

Saint Louis University Journal of Health Law & Policy

Volume 4
Issue 1 *Pandemic Preparedness: Lessons
Learned & Future Challenges*

Article 10

2010

Improving the Treatment & Prevention of Heart Disease

Jeff Herman
herman.jeffa@gmail.com

Follow this and additional works at: <https://scholarship.law.slu.edu/jhlp>



Part of the [Health Law and Policy Commons](#)

Recommended Citation

Jeff Herman, *Improving the Treatment & Prevention of Heart Disease*, 4 St. Louis U. J. Health L. & Pol'y (2010).

Available at: <https://scholarship.law.slu.edu/jhlp/vol4/iss1/10>

This Student Comment is brought to you for free and open access by Scholarship Commons. It has been accepted for inclusion in Saint Louis University Journal of Health Law & Policy by an authorized editor of Scholarship Commons. For more information, please contact [Susie Lee](#).

IMPROVING THE TREATMENT & PREVENTION OF HEART DISEASE

On the morning of January 16, 2006, my mother felt a pressure in the very center of her chest. At first, she thought it was the cold air, but something felt wrong. She went back inside, took an Aspirin, and looked up the symptoms of a heart attack online, which matched hers. The website told her the biggest mistake people make is waiting to get help, so she quickly got a ride to the emergency room. While her electrocardiogram looked normal, her pain did not subside, so a surgeon performed a cardiac catheterization to diagnose the cause. The procedure revealed a 90% blockage in one artery and 80% in another. The surgeon immediately performed angioplasty and inserted a drug-eluting stent.

No one—not her surgeon, cardiologist, general internist, or any health professional—ever told my mom the stent she received, while it relieved her pain in this emergency, would not reduce her risks of dying or having a heart attack in the future. Instead, it was her friend who told her in a casual encounter, “Stents don’t work, you know.” Nor did any health professional tell her there was a diet she could follow that could reverse her heart disease and practically guarantee she would never have a heart attack. Instead, by happenstance, my mother later found a book called *Dr. Dean Ornish’s Program for Reversing Heart Disease*, which told her the power of diet and lifestyle over heart disease, and she began following the diet soon after.¹ The only dietary advice she ever received from a health professional was sheet of paper from a nurse when she was discharged from the hospital, which described the diet advocated by the American Heart Association (AHA), which cannot produce the same benefits as the Ornish program.

Former President Bill Clinton had a similar experience. He underwent quadruple bypass surgery in 2004 for his heart disease, but his new arteries became clogged with plaque in less than six years, and in early 2010 had two stents put in.² Dr. Allan Schwartz, Chief of Cardiology at the hospital where President Clinton was treated, basically said President Clinton

1. DEAN ORNISH, DR. DEAN ORNISH’S PROGRAM FOR REVERSING HEART DISEASE 14 (Ballantine Books 1995).

2. Bill Clinton “In Good Spirits” After Heart Procedure, BBC, <http://news.bbc.co.uk/2/hi/americas/8511817.stm> (last updated Feb. 12, 2010); Clinton Leaves Hospital After Heart Procedure, CNN, Feb. 11, 2010, http://articles.cnn.com/2010-02-11/politics/bill.clinton_1_dr-allan-schwartz-post-bypass-graft?_s=PM:POLITICS.

followed the best diet and exercise program available, but was completely powerless to prevent his arteries from reclogging.³ President Clinton found differently. Motivated by a desire to prevent another stent, he also discovered the research by Dr. Ornish showing individuals can reverse their heart disease through diet and lifestyle.⁴ He decided to follow the diet and find out if he, too, could reverse his heart disease.⁵

My mother and President Clinton had to discover critical information about heart disease on their own, rather than learning it from their treating health professionals. Unfortunately, most others probably never find out at all. This needs to change. We need to improve the treatment and prevention of heart disease by telling patients how to prevent and reverse the disease through diet and lifestyle, and by helping patients willing to make those changes. Heart disease is by far the deadliest and costliest disease in the United States,⁶ and diet and lifestyle is the only way to truly treat the disease, not merely its symptoms.⁷ Individual patients need to be given this information so they can make fully informed choices. It could potentially save their lives, save them lots of money in the process,⁸ and drastically reduce spending by overburdened public and private health insurance programs.⁹

Section I of this article discusses the science: what heart disease is and the effectiveness of surgical, pharmaceutical, and dietary interventions. It shows that diet and lifestyle is the best treatment available for heart disease. Section II discusses the problem: physicians do not usually give dietary

3. *Clinton Leaves Hospital After Heart Procedure*, *supra* note 2 ("Schwartz said the need for the procedure had nothing to do with Clinton's post-bypass diet or exercise, which Schwartz called excellent. Rather, Schwartz said, this is "part of the natural history" of the bypass treatment. "He really toed the line in terms of diet and exercise. He really followed the program.").

4. *Clinton's Weight Loss Secret: Plants*, CNN, Sept. 22, 2010, <http://www.cnn.com/video/#/video/us/2010/09/21/intv.clinton.blitzer.weight.loss.cnn>.

5. *Id.*

6. See Donald Lloyd-Jones et al., *Heart Disease and Stroke Statistics 2009 Update: A Report From the American Heart Association Statistics Committee and Stroke Statistics Subcommittee*, 119 CIRCULATION e21, e32, e172 (2009) [hereinafter American Heart Association Committee Report].

7. See discussion *infra* Section I.A-C (discussing surgical, pharmaceutical, and dietary and lifestyle interventions for heart disease). See generally ORNISH, *supra* note 1, at 12-14 (explaining that surgery "bypassed the underlying causes of the problem" while diet and lifestyle changes impact the causes of heart disease).

8. See generally Dean Ornish, *Avoiding Revascularization with Lifestyle Changes: The Multicenter Lifestyle Demonstration Project*, 82 AM. J. CARDIOLOGY 72T, 75T (1998) [hereinafter Ornish, *Multicenter Lifestyle Demonstration Project*] (explaining the difference in cost per patient between a group of patients undergoing heart surgery and a group using diet and exercise).

9. *Id.* at 72T.

advice, and even when they do, they give poor advice. It is thus no surprise that heart patients have very poor diets and lifestyles since the person they are looking to for the best information and advice on their disease is not providing it. Section III discusses the cause: physicians stick primarily to drugs and surgery and avoid dietary interventions for a lot of reasons, including lack of knowledge, training, and confidence, lack of time, a belief the patient will not comply with the advice, reimbursement issues, and others. Section IV discusses potential cures: ways to use the law to inform physicians and encourage or require them to give this information to their patients. Strategies include reforming medical education,¹⁰ statutorily mandated physician disclosures, private insurance coverage mandates, and holding physicians liable through tort law.¹¹ Each should be considered in order to improve public health.

I. THE SCIENCE

This section discusses (A) what heart disease is, (B) the effectiveness of surgical interventions, (C) the effectiveness of pharmaceutical interventions, and (D) the effectiveness of diet and lifestyle. Heart disease is a terrible problem for individuals and the health system, and the most effective and cost-effective tool for addressing this disease is diet and lifestyle.

A. Heart Disease

Heart disease encompasses several types of diseases affecting the heart and its blood vessels.¹² The most common type of heart disease is coronary artery disease, which occurs when a person's arteries become hard and narrow due to the buildup of atherosclerotic plaque.¹³ Nearly all children

10. See Vilma L. Patel, Nicole A. Yoskowitz & Jose F. Arocha, *Towards Effective Evaluation and Reform in Medical Education: A Cognitive and Learning Sciences Perspective*, 14 ADVANCES IN HEALTH SCI. EDUC. 791, 808 (2009) (discussing the importance of reforming medical education to align with current state of healthcare delivery system).

