38 million American who don't have health insurance, and if we simply put them in the system, business as usual, health care costs go up exponentially, so that if we treat the underlying causes, which to a large degree are life style related, stress management, diet, moderate exercise, support groups, and vitamins and supplements, we are able to show for the first time that heart disease can actually be reversed, and much more quickly than people had once thought possible.

In 1977 when we began doing our work, it was thought that heart disease could only get worse. Maybe you could slow down the rate at which it got worse, but it was going to get worse. And that was because the only mechanism that we understood was the plaque in the arteries, like rust building up in a pipe over a period of decades. We now know that it's a much more dynamic process. The arteries can constrict or dilate. Dr. Benson mentioned nitric oxide. There is direct connections between your brain and the arteries all over your body. There are things that can cause your arteries to constrict or dilate from minute to minute. Blood clots can form or disaggregate. And these are all directly related to stress as well as to diet and smoking.

So when you change your diet and life style, when you manage stress more effectively, you don't have to wait years to see the improvement. Within hours, blood flow to the heart can improve. We found a 91 percent reduction in the frequency of angina within weeks, and people not only felt better but in most cases they were better in ways that we measured and I will show in a moment.

But in addition to these direct mechanisms, using stress management is so important because it affects indirect mechanisms, in other words, behaviors. It's not enough to give people health information and expect them to change. We learned that with smoking, everybody knows it's not healthy, but we have to work at a deeper level. So many people are lonely, depressed, isolated and unhappy, and telling someone who is feeling that way they are going to live longer if they just change their diet or manage stress, or quit smoking, it isn't that motivating. We have to work at a deeper level.

It's like giving smokers a discount, because there isn't as much to tell, it's just a way of talking about, instead of just talking about risk factor reduction and living longer, most people don't think anything bad is ever going to happen to them. We have to work at a deeper level and to deal with the underlying stress because people are more likely to smoke, to overeat, to drink too much, to work too hard, to abuse drugs when they are feeling depressed and lonely and stressed out.

In fact, studies have shown that even medications like taking a pill like a statin drug, two-thirds of the people who take statin drugs are no longer taking them just a year later, and that's just taking a pill once a day. So even in terms of getting people to take their medication, much less make changes in diet and quit smoking and so on, we have to address the emotional, the psychosocial, even the spiritual factors that are underlying these behaviors.

So these people are doing a variety of stretching, breathing, meditation, imaging relaxation techniques, and support groups. These techniques have been around for thousands of years. They have been around since time immemorial, they're found in all religions, all cultures. We present them in ways, as Dr. Benson mentioned, that are not threatening to people.

Now as I mentioned, we have a number of studies showing that heart disease is actually reversible, and ironically we have been using these very high tech expensive diagnostic testing when as Dr. Eisenberg has represented on the wall right now, to document and monitor and prove the power of these very low tech and low cost interventions.

Here is an example of one of our patients. On the upper left is a frame from an x-ray looking at the heart called an angiogram, showing the narrowing, and on the right, a year later, it's not as clogged. These monitoring of the blockages can cause dramatic increases in blood flow. The one on the left is a PET scan; blue and black means no blood flow, and on the lower right, orange and white is maximum blood flow, a 300 percent in blood flow from the PET scan.

This is a man who was told he needed a bypass, decided to do this instead, and now is still 13 years later, 16 years later actually, has been able to avoid the bypass operation whereas by now he

would probably be on his second or third. Somebody saved a lot of money avoiding that procedure, not to mention the trauma.

Overall, we found that blockages got worse and worse in the control group, and better and better in the experimental group. One of the interesting findings after both 1 year and after 5 years, was that the more people changed the better they got. Moderate changes don't go far enough to reverse heart disease for most people, but more significant changes do.

I mean, I would love to be able to tell people that eating chicken and beef and so on can reverse heart disease, but they don't. So it's not that we try to tell people what to do, but at least through the science, we can give people information that Dr. Vernalis at Walter Reed, and others, are doing to give them informed and intelligent choices and whatever they choose, we support.

When we look at the PET scan data, and these were blindly done in Texas, 99 percent of the patients stopped or reversed the progression of their heart disease. We published this in JAMA in 1995. That's pretty good. So not everybody, but most people can stop or reverse the progression of their heart disease with behavioral changes. We even had several patients who were so sick that they needed a heart transplant and waited to avoid it. Of those seven patients, all seven were able to avoid having a heart transplant simply from changing diet, exercise, and practicing the stress management techniques.

More recently we began a training cycle throughout the country. There was \$30 billion spent on bypass surgery and angioplasty procedures last year, \$20 billion of that in the Medicare population, and the cartoon shows the surgeon saying, I can operate on you or give you a strict diet, and we'd better operate because your insurance doesn't cover a strict diet. This is the way Medicare has been until recently as well.

And since 1993, several insurance companies have been covering this program because we trained at a number of sites throughout the country in the life style advantage and what we found was that almost 80 percent of the people who were eligible for bypass surgery or angioplasty were able to safely avoid it for at least 3 years, and that saved an average of almost \$30,000 a patient. More recently, Hallmark Blue Cross/Blue Shield found that in 350 patients that were first scheduled, 348 were able to avoid a vascularization procedure, saving more than \$17,000 per patient.

And as you know, Medicare, thanks to you and your colleagues, is now conducting a demonstration project of 1,800 patients.

The last thing I want to talk about is a more recent study that we did with prostate cancer in collaboration with UCSF and Memorial Sloan-Kettering Cancer Center. They found that PSA levels, as you know, a marker for prostate cancer, rose after a year in people who made more moderate life style changes including stress management, but fell or got better in the experimental group. And again, we found the same correlation, the more people changed, the lower their PSA got, but they had to make really big changes to turn that around.

And looking at MRI and neuroscopy, the two on the left shown in red were diminishing or improved a year later.

## PREPARED STATEMENT

And so, I think it's important that we address, in summary, where we rate behaviors like diet and exercise, plus the psychosocial, and the emotional and spiritual interventions, A, because it's very hard to get people to even take their medication or exercise unless you deal with these deeper issues. And also, study after study has shown that people who are lonely and depressed are many times more likely to get sick and die prematurely than those who have a sense of connection in the community. And my hope is that when people understand how important these factors are, then they can begin to take them more seriously, and that's part of the value of good science. Thank you.

[The statement follows:]

## PREPARED STATEMENT OF DR. DEAN ORNISH

## INTRODUCTION AND BACKGROUND

Mr. Chairman, members of the Committee, distinguished colleagues, thank you very much for the privilege of being here today. My name is Dean Ornish, M.D., founder and president of the non-profit Preventive Medicine Research Institute and Clinical Professor of Medicine at the School of Medicine, University of California, San Francisco (UCSF).

For the past 25 years, my colleagues and I at the Preventive Medicine Research Institute have conducted a series of scientific studies and randomized clinical trials demonstrating, for the first time, that the progression of even severe coronary heart disease often can be reversed by making comprehensive changes in diet and lifestyle, without coronary bypass surgery, angioplasty, or a lifetime of cholesterol-lowering drugs.

These lifestyle changes include stress management techniques (yoga-based stretching exercises, breathing techniques, meditation, imagery, and progressive relaxation); a very low-fat, plant-based, whole foods diet; moderate exercise; smoking cessation; and psychosocial support groups. When these lifestyle causes are addressed, then improvement in coronary heart disease may begin to occur much more quickly than had previously been documented.

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

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

For example, one-third to one-half of angioplastied arteries restenose (clog up) again after only four to six months, and up to one-half of bypass grafts reocclude within only a few years. When this occurs, then coronary bypass surgery or coronary angioplasty is often repeated, thereby incurring additional costs. Over \$30 billion were spent in the United States last year just on these two operations, many of which could be avoided by making comprehensive changes in diet and lifestyle, including stress management techniques.

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

## CAN LIFESTYLE CHANGES REVERSE HEART DISEASE?

We began conducting research in 1977 to determine if coronary heart disease is reversible by making intensive changes in diet and lifestyle. Within a few weeks after making comprehensive lifestyle changes, the patients in our research reported

a 91 percent average reduction in the frequency of angina. Most of the patients became essentially pain-free, including those who had been unable to work or engage in daily activities due to severe chest pain. Within a month, we measured increased blood flow to the heart and improvements in the heart's ability to pump.<sup>1,2</sup> And within a year, even severely blocked coronary arteries began to improve in 82 percent of the patients.<sup>3</sup> The improvement in quality of life was dramatic for most of these patients.

These research findings were published in the most well-respected peer-reviewed medical journals, including the *Journal of the American Medical Association*, *The Lancet*, *Circulation*, *The New England Journal of Medicine*, *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.

In the Lifestyle Heart Trial, we found that most of the study participants were able to maintain comprehensive lifestyle changes for at least five years. On average, they demonstrated even more reversal of heart disease after five years than after one year. In contrast, the patients in the comparison group who made only the moderate lifestyle changes recommended by many physicians and agencies (i.e., a 30 percent fat diet) worsened after one year and their coronary arteries became even more clogged after five years.<sup>4,5</sup>

Thus, instead of getting worse and worse, these patients who made comprehensive lifestyle changes on average got better and better. Also, we found that the incidence of cardiac events (e.g., heart attacks, strokes, bypass surgery, and angioplasty) was 2.5 times lower in the group that made comprehensive lifestyle changes after five years. Cardiac PET scans revealed that 99 percent of these patients were able to stop or reverse the progression of their coronary heart disease.<sup>6</sup> 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. The primary determinant of change in their coronary artery disease was neither age nor disease severity but adherence to the recommended changes in diet and lifestyle. No matter how old they were, on average, the more people changed their diet and lifestyle, the more they improved. Indeed, the oldest patient in our study (now 86) showed more reversal than anyone. This is a very hopeful message for Medicare patients, since the risks of bypass surgery and angioplasty increase with age, but the benefits of comprehensive lifestyle changes may occur at any age.

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

#### MULTICENTER LIFESTYLE DEMONSTRATION PROJECT

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

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

<sup>1</sup>Ornish DM, Scherwitz LW, Doody RS, et al. Effects of stress management training and dietary changes in treating ischemic heart disease. *JAMA*. 1983;249:54-59.

<sup>2</sup>Ornish DM, Gotto AM, Miller RR, et al. Effects of a vegetarian diet and selected yoga techniques in the treatment of coronary heart disease. *Clinical Research*. 1979;27:720A.

<sup>3</sup>Ornish DM, Brown SE, Scherwitz LW, et al. Can lifestyle changes reverse coronary atherosclerosis? The Lifestyle Heart Trial. *The Lancet*. 1990; 336:129-133.

<sup>4</sup>Ornish D, Scherwitz L, Billings J, et al. Can intensive lifestyle changes reverse coronary heart disease? Five-year follow-up of the Lifestyle Heart Trial. *JAMA*. 1998;280:2001-2007.

<sup>5</sup>Gould KL, Ornish D, Kirkeeide R, Brown S, et al. Improved stenosis geometry by quantitative coronary arteriography after vigorous risk factor modification. *American Journal of Cardiology*. 1992; 69:845-853.

<sup>6</sup>Gould KL, Ornish D, Scherwitz L, Stuart Y, Buchi M, Billings J, Armstrong W, Ports T, Scherwitz L. Changes in myocardial perfusion abnormalities by positron emission tomography after long-term, intense risk factor modification. *JAMA*. 1995;274:894-901.

Almost ten 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 of stress management and other lifestyle changes 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.

