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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. memo	Dean Ornish to President Clinton (partial) (1 page)	10/25/2000	P6/b(6)
002. letter	Dean Ornish to Nancy-Ann Min DeParle re: phone number (partial) (1 page)	12/07/1998	P6/b(6)
003a. memo	Dean Ornish to Jeffrey Kang re: phone number (partial) (1 page)	05/05/1999	P6/b(6)
003b. letter	Alcee Hastings to Nancy-Ann Min DeParle (partial) (1 page)	05/04/1999	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20463

FOLDER TITLE:
Dean Ornish [Folder 2]

2012-0463-S
rc739

RESTRICTION CODES

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Preventive Medicine Research Institute

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

cc: Chris Jennings asap response

Dean Ornish, M.D.
Founder and President
Preventive Medicine Research Institute
Clinical Professor of Medicine
School of Medicine, University of California, San Francisco
900 Bridgeway, Suite 1, Sausalito, California 94965

cc: John Podesta
cc: Chuck Bowen

October 25, 2000

TO: President Bill Clinton
FROM: Dean Ornish, M.D.

P6/(b)(6)

[001]

Rep. Charles Rangel introduced a bill, HR 4107, that would provide coverage for any program such as ours that has been scientifically proven to reverse heart disease as a direct alternative to bypass surgery or angioplasty. (I gave you a copy of it last night.) There is strong bipartisan support for our program in both the House and Senate. As far as I know, no one opposes it.

In our earlier demonstration project, published in 1998, we found that almost 80% of people were able to safely avoid bypass surgery or angioplasty for at least three years by changing diet and lifestyle, saving almost $30,000/patient. In the past two years, Highmark Blue Cross Blue Shield found that 299 of the first 300 patients who went through our program were able to safely avoid surgery, saving more than $16,000/patient.

The Congressional Budget Office said that the cost of this legislation is considered negligible over the next five years. Since $20 billion were spent last year on bypass surgery and angioplasty for Medicare beneficiaries, the potential savings are enormous. In addition, avoiding surgery reduces suffering.

I thought that the language in HR 4107 was going to become part of the Medicare Giveback Legislation, but this language is not yet included. I met yesterday with John Podesta and Chris Jennings. who were very helpful, and said that at this stage it is likely that only Reps. Dennis Hastert and Bill Thomas could include the language. I also met with Bill Thomas yesterday, who said he would consider adding this.

Thank you so much for agreeing to call Rep. Dennis Hastert to support the inclusion of this language, especially during such a busy time. It would make a critically-important difference in giving Americans who suffer from heart disease new hope and new choices, adding to your meaningful legacy in innovative health care that is both medically effective and cost effective.

P6/(b)(6)

Preventive Medicine Research Institute

Personal & ~~Confidential~~

To: Mr. Chris Jennings
Company: The White House
Phone: 202/456-5560
Fax: 202/456-5557

From: Dean Ornish, M.D.
Company: Preventive Medicine Research Institute
Phone: 415/332-2525 x222
Fax: 415/332-5730

Date: 1/5/00
Pages including this cover page: 4

Comments:

I also sent this via e-mail with the Federal Register notice attached.

Preventive Medicine Research Institute

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

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

January 5, 2000

TO: Mr. Dan Mendelson

FROM: Dean Ornish, M.D.

I am taking the liberty of speaking very frankly in this memo, so I will apologize in advance if I am being too direct.

I was very disturbed to receive from Dr. Bart McCann the attached notice that appeared earlier today in the Federal Register. (No one from HCFA mentioned in our meeting last night that this notice was appearing today.) Now, I understand why Dr. Jeff Kang was so inflexible at our meeting last night: he already had changed the primary selection criteria for the experimental group patients of our demonstration project despite what we had agreed to do last summer. I am particularly frustrated because it took so many years to come to an agreement with HCFA, which is now being revised unilaterally by Jeff without prior discussion.

The purpose of the demonstration project that we agreed to do (to quote from the HCFA-approved press release) is as follows: "The demonstration project will study up to 1,800 selected Medicare patients with severe coronary artery disease who have elected to follow Dr. Dean Ornish's Program for Reversing Heart Disease as an alternative to bypass surgery and angioplasty."

However, the Federal Register notice today states, "Specifically, we are interested in comparing the outcomes of beneficiaries who go through the demonstration with Medicare beneficiaries who are recommended for revascularization but initially opted for medical management." In other words, they would not include those who are choosing a lifestyle program as a direct alternative to bypass surgery or angioplasty; instead, they would include only those who have refused bypass surgery or angioplasty anyway in favor of medical (drug) management. This is very different from what Jeff and I had agreed to last summer.

Why is this so important? As I wrote in my e-mail to Jeff on December 22, 1999 (a copy of which was sent to you and others), "As we discussed, patients who refuse revascularization in favor of conventional medical (drug) therapy are not candidates for the Medicare Lifestyle Modification Demonstration, because the cost savings (if any) will come from those who choose comprehensive lifestyle changes as a direct alternative to revascularization." This is especially true since, as you know, Medicare does not cover drug therapy.

In other words, if HCFA pays $7,200 for a patient to go through my lifestyle program as a direct alternative to paying $30,000-$50,000 for bypass surgery or $20,000 for an angioplasty, and if the patient is able to avoid these operations by changing lifestyle, then HCFA saves the difference in cost between the lifestyle program and the surgery. The demonstration project will enable HCFA to determine how many people are able to avoid surgery by changing lifestyle instead. If, however, the patient has initially opted for medical management, then there are no savings to be shown from avoiding an operation that the person has already refused.

There are three ways that this demonstration project can be set up to fail. In our meeting, Jeff made it clear that he intends to do all three:

1. Redefining the experimental group patients as described above (i.e., patients who have refused surgery rather than those choosing lifestyle changes as an alternative to surgery), since there are no savings to be shown from avoiding an operation that the person has already refused;

2. Comparing to a control group of patients who are not undergoing revascularization rather than those who are undergoing revascularization, since there are no savings from avoiding revascularization if the control group is not also undergoing revascularization;

3. Comparing to another program that is less expensive and less intensive, even though it has not been proven to reverse heart disease.

