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### 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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- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

#### Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
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- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

**DEPARTMENT OF HEALTH & HUMAN SERVICES****Health Care Financing Administration  
Office of Clinical Standards & Quality**

7500 Security Boulevard  
Baltimore, MD 21244-1850

JUN 21 1999

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

Dear Dr. Ornish:

In my previous letter dated May 20, 1999, I advised you that my staff would develop and draft a proposal to implement a Medicare Lifestyle Modification Program Demonstration for your consideration. I am pleased to attach a copy of our draft proposal which will fund a four-year Medicare demonstration of lifestyle modification for people with cardiovascular disease starting August 1, 1999. We are providing this document to you so you can review it prior to our meeting on June 25, in Baltimore. At that time, we will discuss the content of this proposal to arrive at a final agreement between the Health Care Financing Administration (HCFA) and the Preventive Medicine Research Institute (PMRI) on behalf of its licensed sites. As you review this document, keep in mind that we have worked very hard to consider both the needs of your sites and the basic safeguards needed by Medicare beneficiaries who choose to participate in this payment demonstration.

Please note that we have included the following items in the demonstration proposal for your consideration: Length of Demonstration: This will be a four-year payment demonstration beginning on August 1, 1999, with a 3-year enrollment period ending on July 31, 2002, with payment through July 31, 2003.

Treatment Episode: The demonstration sites will use PMRI's 12-month risk stratification model as outlined in the PMRI Staff Operations Manual.

Payment Rate: The Health Care Financing Administration will pay all sites 80% of \$6,000 per beneficiary for the complete treatment episode. The site may collect the remaining 20% fee from the beneficiary as a program or enrollment fee. Under the demonstration, the site has the option of waiving this fee. Payments will be made on a quarterly basis and upon dis-enrollment from the program, (prior to completion), the demonstration will receive a pro-rated portion of the total amount.

Enrollment Cap : The demonstration will provide services for a maximum of 1,500 Medicare Part B eligible beneficiaries.

Page 2 - Dean Ornish, M.D.

I look forward to meeting with you on Friday so that we can discuss this proposal in detail.  
If you have any questions prior to our meeting, you can call me directly or call 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

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JUNE 21, 1999

**Medicare Lifestyle Modification Program Demonstration  
PROPOSAL DISCUSSION MATERIAL****A. Introduction**

The Health Care Financing Administration (HCFA) will conduct a four-year demonstration program of lifestyle modification for a maximum of 1,500 Medicare enrollees with the Preventive Medicine Research Institute (PMRI) the official licenser of the Dr. Ornish's Program for Reversing Heart Disease (also referred to as the Dr. Ornish's Program). This document is an operational protocol for the conduct of the demonstration. A demonstration evaluation will be conducted through a separate contract with an independent research firm. The demonstration period will commence on August 1, 1999, and will provide a 3-year enrollment period ending on August 1, 2002, with payment through July 31, 2003 (for a total of 4 years). The fourth year of the demonstration will allow Medicare enrollees who enrolled during the third year, to complete the full program at their respective sites.

For purposes of this demonstration, all licensed Dr. Ornish's Program sites participating in this demonstration must provide a basic package of benefits to all Medicare Part B eligible beneficiaries (including HMO, Preferred Provider Plans, etc.) electing to participate in a program of lifestyle modification. The demonstration's basic package is based on the standards required by the Medicare program for cardiac rehabilitation and the guidelines stated in PMRI's Staff Operations Manual.

**B. Certifications**

All services provided must be furnished by Medicare certified facilities or those that certify they can meet the same standards required by Medicare. The demonstration sites must certify that they meet the minimum program requirements based on the standards required by Medicare for cardiac rehabilitation and the guidelines stated in PMRI's Staff Operations Manual. These requirements are summarized in Appendix A: The Core Program, which also contains additional requirements to ensure patient safety, e.g., presence of a cardiologist on site during the exercise session.

**C. Length of Program**

For purpose of this demonstration, the Dr. Ornish's Program of lifestyle modification services must be provided for a period of 12 continuous months at the site of a participant's enrollment. The participating site must provide an exact starting date (e.g., the non-residential retreat or the first day of class) and ending date (e.g., closing night or last class) to HCFA's Office of Financial Management, Demonstrations Management Branch (OFM/DMB) for payment purposes as soon as the beneficiary is enrolled. The site must provide a written notice to the beneficiary as soon as HCFA certifies the beneficiary's Medicare eligibility.

Should a beneficiary disenroll from the program, either voluntarily or involuntarily, the site must notify HCFA's OFM/DMB of the termination date within 10 days of the disenrollment, and

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provide the reason for termination (e.g., death, hospitalization, non-adherence, disruptive personality, moved to another city, etc.)

**D. Demonstration Payments**

Services included in the fixed payment for lifestyle modification at the demonstration sites are currently not covered under the Medicare program. As such, payments, claims review and denial procedures will be performed within systems specially constructed for the demonstration for the Office of Clinical Standards and Quality (OCSQ).

Lifestyle modification programs typically include a prescription of a very low-fat vegetarian diet, counseling and education, aerobic exercise, stress management techniques and smoking cessation. These behavior-oriented programs generally include a few days to a week of intensive orientation with a defined period of maintenance that is based on the program design. The costs of these programs vary depending on the operator of the program, the geographic location, and the type of site providing the services (e.g., hospital based vs. a community based program).

Under the demonstration, all sites will receive 80 percent of the \$6,000 fixed payment amount for the complete treatment episode upon a beneficiary's completion of the 12 month program. The demonstration site may collect the remaining 20% of this amount from the beneficiary as a program or enrollment fee. Under the demonstration, the site has the option of waiving this fee. Payments to each demonstration site for each beneficiary will be made prospectively on a quarterly basis at the 35%, 15%, 15%, and 35% rate. Upon dis-enrollment from the program, (prior to completion), the demonstration site will receive a pro-rated portion of the total payment.

**E. Criteria for Demonstration Sites**

Demonstration sites will be limited to those licensed by PMRI. Since the demonstration is restricted to these sites, it can be implemented rapidly. The duration of the demonstration is expected to be 4 years or less. HCFA will reserve the right to suspend or terminate the demonstration or individual sites at any time during this 4- year period. In this event, HCFA will promptly notify the awardee in writing of the determination and the reasons for the suspension or termination, together with the effective date. The demonstration site may cancel the service agreement on an annual basis with a 90-day notice of intent prior to the start of the next demonstration year.

At a minimum, demonstration sites must agree to adhere to a set of treatment conditions and guidelines modeled after their licensing agreement with PMRI. However, demonstration sites can offer services, within the episode of care, that exceed these requirements provided there is no additional cost to Medicare. A well-developed site is one that offers a full treatment program with appropriate patient screening and monitoring, provides for quality assurance, conducts patient follow-up inquiries, and that can demonstrate that patients can complete the entire program and, after completion, adhere to the lifestyle modification regime.

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## F. Criteria for Patient Selection

Lifestyle modification programs for cardiovascular disease, such as the Dr. Ornish Program, are open to all those who can pay and also can meet the criteria for participation when making application. Under this Medicare demonstration, Medicare will provide payment for services which have not been previously covered under the regular Medicare program. Under these circumstances, the appropriateness of care provided is of obvious concern. The criteria for enrollment in the demonstration should reflect clinical standards such that the services offered can provide the most appropriate and beneficial treatment to those enrolled. HCFA is interested in treatment from which the Medicare patient can experience a measurable immediate benefit with a potential for a lifetime benefit. In this case, HCFA is interested in treatment that brings about the reversal of coronary artery occlusion, amelioration of symptoms from coronary artery disease or some other positive, observable change in the patient's condition. The Medicare beneficiaries who meet the clinical criteria for enrollment under the demonstration are expected to include only people with substantial coronary artery disease (CAD).

The demonstration sites shall be required to add specific requirements to its admission screening criteria. First, demonstration patients must have at least Part B Medicare eligibility. The following are the four clinical criteria required under the demonstration for enrollment of Medicare beneficiaries.

1. Presence of angina
2. One of the following diagnostic studies which demonstrate significant left ventricular myocardium (greater than 50%) at risk for infarction<sup>1</sup>.
  - a. Coronary angiogram 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 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.

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<sup>1</sup> Note: EKG/stress testing/angina surveys without additional imaging studies will not be accepted.

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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
3. CABG surgery within 4 weeks.
4. Previous angioplasty within 6 months.
5. Hypotensive response to exercise ( $> 20$  mm Hg drop in systolic pressure).
6. History of exercise induced ventricular tachycardia or third degree heart block without evidence of current stability.
7. Non-ischemic cardiomyopathy (EF  $< 40\%$ ), without evidence of significant CAD.
8. Class IV CHF
9. History of malignant ventricular arrhythmia or use of automatic implantable defibrillator.
10. Residence beyond 90 minutes commute to the program site.
11. Significantly impaired cognitive function (e.g., dementia).
12. English language illiteracy.
13. Potentially fatal co-morbidity (e.g., metastatic cancer), unlikely to survive on year after entrance into the project.

The demonstration sites must assure that the criteria for inclusion have been met and that none of the exclusion criteria are present for Medicare beneficiaries seeking enrollment in the program. In addition, a physician must certify that a Medicare beneficiary meets the clinical eligibility requirements to participate in the Dr. Ornish Program for Reversing Heart Disease® prior to the beneficiary's enrollment in the program (see Appendix B).

#### **G. Patient Notification**

Demonstration sites will ensure that all Medicare beneficiaries enrolling in the lifestyle modification program under this demonstration are informed about the background and nature of the demonstration and the conditions of their enrollment and financial liability. In addition, demonstration sites will provide each beneficiary with the standardized forms (prepared by HCFA) for patient consent, enrollment, and disenrollment (see Appendix B). A copy of the signed consent forms, along with enrollment information, will be forwarded by each site to HCFA demonstration staff. Disenrollment forms will be forwarded promptly to HCFA's OFM/DMB staff for termination of payment.

#### **H. Additional Program Items**

The site will furnish the following educational materials and items to the participants:

1. A Patient Manual and all handouts necessary for understanding the program requirements,

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2. A copy of either *Dr. Dean Ornish's Program for Reversing Your Heart Disease* or *Eat More, Weigh Less*,
3. One stress management audiotape to use at home, and
4. A Program tee shirt and/or a tote bag.

### I. Marketing Materials

As this is a HCFA demonstration, all marketing materials developed by, or on behalf of participating sites, including the radio and television scripts and web pages, must be approved by the HCFA project officer prior to public use. HCFA will review the materials and provide a response to the submitting site within 15 working days after receipt.

### J. Data Requirements and Patient Information

Due to the escalating cost of care for CAD and the outlay of trust fund expenditures for this service, lifestyle modification may be a viable cost effective alternative for elderly Medicare beneficiaries who are determined to be "good" candidates for this service. In order to make a determination about these services for the Medicare population, HCFA must obtain medical and compliance information about Medicare participants to determine the economic value and health benefits of providing lifestyle changes for the elderly. Consequently, the site will have to agree to cooperate with our quality medical reviewers and evaluation contractors and allow them access to the physical site and to the medical records/ history of each beneficiary as long as this process does not present an unreasonable financial burden. The staff at the sites will also have to be available should HCFA staff members conduct on-site visits in the future.

#### Medical Eligibility Review

Information will be required from the demonstration sites to document and confirm the eligibility of Medicare patients who enroll in the lifestyle modification program according to the admission clinical screening criteria. The purpose of this review is to monitor compliance with the eligibility criteria established for enrollment. The required documentation will be submitted by the sites to the medical review contractor, which will review the necessary information and alert HCFA should the sites admit beneficiaries who do not meet the specified eligibility criteria.

#### Quality and Outcome Monitoring

Paramount to the demonstration and to quality monitoring is the baseline, periodic and discharge outcome measurement of the patient's progress through out the lifestyle modification program. These areas are of primary interest to the quality monitoring contractor and the evaluation contractor.

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It is envisioned that several steps need to be taken in selecting which outcome measurements are pertinent to quality monitoring and for determining program success. For the most part, many of these measurements already exist at the prospective demonstration sites. Ongoing physical examination and laboratory tests, especially those related to cardiovascular functioning, are necessary to monitor the health status of patients, and to determine whether progress has been achieved in ameliorating CAD. However, among the sites selected for this demonstration, there may be variations in periodic outcome measurement according to variations in practice patterns.

Although the quality monitoring contractor will be furnished with a listing of possible measures, it will be the task of the quality monitoring and evaluation contractors to develop a final list of measures that will be required of the demonstration sites. The following process is an obvious suggestion for arriving at such a listing. First, develop a list of pertinent outcome indicators which can be used to demonstrate a successful clinical outcome or which may indicate an adverse change in a patient's health status. Of these, discern which can be reliably measured and verified with the minimum of variation or subjective influence. Of these, discern which can be performed at patient admission, during the course of treatment, and at discharge. Of these measures, discern which are the most feasible in terms of being the least invasive, convenient to the patient, and reasonably inexpensive. Finally, select the measure which can be easily understood by professional and lay personnel without misinterpretation. Obviously, the measures and data items that are already collected and are common across most of the sites may satisfy the requirements of the quality monitoring effort. This will probably include periodic (monthly or quarterly) measurements such as the following:

- weight
- cholesterol (LDL, HDL, triglycerides)
- blood pressure
- participation (number of sessions attended, missed)
- medications
- major cardiovascular tests or procedures (if any)

Certain measurements may not be included in period monitoring but may be useful measures to compare between program entry ( $\pm 2$  weeks) and completion ( $\pm 2$  weeks). These measures might include, at a specified period of time, an electrocardiograph, homocysteine level, inflammation markers, average blood sugar (HgbA1c) in diabetes patients, and Lipoprotein (a).

## Appendix A

### The Core Program

The 12-month, three-stage program provided to Medicare beneficiaries must consist of the four components described in Dr. Ornish's "Core Program." These components include:

1. **Nutritional counseling** - Educating and assisting the participant to adopt and follow a low-fat (10%) plant-based whole foods vegetarian diet. This includes food preparation classes and information on shopping as well as at least one-on-one counseling session with the nutritional educator (dietitian). It is expected that the case manager will determine a participant's need for additional one on one nutritional counseling to ensure an understanding of and adherence to the diet.<sup>1</sup>
2. **Moderate Aerobic Exercise** - Providing an individual with a condition- appropriate aerobic exercise routine and educating the patient on how to continue this regimen on his/her own for a minimum of 3 hours per week.<sup>2</sup> This session must be conducted according to ACSM/AACVPR/AHA guidelines, and must be prescribed by an exercise physiologist. A supervising cardiologist must be present (on site) during the exercise sessions. In order to ensure both the safety of the beneficiary and the quality of the program, class size shall be limited to 15 participants.<sup>3</sup>
3. **Daily stress management techniques** - Educating the individual on adopting a daily one hour (minimum) stress management practice consisting of stretching, breathing, deep relaxation, imagery and meditation (i.e., yoga). Note: The program must provide adaptive techniques and props for participants who cannot do the stretching on the floor because of physical limitations (e.g., arthritis, sciatica, vertigo) or advanced age.
4. **Group Support Meetings** - Educating the individual about the value of the "community" for emotional support and for which long-term support of his/her lifestyle modification will continue.

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<sup>1</sup> Note: Since the diet is a major component of the program and little scientific information is known about the effects of a very-low fat vegetarian diet on elderly Medicare beneficiaries, the case manager should make sure that each medical record is annotated for all negative effects (e.g. fatigue, bowel disturbances, dehydration, rise in triglycerides (LDLs), deterioration in cognitive functioning, etc.) as well as positive ones (e.g., weight loss, lower triglycerides, decrease in sugar levels, etc.)

<sup>2</sup> Note: During the aerobic exercise portion, the sites must comply with the requirements of the November 10, 1985 ECG (telemetry) monitoring guidelines approved by the American College of Cardiology. (JACC, Vol. 7, No2, February 1986: 451-3)

<sup>3</sup> Note: This number is based on the class size recommended by the Dr. Ornish's Program and what has traditionally been done at the sites since 1993.

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## Appendix A

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**DRAFT****A. The Three-Stage Lifestyle Modification Program**

The 12-month program is broken into three distinct stages, one stage building upon the other in informational content. The site has an option of providing a 1.5 to 2 day non-residential retreat prior to the first class of the 12-week Stage I program. If there is no retreat, the site will include the information in the first week of the Stage I. If the site conducts a "retreat", the location must be accessible to all Medicare participants.

All participating Dr. Ornish's Program sites must comply with the provisions of the Americans with Disabilities Act (ADA) and provide a signer for beneficiaries with hearing difficulties. Books, manual, all written and visual materials must be provided in large print for those with visual acuity impairments. Due to the advanced age of some Medicare beneficiaries, and the physical problems many of them experience, the site must provide the appropriate accommodations as required by the ADA (e.g, bathrooms with railings etc).

The program delivered to Medicare beneficiaries should follow the Dr. Ornish's three-stage design and include personal risk stratification. The stages are of the program are:

1. Stage I - Intensive Phase - First 12 weeks of the program. This will include the four parts of the Core Program plus a dining together component (i.e., lunch or dinner).

At a minimum, the site will provide the core elements per the following schedule:

- a. Week one: three, four-hour sessions to introduce the participants to all of the program components, program expectations and the concept of group support from which the long-term adherence to this program will be drawn. Each session shall include: One hour each of exercise, stress management, group support, a prepared meal/and lecture.
- b. Weeks two through eleven: two, four-hour sessions to build upon the information in week one with advancing techniques to reinforce the information learned in preceding weeks. Each session shall include: one hour each of exercise, stress management, group support, a prepared meal/and lecture.

During this period, each participating site shall provide the beneficiary with at least one - one on one appointment with the dietitian, and weekly check-ins by the case manager and all of the modality specialists to assist the beneficiary with making appropriate lifestyle choices.

- c. Week twelve: three four-hour sessions to prepare the participant for the second stage of the program which has less intensity (i.e., the risk stratification portion which builds on the skills of the intensive portion.) and places more responsibility on the individual. This week will provide a mix of core services, including lectures and dining together

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necessary to prepare the participant for entry into Phase II. Each service must be at least one hour in duration in the final week of the intensive phase.

2. **Stage II - Risk Stratification Phase** - The site's team will refer participants to the appropriate level for this portion of the program after completion of Stage I (the 12-week intensive). This referral will be based on an evaluation of the medical risk level of the individual and his/her degree of adherence to lifestyle change guidelines as observed and documented by the program staff in Stage I.

The case manager, with advice from the team members, should refer a participant to the most appropriate level, either up or down, based on the individual's documented clinical and behavioral risk factors at anytime during this Stage of the program. The levels of stratification and the services provided under each one are as follow:

- a. **Stage II A (Low Risk)**: 12 weeks of two-hour, weekly sessions consisting of stress management and group support (one hour of each).

Or

- b. **Stage II B (Moderate Risk)**: 24 weeks of two-hour, weekly sessions consisting of one hour each of stress management and group support.

Or

- c. **Stage II C (High Risk)**: 40 weeks of four-hour, weekly sessions of stress management, group support, exercise, ongoing education and a meal (one hour of each component per session).

During all weeks of Stage II participation, the staff will maintain full medical documentation as well as documentation that indicates the reason for placing the beneficiary in a particular risk level and the resulting patient outcomes - both physically and emotionally. The records should also note if any referrals were made to a clinician for psychological intervention(s) should the participant have difficulties relating to the requirements of a particular level. The case manager must continuously inform the participant of his/her progress and provide the rationale for placement in a particular level of risk stratification.

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At the completion of the Stage II Program Services, the participant will receive a final evaluation from the Registered Nurse/Case Manager, and will be discharged to enter Stage III (and the Self-Directed Community).<sup>4</sup>

3. **Stage III and the Self-Directed Community:** Depending on the level of risk stratification, the participant should be assigned to this level anytime from the 25th week to the end of the year-long program. During this final Stage, participants will receive one two-hour session per week, with an hour each of stress management and group support for the duration of the Program. Each site will provide a closing event or "graduation" night that includes a dining together and a certificate of successful completion of the program.

The program will ensure that the participant understands that when they complete the supervised year long program, he/she will continue with the lifestyle modification via the self-directed community and the support group. The case manager will provide the participant with the information necessary to locate program and community resources to continue the lifestyle modification program in the participant's community.

**B. Staffing Levels**

For purposes of the demonstration, the site must maintain a staff consisting of all of the personnel suggested by PMRI in the Appendix of its Staff Operations Manual. Since the safety and welfare of our beneficiaries is of prime concern, HCFA believes this staffing level is essential to provide for the administrative needs of the site and the provision of the services for Medicare participants.

The staffing requirements are:

1. **Program Director - Educational Background:** The individual must have a background in business/ administrative or medical/administrative duties and must have an educational/work background appropriate for the position (i.e., working in/managing cardiac rehab programs).

Program responsibilities include:

- Orientating team members to the program and arranging training with PMRI as necessary,
- Maintaining the professional certification and licensure of staff as appropriate.

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<sup>4</sup> Note: The site must ensure that any and all patient documentation for the demonstration is treated as part of the medical record and as such the same privacy rules apply. This information, however, will be made available to the appropriate HCFA staff and its contractors for quality monitoring review and medical review. The information will also be made available for purposes of an overall evaluation of the outcomes of the demonstration.

2. **Medical Director - Educational background:** This individual must be State licensed and board certified in Internal medicine or Family medicine (sub-specialty certification in cardiology preferred). Note: The site must have a board certified cardiologist (meeting State licensure requirements) present on site during the aerobic exercise sessions.

Program responsibilities include:

- Reviewing and screening all candidate medical records for clinical appropriateness and the need for additional medical information.
- Providing medical consultation to the clinical team.
- Reviewing medical testing with participants at testing intervals.
- Maintaining visibility to the participants throughout program involvement.

3. **Administrative Assistant - Educational Background:** No specific educational requirements. This individual must have excellent interpersonal and telephone skills and understand Dr. Ornish's Program for Reversing Heart Disease in order to provide information to Medicare beneficiaries who inquire about the program.