Is it safe to offer intensive lifestyle changes as an alternative to revascularization? Bypass surgery is effective in reducing angina and improving cardiac function. However, when compared with medical therapy and followed for 16 years, bypass surgery improved survival only in a very small subgroup of patients (about 2 percent of those undergoing bypass surgery): those with reduced left ventricular function and lesions of the left main coronary artery of at least 60 percent. Median survival was not prolonged in patients with left main disease 60 percent and normal LV function even if a significant right coronary artery stenosis > 70 percent was also present.<sup>7 8 9 10</sup>

Angioplasty was developed with the hope of providing a less invasive, lower risk approach to the management of coronary artery disease and its symptoms. Though widely utilized, there has never been a randomized trial comparing angioplasty to medical therapy in stable patients with coronary artery disease, therefore the mortality and morbidity benefits of angioplasty are unknown. In low-risk patients with stable coronary artery disease, aggressive lipid-lowering therapy is at least as effective as angioplasty and usual care in reducing the incidence of ischemic events.<sup>11</sup>

The use of various types of stents during angioplasty may slow the rate of restenosis, but there are no randomized controlled trial data supporting the efficacy of these approaches. Compared to balloon angioplasty patients, coronary stent patients have no statistically significant differences in regard to additional percutaneous coronary intervention or coronary artery bypass during a six-month follow-up period, although they did have fewer heart attacks.<sup>12</sup> The use of the left internal mammary artery in bypass surgery may reduce reocclusion, but vein grafts also must be used when patients have multivessel disease. Thus, in addition to the costs of the original bypass or angioplasty there are often costs of further procedures when restenosis and reocclusion occur.

The majority of adverse events related to coronary artery disease, MI, sudden death and unstable angina are due to the rupture of an atherosclerotic plaque of less than 40–50 percent stenosis (blockage). This often occurs in the setting of vessel

<sup>7</sup> Alderman EL., Bourassa MG, Cohen LS, et al. Ten year follow up of survival and myocardial infarction in the randomized Coronary Artery Surgical Study. *Circulation*. 1990;82, 1629–1646.

<sup>8</sup> Varnauskas, E., for the European Coronary Surgery Study Group. Twelve-year follow-up of survival in the randomized European Coronary Surgery Study. *New England Journal of Medicine*. 1998;319, 332–337.

<sup>9</sup> Chaitman BR., Fisher LD, Bourassa MG, et al. Effect of coronary bypass surgery on survival patterns in subsets of patients with left main coronary artery disease. *American Journal of Cardiology*. 1981;48, 765–777.

<sup>10</sup> Coronary Artery Bypass Surgery Cooperative Study Group. Eleven-year survival in the Veterans Administration randomized trial of coronary bypass surgery for stable angina. *The New England Journal of Medicine*. 1984;311:1333–1339.

<sup>11</sup> Pitt B, Waters D, Brown WV, et al. Aggressive lipid-lowering therapy compared with angioplasty in stable coronary artery disease. Atorvastatin versus Revascularization Treatment Investigators. *N Engl J Med*. 1999;341(2):70–6.

<sup>12</sup> Heuser R, Houser F, Culler S, et al. A Retrospective Study of 6,671 Patients Comparing Coronary Stenting and Balloon Angioplasty. *J Invas Cardiol*. 2000;12(7):354–362.

spasm and results in thrombosis and occlusion of the vessel.<sup>13</sup> Bypass surgery and angioplasty usually are not performed on lesions < 50 percent stenosed (blocked) and do not affect non-bypassed or non-dilated lesions, whereas comprehensive lifestyle changes (or lipid-lowering drugs) may help stabilize all lesions, including mild lesions (< 50 percent stenosis). Also, mild lesions that undergo catastrophic progression usually have a less well-developed network of collateral circulation to protect the myocardium than do more severe stenoses.

Bypass surgery and angioplasty have risks of morbidity and mortality associated with them, whereas there are no significant risks from eating a well-balanced low-fat, low-cholesterol diet, stopping smoking, or engaging in moderate walking, stress management techniques, and psychosocial support.

COMPARISON OF INTENSIVE LIFESTYLE CHANGES (ILC), ANGIOPLASTY (PTCA), AND BYPASS SURGERY (CABG)

	ILC	PTCA	CABG
Rapid ↓ angina .....	X	X	X
Rapid ↑ myocardial perfusion .....	X	X	X
↓ cardiac events .....	X	.....	<sup>1</sup> X
Continued ↓ in stenosis over time .....	X	.....	.....
Continued ↑ in perfusion over time .....	X	.....	.....
Improvements in non-dilated lesions .....	X	.....	.....
Improvements in non-bypassed lesions .....	X	.....	.....
Costs .....	+	+++	+++++

<sup>1</sup> Subset.

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

A total of 333 patients completed the Multicenter Lifestyle Demonstration Project (194 in the experimental group and 139 in the control group). We found that almost 80 percent of experimental group patients were able to safely avoid bypass surgery or angioplasty for at least three years by making comprehensive lifestyle changes at substantially lower cost without increasing cardiac morbidity and mortality. These patients reported reductions in angina comparable to what can be achieved with revascularization. Mutual of Omaha calculated an immediate savings of almost \$30,000 per patient. At Highmark Blue Cross Blue Shield/Lifestyle Advantage, 348 of 350 patients were able to safely avoid revascularization by making comprehensive lifestyle changes. Patients reported reductions in angina comparable to what can be achieved with bypass surgery or angioplasty without the costs or risks of surgery.

Several patients with such severe heart disease that they were waiting on the heart transplant list for a donor heart (due to ischemic cardiomyopathies secondary to coronary heart disease) improved sufficiently that they were able to get off the heart transplant list. This improvement was not only clinically but also objectively verified by cardiac PET scans and/or echocardiograms. Avoiding a heart transplant saves more than \$500,000 per patient as well as significant physical and emotional trauma. Also, up to one-half of patients waiting for a heart transplant die before a donor becomes available.

In summary, we found that we were able to train other health professionals to motivate their patients to make and maintain comprehensive lifestyle changes to a larger degree than have ever been reported in a real-world environment. These lifestyle changes resulted in cost savings that were immediate and dramatic in most of these patients. These findings are giving many people new hope and new choices.<sup>14</sup>

<sup>13</sup> Fuster V, Badimon L, Badimon JJ, Chesebro JH. The pathogenesis of coronary artery disease and the acute coronary syndromes. *New England Journal of Medicine*. 1992;326, 242-318.

<sup>14</sup> Ornish D. Concise Review: Intensive lifestyle changes in the management of coronary heart disease. In: Harrison's Principles of Internal Medicine (online), edited by Eugene Braunwald et al., 1999. Also to be published in hardcover in 2002.

## MEDICARE

Good science is very important but not always sufficient to motivate lasting changes in medical practice. When reimbursement changes, then medical practice and medical education often follow.

Over 550,000 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 700,000 coronary angioplasties were performed in the United States last year at a combined cost of over \$30 billion, more than for any other surgical procedure. Much of this expense is paid for by Medicare. Not everyone is interested in changing lifestyle, and some people with extremely severe and unstable disease may benefit from surgery, but billions of dollars per year could be saved immediately if only some of the people who were eligible for bypass surgery or angioplasty were able to avoid it by making comprehensive lifestyle changes instead.

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

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

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

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

Also, Congress appropriated funds via the Department of Defense for us to train the Walter Reed Army Medical Center in our program for reversing heart disease. This program began three years ago.

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

The significant benefits of stress management techniques and other lifestyle changes extend beyond reversing and helping to prevent coronary heart disease. Other illnesses that may benefit include diabetes, hypertension, obesity, and cancers of the prostate, breast, and colon.

Five years ago, we began conducting the first randomized controlled trial to determine if prostate cancer may be affected by making comprehensive changes in diet and lifestyle, without surgery, radiation, or drug (hormonal) treatments. The scientific evidence from animal studies, epidemiological studies, and anecdotal case reports in humans is very similar to the way it was with respect to coronary heart disease when my colleagues and I began conducting research in this area over twenty-five years ago. For example, the incidence of clinically significant prostate cancer (as well as heart disease, breast cancer, and colon cancer) is much lower in parts of the world that eat a predominantly low-fat, whole foods, plant-based diet. Subgroups of people in the United States who eat this diet also have much lower rates of prostate cancer and breast cancer than those eating a typical American diet.

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

We enrolled 84 men with biopsy-proven prostate cancer who had elected not to undergo conventional treatment for reasons unrelated to the study. This unique de-

sign allowed us to have a non-intervention control group to study the effects of diet and lifestyle alone on cancer without confounding interventions such as chemotherapy, radiation, and surgery.

These prostate cancer patients were randomly assigned into an experimental group who were asked to make comprehensive lifestyle changes or to a non-intervention control group. The comprehensive lifestyle changes were very similar to the program that we documented could reverse the progression of heart disease, including a very low-fat plant-based diet (predominantly fruits, vegetables, whole grains, beans, and soy products), moderate exercise, stress management techniques (including yoga and meditation), and a weekly support group.

During the first year, none of the experimental group patients and seven of the control group patients underwent conventional treatments such as surgery or radiation.

After three months, PSA levels decreased in the experimental group but remained about the same in the control group. These differences were statistically significant. After one year, PSA levels increased (worsened) in the control group but decreased (improved) in the experimental group. These differences also were statistically significant after one year. This rise in PSA in the control group would have been even greater if they had not also made significant changes in diet and lifestyle. When we examined a different control group of patients at the Walter Reed Army Medical Center with similar disease severity who had not made such significant changes in diet and lifestyle, we found their PSA rose substantially more.

Of particular interest was the strong and statistically significant correlation between adherence to the lifestyle program and changes in PSA across both groups after three months. The more people changed, the more their PSA decreased. We found a similar strong and statistically significant correlation between adherence to the lifestyle program and changes in PSA across both groups after one year. This correlation between adherence to the lifestyle program and changes in PSA was very similar to what we found in our earlier studies when we found a strong correlation between adherence to the lifestyle program and changes in coronary artery disease.

Thus, it appears that comprehensive lifestyle changes may stop or even reverse the progression of both heart disease and prostate cancer. However, adherence needed to be very high (>88 percent) in order to stop the disease from progressing.

#### HOW DOES EMOTIONAL STRESS AFFECT THE HEART?

Emotional stress, in addition to diet and exercise, is one of the underlying causes of coronary heart disease. During the past ten years, increasing scientific evidence has provided a more complete understanding of the mechanisms of coronary heart disease (CHD). This understanding provides increasing justification for using intensive lifestyle changes in managing CHD.

Coronary heart disease is a much more dynamic process than had once been thought. While coronary atherosclerosis (arterial blockages) contributes to myocardial ischemia (reduced blood flow to the heart), so do other mechanisms that may change rapidly—for better and for worse. These include variations in coronary artery vasomotor tone, platelet viscosity, endothelial stability, inflammation, and collateral circulation.

Each of these mechanisms may be directly influenced by lifestyle factors, including cigarette smoking, diet, emotional stress, depression, and exercise. These changes can occur—for better and for worse—much more quickly than had once been believed.

The most common cause of myocardial infarction, sudden cardiac death, or unstable angina is rupture of an atherosclerotic plaque, often associated with localized coronary thrombosis and/or coronary artery spasm.<sup>15 16</sup> Research publications since 1990 have consistently shown that intensive risk factor modification can reduce cardiac events quite rapidly by stabilizing the endothelium within a relatively short period of time, whether via comprehensive changes in diet and lifestyle or with lipid-lowering drugs, or both, even before there is time for meaningful regression in coronary atherosclerosis.<sup>17</sup>

<sup>15</sup> Brown BG, Zhao XQ, Sacco DE, Albers JJ. Lipid lowering and plaque regression: new insights into prevention of plaque disruption and clinical events in coronary artery disease. *Circulation*. 1993;87:1781–1791.

<sup>16</sup> van der Wal AC, Becker AE, van der Loos CM, Das PK. Site of intimal rupture or erosion of thrombosed coronary atherosclerotic plaques is characterized by an inflammatory process irrespective of the dominant plaque morphology. *Circulation*. 1994;89:36–44.

<sup>17</sup> Gould KL. Clinical Cardiology Frontiers: Reversal of Coronary Atherosclerosis. *Circulation*. 1994;90(3):1558–1571.

In addition to these mechanisms, emotional stress often motivates people to overeat, drink too much alcohol, abuse drugs, work too hard, and engage in other self-destructive behaviors. In addition, people who are lonely, depressed, and isolated are many times more likely to get sick and die prematurely than those who feel love, connection, and community. The mechanisms for this understanding are not completely understood: we know that it is true even though we do not always know why it is true.