To address the third issue: In my memo to Jeff on December 22, 1999, I wrote, "As we have discussed, it is not ethical to offer any lifestyle program as a direct alternative to revascularization until it has first been proven to reverse coronary heart disease in randomized controlled trials published in peer-reviewed medical journals without using lipid-lowering drugs (since HCFA does not pay for lipid-lowering drugs) using serial coronary arteriography and other hard endpoint measures. Also, a lifestyle program needs to have documented in randomized controlled trials that it can reduce the frequency of angina in these patients to a degree comparable to that achieved following revascularization. To the best of my knowledge, no other lifestyle modification program has met these criteria."

In other words, a program first needs to be proven to be medically effective before doing a demonstration project to see if it is cost effective. This is particularly important since the demonstration project is not a clinical trial. HCFA will not be measuring changes in hard endpoint measures such as angiography, so it is important that a program has first published these data elsewhere. There are less expensive and less intensive lifestyle programs, but they first need to prove that they can reverse heart disease before being offered as an alternative to proven interventions such as bypass surgery and angioplasty.

Perhaps Jeff may be trying to avoid this issue by redefining the experimental group patients as those who have already refused bypass surgery or angioplasty, not those who are choosing to make lifestyle changes as a direct alternative to these procedures.

In any event, given what has transpired, I propose the following three-arm design. This will allow Jeff to collect all of the information he says that HCFA needs to make a coverage decision in a way that is ethically responsible, scientifically valid, and fair.

1. The first arm is to continue the demonstration project as originally planned and agreed upon. In other words, the experimental group would be 1,800 Medicare beneficiaries with heart disease who meet the patient selection criteria and are choosing my program of comprehensive lifestyle changes as a direct alternative to revascularization. They would receive the year-long program for $7,200. These patients would be compared to 1,800 control group patients who meet the patient selection criteria and are undergoing revascularization. This arm would be limited to my program, since no other lifestyle modification program has been proven to reverse heart disease (as described above).

2. The second arm would be Medicare beneficiaries who are recommended for revascularization but initially opted for medical management, as described in today's Federal Register notice. They would receive a less intensive version of my program for $3,600. Since the expected cost savings are lower than those that accrue from avoiding revascularization, I estimate that 3,000 patients would be required for adequate power to detect significant differences. The control group would be matched similar patients who are not making comprehensive lifestyle changes as described in the Federal Register notice today.

3. The third arm would be the same as the second arm, but the intervention would be provided by a different lifestyle modification program. The control group would be matched similar patients who are not making comprehensive lifestyle changes as described in the Federal Register notice today. The number of patients in this group would be at HCFA's discretion, but the Federal Register notice today specifies 1,800 patients.

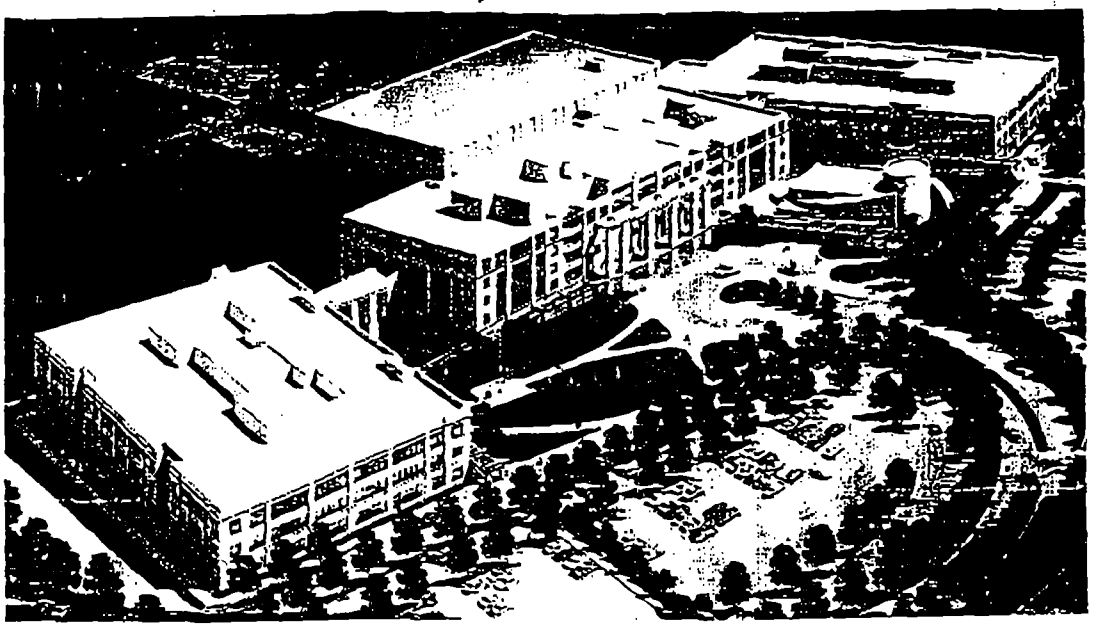
HCFA can compare the relative costs and clinical outcomes of arm 2 and arm 3, so the comparison is fair (comparing apples with apples, so to speak). Arm 1 would not be compared with arms 2 and 3, because the patient population is very different (apples and oranges). In other words, a sicker group of patients who are choosing to make lifestyle changes as a direct alternative to surgery needs a more intensive program than those who have already refused surgery for other reasons. Also, this will allow us to preserve the power of arm 1 (the original design) without diluting it with people who are not choosing comprehensive lifestyle changes in lieu of revascularization.

I hope this will meet everyone's needs so we can move forward. My goal is to advance the field, so including other programs may provide useful information. The more scientifically-proven lifestyle modification programs that are covered by HCFA, the better for everyone. I only want that the comparisons be done fairly.

Thank you so much.

cc: Mr. Chris Jennings
Bart McCann, M.D.