Program responsibilities include:

- Providing initial program screening using the initial inquiry questionnaire. (For purposes of the demonstration, this individual must also record if the inquirer is an elderly Medicare beneficiary and where he or she heard or read about the demonstration.)
- Assisting with the collection and storage of data, and with the billing, reimbursement and insurance protocols. This individual will have responsibility for providing HCFA's OFM/DMB with the Medicare beneficiary enrollment and termination information in order to start and stop payments on a timely basis.
- Sending a list of the beneficiaries' names and Medicare claim numbers to HCFA's OFM/DMB upon the beneficiaries' successful completion of the program.

4. **Registered Dietitian - Educational Background:** This individual must have licensure (national) as a Registered Dietitian (R.D.) or be R.D.E. (eligible).

Program responsibilities include:

- Conducting nutritional analyses or assessments on each participant as necessary. Conducting one on one assessments and monitoring adherence problems.
- Answering questions from participants during meals or exercise classes to determine adherence to the diet.
- Reviewing the food diaries and food records for completeness.
- Assisting the staff during the preliminary screening process.
- Identifying individuals with food allergies and making the necessary adjustments with food service and with the participant's daily food plan and.

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- Identifying and counseling participants who may need therapeutic adjustments to the eating plan.
  - Presenting food lectures and providing educational materials at the intensives and throughout the program.
  - Providing detailed information concerning positive and negative effects of the diet and documenting the adjustments or recommendations made to ensure the safety of Medicare participants who have unfavorable reactions to the diet (e.g., dehydration, bowel disorders rising triglyceride levels).
5. **Stress Management/Yoga Consultant - Educational Background:** The individual should have certification from a school with a traditional hatha yoga teacher training program (i.e., a 200- hour program at the basic certificate level) and should maintain basic life support, CPR certification. The teacher should have a minimum of three years experience with the general population and should have practical experience working with a special needs population, particularly the aged and the cardiac patient.

**Program responsibilities include:**

- Leading the one-hour stress management/yoga/relaxation groups as required by the program.
  - Monitoring stress management adherence (i.e., checking on the individual's daily practice).
  - Providing stress management counseling on an individual basis as needed.
  - Preparing and providing the one-hour yoga audiotape needed for home practice.
6. **Food Service Provider - Educational Background:** Certification from a cooking school or 5 years apprenticeship at a restaurant or with a caterer. Must have experience in cooking low-fat vegetarian meals without added oils. This individual will work closely with the nutrition educator to ensure the food provided meets the nutritional requirements of elderly participants. It is also recommended that this person be certified in CPR.

**Program responsibilities include:**

- Providing:
    - a. 10% low-fat vegetarian recipes and menus that participants can use at home.
    - b. Meals at the dining together that take into consideration any special dietary needs of elderly Medicare participants, and
    - c. Dietary information to participants via cooking demonstrations.
  - Monitoring meal acceptance and providing options when needed.
7. **Group Leader ( Psychologist, Psychiatrist or Social Worker) -Educational Background:** State licensure and experience working with groups. This individual should also have experience working with lifestyle change issues in an aging population and with cardiac patients or those confronting chronic illness.

**DRAFT**

Program responsibilities include:

- Screening candidates and evaluating questionnaires for Dr. Ornish's Program during the patient evaluation process.
- Providing support for individuals working on integrating lifestyle change into their everyday life, and individual and couples counseling as necessary.
- Educating the participants on communication skills, lifestyle changes and stress related topics.
- Facilitating the support groups.

8. **Exercise Physiologist - Educational background:** This individual must have a masters level exercise physiologist with ACSM certification (minimum Exercise Technologist, preferably Exercise Specialist and a minimum of two years of cardiac rehabilitation experience, and meet State Licensure requirements. For purposes of this demonstration, this person must have current certification in Basic Life Support (BLS) or, preferably, Advanced Cardiac Life Support (ACLS).

Program responsibilities include:

- Organizing, supervising and delivering the exercise portion of the Program.
- Performing body composition/BMI assessments as per protocol.
- Providing individual exercise prescriptions based on ACSM guidelines for each participant.
- Updating the exercise prescriptions after each graded exercise test or as necessary.
- Maintaining patient and Program exercise data.
- Monitoring adherence for all participants and providing counseling on an individual basis as needed throughout the program.
- Lecturing the participants on exercise related topics.

9. **Registered Nurse/Case Manager - Educational Background:** Registered nurse with current licensure from the State board of nursing. Formal education should include training in cardiac rehabilitation and/or exercise physiology. The individual should have a minimum of two years clinical experience in adult cardiovascular nursing and/or cardiac rehabilitation and should have a current certification in Advanced Cardiac Life Support (ACLS).

Program responsibilities include:

- Assisting with the recruitment process of potential participants and guiding the potential candidates through the screening process.
- Reviewing the medical records of potential participants for medical eligibility.
- Assisting the Data manager with baseline data collection during the screening process and throughout the program.
- Performing a comprehensive health assessment, including a baseline physical assessment on all participants.

**DRAFT**

- Maintaining ongoing documentation of the health status of each participant and documenting any and all changes in the record. (This documentation will also include information demonstrating that the participant was given strategies to succeed, and full documentation of why it failed and reason for termination.)

The case manager will also act as the liaison between the Program and HCFA and its contractors in providing both access to the site and to the data needed for all evaluations. Each site will provide the name and phone number of its case manager to HCFA upon agreeing to participate in the demonstration.

**C. Certification Statement**

In order to participate in the demonstration, each site will have to certify that their staffing meets the requirements set out in the licensing agreement and that their contract is valid and current at the time of participation.

**DRAFT**

**Appendix B**

**Beneficiary Notification**

**Patient Consent Form**

**Disenrollment Form**

**Physician Certification of Enrollment Eligibility**

DRAFT

**Beneficiary Notification Letter**

[Administrator's letterhead]

Dear Medicare Beneficiary:

The Health Care Financing Administration (HCFA) is the Federal agency that administers the Medicare program. In order to ensure Medicare beneficiaries receive the best quality care in the most efficient way possible, HCFA sometimes sponsors demonstration studies. These studies help us learn more about the health care and Medicare benefits you receive.

Dr. Dean Ornish has asked us to consider including his program called "Reversing Heart Disease<sup>®</sup>" as a service covered under Medicare. We are allowing the program this opportunity to prove to HCFA that this program is medically safe and cost effective for Medicare beneficiaries with heart disease. The Medicare Lifestyle Modification Program Demonstration has been implemented for this purpose.

**You do not have to participate in this demonstration study. Your decision will have no effect on your Medicare benefits. All information you and the other participants provide is strictly confidential and protected under Federal law by the Privacy Act.**

If you have any questions about the Medicare Lifestyle Modification Program Demonstration, please contact Dr. Armen Thounaian of my staff at 410-786-6672. Thank you for your cooperation.

Sincerely,

Nancy-Ann Min DeParle  
Administrator

DRAFT

(HCFA LOGO HERE)

**Beneficiary Participant Informed Consent Form**

Name of Medicare Beneficiary: (please print)

I understand that the Health Care Financing Administration (HCFA) is supporting a demonstration study called the Medicare Lifestyle Modification Program demonstration offering "Dr. Ornish's Program for Reversing Heart Disease®."

I understand that I do not have to participate in this study, and that my decision will have *no* effect on my Medicare benefits. HCFA is investigating Lifestyle Modification programs as an additional service covered under Medicare. However, I understand that there is no evidence that programs such as this are both medically safe and cost effective for Medicare beneficiaries with heart disease.

If I elect to participate in the Medicare Lifestyle Modification Demonstration, I understand that I *may* be required to pay a fee of up to 20% of the total cost that Medicare has agreed to pay the demonstration site for services provided.

I understand that the program will ask me personal questions about my lifestyle and my medical history. I understand that the program is for people with a heart disease who meet certain criteria. I have talked with my personal doctor about other available treatments for my heart condition. My personal doctor recommends my participation in this program.

I understand that the program will have a State-licensed physician named Dr. \_\_\_\_\_ as part of their staff. However, Dr. Ornish's program involves a very low fat vegetarian diet, moderate aerobic exercise, stress management, group support, and other lifestyle changes that may not be safe for everyone.

I have read the program materials and understand all the health and financial risks involved as identified in "Dr. Ornish's Program for Reversing Heart Disease®". For example, Dr. Ornish warns you may experience changes in your blood pressure, heart rate, ineffective heart function, heart attack, weight loss, gall stone formation, physical injury, and/or emotional upheaval.

I understand that "Dr. Ornish's Program for Reversing Heart Disease®" also claims potential benefits if participants follow the program guidelines. These benefits may include reducing episodes of chest pain, reducing cholesterol levels, weight loss, generally feeling better, and reducing blocked arteries.

I understand that HCFA will also be monitoring the program through its own "medical review" process, commonly used to ensure the safety and quality of care for Medicare beneficiaries.

DRAFT

I have discussed with my physician any and all possible risks to me if I should choose to participate in a program which involves a very low fat vegetarian diet, moderate aerobic exercise, stress management, group support, and other lifestyle changes.

I understand that all the information I provide is strictly confidential and protected under Federal law by the Privacy Act. I also understand that this information will be shared with HCFA in order to evaluate "Dr. Ornish's Program for Reversing Heart Disease®" for Medicare purposes. I also understand that HCFA may contact me to ask questions about my experience with the program.

I understand that this is a one year long (twelve months) program, but that I have the right at any time, to notify the program if I am not able or willing to continue with "Dr. Ornish's Program for Reversing Heart Disease®." I have been given a copy of the "Beneficiary Disenrollment Form" in case I do chose to discontinue my participation. I also understand that using the form is not required, but is recommended for documentation purposes and to submit suggestions for the demonstration program.

I understand that I may telephone the project officer for the Medicare demonstration, Dr. Armen Thounaian at 410-786-6672 if I have any questions about my participation in Dr. Dean Ornish Program for Reversing Heart Disease® and the Medicare demonstration project.

No one has forced, pressured, paid, or coerced me into volunteering to participate in this program. No benefits will be taken from me, nor will I be dropped from the Medicare program if I should at any time, choose not to participate in this demonstration project. I understand all of the information above and agree to participate.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Witness: \_\_\_\_\_ Date: \_\_\_\_\_

Location of site: \_\_\_\_\_

DRAFT

( HCFA LOGO HERE)

**Beneficiary Disenrollment Form**

I understand that this is a one year long (twelve months) program that started on \_\_\_\_\_ (month / day / year).

I am exercising my right to notify the program that I am — (please check one):

\_\_\_ *not able* to continue with "Dr. Ornish's Program for Reversing Heart Disease®."

\_\_\_ *not willing* to continue with "Dr. Ornish's Program for Reversing Heart Disease®."

Please tell us in your own words why you have decided to drop out of the "Dr. Ornish's Program for Reversing Heart Disease®" before the year is over:

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I understand that the Health Care Financing Administration (HCFA) would like to know why I am no longer able or willing to participate in the study, and that someone from the Medicare program may phone me to ask why I decided to discontinue "Dr. Ornish's Program for Reversing Heart Disease®" and the Medicare demonstration.

Name of Medicare Beneficiary: (please print):

\_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Telephone Number: ( ) \_\_\_\_\_

Witness: \_\_\_\_\_ Date: \_\_\_\_\_

Location of site: \_\_\_\_\_

**Medicare Lifestyle Modification Program Demonstration  
Dr. Ornish's Program for Reversing Heart Disease®**

**Physician Certification of Enrollment Eligibility**

I certify that I have discussed the requirements of the Dr. Ornish's Program for Reversing Heart Disease® with the Medicare beneficiary named below and conducted a physical examination and/or reviewed the clinical information submitted about the beneficiary to determine his/her eligibility for enrollment in the Program in accordance with the clinical requirements specified for enrollment. I further certify that I have found that the beneficiary:

\_\_\_\_\_ Meets the clinical eligibility requirements to participate in the Medicare Lifestyle Modification Program demonstration.

\_\_\_\_\_ Does not meet the eligibility requirements to participate in the Medicare Lifestyle Modification Program demonstration.

Date of eligibility determination \_\_\_\_\_

Name of Medicare Beneficiary: \_\_\_\_\_

Name of Physician making certification \_\_\_\_\_

Signature of Physician making certification \_\_\_\_\_ DATE \_\_\_\_\_

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**Note:** Anyone who misrepresents, falsifies, or conceals essential information required for payment of Federal funds may be subject to fine, imprisonment, or civil penalty under applicable Federal laws.

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## **Appendix C**

### **Payment Process**

#### **Medicare Lifestyle Modification Program Demonstration**

1. Before the payment process can begin, each provider must FAX their financial information to the Demonstrations Management Branch (DMB), HCFA (see Attachment A).
2. Providers are encouraged to FAX a list of potential Medicare enrollees for the Demonstration to DMB to verify Medicare entitlement (see Attachment B). DMB will verify entitlement within 1 day and FAX the list back to the providers.
3. Providers will FAX to DMB their enrollment list including the program start and end dates (see Attachment C).
4. Providers must immediately notify DMB by FAX of any disenrollments (see Attachment D). If a beneficiary disenrolls for any reason during the program, the termination date will be effective the end of the month that the disenrollment occurred. DMB will recoup a monthly percentage from the quarterly payment that was made. If the beneficiary fails to complete the entire program, HCFA reserves the right to recoup the last month's payment percentage.
5. DMB will process the data received from the providers. The quarterly payment cycle and rates (35%, 15%, 15%, and 35% of the bundled payment) will start the beginning of the month that each program begins. If enrollment data are received in DMB by the end of the month, a check should be deposited in the provider's account by the 10th of the following month. DMB will continue to make the quarterly payments for each beneficiary for 1 year or until notification of a disenrollment or Medicare ineligibility. (See Attachment E for an illustration of the payment and recoupment process.)

Attachment A

Required Payment Information

The information concerning your financial institution should be available through your agency's treasurer or financial institution. A contact person and phone number at your financial institution are important for verification purposes. Your financial institution can assist you in providing the routing number. The numbers in parentheses indicate the maximum number of positions for a particular field. Not all fields have a restricted length. Please complete all items listed and FAX to the number shown below:

Provider Information - Name and address of provider (payee):

Name (35) \_\_\_\_\_  
Address Line 1 **Medicare Lifestyle Modification Program Demonstration**  
Address Line 2 (35) \_\_\_\_\_  
Address Line 3 (30) \_\_\_\_\_  
City (20) \_\_\_\_\_ State (2) \_\_ Zip Code (5) \_\_\_\_\_

Tax ID Number (EIN) (9) \_\_\_\_\_ Provider Phone Number: ( ) \_\_\_\_\_

Financial Information - Name and address of financial institution:

Name \_\_\_\_\_  
Address \_\_\_\_\_  
City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_  
Account Number at your financial institution to be credited with the funds: \_\_\_\_\_ Type of  
Account (Circle One): CHECKING SAVINGS  
Financial Institution's Routing Number (9) \_\_\_\_\_  
Phone Number: ( ) \_\_\_\_\_

Contact Person: \_\_\_\_\_

\_\_\_\_\_  
person completing this information Phone Number Date Signature/Title of

**FAX to: HCFA, Demonstrations Management Branch, 410-786-3027**

Draft: rev. 6/16/99

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**Attachment B**  
**Inquiry for Medicare Eligibility**  
**for Medicare Lifestyle Modification Program Demonstration**

**FAX to: HCFA, Demonstrations Management Branch, 410-786-3027**

Date Requested: \_\_\_\_\_

Provider Name: \_\_\_\_\_ Requestor's Name: \_\_\_\_\_ Phone No. \_\_\_\_\_

State: \_\_\_\_\_ Provider ID: LMP \_\_\_\_\_ FAX No. \_\_\_\_\_

| Medicare Claim No. | Last Name | First Name | MI | Sex | Birth Date | HCFA Use Only |
|--------------------|-----------|------------|----|-----|------------|---------------|
|                    |           |            |    |     |            |               |
|                    |           |            |    |     |            |               |
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Draft rev. 6/16/99

**Attachment C**  
**ENROLLMENT FORM**  
**for Medicare Lifestyle Modification Program Demonstration**

**FAX to: HCFA, Demonstrations Management Branch, 410-786-3027**

Provider Name: \_\_\_\_\_ Provider ID: LMP \_\_\_\_\_

Address: \_\_\_\_\_ Telephone # \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP \_\_\_\_\_ FAX # \_\_\_\_\_

Program Enrollment Date: \_\_\_\_\_

Program End Date: \_\_\_\_\_

| Medicare Claim No. | Last Name | First Name | Sex | Birth Date |
|--------------------|-----------|------------|-----|------------|
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|                    |           |            |     |            |

Signature of Provider/Authorized Representative

Date

Patient Signatures on File

Draft: rev. 6/16/99

**Attachment D**  
**DISENROLLMENT FORM**  
**for Medicare Lifestyle Modification Program Demonstration**

**FAX to: HCFA, Demonstrations Management Branch, 410-786-3027**

Provider Name: \_\_\_\_\_ Provider ID: LMP \_\_\_\_\_

Address: \_\_\_\_\_ Telephone # \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP \_\_\_\_\_ FAX # \_\_\_\_\_

| Medicare Claim No. | Last Name | First Name | Enrollment Date | Disenrollment Date/Reason |
|--------------------|-----------|------------|-----------------|---------------------------|
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|                    |           |            |                 |                           |

\_\_\_\_\_  
Signature of Provider/Authorized Representative  
Draft: rev. 6/16/99

\_\_\_\_\_  
Date

## Attachment E

### Illustration of the Payment and Recoupment Process

Illustration of Payment Process  
for Medicare Lifestyle Modification Program Demonstration

Attachment E

|                                  |                                | PAYMENTS/RECOUPMENTS |         |         |               |        |        |               |     |     |               |         |         |         |            |
|----------------------------------|--------------------------------|----------------------|---------|---------|---------------|--------|--------|---------------|-----|-----|---------------|---------|---------|---------|------------|
| Bundled Pymt                     | Qtrly Pymts                    | 1st Qtr (35%)        |         |         | 2nd Qtr (15%) |        |        | 3rd Qtr (15%) |     |     | 4th Qtr (35%) |         |         | Total   | Reimbursed |
| \$1,000                          | Mthly Rcpts                    | 15%                  | 10%     | 10%     | 5%            | 5%     | 5%     | 5%            | 5%  | 5%  | 10%           | 10%     | 15%     |         |            |
| Beneficiary                      | Program                        | 9/1                  | 10/1    | 11/1    | 12/1          | 1/1    | 2/1    | 3/1           | 4/1 | 5/1 | 6/1           | 7/1     | 8/1-End |         |            |
| John Doe 1<br>000-00-0000A       | Start: 9/1/99<br>End: 8/31/00  | \$350                |         |         | \$150         |        |        | \$150         |     |     | \$350         |         |         | \$1,000 |            |
| Completed                        |                                |                      |         |         |               |        |        |               |     |     |               |         |         | \$0     | \$1,000    |
| John Doe 2<br>000-00-0000B       | Start: 9/1/99<br>End: 8/31/00  | \$350                |         |         |               |        |        |               |     |     |               |         |         | \$350   |            |
| Disenrolled: 8/31/99 (Pt B Term) |                                | (\$150)              | (\$100) | (\$100) |               |        |        |               |     |     |               |         |         | (\$350) | \$0        |
| John Doe 3<br>000-00-0000C1      | Start: 9/1/99<br>End: 8/31/00  | \$350                |         |         |               |        |        |               |     |     |               |         |         | \$350   |            |
| Disenrolled: 9/17/99 (withdrew)  |                                |                      | (\$100) | (\$100) |               |        |        |               |     |     |               |         |         | (\$200) | \$150      |
| John Doe 4<br>000-00-0000D       | Start: 9/15/99<br>End: 9/14/00 | \$350                |         |         |               |        |        |               |     |     |               |         |         | \$350   |            |
| Disenrolled: 10/5/99 (died)      |                                |                      |         | (\$100) |               |        |        |               |     |     |               |         |         | (\$100) | \$250      |
| John Doe 5<br>000-00-0000C2      | Start: 9/15/99<br>End: 9/14/00 | \$350                |         |         | \$150         |        |        |               |     |     |               |         |         | \$500   |            |
| Disenrolled: 11/30/99 (moved)    |                                |                      |         |         | (\$50)        | (\$50) | (\$50) |               |     |     |               |         |         | (\$150) | \$350      |
| John Doe 6<br>000-00-0000A       | Start: 9/15/99<br>End: 9/14/00 | \$350                |         |         | \$150         |        |        | \$150         |     |     | \$350         |         |         | \$1,000 |            |
| Disenrolled: 8/27/00 (hospice)   |                                |                      |         |         |               |        |        |               |     |     |               | (\$100) | (\$150) | (\$250) | \$750      |
| John Doe 7<br>000-00-0000B       | Start: 9/30/99<br>End: 9/29/00 | \$350                |         |         | \$150         |        |        | \$150         |     |     | \$350         |         |         | \$1,000 |            |
| Disenrolled: 9/2/00 (incomplete) |                                |                      |         |         |               |        |        |               |     |     |               |         | (\$150) | (\$150) | \$850      |

TOTAL P. 30

DRAFT: rev. 6/18/99

JUN-23-99 11:29 FROM: Preventive Medicine

ID: 4153325730

PAGE 30/30

# Withdrawal/Redaction Marker

## Clinton Library

| DOCUMENT NO.<br>AND TYPE | SUBJECT/TITLE                                                     | DATE       | RESTRICTION |
|--------------------------|-------------------------------------------------------------------|------------|-------------|
| 001. letter              | Dean Ornish to Chris Jennings re: phone number (partial) (1 page) | 06/23/1999 | P6/b(6)     |

### COLLECTION:

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Domestic Policy Council  
Devorah Adler  
OA/Box Number: 20463

### FOLDER TITLE:

Dean Ornish [Folder 1]

2012-0463-S

rc738

### 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]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

#### Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

CONFIDENTIAL FROM PREVENTIVE MEDICINE 1014155325730 PAGE 2/1

# 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  
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900 Bridgeway, Suite 1, Sausalito, California 94965  
phone: 415/332-2525 x222; FAX: 415/332-5730  
e-mail: DeanOrnish@aol.com

June 23, 1999

Mr. Chris Jennings  
Deputy Assistant to the President for Health Policy  
The White House  
Old Executive Office Building, Room 216  
Washington, DC 20502  
ATTENTION: Ms. Teresa Jones

Dear Chris,

I remain deeply grateful to you for your ongoing advice and support.