In this testimony, I will discuss some of these mechanisms, describe the evidence from lifestyle intervention trials, and summarize strategies that may be helpful in motivating patients to make and to maintain beneficial changes in diet and lifestyle.<sup>18</sup>

#### EMOTIONAL STRESS AND HOSTILITY

Emotional stress may lead to chest pain and heart attacks both via coronary artery spasm and by increased platelet aggregation (blood clots) within coronary arteries.<sup>19</sup> Stress may lead to coronary spasm (constriction of coronary arteries) mediated either by direct alpha-adrenergic stimulation (i.e., direct connections between the brain and the heart) or secondary to the release of hormones such as thromboxane A<sub>2</sub> from platelets, perhaps via increasing circulating stress hormones or other mediators.<sup>20</sup> Both thromboxane A<sub>2</sub> and catecholamines (stress hormones) are potent constrictors of arterial smooth muscle and powerful endogenous stimulators of platelet aggregation.<sup>21</sup>

Personally relevant mental stress may be an important precipitant of reduced blood flow to the heart—often silent—in patients with coronary artery disease.<sup>22</sup> Acute mental stress may be a frequent trigger of transient reductions in blood flow to the heart, heart attacks and sudden cardiac death.<sup>23</sup>

Women of postmenopausal age may have greater cardiovascular responses to stress than men or premenopausal women.<sup>24</sup> Atherosclerotic monkeys with chronic psychosocial disruption had coronary artery constriction in response to acetylcholine, whereas atherosclerotic monkeys living in a stable social setting had coronary artery vasodilation in response to acetylcholine, even though both groups of monkeys were consuming a cholesterol-lowering diet.<sup>25</sup>

In an analysis of over forty-five studies, hostility has emerged as one of the most important personality variables in coronary heart disease.<sup>26</sup> The effects of hostility are equal to or greater in magnitude to the traditional risk factors for heart disease.<sup>27</sup> Hostility and cynicism appear to be the primary toxic components of the Type A behavioral pattern. Other aspects of Type A behavior do not seem to be harmful.

#### DEPRESSION

Several studies have shown that depression significantly increases the risk of developing coronary heart disease. One study of 1,551 people in the Baltimore area who were free of heart disease in 1981 found that those who were depressed were

<sup>18</sup>Ornish D. Dr. Dean Ornish's Program for Reversing Heart Disease. New York: Random House, 1990; Ballantine Books, 1992.

<sup>19</sup>Oliva, P. B. (1981). Pathophysiology of acute myocardial infarction. *Annals of Internal Medicine*, 94, 236–250.

<sup>20</sup>Schiffer, F., Hartley, L. H., Schulman, C. L., & Abelman, W. H. (1980). Evidence for emotionally induced coronary arterial spasm in patients with angina pectoris. *British Heart Journal*, 44, 62–66.

<sup>21</sup>Moncada, S., & Vane, J. R. (1979). Arachidonic acid metabolites and the interactions between platelets and blood vessel walls. *New England Journal of Medicine*, 300, 1142–1147.

<sup>22</sup>Rozanski A, Bairey CN, Krantz DS, et al. Mental stress and the induction of silent myocardial ischemia in patients with coronary artery disease. *New England Journal of Medicine*. 318(16):1005–12, 1988 Apr 21.

<sup>23</sup>Bairey CN, Krantz DS, Rozanski A. Mental stress as an acute trigger of ischemic left ventricular dysfunction and blood pressure elevation in coronary artery disease. *American Journal of Cardiology*. 66(16):28G–31G, 1990 Nov 6.

<sup>24</sup>Bairey Merz CN, Kop W, Krantz DS, et al. Cardiovascular stress response and coronary artery disease: evidence of an adverse postmenopausal effect in women. *American Heart Journal*. 135(5 Pt 1):881–7, 1998 May.

<sup>25</sup>Williams JK, Vita JA, Manuck SB, Selwyn AP, Kaplan JR. Psychosocial factors impair vascular responses of coronary arteries. *Circulation*. 1991;84(5):2201–2.

<sup>26</sup>Miller TQ, Smith TW, Turner CW, et al. A meta-analytic review of research on hostility and physical health. *Psychological Bulletin*. 1996;119:322–348.

<sup>27</sup>Review Panel on Coronary-Prone Behavior and Coronary Heart Disease. Coronary-prone behavior and coronary heart disease: a critical review. *Circulation*. 1978;65:1199–1215.

more than four times as likely to have a heart attack in the next 14 years. Depression increased risk as much as did hypercholesterolemia.<sup>28</sup>

Depression also increases the risk of subsequent myocardial infarction in patients with existing coronary heart disease. Unfortunately, depression often goes untreated.

One study examined the survival of elderly men and women hospitalized for an acute heart attack who had emotional support compared with those patients who lacked such emotional support. More than three times as many men and women died in the hospital who had no source of emotional support compared with those with two or more sources of support. Among those who survived and were discharged from the hospital, after six months 53 percent of those with no source of support had died compared with 36 percent of those with one source and 23 percent of those with two or more sources of support. These figures did not change significantly after one year. When they looked at all patients and controlled for other factors that might have influenced survival (such as severity of the heart attack, age, gender, other illnesses, depression), men and women who reported no emotional support had almost three times the mortality risk compared with those who had at least one source of support.<sup>29</sup>

In another study, researchers followed 222 patients who had suffered myocardial infarction and found that those who were depressed were four times as likely to die in the next six months as those who were not depressed.<sup>30</sup>

Many depressed patients are, paradoxically, in a constant state of hyperarousal, causing sustained hyperactivity of the two principal effectors of the stress response, the corticotropin-releasing-hormone, or CRH, system, and the locus ceruleus-norepinephrine, or LC-NE, system. Norepinephrine may precipitate vasoconstriction, platelet aggregation, and arrhythmias. Cortisol may accelerate atherosclerosis.<sup>31</sup> When patients are treated for depression, these changes in CRH and LC-NE may return to normal. Beta-blockers help blunt the hyperarousal state but may exacerbate depression, whereas meditation may reduce hyper-reactivity without causing depression.

Social factors, including social support, play an important role in both adherence to comprehensive lifestyle changes and may have powerful effects on morbidity and mortality independent of influences on known risk factors. An increasing number of studies has shown that those who feel socially isolated have three to five times the risk of premature death not only from coronary heart disease but also from all causes when compared to those who have a sense of connection and community.<sup>32 33</sup>

For example, researchers at Duke studied almost 1,400 men and women who underwent coronary angiography and were found to have had at least one severe coronary artery stenosis. After five years, men and women who were unmarried and who did not have a close confidante—someone to talk with on a regular basis—were over three times as likely to have died than those who were married, had a confidant, or both. These differences were independent of any other known medical prognostic risk factors.<sup>34</sup>

#### EXERCISE

One of the benefits of exercise is to help reduce stress and combat depression. The role of exercise in the prevention and treatment of coronary heart disease is well-known and is supported by several reviews of the literature. Two meta-analyses indicate that the risk of death was doubled in those who were physically inactive

<sup>28</sup> Pratt LA, Ford DE, Crum RM, et al. Depression, psychotropic medication, and risk of myocardial infarction. *Circulation*. 1996;94(12):3123–9.

<sup>29</sup> Berkman LF, Leo-Summers L, Horwitz RI. Emotional support and survival after myocardial infarction. A prospective, population-based study of the elderly. *Annals of Internal Medicine*. 1992;117(12):1003–9.

<sup>30</sup> Lesperance F, Frasare-Smith N, Talajic M. Major depression before and after myocardial infarction: its nature and consequences. *Psychosomatic Medicine*. 1996;58(2):99–110.

<sup>31</sup> Gold PW, Chrousos GP. The endocrinology of melancholic and atypical depression. *Proceedings of the Association of American Physicians*. 1999;111(1):22–34.

<sup>32</sup> House JS, Landis KR, Umberson D. Social relationships and health. *Science*. 1988;241(4865):540–5.

<sup>33</sup> Ornish D. *Love & Survival: The Scientific Basis for the Healing Power of Intimacy*. New York: HarperCollins, 1998.

<sup>34</sup> Williams RB, Barefoot JC, Califf RM, et al. Prognostic importance of social and economic resources among medically treated patients with angiographically documented coronary artery disease. *Journal of the American Medical Association*. 1992;267(4):520–524.

when compared with more active individuals.<sup>35 36</sup> Rehabilitation programs incorporating exercise also show modest benefits of exercise in preventing recurrent CHD events. None of 22 randomized trials in the meta-analysis had the power to show a significant treatment effect, but in a meta-analysis employing the intention-to-treat analysis, there was a significant reduction of 25 percent in 1- to 3-year rates of CHD and total mortality in the patients receiving cardiac rehabilitation when compared with control patients.

Moderate exercise provides most of the improvement in longevity as more intensive exercise while minimizing the risks of exercising. In one study, investigators performed treadmill testing on 10,224 men and 3,120 women who were apparently healthy. Based on their fitness level, these participants were divided into five categories, ranging from least fit (group 1) to most fit (group 5). The researchers followed these people to determine how their level of physical fitness related to their death rates. After eight years, the least fit (the sedentary group 1) had a death rate more than three times greater than the most fit (the very active group 5). More important, though, was the finding that most of the benefits of physical fitness came between group 1 and group 2, particularly in men.<sup>37</sup>

Even substantial decreases in cardiovascular fitness resulting from decades of inactivity can be substantially reversed with modest endurance training.

#### PRACTICAL CONSIDERATIONS

Lifestyle factors such as diet, smoking, and emotional stress often interact. For example, people are often more likely to overeat, smoke, work too hard, or abuse drugs and alcohol when they feel lonely, depressed, or isolated. As one patient told me, "I've got 20 friends in this package of cigarettes and they're always there for me. Are you going to take away my 20 friends? What are you going to give me instead?"

Providing health information is important but not usually sufficient to motivate lasting changes in behavior unless the underlying psychosocial issues are also addressed. Thus, stress management techniques and group support may address some of these deeper concerns, thereby making it easier for patients to change diet and quit smoking.<sup>38 39</sup> Sometimes, patients also may benefit from referral to a psychotherapist for treatment of depression with counseling and/or antidepressants.

The conventional medical thinking is that taking a statin drug is easy and most patients will comply, but making comprehensive lifestyle changes is virtually impossible for almost everyone. In fact, less than 50 percent of patients who are prescribed statin drugs are taking them as prescribed just one year later.<sup>40</sup>

One might think that compliance to lipid-lowering drugs would always be much higher than to comprehensive diet and lifestyle changes, since taking pills is relatively easy and the side-effects are minimal for most patients. However, cholesterol lowering drugs do not make most patients feel better. They are taken today in hopes that there may be a long-term benefit by reducing the risk of a myocardial infarction or sudden cardiac death.

To many patients, concepts such as "risk factor modification" and "prevention" are considered boring and they do not initiate or sustain the levels of motivation needed to make intensive lifestyle changes. "Am I going to live longer, or is it just going to seem longer?"

Also, the prospect of a heart attack or death is so frightening for many patients that their denial often keeps them from thinking about it at all. Because of this, adherence becomes difficult for them to maintain. (Patients often will adhere very well for a few weeks after a heart attack until the denial returns.) Fear is a powerful motivator in the short run but not in the long run, for when it's too scary to think about something, many people simply don't.

While fear of dying may not be a sustainable motivator, joy of living often is. In our experience, paradoxically, it may be easier for some patients to make com-

<sup>35</sup> Berlin, J. A., & Colditz, G. A. A meta-analysis of physical activity in the prevention of coronary heart disease. *American Journal of Epidemiology*, 1990;132, 612-628.

<sup>36</sup> Powell, K. E., Thompson, P. D., Caspersen, C. J., & Kendrick, J. S. Physical activity and the incidence of coronary heart disease. *Annual Review of Public Health*. 1987;8, 253-287.

<sup>37</sup> Blair SN, Kohl HW, Paffenbarger RS, et al. "Physical fitness and all-cause mortality." *JAMA*. 1989;262:2395-2401.

<sup>38</sup> Ornish D. *Love & Survival: The Scientific Basis for the Healing Power of Intimacy*. New York: HarperCollins, 1998.

<sup>39</sup> Ornish D, Hart J. Intensive Risk Factor Modification. In: Hennekens C, Manson J, eds. *Clinical Trials in Cardiovascular Disease*. Boston: W.B. Saunders, 1998.