11. See generally William B. Runciman, Alan F. Merry & Fiona Tito, *Error, Blame and the Law in Health Care – An Antipodean Perspective*, 138 ANNALS INTERNAL MED. 974, 977-78 (2003) (describing how tort law influences physician and patient interaction); Doug Wojcieszak, John Banja & Carole Houk, *The Sorry Works! Coalition: Making the Case for Full Disclosure*, 32 JOINT COMM'N J. ON QUALITY & PATIENT SAFETY 344, 344 (2006) (advocating the use of full disclosure to inform patients and change the culture of medicine).

12. Mayo Clinic Staff, *Heart Disease Definition*, MAYO CLINIC (Jan. 28, 2009), <http://www.mayoclinic.com/health/heart-disease/DS01120> [hereinafter *Heart Disease Definition*] ("The term 'heart disease' is often used interchangeably with 'cardiovascular disease' — a term that generally refers to conditions that involve narrowed or blocked blood vessels that can lead to a heart attack, chest pain (angina) or stroke.").

13. *Heart Disease: Frequently Asked Questions*, NAT'L WOMEN'S HEALTH INFO. CTR. (Feb. 2, 2009), <http://www.womenshealth.gov/faq/heart-disease.cfm#a>. Other, less common

have fatty streaks in their arteries by age three¹⁴ and atherosclerotic plaque by adolescence.¹⁵ A heart attack occurs when the plaque ruptures, creating a clot that blocks the flow of oxygen-rich blood to the heart.¹⁶

Heart disease is easily the deadliest disease in the United States.¹⁷ In 2005, it caused 35.3% of all deaths in the United States, killing more Americans than cancer, accidents, chronic lower respiratory disease, and diabetes combined.¹⁸ It is estimated that 80 million American adults current have a cardiovascular disease, including 16.8 million adults with coronary artery disease.¹⁹ An American has a heart attack every thirty-four seconds.²⁰

Treating heart disease is a huge financial burden. In 2009, the total direct and indirect costs of heart disease were estimated at \$304.6 billion in the United States alone.²¹ Overall, cardiovascular diseases were estimated to cost Americans \$475.3 billion in 2009, more than any other diagnostic group, including cancer.²²

Due to the large human and financial toll caused by heart disease, promoting the most effective and cost-effective therapies to treat and prevent the disease should be a top priority for healthcare providers and the government. There are three basic types of therapies to choose from—surgery, drugs, and diet and lifestyle.²³

types of heart disease include heart failure and heart arrhythmia, *id.*, as well as congenital heart defects, *Heart Disease Definition*, *supra* note 12.

14. Elaine M. Urbina et al., *Noninvasive Assessment of Subclinical Atherosclerosis in Children and Adolescents: Recommendations for Standard Assessment for Clinical Research: A Scientific Statement from the American Heart Association*, 54 HYPERTENSION 919, 919 (2009) (citing C. Napoli et al., *Childhood Infection and Endothelial Dysfunction: A Potential Link in Atherosclerosis?*, 111 CIRCULATION 1568, 1568 (2005)).

15. *Id.* (citing Herbert C. Stary et al., *A Definition of the Intima of Human Arteries and of Its Atherosclerosis-prone Regions: A Report from the Committee on Vascular Lesions of the Council on Arteriosclerosis, American Heart Association*, 85 CIRCULATION 391-405 (1992)).

16. *What Is a Heart Attack?*, NAT'L HEART LUNG & BLOOD INST. (Mar. 2008), http://www.nhlbi.nih.gov/health/dci/Diseases/HeartAttack/HeartAttack_WhatIs.html.

17. See *Cardiovascular Diseases*, WORLD HEALTH ORG. (Sept. 2009), <http://www.who.int/mediacentre/factsheets/fs317/en/index.html>.

18. American Heart Association Committee Report, *supra* note 6, at e32.

19. *Id.* at e31.

20. *Id.* at e60.

21. *Id.* at e172. Similarly, the EU spent \$285 billion on heart disease. Nick Prag, *Heavy Price of Heart Disease in Europe*, 390 EU BUSINESS WEEK (Feb. 29, 2008), <http://www.eu-business.com/Newsire/newsletter390.2008-02-28/?searchterm=heart%20disease>.

22. American Heart Association Committee Report, *supra* note 6, at e192.

23. Mayo Clinic Staff, *Heart Disease: Treatments and Drugs*, MAYO CLINIC (Jan. 28, 2009), <http://www.mayoclinic.com/health/heart-disease/DS01120/DSECTION=treatments-and-drugs>.

B. Surgical Interventions

There are two basic types of surgical interventions for heart disease: bypass surgery and angioplasty.²⁴ In 2006, 448,000 bypass surgeries and over 1.31 million angioplasties were performed in the United States.²⁵ At an average cost of \$99,743 for bypass surgery and \$48,399 for angioplasty, these two procedures alone cost over \$100 billion in 2006.²⁶ In bypass surgery, blood is rerouted around the diseased, blocked artery, improving blood flow.²⁷ In angioplasty, a balloon is inflated inside the blocked artery, which pushes the blockage against the artery walls, increasing blood flow.²⁸ During angioplasty, a "stent" (a small, hollow metal tube) may be permanently left in the artery, pushing the blockage against the artery walls.²⁹ There are both bare metal stents and drug-eluting stents, the latter of which are coated with a drug that is slowly released in the hopes it will prevent the artery from reclosing.³⁰

The operations themselves carry significant risks. Roughly 3% to 6% of patients undergoing bypass surgery die as a result of the procedure.³¹ The risk of death substantially increases with age, a recent heart attack, left ventricular failure, additional health problems, total body surface area, and with each subsequent bypass surgery performed.³² Patients undergoing

24. AM. HEART ASS'N, INC., CARDIAC PROCEDURES AND SURGERIES AT-A-GLANCE (2008), available at http://www.heart.org/idc/groups/heart-public/@wcm/@hcm/documents/downloadable/ucm_304569.pdf. Bypass surgery is also called Coronary Artery Bypass Graft, or CABG, which is pronounced "cabbage." *Id.* Angioplasty also goes by the name of Percutaneous Coronary Interventions, or PCI. *Id.*

25. American Heart Association Committee Report, *supra* note 6, at e63.

26. Dean Ornish, *Intensive Lifestyle Changes and Health Reform*, 10 LANCET ONCOLOGY 638, 638-39 (2009). See also American Heart Association Committee Report, *supra* note 6.

27. AM. HEART ASS'N, *supra* note 24, at 2.

28. *Id.* at 1.

29. See *id.*

30. Mayo Clinic Staff, *Coronary Artery Disease: Drug-Eluting Stents: Do They Increase Heart Attack Risk?*, MAYO CLINIC (July 16, 2009), <http://www.mayoclinic.com/health/drug-eluting-stents/HB00090>.

31. Compare Peter Peduzzi, Ayumi Kamina & Katherine Detre, *Twenty-Two-Year Follow-Up in the VA Cooperative Study of Coronary Artery Bypass Surgery for Stable Angina*, 81 AM. J. CARDIOLOGY 1393, 1396 (1998) (finding operative mortality for bypass patients in the study sample to be 5.8%) and Navid Sadeghi et al., *Determinants of Operative Mortality Following Primary Coronary Artery Bypass Surgery*, 21 EUR. J. CARDIO-THORACIC SURGERY 187, 188 (2001) (finding operative mortality for one surgeon to be 2.98%) with Yoshito Kawachi et al., *Risk Stratification Analysis of Operative Mortality in Coronary Artery Bypass Surgery*, 49 JAPANESE J. THORACIC & CARDIOVASCULAR SURGERY 557, 558-59 (2001) (finding operative mortality rate of 4.0-4.8% among patients under eighty).