HEALTH CARE FINANCING ADMINISTRATION
NATIONAL HEADQUARTERS
7500 Security Boulevard
Baltimore, MD 21244-1850



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Dan Mendelsin
Chris Jennings

Phone: _____

FROM: Maria Martin

OFFICE OF THE ADMINISTRATOR
C5-26-11-Location
C5-16-03-Mail Stop
Phone: (410) 786-3151 /Fax (410) 786-8060

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DEPARTMENT OF HEALTH & HUMAN SERVICES Health Care Financing Administration

Office of Clinical Standards & Quality
7500 Security Boulevard
Baltimore, MD 21244-1850

December 21, 1999

Dean Ornish, M.D.
President & Director
Preventive Medicine Research Institute
900 Bridgeway, Suite 1
Sausalito, California 94965

Dear Dr. Dean Ornish,

After discussions with my staff, I have decided to propose specific changes to the clinical eligibility criteria for enrollment in the Medicare Lifestyle Modification Demonstration. These changes are intended to bring the eligibility criteria more in accord with the upper limits of your regular program, and address concerns expressed by our quality monitoring and review contractor, the Delmarva Foundation for Medical Care.

I have attached that portion of the text containing these changes for your review as Tab A with additions in bold type and deletions struck out. You will find the previously agreed upon Demonstration Protocol attached as Tab B revised to incorporate these changes.

I have also attached a new Memorandum of Agreement as Tab C. If you are satisfied with the changes made to the Demonstration Design Protocol, please sign and return the original Memorandum of Understanding.

Please respond with a letter indicating that you have received the enclosed documents. Although a facsimile copy of your response is appreciated, we will require the original letter and Memorandum of Agreement for the official files. If you agree to the changes, we would appreciate a faxed response as soon as possible that we may inform demonstration sites of the changes before beneficiary enrollment begins (FAX number (410) 786-6857). If you have any questions, please call me directly, or call Mr. John Thomas of my staff at (410) 786-2908.

Sincerely,

Jeffrey L. Kang, M.D., M.P.H.
Director
Office of Clinical Standards and Quality

Enclosures:
Tab A - Specific Changes to Demonstration Design Protocol
Tab B - Revised Demonstration Design Protocol
Tab C - Memorandum of Understanding

Specific Changes to Demonstration Design Protocol

2. One of the following diagnostic studies which demonstrate clinically significant ventricular myocardium at risk for infarction [1]:

   a. Coronary angiogram **(with estimated ejection fraction)** demonstrating lesions in certain vessels -
   > 70% LAD
   > 70% RCA
   > 70% left circumflex
   ~~> 50% left main~~

   b. Reversible perfusion defect on nuclear imaging study.
   c. Inducible wall motion abnormality on stress echo.
   d. Cardiac PET scan with rubidium-82 showing perfusion defect.

3. Patient's physician must have recommended that, as an option, that he/she undergo revascularization (CABG or angioplasty) in the near future, and is comfortable that the patient is clinically stable to undergo comprehensive lifestyle changes as an alternative intervention.

4. The patient must be willing to make these comprehensive lifestyle changes.

The following are the clinical criteria for the exclusion from enrollment of Medicare beneficiaries.

1. Acute myocardial infarction (within 2 weeks).
~~2. Critical left main disease~~
2. Left main disease > 50% occlusion
3. Three-vessel disease with decreased ejection fraction
4. Unstable angina
5. CABG surgery within 4 weeks (unless otherwise approved by his or her physician).
6. Previous angioplasty within 6 months.
7. Hypotensive response to exercise (> 20 mm Hg drop in systolic pressure).
8. History of exercise induced ventricular tachycardia or third degree heart block without evidence of current stability.
9. Non-ischemic cardiomyopathy (EF < 40%), without evidence of significant CAD.
10. Class IV CHF
11. History of malignant ventricular arrhythmia or use of automatic implantable defibrillator.
12. Residence beyond 90 minutes commute to the program site.
13. Significantly impaired cognitive function (e.g., dementia).
14. Potentially fatal co-morbidity (e.g., metastatic cancer), unlikely to survive on year after entrance into the project.

---

[1] Note: EKG/stress testing/angina surveys without additional imaging studies will not be accepted.

Preventive Medicine Research Institute

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

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

December 7, 1998

Honorable Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration
Room 314-G
200 Independence Avenue, SW
Washington, DC 20201

Dear Ms. DeParle,

Thank you very much for agreeing to meet with me on December 11th at 1:00 p.m. I appreciate very much your interest in my work as well as that of your staff. I have had an opportunity to meet and speak with Dr. Jeff Kang and Dr. John Whyte on several occasions during the past few months. I appreciate their openness as well as their requirement for scientific data and documented benefits to the Medicare population.

I am aware that there are many misconceptions about my work. However, the program which I recommend decreases cardiac events, reduces the need for revascularization, and improves the quality of life for those persons with known coronary disease. These data have been documented by the scientific community through peer review and have been published in the most well-respected scientific journals, including *The Journal of the American Medical Association* (three times), *the American Journal of Cardiology* (twice), *The Lancet, Circulation*, and *The New England Journal of Medicine*, among others. I emphasize this point because no other lifestyle modification program has undergone this degree of scientific rigor.

This program is not new. I have been working in this area for over 20 years. During the past two decades, my colleagues and I have conducted a series of scientific studies demonstrating that the course of severe coronary heart disease can be reversed in many patients by a program of comprehensive lifestyle changes, without coronary by pass surgery, angioplasty, or a lifetime of cholesterol-lowering drugs. Having seen what a powerful and often dramatic difference these changes in diet and lifestyle can make, I want to make it available to the Medicare population who can benefit from it. This has been the reason for my perseverance in pursuing Medicare coverage. Most patients with such severe angina (chest pain) that they can barely walk become essentially pain-free within weeks after beginning this program. The need for medications is often greatly reduced. Quality of life often improves dramatically in these patients.

In the past, lifestyle changes have been viewed as prevention, increasing costs in the short run for a possible savings years later. However, this program is an effective treatment for many patients with coronary heart disease. As envisioned for the Medicare program, I would view this benefit primarily for those patients with documented coronary heart disease. Throughout the country, this program is presently being offered by over 40 major insurers as a scientifically-proven treatment to many patients who otherwise were eligible for coronary artery bypass surgery or angioplasty. This has resulted in immediate and substantial cost savings.