<sup>40</sup> Rogers PG, Bullman WR. Prescription medication compliance: a review of the baseline of knowledge. A report of the National Council on Patient Information and Education. *J Pharmacoepidemiology*. 1995;2:3-36.

prehensive changes all at once than to make small, gradual changes or even to take a cholesterol-lowering drug.

For example, when patients follow a Step 2 diet, they often have a sense of deprivation but not much apparent benefit. LDL-cholesterol is reduced by an average of only 5 percent,<sup>41</sup> frequency of angina does not improve much, lost weight is usually regained, and coronary artery lesions tend to progress. However, patients who make comprehensive lifestyle changes often experience significant and sustained reductions in frequency of angina, LDL-cholesterol, and weight; also, coronary artery lesions tend to regress rather than progress.

Patients usually report rapid decreases in angina and often describe other improvements within weeks; these rapid improvements in angina, well-being, and quality of life sustain motivation and help to explain the high levels of adherence in these patients. Instead of viewing lifestyle changes solely in terms of risk factor reduction in hopes of future benefit, patients began to experience more immediate benefits, thereby reframing the reason for making these changes in behavior from fear of dying to joy of living.

This is a particularly rewarding and emotionally fulfilling way to practice medicine, both for patients and the physicians and other health professionals who work with them. Much more time is available to spend with patients addressing the underlying lifestyle factors that influence the progression of coronary artery disease, yet costs are substantially lower.

As discussed earlier, the major reason that most stable patients undergo bypass surgery or angioplasty is to reduce the frequency of angina, and comparable results may be obtained by making comprehensive lifestyle changes alone. Instead of pressuring physicians to see more patients in less time, this is a different approach to reducing medical costs that is caring and compassionate as well as cost-effective and competent.

The physician, who is often pressed for time, need not provide all of the training in changing diet and lifestyle. He or she can act as the "quarterback," providing direction and supervision. My colleagues and I at the non-profit Preventive Medicine Research Institute and at Lifestyle Advantage have trained teams of health professionals at clinical sites around the country in this program of comprehensive lifestyle changes. These include cardiologists, registered dietitians, exercise physiologists, psychologists, chefs, stress management specialists, registered nurses, and administrative support personnel. These teams, in turn, work with their patients to motivate them to make and maintain comprehensive lifestyle changes.

In practice, patients with coronary heart disease should be offered a range of therapeutic options, including comprehensive lifestyle changes, medications (including lipid-lowering drugs), angioplasty, and bypass surgery. The physician should explain the relative risks, benefits, costs, and side-effects of each approach and then support whatever the patient decides. Whether or not a patient chooses to make intensive lifestyle changes is a personal decision, but he or she should have all the facts in order to make an informed choice.

Emotional stress affects the health and productivity of almost all Americans. Therefore, I respectfully request the Committee on Appropriations of the U.S. Senate to consider substantial increases in funding for rigorous scientific research into the effects of emotional stress on health and disease.

Those approaches that are found to be safe and effective should be covered by Medicare and other third-party payers so that these methods can be more widely available to other Americans who may benefit from them regardless of socioeconomic and demographic background. Scientific studies that find other approaches to be ineffective or unsafe will be of great value in helping to protect the American people as well as Medicare from fraud and abuse.

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

**STATEMENT OF KAREN MATTHEWS, Ph.D., DIRECTOR, CARDIOVASCULAR BEHAVIORAL MEDICAL RESEARCH TRAINING PROGRAM, UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE**

Senator SPECTER. Thank you very much, Dr. Ornish. We now turn to Dr. Karen Matthews. We kind of skipped in our order, but we are now coming back to alphabetical order. She is the program director of the Cardiovascular Behavioral Medicine Research Train-

<sup>41</sup> Hunninghake DB, Stein EA, Dujovne CA, et al. The efficacy of intensive dietary therapy alone or combined with lovastatin in outpatients with hypercholesterolemia. *N Engl J Med.* 1993;328(17):1213-9.

ing program at the University of Pittsburgh, director of the Pittsburgh Mind Body Center, professor of psychology, psychiatry and epidemiology at the University of Pittsburgh. She received her bachelor's degree in psychology at University of California at Berkeley and her Ph.D. in psychology at the University of Texas. So welcome, Dr. Matthews, and we look forward to your testimony.

Dr. MATTHEWS. Thank you for including me in this panel today. I want to thank you for your past support of the mechanisms supporting the Mind Body Centers as well as your efforts and the efforts of the committee in increasing financial support for biomedical research. It is much appreciated.

I want to make three points in my testimony today. The first point is that psychological stress can trigger a heart attack and lead to premature death. It may also accelerate the rate of atherosclerosis in the coronary arteries prior to the first heart attack. So theoretically then, it makes a lot of sense in stress management techniques to reduce the risk of first or second heart attack.

The second point is that there are relatively few clinical trials of stress management that meet standard criteria for clinical trials with heart disease patients, but combining the data from smaller scale clinical trials does show that psychosocial interventions are a useful adjunct to standard care.

The third point I would like to make is that the science of behavior change and practical knowledge of how to conduct clinical trials has advanced sufficiently now so that I think it really is a good time for larger scale studies to evaluate how we can best promote health in coronary patients as well as prevent the first occurrence of heart disease.

So let me go over the points in a little more detail. First of all, regarding the role of stress in heart disease, risk factors for heart disease can be subdivided into those that are related to the development of disease prior to the symptoms as well as those that can be important after the onset of symptoms, like a heart attack. So we really think about the risk factors as having two major stages, I guess you would say.

Development of atherosclerosis begins in adolescence and young adulthood, that early, whereas alterations in plaque readings, rupture and heart attack usually is seen in men beginning in the 50s and in women beginning in the 60s. Typically the first presentation of symptoms is angina for women, or chest pain, and for men is a heart attack, but if women have a heart attack it is actually worse for them than it is for men, and they are more likely to have a recurrent event and they are more likely to die relative to men.

Evidence shows that stressful events such as things like earthquakes or the death of a spouse or child, or missile attacks during war do lead to plaque, rupture and heart attack. Accumulation of stressors at home or at work may also be related to earlier development of atherosclerosis. We haven't had simple measures of sub-clinical or silent atherosclerosis until rather recently for research purposes, because the techniques that we have had available to us have not been safe or recommended for people unless we know that they have serious disease.

Thus, at this point we are really accumulating the data on what's important in terms of stress and early disease markers. Nonethe-

less, at this point it appears that individuals at higher risk for sub-clinical atherosclerosis experience economic hardship, are employed in stressful jobs, and have negative emotions such as depression or feeling isolated from others. So to the extent that stress management interventions do lower stress, interventions should be able to assist in lowering the risk of initial or a second event in individuals under high stress.

Regarding the second point, which is the current status of intervention research, clinical trials evaluating any intervention should include random assignment to an intervention or an appropriate comparison group, a representative sample of the target population, and a sufficient sample size relative to the health outcomes to allow accurate statistical tests. These features are true for any evaluation of treatment, whether it be behavioral treatment or a pharmacologic treatment.

There are relatively few studies of stress management of heart disease patients that have met these three criteria. One study found that very long term behavioral treatment, which included stress management, reduced type A behaviors and reduced rates of a second heart attack compared to those in a comparison group. But two large scale trials, one conducted in England and one conducted in Canada, did not find that stress management reduced either the stress in individuals or patients or the rates of recurrent events. Now those studies were very short in duration and probably not effective enough to get the kind of changes that we need to see in order to promote health in heart disease patients.

The third point that I wanted to make is that we really need further studies at this point on the impact of behavioral interventions on reversing heart disease. I think adaptations to standard stress management interventions may be necessary to make them more effective for our heart attack patients, especially since many of these individuals are getting their behavioral counseling while they are in the hospital and under a lot of distress, and their families of course are panicked as well.

Women I think deserve special consideration, given their high risk following a heart attack as well as in one of those three large scale studies, the efforts to reduce stress in women actually led to an increase in heart attack rates compared to usual care. It's not really understood why that's the case, but the timing is extremely important and very striking, and we need to understand that.

Studies on behavioral interventions to prevent heart disease are worth looking at. We know that a combination of not smoking, having a healthy diet, and higher levels of physical activity, moderate alcohol consumption and not being overweight is associated with very low risk of heart disease in the nurses health study, a very large scale study of nurses throughout the United States. But unfortunately, only 3 percent of the nurses were in this category and if anyone should know about healthy life style, it should be nurses.

#### PREPARED STATEMENT

Very few people in the United States have adopted life styles that are associated with very low risk for heart disease, in part because of the difficulty in changing well practiced behaviors later in life and in part because stress may interfere with the ability to

adopt health promoting behaviors. We need studies to better understand how the role of stress accelerates heart disease risk early in life and to evaluate how stress management interventions might impact earlier risk conditions. Thank you.

[The statement follows:]

PREPARED STATEMENT OF DR. KAREN A. MATTHEWS

It is a pleasure for me to participate in the hearing today on the impact of stress management in reversing heart disease. I am Professor of Psychiatry at the University of Pittsburgh and Director of the Pittsburgh Mind-Body Center, one of five scientific centers established by the National Institutes of Health in 1999 at the encouragement of this committee. My own research is on the role of stress in the development of heart disease, with an emphasis on young adults and on women during the menopausal transition. Our Center is dedicated to understanding how stress and other psychological factors translate into risk for diverse diseases, including heart disease.

Today I would like to make four points:

1. Psychological stress is typically considered to be a process and not a single event. Stress management techniques can intervene in multiple ways in the stress process.

2. Psychological stress can trigger ischemia, heart attack, and premature death. It may also accelerate the rate of atherosclerosis prior to the first heart attack or other clinical event, especially among those who already have high levels of "sub-clinical or silent disease." Thus, effective stress management techniques should theoretically be able to prevent a first or second heart attack.

3. Adequate tests of the impact of stress management interventions in heart disease patients have been few in number, but combining together the data from small clinical trials shows that psychosocial interventions can be a useful adjunct to other therapies.

4. The science of behavior change and practical knowledge of how to conduct clinical trials have advanced sufficiently so that now is an opportune time to conduct high quality studies on the impact of stress reduction on preventing or reversing heart disease.

*Psychological Stress as a Process*

Psychological stress is defined as an individual's perception that environmental demands exceed or tax the resources that s/he has to deal with those demands. It starts with an awareness of an anticipated or acute event in which an individual appraises the event as potentially exceeding the resources that can be brought to bear to deal with the event. When a person is unable to deal with the event, then the person feels a reduction in physical and psychological well being, e.g., reduced energy and increased anxiety. Ways of coping with stress are typically categorized according to whether the aim is to alter the event in some way or to mitigate one's reaction to the event. Examples of events that most people would consider stressful are work overload, marital conflict, children's school failure, and job insecurity. Coping with work overload, for example, could take the form of renegotiating work objectives and reducing the arousal associated with fast paced work through stress management techniques.

Psychological stress rarely is a single event. Rather the events are chained together and can be cumulative in their impact. For example, work overload can reduce the time for high quality interactions with spouse and family, which, in turn, can lead to both neglect and greater conflict, which in turn could lead to marital dissolution. Even when events are not chained together, an event can have a different impact depending on other life circumstances. For example, the death of one's dog may have a more substantial impact if it co-occurs with children leaving the home. The perspective of psychological stress as a process suggests that stress management techniques can intervene in the sequences of stressful events in many different ways depending on the specific circumstances.

*Psychological Stress as a Risk Factor for Heart Disease*

Risk factors for heart disease can be subdivided into those related to the development of atherosclerosis and those related to changes in atherosclerotic plaque, thrombosis, and fibrinolysis (the latter two being clotting and dissolution of clots). The development of atherosclerosis can be traced to adolescence and young adulthood, whereas alterations in plaque leading to rupture and a heart attack begin in the fifties for men and in the sixties for women. The initial presentation of symp-

toms for heart disease tends to be angina for women, whereas it is a heart attack for men. However, if women experience a heart attack, their prognosis is worse relative to men.