32. See L.E. Daly, M. Lonergan & I. Graham, *Predicting Operative Mortality After Coronary Artery Bypass Surgery in Males*, 86 Q.J. MED. 771, 773 tbl.2 (1993). See also Kawachi et al., *supra* note 31 (finding a 14% hospital mortality rate in patients older than

bypass surgery have also been shown to suffer significant short-term and long-term declines in cognitive functioning.³³ While the mortality rate for angioplasty is much lower than for bypass surgery (likely less than 1%),³⁴ about 4% of patients undergoing angioplasty experience major complications, such as further emergency surgery, heart attack, or death.³⁵

These procedures are also not very effective. Several studies have evaluated these procedures by determining whether those who have the procedure are significantly less likely over time to die or have a heart attack than those who receive non-surgical medical treatment (i.e., prescription drugs and a doctor's advice to eat well and exercise).³⁶ The results are not encouraging.³⁷

Generally, bypass surgery may have short-term survival benefits—especially for high-risk individuals—but no long-term survival benefits.³⁸ The Veterans Affairs Cooperative Study of Coronary Artery Bypass Surgery (VA Study) randomized 686 patients with heart disease into a control group receiving medical therapy or an experimental group receiving bypass

eighty years); Peduzzi, Kamina & Detre, *supra* note 31; Guo-wei He et al., *Determinants of Operative Mortality in Reoperative Coronary Artery Bypass Grafting*, 110 J. THORACIC & CARDIOVASCULAR SURGERY 971, 971 (1995) (finding higher incidence of mortality in reoperation patients).

33. See Stephan C. Knipp et al., *Cognitive Outcomes Three Years After Coronary Artery Bypass Surgery: Relation to Diffusion-Weighted Magnetic Resonance Imaging*, 85 ANNALS THORACIC SURGERY 872, 876 (2008) (finding that cognitive functioning declined on seven measures immediately after discharge, with most improving after three months, followed by late decline on two measures and persistent deterioration of verbal memory); Mark F. Newman et al., *Longitudinal Assessment of Neurocognitive Function After Coronary-Artery Bypass Surgery*, 344 NEW ENG. J. MED. 395, 397 (2001) (finding that 53% of patients experienced significant cognitive decline at discharge, 36% after six weeks, 24% after six months, and 42% after five years). But see Ola A. Selnes et al., *Cognitive Outcomes Three Years After Coronary Artery Bypass Surgery: A Comparison of On-Pump Coronary Artery Bypass Graft Surgery and Nonsurgical Controls*, 79 ANNALS THORACIC SURGERY 1201, 1206-08 (2005) (finding no significant change in cognitive functioning of a bypass surgery group compared to a nonsurgical group).

34. See, e.g., N.Y. STATE DEP'T OF HEALTH, PERCUTANEOUS CORONARY INTERVENTIONS (PCI) IN NEW YORK STATE 2004-2006 8 tbl.1 (2009), available at http://www.health.state.ny.us/statistics/diseases/cardiovascular/docs/pci_2004-2006.pdf (finding the overall mortality rate for angioplasty in all hospitals in New York State was 0.87% between 2004-2006).

35. See, e.g., Clayton E. Bredlau et al., *In-Hospital Morbidity and Mortality in Patients Undergoing Elective Coronary Angioplasty*, 72 CIRCULATION 1044, 1046 (1985).

36. Ornish, *Multicenter Lifestyle Demonstration Project*, *supra* note 8.

37. *Id.* at 74T.

38. See, e.g., Veterans Admin. Coronary Artery Bypass Surgery Cooperative Study Group, *Eleven-Year Survival in the Veterans Administration Randomized Trial of Coronary Bypass Surgery for Stable Angina*, 311 NEW ENG. J. MED. 1333, 1336 (1984) [hereinafter Veterans Admin., *Eleven-Year Survival*].

surgery.³⁹ After seven years, the survival rate was higher in the surgical group (77% to 70%).⁴⁰ After eleven years, however, the survival rate was 58% in both groups,⁴¹ and after eighteen years⁴² and twenty-two years⁴³ the survival rate in the medical group exceeded the survival rate in the surgery group (the differences were not statistically significant).⁴⁴ Moreover, after twenty-two years, low-risk patients were more likely to have survived in the medical group rather than the surgery group.⁴⁵ Also, though three types of high-risk patients had higher survival rates with surgery after both seven and eleven years,⁴⁶ there was no benefit after eighteen years⁴⁷ or twenty-two years.⁴⁸ The European Coronary Surgery Study⁴⁹ and the Coronary Artery Surgery Study (CASS)⁵⁰ reached similar results. An analysis of all these

39. *Id.* at 1333.

40. *Id.* at 1335.

41. *Id.*

42. Veterans Admin. Coronary Artery Bypass Surgery Cooperative Study Group, *Eighteen-Year Follow-up in the Veterans Affairs Cooperative Study of Coronary Artery Bypass Surgery for Stable Angina*, 86 CIRCULATION 121, 123 (1992) [hereinafter Veterans Admin., *Eighteen-Year Follow-up*].

43. Peduzzi, Kamina & Detre, *supra* note 31, at 1394-95.

44. *Id.* at 1395.

45. *Id.* at 1393 (31% to 24%). Low-risk patients were those with one-, two-, or three-vessel disease and normal left ventricular function. *Id.* However, while those with two-vessel disease experienced no survival benefit with surgery after seven years, Veterans Admin., *Eleven-Year Survival*, *supra* note 38, at 1335, or twenty-two years, Peduzzi, Kamina & Detre, *supra* note 31, there were marginally significant benefits after eleven years, Veterans Admin., *Eleven-Year Survival*, *supra* note 38, at 1335, and eighteen years, Veterans Admin., *Eighteen-Year Follow-up*, *supra* note 42, at 124 (34% to 30%, p-value of 0.09, significant only at an alpha of 0.10).

46. Veterans Admin., *Eleven-Year Survival*, *supra* note 38, at 1333 (the groups were: (1) those with three-vessel disease and impaired left ventricular function; (2) those with at least two of the following: resting ST depression, history of myocardial infarction, and history of hypertension; and (3) those falling into both groups).

47. Veterans Admin., *Eighteen-Year Follow-up*, *supra* note 42, at 123-24.

48. Peduzzi, Kamina & Detre, *supra* note 31, at 1397.

49. Eur. Coronary Surgery Study Group, *Long-Term Results of Prospective Randomised Study of Coronary Artery Bypass Surgery in Stable Angina Pectoris*, 2 LANCET 1173, 1173-80 (1982); Edvardas Varnauskas & Eur. Coronary Surgery Study Group, *Twelve-Year Follow-up of Survival in the Randomized European Coronary Surgery Study*, 319 NEW ENG. J. MED. 332, 335-36 (1988). That study, involving 767 men, found a survival benefit after five years for those receiving surgery, but thereafter a significantly larger percentage of patients in the surgery group died. *Id.* However, after twelve years, overall there was still a survival benefit for the surgery group, though the size of the benefit had significantly diminished. *Id.*