I will be traveling to Washington, DC to meet with Jeff Kang, M.D., and his colleagues at HCFA from 8:30-10:30 am this Friday morning. I just received the enclosed proposal from HCFA. I am delighted that they are planning to begin the demonstration project in August, and I appreciate the extraordinary efforts that everyone seems to be making.

At the same time, there are some problems with the proposal that I am hoping can be resolved in the meeting at HCFA on Friday morning. Enclosed please find a letter from Bart McCann, M.D. and Tom Ault outlining some of their concerns.

Enclosed is a statement that Congressman Rangel will be introducing into the Congressional Record. He will be sponsoring legislation to authorize HCFA to cover the program. Also enclosed is a draft of a letter that will go to members of Congress (House and Senate) inviting them to two retreats.

I know your schedule is jammed, but I would be thankful if you have time to see me for a few minutes on Friday afternoon after 2:00 p.m. It will give me a chance to debrief you on the outcome of my meeting with HCFA earlier that day. Also, on a personal note, I would enjoy seeing you. The best way to reach me is on my cellular phone at P6(b)(6) (001)

Again, thank you so much. With best wishes and warm personal regards,

Sincerely,



Dean Ornish, M.D.

PROMOTING HEALTHY HEARTS AND HEALTHY LIVES:  
DEAN ORNISH, M.D.

HON. CHARLES B. RANGEL

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, June 8, 1999*

Mr. RANGEL. Mr. Speaker, I am privileged to pay tribute to Dr. Dean Ornish, a man who has dedicated his career to building healthier lives. Dr. Ornish is considered by many as the leading authority on the effects of diet and lifestyle on health and well-being. His groundbreaking research has resulted in the discovery that comprehensive changes in diet and lifestyle can reverse even severe coronary heart disease without drugs or surgery. Dr. Ornish has produced valuable research that can empower individuals and build healthier communities. He is a talented, dedicated researcher whose work must not go unappreciated or unnoticed.

Dr. Ornish is the founder, president and director of the non-profit Preventive Medicine Research Institute in Sausalito, California, where he holds the Bucksbaum Chair. He is Clinical Professor of Medicine at the University of California, San Francisco, and a founder of the Center for Integrative Medicine at the university. Dr. Ornish received an M.D. from Baylor College of Medicine, was a clinical fellow in medicine at Harvard Medical School and completed his internship and residency in internal medicine at the Massachusetts General Hospital in Boston.

Dr. Ornish is the author of five best-selling books, including *New York Times* bestsellers: *Dr. Dean Ornish's Program for Reversing Heart Disease*; *Eat More, Weigh Less*; and *Love & Survival*. His research and writings have been published in the *Journal of the American Medical Association*, *The Lancet*, *Circulation*, *The New England Journal of Medicine*, *the American Journal of Cardiology*, and elsewhere. A one-hour documentary of his work was broadcast on NOVA, the PBS science series, and was featured on Bill Moyers' PBS series, "Healing & The Mind". His work has been featured in virtually all major media; he was on the cover of the March 16, 1998, issue of *Newsweek* magazine.

JUN-25-85 11:12 FROM: Preventive Medicine ID: 4153325730

Dr. Ornish has received several awards, including the 1996 Beckmann Medal from the German Society for Prevention and Rehabilitation of Cardiovascular Diseases, the U.S. Army Surgeon General Medal, and the 1994 Outstanding Young Alumnus Award from the University of Texas, Austin. He is listed in the *Dictionary of International Biography*, *Who's Who in America*, and in *Men of Achievement*. He was recognized as one of the most interesting people of 1995 by *People* magazine and by *LIFE* Magazine as one of the 50 most influential members of his generation.

Mr. Speaker, I have great admiration for Dr. Dean Ornish. He is truly a remarkable individual whose outstanding research and effective programs have improved the overall quality of life for many people. His proven research on behavior modification has the potential to revolutionize the way modern medicine approaches heart disease. Dr. Ornish's promotion of healthy hearts and healthy lives is an inspiration for all Americans.

June 21, 1999

**JOIN US FOR A BIPARTISAN CONGRESSIONAL RETREAT TO  
BUILD HEALTHY HEARTS AND HEALTHY LIVES**

Dear Colleague:

We are writing to invite you to participate in a special bipartisan Congressional retreat led by Dean Ornish, M.D. Interested members of the House of Representatives and their spouses or significant others will be given the opportunity to attend a retreat designed to provide education about diet and lifestyle. To encourage maximum participation, Members will be given the option of attending either a weeklong Congressional retreat, to be held August 29 through September 4 in California, or a two day Congressional retreat, to be held October 22-23 in Washington, D.C.

This is a rare opportunity. Dr. Dean Ornish is considered by many to be the leading authority on the effects of diet and lifestyle on health and well-being. For the past 22 years, Dr. Ornish has directed a series of clinical studies demonstrating--for the first time ever--that the progression of even severe coronary heart disease often may be reversed by making comprehensive changes in diet and lifestyle. These lifestyle changes include a low-fat diet, stress management techniques, moderate exercise, smoking cessation, and psychosocial support.

Dr. Ornish's research has focused on reversing heart disease as a model for demonstrating the power of comprehensive lifestyle changes, but these benefits extend to anyone interested in improving their health and well-being. The purpose of this retreat is to give you both the scientifically-based information you need to make lifestyle changes and the direct experience of how powerful and quickly these improvements can occur. By the end of the week, most people report feeling so much better, so quickly, that it shifts their reason for changing lifestyle from fear of dying to joy of living.

In Dr. Ornish's studies, cholesterol levels fell an average of 40%, weight decreased by 25 pounds, and most people reported having more energy, enhanced awareness, thinking more clearly, and an overall improved sense of inner peace, joy, and well-being.

Dr. Ornish and his colleagues are donating their time and expenses, so this retreat is offered at no cost to you other than direct expenses of travel. The week-long

session will be held at the world-class Claremont Resort in Berkely, California. The two-day session will be held at a conference center (to be announced) in the D.C. area. Gourmet low-fat, low-cholesterol meals will be provided by Jean-Marc Fullsack, a gifted chef formerly of Lutece in New York and the California Culinary Academy in San Francisco.

You know how difficult our jobs can be. With all the competing demands on our time, our own health may not be a priority. When we take care of ourselves, we can better serve our families and constituents while setting a good health example.

We have attached Dr. Ornish's biographical information for your information. If you are interested in attending the week long session, call Maya Rockeymoore at X54365. For more information about the two day session, call Beth Clay at X55074.

Please join us for a fun and perhaps life-transforming experience.

Sincerely,

Charles B. Rangel  
Member of Congress

Dan Burton  
Member of Congress



**Health  
Policy  
Alternatives, Inc.**

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Principals

John H. Ferman  
Richard A. Lauderbaugh, J.D.  
Thomas A. Ault  
Julia A. James  
Barton C. McCann, M.D.  
Beth C. Fuchs, Ph.D.

June 17, 1999

Dean Ornish, M.D.  
President and Director  
Preventive Medicine Research Institute  
Suite 2  
900 Bridgeway  
Sausalito, California 94965

Dear Dr. Ornish:

We have completed our preliminary cost analysis of the HCFA demonstration project that will evaluate the Preventive Medicine Research Institute (PMRI) Program for providing lifestyle changes as a direct alternative for patients who otherwise would receive coronary bypass surgery or coronary angioplasty.

With the assistance of your staff, we obtained detailed information from each of eleven sites that are expected to participate in the demonstration project. The information we attempted to collect included: 1) direct costs, such as staff salaries, supplies and equipment; 2) indirect costs, such as rent, phones, utilities and insurance; 3) structure and duration of the Program; and, 4) charges.

We noted considerable variation in the structure and duration of the Program at the different sites. This turned out to be due to the fact that most of the sites stratify patients according to risk. Patients at lower risk receive less intense services than patients at higher risk. This clinically appropriate variation in Program structure and content made analysis difficult because many of the sites have not established charges or allocated costs in a manner that corresponds to the clinical stratification they employ.

We also noted that most of the sites do not have a clear picture of their overhead costs. While some pay rent to the hospital and others share costs and space with other programs, most were simply unable to provide us with specific information.

We concluded that the most appropriate way to analyze costs - until such time as actual cost data can be collected as part of the demonstration - would be to apply the average direct salary costs (obtained from each of the sites) to the time required to perform the specific tasks that are required of the key personnel in both stages of the Program. Our analysis focused on the services that will be provided to the Medicare patients in the demonstration project. Because these patients are considered to be at higher risk, they will complete Stage I and Stage IIC, which is the most intense Program. The duration of Stage I is 12 weeks. There are 3 sessions/week for the first week and 2 sessions/week for the second through twelfth weeks. There are 25 total sessions and all sessions are 4 hours long. Each patient spends 100 total hours in Stage I. The duration of Stage IIC is 40 weeks. There is 1 session/week for each week for a total of 40 sessions. All sessions are 4 hours long. Each patient spends 160 total hours in Stage II.

Attached is a one page summary titled "Analysis of Total Per Patient Costs." It lists the key personnel and their average wage rates from our survey of the sites. We assumed there would be 15 patients in each cohort. The hours per cohort were derived from the information we received from the survey supplemented by information we received from members of your staff who are knowledgeable about the content of the Program. Details about the tasks performed and the time required to perform them are included in the enclosed spreadsheet titled "Analysis of Tasks, Time and Costs by Stage and Modality." The following additional assumptions were made:

- To allocate the annual (2,080 hours per year) salaries of the Program Director and the Administrative Support we needed to make an assumption about the number of patients that would receive services in one year. We decided to assume that all the facilities would be at their mature patient load (135 patients) for the purpose of rate setting.
- We did not include any costs for the data manager under the "additional direct labor" because we assumed these costs would be covered through HCFA's payments to a data coordinating center. If that is not correct, the costs of this staff type will need to be added to the table.
- We used 50 percent for the overhead rate.
- We calculated fringe benefits at 20 percent of the direct labor costs.
- We included the \$50,000 annual maintenance fee and allocated it

over 135 patients. This fee is consistent with the current fees for new sites. Although some of the existing sites are paying a higher fee than \$50,000, we assumed that \$50,000 was reasonable for the purpose of this analysis. We believe this fee, which covers the costs of PMRI for activities such as Program direction, oversight, training and quality assurance, would be an allowable cost by a fiscal intermediary.

You will note that the "Analysis of Total Per Patient Costs" shows the total program costs to be either \$8,978.98 or \$9,324.63. The difference relates to the concern of your staff and Health Policy Alternatives that one of the direct costs obtained through the survey was inappropriate. If you compare the column \$/hr Survey with the column \$/hr Summary, you will note that the figures are identical except for the group support facilitator. This individual should be a licensed mental health professional such as a psychiatrist or psychologist. The wage rate of \$22/hour obtained from the survey is inconsistent with the costs associated with these highly trained individuals. Through conversations with the sites, we learned that some have substituted lower cost personnel such as nurses to perform the function of group support facilitator.

We believe such a substitution is inappropriate and could potentially affect the outcome of the demonstration because group support is a critical component of the Program that cannot be facilitated by inadequately trained individuals. Therefore, we substituted a wage rate of \$36.06/hour for the surveyed rate of \$22/hour. The result is a total program cost per patient of \$9,324.63.

Based on our analysis, we conclude that most of the sites are submitting charges that are actually below their costs. We believe this has occurred for three main reasons. First, some of the sites do not seem to be aware of their actual costs and have not adjusted their charges accordingly. Second, some of the sites have kept their charges low so they will be able to continue to enroll patients. In the short term such a strategy may work, but in the long term it threatens their financial viability. Third, and of the greatest concern, is that the sites may be modifying the Program to reduce their costs in a way that could affect the outcomes of the intervention. The substitution of lower cost staff to perform the functions of the group support facilitator is a real example of this problem.

We understand that you have shared with HCFA staff your belief that a Medicare

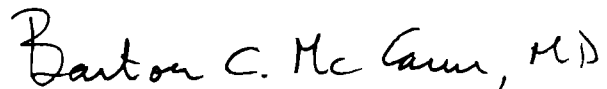
payment of less than \$7,500 per patient would be insufficient. Our analysis suggests that a fee of \$7,500 per patient will not cover the actual costs of the Program.

As you have requested, we will forward this preliminary analysis to HCFA staff.

Sincerely,



Thomas A. Ault  
Principal



Barton C. McCann, MD  
Principal

**Analysis of Total Per Patient Costs**  
**Preventive Medicine Research Institute** **HCFA Demonstration Project Cost Analysis**

|                                       | <u>\$/Hr</u><br><u>Survey</u> | <u>\$/Hr</u><br><u>Summary</u> | <u>Hrs/Cohort</u><br><u>(n=15)</u> | <u>Hrs/Patient</u> | <u>\$/Patient</u><br><u>Survey</u> | <u>\$/Patient</u><br><u>Summary</u> |
|---------------------------------------|-------------------------------|--------------------------------|------------------------------------|--------------------|------------------------------------|-------------------------------------|
| <b>Direct Labor</b>                   |                               |                                |                                    |                    |                                    |                                     |
| <b><u>Stage I</u></b>                 |                               |                                |                                    |                    |                                    |                                     |
| Medical Director                      | \$150.00                      | \$150.00                       | 101.75                             | 6.78               | \$1,017.50                         | \$1,017.50                          |
| Registered Dietician                  | 20.00                         | 20.00                          | 195.75                             | 13.05              | 261.00                             | 261.00                              |
| Exercise Physiologist                 | 18.00                         | 18.00                          | 103.75                             | 6.92               | 124.50                             | 124.50                              |
| Nurse Case Manager                    | 22.00                         | 22.00                          | 183.00                             | 12.20              | 268.40                             | 268.40                              |
| Stress Management Specialist          | 22.00                         | 22.00                          | 98.25                              | 6.55               | 144.10                             | 144.10                              |
| Group Support Facilitator             | 22.00                         | 36.06                          | <u>104.00</u>                      | <u>6.93</u>        | <u>152.53</u>                      | <u>250.00</u>                       |
| Sub-Total Direct Labor (Stage I)      |                               |                                | 786.50                             | 52.43              | \$1,968.03                         | \$2,065.50                          |
| <b><u>Stage II</u></b>                |                               |                                |                                    |                    |                                    |                                     |
| Medical Director                      | \$150.00                      | \$150.00                       | 80.90                              | 5.39               | \$809.00                           | \$809.00                            |
| Registered Dietician                  | 20.00                         | 20.00                          | 100.90                             | 6.73               | 134.53                             | 134.53                              |
| Exercise Physiologist                 | 18.00                         | 18.00                          | 100.90                             | 6.73               | 121.08                             | 121.08                              |
| Nurse Case Manager                    | 22.00                         | 22.00                          | 299.65                             | 19.98              | 439.49                             | 439.49                              |
| Stress Management Specialist          | 22.00                         | 22.00                          | 100.20                             | 6.68               | 146.96                             | 146.96                              |
| Group Support Facilitator             | 22.00                         | 36.06                          | 100.90                             | <u>6.73</u>        | <u>147.99</u>                      | <u>242.55</u>                       |
| Sub-Total Direct Labor (Stage II)     |                               |                                | 783.45                             | 52.23              | \$1,799.05                         | \$1,893.61                          |
|                                       |                               |                                |                                    |                    |                                    |                                     |
|                                       | <u>\$/Hr</u><br><u>Survey</u> | <u>\$/Hr</u><br><u>Summary</u> | <u>Hrs/Year</u>                    | <u>Patients/Yr</u> | <u>\$/Patient</u><br><u>Survey</u> | <u>\$/Patient</u><br><u>Summary</u> |
| <b><u>Additional Direct Labor</u></b> |                               |                                |                                    |                    |                                    |                                     |
| Program Director                      | \$26.00                       | \$26.00                        | 2,080.00                           | 135.00             | \$400.59                           | \$400.59                            |
| Data Manager                          |                               |                                |                                    | 135.00             | 0.00                               | 0.00                                |
| Administrative Support                | \$12.00                       | \$12.00                        | 2,080.00                           | 135.00             | <u>184.89</u>                      | <u>184.89</u>                       |
| Sub-Total Additional Direct Labor     |                               |                                |                                    |                    | \$585.48                           | \$585.48                            |
| Total Direct Labor (Salaries)         |                               |                                |                                    |                    | \$4,352.56                         | \$4,544.59                          |
| Fringe Benefits @ 20%                 |                               |                                |                                    |                    | <u>870.51</u>                      | <u>908.92</u>                       |
| <b>Total Direct Labor</b>             |                               |                                |                                    |                    | <b>\$5,223.07</b>                  | <b>\$5,453.51</b>                   |
| <b><u>Other Direct Costs</u></b>      |                               |                                |                                    |                    |                                    |                                     |
|                                       | <u>Meal cost</u>              | <u>Meal cost</u>               | <u>Meals/Patient</u>               |                    |                                    |                                     |
| Food                                  | \$8.00                        | \$8.00                         | 62                                 |                    | \$496.00                           | \$496.00                            |
| Program Materials (\$/Patient)        |                               |                                |                                    |                    | <u>20.00</u>                       | <u>20.00</u>                        |
| <b>Total Other Direct Costs</b>       |                               |                                |                                    |                    | <b>\$516.00</b>                    | <b>\$516.00</b>                     |
| <b>Total Direct Costs</b>             |                               |                                |                                    |                    | <b>\$5,739.07</b>                  | <b>\$5,969.51</b>                   |
|                                       |                               |                                |                                    |                    |                                    |                                     |
| Genl & Admin Costs (% Of Direct)      | 50%                           | 50%                            |                                    |                    | <u>\$2,869.54</u>                  | <u>\$2,984.75</u>                   |
| <b>Sub-Total Program Costs</b>        |                               |                                |                                    |                    | <b>\$8,608.61</b>                  | <b>\$8,954.26</b>                   |
|                                       |                               |                                |                                    |                    |                                    |                                     |
| Annual Maintenance Fee (\$/Year)      | \$50,000.00                   | \$50,000.00                    |                                    | 135.00             | <u>\$370.37</u>                    | <u>\$370.37</u>                     |
| <b>Total Program Costs</b>            |                               |                                |                                    |                    | <b>\$8,978.98</b>                  | <b>\$9,324.63</b>                   |

# Analysis of Tasks, Time and Costs by Stage and Modality

Preventive Medicine Research Institute

HCFA Demonstration Project Cost Analysis

| Stage | Modality        | Tasks                                                          | Comments                                                 | Total time (hours) | Wage rate in \$/hour | Total cost |
|-------|-----------------|----------------------------------------------------------------|----------------------------------------------------------|--------------------|----------------------|------------|
| 1     | Case management | Prepare for pre-cohort planning meeting                        | Requires 1 hour                                          | 1                  | \$22.00              | \$22.00    |
| 1     | Case management | Attend pre-cohort planning meeting                             | Requires 2 hours                                         | 2                  | \$22.00              | \$44.00    |
| 1     | Case management | Review medical records                                         | Requires 0.5 hours/patient X 15 patients                 | 7.5                | \$22.00              | \$165.00   |
| 1     | Case management | Perform intake interview                                       | Requires 1 hour/patient X 15 patients                    | 15                 | \$22.00              | \$330.00   |
| 1     | Case management | Prepare summary sheets/patient profiles                        | Requires 0.5 hours/patient X 15 patients                 | 7.5                | \$22.00              | \$165.00   |
| 1     | Case management | Attend cohort case review                                      | Requires 4 hours                                         | 4                  | \$22.00              | \$88.00    |
| 1     | Case management | Deliver lectures                                               | Requires 3 lectures X 1 hour/lecture                     | 3                  | \$22.00              | \$66.00    |
| 1     | Case management | Attend modality session (assist exercise supervision)          | Requires 1.5 hours/session X 22 sessions                 | 33                 | \$22.00              | \$726.00   |
| 1     | Case management | Attend modality session (assist stress management supervision) | Requires 1 hour/session X 24 sessions                    | 24                 | \$22.00              | \$528.00   |
| 1     | Case management | Input clinical and adherence data                              | Requires 5 minutes/patient/week X 12 weeks X 15 patients | 15                 | \$22.00              | \$330.00   |
| 1     | Case management | Maintain medical records                                       | Requires 15 minutes/month X 3 months X 15 patients       | 11.25              | \$22.00              | \$247.50   |
| 1     | Case management | Maintain/monitor clinical pathway                              | Requires 0.25 hours/patient X 15 patients                | 3.75               | \$22.00              | \$82.50    |
| 1     | Case management | Participate in case conference/team meetings                   | Attend 1 meeting/week X 12 weeks X 2 hours/meeting       | 24                 | \$22.00              | \$528.00   |
| 1     | Case management | Participate in network case management conference call         | Requires 2 call X 1 hour/call                            | 2                  | \$22.00              | \$44.00    |
| 1     | Case management | Perform transition interview                                   | Requires 1 hour/patient X 15 patients                    | 15                 | \$22.00              | \$330.00   |
| 1     | Case management | Prepare letter/outcomes summary for referring physician        | Requires 0.5 hours/patient X 15 patients                 | 7.5                | \$22.00              | \$165.00   |