Evidence shows that stressful events can trigger plaque rupture and a heart attack. For example, on the day of the North ridge earthquake, the Los Angeles coroner's office increased five-fold in the number of deaths from cardiac causes, compared with the previous week. Most of these deaths occurred within the first hour of the earthquake. During the 1991 Iraqi missile crisis, the number of heart attacks increased in the areas of Tel Aviv, Israel, that were attacked, compared to numbers in the prior year. Most victims of a heart attack, especially male, have significant underlying atherosclerosis. It is thought that the emotional distress associated with stressful events leads to vasospasm or ventricular arrhythmia in those with significant underlying disease.

Accumulation of stressors, i.e. chronic stress, may also be related to the development of atherosclerosis. However, the data are not definitive because we have not had suitable measures of subclinical atherosclerosis for use in ostensibly healthy people. A common method of measuring coronary atherosclerosis, e.g., angiography, has some risk and is not used unless individuals are strongly suspected of having heart disease. More recently, new measures of subclinical carotid atherosclerosis and calcified plaque have come available for research and clinical purposes and are being used in ongoing studies. The availability of these measurements has increased enormously the potential for understanding the development of disease, long before heart damage is permanent and when prevention is possible.

Thus far, evidence based on subclinical measures of atherosclerosis suggest that individuals who experience economic hardship, who are employed in demanding jobs and are physiologically reactive to stress, who are depressed, mistrustful of others, hold their anger inwardly, and anxious are at higher risk for subclinical atherosclerosis. Primate studies also find that the combination of the usual American high fat diet and psychosocial stress leads to the development of atherosclerosis in the large coronary vessels, the inability to dilate coronary arteries when oxygen demand is increased, and adverse changes in reproductive hormones in females. Taken together, these findings suggest theoretically that effective stress management techniques should be able to reduce the risk of a first or second heart attack.

#### *Status of Stress Management Interventions in Reversing Heart Disease*

Stress management interventions typically have a number of components. These include training people to recognize the kinds of circumstances that lead them to be emotionally aroused, to practice skills to reduce the affective, behavioral, and physiologic components of stress, and to reinterpret arousing circumstances in a more benign way, e.g., to look for the potential for good and not just harm. Often stress management interventions are combined with other interventions, including modification of diet and exercise patterns.

Ideally studies that evaluate any intervention should include random assignment to the intervention vs. an appropriate comparison group, a representative sample of the target population, and sufficient sample size in relation to the number of health outcomes to allow adequate statistical power to test the study hypothesis. There are relatively few stress management studies that meet these criteria. Friedman and colleagues evaluated a long-term intervention to reduce Type A behavior (being hard driving, competitive, and easily annoyed) among 862 heart attack patients, almost all men; diabetics and smokers were excluded. The behavioral treatment included training in progressive muscle relaxation, changes in belief systems that support Type A behavior, behavioral alterations, practicing specific drills, and health education; the comparison group had only health education delivered by cardiologists. The treatment successfully reduced Type A behavior. Patients who were in the behavioral treatment group had reduced rates of a second heart attack, compared to those in the comparison group.

Jones and West studied 2,315 MI patients who were randomized to seven weeks of stress management or usual care after hospital discharge. The intervention included teaching relaxation training, skills to recognize stressful circumstances and how to respond to them. Those in the intervention group experienced neither a reduction in anxiety and depression nor a reduction in risk of heart attack or other clinical complications or death in the following year. Frasure-Smith evaluated a home-based intervention designed to reduce distress among 1,376 heart attack patients who reported high stress scores. The intervention included emotional support, practice advice, education, and referral as appropriate offered by nurse clinicians; the comparison group was usual care. This intervention neither reduced anxiety and depression nor lead to a reduction in the mortality among men. Women had higher distress scores, had more intensive intervention, and also experienced higher mor-

tality rates in the intervention group than in the usual care group. The authors speculated that the monthly screening for signs of distress may have had an untoward effect on the patients.

Given that few individual studies meet standard study criteria for evaluating intervention effectiveness, combining the results of small scale trials via a statistical technique called meta-analysis is useful to address the subject of this hearing. Linden et al summarized the results of 22 studies that in combination evaluated the benefits of psychosocial interventions added to standard care among a total of 2,024 patients as compared to 1,156 standard care participants. The interventions were quite varied and included relaxation training, group psychotherapy, and individual counseling, whereas standard care included medical management, exercise and diet information and sometimes active intervention. In the aggregate, these studies were successful in reducing psychological distress. Among the participants in the 10 fully randomized clinical trials, those assigned to the psychosocial intervention had lower morbidity rates throughout the reporting period and lower mortality rates during the first two years of follow-up in relation to the rehabilitation comparison groups. Those comparison groups typically included exercise and diet intervention and medical management. These authors commented on the cost-effectiveness of adding psychosocial intervention to standard care.

The latter point is underscored by Blumenthal et al. A small group of men with coronary artery disease and exercise-induced ischemia were randomized to either four months of aerobic exercise or weekly classes on stress management and were followed for five years. Another group was followed for comparison purposes. Results showed that patients who experienced the stress management intervention had reduced rates of ischemia during mental stress and throughout the day, reduced numbers of clinical coronary events, and reduced medical costs as compared to patients in usual care.

#### OPPORTUNITIES FOR BEHAVIORAL INTERVENTIONS IN PREVENTING OR REVERSING HEART DISEASE

Economic costs of treating heart disease are enormous. For example, coronary bypass surgery with cardiac catheterization costs about \$42K and coronary angioplasty about \$11K. Societal costs of heart disease in terms of reduction in work capacity, increased distress and pain, and reduction in ability to carry out everyday activities, are difficult to estimate, but substantial. Therefore, it makes sense to use all the tools at our disposal to reduce the likelihood of additional adverse events in those at highest risk. Psychosocial interventions may be an important part of the therapeutic prescription along with pharmacologic therapy, weight reduction, and exercise. Large scale stress management studies are few in number and several are inconclusive because they have not reduced emotional distress, perhaps because the interventions were quite short. It is most likely that stress management interventions will be clinically effective when they improve psychosocial functioning and are targeted at those individuals at increased risk for adverse events. Stress management interventions have been used frequently in other contexts, are standardized, and have demonstrated effects on distress and physiologic responses. Adaptations may be necessary to make them effective for heart attack patients, especially those treated early after a heart attack. Women deserve special consideration, given their adverse response to the home-based nursing intervention described above, and their high risk following a heart attack. It is important to conduct behavioral intervention studies to try to reverse heart disease.

Studies on behavioral interventions to prevent heart disease may be worthwhile. Stress may accelerate the rate of atherosclerosis and early signs of heart disease can be observed in adolescents and young adults. We know that the combination of not smoking, having a healthy diet, higher levels of physical activity, moderate alcohol consumption, and not being overweight is associated with very low risk of heart disease in the Nurses' Health Study. Unfortunately, only 3 percent of the nurses were in this category. Very few people in the United States have adopted life styles that are associated with very low risk for heart disease, in part because of the difficulty in changing well-practiced behaviors later in life and in part because stress may interfere with altering behaviors to more health-promoting forms. We need a better understanding of the role of stress in accelerating disease risk early in life and how stress management interventions might impact early risk trajectories. Stress management combined with promoting healthy life styles in adolescence and young adulthood may have long term economic and social advantages.

**STATEMENT OF COLONEL MARINA VERNALIS, MC, USA, D.O., MEDICAL  
DIRECTOR, CARDIAC RISK PREVENTION CENTER, WALTER REED  
ARMY MEDICAL CENTER**

Senator SPECTER. Thank you very much, Dr. Matthews. Our next witness is Dr. Marina Vernalis, a Colonel in the Medical Corps of the U.S. Army, medical director of the Cardiac Risk Prevention Center at Walter Reed Army Medical Center, and associate professor of clinical medicine at the Uniformed Services University of Health Sciences. Dr. Vernalis has been very helpful to the subcommittee in structuring these hearings and she met with me yesterday to discuss quite a number of aspects of stress reduction.

She is accompanied by Ms. Maureen Miller, RN, who is a participant in the Walter Reed program. Ms. Miller is a healthcare consultant currently working on the White House report on complementary and alternative medicine policy. From 1978 to 1998 she was a nurse officer in the U.S. Public Health Service. She has a BS in nursing from St. Louis University and a master's in public health from Tulane University.

Thank you for joining us, Dr. Vernalis and Ms. Miller. We look forward to your testimony.

Colonel VERNALIS. Good morning, Mr. Chairman. For years, I have had a strong commitment to study strategies in reversing heart disease and feel very privileged to be on this panel. I would like to address the issue of stress management in reversal of heart disease not only from my perspective as a clinical cardiologist but also as a military officer who knows that stress is part of military life, especially in times like these. The Department of Defense has a strong interest in stress as it affects cardiac health, and the role of stress management in reversing heart disease. The Department is interested in identifying these issues early in military careers to help maintain a healthy force and a healthy beneficiary population.

If early interventions can indeed play a role in reversing heart disease and improving outcomes, we need to partner in this effort. Over the past 25 years we have reduced cardiovascular mortality by over 50 percent and improved the quality of life, but most of our science efforts have been directed at drug therapy and invasive technology, such as balloon angioplasty and bypass surgery. These interventions are wonderful lifesaving methods, but our efforts are directed to the treatment of disease where it's already advanced and necessitates costly procedures, invasive procedures that have taken a costly toll on our patients and to their families.

Just ask anyone who has coronary disease or a relative with coronary disease. I know. Both of my parents had two bypass operations each, and my brother has suffered a heart attack and has had a bypass operation. Mental stress has long been implicated as a trigger of adverse cardiac events. Studies have been conducted on the use of psychosocial interventions. Much of the existing data suggests that these interventions are additive components to usual care. However, the evidence for using psychosocial treatment methods to not only reduce mental stress but to prevent stress induced cardiac events is not as well established. Further, to my knowledge, there are no differentiating measures to determine which method of stress management has the greatest benefit or which method is most beneficial to either gender or ethnic differences.

For example, a recent abstract that Dr. Matthews alluded to which was presented at the American Heart Association meeting last fall, suggests that the use of group intervention positively impacts white men but the finding did not hold true for minorities or women.

At Walter Reed we have a comprehensive life style modification program that we call the coronary artery disease reversal program, or CADRe. It is modeled after Dr. Ornish's work.

Two of the four components include group support and stress management using the techniques of yoga, relaxation, meditation, and imagery. The other components include an individualized exercise prescription and a plant based vegetarian diet. Right now we believe these components are synergistic. There is a need for an improved understanding of the individual components of the CADRe program and how they contribute to the overall positive outcomes or benefit of the program.

Currently we have 122 military beneficiaries enrolled in our program, ranging in age from 31 to 80. Most are retired military, 15 percent are active duty. A third are women, 20 percent are minorities, and the majority of them have coronary disease. In our patient population, the results of the program is remarkably wide. We have seen a reduction in stress, a reduction in symptoms, improvement in functional capacity and exercise time, as well as improvement in lipids, their blood pressure, their weight and their body fat composition.

Most of the patients who were limited by their heart disease before they started the program within 3 months were able to bathe, walk, shop, and do ordinary day-to-day activities without any difficulty. And this is coupled with significant overall improvement in their cardiovascular fitness which increased to an average pace increase of 4.8 miles per hour to 6.2 miles per hour on a flat surface.

You often hear people comment that they just can't handle a vegetarian diet. However, the overall adherence to the diet at 1 year is 92 percent. The average weight loss at 3 months is 11 pounds with a 4 percent reduction in body fat, and they seem to maintain this after 1 year.

We recommend 60 minutes of stress management every day, very much like Dr. Ornish, and overall the stress management adherence is approximately 62 percent. It's ironic that people say they just can't carve out 1 hour per day to relax, meditate or de-stress, or prefer exercise as a way of managing stress. Regardless, we have been able to document a significant reduction in stress and depression and hostility. However, it's interesting to note that when scores on psychosocial change are compared by gender, the males seem to benefit most.

I believe that the preliminary data from our program is quite impressive and I believe it will produce outcomes for the day that we will make a difference in the way we care for military beneficiaries in the future and maybe the general population as well.

Of great interest is the fact that our data validates the gender different response in psychosocial measures, raising the question, we need to develop new ways to treat women with stress. We need to explore and identify psychosocial interventions that are specifically gender and minority relevant, as well as clinically efficacious

through controlled research trials, and I believe there is an urgent need to further study the healing potential of the spiritual and emotional relations within each human life.