Enclosed is an article that was just published in the *American Journal of Cardiology*. In brief, my colleagues and I found that almost 80% of people who were eligible for bypass surgery or angioplasty were able to safely avoid it by making comprehensive lifestyle changes in the 15 hospitals we have trained. Mutual of Omaha saved nearly $30,000 per patient in immediate savings.

Also enclosed is an article that will be published next week in the *Journal of the American Medical Association*. We found even more reversal of severe coronary heart disease after five years than after one year in the patients who followed my program. In contrast, we found that the control group of patients who made more moderate changes in diet showed even more progression (worsening) of their heart disease after five years than after one year. Also, there were over twice as many cardiac events (including deaths, heart attacks, bypass operations, and angioplasties) in the control group than in the experimental group.

We found a strong correlation after one year and also after five years between adherence to this lifestyle intervention and changes in underlying coronary artery disease—in other words, the more people changed their diet and lifestyle, the more they improved. Each lifestyle component played an important role. The oldest patients showed as much improvement in heart disease as the younger ones; this has particular relevance for Medicare patients, since the risks of surgery increase with age but the benefits of changing diet and lifestyle are not age-related. Women showed even more improvement than men. This research was funded in part by the National Heart, Lung, and Blood Institute of the National Institutes of Health.

Several groups have looked at our data and realized its appropriateness and reasonableness for their beneficiaries. For instance, the Technology Assessment Committees of both Blue Cross of California and, separately, Blue Shield of California have evaluated this program and determined it to be reimbursable and non-investigational.

I understand that two major concerns of payors are patient selection as well as patient adherence. More motivated patients enroll in this program, so patients self-select and thus limit this program to those who are most likely to benefit. Because of the intensity of our intervention, patients are unlikely to participate in this program just because it may be a covered benefit. My colleagues and I have developed patient selection criteria and would be happy to work with your staff if they desire any modifications. If a procedure or benefit can be demonstrated to be effective for a defined patient population (as this program is), then these patients in the Medicare population should have access to it. Concerning patient adherence, a very small number of patients (less than 1%/month) actually drop out of the program. As mentioned earlier, almost 80% of patients in our demonstration project who were eligible for revascularization were able to avoid it by going on this lifestyle program.

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No other lifestyle intervention has this proven medical effectiveness, scientific acceptance, adherence data, and cost-effectiveness. Therefore, I am respectfully requesting HCFA to conduct a demonstration project of this program. In brief, HCFA would pay for patients with severe coronary heart disease to go through this program in the hospitals and other sites that we have trained and new ones that we are training; these patients would be compared to a matched control group of patients from the HCFA database. I would be happy to work with Dr. Kang and other HCFA staff in any way necessary in order to expedite such a demonstration.

As you know, over 500,000 Americans die annually from coronary heart disease, making it the leading cause of death in this country. Approximately 500,000 coronary artery bypass operations and approximately 600,000 coronary angioplasties were performed in the United States in 1994 at a combined cost of approximately $15.6 billion, more than for any other surgical procedure. Much of this expense is paid for by Medicare. Not everyone is interested in changing lifestyle, but the potential cost savings are considerable and immediate—billions of dollars per year—if only one-fourth of people who were eligible for bypass surgery or angioplasty were able to avoid it by going through a scientifically proven lifestyle program instead.

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

In closing, I look forward to our meeting on December 11th. Again, I appreciate the time that HCFA staff have spent with me on this topic. I believe this is a unique opportunity for HCFA to be innovative. Please do not hesitate to contact me at P6/(b)(6) or 415/332-2525 x222 with any questions or concerns you may have prior to our meeting. In the meantime, please accept my sincere appreciation. [002]

Sincerely,

Dean Ornish

Dean Ornish, M.D.
Clinical Professor of Medicine
School of Medicine
University of California, San Francisco

encl.

Preventive Medicine Research Institute

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

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

Chris Jennings
Pls, try to handle
Thx

Saturday, December 12, 1998

TO: President Bill Clinton

FROM: Dean Ornish, M.D. Dean

As always, it was great seeing you and Hillary again on Thursday. Your speech celebrating the Universal Declaration of Human Rights was so moving! You seemed even more open and compassionate yet more powerful than ever. If anything positive is coming out of this nightmare with Congress, perhaps it is that suffering can lead to compassion—although, just as easily, to cynicism and despair.

And what happened yesterday in Congress is a nightmare. As we discussed, I am asking the following people to call members of Congress to express their outrage, especially those you suggested—Reps. Tom Campbell, Brian Bilbray, Stephen Horn, and Jerry Lewis. These include: Steve Jobs, Kim Polese, Larry Ellison, Lisa Pritzker, Susie Tompkins Buell, Steve Swig, Cissie Swig, Stuart Moldaw, Rev. Cecil Williams, and Brook Byers. Also, Laura Dern, Jeff Goldblum, Clint Eastwood, Alan Arkin, Mary Steenburgen/Ted Danson, Mariel Hemingway, and Quincy Jones, among others.

I met yesterday with Nancy-Ann Min DeParle, along with Jeff Kang, M.D. (Chief Clinical Officer, HCFA) and Bob Berenson, M.D. The meeting was both encouraging and frustrating. Nancy-Ann said she would support the prospective demonstration project I am requesting instead of the planned retrospective demonstration project, but not if it costs $30 million just for the assessment that Jeff estimated. I replied that this is way off; in our recently-published demonstration project described below, our data coordinating center at Harvard cost only $250,000 per year, plus one full-time person at Mutual of Omaha was also needed. Thus, even recognizing HCFA's administrative costs, the assessment of our proposed prospective demonstration project could be conducted for less than the $2.5 million/year already budgeted for a retrospective demonstration project.

My colleagues and I have spent over $10 million training 15 sites during the past five years to offer a comprehensive lifestyle change program. These include (including Scripps, UCSF, Harvard, Broward General Hospital in Ft. Lauderdale, etc.) We published our findings last week in the peer-reviewed *American Journal of Cardiology*; in brief, almost 80% of people who were eligible for bypass surgery or angioplasty were able to avoid these operations by making comprehensive lifestyle changes in the sites we have trained. Mutual of Omaha immediately saved almost $30,000 per patient. Nancy-Ann agreed that it would

make more sense to conduct a prospective demonstration project than a retrospective one, since we have now already published the data from a retrospective study.