# Analysis of Tasks, Time and Costs by Stage and Modality

Preventive Medicine Research Institute

HCFA Demonstration Project Cost Analysis

| Stage | Modality        | Tasks                                                                  | Comments                                                    | Total time (hours) | Wage rate in \$/hour | Total cost |
|-------|-----------------|------------------------------------------------------------------------|-------------------------------------------------------------|--------------------|----------------------|------------|
| 1     | Case management | Prepare letter/summary for payers                                      | Requires 0.5 hours/patient X 15 patients                    | 7.5                | \$22.00              | \$165.00   |
| 2     | Case management | Check-in with modality specialists                                     | Requires 0.5 hours/patient/month X 9 months X 15 patients   | 67.5               | \$22.00              | \$1,485.00 |
| 2     | Case management | Attend modality session (assist exercise supervision)                  | Requires 1.5 hours/session X 1 session/week X 40 weeks      | 60                 | \$22.00              | \$1,320.00 |
| 2     | Case management | Deliver lectures                                                       | Requires 2 lectures X 1 hour/lecture                        | 2                  | \$22.00              | \$44.00    |
| 2     | Case management | Check-in with patient by telephone                                     | Requires 0.5 hours/patient/month X 9 months X 15 patients   | 67.5               | \$22.00              | \$1,485.00 |
| 2     | Case management | Perform charting/follow-up/outcomes assessment                         | Requires 7.5 minutes/patient/month X 15 patients X 9 months | 16.9               | \$22.00              | \$371.80   |
| 2     | Case management | Input clinical data                                                    | Requires 5 minutes/patient/month X 9 months X 15 patients   | 11.25              | \$22.00              | \$247.50   |
| 2     | Case management | Input adherence data                                                   | Requires 5 minutes/patient/month X 9 months X 15 patients   | 11.25              | \$22.00              | \$247.50   |
| 2     | Case management | Maintain medical records                                               | Requires 10 minutes/month X 9 months X 15 patients          | 22.5               | \$22.00              | \$495.00   |
| 2     | Case management | Maintain/monitor clinical pathway                                      | Requires 0.75 hours/patient X 15 patients                   | 11.25              | \$22.00              | \$247.50   |
| 2     | Case management | Participate in case conference/team meetings                           | Attend 1 meeting/week X 40 weeks X 0.5 hours/meeting        | 20                 | \$22.00              | \$440.00   |
| 2     | Case management | Participate in network case management conference call                 | Requires 2 calls X 1 hour/call                              | 2                  | \$22.00              | \$44.00    |
| 2     | Case management | Prepare letter/outcomes summary for referring physician at end of year | Requires 0.5 hours/patient X 15 patients                    | 7.5                | \$22.00              | \$165.00   |
| 1     | Exercise        | Attend pre-cohort planning meeting                                     | Requires 2 hours                                            | 2                  | \$18.00              | \$36.00    |
| 1     | Exercise        | Assess body composition                                                | Requires 15 minutes/patient X 15 patients                   | 3.75               | \$18.00              | \$67.50    |
| 1     | Exercise        | Review graded exercise test and prescribe exercise program             | Requires 30 minutes/patient X 15 patients                   | 7.5                | \$18.00              | \$135.00   |
| 1     | Exercise        | Attend cohort case review                                              | Requires 4 hours                                            | 4                  | \$18.00              | \$72.00    |

# Analysis of Tasks, Time and Costs by Stage and Modality

Preventive Medicine Research Institute

HCFA Demonstration Project Cost Analysis

| Stage | Modality      | Tasks                                                                             | Comments                                                    | Total time (hours) | Wage rate in \$/hour | Total cost |
|-------|---------------|-----------------------------------------------------------------------------------|-------------------------------------------------------------|--------------------|----------------------|------------|
| 1     | Exercise      | Perform weekly check-in/ assessment/ charting                                     | Requires 7.5 minutes/patient/week X 15 patients X 12 weeks  | 22.5               | \$18.00              | \$405.00   |
| 1     | Exercise      | Attend modality session (supervise exercise)                                      | Requires 1.5 hours/session X 22 sessions                    | 33                 | \$18.00              | \$594.00   |
| 1     | Exercise      | Deliver lectures                                                                  | Requires 5 lectures X 1 hour/lecture                        | 5                  | \$18.00              | \$90.00    |
| 1     | Exercise      | Participate in case conference/team meetings                                      | Attend 1 meeting/week X 12 weeks X 2 hours/meeting          | 24                 | \$18.00              | \$432.00   |
| 1     | Exercise      | Participate in network exercise conference call                                   | Requires 2 calls X 1 hour/call                              | 2                  | \$18.00              | \$36.00    |
| 2     | Exercise      | Attend modality session (supervise exercise)                                      | Requires 1.5 hours/session X 1 session/week X 40 weeks      | 60                 | \$18.00              | \$1,080.00 |
| 2     | Exercise      | Deliver lectures                                                                  | Requires 2 lectures X 1 hour/lecture                        | 2                  | \$18.00              | \$36.00    |
| 2     | Exercise      | Perform charting/follow-up/outcomes assessment                                    | Requires 7.5 minutes/patient/month X 15 patients X 9 months | 16.9               | \$18.00              | \$304.20   |
| 2     | Exercise      | Participate in case conference/team meetings                                      | Attend 1 meeting/week X 40 weeks X 0.5 hours/meeting        | 20                 | \$18.00              | \$360.00   |
| 2     | Exercise      | Participate in network exercise conference call                                   | Requires 2 calls X 1 hour/call                              | 2                  | \$18.00              | \$36.00    |
| 1     | Group support | Attend pre-cohort planning meeting                                                | Requires 2 hours                                            | 2                  | \$36.06              | \$72.12    |
| 1     | Group support | Review medical records                                                            | Requires 0.25 hours/patient X 15 patients                   | 3.75               | \$36.06              | \$135.23   |
| 1     | Group support | Review psychosocial questionnaire                                                 | Requires 8 minutes/patient X 15 patients                    | 2                  | \$36.06              | \$72.12    |
| 1     | Group support | Conduct psychosocial follow-up for potential barriers to participation in program | Requires 0.25 hours/patient X 15 patients                   | 3.75               | \$36.06              | \$135.23   |
| 1     | Group support | Attend cohort case review                                                         | Requires 4 hours                                            | 4                  | \$36.06              | \$144.24   |
| 1     | Group support | Perform weekly check-in/ assessment/ charting                                     | Requires 7.5 minutes/patient/week X 15 patients X 12 weeks  | 22.5               | \$36.06              | \$811.35   |
| 1     | Group support | Attend modality session (supervise group support session)                         | Requires 1.5 hours/session X 24 sessions                    | 36                 | \$36.06              | \$1,298.16 |
| 1     | Group support | Deliver lectures                                                                  | Requires 4 lectures X 1 hour/lecture                        | 4                  | \$36.06              | \$144.24   |

**Analysis of Tasks, Time and Costs by Stage and Modality**

**Preventive Medicine Research Institute**

**HCFA Demonstration Project Cost Analysis**

| <b>Stage</b> | <b>Modality</b> | <b>Tasks</b>                                                                            | <b>Comments</b>                                             | <b>Total time (hours)</b> | <b>Wage rate in \$/hour</b> | <b>Total cost</b> |
|--------------|-----------------|-----------------------------------------------------------------------------------------|-------------------------------------------------------------|---------------------------|-----------------------------|-------------------|
| 1            | Group support   | Participate in case conference/team meetings                                            | Attend 1 meeting/week X 12 weeks X 2 hours/meeting          | 24                        | \$36.06                     | \$865.44          |
| 1            | Group support   | Participate in network group support conference call                                    | Requires 2 calls X 1 hour/call                              | 2                         | \$36.06                     | \$72.12           |
| 2            | Group support   | Attend modality session (supervise group support session)                               | Requires 1.5 hours/session X 1 session/week X 40 weeks      | 60                        | \$36.06                     | \$2,163.60        |
| 2            | Group support   | Deliver lectures                                                                        | Requires 2 lectures X 1 hour/lecture                        | 2                         | \$36.06                     | \$72.12           |
| 2            | Group support   | Perform charting/follow-up/outcomes assessment                                          | Requires 7.5 minutes/patient/month X 15 patients X 9 months | 16.9                      | \$36.06                     | \$609.41          |
| 2            | Group support   | Participate in case conference/team meetings                                            | Attend 1 meeting/week X 40 weeks X 0.5 hours/meeting        | 20                        | \$36.06                     | \$721.20          |
| 2            | Group support   | Participate in network group support conference call                                    | Requires 2 calls X 1 hour/call                              | 2                         | \$36.06                     | \$72.12           |
| 1            | Medical         | Prepare for pre-cohort planning meeting                                                 | Requires 1 hour                                             | 1                         | \$150.00                    | \$150.00          |
| 1            | Medical         | Attend pre-cohort planning meeting                                                      | Requires 2 hours                                            | 2                         | \$150.00                    | \$300.00          |
| 1            | Medical         | Review medical records                                                                  | Requires 0.25 hours/patient X 15 patients                   | 3.75                      | \$150.00                    | \$562.50          |
| 1            | Medical         | Attend cohort case review                                                               | Requires 4 hours                                            | 4                         | \$150.00                    | \$600.00          |
| 1            | Medical         | Attend modality session (attendance and/or dedicated availability for exercise session) | Requires 1 hour/session X 22 sessions                       | 22                        | \$150.00                    | \$3,300.00        |
| 1            | Medical         | Deliver lectures                                                                        | Requires 2 lectures X 1 hour/lecture                        | 2                         | \$150.00                    | \$300.00          |
| 1            | Medical         | Consult with case manager                                                               | Requires 1 hour/week X 12 weeks                             | 12                        | \$150.00                    | \$1,800.00        |
| 1            | Medical         | Consult with individual patients                                                        | Requires 2 hours/week X 12 weeks                            | 24                        | \$150.00                    | \$3,600.00        |
| 1            | Medical         | Consult with referring physician                                                        | Requires 20 minutes/patient X 15 patients                   | 5                         | \$150.00                    | \$750.00          |
| 1            | Medical         | Participate in case conference/team meetings                                            | Attend 1 meeting/week X 12 weeks X 2 hours/meeting          | 24                        | \$150.00                    | \$3,600.00        |
| 1            | Medical         | Participate in network medical conference call                                          | Requires 2 calls X 1 hour/call                              | 2                         | \$150.00                    | \$300.00          |

# Analysis of Tasks, Time and Costs by Stage and Modality

Preventive Medicine Research Institute

HCFA Demonstration Project Cost Analysis

| Stage | Modality  | Tasks                                                                                              | Comments                                                                            | Total time (hours) | Wage rate in \$/hour | Total cost |
|-------|-----------|----------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------|----------------------|------------|
| 2     | Medical   | Attend modality session (attendance and/or dedicated availability for exercise session)            | Requires 1 hour/session X 1 session/week X 40 weeks                                 | 40                 | \$150.00             | \$6,000.00 |
| 2     | Medical   | Deliver lectures                                                                                   | Requires 2 lectures X 1 hour/lecture                                                | 2                  | \$150.00             | \$300.00   |
| 2     | Medical   | Perform charting/follow-up/outcomes assessment                                                     | Requires 7.5 minutes/patient/month X 15 patients X 9 months                         | 16.9               | \$150.00             | \$2,535.00 |
| 2     | Medical   | Participate in case conference/team meetings                                                       | Attend 1 meeting/week X 40 weeks X 0.5 hours/meeting                                | 20                 | \$150.00             | \$3,000.00 |
| 2     | Medical   | Participate in network medical conference call                                                     | Requires 2 calls X 1 hour/call                                                      | 2                  | \$150.00             | \$300.00   |
| 1     | Nutrition | Attend pre-cohort planning meeting                                                                 | Requires 2 hours                                                                    | 2                  | \$20.00              | \$40.00    |
| 1     | Nutrition | Review medical records                                                                             | Requires 0.25 hours/patient X 15 patients                                           | 3.75               | \$20.00              | \$75.00    |
| 1     | Nutrition | Attend cohort case review                                                                          | Requires 4 hours                                                                    | 4                  | \$20.00              | \$80.00    |
| 1     | Nutrition | Assess patient at baseline and 12 weeks; includes 3-day diary assessment and interview w/ f/u note | Requires 1.5 hours per patient assessment X 2 assessments X 15 patients             | 45                 | \$20.00              | \$900.00   |
| 1     | Nutrition | Input 3-day diary                                                                                  | Requires 0.5 hours to input each day's diary X 3 days X 2 assessments X 15 patients | 45                 | \$20.00              | \$900.00   |
| 1     | Nutrition | Perform weekly check-in/ assessment/ charting                                                      | Requires 7.5 minutes/patient/week X 15 patients X 12 weeks                          | 22.5               | \$20.00              | \$450.00   |
| 1     | Nutrition | Attend modality session (meals/potluck/cooking demos)                                              | Requires 1.5 hours/session X 25 sessions                                            | 37.5               | \$20.00              | \$750.00   |
| 1     | Nutrition | Deliver lectures                                                                                   | Requires 10 lectures X 1 hour/lecture                                               | 10                 | \$20.00              | \$200.00   |
| 1     | Nutrition | Participate in case conference/team meetings                                                       | Attend 1 meeting/week X 12 weeks X 2 hours/meeting                                  | 24                 | \$20.00              | \$480.00   |
| 1     | Nutrition | Participate in network nutrition conference call                                                   | Requires 2 calls X 1 hour/call                                                      | 2                  | \$20.00              | \$40.00    |
| 2     | Nutrition | Attend modality session (meals/potluck/cooking demos)                                              | Requires 1.5 hours/session X 1 session/week X 40 weeks                              | 60                 | \$20.00              | \$1,200.00 |
| 2     | Nutrition | Deliver lectures                                                                                   | Requires 2 lectures X 1 hour/lecture                                                | 2                  | \$20.00              | \$40.00    |

**Analysis of Tasks, Time and Costs by Stage and Modality**

**Preventive Medicine Research Institute**

**HCFA Demonstration Project Cost Analysis**

| <b>Stage</b> | <b>Modality</b>   | <b>Tasks</b>                                             | <b>Comments</b>                                             | <b>Total time (hours)</b> | <b>Wage rate in \$/hour</b> | <b>Total cost</b> |
|--------------|-------------------|----------------------------------------------------------|-------------------------------------------------------------|---------------------------|-----------------------------|-------------------|
| 2            | Nutrition         | Perform charting/follow-up/outcomes assessment           | Requires 7.5 minutes/patient/month X 15 patients X 9 months | 16.9                      | \$20.00                     | \$338.00          |
| 2            | Nutrition         | Participate in case conference/team meetings             | Attend 1 meeting/week X 40 weeks X 0.5 hours/meeting        | 20                        | \$20.00                     | \$400.00          |
| 2            | Nutrition         | Participate in network nutrition conference call         | Requires 2 calls X 1 hour/call                              | 2                         | \$20.00                     | \$40.00           |
| 1            | Stress management | Attend pre-cohort planning meeting                       | Requires 2 hours                                            | 2                         | \$22.00                     | \$44.00           |
| 1            | Stress management | Review medical records                                   | Requires 0.25 hours/patient X 15 patients                   | 3.75                      | \$22.00                     | \$82.50           |
| 1            | Stress management | Attend cohort case review                                | Requires 4 hours                                            | 4                         | \$22.00                     | \$88.00           |
| 1            | Stress management | Perform weekly check-in/ assessment/ charting            | Requires 7.5 minutes/patient/week X 15 patients X 12 weeks  | 22.5                      | \$22.00                     | \$495.00          |
| 1            | Stress management | Attend modality session (supervise stress management)    | Requires 1.5 hours/session X 24 sessions                    | 36                        | \$22.00                     | \$792.00          |
| 1            | Stress management | Deliver lectures                                         | Requires 4 lectures X 1 hour/lecture                        | 4                         | \$22.00                     | \$88.00           |
| 1            | Stress management | Participate in case conference/team meetings             | Attend 1 meeting/week X 12 weeks X 2 hours/meeting          | 24                        | \$22.00                     | \$528.00          |
| 1            | Stress management | Participate in network stress management conference call | Requires 2 calls X 1 hour/call                              | 2                         | \$22.00                     | \$44.00           |
| 2            | Stress management | Attend modality session (supervise stress management)    | Requires 1.5 hours/session X 1 session/week X 40 weeks      | 60                        | \$22.00                     | \$1,320.00        |
| 2            | Stress management | Deliver lectures                                         | Requires 2 lectures X 1 hour/lecture                        | 2                         | \$22.00                     | \$44.00           |
| 2            | Stress management | Perform charting/follow-up/outcomes assessment           | Requires 7.5 minutes/patient/month X 15 patients X 9 months | 16.9                      | \$22.00                     | \$371.80          |
| 2            | Stress management | Participate in case conference/team meetings             | Attend 1 meeting/week X 40 weeks X 0.5 hours/meeting        | 20                        | \$22.00                     | \$440.00          |
| 2            | Stress management | Participate in network stress management conference call | Requires 2 calls X 1 hour/call                              | 2                         | \$22.00                     | \$44.00           |

# 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

June 27, 1999

TO: President Bill Clinton  
Ms. Hillary Rodham Clinton

FROM: Dean Ornish, M.D. *Dean*

I hope this finds you well and happy. Congratulations on your success in Kosovo!

As we discussed, my colleagues and I will be conducting a bipartisan week-long residential retreat for members of Congress during the last week of August here in the San Francisco area. Also, we will be offering a two-day retreat in Washington, DC the third weekend in October.

While the topic is to teach them about diet and lifestyle, the other agenda will be to also help them learn to develop more trust, to find common ground, and even to open their hearts a little to each other. (Please see the enclosed letter.) I may be naïve, but I hope something good comes from it. Also enclosed is a statement that Congressman Rangel will be reading into the Congressional Record about my work.

We are making progress with Medicare; they have agreed to move forward with a demonstration project. I remain deeply grateful for your advice and support, which made a critically-important difference. The only remaining obstacle is the level of reimbursement. At the suggestion of Nancy-Ann Min DeParle and Chris Jennings in April, I consulted with Dr. Bart McCann and his colleagues at Health Policy Alternatives. After extensive analysis, they determined that \$9,324 would be the appropriate payment to the hospitals offering my year-long program as a less-expensive alternative to bypass surgery or angioplasty. Unfortunately, Dr. Jeff Kang at HCFA is offering only 80% of \$6,000. At this level, it will be difficult to recruit patients as the hospitals will lose several thousand dollars on each one. I will discuss this with Chris Jennings.

I hope you take pleasure in knowing that your support of this work is giving new hope and new choices to literally millions of Americans.

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

*cc: Chris Jennings*  
Chris  
*can't use for this - is HCFA still trying to kill it? -*  
BS

PROMOTING HEALTHY HEARTS AND HEALTHY LIVES:  
DEAN ORNISH, M.D.

**HON. CHARLES B. RANGEL**

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, June 8, 1999*

Mr. RANGEL. Mr. Speaker, I am privileged to pay tribute to Dr. Dean Ornish, a man who has dedicated his career to building healthier lives. Dr. Ornish is considered by many as the leading authority on the effects of diet and lifestyle on health and well-being. His groundbreaking research has resulted in the discovery that comprehensive changes in diet and lifestyle can reverse even severe coronary heart disease without drugs or surgery. Dr. Ornish has produced valuable research that can empower individuals and build healthier communities. He is a talented, dedicated researcher whose work must not go unappreciated or unnoticed.

Dr. Ornish is the founder, president and director of the non-profit Preventive Medicine Research Institute in Sausalito, California, where he holds the Bucksbaum Chair. He is Clinical Professor of Medicine at the University of California, San Francisco, and a founder of the Center for Integrative Medicine at the university. Dr. Ornish received an M.D. from Baylor College of Medicine, was a clinical fellow in medicine at Harvard Medical School and completed his internship and residency in internal medicine at the Massachusetts General Hospital in Boston.

Dr. Ornish is the author of five best-selling books, including *New York Times* bestsellers: *Dr. Dean Ornish's Program for Reversing Heart Disease*; *Eat More, Weigh Less*; and *Love & Survival*. His research and writings have been published in the *Journal of the American Medical Association*, *The Lancet*, *Circulation*, *The New England Journal of Medicine*, *the American Journal of Cardiology*, and elsewhere. A one-hour documentary of his work was broadcast on NOVA, the PBS science series, and was featured on Bill Moyers' PBS series, "Healing & The Mind". His work has been featured in virtually all major media; he was on the cover of the March 16, 1998, issue of *Newsweek* magazine.

Dr. Ornish has received several awards, including the 1996 Beckmann Medal from the German Society for Prevention and Rehabilitation of Cardiovascular Diseases, the U.S. Army Surgeon General Medal, and the 1994 Outstanding Young Alumnus Award from the University of Texas, Austin. He is listed in the *Dictionary of International Biography*, *Who's Who in America*, and in *Men of Achievement*. He was recognized as one of the most interesting people of 1995 by *People* magazine and by *LIFE* Magazine as one of the 50 most influential members of his generation.

Mr. Speaker, I have great admiration for Dr. Dean Ornish. He is truly a remarkable individual whose outstanding research and effective programs have improved the overall quality of life for many people. His proven research on behavior modification has the potential to revolutionize the way modern medicine approaches heart disease. Dr. Ornish's promotion of healthy hearts and healthy lives is an inspiration for all Americans.

# Congress of the United States

Washington, DC 20515

June 21, 1999

## JOIN US FOR A BIPARTISAN CONGRESSIONAL RETREAT TO BUILD HEALTHY HEARTS AND HEALTHY LIVES

Dear Colleague:

We are writing to invite you to participate in a special bipartisan Congressional retreat led by Dean Ornish, M.D. Interested members of the House of Representatives and their spouses or significant others will be given the opportunity to attend a retreat designed to provide education about diet and lifestyle. To encourage maximum participation, Members will be given the option of attending either a weeklong Congressional retreat, to be held August 29 through September 4 in California, or a two day Congressional retreat, to be held October 22-23 in Washington, D.C.

This is a rare opportunity. Dr. Dean Ornish is considered by many to be the leading authority on the effects of diet and lifestyle on health and well-being. For the past 22 years, Dr. Ornish has directed a series of clinical studies demonstrating—for the first time ever—that the progression of even severe coronary heart disease often may be reversed by making comprehensive changes in diet and lifestyle. These lifestyle changes include a low-fat diet, stress management techniques, moderate exercise, smoking cessation, and psychosocial support.

Dr. Ornish's research has focused on reversing heart disease as a model for demonstrating the power of comprehensive lifestyle changes, but these benefits extend to anyone interested in improving their health and well-being. The purpose of this retreat is to give you both the scientifically-based information you need to make lifestyle changes and the direct experience of how powerful and quickly these improvements can occur. By the end of the week, most people report feeling so much better, so quickly, that it shifts their reason for changing lifestyle from fear of dying to joy of living.

In Dr. Ornish's studies, cholesterol levels fell an average of 40%, weight decreased by 25 pounds, and most people reported having more energy, enhanced awareness, thinking more clearly, and an overall improved sense of inner peace, joy, and well-being.