PREPARED STATEMENT

And in closing, I would like to say some words from one of our participants that describe the value of our program. I started this program thinking I would get a head start on being healthy only to find out that I should have done this life style change 20 years ago. I certainly feel better in this life style than any other I have tried.

Thank you very much for the opportunity to testify today.  
[The statement follows:]

PREPARED STATEMENT OF COL. MARINA N. VERNALIS

For years, I have had a strong interest and commitment to study strategies on reversing heart disease and feel privileged to participate on this panel. I would like to address the issue of stress management and reversing heart disease not only from my point of view as a clinical cardiologist but also as a military officer who knows that stress is part of military life, especially in times like these. The military health care system has a very large number of beneficiaries both active duty and retired who are at risk for cardiovascular disease or already have heart disease. It has a strong interest in stress induced cardiac events and the role of stress management measures for heart disease prevention and reversal. And it makes sense to identify these issues early in military careers to help maintain a healthy force. If early interventions can play a role in reversing cardiovascular disease and improving outcomes, and I think they can, then we need to be partners in this effort. I believe there is an urgent need to further study the use of psychosocial interventions and other lifestyle modifications for preventing cardiac events and reversing coronary artery plaque in the military population.

Mental stress has long been implicated as a trigger of adverse cardiac events in the literature. The evidence regarding the use of psychosocial measures for preventing stress induced cardiac events is not as clear. To my knowledge, there are no differentiating measures to determine which type of stress management measures has the greatest benefit. Until recently the existing data suggests that psychosocial interventions are an additive component to coronary artery disease outcomes. However, a recent abstract presented at the American Heart Association meeting last fall suggests that the use of group intervention positively impacts white men but doesn't hold true with minorities or women (ENRICH study). Our program, like the traditional Ornish model, has four separate core components. Two of the core components include group support and stress management using the techniques of yoga poses, deep relaxation, imagery, and meditation. The other components include individualized exercise prescriptions, and a plant-based vegetarian diet. It makes sense that exercise and diet result in an improvement in self-image and a generalized feeling of well being that enables people to manage life stressors better. It is believed the program components are synergistic and are directly related to adherence. A single component effect on cardiac outcomes cannot be determined. This needs further exploration. With this background, I wish to share with you some of the preliminary data in our Coronary Artery Disease Reversal program which we call CADRe at Walter Reed Army Medical Center.

In 1999, we initiated a federally funded program to study coronary artery disease reversal and prevention non-invasively. It is modeled after Dr. Dean Ornish's lifestyle modification program. It is open to TriService military beneficiaries who are at risk for heart disease as well as those patients with coronary artery disease. We measure a wide range of clinical, physiologic and quality of life outcomes which ultimately will serve as benchmarks for optimal cardiovascular care strategies not only for military beneficiaries but hopefully, the entire health community. We also integrated innovative technology such as carotid intima media thickness (CIMT), which is a validated way to measure plaque regression. We are encouraged by our ability to enroll participants and we believe our research study may have the largest cohort of patients longitudinally followed in this model.

The program began enrolling its first participants in February of 2000. Currently 122 military health care beneficiaries are enrolled. All branches of the federal serv-

ices are represented in the population. All are at least high school educated. All of the participants are highly motivated to participate in their own health care. Forty-seven have completed one year and the rest are actively participating in the maintenance program. Participants span the age spectrum of 31 to 80 years old, 34 percent are female, and 20 percent are from minority groups. Sixty-six percent have documented coronary artery disease (CAD). Of those with CAD, 57 percent have had at least one revascularization procedure (bypass surgery or angioplasty). Additionally, 66 percent of the participants suffer from hypertension, 18 percent with diabetes and 71 percent are taking cholesterol-lowering medications. Of the enrolled participants, 19 are active duty, 71 are from the retired ranks, 31 are eligible family members and one is a Secretary of Defense designee. Twenty participants (16 percent dropout rate) have either voluntarily withdrawn or have been medically withdrawn from this study. Reasons for withdrawal are varied and include lack of commitment to continue the program, co-morbid health factors, and military duties. There also have been no serious adverse events as a result of program participation.

Outcome variables include: (1) reduction in symptoms; (2) improvement in functional capacity and exercise tolerance; (3) compliance; (4) evidence of atherosclerotic regression; (5) reduction of stress, and; (6) improvement in lipids, blood pressure, and weight and body composition. We are also monitoring other CAD associated "markers" such as homocysteine, C-reactive protein, fibrinogen, lipoprotein-a.

At enrollment, one third of those with known CAD had significant functional limitations upon enrollment. After 3 months, over 75 percent of those same patients significantly improved their functional ability. This means they were able to bathe, walk, shop, and do other ordinary day-to-day activities without difficulty.

Each of our participants has a tailored exercise prescription. Both aerobic (exercise in target heart rate) and non-aerobic exercise has been measured. Our participants exercise for an average of 3.6 hours per week. Treadmill exercise testing data is available on 60 participants who have completed 3 months of program participation. Preliminary results on those who have completed 12 months of program participation shows that 55 percent of the total exercise time is attributable to non-aerobic exercise because of limiting musculoskeletal conditions or symptoms due to panvascular disease. Despite the latter, preliminary results show a significant improvement in treadmill exercise time since enrollment and suggests the duration and not necessarily the type of activity plays a role in the sustainment of the improved function. This is coupled with a significant overall improvement in cardiovascular fitness as defined by METS (metabolic equivalent) or the power output of the human body, much like the horsepower of an engine. This power is enhanced by improvements in the entire cardiovascular system from the heart's pumping ability to the size and number of blood vessels to the cellular level improvements. After 3 months, our patients increased their fitness level by 1.7 METS. This equates to an increase in walking from 1.8 miles per hour (mph) to 3.4 mph on a flat surface. Twelve-month preliminary data shows sustainment of both exercise time and workload at a significant level. This is very encouraging since there is evidence-based data that an increase of 1-MET in functional capacity may convey a 12 percent increase in survival. In addition, blood pressure is reduced and some patients require less medication.

Functional health improvement has also been validated in this population through the use of the Health Status Survey (SF-36), which is a widely used tool for measuring health status and outcomes. Improvements have been seen in both the physical and mental components of this tool. The overall mean compliance with the plant-based vegetarian dietary guidelines after 12 months of participation is 92 percent. Participants have done remarkably well in integrating this ultra-low fat diet into their daily routine. Although Dr. Ornish did not design this program for weight loss, reduction in weight and body fat is a natural by-product. The average weight loss at 3-month is 11 pounds with almost 4 percent reduction in body fat and seems to hold steady at one year.

After 3 months, there is a mean reduction in total cholesterol for the 85 participants of 21 points and the LDL by 19 points. This is seen in patients on statin therapy as well. High-density lipoprotein (HDL) levels decrease by 8 points and triglycerides increase slightly. The decrease in HDL and increase in triglycerides are similar to the findings of Dr. Dean Ornish in both his initial Lifestyle Heart Trial as well as the Multicenter Lifestyle Demonstration Project. Although the Lifestyle Heart Trial showed plaque regression, there appears to be competing effects of the program on the HDL and triglycerides. The importance of the latter is not clear and needs further clarification.

We adopted the Ornish Program model which recommends 60 minutes of stress management every day. Overall stress management adherence is highest during the first 12 weeks (69 percent or 41 minutes/day) and decreases to 37 minutes/day at

12 months. This has been a difficult component for this population to integrate into their lives. It is ironic that people can't seem to carve out one hour per day to relax, de-stress or meditate. Some prefer exercise as a way to manage their stress. Regardless, reduction in stress as measured by the Perceived Stress Scale (PSS) is significant at both 3 month and 12 month time periods. However, when the data is compared by gender, the benefit is only seen in men at both 3-months and 12-months.

Group support is the other psychosocial interventional component of the program. The Center for Epidemiological Studies Depression Scale (CESD) and the Modified Cook Medley Hostility Scale (CMHS) are reliable tools that we use to measure the value of group support. Both these instruments have shown a decrease of depression and hostility. Again, when groups are compared by gender, only males seem to benefit.

In conclusion, the short-term data we have achieved in our program is impressive by way of emotional and physiologic measures. These changes argue well for being able to demonstrate long-term success with respect to more definitive outcomes such as adverse clinical CV events including hospitalization for an acute coronary syndrome or the need for future coronary revascularization procedures. In addition, the effects of the core components on carotid intima media thickness, a validated measure of atherosclerosis burden, will shed important information on the regression or stabilization of plaque. We hope to identify psychosocial interventions that are specific, gender and minority relevant as well as clinically efficacious and resource prudent via controlled research studies.

Our program has the potential to operationalize bench research and to identify what is clinically applicable not only to the military population but the general population as well. Future program goals include a randomized, prospective study to tease out the relevance of the core components especially as it relates to psychosocial interventions. It will also be important to identify the additive effects of lifestyle modification to pharmacoprevention of atherosclerotic cardiovascular disease.

In closing, these words from one of the participants describe the value of this program:

"I started this program thinking I would get a head start on being healthy only to find that I should have done this lifestyle change 20 years ago. I have gotten more out of CADRE than reversing heart disease. I have learned a lot about myself. I have learned that I have physical problems that contribute to heart disease but can do something about them. I am in control of what goes in my mouth and how far I push my body for training and for accomplishing relaxation. However, it takes every part of the program to make it work. I certainly feel better in this lifestyle than any other I have tried."

Thank you for this opportunity to testify about our program.

NOTE.—The opinions or assertions herein are the private views of the author and are not be construed as reflecting the views of the Department of the Army or the Department of Defense.

Senator SPECTER. Thank you very much, Dr. Vernalis. It is interesting to comment that it should have begun 20 years ago. I think Dr. Eisenberg would put a larger figure than the 20 years, so we will have to do the best we can now.

We have a very unique State senator from Pennsylvania named Marvin Taylor, in his 90s, who said if he had known that he was going to live so long, he would have taken better care of his health.

#### FUNDING FOR BEHAVIORAL RESEARCH

On to the subject matter. Dr. Kaufmann, I want to address the first question to you concerning NIH funding. There has been an enormous increase in NIH generally, from \$11 or \$12 billion to \$23 billion, and now the President is asking for an additional \$3.4 billion. So, we will be more than doubling the funding. We have increased heart research from fiscal year 2000, under \$1.4 billion to now almost \$1.9 billion. Behavior and cardiovascular disease in fiscal year 1999, \$75 million, to now almost \$92 million. Also, mind body has gone up proportionately the same.

Perhaps the greatest increase came in the National Center for Complementary and Alternative Medicine. My wife took a serious interest in this a number of years ago when I was chairman of the subcommittee. The funding was at \$7 million in fiscal 1996, and now it's in excess of \$113 million.

I know you have some limitations within the protocol at NIH, but is there an adequate allocation to do research on the kinds of subjects we're discussing here today?

Dr. KAUFMANN. There is. We have a very complicated issue because at one level, of course, the amount that is expended in any particular area, whether it be behavioral prevention research, et cetera, or technological developments as we have seen here today or other matters, is determined to a large extent by the scientific community in the sense that better than 80 percent of our budget is spent on research that is unsolicited. In other words, the scientific community proposes it, and this is particularly true for the behavioral research community.

And we have the same pay line and the same criteria for paying behavioral research and intervention research as we have for all other areas within our system without making a distinction. So that, given that particular applications go through our peer review process and are deemed acceptable and are deemed worthy of our support after our review process, they go to our advisory council and they are funded.

I think we have been very successful in doing so. I think also, it's fair to say, that over the last 20 years or close to 20 years that I have been associated with NHLBI, I have seen tremendous progress in the capacity of the behavioral research community to advance the science and advance the knowledge, and we are in a much better position to do some of the things that we are talking about today than we were 10 years ago or even 5 years ago.

So I think that the financial support is not the only measure, but I think the scientific productivity is another measure, and I think also the activity and the proactive stance in the scientific community itself in proposing cutting edge science also drives much of what we do.

Senator SPECTER. I would like to have the views of the participants on the panel as to where you would like to see NIH go beyond where NIH is today. NIH makes its own allocations and we do not, the Congress does not allocate NIH's money. We do express an opinion and then NIH makes the final decision.