50. Edwin L. Alderman et al., *Ten-Year Follow-up of Survival and Myocardial Infarction in the Randomized Coronary Artery Surgery Study*, 82 CIRCULATION 1629, 1636 (1990) [hereinafter Alderman et al., *CASS Study*]. Study, involving 780 patients, after ten years found no difference in survival or the percentage of those still alive and heart attack-free. *Id.* Low-risk patients (those with an ejection fraction of 0.50 or more) were more likely to be alive and

studies showed that, on average, bypass surgery adds about 4.3 months to a person's life over ten years, but none thereafter.⁵¹

With respect to future heart attacks, surgery may be worse than medical therapy. In the VA Study, after eighteen years, those receiving surgery were more likely to have had a fatal heart attack (44% to 32%),⁵² and less likely to be both alive and heart attack-free (18% to 25%).⁵³ After twenty-two years, those in the surgical group were more likely to have had a fatal or non-fatal heart attack (59% to 43%) and again less likely to be both alive and heart attack-free (11% to 18%).⁵⁴ The CASS Study similarly found no difference in the occurrence of non-fatal heart attacks after ten years,⁵⁵ and low-risk patients were more likely to be alive and heart-attack free without bypass surgery.⁵⁶ Overall, bypass surgery is recommended in only limited circumstances.⁵⁷

In emergency situations, such as in the midst of a heart attack, angioplasty can save a person's life.⁵⁸ In non-emergency situations, however, no form of angioplasty reduces the risks of death or heart attack compared to non-surgical medical therapy.⁵⁹ A 2009 meta-analysis examined the results of seven studies of basic angioplasty and four studies

heart attack-free with initial medical therapy (75% to 68%), but overall no more likely to have survived. *Id.* However, high-risk patients (those with an ejection fraction of less than 0.50) had better survival rates with initial surgery (79% to 61%). *Id.* This is similar to the VA Study, which found that high-risk patients had greater survival after seven and eleven years, but not after eighteen or twenty-two years. See *supra* notes 45-47 and accompanying text.

51. Am. C. of Cardiology/Am. Heart Ass'n Task Force on Prac. Guidelines, *ACC/AHA 2004 Guideline Update for Coronary Artery Bypass Graft Surgery*, 110 CIRCULATION e340, e354 (2004) [hereinafter *ACC/AHA 2004 Guideline Update*] (finding that the survival benefit for those with left main disease is 19.3 months).

52. Veterans Admin., *Eighteen-Year Follow-up*, *supra* note 42, at 121.

53. *Id.* at 125.

54. Peduzzi, Kamina & Detre, *supra* note 31, 1396 tbl.II.

55. Alderman et al., *CASS Study*, *supra* note 50, at 1629.

56. *Id.*

57. See *ACC/AHA 2004 Guideline Update*, *supra* note 51, at e406 (identifying recommendations in various situations).

58. See Ellen C. Keeley, Judith A. Boura & Cindy L. Grines, *Primary Angioplasty Versus Intravenous Thrombolytic Therapy for Acute Myocardial Infarction: A Quantitative Review of 23 Randomised Trials*, 361 LANCET 13, 13 (2003); Shamir R. Mehta et al., *Routine vs. Selective Invasive Strategies in Patients with Acute Coronary Syndromes: A Collaborative Meta-Analysis of Randomized Trials*, 293 JAMA 2908, 2913-14 (2005).

59. Thomas A. Trikalinos et al., *Percutaneous Coronary Interventions for Non-Acute Coronary Artery Disease: A Quantitative 20-Year Synopsis and a Network Meta-Analysis*, 373 LANCET 911, 915 (2009) (finding no difference between surgical and medical therapy on non-acute coronary artery disease).

of bare metal stents.⁶⁰ Compared to standard medical therapy, *neither* procedure reduced the risks of death or heart attack over time *at all*.⁶¹ The authors also found that drug-eluting stents performed no better.⁶² Angioplasty is even less effective and far more expensive than simply exercising twenty minutes a day.⁶³ Today, the American College of Cardiologists warns patients that “stents. . . don’t prevent heart attacks [They] are only indicated for patients who are having angina symptoms or are in the midst of having a heart attack.”⁶⁴

C. Pharmaceutical Interventions

Statins are a class of drugs designed to lower cholesterol.⁶⁵ They are the best-selling drugs in the world,⁶⁶ and more than seventeen thousand articles have been published about them in peer-reviewed journals.⁶⁷ The side effects of statins include muscle pain, liver damage, and digestive

60. See *id.* at 911-17 (finding the seven studies of basic angioplasty had a median of 201 patients and sixty months of follow-up, and four studies of bare metal stents had a median of 1,134 patients and thirty months of follow-up).

61. *Id.* at 915.

62. *Id.*

63. Rainer Hambrecht et al., *Percutaneous Coronary Angioplasty Compared with Exercise Training in Patients with Stable Coronary Artery Disease*, 109 CIRCULATION 1371, 1374-76 (2004) (patients who exercised were more likely to live without a cardiovascular event than those who received angioplasty (88% versus 70%), and for about 60% of the cost (an average of \$3,708 for exercise versus \$6,086 for angioplasty)). Also, the heart disease worsened in significantly more of the patients receiving surgery. *Id.* at 1376.

64. *Do Stents Prevent Heart Attacks?*, AM. C. OF CARDIOLOGY, <http://www.cardiosmart.org/MakeConnections/AskCardiologist.aspx?id=362> (last visited Sept. 22, 2010). CardioSmart is the patient education site of the American College of Cardiology. *About CardioSmart and the ACC*, AM. C. OF CARDIOLOGY, <http://www.cardiosmart.org/CardioSmart/Default.aspx?id=920> (last visited Dec. 29, 2009).

65. Mayo Clinic Staff, *Statin Side Effects: Weigh the Benefits and Risks*, MAYO CLINIC (Oct 28, 2010), <http://www.mayoclinic.com/health/statin-side-effects/MY00205> [hereinafter Mayo Clinic, *Statin Side Effects*]; Robert W. Mahley & Thomas P. Bersot, *Drug Therapy for Hypercholesterolemia and Dyslipidemia*, in GOODMAN & GILMAN’S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 933, 933 (Laurence L. Brunton, John S. Lazo & Keith L. Parker eds., 11th ed. 2006). Statins are also known as HMG CoA reductase inhibitors. *Id.* They primarily work by lowering LDL, the “bad” cholesterol. *Id.*

66. Matthew Herper & Peter Kang, *The World’s Ten Best-Selling Drugs*, FORBES.COM (Mar. 22, 2006), http://www.forbes.com/2006/03/21/pfizer-merck-amgen-cx_mh_pk_0321_topdrugs.html (Pfizer manufactures Lipitor, which is the best-selling drug in the world by far, with sales of over \$12.9 billion in 2006, more than double its nearest competitor); *Do Statins Increase Cancer Risk?*, CANCER DECISIONS (Oct. 14, 2007), <http://www.cancerdecisions.com/content/view/34/2/lang,english/> (144.5 million prescriptions for statins were written in 2005 alone).

67. *Do Statins Increase Cancer Risk?*, *supra* note 66.

problems,⁶⁸ although the risks associated with the long-term use of statins (e.g., over decades) remain unknown.⁶⁹

Statins are not a magic pill when it comes to heart disease, but they can help some people. It is uncontroversial for people already diagnosed with heart disease to take statins,⁷⁰ as statins can reduce their risks of death and future heart attack.⁷¹ However:

statins should not be prescribed for true primary prevention [those not diagnosed with occlusive vascular disease] in women of any age or for men older than 69 years. High-risk men aged 30 to 69 years should be advised that about 50 patients need to be treated for 5 years to prevent one [cardiac] event. In our experience, many men presented with this evidence do not choose to take a statin, especially when informed of the potential benefits of lifestyle modification on cardiovascular risk and overall health.⁷²

Ultimately, contrary to what many people might believe, drugs and surgery are not very effective solutions to heart disease. If they were, heart disease would not still be far and away the deadliest disease in this country. Neither intervention addresses the cause of heart disease—a person's diet and lifestyle—and neither can reverse the disease process or totally prevent future heart attacks. There is only one way to do so.