Thank you very much for agreeing to contact Nancy-Ann and Donna Shalala. I would be very grateful if you would please encourage them to:

- make a written commitment in the next few weeks to conduct this prospective demonstration project;
- to begin this demonstration project in the next few months; and
- to focus this demonstration project on the sites we trained, which would enable the project to begin without further delay and much less expensively.

If this demonstration project is successful, as we anticipate it will be, then a coverage decision could include *all* qualified comprehensive lifestyle change programs. We would be happy to work with HCFA to find an independent agency (e.g., the American College of Cardiology or American Heart Association) to develop certification and credentialing programs on a non-exclusive, non-proprietary basis.

Having seen what a powerful difference a program of comprehensive lifestyle changes can make, I want to make it available to Americans who can benefit from it. This program can save potentially billions of dollars per year that would have been spent on bypass surgery, angioplasty, and a lifetime of cardiac and cholesterol-lowering drugs. For most Americans, the denial of HCFA coverage is the denial of access.

I remain deeply grateful to you.

Enclosed is the new foreword to the paperback edition of *Love & Survival*, which will be published next month. I hope you enjoy it.

Molly joins me in sending our love and best wishes to you and Hillary.

FOREWORD

It has been almost a year since the publication of *Love & Survival.* Much has happened in my life since then.

During the past year, I have received thousands of letters from people who told me how meaningful and even healing it was for them to learn that they were not alone in their feelings. Many of these letters were from physicians. They often shared their desire to reclaim the soul of medicine, to be healers and not merely technicians.

I learned from these letters that I had given voice to the suffering that so many people have been experiencing, both within and outside the medical profession. My willingness to talk openly made it easier for many others to do so. In some ways, this book has served the same function as a stable community, an extended family, or a group support session: a place to realize that you're not alone and that your private feelings are often shared by others.

One of the most painful parts about feeling isolated and depressed is that it may seem like you're the only one who feels this way. Everyone else appears to have it together and to be doing just fine—because if you don't have anyone with whom to talk openly, then you don't have the opportunity to experience how much suffering is all around you. There is a conspiracy of silence. Suffering can lead to compassion and transformation or, just as easily, to cynicism and despair.

Giving voice to suffering often makes it easier for others to experience and express their pain more fully and then to let go of it. Community and intimacy—in any form—help us to bear suffering. When we realize that we are not alone in our distress, the pain becomes much more bearable. We can then use the pain as a catalyst to transform suffering into joy, loneliness

into intimacy. Paradoxically, in the process of sharing loneliness, we experience that we are not alone.

Writing chapter 3 of this book was especially hard, since I revealed a lot of my personal struggles and difficulties in learning how to be in an intimate relationship. I wanted to share part of my journey in hopes that it would be helpful, but it was a little scary to be that open and self-disclosing. I was also concerned that my willingness to describe my shortcomings might compromise my credibility, at least in some people's eyes.

Instead, I was reminded from the letters I received—yet again—that the very actions that I thought were the most likely to cause me to lose credibility and support from others were the ones that were the most meaningful to so many people. And vice versa—I quoted a lot of studies in chapter 2 in order to provide credibility for the importance of love and intimacy, but some people thought I had included too many. They wanted to get right to the chapters that described how what I am learning in my journey for love and intimacy could help them in their own process. They wanted a trusted field guide who could help them navigate the eight pathways to intimacy described in chapter 4.

On June 7, 1998, Molly and I were married. Although we had been in a committed relationship for some time, I was surprised to experience that being married really *did* make a profound difference.

It took a while—several months, actually—before it really sank in. "We are *married*," we would say to each other incredulously, from time to time. "We are husband and wife." The joy and ecstasy that we experience in this relationship exceed anything I have ever dreamed about. Day by day, I am learning to trust, to grow, to give and receive love more fully. In chapter 3 of this book, I wrote that there is no point in taking a chance to open your heart to another person and risk pain unless the ecstasy is worth it.

I can now tell you even more fully from my own experience that it's worth it. It's worth all the pain and suffering that it took to get to this place. And this experience of intimacy is available to anyone who has the courage to open his or her heart to another and to put into practice the pathways to intimacy that I describe in this book. Romantic intimacy is only one form and expression of it.

Last month, the *Journal of the American Medical Association* published the five-year results from the Lifestyle Heart Trial. In brief, my colleagues and I found even more reversal of severe coronary heart disease after five years than after one year in the patients who followed my program. (Not every patient and not every artery showed improvement, but most did.) In contrast, we found that the comparison group of patients who made more moderate changes in diet (and who did not receive support groups, meditation, or other training in love and intimacy) showed even more worsening of their heart disease after five years than after one year. Also, there were over twice as many cardiac events (including deaths, heart attacks, bypass operations, and angioplasties) in that group than in the experimental group of patients who followed my program.

Two months ago, the *American Journal of Cardiology* published results of the Multicenter Lifestyle Demonstration Project from sites around the country that are offering my program. We found that almost 80% of patients who were eligible for coronary bypass surgery or angioplasty were able to avoid these safely by making comprehensive lifestyle changes instead. Almost $30,000 were saved immediately per patient.

Having seen what a powerful difference changes in diet, love, and intimacy can make, I hope that these studies will help to increase insurance reimbursement for my program to make it more widely available to those who may benefit from it. Talking with an insurance company about the health benefits of love and intimacy is less persuasive than presenting

data showing an immediate savings of almost $30,000 per patient. Reimbursing this program for reversing physical heart disease also makes it possible to train people in how to open their hearts in emotional, psychosocial, and spiritual ways as well.

Awareness is the first step in healing, both individually and socially. Part of the value of science is to increase the level of awareness of how much these choices matter that we make each day. Not just a little, but a lot, and not just to the quality of life but also the quantity of life—to our survival.

Just as individual suffering can be a catalyst for changing your life, I hope that the experience of suffering that is so widespread in our society can be a catalyst for social and political changes. By addressing the more fundamental causes of suffering and illness rather than just literally or figuratively bypassing them, my colleagues and I are demonstrating that a new model of medicine that is more caring and compassionate is also more cost-effective and competent.