I wonder if you could respond, perhaps in alphabetical order, and you may want to supplement this in writing, because we will pay close attention to what you say. Dr. Abrams, what would you like to see NIH do with the billions that it is now allocated?

Dr. ABRAMS. Two things. I do think we need a better understanding of the basic mechanisms and especially the interactions between stress, the other life style factors, and disease. So I would like to see more research done in that domain that will form more effective and more cost efficient treatments down the line in the future, so that would be the fundamental science recommendation.

I also think critically, we don't have enough research on how to put what we know today, which is substantial, into practice, and how to diffuse it effectively to what I call every nook and cranny

of every community in the United States, paying particular attention to tailoring the treatments to the unique needs of populations at disproportionate risk, women, and I think we do have technologies to begin to do that, but the research isn't there on the diffusion and dissemination to large populations. So, I would like to see more research on how we can do that effectively.

And then I think finally, we don't have enough research into health policy and health economics now, because unless you change the larger environment of policy and economics in our society, it's very hard for individuals to sustain individual change. The image that comes to mind is that you're rowing a boat against the current, and no matter how much personal conviction and motivation you have, if you're living in a society where all the incentives and temptations are to do fast foods or to use tobacco as a means of helping you get through a busy workday, and if you don't attend to stress and balancing your life style in a way that Dr. Ornish, Benson and others have said, you can't really do it at an individual level.

So I think the Public Health Service needs a different infrastructure to disseminate and diffuse information, much like we could do and are doing to revamp the Public Health Service for bioterrorism. I think that would require significant effort, to take what we know from behavioral biomedical science, the state of the art, and evaluate it in a scientific way in large scale diffusion and dissemination.

Senator SPECTER. I would like to ask for briefer answers, if you can. As I said, you may supplement in writing, so that we can have some more background. Dr. Benson.

Dr. BENSON. Thank you. I would view health and well being as being akin to a three-legged stool being held up by one leg of pharmaceuticals, a second leg of surgery and procedures. Most of our, the direction in research is really being spent, money is being spent on these first two legs, pharmaceuticals and surgery. We haven't paid attention to a third leg, and that is self care, because within that third leg we have over 60 percent of physicians that are poorly treated by both drugs and surgery.

And I think the way to do this is to follow almost exactly what Dr. Abrams just said. We must first identify the basic mechanisms involved. That will lead to an efficiency in the way the work is disseminated. Second, we have to look to the dissemination to the population, and this will take long term behavioral change that will go beyond, I believe, health care, and we should be in the educational system teaching children early in life how to do appropriate behaviors of stress management. And third, we must then disseminate these programs widely throughout the nation in a concerted effort to define how important self care is. And many of the people at this table are speaking to self care mechanisms and I endorse them and would add more emphasis on them.

[The information follows:]

As I testified on May 16, 2002, stress is a significant component in the genesis of heart disease and should be treated in programs designed to reverse cardiac disease. In addition to stress management approaches, diet modifications and exercise programs should also be offered. Stress management, dietary changes and exercise should and can be effectively integrated with each other as well as with pharmacological and surgical treatments.

The Cardiac Wellness Programs of the MBMI are efficient and so readily accepted and maintained as a part of lifestyle changes by patients after they are learned. They consist of:

- A safe, supervised exercise program
- An individualized nutrition plan
- Comprehensive stress management with an emphasis on learning relaxation response techniques, and
- Group discussion series designed to provide information necessary to support lifestyle changes

The Cardiac Wellness Programs of the MBMI were directly compared to other more demanding cardiac reversal programs in a pilot project of the Commonwealth of Massachusetts General Insurance Commission (GIC) in 1994.

In 1994, the Group Insurance Commission (GIC) of Massachusetts supported a pilot project designed to provide patients with coronary artery disease opportunity to participate in a comprehensive lifestyle modification program that compared the MBMI program to that of a more demanding program.

Both programs were of 12-month duration and included supervised exercise, nutrition, yoga/relaxation response/stress management and group support. The major differences between the programs were: 1. The frequency, the length and the total number of sessions over the 12-month period: The total number of hours spent in the MBMI program totaled 126, whereas 264 hours were required in the more extensive program. 2. Emphasis on diet: MBMI utilized a 15 percent fat diet emphasizing soy, in comparison to the more restrictive program that promoted a 10 percent fat, vegetarian diet. 3. Drug management of blood lipids: The MBMI program included drugs in its lipid management when necessary. The other program did not utilize drugs. 4. Cost: The cost of the MBMI program was about \$5,000 compared to the other program which cost between \$7,000 and \$8,000.

Both programs demonstrated similar success in clinical outcomes that included weight loss, lipid and blood pressure reduction, improvement in clinical symptoms and exercise tolerance as well as reduction in psychological distress. However, the MBMI program had more people not only choosing it, but also remaining in it. In other words, it was more readily accepted and once chosen, better adhered to in the long run. Therefore, a coronary artery disease patient in the MBMI program got the same results for less time and less money that with the more demanding program.

As a result of this pilot study, the GIC and several other major third party payers (Unicare, Harvard Pilgrim Health Plan, Tufts Health Plan and Neighborhood Health Plan) now cover the MBMI program for state employees.

Further, the Centers for Medicare and Medicaid Service (CMS) project is underway to test further the efficacies and costs of these two cardiac approaches. Titled, Medicare "Lifestyle Modification Program Demonstration", its results should be available in several years.

#### PREVENTION-STRESS MANAGEMENT PROGRAMS FOR THE SCHOOLS OF AMERICA

As I also testified on May 16, 2002, stress is a factor in 60 percent to 90 percent of visits to health care professionals. It contributes not only to cardiac symptoms, but also to many other diseases.

Stress is an all too prevalent component of childhood in the United States today made even worse by the necessity to cope with fears of terrorism. Our educational system should be offering stress management programs in their curricula for its short-term beneficial effects in young life and for its long-term effects on adult health and well-being.

The MBMI has addressed the need for stress management programs in schools since 1989 through its Educational Initiative. The Institute offers a relaxation-response based curriculum that teaches coping skills to students and educators for life-long use. The programs have been scientifically demonstrated to improve students' self-esteem, self-efficacy, loss of control, grade point average, work habits, memory and cooperation. The results are presented in three articles entitled "Increases in Positive Psychological Characteristics with a New Relaxation-Response Curriculum in High School Students,"<sup>1</sup> "Academic Performance Among Middle School Students After Exposure to a Relaxation Response Curriculum,"<sup>2</sup> and "The

<sup>1</sup>Benson H, Kornhaber A, Kornhaber C, LeChanu MN, Myers P, Friedman R. Increases in Positive Psychological Characteristics with a New Relaxation-Response Curriculum in High School Students. *Journal of Research and Development in Education* 1994; 27:226-231.

<sup>2</sup>Benson H, Wilcher M, Greenberg B, Higgins E, Ennis M, Zuttermeister PC, Myers P, Friedman R. Academic performance Among Middle School Students after Exposure to a Relaxation-Response Curriculum. *Journal of Research and Development in Education* 2000; 33:156-165.

Evaluation of a Mind/Body Intervention to Reduce Psychological Distress and Perceived Stress in College Students.”<sup>3</sup>

These results are especially important, as the curriculum was successful in two of the studies with ethnically diverse students who live in economically disadvantaged neighborhoods. Children in these environments are at risk of developing psychological disabilities such as depression and post-traumatic-stress disorder, in addition to an increase in their chances of becoming victims or perpetrators of violence themselves.

It has been documented that children are better able to cope with demanding situations if they have an internal locus of control and a sense of self-efficacy. The goal of the Education Initiative is to support the nation’s schools by teaching children and their educators to recognize their inherent capabilities to effectively shape their world. By using the simple, easily implemented interventions taught in the Education Initiative’s relaxation response based curriculum, we are creating more self-aware children, as well as more effective, safer schools. The long term health benefits of being better able to handle stressful circumstances are yet another reason to start the relaxation response early in life.

#### SUGGESTED NEXT STEPS

1. Stress management programs such as the Mind/Body Medical Institute’s relaxation response curriculum should be offered to schools across the United States. Funding should be supplied for a “train the trainer” Demonstration Project through the Department of Education to teach teachers of students how to impart these proven, stress management courses.

2. The Walter Reed Medical Center should conduct a controlled, prospective, randomized trial to compare the outcomes of utilizing a demanding vegetarian diet with a more liberal diet that would also utilize lipid-lowering drugs. Both groups would either be exposed to a relaxation-response based stress management program to a control condition. Such a trial should take place over a ten-year period to be able to assess long-term outcomes. A competent leader of this project could be Marina Vernalis, D.O., Medical Director of the Cardiac Risk Prevention Center, Walter Reed Medical Center. This would be a Department of Defense project.

Senator SPECTER. I would broaden the question beyond NIH and CDC, and for you, Dr. Eisenberg, even beyond that to the Department of Defense. We had the three Surgeon Generals in this room about a week ago, and I brought up the matters that you had told me about. I don’t know if you got a copy of that hearing transcript, but I would be interested for you to include DARPA and CDC in your response.

Dr. EISENBERG. I was part of the presentation in 1994 called re-engineering healthcare, where we were laying out how the entire healthcare delivery system could be dramatically overhauled, including advances in technology that are within our grasp, but need a lot of help, because we haven’t really seen these things happen on their own in medicine.

I have been a consultant to industry for 35 years, including the military-industrial complex, and trying to get risk research done at the core of technology advancement has been almost impossible. The only place we’ve seen that happen is at agencies like DARPA, the Defense Advanced Research Projects Agency, who developed the Internet and where we began telemedicine and moved over now to additional participation by Fort Detrick and the Army Medical Research Command.

So we feel the Defense Department, which of course has the interest in this because it is the largest managed care system in the country, as well as the battlefield care that we need, but the funda-

<sup>3</sup>Deckro GR, Ballinger KM, Hoyt M, Wilcher M, Dusek J, Myers P, Greenberg B, Rosenthal DS, Benson H. The Evaluation of a Mind/Body Intervention to Reduce Psychological Distress and Perceived Stress in College Students. *Journal of American College Health* 2000; 50:281–287.

mental issue is technology advancement and it needs a lot of help, and at many levels.

The imaging technologies are expensive and at their core we need the risk research to develop new materials. X-rays using electron microscopy, we don't even come close to that in a human being, largely because we haven't gone far enough in research that really isn't that difficult or even that far beyond our grasp to be able to achieve the kind of high resolutions of imaging the human body and even simultaneously imaging the physiology and the biochemistry so we get a fused image. All pathology is defined around the anatomy, physiology and chemistry, and electroactivity, and we are now ourselves building a device that will fuse all of these.

But, there are so many spin-off opportunities. Early diagnosis, as we've talked about here, compacting the diagnostic process. We have a huge problem in this country right now where diagnostic imaging is on a rapid rise, and a baby boomer is turning 50 every 69 seconds, and it's going to escalate beyond our capability to handle it economically, and we're trying to create a single device which could potentially replace \$80,000 worth of testing with a single \$1,500 noninvasive test.

These types of technologies are within our grasp. They also are the core of changing the whole way we do therapies. We need assimilation of training, assimilation before we do procedures, imaging and computers guiding procedures so that they can be done far more precisely. The powerful electronics that are developed for the computation and even the transmission of this data can be translated into new types of information systems. Even a new type of doctor's bag which allows a physician individually far more powerful levels of information access, artificial intelligence decision making, and all of this can be wrapped up into a system that can go into the home, much as we're trying to take it to the forward battlefield for peripheral care or telepresent healthcare.

So these are major opportunities that are here and now, they are not years in the future, they are within our grasp, but they absolutely need support. They're not going to happen within industry, which is driven by a profit potential and is not going to do the risk research, so we need this help from the government, and the payoff would be extraordinary.

Senator SPECTER. Dr. Eisenberg, I would like you to supplement that with a written follow-up. I serve on the Defense Appropriations Subcommittee, and the committee directs or suggests specifically what we would like DOD to do.

Dr. EISENBERG. I will.

Senator SPECTER. Dr. Matthews.

Dr. MATTHEWS. I would like to make two points and I will respond and write them in more detail, but I would like to take advantage of some of these new techniques that are being developed to understand the role of stress in the early phases where the potential of prevention of progression of atherosclerosis is at its highest.