D. Diet and Lifestyle

The INTERHEART study found that 90% of heart attacks in men and 94% of heart attacks in women can be predicted based on nine factors, each

68. Mayo Clinic, *Statin Side Effects*, *supra* note 65.

69. S. Ward et al., *A Systematic Review and Economic Evaluation of Statins for the Prevention of Coronary Events*, 11 HEALTH TECH. ASSESSMENT, Apr. 2007 AT 1, 78.

70. J. Abramson & J.M. Wright, Comment, *Are Lipid-Lowering Guidelines Evidence-Based?*, 369 LANCET 168, 168 (2007). This is known as the "secondary" prevention of heart disease, as opposed to "primary" prevention, which occurs before the person has been diagnosed with heart disease. *Id.*

71. Kiranbir Josan, Sumit R. Majumdar & Finlay A. McAlister, *The Efficacy and Safety of Intensive Statin Therapy: A Meta-Analysis of Randomized Trials*, 178 CAN. MED. ASS'N J. 576, 581-82 (2008) (finding approximately a 17% reduced risk of heart attack and stroke, but no reduced risk of mortality); Girish R. Mood et al., *Meta-Analysis of the Role of Statin Therapy in Reducing Myocardial Infarction Following Elective Percutaneous Coronary Intervention*, 100 AM. J. CARDIOLOGY 919, 921 (2007) (showing that statin therapy reduces risk of future heart attack following angioplasty); Caroline G.P. Roberts, Eliseo Guallar & Annabelle Rodriguez, *Efficacy and Safety of Statin Monotherapy in Older Adults: A Meta-Analysis*, 62A J. GERONTOLOGY: MED. SCI. 879, 884 (2007) (finding that statin therapy reduces risks of death, heart attack, and stroke in older adults); Ward et al., *supra* note 69, at 26 (finding a reduced risk of mortality, cardiovascular mortality, coronary heart disease mortality, and fatal heart attack).

72. Abramson & Wright, *supra* note 70 (emphasis added).

modifiable through diet and lifestyle.⁷³ Similarly, the World Health Organization estimates that 80% of deaths from heart disease and stroke are caused by five modifiable lifestyle factors.⁷⁴ However, two clinical studies in particular provide compelling evidence that diet and lifestyle can prevent and even reverse heart disease.

One of these studies was conducted by Caldwell Esselstyn. He put twenty-two patients with severe heart disease on a plant-based diet, which included vegetables, fruits, grains, and legumes, and which excluded oils, meat, fish, fowl, and all dairy products except for skim milk and nonfat yogurt.⁷⁵ The patients also took cholesterol-lowering drugs.⁷⁶ After both five years⁷⁷ and twelve years,⁷⁸ none of the patients who stuck to the diet experienced a single coronary event (including heart attacks), though they had experienced many prior to the study. Study dropouts who returned to their pre-study diets fared decisively worse.⁷⁹ Further, follow-up analyses on

73. Salim Yusuf et al., *Effect of Potentially Modifiable Risk Factors Associated with Myocardial Infarction in 52 Countries (the INTERHEART Study): Case-control Study*, 364 LANCET 942 (2004). The nine factors are: (1) high cholesterol (raised plasma lipids); (2) smoking; (3) high blood pressure (hypertension); (4) abdominal obesity; (5) psychosocial health; (6) consumption of fruits and vegetables; (7) alcohol consumption; (8) diabetes; and (9) regular exercise. *Id.*

74. WORLD HEALTH ORG., PREVENTING CHRONIC DISEASES: A VITAL INVESTMENT 52 (2005), available at http://www.who.int/chp/chronic_disease_report/full_report.pdf (The leading risk factor for heart disease deaths globally is raised blood pressure, followed by tobacco use, high cholesterol, and low consumption of fruits and vegetables.) [hereinafter WHO, PREVENTING CHRONIC DISEASES].

75. Caldwell B. Esselstyn, Jr. et al., *A Strategy to Arrest and Reverse Coronary Artery Disease: A 5-Year Longitudinal Study of a Single Physician's Practice*, 41 J. FAM. PRAC. 560, 560-61 (1995) [hereinafter Esselstyn 5-Year Study]. See also CALDWELL B. ESSELSTYN, JR., PREVENT AND REVERSE HEART DISEASE 22-28 (2007) (describing the patients' conditions before entering the program, some of whom were told that conventional medical therapies could no longer help them).

76. Esselstyn 5-Year Study, *supra* note 75, at 561.

77. Eleven patients stuck to the diet and were available for follow-up testing; they had experienced thirty-seven cardiac events in the eight years prior to the study. *Id.* at 562. Five patients who dropped out of the study stuck to the diet; the number of cardiac events prior to the study for this group was not reported. *Id.* at 565.

78. Caldwell B. Esselstyn, Jr., *Updating a 12-Year Experience with Arrest and Reversal Therapy for Coronary Heart Disease (An Overdue Requiem for Palliative Cardiology)*, 84 AM. J. CARDIOLOGY 339, 340 (1999) [hereinafter Esselstyn 12-Year Study Update] (no cardiac events among a total of now eighteen compliant patients, who had experienced a total of forty-nine coronary events prior to the study).

79. Esselstyn 12-Year Study Update, *supra* note 78 (noting that six dropouts experienced thirteen cardiac events); Esselstyn 5-Year Study, *supra* note 75 (after five years, five study dropouts experienced "four instances of increased angina, two episodes of ventricular tachycardia, one coronary arterial bypass operation, one angioplasty, one case of congestive heart failure, and one death from complications of arrhythmia").

adherent patients after five years showed that heart disease had *regressed* (i.e., the amount of narrowing of the artery caused by the blockage actually decreased) in eight patients and had not progressed in the other three.⁸⁰ No one received any surgical interventions for their heart disease.⁸¹ Moreover, adherent patients significantly reduced their angina⁸² and total cholesterol.⁸³

The other study was conducted by Dean Ornish. Ornish put twenty-two patients with severe heart disease in an experimental group following his program, and twenty patients in a control group following their doctor's regular advice.⁸⁴ The program had (and still has) four parts: diet, exercise, stress management, and social support.⁸⁵ First, the patients ate a plant-based diet which included vegetables, fruits, grains, and legumes, and which excluded all animal products but egg whites and up to one cup of non-fat milk or yogurt a day.⁸⁶ Second, patients were asked to exercise a minimum of three hours a week at their target heart rates.⁸⁷ Third, patients were asked to practice a stress reduction technique—stretching, breathing, meditation, progressive relaxation, or guided imagery—for at least one hour a day.⁸⁸ Finally, patients began the program with a week-long retreat and followed-up with two group meetings a week thereafter.⁸⁹

Ornish's study produced results nearly identical to those in the Esselstyn study. After five years, those in the control group experienced fewer angioplasties, hospitalizations, and overall cardiac events than those in the control group.⁹⁰ After both one year⁹¹ and five years,⁹² heart disease had

80. Esselstyn 5-Year Study, *supra* note 75, at 563 (reporting that the mean percent stenosis (narrowing of the artery) on each lesion went from 53.4% to 46.2%). One of the eleven patients died of arrhythmia after the study, but had shown disease regression. Esselstyn 12-Year Study Update, *supra* note 78. His autopsy showed no myocardial infarction. *Id.*

81. Esselstyn 12-Year Study Update, *supra* note 78.

82. Esselstyn 5-Year Study, *supra* note 75, at 564.

83. *Id.* at 563; Esselstyn 12-Year Study Update, *supra* note 78.