The desire for love and intimacy is a basic human need, as fundamental as eating, breathing, or sleeping—and the consequences of ignoring it are just as dire. You are likely to live longer if you put into practice what I describe in this book. However, the mortality rate is still 100 percent, one per person. When we are able to open our hearts on all levels—anatomically, emotionally, and spiritually—then we can live every moment in fullness. And when the time comes to die, we will know that we have fully lived.

Dean Ornish, M.D.

Sausalito, California

January 1999

Preventive Medicine Research Institute

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

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

March 11, 1999

Hon. Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration
200 Independence Avenue, S.W., Room 314-G
Washington, DC 20201

Dear Ms. DeParle,

Thank you so much for your telephone call earlier this week. I appreciate so much your interest in my work and for helping me to better understand the process.

As we discussed, I am respectfully requesting that HCFA now make a decision to cover this program for selected patients. Coverage would be limited to patients with documented coronary heart disease who are choosing this program of comprehensive lifestyle changes as a direct alternative to bypass surgery or angioplasty. These are the patients in whom the cost savings are the most dramatic and immediate, and it would be the easiest group in which to prevent fraud or abuse.

It is my understanding from our discussion and from talking with Mr. Chris Jennings that you plan to consult with HCFA's counsel to determine if this program is experimental and whether or not HCFA needs additional statutory authority to cover it. I would be grateful if you would please pass along this information to your counsel so she can consider this information in making her evaluation. I understand that if the program is evaluated to be non-investigational and if HCFA does not need additional statutory authority, then it would need to be scored by HCFA actuaries to determine if it would save money or cost money. If it is evaluated to cost money, then either an offset would need to be found or additional Congressional statutory authority would be required. (Please accept my apologies if I have not accurately understood this algorithm.)

Is This Program Experimental?

The Technology Assessment Committees of Blue Shield of California (in 1993) and, separately, of Blue Cross of California (in 1996) have evaluated this program and determined it to be reimbursable and non-investigational. There are even more data and publications in peer-reviewed journals now than then in support of this decision. 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. Also, Highmark Blue Cross Blue Shield of Western Pennsylvania is both covering and providing this program to its members.

During the past 22 years, my colleagues and I have conducted a series of clinical trials demonstrating, for the first time, that the progression of even severe coronary heart disease often can be reversed by making comprehensive changes in diet and lifestyle, without coronary bypass surgery, angioplasty, or a lifetime of cholesterol-lowering drugs. These lifestyle changes include a very low-fat, low-cholesterol diet, stress management techniques, moderate exercise, smoking cessation, and psychosocial support. This idea has become mainstream and is generally accepted as true by most cardiologists and scientists.

Within a few weeks after making comprehensive lifestyle changes, the patients in our research reported a 91 percent average reduction in the frequency of angina. Most of the patients became essentially pain-free, including those who had been unable to work or engage in daily activities due to severe chest pain. Within a month, we measured increased blood flow to the heart and improvements in the heart's ability to pump. And within a year, even severely blocked coronary arteries began to improve in 82% of the patients.

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

In our latest report, published in the December 16, 1998, issue of the *Journal of the American Medical Association,* we found that most of the study participants were able to maintain comprehensive lifestyle changes for 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 (i.e., a 30% fat diet) worsened after one year and their coronary arteries became even more clogged after five years. Also, we found that the incidence of cardiac events (e.g., heart attacks, strokes, bypass surgery, and angioplasty) was 2.5 times lower in the group that made comprehensive lifestyle changes after five years. A one-hour documentary of this work was broadcast on *NOVA*, the PBS science series, and was featured on Bill Moyers' PBS series, *Healing & The Mind.*

These research findings have particular significance for Americans in the Medicare population. One of the most meaningful findings in our research was that the older patients improved as much as the younger ones. When I began the research, I believed that the younger patients with milder disease would be more likely to show regression, but I was wrong. Instead, the primary determinant of change in their coronary artery disease was neither age nor disease severity but adherence to the recommended changes in diet and lifestyle. No matter how old they were, on average, the more people changed their diet and lifestyle, the more they improved. Indeed, the oldest patient in our study (now 83) showed more reversal than anyone. We found this correlation between adherence and

improvements in heart disease after one year and also after five years. This is a very hopeful message for Medicare patients, since the risks of bypass surgery and angioplasty increase with age, but the benefits of comprehensive lifestyle changes may occur at any age.

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

In summary, this program is neither investigational nor experimental.

Would This Program Cost Money or Save Money?

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

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

For every patient who chooses this lifestyle program rather than undergoing bypass surgery or angioplasty , thousands of dollars are immediately saved that otherwise would have been spent; much more when complications occur. (Of course, this does not include sparing the patient the trauma of undergoing cardiac surgery.)

Also, providing lifestyle changes as a direct alternative for patients who otherwise would receive coronary bypass surgery or coronary angioplasty may result in significant *long-term* cost savings. Despite the great expense of bypass surgery and angioplasty, up to one-half of bypass grafts reocclude after only five to seven years, and 30-50% of angioplastied arteries restenose after only four to six months—an example of mopping up the floor around the overflowing sink without also turning off the faucet. When this occurs, then coronary bypass surgery or coronary angioplasty is often repeated, thereby incurring additional costs.

Beginning five years ago, my colleagues and I at the non-profit Preventive Medicine Research Institute 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 selected patients avoid bypass surgery and angioplasty by making comprehensive lifestyle changes at lower cost without increasing cardiac morbidity and mortality?

We trained a diverse selection of hospitals around the country. The initial sites were Alegent Immanuel Medical Center/Alegent Heart Institute, Omaha, NB; Alegent Bergen Mercy Medical Center, Omaha, NB; Beth Israel Medical Center, New York, NY; Mercy Hospital Medical Center/Iowa Heart Center, Des Moines, IA; Broward General Medical Center, Fort Lauderdale, FL; Palmetto Richland Memorial Hospital, Columbia SC; Mt. Diablo Medical Center, Concord, CA; Beth Israel Deaconess Medical Center/Harvard Medical School, Boston, MA; Scripps Hospitals and Clinics, La Jolla, CA. Additional program sites included the School of Medicine, University of California, San Francisco; California Pacific Medical Center, San Francisco; Franciscan Health System of the Ohio Valley, Cincinnati Ohio; Swedish American Health System, Rockford, IL; and Swedish Medical Center/First Hill, Seattle, WA. The data coordinating center was chaired by Alexander Leaf, M.D., at the Massachusetts General Hospital/Harvard Medical School.