- OVER -

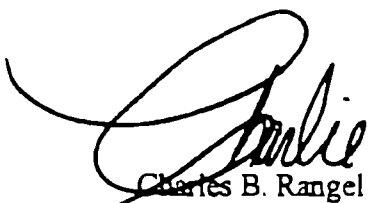
Dr. Ornish and his colleagues are donating their time and expenses, so this retreat is offered at no cost to you other than direct expenses of travel. The week-long session will be held at the world-class Claremont Resort in Berkeley, California. The two-day session will be held at a conference center (to be announced) in the D.C. area. Gourmet low-fat, low-cholesterol meals will be provided by Jean-Marc Fullsack, a gifted chef formerly of Lutece in New York and the California Culinary Academy in San Francisco.

You know how difficult our jobs can be. With all the competing demands on our time, our own health may not be a priority. When we take care of ourselves, we can better serve our families and constituents while setting a good health example.

We have attached Dr. Ornish's biographical information for your information. If you are interested in attending the week long session, call Maya Rockeymoore at X54365. For more information about the two day session, call Beth Clay at X55074.

Please join us for a fun and perhaps life-transforming experience.

Sincerely,



Charles B. Rangel  
Member of Congress



Dan Burton  
Member of Congress

# Preventive Medicine Research Institute

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

Dean Ornish, M.D.  
Founder, President & Director  
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Clinical Professor of Medicine  
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900 Bridgeway, Suite 1, Sausalito, California 94965  
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e-mail: DeanOrnish@aol.com

July 13, 1999

Mr. Chris Jennings  
Deputy Assistant to the President for Health Policy  
The White House  
Old Executive Office Building, Room 216  
Washington, DC 20502

Dear Chris,

As always, it was great hearing from you earlier today.

Now that Dr. Kang and I have come to agreement on everything, I would appreciate very much if there is anything you can do to expedite the process through the Office of the Secretary and through OMB. Dr. Kang again asked me again to convey to you that he would value your support in asking Allison Eydt to expedite the paperwork reduction requirement. Also, he is requesting \$2 million for HCFA to cover their costs of conducting the demonstration project.

Enclosed is a statement that Congressman Rangel will be introducing into the Congressional Record. He said he will sponsor legislation to authorize HCFA to cover the program.

I really don't have the words to adequately thank you.

With best wishes and warm personal regards,

Sincerely,



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

PROMOTING HEALTHY HEARTS AND HEALTHY LIVES:  
DEAN ORNISH, M.D.

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Anna L. Silberstein  
Vice President

October 16, 1998

Robert A. Berenson, M.D., F.A.C.P.  
Jeffrey Kang, M.D., M.P.H.  
c/o Dean Ornish, MD  
Clinical Professor of Medicine  
University of California, School of Medicine  
San Francisco, CA 94115

Dear Drs. Berenson and Kang:

Due to a prior commitment, I regrettably will not be able to join you at the meeting on October 20<sup>th</sup>. I would, however, like to express my support of the Dr. Dean Ornish Program for Reversing Heart Disease.

The first time I heard Dr. Ornish speak, my professional and personal attitudes toward heart disease were transformed. I began to envision a way to make this scientifically-based program available not only to those who are financially and educationally privileged, but also to "Mainstream America." HCFA has the opportunity to do the same, on a much broader scale.

I took my vision back to Highmark Blue Cross Blue Shield decision-makers. They agreed that the program made sense; for patient quality of life and cost containment. In January 1998, Highmark became the first insurer in the country to provide the program to its subscribers and cover the entire cost.

As you know, adding to administrative costs is something most insurance companies avoid. This project justifies an exception. Highmark has further invested in the community by instituting Health Education Center scholarships, which make the program available to financially and medically eligible non-Highmark members. The corporation is willing to take these short-term financial risks because of its commitment to quality care, and its determination that economic benefits will ultimately be realized through the Dean Ornish Program.

I have attached documentation of the outcomes of participants who have Medicare coverage, both traditional and SecurityBlue, which is Highmark's Medicare HMO. Similar outcomes have also been achieved by more than 105 other participants. You will notice that preliminary results among these patients confirm those reported by the Preventive Medicine Research Institute studies. Clinical gains among participants include reduction of cholesterol, triglycerides, and blood pressure, and increased exercise capacity. Not noted are markedly decreased incidences of angina. Furthermore, none have required an invasive procedure since starting the program.

I hope that HCFA will share this vision and take action to revolutionize the way our health care system confronts heart disease in the United States.

Sincerely,

A handwritten signature in dark ink, appearing to read "Anna L. Silberstein".

Enclosure

ENCLOSURE

Fifth Avenue Place • 120 Fifth Avenue • Suite 1721 • Pittsburgh, PA 15222-3099 • Telephone: (412) 544-4142 • Fax: (412) 544-7131

Highmark Blue Cross Blue Shield is an independent licensee of the Blue Cross and Blue Shield Association

# Highmark Dean Ornish Program

## Medicare Eligible Participants

### Cohorts 1 & 2

October 9, 1998

#### Number of Participants by Insurance Type:

|                        |           |
|------------------------|-----------|
| Medicare:              | 1         |
| Medicare Supplemental: | 2         |
| Medicare HMO:          | 10        |
| <b>Total</b>           | <b>13</b> |

Sex: 11 Males, 2 females

Number with Heart Disease: 12

Number who had PTCA or CABG: 7

#### Average Clinical Values and Survey Scores Before the Program and at 12-Week Follow-up:

| Measure                           | Baseline<br>Average | 12-Week<br>Average | Average<br>Change |
|-----------------------------------|---------------------|--------------------|-------------------|
| Weight (n = 13)                   | 174.3               | 167.1              | -7.2 lbs.         |
| Systolic Blood Pressure (n = 13)  | 134.4               | 122.9              | -11.5             |
| Diastolic Blood Pressure (n = 13) | 79.8                | 72                 | -7.8              |
| Cholesterol (n = 13)              | 199.3               | 166.9              | -32.4             |
| LDL (n = 11)                      | 115                 | 104.1              | -10.9             |
| HDL (n = 12)                      | 44                  | 36.7               | -7.3              |
| Triglycerides (n = 12)            | 271.3               | 165.1              | -106.2            |
| Exercise Capacity (Bruce, n = 10) | 8.6                 | 10.2               | +1.8              |
| Oxygen Capacity (METs, n = 10)    | 10.0                | 11.9               | +1.9              |
| Depression Scale (n = 12)         | 12.6                | 9.1                | -3.5              |
| Hostility Scale (n = 12)          | 6.2                 | 5.6                | -.6               |
| Perceived Stress Scale (n = 12)   | 9.6                 | 8.3                | -1.3              |

# The American Journal of Cardiology.

NOVEMBER 26, 1998

**A Symposium:  
Summit on Cholesterol and  
Coronary Disease**

**2<sup>ND</sup> NATIONAL CONFERENCE ON LIPIDS IN THE  
ELIMINATION AND PREVENTION OF CORONARY DISEASE**

GUEST EDITOR:

**Caldwell B. Esselstyn, Jr., MD**  
Department of General Surgery  
The Cleveland Clinic Foundation  
Cleveland, Ohio

**CME ISSUE SPONSORED BY THE CLEVELAND CLINIC FOUNDATION**

# Avoiding revascularization with Lifestyle Changes: The Multicenter Lifestyle Demonstration Project

Dean Ornish, MD, for the Multicenter Lifestyle Demonstration Project Research Group

The Multicenter Lifestyle Demonstration Project was designed to determine if comprehensive lifestyle changes can be a direct alternative to revascularization for selected patients without increasing cardiac events. A total of 333 patients completed this demonstration project (194 in the experimental group and 139 in the control group). We found that experimental group patients

were able to avoid revascularization for at least 3 years by making comprehensive lifestyle changes at substantially lower cost without increasing cardiac morbidity and mortality. These patients reported reductions in angina comparable with what can be achieved with revascularization. ©1998 by Excerpta Medica, Inc.

Am J Cardiol 1998;82:72T-76T

**T**he idea that the progression of coronary artery disease is often reversible was once a radical concept but now has become mainstream, as these proceedings clearly demonstrate. A number of interventions have been shown to arrest or reverse the progression of coronary atherosclerosis, many of which have been detailed in this symposium. These include comprehensive changes in diet and lifestyle,<sup>1-3</sup> lipid-lowering drug therapy,<sup>4-6</sup> partial ileal bypass surgery,<sup>7</sup> and parenteral nutrition.<sup>8</sup>

Approximately 500,000 coronary artery bypass graft (CABG) operations and approximately 600,000 percutaneous transluminal coronary angioplasties (PTCAs) were performed in the United States in 1994 at a combined cost of approximately \$15.6 billion, more than for any other surgical procedure. The cost of treatment of coronary artery disease (CAD) in the United States was estimated to be \$56.3 billion in 1994.<sup>9</sup> Thus, there is a potential for significant cost savings if safe and comparably effective, but less expensive, alternative interventions can be implemented.

The Multicenter Lifestyle Demonstration Project was designed to determine (1) if we could train other teams of health professionals in diverse regions of the country to motivate their patients to follow a program of comprehensive lifestyle changes; (2) if this lifestyle program may be an equivalently safe and medically effective but more cost-effective alternative to revascularization in selected patients with severe but stable coronary artery disease; and (3) what the resulting cost savings might be. In other words, can patients avoid revascularization by making comprehensive lifestyle changes at lower cost without increasing cardiac morbidity and mortality?

Earlier studies demonstrated that the progression of even severe coronary artery disease often can begin to reverse in many patients by an intensive, multifactorial program of comprehensive lifestyle changes.

These lifestyle changes include a very low-fat, low-cholesterol diet (approximately 10% fat, <10 mg/day dietary cholesterol, a whole-foods vegetarian diet high in complex carbohydrates and low in simple sugars), stress management techniques, moderate exercise, and psychosocial support. Endpoint measures included quantitative coronary arteriography to assess coronary artery stenosis and cardiac positron emission tomography to assess myocardial perfusion.<sup>2,10</sup>

In the past, insurance companies, managed care organizations, and Medicare have been reluctant to pay for lifestyle interventions, in part because these have been viewed as prevention—increasing costs in the short run for a possible savings years later. Also, since approximately 20–30% of patients change their insurance plans each year, even if cost savings result from lifestyle interventions, they may accrue to another insurance company.

However, a program of comprehensive lifestyle changes may be offered as a much less costly alternative treatment to revascularization for selected patients who are eligible for CABG or PTCA (under the supervision of the referring physician), thereby resulting in immediate and substantial cost savings.

Also, providing lifestyle changes as a direct alternative for patients who otherwise would receive CABG or PTCA may result in significant long-term cost savings. Despite the expense of bypass surgery and angioplasty, 30–50% of bypass grafts reocclude after only 5–7 years, and 30–50% of angioplastied arteries restenose after only 4–6 months.<sup>11,12</sup> When this occurs, then bypass surgery or angioplasty is often repeated, thereby incurring additional costs.

CABG is effective in decreasing angina and improving cardiac function. However, when compared with medical therapy and 16 years of follow-up, CABG improved survival only in a very small subgroup of patients: those with decreased left ventricular function and stenotic lesions of the left main coronary artery of >59%. Median survival was not prolonged in patients with left main coronary artery stenosis <60% and normal left ventricular function, even if a significant right coronary artery stenosis >70% was also present.<sup>13-16</sup>

From the Preventive Medicine Research Institute, Sausalito, California.  
Address for reprints: Dean Ornish, MD, University of California-San Francisco School of Medicine; Preventive Medicine Research Institute, 900 Bridgeway, Suite 1, Sausalito, California 94965.

PTCA was developed with the hope of providing a less invasive, lower-risk approach to the management of coronary artery disease and its symptoms. Although widely utilized, PTCA has never been compared with medical therapy in a randomized trial in stable patients with coronary artery disease; therefore, the mortality and morbidity benefits of PTCA are unknown.

The use of various types of stents (the insertion of a mesh brace into the lumen of the coronary artery during angioplasty) may slow the rate of restenosis, but there are no randomized controlled trial data supporting the efficacy of these approaches. 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 costs of further procedures when restenosis and reocclusion occur.

The majority of adverse events related to coronary artery disease, myocardial infarction, sudden death, and unstable angina are due to the rupture of an atherosclerotic plaque of <40–50% stenosis. This often occurs in the setting of vessel spasm and results in thrombosis and occlusion of the vessel.<sup>17</sup> CABG and PTCA usually are not performed on lesions <50% stenosed and do not affect nonbypassed or nondilated lesions, whereas comprehensive lifestyle changes (or lipid-lowering drugs) may help stabilize all lesions, including mild lesions (<50% 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.

## ASSESSING COSTS OF LIFESTYLE CHANGE

Thousands of dollars are saved immediately for every CABG candidate who can avoid the procedure by making intensive changes in diet and lifestyle. However, cost savings in avoided revascularization will occur only if patients who are trained in this lifestyle program adhere to it over time. If patients do not adhere, costs would increase rather than decrease because insurers would end up paying for both lifestyle training and subsequent revascularization. The missing link, therefore, are the data to demonstrate whether patients will adhere to this intensive lifestyle program. We wanted to determine whether patients who are motivated to make comprehensive lifestyle changes can maintain these changes in an ambulatory setting if given the proper support.

To address this question, we began the Multicenter Lifestyle Demonstration Project in 1993 at 8 sites. Also, we have trained practitioners at 0001 additional sites whose data are not included here. These sites are geographically, socioeconomically, racially, and cul-

turally diverse. Approximately 40 insurance companies are now reimbursing at least part of the cost of this program at these sites for selected patients.

We trained teams of health professionals at each of these clinical sites, including cardiologists, registered dietitians, exercise physiologists, psychologists, chefs, stress management specialists, registered nurses, and administrative support personnel. These teams, in turn, worked with their patients to motivate them to make and maintain comprehensive lifestyle changes.

Patients were selected who had angiographically documented coronary artery disease severe enough to warrant revascularization and who were approved for insurance indemnity to undergo a procedural intervention.

In addition, patients were excluded for any of the following: (1) >50% stenosis in the left main coronary artery; (2) CABG within 6 weeks or angioplasty within 6 months; (3) chronic unresponsive congestive heart failure; (4) malignant uncontrolled arrhythmias; (5) myocardial infarction within 1 month; (6) homozygous hypercholesterolemia; (7) psychosis; (8) hypotensive response to exercise; (9) alcohol or drug abuse; and (10) life-threatening comorbidity.

Patients and staff met 3 times per week for 12 weeks plus once per week for the remaining 9 months. Most sessions were 4 hours long: 1 hour of exercise, 1 hour of stress management techniques, 1 hour of group support, and a 1-hour meal. The cost of the 1-year program averaged \$7,000 per person. (Shorter and less-expensive versions of the program are now available for people with less severe coronary artery disease.)

All hospitals sent data directly to the independently funded data coordinating center at the Massachusetts General Hospital. Matched control-group patients were provided by Mutual of Omaha. Patients were matched for age, gender, left ventricular ejection fraction (<25%, 25–40%, or >40%), and cardiac score defined as the sum of the severity score for each of the 3 main coronary arteries rated as 0 (<50% stenosis), 0.5 (50–75% stenosis), or 1.0 (>75% stenosis). All control group patients were within 1 month of having undergone revascularization.

Although a randomized controlled trial intervention comparing comprehensive lifestyle changes with revascularization may seem ideal, it is not feasible in practice. The attitude of someone willing to make comprehensive lifestyle changes is often quite different from that of someone who wants to undergo revascularization. The decision to make comprehensive lifestyle changes requires commitment, discipline, and a willingness to assume personal responsibility for one's health. The decision to undergo revascularization is often made by patients who want the doctor to "fix" them—the other end of the personal responsibility spectrum. This is not a value judgment, only a reflection of different approaches, both of which may be valid. To be randomized, a patient has to be willing to undergo either treatment (revascularization or comprehensive lifestyle changes). Since the mindset is so different, it would be very difficult to find patients

who were willing to accept either choice determined by someone else; most patients want to choose one or the other for themselves.

**Baseline demographics:** A total of 333 patients completed this demonstration project. Of these, 194 were in the experimental group and 139 were in the control group.

At baseline, there were no significant differences between the experimental group and control group in age, gender, marital status, employment status, or history of hypertension, hypercholesterolemia, diabetes, smoking, or family history of heart disease. In the experimental group, the average age was 58 years, 79% were male, and 77% were married. Of particular note is that 63.5% of these patients were currently working yet were able to find time to adhere to the intervention of comprehensive lifestyle changes. Furthermore, 50% were hypertensive, 62% had hyperlipidemia, 19.6% had diabetes, 66% had smoked cigarettes, and 58% had a family history of heart disease. Finally, 54% of the experimental group patients and 32% of control group patients were taking lipid-lowering drugs.

Angiographic severity of coronary artery disease was comparable in both groups. However, 55% of experimental group patients had a prior myocardial infarction compared with only 28% in the control group; also, experimental group patients had a longer history of coronary artery disease than those in the experimental group. Taken together, these factors may bias toward higher morbidity for the experimental group than the control group during the demonstration project.

**Adherence and changes in risk factors:** These adherence data, changes in risk factors, and a more detailed description of the demonstration project will be described in greater detail in a forthcoming article. Not all patients completed adherence questionnaires; the validity of our adherence data depends on the assumption that the patients who did not provide follow-up data had the same adherence as those who did. If patients who had low adherence were more likely to avoid follow-up, then the adherence rates that we estimated would be overly optimistic.

## RESULTS

In brief, patients exercised an average of 1.6 hours/week at baseline, increasing to 3.9, 3.5, 2.9, and 2.7 hours/week at 3 months, 1 year, 2 years, and 3 years, respectively. Patients practiced stress management techniques an average of 0.19 hours/week at baseline and 4.5, 2.6, and 2.0 hours/week at 1 year, 2 years, and 3 years, respectively.

Based on the results of 3-day diet diaries, the percentage of total calories as dietary fat was 6.5%, 6.8%, 7.4%, and 8.3% after 3 months, 1 year, 2 years, and 3 years. The cholesterol intakes for these 4 time periods were 14.1, 19.0, 22.7, and 25.7 mg/day.

Low-density lipoprotein (LDL) cholesterol levels decreased from a mean of 122.9 mg/dL at baseline to 106.1 mg/dL after 3 months ( $p < 0.0001$ ), 104.2 mg/dL after 1 year ( $p < 0.0001$ ), 107.5 mg/dL after 2

years ( $p < 0.0001$ ), and 101.7 mg/dL after 3 years ( $p < 0.0001$ ). Total cholesterol decreased from a mean of 202.0 mg/dL at baseline to 183.7 mg/dL after 3 months ( $p < 0.0001$ ), 182.6 mg/dL after 1 year ( $p < 0.0001$ ), 187.3 mg/dL after 2 years ( $p < 0.0001$ ), and 183.4 mg/dL after 3 years ( $p < 0.0001$ ). Thus, reductions in LDL and total cholesterol levels were maintained throughout the 3-year interval, although the lifestyle intervention was only 1 year long.

High-density lipoprotein (HDL) cholesterol levels initially decreased from 36.7 mg/dL to 32.8 mg/dL after 3 months ( $p < 0.0001$ ) and to 36.1 mg/dL after 1 year ( $p = 0.120$ ) but increased to 40.1 mg/dL after 2 years ( $p < 0.005$ ) and increased to 42.2 mg/dL after 3 years ( $p = 0.001$ ). Triglycerides initially increased nonsignificantly from 229.8 mg/dL to 235.7 after 3 months ( $p = 0.494$ ), but stabilized after 1 year to 228.8 ( $p = 0.946$ ) to 213.0 ( $p = 0.607$ ) to 200.8 after 3 years ( $p = 0.339$ ). These changes in HDL-cholesterol and triglyceride levels are particularly relevant in light of recent controversies in this area.<sup>18</sup>

Mean weight decreased from 187.3 lb at baseline to 178.0 lb after 3 months ( $p < 0.0001$ ), to 177.0 lb after 1 year ( $p < 0.0001$ ), to 176.6 after 2 years ( $p < 0.0001$ ), to 179.9 lb after 3 years ( $p = 0.007$ ). Long-term reductions in weight are unusual.<sup>19</sup> Percent body fat decreased from 25.7% at baseline to 22.9% after 3 months ( $p < 0.0001$ ), to 21.3% after 1 year ( $p < 0.0001$ ), to 22.4% after 2 years ( $p < 0.0001$ ), to 23.4% after 3 years ( $p = 0.134$ ).

Exercise capacity increased from 9.59 METS at baseline to 11.15 after 3 months ( $p < 0.0001$ ), to 11.66 after 1 year ( $p < 0.0001$ ), to 10.88 after 2 years ( $p < 0.0001$ ), to 11.03 after 3 years ( $p < 0.0001$ ).

## CAN PATIENTS SAFELY AVOID REVASCULARIZATION?

We found that 150/194 of experimental-group patients were able to avoid revascularization and the frequency of adverse cardiac events was not increased. The number of cardiac events per patient-year of follow-up when comparing the experimental group with the control group was as follows: 0.012 versus 0.012 for myocardial infarction ( $p =$  not significant), 0.014 versus 0.006 for stroke ( $p =$  not significant), 0.006 versus 0.012 for noncardiac deaths ( $p =$  not significant), and 0.014 versus 0.012 for cardiac deaths ( $p =$  not significant).

As described above, a primary benefit of revascularization is reduction of angina. In the Multicenter Lifestyle Demonstration Project, we used a very conservative measure of angina: no angina at all in during the prior 30 days. For example, if a patient who had frequent angina at baseline—as many as 10 episodes per day—had even 1 episode in the prior 30 days, then the patient was still considered to have angina.

Of the experimental group patients who reported angina at baseline, 49% had no chest pain during the prior 30 days after 3 months, 65% had no chest pain during the prior 30 days after 1 year, 61% had no chest pain during the prior 30 days after 2 years, and 61% had no chest pain during the prior 30 days after 3

years. These reductions in angina are comparable with what can be achieved with revascularization but without the morbidity and costs.