84. Dean Ornish et al., *Can Lifestyle Changes Reverse Coronary Heart Disease?: The Lifestyle Heart Trial*, 336 LANCET 129, 129 (1990) [hereinafter *Lifestyle Heart Trial*].

85. *Id.*

86. *Id.* at 130.

87. *Id.* Also, the patients were asked to exercise a minimum of thirty minutes at any one time. *Id.*

88. *Id.*

89. *Lifestyle Heart Trial*, *supra* note 84, at 130.

90. Dean Ornish et al., *Intensive Lifestyle Changes for Reversal of Coronary Heart Disease*, 280 JAMA 2001, 2005 (1998) [hereinafter *Lifestyle Heart Trial Follow-up*]. Unlike Esselstyn's study, however, two patients in the experimental group died and two had heart attacks. *Id.* at 2006.

91. *Lifestyle Heart Trial*, *supra* note 84, at 132 (mean percent stenosis decreased from 40% to 37.8% in the experimental group, but increased from 42.7% to 46.1% in the control group). See also K. Lance Gould et al., *Improved Stenosis Geometry by Quantitative*

regressed or went unchanged in the experimental group, but had progressed substantially in the control group. The amount of regression in the experimental group was directly related to adherence to the program, not age or disease severity.⁹³ Also, after one year, those in the experimental group significantly reduced both the frequency and severity of their angina, while it only got worse in the control group.⁹⁴ The experimental group also reduced their weight and improved their cholesterol without any drugs.⁹⁵ Many further studies have documented the benefits of the Ornish program,⁹⁶ including its dramatic cost advantages compared to surgical interventions.⁹⁷

Coronary Arteriography After Vigorous Risk Factor Modification, 69 AM. J. CARDIOLOGY 845, 846-49 (1992) (showing there was actual disease regression using a more sophisticated methodology).

92. *Lifestyle Heart Trial Follow-up*, *supra* note 90, at 2003 tbl. 3 (mean percent stenosis decreased 3.07 absolute percentage points in the experimental group (a 7.9% relative improvement), but increased by 11.77 absolute percentage points in the control group (a 27.7% relative worsening)).

93. *Id.* at 2004-05 (The six patients with most adherence averaged a reduction in stenosis of 6.81 absolute percentage points; the seven patients with medium adherence averaged a reduction in stenosis of 3.02 absolute percentage points; and those with least adherence averaged a reduction of just 0.37 absolute percentage points.).

94. *Id.* at 2004. After five years, the differences between the two groups were no longer statistically significant, because many in the control group addressed their angina by undergoing surgery. *Id.*

95. *Id.* The difference in total cholesterol between the groups after five years was not statistically significant because many in the control group began taking cholesterol-lowering drugs. *Id.* The control group patients who took cholesterol-lowering drugs experienced smaller increases in percent stenosis than those in the control group not taking drugs. *Id.* at 2005.

96. See Steven G. Aldana et al., *The Effects of an Intensive Lifestyle Modification Program on Carotid Artery Intima-media Thickness: A Randomized Trial*, 21 AM. J. HEALTH PROMOTION 510, 513 (2007) (study of forty-six patients on the Ornish program and forty-seven in a control group, finding significant improvement in cardiovascular risk factors for those on the Ornish program, except for the thickness of their carotid artery intima-media); Steven G. Aldana et al., *Cardiovascular Risk Reductions Associated with Aggressive Lifestyle Modification and Cardiac Rehabilitation*, 32 HEART & LUNG 374, 377-78 (2003) (showing that, after bypass surgery or angioplasty, those following the Ornish program experienced larger improvements in more risk factors for cardiovascular disease compared to both a control group and an alternative rehabilitation group); Neal D. Barnard, Larry W. Scherwitz & Dean Ornish, *Adherence and Acceptability of a Low-Fat, Vegetarian Diet Among Patients with Cardiac Disease*, 12 J. CARDIOPULMONARY REHABILITATION & PREVENTION 423, 428 (1992) (showing other improvements in cardiovascular disease risk factors after one year on the Ornish program for the participants in the original study); Jennifer J. Daubenmier et al., *The Contribution of Changes in Diet, Exercise, and Stress Management to Changes in Coronary Risk in Women and Men in the Multisite Cardiac Lifestyle Intervention Program*, 33 ANNALS BEHAV. MED. 57, 61-62 (2007) (finding beneficial changes in health behaviors, coronary risk factors, and psychosocial variables—depressive symptoms, hostility, and perceived stress—in both men and women after three months on the Ornish program); Jenny Koertge et al.,

As noted by the AHA, “[a]lthough great advances have been made in prevention and treatment of [cardiovascular disease (CVD)] through drug therapies and procedures, [m]aintaining a healthy diet and lifestyle offers the

Improvement in Medical Risk Factors and Quality of Life in Women and Men with Coronary Artery Disease in the Multicenter Lifestyle Demonstration Project, 91 AM. J. CARDIOLOGY 1316, 1318-20 (2003) (showing significant improvements in cardiovascular disease risk factors among 440 patients following the Ornish program, as well as significant psychosocial benefits, such as feelings of vitality, social functioning, emotional health, and mental health); Ornish, *Multicenter Lifestyle Demonstration Project*, *supra* note 8, at 74T (showing improvements in exercise, exercise capacity, diet, cholesterol, and weight, and that 150 out of 194 patients following the Ornish program were able to avoid revascularization for three years, without any significant increases in cardiac events compared to the control group undergoing bypass surgery or angioplasty, even though those following the Ornish program had experienced more heart attacks and had a longer histories of heart disease); and *infra* Section III.C (discussing whether patients can adhere to the diet).

The Ornish program has also been shown to have benefits outside of the context of heart disease. One study put men with low-risk prostate cancer on a vegan diet of fruits, vegetables, whole grains, and soy. Dean Ornish et al., *Intensive Lifestyle Changes May Affect the Progression of Prostate Cancer*, 174 J. UROLOGY 1065, 1066 (2005). The diet was supplemented with soy, fish oil, selenium, and vitamins E and C. *Id.* The participants also walked thirty minutes per day, six days per week, practiced stress management, and participated in a one-hour social support group each week. *Id.* After one year, cancer activity in the diet group decreased by an average of 4%, while it increased in a control group by 6%. *Id.* at 1067. The researchers also mixed patients’ blood with prostate cancer cells. *Id.* at 1065-67. Blood from the diet group inhibited the growth of prostate cancer cells by 70%, compared to just 9% with the control group. *Id.* at 1067. Patients experienced greater benefits the more they stuck to the diet. *Id.*

In a similar study, a group of thirty men with low-risk prostate cancer were put on the Ornish program. Dean Ornish et al., *Changes in Prostate Gene Expression in Men Undergoing an Intensive Nutrition and Lifestyle Intervention*, 105 PROC. NAT’L ACAD. SCI. 8369, 8369 (2008). After only three months, gene expression in the men’s prostates had decreased in 453 transcripts and increased in only forty-eight. *Id.* at 8371. No surgery or radiation was involved. *Id.* at 8369. Another study found that these men experienced significant increases in telomerase enzymatic cellular activity, which was associated with improvements in risk factors for various diseases, including cardiovascular disease and cancer. Dean Ornish et al., *Increased Telomerase Activity and Comprehensive Lifestyle Changes: A Pilot Study*, 9 LANCET ONCOLOGY 1048, 1052 (2008).