In brief, we found that 77% of people who were eligible for bypass surgery or angioplasty were able to avoid it safely by making comprehensive lifestyle changes in the hospitals we trained. Mutual of Omaha calculated an immediate savings of $29,529 per patient. These patients reported reductions in angina comparable to what can be achieved with bypass surgery or angioplasty without the costs or risks of surgery. These findings were published in the *American Journal of Cardiology* in November 1998. We also found that patients who needed bypass surgery or angioplasty were able to reduce the likelihood of needing another operation by making comprehensive lifestyle changes after surgery. Also, billions of dollars per year are spent on lipid-lowering drugs and other cardiac medications, many of which can be avoided by making comprehensive lifestyle changes. Although HCFA does not currently pay for these drugs, it is possible that it may do so in the future.

In response to an earlier request from Bruce Vladeck, Dr. Claude Lenfant (Director, National Heart, Lung, and Blood Institute, National Institutes of Health) evaluated this program and found it to be safe for Americans in the Medicare population. Also, letters of support for HCFA to cover this program were written by leading medical authorities including Christine Cassel, M.D. (Professor and Chairman, Department of Geriatrics and Adult Development, The Mount Sinai Medical Center, Immediate Past President, American College of Physicians, Chair, American Board of Internal Medicine), Alexander Leaf, M.D. (Jackson Professor of Clinical Medicine, Emeritus, Chairman, Department of Medicine, Emeritus, Chairman, Department of Preventive Medicine & Clinical Epidemiology, Emeritus, Harvard Medical School and Massachusetts General Hospital), Marion Nestle, Ph.D. (Professor and Chair, Department of Nutrition and Food Studies, New York University), former Surgeon General C. Everett Koop, AARP executive director Horace Deets, and others.

We recently received an appropriation from Congress to the Department of Defense to make this comprehensive lifestyle change program available by training teams of physicians and other health professionals at the Walter Reed Army Medical Center and the Bethesda National Naval Medical Center.

A recent editorial by the editors of *The New England Journal of Medicine* (1998;339(12), p. 839-841) stated, "There cannot be two kinds of medicine—conventional and alternative. There is only medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work. Once a treatment has been tested

rigorously, it no longer matters whether it was considered alternative at the outset. If it is found to be reasonably safe and effective, it will be accepted." This program has been tested rigorously and was found to be reasonably safe and effective.

Over 500,000 Americans die annually from coronary artery disease, making it the leading cause of death in this country. Approximately 500,000 coronary artery bypass operations and approximately 600,000 coronary angioplasties were performed in the United States in 1994 at a combined cost of approximately $15.6 billion, more than for any other surgical procedure. Much of this expense is paid for by Medicare. Not everyone is interested in changing lifestyle, and some people with extremely severe disease need surgery, but billions of dollars per year could be saved immediately if only some of the people who were eligible for bypass surgery or angioplasty were able to avoid it by making comprehensive lifestyle changes instead. 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. Unfortunately, for many Americans on Medicare, the denial of coverage is the denial of access.

This approach empowers the individual, may immediately and substantially reduce health care costs while improving the quality of care, offering 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.

We are requesting coverage from HCFA to be limited to patients who are choosing this program of comprehensive lifestyle changes as a direct alternative to bypass surgery or angioplasty. As described earlier, these are the patients in whom the cost savings are the most dramatic and immediate , and it would be the easiest group in which to prevent fraud or abuse.

In summary, unlike most prevention interventions that may take years to demonstrate cost effectiveness or cost benefit, we have demonstrated that this program may immediately save money for HCFA as an alternative to bypass surgery or angioplasty for selected patients.

My colleagues and I would be happy to work with HCFA to develop standards for any comprehensive lifestyle program that has sufficient scientific evidence of safety, medical effectiveness and cost effectiveness to justify coverage.

Thank you so much for your consideration. Please call me if you have any questions or would like any additional information. With best wishes and warm personal regards,

Sincerely,

Dean Ornish

Dean Ornish, M.D.
Clinical Professor of Medicine
School of Medicine
University of California, San Francisco

cc: Mr. Chris Jennings

Preventive Medicine Research Institute

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

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

May 5, 1999

TO: Jeffrey Kang, M.D., M.P.H.
Director, Office of Clinical Standard and Quality
Chief Clinical Officer
Health Care Financing Administration

FROM: Dean Ornish, M.D.

Thank you so much for agreeing to move forward on a demonstration project according to the parameters we discussed. I appreciate your continued advice and support. Although I preferred a decision to cover this program, a demonstration project is a workable compromise and may be to everyone's benefit.

Debbie Grossblatt asked me to send a memo to you clarifying the difference in reimbursement rates and program duration at the hospital sites that the non-profit Preventive Medicine Research Institute has trained in our intensive multifactorial lifestyle modification program.

The data we reported last November in the *American Journal of Cardiology* from the Multicenter Lifestyle Demonstration Project were based on a one year program. This article also reported that the average cost per patient for the one year program was $7,000. (Each hospital determined the program cost.) Based on data from Mutual of Omaha, the calculated savings were almost $30,000 per patient at this level of reimbursement. Because these programs began over five years ago, I adjusted this figure for inflation by adding $500. Thus, we are requesting HCFA to reimburse $7,500 per patient for the one year program.

As we have discussed, third party reimbursement has been limited at many of these sites. Because of this, many patients have needed to pay for the program out of pocket in order to receive it, but many could not afford to pay the full cost of the program. Some hospital sites responded either by reducing the amount they charge patients below what it actually costs them to provide the program (in hopes that Medicare funding would soon be available), or by offering a program that is less than one year in duration for patients who have less severe coronary artery disease and are not eligible for revascularization.