As noted above, the average cost of the 1-year intensive lifestyle intervention was \$7,000. The average cost for PTCA (with cardiac catheterization) was \$31,000 and for CABG was \$46,000. All of the experimental group patients were eligible for revascularization both by medical criteria and by reimbursement criteria from Mutual of Omaha. However, only 31 PTCAs were performed on the 194 experimental group patients (0.064 events per patient-year of follow-up) and 26 CABGs were performed on the 194 experimental group patients (0.053 events per patient-year of follow-up) after entry. Thus, the costs in the experimental group were:  $(31 \times \$31,000) + (26 \times \$46,000) + (194 \times \$7,000) = \$3,515,000$ , or an average cost of \$18,119/patient.

All of the 139 control group patients were selected for having had a recent PTCA or CABG before entry: 66 underwent PTCA, and 73 underwent CABG. In addition, there were 23 PTCAs and 11 additional CABGs in the control group after entry. Thus, the costs in the control group were:  $(66 \times \$31,000) + (23 \times \$31,000) + (73 \times \$46,000) + (11 \times \$46,000) = \$6,623,000$ , or an average cost of \$47,647/patient.

The average savings per patient, therefore, were:  $\$47,647 - \$18,119 = \$29,529$ . This number is a conservative estimate, since 8 experimental group patients who had a PTCA after enrolling had  $\geq 1$  additional PTCAs or CABGs during the study. Restenosis within 6 months following PTCA is a failure of the angioplasty rather than intensive lifestyle changes, yet we counted all procedures in this cost analysis, even PTCAs occurring within 6 months after a prior PTCA.

There is no way to know with certainty how many of the patients who were eligible for revascularization actually would have undergone revascularization in the absence of the lifestyle program. Whether or not a patient undergoes revascularization is a function of many factors, including disease severity, patterns of practice in the local community, individual preferences among cardiologists and cardiac surgeons, and method of reimbursement. Revascularization rates tend to be much higher when reimbursed on a fee-for-service basis than on a capitated basis. One of the sites in our demonstration project, for example, performed more angioplasties (17) than the other 7 hospital sites combined (14).

Given the large cost differential between the cost of revascularization and the cost of the year-long lifestyle intervention program, it would have been cost-effective to offer comprehensive lifestyle changes even if only 18% of patients who were eligible for revascularization actually would have had it in the absence of this program.

In practice, we believe that patients with coronary artery 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.<sup>20</sup> At this time, however, most third-party payers will cover most of the costs of drug therapy and revascularization but not the costs of training patients in a program of comprehensive lifestyle changes. Approximately 40 insurance companies are covering this lifestyle program in the sites we have trained, but this is still a relatively small number.

Comprehensive lifestyle changes are not for everyone. We do not know how many patients with coronary artery disease in the United States would be interested in choosing to make comprehensive lifestyle changes rather than undergo revascularization. In practice, however, the primary limiting factor has been the lack of widespread insurance coverage rather than a shortage of motivated patients.

This is a particularly rewarding and emotionally fulfilling way to practice medicine, both for patients and the physicians and other healthcare 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. Patients usually show rapid decreases in angina and often report other improvements within weeks; these rapid improvements in well-being sustain motivation and help to explain the high levels of adherence in these patients. The major reason that most stable patients undergo CABG or PTCA is to decrease 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 that is caring and compassionate as well as cost-effective and competent.

## CONCLUSION

In summary, in the Multicenter Lifestyle Demonstration Project, we found that experimental group patients were able to avoid revascularization for at least 3 years by making comprehensive lifestyle changes at substantially lower cost without increasing cardiac morbidity and mortality.

**Acknowledgment.** Special appreciation to Marjorie McClain, Sam Lind, Zanse Smith and Bob Finkel for their invaluable assistance.

## APPENDIX

**Multicenter Lifestyle Demonstration Project Research Group:** *Preventive Medicine Research Institute, Sausalito, CA:* Dean Ornish, MD, President and Director; James H. Billings, PhD, MPH, Director, Clinical Services; Lee Lipsenthal, MD, Medical Director; Melanie Elliot-Eller, MSN, RN, Director of Nursing Services; Terri Merritt-Worden, MS, Director of Exercise Science Services; Nischala Devi, Director of Stress Management Services; Sarah Ellis, RD, Director of Nutrition Services; Helen Roe, RD, Former Director of Nutrition Services; Larry Scherwitz, PhD, Director of Research; Jean-Marc Fulsack, Director, Food Services; Glenn Perelson, Director, Network Development; Patty McCormac, RN, Hospital Liaison; Ruth Marlin, MD, Hospital Liaison; Ana Regalia, CPA, Director, Grants & Contracts; Bryce Williams, MS, Controller; *Massachusetts General Hospital Data Coordinating Center, Charlestown, MA:* Alexander Leaf, MD, Director; Judy Scheer, MPH, RN, Center Coordinator; David Schoenfeld, PhD, Consulting Statistician.

**Program Sites:** *Alegent Immanuel Medical Center/Alegent Heart Institute, Omaha, NE:* Richard Collins, MD, Medical Director; Sheila McGuire, Program Director; *Alegent Bergen Mercy Medical Center, Omaha, NE:* Dennis Tierney,

MD, Medical Director; Steve Luppess, Program Director; *Beth Israel Medical Center, New York, NY*: Steven Horowitz, MD, Medical Director; Roberto Roberti, MD, Co-Medical Director; Laurie Jones, Program Director; *Mercy Hospital Medical Center/Iowa Heart Center, Des Moines, IA*: William Wickemeyer, MD, Medical Director; Philip Bear, MD, Co-Medical Director; Shikun Advani, MD, Co-Medical Director; Diane McIlhonn, RD, Program Director; *Broward General Medical Center, Fort Lauderdale, FL*: Brenda Sanzobrin, MD, Medical Director; Carol Moody, MD, Co-Medical Director; Michael Chizner, MD, Co-Medical Director; Terry Ray, RN, Program Director; *Palmetto Richland Memorial Hospital, Columbia, SC*: Donald Saunders, MD, Medical Director; Joseph Hollins, MD, Co-Medical Director; Donna Greenwald, RN, Program Director; *Mt. Diablo Medical Center/Heart Health Center*: Peter Kunkel, MD, Medical Director; Lynn Olson, PhD, Program Director; *Beth Israel Deaconess Medical Center/Harvard Medical School, Boston, MA*: Jackie Hart, MD, Medical Director; Caitlin Hosmer, RD, Program Director; *ScrippsHealth, Shiley Sports & Health Center, La Jolla, CA*: Erminia Guarnieri MD, Medical Director; Betty Christensen, Program Director.

**Additional Program Sites:** *University of California San Francisco/California Pacific Medical Center, San Francisco, CA*: Anne Thorson, MD, Medical Director; Kevin Worth, RN, Program Director; *Highmark Blue Cross/Blue Shield of Western Pennsylvania, Pittsburgh, PA*: Howard Grill, MD, Medical Director; Anna Silberman, MPH, Vice President; Tina Palaggo-Toy, MS, Director, Health Place; Amy Wilhelm, MEd, Program Administrator; *Franciscan Health System of the Ohio Valley, Cincinnati OH*: Freidoon Ghazi, MD, Medical Director; Roy Jacobsen, MD, Co-Medical Director; Judy Steele, RN, Program Director; Michael Wizer, PhD, Co-Program Director; *SwedishAmerican Health System, Rockford, IL*: Dean Thomas, MD, Medical Director; Roger Greenlaw, MD, Co-Medical Director; Carol Klint, RN, Program Director; Nancy Halberstadt-Dagerfoerde, RN, Co-Program Director; *Swedish Medical Center/First Hill, Seattle, WA*: Anne Kinnaman, Program Director; Suzanne Westcott, Program Coordinator.

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## Unique Collaboration Introduced at Windber Medical Center Brings Renowned Dr. Dean Ornish Heart Disease Reversal Program To Military Population and Area Residents

December 3, 1998

WINDBER, Pa., Dec. 2 /PRNewswire/ via NewsEdge Corporation -- Windber Medical Center today was named as one of several partners in a unique nationwide, non-invasive heart disease reversal program for military personnel and their families.

The announcement was made in Windber by U.S. Rep. John Murtha (D-Pa), who inserted \$2.5 million for the program into the appropriation for the U.S. Department of Defense. The initiative brings to Windber Medical Center the celebrated heart disease reversal program begun in 1977 as a research project by Dr. Dean Ornish.

The program also will be available to residents of south-central Pennsylvania in cooperation with Highmark Blue Cross Blue Shield of Pittsburgh, PA. Highmark Blue Cross Blue Shield brought the Ornish program to Western Pennsylvania in late 1997 and has successfully delivered the program here the last year. It is the only health insurer in the United States to provide and pay for the program for its members. It also provides scholarships to nonmembers.

Congressman Murtha was joined in Windber for the announcement by Dr. Ornish and Anna L. Silberman, Vice President for the HealthPLACE System at Highmark Blue Cross Blue Shield. Other partners in the project include, Walter Reed Army Hospital, Bethesda Naval Hospital, Uniformed Services University, and Preventive Medicine Research Institute.

"We spend over \$10 billion a year for medical care in the Defense Department alone, so we're always looking to improve available treatment and reduce costs,"

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Murtha said. "This cutting-edge program will help us provide better care to Defense personnel and their families while saving tax dollars. At the same time we are able to make this widely respected concept available to the people here in our area."

Dr. Dean Ornish's program for reversing heart disease created enormous interest when it was introduced to the world in 1993. It is a comprehensive, life changing health care alternative embracing exercise, stress management, group support, and nutrition. The goal of the program is to improve cardiac function, reduce angina, and improve the quality of life while decreasing overall costs of coronary artery disease that afflicts 13.9 million Americans. Studies have shown coronary artery disease is the single largest killer of American males and females.

"Defense Department officials and Congressman Murtha are to be complimented for making available to the military a concept that has been proven in controlled research to actually reduce coronary artery disease," Dr. Ornish said. "It is a bonus for this community that one of the several centers planned to introduce the program in the military will be located here. The fact that Highmark Blue Cross Blue Shield recognizes the validity of the program increases its value to area residents."

Vice President Anna L. Silberman of Highmark Blue Cross Blue Shield said the Ornish program works for many people who have heart disease. "We have seen participants improve their risk factor dramatically by changing their health practices dramatically," she said. "We have learned the fundamental importance of treating the underlying causes of heart disease, such as stress, poor eating habits, lack of exercise and isolation. As a result, the Dr. Dean Ornish program is certainly less expensive to deliver than the alternatives."

Nick Jacobs, President of Windber Medical Center, said locating the Ornish program in Windber is appropriate and necessary. "Somerset and Cambria counties have perhaps the highest rate coronary artery disease in Pennsylvania," he noted.

William Casey, Chief Executive Officer of

Conemaugh Health System, of which Windber Medical Center is an integral part, said the parent organization enthusiastically supports the implementation of the Ornish program at Windber. "It fits right into our goal of providing the most comprehensive health care delivery system for our citizens," he remarked.

The Dr. Dean Ornish Heart Disease Reversal Program will be located in a new free-standing, 12,000-square-foot building now under construction on the Windber Medical Center campus.

David Klementik, Chairman of Windber Medical Center's Board of Directors, said today the new facility will have in it all of the necessary components for the effective operation and management of the Ornish program.

Initially, the Ornish program will be available to the military for two centers, Washington and Windber. Each location will receive approximately \$950,000 to offset start-up costs and the training of personnel. The remaining \$600,000 will be used by Ornish Preventive Medicine Research Institute to further investigate non-invasive treatment of prostate disease.

SOURCE Windber Medical Center

/CONTACT: Lori Knox of Windber Medical Center, 814-467-3488, or fax, 814-467-3603, or Brad Clemenson of Congressman Murtha's Office, 814-535-2642, or Phyl Neubauer of Highmark Blue Cross Blue Shield, 412-544-7448/ /Web site: <http://www.highmark.com/>

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Alexander Leaf, M.D.  
*Jackson Professor of Clinical Medicine,  
Emeritus  
Harvard Medical School*

October 13, 1998

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

Dear Ms. Min DeParle,

Dr. Dean Ornish has indicated that he will be discussing his Life Style intervention program to prevent the high mortality from coronary heart disease with you at HCFA with hopes of having HCFA recognize his program as an reimbursable, inexpensive alternative to the very high cost interventions which are currently being used and which HCFA reimburses.

I have known Dr. Ornish while he was still a medical student at Baylor prior to his coming to Boston for his medical residency on my service at this Hospital. I have followed his career since then closely and with great interest. The demonstration by Dr. Ornish that simple, inexpensive, life style measures can reverse established and even advanced coronary artery disease, I think constitutes a most important advance in the management of a lethal and very prevalent disease. At a time when the medical profession and public have been virtually obsessed by expensive medications, angioplasty and bypass surgery for this condition, his clear and convincing demonstration that lifestyle changes can reverse established coronary disease should affect physicians regard this disease and how they manage it. But it won't be easy to alter customary (and very profitable) practices and to make his less expensive intervention generally available, unless third party payers will reimburse for this alternative. Since both angioplasty and coronary bypass surgery are merely palliative, while Dr. Ornish's intervention is actually curative and safe, the rationale for providing this alternative seems very strong and the lower cost would seem to make it convincing, even imperative.

The reason I strongly support Dr. Ornish's program is that, unlike all other "alternative medical proposals" for preventing or treating this epidemic lethal disease, he had done a rigorous clinical trial and this multicenter demonstration, which clearly support his hypothesis that his program is clinically effective. The clinical trial he had done before he started to advocate the clinical application of his program. The recent clinical studies to assess the ability of his program to replace the recommended angioplasty and bypass surgery in a cohort of patients at different medical centers seems convincing. My Data Processing Center here at the Massachusetts General Hospital was funded for this demonstration study by Mutual of Omaha and operated independently and autonomously. The Center has had experience with previous NIH Clinical trials



Health Care System Member

Page 2

Ms. Min DeParle

October 13, 1998

and other very competitive government funded trials. They are now led by a professor of Biostatistics and the staff operates in part from my office. I founded the Center in 1990 for an NIH study I was doing and a more efficient and objective Data Processing Center, I don't believe exists. Not everyone might agree with the judgement of the physicians who recommended the invasive procedure to the patients in this Demonstration Trial, but today it is just such medical recommendations which direct the patients to the operating room for expensive cardiac surgery. The bulk of the patients on Dr. Ornish's program seem to have done well and were able to avoid the surgery during this study.

I am confident that it would result in a large change in the medical management of coronary heart disease and the associated high medical costs, if your Agency determines to support the health measures Dr. Ornish recommends for patients with coronary heart disease.

Respectfully submitted,

A handwritten signature in cursive script that reads "Alexander Leaf". The signature is written in dark ink and is positioned above the printed name.

Alexander Leaf, M.D.

# Preventive Medicine Research Institute

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

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June 27, 1999

TO: President Bill Clinton  
Ms. Hillary Rodham Clinton

FROM: Dean Ornish, M.D. *Dean*

I hope this finds you well and happy. Congratulations on your success in Kosovo!

As we discussed, my colleagues and I will be conducting a bipartisan week-long residential retreat for members of Congress during the last week of August here in the San Francisco area. Also, we will be offering a two-day retreat in Washington, DC the third weekend in October.

While the topic is to teach them about diet and lifestyle, the other agenda will be to also help them learn to develop more trust, to find common ground, and even to open their hearts a little to each other. (Please see the enclosed letter.) I may be naïve, but I hope something good comes from it. Also enclosed is a statement that Congressman Rangel will be reading into the Congressional Record about my work.

We are making progress with Medicare; they have agreed to move forward with a demonstration project. I remain deeply grateful for your advice and support, which made a critically-important difference. The only remaining obstacle is the level of reimbursement. At the suggestion of Nancy-Ann Min DeParle and Chris Jennings in April, I consulted with Dr. Bart McCann and his colleagues at Health Policy Alternatives. After extensive analysis, they determined that \$9,324 would be the appropriate payment to the hospitals offering my year-long program as a less-expensive alternative to bypass surgery or angioplasty. Unfortunately, Dr. Jeff Kang at HCFA is offering only 80% of \$6,000. At this level, it will be difficult to recruit patients as the hospitals will lose several thousand dollars on each one. I will discuss this with Chris Jennings.

I hope you take pleasure in knowing that your support of this work is giving new hope and new choices to literally millions of Americans.

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

PROMOTING HEALTHY HEARTS AND HEALTHY LIVES:  
DEAN ORNISH, M.D.

**HON. CHARLES B. RANGEL**

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, June 8, 1999*

Mr. RANGEL. Mr. Speaker, I am privileged to pay tribute to Dr. Dean Ornish, a man who has dedicated his career to building healthier lives. Dr. Ornish is considered by many as the leading authority on the effects of diet and lifestyle on health and well-being. His groundbreaking research has resulted in the discovery that comprehensive changes in diet and lifestyle can reverse even severe coronary heart disease without drugs or surgery. Dr. Ornish has produced valuable research that can empower individuals and build healthier communities. He is a talented, dedicated researcher whose work must not go unappreciated or unnoticed.

Dr. Ornish is the founder, president and director of the non-profit Preventive Medicine Research Institute in Sausalito, California, where he holds the Bucksbaum Chair. He is Clinical Professor of Medicine at the University of California, San Francisco, and a founder of the Center for Integrative Medicine at the university. Dr. Ornish received an M.D. from Baylor College of Medicine, was a clinical fellow in medicine at Harvard Medical School and completed his internship and residency in internal medicine at the Massachusetts General Hospital in Boston.

Dr. Ornish is the author of five best-selling books, including *New York Times* bestsellers: *Dr. Dean Ornish's Program for Reversing Heart Disease*; *Eat More, Weigh Less*; and *Love & Survival*. His research and writings have been published in the *Journal of the American Medical Association*, *The Lancet*, *Circulation*, *The New England Journal of Medicine*, the *American Journal of Cardiology*, and elsewhere. A one-hour documentary of his work was broadcast on NOVA, the PBS science series, and was featured on Bill Moyers' PBS series, "Healing & The Mind". His work has been featured in virtually all major media; he was on the cover of the March 16, 1998, issue of *Newsweek* magazine.

Dr. Ornish has received several awards, including the 1996 Beckmann Medal from the German Society for Prevention and Rehabilitation of Cardiovascular Diseases, the U.S. Army Surgeon General Medal, and the 1994 Outstanding Young Alumnus Award from the University of Texas, Austin. He is listed in the *Dictionary of International Biography*, *Who's Who in America*, and in *Men of Achievement*. He was recognized as one of the most interesting people of 1995 by *People* magazine and by *LIFE* Magazine as one of the 50 most influential members of his generation.

Mr. Speaker, I have great admiration for Dr. Dean Ornish. He is truly a remarkable individual whose outstanding research and effective programs have improved the overall quality of life for many people. His proven research on behavior modification has the potential to revolutionize the way modern medicine approaches heart disease. Dr. Ornish's promotion of healthy hearts and healthy lives is an inspiration for all Americans.

# Congress of the United States

Washington, DC 20515

June 21, 1999

## JOIN US FOR A BIPARTISAN CONGRESSIONAL RETREAT TO BUILD HEALTHY HEARTS AND HEALTHY LIVES

Dear Colleague:

We are writing to invite you to participate in a special bipartisan Congressional retreat led by Dean Ornish, M.D. Interested members of the House of Representatives and their spouses or significant others will be given the opportunity to attend a retreat designed to provide education about diet and lifestyle. To encourage maximum participation, Members will be given the option of attending either a weeklong Congressional retreat, to be held August 29 through September 4 in California, or a two day Congressional retreat, to be held October 22-23 in Washington, D.C.

This is a rare opportunity. Dr. Dean Ornish is considered by many to be the leading authority on the effects of diet and lifestyle on health and well-being. For the past 22 years, Dr. Ornish has directed a series of clinical studies demonstrating—for the first time ever—that the progression of even severe coronary heart disease often may be reversed by making comprehensive changes in diet and lifestyle. These lifestyle changes include a low-fat diet, stress management techniques, moderate exercise, smoking cessation, and psychosocial support.

Dr. Ornish's research has focused on reversing heart disease as a model for demonstrating the power of comprehensive lifestyle changes, but these benefits extend to anyone interested in improving their health and well-being. The purpose of this retreat is to give you both the scientifically-based information you need to make lifestyle changes and the direct experience of how powerful and quickly these improvements can occur. By the end of the week, most people report feeling so much better, so quickly, that it shifts their reason for changing lifestyle from fear of dying to joy of living.

In Dr. Ornish's studies, cholesterol levels fell an average of 40%, weight decreased by 25 pounds, and most people reported having more energy, enhanced awareness, thinking more clearly, and an overall improved sense of inner peace, joy, and well-being.

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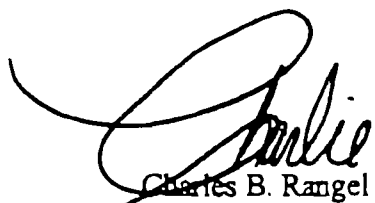
Dr. Ornish and his colleagues are donating their time and expenses, so this retreat is offered at no cost to you other than direct expenses of travel. The week-long session will be held at the world-class Claremont Resort in Berkeley, California. The two-day session will be held at a conference center (to be announced) in the D.C. area. Gourmet low-fat, low-cholesterol meals will be provided by Jean-Marc Fullsack, a gifted chef formerly of Lutece in New York and the California Culinary Academy in San Francisco.

You know how difficult our jobs can be. With all the competing demands on our time, our own health may not be a priority. When we take care of ourselves, we can better serve our families and constituents while setting a good health example.

We have attached Dr. Ornish's biographical information for your information. If you are interested in attending the week long session, call Maya Rockeymoore at X54365. For more information about the two day session, call Beth Clay at X55074.

Please join us for a fun and perhaps life-transforming experience.

Sincerely,



Charles B. Rangel  
Member of Congress



Dan Burton  
Member of Congress



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## News Release

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**EMBARGOED FOR RELEASE: 3 p.m. (CT) Tuesday, December 15, 1998**

Media Advisory: To contact Dean Ornish, M.D., call 800/775-7674, ext. 222.