While diet is likely the most important factor in the Ornish and Esselstyn studies, as it is the only similarity between the two programs, other aspects of the Ornish program are also beneficial, both independently and in conjunction with diet. See Daubenmier et al., *supra* note 96, at 57 (“Improvements in dietary fat intake, exercise, and stress management were individually, additively and interactively related to coronary risk and psychosocial factors, suggesting that multicomponent programs focusing on diet, exercise, and stress management may benefit patients with CHD.”).

97. Ornish, *Multicenter Lifestyle Demonstration Project*, *supra* note 8, at 75T (finding that the average cost per patient for those following the Ornish program—including those who elected to have surgery during the study—was \$18,119, compared to an average cost of \$47,647 per patient for those initially receiving bypass surgery or angioplasty).

greatest potential of all known approaches for reducing the risk for CVD in the general public.”⁹⁸ Unfortunately, modern medicine is dangerously behind:

[T]he disease that accounts for the most premature deaths and costs Americans more than any other illness is almost completely preventable, and even reversible, simply through changes in lifestyle. We don’t have to wait for a new breakthrough in drugs or surgery; we just need to put into practice what we already know.⁹⁹

It has been *twenty years* since Ornish and Esselstyn first showed that diet and lifestyle can reverse heart disease and prevent heart attacks, and still, as shown in section II, this research is mostly ignored by the medical community, preventing most of the public from knowing about it or benefiting from it.

II. THE PROBLEM

Given that changing one’s diet and lifestyle is the cheapest and most-effective way to treat and prevent heart disease, there are serious problems with how physicians choose to address the disease with their patients. This section discusses three of those problems: (A) physicians giving no dietary advice; (B) physicians giving poor dietary advice; and (C) heart patients having little dietary knowledge and leading very unhealthy lifestyles.

A. Physicians Giving No Dietary Advice

Several large studies show that physicians rarely give dietary advice in America. In *Healthy People 2010*, the government used three very large, nationally representative datasets to show that patients with cardiovascular disease received dietary counseling from their physicians in just 36% of office visits.¹⁰⁰ Similarly, a 2004 study analyzed data from the 2000 National Health Interview Survey (NHIS), which included 26,255 respondents.¹⁰¹ Just 21.3% of respondents indicated that their physician

98. Alice H. Lichtenstein et al., *Diet and Lifestyle Recommendations Revision 2006: A Scientific Statement from the American Heart Association Nutrition Committee*, 114 CIRCULATION 82, 83 (2006) (emphasis added). For the distinction (or lack thereof) between heart disease and cardiovascular disease, see Ornish, *Multicenter Lifestyle Demonstration Project*, *supra* note 8.

99. Ornish, *Intensive Lifestyle Changes and Health Reform*, *supra* note 26, at 639.

100. U.S. DEP’T HEALTH & HUMAN SERVS., HEALTHY PEOPLE 2010: VOLUME II 19-42 (2000), available at <http://www.healthypeople.gov/2010/Document/pdf/Volume2/19Nutrition.pdf> (noting that the findings used 1997 data that was age-adjusted to the year 2000 population).

101. Keiko Honda, *Factors Underlying Variation in Receipt of Physician Advice on Diet and Exercise: Applications of the Behavioral Model of Health Care Utilization*, 18 AM. J. HEALTH PROMOTION 370, 371 (2004).

had given them dietary advice in the last year.¹⁰² Many other studies have reached similar results.¹⁰³

A couple studies have looked specifically at whether physicians prescribe fish oil or omega-3 fats for their patients. Fish oil may help in the secondary prevention of heart disease, leading the AHA to recommend that patients with heart disease get one gram a day through diet or supplements.¹⁰⁴ A 2006 study of Washington State primary care physicians found that just 17% were high-prescribers of fish oil.¹⁰⁵ A 2009 study found that just 36.2% of

102. *Id.* at 372. Other studies often look only at individual office visits, where a low percentage of discussions about diet could be misleading if it was discussed in prior visits. For example, a 2004 study analyzed data from two large nationally representative surveys, finding that 35% of individual office visits included some form of dietary counseling, as reported by the physician. Philip B. Mellen et al., *Prevalence of Nutrition and Exercise Counseling for Patients with Hypertension: United States, 1999 to 2000*, 19 J. GEN. INTERNAL MED. 917, 919 (2004). The authors recognized that this “may underestimate the incidence of lifestyle counseling over a period of time.” *Id.* at 923.

103. Ctrs. for Disease Control & Prevention, U.S. Dep’t of Health & Human Servs., *Physician Advice and Individual Behaviors About Cardiovascular Disease Risk Reduction – Seven States and Puerto Rico, 1997*, 48 MORBIDITY & MORTALITY WKLY. REP. 91, 92 (1999) [hereinafter *Cardiovascular Disease Risk Reduction*] (Analyzing data from the Behavioral Risk Factor Surveillance System (“BRFSS”) survey, which included 20,847 adults in seven states, finding that 41.5% of those surveyed reported receiving physician advice to eat fewer high-fat or high-cholesterol foods. Further, the survey appears to have asked a general question, not limited to particular visits or even to a particular time period, so respondents may have been answering to the extent of their memories.); Ctrs. for Disease Control & Prevention, U.S. Dep’t of Health & Human Servs., *Missed Opportunities in Preventive Counseling for Cardiovascular Disease – United States, 1995*, 47 MORBIDITY & MORTALITY WKLY. REP. 91, 92 (1997) (using data from a 1995 national survey of 29,273 office visits, finding that physicians reported giving dietary advice in just 22.8% of office visits); Susan A. Flocke et al., *Exercise, Diet, and Weight Loss Advice in the Family Medicine Outpatient Setting*, 37 FAM. MED. 415, 417 (2005) (observing three hundred primary care office visits to find that just 31% included discussions of diet); Robert F. Kushner, *Barriers to Providing Nutrition Counseling by Physicians: A Survey of Primary Care Practitioners*, 24 PREVENTIVE MED. 546, 547-48 (1995) (study of 1,030 primary care physicians in the US, finding that 69% gave dietary counseling to 40% or less of their patients); Henry Wechsler et al., *The Physician’s Role in Health Promotion Revisited—A Survey of Primary Care Practitioners*, 334 NEW ENG. J. MED. 996, 996-97 (1996) (finding that 56% of Massachusetts general internists reported “routinely” asking patients about diet, up from 47% in 1981).

104. Robert C. Oh, Shirley A. A. Beresford & William E. Lafferty, *The Fish in Secondary Prevention of Heart Disease (FISH) Survey—Primary Care Physicians and Ω Fatty Acid Prescribing Behaviors*, 19 J. AM. BOARD FAM. MED. 459, 460 (2006).