In the HCFA demonstration project, we are requesting HCFA to cover only patients who are eligible for revascularization, since the potential cost savings are the most immediate and dramatic in this group. By definition, these patients have severe coronary artery disease. We do not know if shorter programs are as clinically safe and effective as the year-long program,

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003a. memo	Dean Ornish to Jeffrey Kang re: phone number (partial) (1 page)	05/05/1999	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20463

FOLDER TITLE:
Dean Ornish [Folder 2]

2012-0463-S
rc739

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
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so it would not be medically appropriate to offer a program less than one year in duration for patients in the proposed HCFA demonstration project since these patients are quite sick.

Most sites are enduring significant financial losses offering the program at below-cost rates in the absence of third party reimbursement and cannot continue to sustain these losses. Thus, it is important that HCFA reimburse the real costs of the program, or the demonstration project will not be able to move forward. At the end of the HCFA demonstration project, the payment can be revised up or down in a coverage decision depending on the cost effectiveness of the intervention.

I look forward to our scheduled conversation on Friday afternoon at 4:30 p.m. I will be in Washington, DC to give a lecture at 8:15 p.m. that evening, so I would be happy to meet in person if that is convenient for you. If not, then we can talk by telephone. In the meantime, please call me if you have any questions or would like any additional information on my cellular phone at [redacted] [003a]

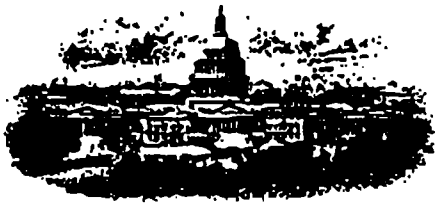
Thank you very much. All of us at PMRI are very grateful for the opportunity to move forward.

cc: Debbie Grossblatt

ALCEE L. HASTINGS
Member of Congress
Florida

COMMITTEE ON
INTERNATIONAL RELATIONS

SELECT COMMITTEE
ON INTELLIGENCE



PLEASE RESPOND TO:

2235 Rayburn Building
Washington, DC 20515-0923
Telephone (202) 225-1313

2701 W. Oakland Park Boulevard
Suite 280
Ft. Lauderdale, FL 33311
Telephone (954) 733-2800
Fax (954) 735-9444

5725 Corporate Way
Suite 208
West Palm Beach, FL 33407
Telephone (561) 684-0606
Fax (561) 684-3613

E-Mail Address:
alcee.hastings@mail.house.gov
World Wide Web Page:
http://www.house.gov/hastings/alcee.htm

Congress of the United States
House of Representatives
Washington, DC 20515-0923

May 4, 1999

The Honorable Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration
Room 314-G
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Ms. DeParle:

Thank you very much for taking the time to meet with Chairman Dan Burton, Mr. Chris Jennings, Dr. Dean Ornish, myself and others today. I appreciate very much your decision to move forward with the demonstration project for Dr. Ornish's program for reversing heart disease. As I understand it, you kindly agreed to the following:

- To begin the demonstration project in the next two to three months. In other words, patients who meet the criteria (i.e., those who are choosing this program as an alternative to bypass surgery or angioplasty) may begin entering the hospital sites trained by the non-profit Preventive Medicine Research Institute (PMRI) after August 1, 1999, and the hospitals will receive reimbursement from HCFA as noted below;

- The HCFA demonstration project should provide payment to these hospitals at a level comparable to what they are currently charging (and being reimbursed) as a defined program, i.e., $7,500.00 for the one-year program. Over 40 insurance companies are paying for this program in the sites that PMRI has trained. In an article published in the November issue of the American Journal of Cardiology, Mutual of Omaha calculated saving almost $30,000.00 per patient. At the end of the demonstration project, the payment can be revised up or down depending upon the results of the project. Dr. Ornish and his colleagues will work with representatives from the Office of Management and Budget and or HCFA to validate the costs of this program to date int he sites that PMRI has trained.

- The demonstration project should be limited to a study of Dr. Ornish's program. This will enable the program to begin quickly with the greatest likelihood of success. As you know, this program remains the only one proven to reverse coronary heart disease in randomized controlled trials using coronary arteriography. If the program is shown to be

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003b. letter	Alcee Hastings to Nancy-Ann Min DeParle (partial) (1 page)	05/04/1999	P6/b(6)

COLLECTION:
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b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

successful, then HCFA should consider converge for any similar programs that have data demonstrating medical effectiveness and cost effectiveness in controlled clinical trials.

- New sites can be included in the demonstration project after they have been trained and certified by PMRI. This allows patients to be recruited more quickly, thereby reducing the length and cost of the demonstration project. The only patients eligible for the study are those who have been told that they need bypass surgery or angioplasty and are choosing this lifestyle program as a direct alternative. These patients are the ones for whom cost savings are the most dramatic and the most immediate (i.e., instead of paying $50,000.00 for a bypass operation, HCFA could pay only $7,500.00 for a lifestyle intervention). Also, the potential for fraud and abuse is greatly reduced, since a physician would be required to certify and document that a patient had severe coronary artery disease requiring revascularization before the patient would be eligible. However, these patients are only eligible during the narrow time period between diagnosis and surgery. Thus, the more sites that are trained, the faster the patients can be recruited and the sooner the demonstration project can be completed at the lowest cost.

- It is acceptable to include an external data coordinating center, as long as this does not delay the start of the project. An alternative strategy would be to manage the data from within HCFA.

- Chairman Burton and I, as well as others, will pursue legislation parallel with this demonstration project so that when the demonstration project is successful, you will have the legislative authority to reimburse this project as a defined project.

- Mr. Richard Lauderbaugh and his colleagues at Health Policy Alternatives will be available to work with you and your colleagues (at PMRI's expense) to help provide any documentation and information that would be helpful in beginning this demonstration project.

Please feel free to contact me directly should you need to discuss any of these points.

I appreciate your consideration. I personally believe that this program can help others with heart disease to alleviate their suffering at a lower cost, particularly those who do not have access to conventional treatments. We have the opportunity to do something innovative that I believe will also prove more cost efficient to the government than conventional treatments P6/(b)(6) [003 b]

P6/(b)(6)

Sincerely,

Alcee L. Hastings
Member of Congress

Thanks for everything. God Bless you now and always!