### **Long-Term Lifestyle Changes Increase Regression of Coronary Heart Disease**

*Coronary atherosclerosis continued to progress in those with conventional lifestyle*

CHICAGO--Patients in an experimental group who made intensive changes in diet, exercise, stress management, and other lifestyle factors showed greater reversal of coronary heart disease after five years than after one year in the Lifestyle Heart Trial, according to an article in the December 16 issue of *The Journal of the American Medical Association (JAMA)*.

In contrast, the authors found that control group patients showed much more progression (continued worsening) in average percent diameter stenosis after five years than after one year, even though more than half of the control group patients were prescribed lipid-lowering medications during the course of the study.

Dean Ornish, M.D., of the Preventive Medicine Research Institute, Sausalito, Calif., and the University of California at San Francisco School of Medicine, and colleagues conducted a five-year follow-up of the Lifestyle Heart Trial. The original trial found that after one year, heart patients who made intensive lifestyle changes had a 37.2 percent reduction in LDL cholesterol, less frequent angina, and a reduction in stenosis. By contrast, patients who made moderate changes reduced LDL cholesterol by only 6 percent, had more frequent angina, and greater narrowing of the blood vessels. Among the 48 patients from the original study, 35 agreed to take part in the follow-up and continued through the entire five years.

Patients in the experimental group were prescribed an intensive program that included a 10 percent fat vegetarian diet, moderate aerobic exercise, stress management training, smoking cessation, and group psychosocial support. Control group patients were asked to follow the advice of their personal physicians regarding lifestyle changes, consistent with the American Heart Association's Step II diet guidelines. No experimental group patients took lipid-lowering drugs, while 60 percent of control patients received lipid-lowering medication. Angiograms were done at the end of five years for the 20 experimental group and 15 control patients who completed the follow-up.

Jeff Molter, Director  
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## (LIFESTYLE CHANGES)

Among the findings of the study:

- Experimental group patients had a 91 percent reduction in frequency of angina after one year, and a 72 percent reduction after five years. Control patients had a 186 percent increase after one year, and a 36 percent decrease after five years. Three of the five control patients who reported an increase from baseline to year one underwent coronary angioplasty before year five.
- The reduction in LDL cholesterol levels in the experiment group was comparable with results achieved by lipid-lowering drugs for ambulatory patients.
- In the experimental group, the average percent diameter stenosis (narrowing of the blood vessels) showed a 7.9 percent relative improvement after five years, while the control group showed a 27.7 percent relative worsening.

The researchers also found more than twice as many cardiac events in the control group (45 events, 2.25 events per patient) than in the experimental group (25 events, 0.89 events per patient). Events included heart attacks, coronary angioplasty, coronary bypass surgery, cardiac-related hospitalizations, and cardiac-related deaths.

The authors write: "These findings support the feasibility of intensive lifestyle changes in delaying, stopping, or reversing the progression of coronary artery disease in ambulatory patients over prolonged periods."

The authors conclude: "In summary, these ambulatory patients were able to make and maintain comprehensive changes in diet and lifestyle for five years and showed even more regression of coronary atherosclerosis after five years than after one year as measured by percent diameter stenosis. In contrast, patients following more conventional lifestyle recommendations showed even more progression of coronary atherosclerosis after five years than after one year, and had more than twice as many cardiac events as patients making comprehensive lifestyle changes."

(*JAMA*. 1998;280:2001-2007)

Editor's Note: The Preventive Medicine Research Institute is a non-profit organization. Major support for this study was provided by grants from the National Heart, Lung, and Blood Institute of the National Institutes of Health, Bethesda, Maryland and numerous other organizations. For a complete listing, please see the *JAMA* article.

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**For more information: contact the AMA's Science News Department at 312/464-5374.  
<http://www.ama-assn.org/jama>**

# Intensive Lifestyle Changes for Reversal of Coronary Heart Disease

Dean Ornish, MD; Larry W. Scherwitz, PhD; James H. Billings, PhD, MPH; K. Lance Gould, MD; Terri A. Merritt, MS; Stephen Sparler, MA; William T. Armstrong, MD; Thomas A. Ports, MD; Richard L. Kirkeeide, PhD; Charissa Hogeboom, PhD; Richard J. Brand, PhD

**Context.**—The Lifestyle Heart Trial demonstrated that intensive lifestyle changes may lead to regression of coronary atherosclerosis after 1 year.

**Objectives.**—To determine the feasibility of patients to sustain intensive lifestyle changes for a total of 5 years and the effects of these lifestyle changes (without lipid-lowering drugs) on coronary heart disease.

**Design.**—Randomized controlled trial conducted from 1986 to 1992 using a randomized invitational design.

**Patients.**—Forty-eight patients with moderate to severe coronary heart disease were randomized to an intensive lifestyle change group or to a usual-care control group, and 35 completed the 5-year follow-up quantitative coronary arteriography.

**Setting.**—Two tertiary care university medical centers.

**Intervention.**—Intensive lifestyle changes (10% fat whole foods vegetarian diet, aerobic exercise, stress management training, smoking cessation, group psychosocial support) for 5 years.

**Main Outcome Measures.**—Adherence to intensive lifestyle changes, changes in coronary artery percent diameter stenosis, and cardiac events.

**Results.**—Experimental group patients (20 [71%] of 28 patients completed 5-year follow-up) made and maintained comprehensive lifestyle changes for 5 years, whereas control group patients (15 [75%] of 20 patients completed 5-year follow-up) made more moderate changes. In the experimental group, the average percent diameter stenosis at baseline decreased 1.75 absolute percentage points after 1 year (a 4.5% relative improvement) and by 3.1 absolute percentage points after 5 years (a 7.9% relative improvement). In contrast, the average percent diameter stenosis in the control group increased by 2.3 percentage points after 1 year (a 5.4% relative worsening) and by 11.8 percentage points after 5 years (a 27.7% relative worsening) ( $P = .001$  between groups). Twenty-five cardiac events occurred in 28 experimental group patients vs 45 events in 20 control group patients during the 5-year follow-up (risk ratio for any event for the control group, 2.47 [95% confidence interval, 1.48–4.20]).

**Conclusions.**—More regression of coronary atherosclerosis occurred after 5 years than after 1 year in the experimental group. In contrast, in the control group, coronary atherosclerosis continued to progress and more than twice as many cardiac events occurred.

JAMA. 1998;280:2001–2007

From the Department of Medicine (Dr Ornish), and the Division of Cardiology (Dr Armstrong), California Pacific Medical Center, San Francisco; the Department of Medicine (Dr Ornish), the Division of Cardiology, Cardiac Catheterization Laboratory, Cardiovascular Research Institute (Dr Ports), and the Division of Biostatistics (Drs Brand and Hogeboom), School of Medicine, University of California, San Francisco; the

Division of Cardiology, University of Texas Medical School, Houston (Drs Gould and Kirkeeide); and the Preventive Medicine Research Institute, Sausalito, Calif (Drs Ornish Scherwitz, and Billings, Mr Sparler, and Ms Merritt).

Reprints: Dean Ornish, MD, Preventive Medicine Research Institute, 900 Bridgeway, Suite 1, Sausalito, CA 94965 (e-mail: DeanOrnish@aol.com).

THE LIFESTYLE Heart Trial was the first randomized clinical trial to investigate whether ambulatory patients could be motivated to make and sustain comprehensive lifestyle changes and, if so, whether the progression of coronary atherosclerosis could be stopped or reversed without using lipid-lowering drugs as measured by computer-assisted quantitative coronary arteriography. This study derived from earlier studies that used noninvasive measures.<sup>1,2</sup>

After 1 year, we found that experimental group participants were able to make and maintain intensive lifestyle changes and had a 37.2% reduction in low-density lipoprotein (LDL) cholesterol levels and a 91% reduction in the frequency of anginal episodes.<sup>3</sup> Average percent diameter stenosis regressed from 40.0% at baseline to 37.8% 1 year later, a change that was correlated with the degree of lifestyle change. In contrast, patients in the usual-care control group made more moderate changes in lifestyle, reduced LDL cholesterol levels by 6%, and had a 165% increase in the frequency of reported anginal episodes. Average percent diameter stenosis progressed from 42.7% to 46.1%.

Given these encouraging findings, we extended the study for an additional 4 years to determine (1) the feasibility of patients sustaining intensive changes in diet and lifestyle for a much longer time, and (2) the effects of these changes on risk factors, coronary atherosclerosis, myocardial perfusion, and cardiac events after 4 additional years.

## METHODS

The design, recruitment, and study population were previously described.<sup>3,5</sup> In brief, we recruited men and women

Table 1.—Baseline Characteristics of Experimental and Control Groups\*

| Characteristic                                                     | Experimental<br>(n = 20) | Control<br>(n = 15) | P<br>Value |
|--------------------------------------------------------------------|--------------------------|---------------------|------------|
| Men, No.                                                           | 20                       | 12                  | .07        |
| Women, No.                                                         | 0                        | 3                   |            |
| Age, mean (SD), y                                                  | 57.4 (6.4)               | 61.8 (7.5)          | .08        |
| Education, mean (SD), y                                            | 15.5 (2.7)               | 14.5 (3.4)          | .29        |
| Employed, No.                                                      | 14                       | 6                   | .10        |
| Body mass index, mean (SD), kg/m <sup>2</sup>                      | 28.4 (4.1)               | 25.4 (3.5)          | .03        |
| No. with history of myocardial infarction                          | 12                       | 5                   | .17        |
| Average No. of lesions studied, mean (SD)                          | 5.3 (2.7)                | 5.3 (3.2)           | .93        |
| No. with history of percutaneous transluminal coronary angioplasty | 5                        | 4                   | >.99       |
| No. with history of coronary artery bypass graft                   | 1                        | 0                   | >.99       |
| Reported angina, No. (%)                                           | 11 (55)                  | 6 (40)              | .49        |

\*Values are statistics unless otherwise indicated. P values are 2-tailed.

with coronary atherosclerosis documented by quantitative coronary arteriography.

We identified 193 patients as potentially eligible for our study who agreed to undergo quantitative coronary arteriography. Following angiography, 93 patients remained eligible and were randomly assigned to experimental or control groups using a randomized invitation design to minimize crossover, ethical concerns, nocebo effects, and dropout. Of these 93 patients who were eligible, 53 were randomly assigned to the experimental group and 40 to the usual-care control group. Patients were then contacted and invited to participate in the study; 28 (53%) and 20 (50%) agreed to participate in the experimental and control groups, respectively. The primary reason for refusal in the experimental group was not wanting to undergo intensive lifestyle changes and/or not wanting a second coronary angiogram; control patients refused primarily because they did not want to undergo a second angiogram. To detect possible selection biases, we collected data on age, marital status, reported angina, history of myocardial infarction, height, weight, number of diseased lesions, and stenosis severity for all patients who were randomized into the study but refused to participate. We did not exclude any experimental group patients who volunteered even if we doubted their ability to adhere to the lifestyle program. All patients who volunteered were followed up using the intention-to-treat principle.

After 1 year, 7 patients did not provide angiographic data, and the reasons for loss to follow-up have been reported.<sup>3</sup> Of the remaining 41 patients at baseline most had severe coronary atherosclerosis: 28 had 3-vessel disease, 12 had 2-vessel disease, and 1 had 1-vessel disease. Two of these patients whose angiographic data were not usable after year agreed to undergo quantitative coronary arteriography after 5 years; results are included in the baseline

to 5-year comparisons.

Four experimental and 4 control patients who had an angiogram at 1 year did not have a third angiogram after 5 years. Three of these 4 patients in the experimental group refused a third angiogram (patients only volunteered for a 1-year study that was subsequently extended), and 1 died between years 1 and 4; of the 4 control group patients who did not undergo a third angiogram, 1 died, 2 underwent revascularization of the arterial lesions under study, and 1 developed Parkinson disease and became too ill to be safely tested. Cine arteriograms made in San Francisco, Calif, were sent to the University of Texas Medical School, Houston, for blinded quantitative analyses as previously described in detail.<sup>4</sup>

All results, except lesion changes at 1 year (18 experimental and 15 control subjects) and cardiac events after 5 years (all 28 experimental and 20 control subjects), are based on the total of 35 patients (20 experimental and 15 control subjects) who had both baseline and 5-year angiograms. From these 35 patients, there were 224 lesions studied at baseline, of which 24 were 100% occluded and were excluded a priori from the lesion-change analyses per the study protocol. Of the remaining 200 lesions, 14 were lost to the 4-year follow-up, as follows: in the experimental group, 2 lesions were excluded due to technical failure during the angiogram and 2 had views that did not match; in the control group, views did not match for 3 lesions, 3 lesions were excluded due to technical failure, 1 was excluded due to angioplasty, and 3 were excluded due to coronary artery bypass surgery. Of the 186 lesions available for analysis at 4 years, 109 were from the experimental group and 77 were from the control group.

The 1-year original study and the 4-year extension were approved by the committees on human research at California Pacific Medical Center and University of California, San Francisco, and each patient signed a written consent

form after being fully informed of the study requirements.

Patients completed a 3-day diet diary at baseline and after 1 and 5 years to assess nutrient intake and dietary adherence.<sup>6</sup> Methods of lipid assays were the same as previously reported.<sup>3</sup> These 3-day diet diaries were analyzed with a software package (CBORD Diet Analyzer; CBORD Group Inc; Ithaca, NY) using the US Department of Agriculture database. Also, patients were asked to complete a questionnaire reporting the frequency and duration of exercise and of each stress management technique. Information from these sources was quantified into continuous scores using an a priori determined formula. The adherence measure was a continuous score reflecting daily intake of cholesterol (in milligrams), fat (in grams), frequency and duration of exercise, frequency and duration of stress management techniques, and smoking. A score of 1.0 equalled 100% adherence but scores could be greater than 1.0 if participants exceeded the recommended intensive lifestyle changes.

The technicians responsible for performing all medical tests were blinded to patient group assignment. Also, different personnel implemented the lifestyle intervention, conducted the tests, and computed statistical analyses, although the dietitian was made aware of the nutrient analysis to monitor patients' safety and adherence. Quantitative coronary arteriograms were blindly analyzed without knowledge of group assignment.

### Program Intervention

Experimental group patients were prescribed an intensive lifestyle program that included a 10%-fat vegetarian diet, moderate aerobic exercise, stress management training, smoking cessation, and group psychosocial support previously described in detail.<sup>3,7-10</sup> Patients were encouraged to avoid simple sugars and to emphasize the intake of complex carbohydrates and other whole foods. Only 1 patient in the experimental group was actively smoking at baseline, and she quit at entry. Control group patients were asked to follow the advice of their personal physicians regarding lifestyle changes.

### Statistical Methods

We decided a priori to use percent diameter stenosis as the primary dependent variable. Statistical methods to compare the 2 groups were previously described.<sup>3</sup> Analysis of adherence variables and risk factor levels used time-structured repeated measures in which levels from all 3 measurement times (baseline, 1 year, and 5 years) were in-

Table 2.—Adherence to Exercise, Stress Management, and Dietary Gu 85

|                                     | Mean (SEM) at Baseline         |                                | Mean (SEM) at 1 Year        |                                |                             | (SEM) at 5 Years             |                                |                              |
|-------------------------------------|--------------------------------|--------------------------------|-----------------------------|--------------------------------|-----------------------------|------------------------------|--------------------------------|------------------------------|
|                                     | Experimental<br>(n = 20)       | Control<br>(n = 15)            | Experimental<br>(n = 20)    | Control<br>(n = 15)            | P Value*<br>Baseline-1 Year | Experimental<br>(n = 20)     | Control<br>(n = 15)            | P Value*<br>Baseline-5 Years |
| Exercise                            |                                |                                |                             |                                |                             |                              |                                |                              |
| Times per week                      | 2.66 (0.84)                    | 2.38 (0.77)                    | 4.97 (0.35)                 | 2.87 (0.70)                    | .06                         | 4.34 (0.49)                  | 3.57 (0.56)                    | .64                          |
| Hours per week                      | 2.26 (0.85)                    | 2.42 (0.99)                    | 5.02 (0.61)                 | 2.52 (0.70)                    | .12                         | 3.56 (0.56)                  | 2.90 (0.65)                    | .50                          |
| Stress management                   |                                |                                |                             |                                |                             |                              |                                |                              |
| Times per week                      | 0.70 (0.41)                    | 0.15 (0.10)                    | 8.22 (0.73)                 | 0.49 (0.25)                    | <.001                       | 4.93 (1.02)                  | 0.74 (0.39)                    | <.001                        |
| Minutes per day                     | 6.01 (3.56)                    | 1.71 (1.19)                    | 87.25 (7.85)                | 4.47 (2.79)                    | <.001                       | 48.53 (10.36)                | 8.44 (6.11)                    | .001                         |
| Fat intake                          |                                |                                |                             |                                |                             |                              |                                |                              |
| Grams per day                       | 63.67 (4.35)                   | 57.42 (5.94)                   | 12.71 (1.06)                | 52.38 (5.31)                   | <.001                       | 17.34 (2.30)                 | 44.09 (6.66)                   | <.001                        |
| % of Energy intake                  | 29.71 (1.8)                    | 30.52 (2.9)                    | 6.22 (0.3)                  | 28.76 (2.3)                    | <.001                       | 8.51 (1.0)                   | 25.03 (2.7)                    | <.001                        |
| Dietary cholesterol, mmol/L [mg/dL] | 5.47 (0.672)<br>[211.4 (26.0)] | 5.49 (0.908)<br>[212.5 (35.1)] | 0.08 (0.002)<br>[3.3 (0.8)] | 4.69 (0.636)<br>[181.3 (24.6)] | <.001                       | 0.48 (0.140)<br>[18.6 (5.4)] | 3.59 (0.641)<br>[138.7 (24.8)] | .002                         |
| Energy intake, J/d                  | 8159 (473)                     | 7159 (489)                     | 7623 (473)                  | 7004 (489)                     | .64                         | 7724 (485)                   | 6581 (489)                     | .86                          |
| Total adherence score†              | 0.62 (0.08)                    | 0.60 (0.07)                    | 1.29 (0.08)                 | 0.64 (0.07)                    | <.001                       | 1.06 (0.08)                  | 0.72 (0.07)                    | <.001                        |

\*All P levels are 2-tailed and each is a result of a test of the null hypothesis that the change between 2 particular visits (eg, baseline and 1 year) does not differ between the experimental and control groups.

†Percentage of minimum recommended level of combined lifestyle change; includes all the above plus smoking cessation.

Table 3.—Baseline Levels, 1-Year, and 5-Year Change Scores in Coronary Artery Lesions\*

|                      | Mean at Baseline (95% CI) |                           | Change Scores at 1 Year (95% CI) |                            |                             | Change Scores at 5 Years (95% CI) |                           |                              |
|----------------------|---------------------------|---------------------------|----------------------------------|----------------------------|-----------------------------|-----------------------------------|---------------------------|------------------------------|
|                      | Experimental<br>(n = 20)  | Control<br>(n = 15)       | Experimental<br>(n = 18)         | Control<br>(n = 15)        | P Value†<br>Baseline-1 Year | Experimental<br>(n = 20)          | Control<br>(n = 15)       | P Value†<br>Baseline-5 Years |
| Diameter stenosis, % | 38.92<br>(35.29 to 42.54) | 42.50<br>(38.18 to 46.81) | -1.75<br>(-4.08 to 0.58)         | 2.28<br>(-3.0 to 4.86)     | .02                         | -3.07<br>(-5.91 to -0.24)         | 11.77<br>(3.40 to 20.14)  | .001                         |
| Minimum diameter, mm | 1.64<br>(1.44 to 1.84)    | 1.74<br>(1.50 to 1.97)    | 0.01<br>(-0.10 to 0.12)          | -0.12<br>(-0.25 to -0.001) | .11                         | 0.001<br>(-0.11 to 0.11)          | -0.34<br>(-0.66 to -0.02) | .05                          |
| Normal diameter, mm  | 2.65<br>(2.39 to 2.92)    | 2.96<br>(2.64 to 3.27)    | -0.06<br>(-0.16 to 0.03)         | -0.10<br>(-0.27 to 0.06)   | .68                         | -0.13<br>(-0.26 to 0.01)          | 0.045<br>(0.017 to 0.072) | .01                          |

\*CI indicates confidence interval.

†All P levels are 2-tailed and each is a result of a test of the null hypothesis that the change between 2 particular visits (eg, baseline and 1 year) does not differ between the experimental and control groups.

cluded in a single regression model. Statistical significances of group differences were obtained for baseline levels, 1-year changes, and 5-year changes using F tests. All repeated measures analyses were implemented using PROC MIXED under SAS version 6.08.<sup>11</sup> Analysis of lesion data used a repeated measures model in which the repeated measures were baseline or change values for multiple lesions within each subject. Change scores were used for the baseline to 1-year and baseline to 5-year follow-up periods, and analysis of baseline levels, 1-year changes, and 5-year changes were done separately. Again, F tests provided by SAS PROC MIXED were used to test significance of differences between groups with respect to baseline levels, 1-year changes, and 5-year changes. The SAS PROC MIXED linear regression, which allowed for dependence in data, was used to determine the relationship between adherence and percent diameter stenosis changes. Relative rates for cardiac events were analyzed and tested by Poisson regression using exact tests (Stata 5.0, College Station, Tex).

## RESULTS

### Baseline Comparisons of Volunteers With Refusals

Those who declined the invitation to be in the study were similar to those who

volunteered in all available data except those who volunteered were more likely to have a history of angina (87% vs 65%;  $P = .02$ ), a greater number of lesions (4.5 vs 3.5;  $P = .04$ ), and slightly more severely stenosed lesions (2.3 vs 2.0 on a 3-point scale;  $P = .05$ ).

### Baseline Comparisons of Experimental Group With Control Group

Analyses across the 35 volunteers at baseline for whom 4-year lesion data were available showed no significant differences between the experimental group and the control group in demographic characteristics, history of myocardial infarction, angioplasty, bypass surgery, lesion number, lesion stenosis, dietary fat or cholesterol intake, exercise and stress management practice, blood pressure, exercise capacity, and psychosocial measures (Tables 1-3).

Among the many comparisons, only a few differed significantly ( $P < .05$ ). More women were randomly assigned to the control group (4) than to the experimental group (1); this fact accounted for half the weight difference (10 kg) between the 2 groups and most of the height difference (6 cm).