And second, I think there are many many talented investigators who have worked very hard to develop stress management programs and techniques that clearly work in small scale studies, but we haven't yet been able to take what they have been able to do

in the small scale studies and translate that into the larger clinical trial, which would be very helpful to have. Developmental work in how to take those studies and make them able to be used for general population studies.

Senator SPECTER. Dr. Ornish.

Dr. ORNISH. Senator, I appreciate the question. I just want to mention that Dr. Vernalis, when she explained to the adherence to the meditation and diet is so great, is because she can order people to follow the program at Walter Reed.

#### BUDGET ALLOCATED TO BEHAVIORAL APPROACHES

May I ask a question of Dr. Kaufmann? I'm just curious to know what the percentage of NIH funding that goes to these kinds of approaches is.

Dr. KAUFMANN. Well, I can speak for NHLBI. I think within the heart program, I think our data shows that we spend about 6 percent of our budget on behavioral research concerning cardiovascular disease.

Dr. ORNISH. Six percent? I guess one of the two points I would make would be that that percentage could be increased, since this clearly affects so many people. But I also, even though I spend most of my time with the science, I have come to learn over many years that the problem is not a lack of science, there is already so much science out there, the problem is one of reimbursement. And that we doctors tend to do what we get reimbursed to do and what we get trained to do what we get paid to do.

And so, that's why we have put so much effort in trying to have Medicare do a demonstration project, because ultimately if Medicare begins to fund and cover programs like this, even in a generic way, that more than anything will change the practice of medicine and medical education.

And yes, we do need to better understand the mechanisms by which stress affects the heart and affects other organ systems, but there is so much information already out there that has not been implemented as everyone here has indicated, that to whatever degree you and your colleagues can help influence CMS to not just cover surgical interventions but approaches that involve empowering the individual, personal responsibility, freedom of choice, I think this more than anything can really give people the multiple choices that are currently available to most people now.

Senator SPECTER. Dr. Vernalis, here's your chance to direct the Chairman of the Joint Chiefs of Staff and the Secretary of Defense on how they ought to spend almost \$400 billion a year.

Colonel VERNALIS. We need to seize the opportunity to be more focused on prevention and develop the strategies that we know will work, and we need to further explore the mechanisms of stress and the need for psychosocial interventions, particularly as it refers to gender and minorities.

As you know, we do our work at Walter Reed through a federally funded grant, and if there is in fact room in the President's budget, we would be more than happy to partner this effort and enlarge the program we're conducting right now.

## STRESS MANAGEMENT MESSAGES FOR THE PUBLIC

Senator SPECTER. I would like to hear from each of you as to an abbreviated suggestion on the issue of stress management. Focusing on that alone, what would you say to the man on the street, succinctly and in common jargon, as to what he or she should do as a first step if they can't undertake one of the wonderful programs available or spend a week with Dr. Ornish or a week with Dr. Vernalis. Dr. Kaufmann, we start with you.

Dr. KAUFMANN. I think that is probably the crux of the matter here.

Senator SPECTER. Occasionally we get there.

Dr. KAUFMAN. Yes. Basically, it is clear certainly from anecdotal evidence and certainly all of my friends and certainly everyone that I associate with, everyone agrees that stress is something that is very much a factor in their lives.

From the research perspective, and I will put on my research hat, I have to recognize that we don't have—

Senator SPECTER. Just to let you know, they started a vote, which means we have to conclude in about 14 minutes. So I would ask you to focus directly when you're talking to a man or woman in the street, stress management. What do you say?

Dr. KAUFMANN. I would say that setting one's priorities and making choices that are realistic within the time frame that people have, and spending time in reflection and in some of the pursuits that matter with individuals around them, and people close to them, are things that are worth practicing that will enrich their lives and foster health.

Senator SPECTER. Dr. Abrams.

Dr. ABRAMS. I would say step back and don't let your environment control you. Try to take charge and control your environment.

Senator SPECTER. Dr. Benson.

Dr. BENSON. Stress evokes a fight or flight response. You have within yourself the ability that's opposite the stress response that's called a relaxation response. Put aside 10 to 20 minutes once or twice daily to either pray, meditate, do yoga or what have you, to bring about this response which will counteract the harmful effects of the stress.

Senator SPECTER. Dr. Eisenberg.

Dr. EISENBERG. I would say to my patients, you do want to know what's happening with your body. And while looking inside your body is potentially an intimidating process, we have actually found it to be an extraordinarily empowering process and even when people are very fearful of it, finding what is and isn't going on to a large extent is indeed very empowering, and pushes people into the act of being proactive rather than fear based, not knowing is a fear of death in a way, and that is not a good way to live your life. So pushing people into a proactive place where they are empowered by knowledge, to me this is the basis for moving forward and moving into behavioral changes.

Senator SPECTER. Dr. Matthews.

Dr. MATTHEWS. If I may reframe the question, because of my interest in the early development of atherosclerosis, I will say what I would say to a young adult and that would be to get the best edu-

cation possible, because we know the higher the education the lower the risk of coronary disease.

And I would also suggest for the more average person on the street to anticipate stress and plan for it.

Senator SPECTER. Dr. Ornish.

Dr. ORNISH. I would try to help the person understand that the stress, you have to know that the stress is out there, so either you choose to treat this really interesting and productive life that is filled with stress and you die early, or you sit under a tree and watch your life go by, and that isn't your choice. The stress isn't so much in what you do, it's how you react to what you do. Practicing even a minute a day of meditation or prayer, or self imaging as others have said, on a regular basis can allow you to be in the same job, the same environment, even the same family, and not react in the same way.

Sometimes patients say things like I used to have a short fuse and I'd explode easily. Now my fuse is longer, things don't bother me as much. And so, one thing I would add to what Dr. Eisenberg just alluded to, it's not about just preventing something bad from happening. It's not about risk factor reduction and prevention that's the most important, it's about feeling better, and accomplishing more and enjoying life.

And it's even more than just stress management. It's really about reacquainting yourself with inner peace and what it feels like to be peaceful and to realize that that doesn't come about because of something you need to do but rather, that's our natural state until we disturb it, so, there is a lot people can do.

Senator SPECTER. We have a colleague here who was accused of having a short fuse, that I was asked about recently and I said he was wrong, he had no fuse.

Dr. Vernalis.

Colonel VERNALIS. We need to educate our patients so they are actively involved in their own healthcare and their outcomes.

#### EDUCATION AND DISSEMINATION

Senator SPECTER. The next question that I would like your comments on is how we educate the people as to these issues. Dr. Eisenberg has a marvelous method of showing them a picture that illustrates the body, showing the lungs of a smoker. It's an integral, but terrifying experience to see it all black. I have had some terrors of my own with that particular one. You can't hear everything that's been written in Dr. Ornish's books or Dr. Benson's books. You may want to supplement this answer, but I would be interested in your views as to what NIH or CDC might be doing, or perhaps the Department of Education, this subcommittee has jurisdiction over the Department of Education, in carrying this message directly to the people.

Dr. Abrams talks about reeducating society on fast food. That's a pretty tough order because of the competition with Burger King, McDonald's and all the rest of those agencies. It would be a big line for undertaking, but I would be interested in your succinct views, and as I say, you can supplement it in writing, how to communicate this message. Dr. Kaufmann.

Dr. KAUFMANN. Well, at NHLBI we actually have a very active program called education and dissemination. We have, for example, the blood cholesterol program, the high blood pressure prevention program, as an education, and several initiatives along those lines and others being planned to disseminate this work. It is one of the most important aspects of our work.

I think that the greatest challenge, however, today is the area of health disparities, and reaching individuals at all levels of our society is really a challenge that we have in this country.

Senator SPECTER. Dr. Abrams, you have 1 minute.

Dr. ABRAMS. I would say the most important thing is to get away from simple brochures and pamphlets, but try to teach people some simple behavioral skills and spread that into communities through role models and to perhaps training a new cadre of public health workers in the techniques of behavior change to get into some of those things.

Senator SPECTER. We have 7 minutes left on the vote, so we have 1 minute for you, Dr. Benson.

Dr. BENSON. I would get into education very quickly. We have done this work at preschool levels and to affect change throughout our Nation, what is needed is for people to learn early how to manage stress. This can be approached throughout our school system and I would start there.

Senator SPECTER. Dr. Eisenberg.

Dr. EISENBERG. One area is teaching physicians how to talk to patients, which Dr. Abrams has been fortunately able to teach me how to do. I think the other area of course, is that technology has great power. The use of graphics is an extremely powerful tool that is not only done in my office, but taken directly into the patient's home for a very advanced and continuing form of education and reinforcement.

Senator SPECTER. Dr. Matthews.

Dr. MATTHEWS. Improving education both in terms of medical school training as well as high schools on this topic. Adolescence is a very important time for forming health habits that last the rest of their lives.

Senator SPECTER. Dr. Ornish.

Dr. ORNISH. Well, actually having consulted with development of these programs, I am encouraged that there is more interest in it, and I would agree with everyone who says that we should look to education. We can teach meditation in a secular way, school lunch programs can serve healthier food. They are cutting back on physical education programs nationwide, and I think this mortgaging our kids future, so there is a lot through the Department of Education that can be done. And if you start early, it is so much easier. You don't have to make such big changes early on; an ounce of prevention is really worth the pound of cure if you start earlier.

Senator SPECTER. Soy burgers?

Dr. ORNISH. Soy burgers, kids love it.

Senator SPECTER. Do you counsel McDonald's?

Dr. ORNISH. I have been talking with McDonald's about serving, and not just serving, but including healthier items in their line, and I think there is a receptivity to that now that there wasn't 5 years ago.

Senator SPECTER. Dr. Vernalis.

Colonel VERNALIS. Education needs to start earlier, and I agree with my colleagues with what they said. One in three of our children are obese now and the ACC projects that cardiovascular disease is going to double over the next 10 to 20 years. We are going to be seeing people having events in their 30s instead of their 50s, so we need to start something earlier.

Senator SPECTER. Miss Miller, let me turn to you to ask you about the Walter Reed program, your experience there, and how you're finding it.

Ms. MILLER. Well, we start out the program where we gather for a week, we stay at a facility on the site and we learn everything we need to know about each one of the four components of the program. And then we spend 3 months going twice a week, for 4 hours twice a week, and we complete all, again, together as a group, all four aspects. And then we move to once a week for 6 months, and then the last 3 months we're on our own. That's the methodology for the program.

And we do the diet, we do a low fat plant-based diet. We exercise 180 minutes a week, at least that much, in our appropriate zone. We have group support and then we have the stress management which combines yoga, meditation, guided imagery and relaxation.

Senator SPECTER. Thank you all very much. We're going to continue this discussion informally. The panelists are invited to be my guests at lunch. We have a big round table in the center of the dining room.

I would like you to supplement your oral testimony in two respects. I would like you to give the subcommittee in writing what you think NIH should be doing that NIH is not currently doing, and feel free to specify your own pet projects that you might want to apply for grants. Don't be bashful about a little self interest regarding what you know about and would like to happen. And as I said earlier, broaden it actually beyond NIH to CDC, or DARPA, because we have a fair amount of persuasion when we put up the money.

The other item I would like your written views on would be the communications line. How does this message get out to the man on the street? I do not think that this hearing is going to be widely communicated to the media, but we do have resources at our disposal to get the message out with some direction to NIH, CDC, DARPA or the Departments of Education, Health and Human Services. Dr. Ornish, you made the comment about what is reimbursed and that could be included in part one, because we have some influence with Medicare through the Department of Health and Human Services.

Everyone is invited back for the health fair in this room at 1:00 to 3:00, where we will have displays at the suggestion of Dr. Eisenberg, and we are prepared to let people take a look. President Kennedy had a very famous statement when he asked a group of Nobel laureates and high-powered scientists, and he said, "there was more talent in the White House tonight at any time since Jefferson died alone."

I think we have more talent here even than when Kennedy was commenting. See you all at lunch.

CONCLUSION OF HEARING

Thank you all very much for being here, that concludes our hearing.

[Whereupon, at 11:38 a.m., Thursday, May 16, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

○