Experimental group patients had a slightly larger body mass index (measured as the weight in kilograms divided

by the square of the height in meters) (23.4 vs 25.4 kg/m<sup>2</sup>;  $P = .03$ ) and had lower high-density lipoprotein (HDL) cholesterol levels (1.04 mmol/L [40.1 mg/dL] vs 1.36 mmol/L [52.4 mg/dL];  $P = .04$ ), which was also reflected in lower apolipoprotein A-I levels (3.45 mmol/L [133.1 mg/dL] vs 4.08 mmol/L [157.5 mg/dL];  $P = .03$ ). The lower body mass index in the control group may be due to the larger number of women in the control group. Other lipid values, including ratios of total cholesterol to HDL and LDL to HDL, did not differ significantly at baseline (Table 4).

### Program Adherence

In the experimental group, adherence to all aspects of the program was excellent during the first year and good after 5 years, whereas control group patients maintained more moderate changes during the 5 years consistent with conventional guidelines (Table 2). The percentage of daily energy (calories) provided by fruits, vegetables, whole grains, soy, other legumes, nonfat dairy, and alcohol was comparable at 1 year and at 5 years. In the experimental group, fat intake decreased from approximately 30% to 8.5%, cholesterol from 211 to 18.6 mg/d, energy from 8159 to 7724 J (1950-1846 cal), protein from 17% to 15%, and carbohydrates increased from 53% to 76.5%. In

Table 4.—Changes in Risk Factors

| Risk Factor                  | Mean (SEM) at Baseline       |                             | Mean (SEM) at 1 Year       |                              |
|------------------------------|------------------------------|-----------------------------|----------------------------|------------------------------|
|                              | Experimental (n = 20)        | Control (n = 15)            | Experimental (n = 20)      | Control (n = 15)             |
| Serum lipids, mmol/L [mg/dL] |                              |                             |                            |                              |
| Total cholesterol            | 5.83 (0.31) [225.1 (11.9)]   | 6.42 (0.24) [247.9 (9.4)]   | 4.22 (0.22) [162.9 (8.4)]  | 6.33 (0.38) [244.3 (14.7)]   |
| Low-density lipoprotein      | 3.72 (0.29) [143.80 (11.21)] | 4.30 (0.19) [166.40 (7.46)] | 2.24 (0.24) [86.56 (9.41)] | 4.25 (0.38) [164.13 (14.85)] |
| High-density lipoprotein     | 1.04 (0.07) [40.05 (2.78)]   | 1.26 (0.14) [52.36 (5.54)]  | 0.94 (0.10) [36.28 (3.81)] | 1.34 (0.10) [51.87 (3.81)]   |
| Triglyceride                 | 5.90 (0.69) [227.8 (26.5)]   | 5.78 (1.63) [223.3 (63.0)]  | 6.69 (0.75) [258.2 (29.1)] | 4.30 (0.40) [166.1 (15.5)]   |
| Apolipoproteins, g/L         |                              |                             |                            |                              |
| A-I                          | 1.331 (0.046)                | 1.575 (0.092)               | 1.308 (0.057)              | 1.761 (0.121)                |
| B                            | 1.000 (0.054)                | 1.024 (0.062)               | 0.7685 (0.046)             | 1.085 (0.053)                |
| Blood pressure, mm Hg        |                              |                             |                            |                              |
| Systolic                     | 135.3 (4.0)                  | 137.2 (4.5)                 | 126.4 (3.9)                | 128.8 (4.5)                  |
| Diastolic                    | 81.70 (2.05)                 | 80.27 (3.15)                | 77.03 (2.01)               | 75.07 (8.15)                 |
| Weight, kg                   | 91.40 (3.42)                 | 75.74 (4.37)                | 80.64 (2.48)               | 77.18 (4.73)                 |

\*All *P* levels are 2-tailed and each is a result of a test of the null hypothesis that the change between 2 particular visits (eg, baseline and 1 year) does not differ between the experimental and control groups.

Table 5.—Reported Angina Symptoms

|                                      | Mean (SD) at Baseline |                  | Mean (SD) at 1 Year   |                  | <i>P</i> Value*<br>Baseline-1 Year | Mean (SD) at 5 Years  |                  | <i>P</i> Value*<br>Baseline-5 Years |
|--------------------------------------|-----------------------|------------------|-----------------------|------------------|------------------------------------|-----------------------|------------------|-------------------------------------|
|                                      | Experimental (n = 18) | Control (n = 14) | Experimental (n = 18) | Control (n = 14) |                                    | Experimental (n = 18) | Control (n = 14) |                                     |
| Chest pain frequency, times per week | 5.8 (14.7)            | 1.4 (1.8)        | 0.5 (0.8)             | 4.0 (9.3)        | .08                                | 1.6 (2.7)             | 0.9 (1.9)        | .32                                 |
| Chest pain duration, min             | 3.1 (4.8)             | 3.2 (8.4)        | 1.8 (4.7)             | 7.6 (15.9)       | .11                                | 0.9 (1.3)             | 1.0 (2.7)        | .93                                 |
| Chest pain severity (1-7 scale)      | 1.5 (1.5)             | 0.6 (0.8)        | 0.7 (1.2)             | 1.4 (1.2)        | <.001                              | 0.9 (1.4)             | 0.6 (1.1)        | .29                                 |

\*All *P* levels are 2-tailed and each is a result of a test of the null hypothesis that the change between 2 particular visits (eg, baseline and 1 year) does not differ between the experimental and control groups.

the control group, fat intake decreased from 30% to 25%, cholesterol from 212.5 to 138.7 mg/d, energy from 5.49 to 3.59 J (1711-1573 cal), protein from 19% to 18%, and carbohydrates increased from 51% to 52%. Since patients volunteered originally only for a 1-year study, there was a significant decrease in meeting attendance after 1 year for 4 of the patients. Walking was the recommended form of exercise, but some patients jogged or did more strenuous exercise.

### Risk Factor Changes

Patients in the experimental group lost 10.9 kg (23.9 lbs) at 1 year and sustained a weight loss of 5.8 kg (12.8 lbs) at 5 years, whereas weight in the control group changed little from baseline. In the experimental group, LDL cholesterol levels decreased by 40% at 1 year and remained 20% below baseline at 5 years. In the control group, LDL cholesterol levels decreased by 1.2% at 1 year and by 19.3% at 5 years. There were no statistically significant differences in LDL levels between the 2 groups at 5 years, primarily because 9 (60%) of 15 control patients took lipid-lowering drugs between year 1 and year 5 of the study. None of the experimental group patients took lipid-lowering drugs during the 5 years of the study. Fourteen patients in the experimental group and 11 patients in the control group took aspirin during the study.

Triglycerides did not change significantly in either group. Apolipoprotein

A-I did not change in the experimental group, but it increased in the control group (*P* = .04). High-density lipoprotein levels and blood pressure did not differ between the 2 groups.

### Angina Pectoris

Experimental group patients had a 91% reduction in reported frequency of angina after 1 year and a 72% reduction after 5 years (Table 5). In contrast, control group patients had a 186% increase in reported frequency of angina after 1 year and a 36% decrease in frequency after 5 years. The decrease in angina in the control group after 5 years was in large part because 3 of the 5 patients who reported an increase in anginal episodes from baseline to 1 year underwent coronary angioplasty between years 1 and 5. Because of this reduction in angina in control group patients who underwent revascularization, the between-group differences were no longer significant after 5 years (Table 5).

### Angiographic Changes

All detectable lesions that matched at baseline and 5-year follow-up and were not 100% occluded at baseline were included in the analyses (*n* = 186). At baseline, there were no significant differences between the experimental and control groups in any measure of lesion severity (Table 3). In the experimental group, the average percent diameter stenosis at baseline decreased 1.75 absolute percentage points after 1 year (a

4.5% relative improvement) and by 3.1 absolute percentage points after 5 years (a 7.9% relative improvement). In contrast, the average percent diameter stenosis in the control group increased by 2.3 percentage points after 1 year (a 5.4% relative worsening) and by 11.8 percentage points after 5 years (a 27.7% relative worsening). These between-group differences were statistically significant after both 1 year and 5 years (*P* = .02 and *P* = .001, respectively, Figure 1).

Figure 2 shows the experimental group changes in percent diameter stenosis from baseline to 5 years according to tertiles of adherence to the lifestyle intervention. As seen at 1 year,<sup>3</sup> there was also a strong correlation between adherence and percent diameter stenosis after 5 years in a dose-response relationship; the tertile of patients that was most adherent to the program had the most regression, the tertile with intermediate adherence had less regression, and the tertile with the least adherence halted the progression of disease without regression (*P* = .04). Of interest is that this relationship was not related to age or disease severity. There was no significant relationship between adherence and lesion changes in the control group, perhaps because many of these patients began taking lipid-lowering drugs, which may have confounded the ability to detect a possible relationship. Indeed, we found significant correlations between changes in lipid levels (LDL and total cholesterol) and changes

| P Value*<br>Baseline-1 Year | Mean (SEM) at 5 Years       |                             | P Value*<br>Baseline-5 Years |
|-----------------------------|-----------------------------|-----------------------------|------------------------------|
|                             | Experimental<br>(n = 20)    | Control<br>(n = 15)         |                              |
| .004                        | 4.87 (0.20) [188.0 (7.8)]   | 5.62 (0.20) [217.0 (7.9)]   | .60                          |
| .003                        | 2.99 (0.20) [115.35 (7.59)] | 3.47 (0.21) [133.80 (8.25)] | .76                          |
| .35                         | 0.90 (0.05) [34.75 (2.03)]  | 1.28 (0.12) [49.27 (4.47)]  | .54                          |
| .17                         | 6.11 (0.59) [236.1 (22.9)]  | 5.48 (0.78) [211.5 (30.2)]  | .78                          |
| .11                         | 1.302 (0.092)               | 1.839 (0.139)               | .04                          |
| .004                        | 1.014 (0.072)               | 0.991 (0.083)               | .63                          |
| .96                         | 130.0 (3.9)                 | 123.3 (4.7)                 | .19                          |
| .91                         | 76.63 (2.01)                | 73.61 (3.25)                | .74                          |
| .001                        | 85.64 (2.88)                | 77.09 (4.5)                 | .001                         |

in lesions in both groups. These correlations remained significant when examining either the lipid values at 5 years or the change in lipid values from baseline to 5 years.

As a secondary analysis, we examined the results in control group patients who began taking lipid-lowering drugs during the study. Percent diameter stenosis progressed from 45.7% to 51.7%, a change of 6.0 absolute percentage points. In the control patients who did not take lipid-lowering drugs the disease progressed from 40.7% to 59.7%, a much greater change of 19.0 absolute percentage points. (No experimental group patients took lipid-lowering drugs during the study.)

The change in body mass index from baseline to 1 year ( $r = -0.85$ ;  $P < .001$ ) and from baseline to 5 years ( $r = -0.72$ ;  $P = .001$ ) was significantly correlated with the change in percent diameter stenosis in the control group only. In other words, those who gained weight were more likely to show progression of atherosclerosis.

### Cardiac Events

Data on cardiac events were obtained from all 48 patients. Cardiac events included myocardial infarction, coronary angioplasty, coronary artery bypass surgery, cardiac-related hospitalizations, and cardiac-related deaths. At 5 years, there were more cardiac events in the control group (45 events for 20 patients, or 2.25 events per patient) than the experimental group (25 events for 28 patients, or 0.89 events per patient) (Table 6). Control group patients were more likely to have undergone coronary angioplasty and bypass surgery and/or to have been hospitalized for cardiac-related problems than were experimental group patients.

### COMMENT

The primary end point of this study, chosen a priori, was percent diameter stenosis. On average, there was more re-

duction (continued improvement) after 5 years than after 1 year in experimental group patients who were asked to make intensive lifestyle changes. In contrast, control group patients showed much more progression (continued worsening) in average percent diameter stenosis after 5 years than after 1 year, even though more than half of the control group patients were prescribed lipid-lowering medications during the course of the study. Although the sample size was relative small,<sup>12</sup> these differences were statistically significant at both 1 year and 5 years. These findings support the feasibility of intensive lifestyle changes in delaying, stopping, or reversing the progression of coronary artery disease in ambulatory patients over prolonged periods.

We found more than twice as many cardiac events per patient in the control group than in the experimental group. These findings are consistent with other clinical trials showing that even small changes in percent diameter stenosis are often accompanied by marked reductions in cardiac events.<sup>13-16</sup> Other studies have demonstrated how quickly the coronary artery endothelium stabilizes in response to lipid-lowering drugs.<sup>17,18</sup>

Although there was some reduction in adherence to the intensive lifestyle intervention between years 1 and 5 in the experimental group, long-term adherence remained remarkably high in this sample of self-selected patients. The level of lifestyle change, even at 5 years, is greater than in any other published study of ambulatory populations. These results are especially encouraging because these patients initially volunteered to participate for only 1 year when they entered the study.

The experimental group reduced LDL cholesterol levels by 40% at 1 year and by 20% after 5 years; these reductions are comparable with those achieved with lipid-lowering drugs in an ambulatory

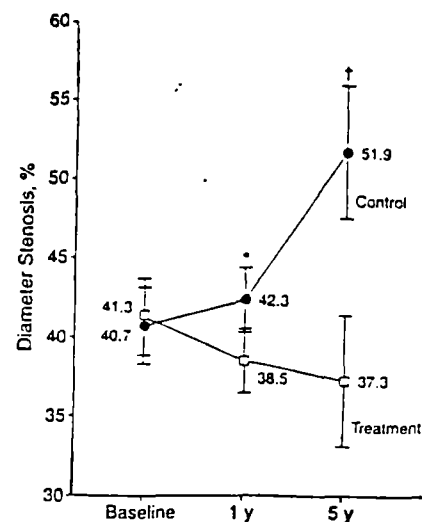


Figure 1.—Mean percentage diameter stenosis in treatment and control groups at baseline, 1 year, and 5 years. Error bars represent SEM; asterisk,  $P = .02$  by between-group 2-tailed test; dagger,  $P = .001$  by between-group 2-tailed test.

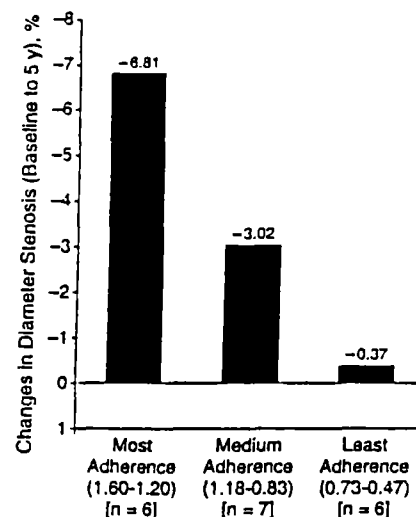


Figure 2.—Changes in percentage diameter stenosis by 5-year adherence tertiles for the experimental group.

population.<sup>19</sup> In contrast, the Step II diet reduces LDL cholesterol by only 5% or less.<sup>20,21</sup>

High-density lipoprotein levels decreased and triglycerides increased in experimental group patients overall, although the ratio of LDL to HDL was improved. Recent reports assert that this phenomenon, which is often seen in very low-fat diets, may be harmful.<sup>22,23</sup> However, patients in the Lifestyle Heart Trial showed even more regression of coronary atherosclerosis after 5 years than after 1 year as well as significantly decreased cardiac events. Low

Table 6.—Cardiac Events During 5-Year Follow-up

|                                                | No. of Events          |                   | Risk Ratio | 95% Confidence Interval | P Value |
|------------------------------------------------|------------------------|-------------------|------------|-------------------------|---------|
|                                                | Experimental* (n = 28) | Control† (n = 20) |            |                         |         |
| Myocardial infarction                          | 2                      | 4                 | 2.74       | 0.393-30.3              | .26     |
| Percutaneous transluminal coronary angioplasty | 8                      | 14                | 2.40       | 0.939-6.60              | <.05    |
| Coronary artery bypass graft                   | 2                      | 5                 | 3.43       | 0.561-36.0              | .14     |
| Cardiac hospitalizations‡                      | 23                     | 44                | 2.62       | 1.55-4.55               | <.001   |
| Deaths                                         | 2                      | 1                 | 0.685      | 0.012-13.2              | .81     |
| Any event                                      | 25                     | 45                | 2.47       | 1.48-4.20               | <.001   |

\*Person-years of observation was 108.04.

†Person-years of observation was 78.81.

‡Includes myocardial infarction, percutaneous transluminal coronary angioplasty, and coronary artery bypass graft.

HDL cholesterol levels due to reduced fat intake are the result of a decreased transport rate rather than the increased catabolism that is responsible for most cases of low HDL cholesterol levels in persons consuming a typical Western diet.<sup>24</sup> Populations consuming low-fat, plant-based diets have low HDL cholesterol levels and low rates of coronary heart disease. Our data provide evidence using quantitative coronary arteriography in this population that diet-induced lowering of HDL cholesterol does not confer the same risk of atherosclerosis as do low HDL cholesterol levels in Americans consuming a high-fat diet.<sup>25</sup> Experimental group patients whose triglycerides increased during the first year were asked to minimize their intake of simple carbohydrates, and triglyceride levels decreased between year 1 and year 5.

The experimental group's marked reduction in frequency, severity, and duration of angina after 1 year was sustained at similar levels after 5 years. This long-term reduction in angina is comparable with that achieved following coronary artery bypass surgery or angioplasty and helps to maintain long-term adherence.<sup>26</sup> Between-group differences in most measures of chest pain were not statistically significant after 5 years because there was a large variability in angina and control group patients who were the most symptomatic underwent revascularization.

When we began this study, we believed that the younger patients with milder disease would be more likely to show regression, but we did not find this to be true. Instead, we found that the primary determinant of change in percent diameter stenosis in the experimental group was neither age nor disease severity but adherence to the recommended changes in diet and lifestyle. This relationship of adherence to percent diameter stenosis in the experimental group was found after 1 year<sup>2</sup> and also after 5 years in a dose-response relationship. Coronary artery minimum diam-

eter remained stable in the experimental group but markedly narrowed in the control group during the 5 years of the study. At 5 years, the differences between the experimental and control groups were statistically significant for both percent diameter stenosis and minimum diameter, even though control group patients reported risk reduction behavior consistent with a Step II diet of the National Cholesterol Education Program and the American Heart Association: they consumed an average of 25% of energy (calories) from fat and exercised an average of 3.5 times per week. These data are consistent with other studies indicating that moderate changes in diet and lifestyle may not be sufficient to stop the progression of coronary atherosclerosis unless combined with lipid-lowering drugs.<sup>27</sup>

After 5 years, the normal diameter (the segment of least narrowing proximal to the minimum diameter) decreased slightly in the experimental group but widened slightly in the control group. A slight decrease in normal diameter, at least up to a point, may improve myocardial perfusion by streamlining flow—decreasing the forward flow losses that occur when going from a larger to a sharply reduced lumen diameter.<sup>4</sup> Conversely, the slight increase in the normal diameter and reduction in the minimum diameter seen in control group patients increased the entry angle, further reducing blood flow. These theoretical considerations are consistent with the substantially increased myocardial perfusion in the experimental group and decreased myocardial perfusion in the control group that we measured using cardiac positron emission tomography scans.<sup>5</sup>

A much earlier study by Morrison<sup>28</sup> found that moderate reductions in fat and cholesterol intake improved cardiac survival: after 12 years, all of the control group patients had died compared with only 62% of experimental group patients in a nonrandomized trial. More recently, an important study by Esselstyn

et al<sup>29</sup> reported that a similar diet plus lipid-lowering drugs in 11 patients caused regression of 11 lesions and stabilization in the remaining 14 lesions after 5.5 years. Although there was no control group, those who were adherent to the diet reported substantially fewer cardiac events than those who were not adherent.<sup>29</sup>

Like all clinical trials, our study has limitations. Although the study participants were a diverse group, they may not be representative of the general population of patients with coronary heart disease. Half of the patients who underwent quantitative coronary arteriography in the participatory hospitals did not meet all of the inclusion and exclusion criteria and were not invited to participate in the study. Also, half of the patients who were invited declined to enroll in the study. Nevertheless, it is encouraging that 50% of the patients who were contacted agreed to volunteer despite the requirement for repeated arteriography and that experimental group patients were able to make and maintain comprehensive lifestyle changes. The angiographic measures lost to follow-up may have affected the treatment and control groups differently, although there are no data to suggest that this occurred. In addition, there is a possibility of differential loss of lesions in patients, although no evidence indicates that this occurred; in both groups, there were 14 lesions that were lost to follow-up. Also, 4 lesions were lost in the control group to bypass surgery or angioplasty; since these lesions were worsening sufficiently to require revascularization, the exclusion of these lesions from analysis would make between-group differences more difficult to detect. We recently completed a multicenter demonstration project to assess the practicality and cost-effectiveness of this intervention in a larger sample of economically and geographically diverse patients with coronary heart disease.<sup>30</sup>

Although we did not use lipid-lowering drugs in the experimental group, their value has been demonstrated in studies that have been published since the Lifestyle Heart Trial began. We do not know if experimental group patients may have demonstrated even more improvement by including lipid-lowering drugs.<sup>14-16</sup> Patients in the control group who were not prescribed lipid-lowering drugs during the study showed more than 3 times as much progression in percent diameter stenosis as those who were. No experimental group patients took lipid-lowering drugs during the study, yet they showed better results than control group patients who were taking these drugs. Lipid-lowering drugs are expensive, compli-

ance is difficult to achieve,<sup>31</sup> and long-term safety is unknown.<sup>32</sup> In practice, patients may be offered a range of therapeutic options, including comprehensive lifestyle changes, lipid-lowering drug therapy, and revascularization, either separately or in combination.

In summary, these ambulatory patients were able to make and maintain comprehensive changes in diet and lifestyle for 5 years and showed even more regression of coronary atherosclerosis after 5 years than after 1 year as measured by percent diameter stenosis. In contrast, patients following more conventional lifestyle recommendations showed even more progression of coronary atherosclerosis after 5 years than after 1 year, and had more than twice as

many cardiac events as patients making comprehensive lifestyle changes.

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