105. *Id.* at 461 (describing high prescribers as those who reported prescribing fish to their CVD patients greater than 60% of the time and who prescribed fish to a hypothetical CVD patient in the survey).

cardiologists surveyed in Pakistan were high-prescribers of omega-3 fatty acids.¹⁰⁶

The problem is also prevalent among other countries and sub-populations. Studies have shown that physicians rarely give dietary advice in Canada,¹⁰⁷ England,¹⁰⁸ and Pakistan.¹⁰⁹ Physicians rarely discuss diet even with children. A 2004 survey found that just 39% of pediatric cardiologists discussed diet with children and their families if the child was not yet diagnosed with a CVD, although the figure jumped to 63% for children with known CVD, still far from perfect.¹¹⁰ The authors found the lack of consistent advice particularly troubling since interventions must begin early in life to curtail the onset of chronic diseases later in life.¹¹¹

Many factors influence the likelihood of a physician giving dietary advice. Studies have shown that patients are more likely to receive dietary advice the lower their self-reported health status is,¹¹² suggesting that, the sicker the patient feels, the more likely he or she is to raise dietary issues with the doctor.¹¹³ Similarly, many studies show that those with known chronic diseases are more likely to receive dietary advice,¹¹⁴ particularly

106. Saqib A. Gowani et al., *Secondary Prevention of Heart Disease – Knowledge Among Cardiologists and Ω-3 (Omega-3) Fatty Acid Prescribing Behaviors in Karachi, Pakistan*, BMC CARDIOVASCULAR DISORDERS, Jan. 27, 2009, at 1, 4, 6 (high prescribers were those cardiologists who self-reported prescribing dietary fish advice at least 60% of the time and who would have prescribed a fish diet to a hypothetical patient in the survey).

107. See Jennifer Sinclair, Beverley Lawson & Fred Burge, *Which Patients Receive Advice on Diet and Exercise?: Do Certain Characteristics Affect Whether They Receive Such Advice?*, 54 CAN. FAM. PHYSICIAN 404, 407 (2008) (survey of 1,562 Canadian patients finding that 62.4% of patients reported rarely or never receiving advice from their physician on healthy eating).

108. Helen Moore & Ashley J. Adamson, *Nutrition Interventions by Primary Care Staff: A Survey of Involvement, Knowledge and Attitude*, 5 PUB. HEALTH NUTRITION 531, 533 (2002) (survey of 2,400 primary care patients in England found that just 13% had discussed diet in the medical appointment they just left).

109. Gowani et al., *supra* note 106 (study found that just 36.2% of cardiologists surveyed in Pakistan were high-prescribers of omega-3 fatty acids; those who self-reported as high-prescribers of dietary fish advice, and who would have prescribed a fish diet to a hypothetical patient in the survey).

110. Benjamin J. Lentzner, Dana M. Connolly & Colin K.L. Phoon, *Do Paediatric Cardiologists Discuss Cardiovascular Risk Factors with Patients and Their Families?*, 13 CARDIOLOGY IN YOUNG 551, 554 (2003).

111. *Id.* at 555.

112. Honda, *supra* note 101, at 372, 374 (noting that self-reported health status is by far the most significant factor); Sinclair, Lawson & Burge, *supra* note 107, at 407, 409 (significant when comparing those reporting poor health status with those reporting excellent health status).

113. Honda, *supra* note 101, at 375.

114. Mayur M. Desai et al., *Receipt of Nutrition and Exercise Counseling Among Medical Outpatients with Psychiatric and Substance Use Disorders*, 17 J. GEN. INTERNAL MED. 556, 558-

those with known CVD.¹¹⁵ Physicians who themselves have changed, or are willing to change, their own diets are more likely to give dietary advice,¹¹⁶

59 (2002) (finding that 90.4% of patients with hypertension and/or obesity received nutrition counseling when obtaining services from Veterans Affairs medical centers); Leonard E. Egede & Deyi Zheng, *Modifiable Cardiovascular Risk Factors in Adults with Diabetes: Prevalence and Missed Opportunities for Physician Counseling*, 162 ARCHIVES INTERNAL MED. 427, 431 (2002) (finding that physicians counseled 20.8% and 70.7% of patients without diabetes about losing weight and eating less fat, respectively, and these figures increased to 49.8% and 77.9% for patients with diabetes); Flocke et al., *supra* note 103, at 418-19 (2005 study involving the direct observation of three hundred primary care office visits finding that physicians were significantly more likely to give diet, exercise, and weight loss advice to patients with chronic diseases than to those with none); Kurt J. Greenlund et al., *Physician Advice, Patient Actions, and Health-Related Quality of Life in Secondary Prevention of Stroke Through Diet and Exercise*, 33 STROKE 565, 567 (2002) (finding that approximately 60% of stroke victims, and only 36.2% of non-stroke victims, received physician advice to eat fewer foods high in fat and cholesterol to lower the risk of heart attack or stroke); Mellen et al., *supra* note 102 (finding patients more likely to receive advice if visited specifically because of a chronic condition, had diabetes, or had one or more comorbidities); James B. Meigs & Randall S. Stafford, *Cardiovascular Disease Prevention Practices by U.S. Physicians for Patients with Diabetes*, 15 J. GEN. INTERNAL MED. 220, 222-23 (2000) (finding that patients with diabetes are more likely than other patients to receive counseling on cholesterol and weight reduction); Sinclair, Lawson & Burge, *supra* note 107, at 407-09 (Canadian patients were more likely to receive dietary advice the more chronic diseases they reported having). See also Honda, *supra* note 101, at 372, 374 (obese patients are more likely to receive dietary advice); C. Tracy Orleans et al., *Health Promotion in Primary Care: A Survey of U.S. Family Practitioners*, 14 PREVENTIVE MED. 636, 640 tbl.1 (1985) (study of 350 primary care physicians found that 58.3% discussed health risks and recommended a specific diet to more than half of their obese patients).

115. *Cardiovascular Disease Risk Reduction*, *supra* note 103, at 75-76 (large study using BRFSS survey data finding that while 38.9% of persons with no history of CVD reported receiving dietary advice at some point from a physician, this number nearly doubled to 73.8% for those with a history of CVD); Gowani et al., *supra* note 106, at 3 (finding that 78.5% of cardiologists surveyed in Pakistan reported giving dietary advice to greater than 60% of their patients with known CVD); Lentzner, Connolly & Phoon, *supra* note 110, at 554-55 (finding the percentage of pediatric cardiologists discussing diet with patients increases from 39% to 63% when the child has a known CVD); Oh, Beresford & Lafferty, *supra* note 104, at 462 tbl.2 (2006 survey finding that 69% of primary care physicians in Washington reported giving dietary advice to greater than 60% of their patients with known CVD); Randall S. Stafford, David Blumenthal & Richard C. Pasternak, *Variations in Cholesterol Management Practices of U.S. Physicians*, 29 J. AM. C. CARDIOLOGY 139, 140, 142-43 (1997) (study including over 56,000 office visits nationwide finding that patients both with and without high cholesterol were significantly more likely to receive dietary advice on lowering cholesterol if they had a known CVD). But see Honda, *supra* note 101, at 373 (very large study using NHIS data found that patients with either coronary heart disease or other heart conditions were no more likely to have received dietary advice in the past year).

116. Barbara S. Levine et al., *A National Survey of Attitudes and Practices of Primary-Care Physicians Relating to Nutrition: Strategies for Enhancing the Use of Clinical Nutrition in Medical Practice*, 57 AM. J. CLINICAL NUTRITION 115, 117 (1993) (survey of physicians finding

perhaps because they recognize the ability of people to change. Interestingly, physicians may be more likely to raise the issue than patients.¹¹⁷ However, if the patient brings up a *specific* dietary issue (e.g., whether he or she should take fish oil), the physician is far more likely to give dietary advice.¹¹⁸ Oddly, however, if the patient raises the issue of diet more *generally*, the physician may be less likely to give any actual advice.¹¹⁹ Also, a variety of demographic factors, such as age, have been found to increase the likelihood of receiving dietary advice.¹²⁰

Ultimately, the best thing a patient can do is to ask his or her doctor about specific dietary advice. But patients who choose not to speak up and have not been diagnosed with a chronic disease are not likely to receive any advice.¹²¹

that those willing to change their own diets were more likely to have favorable attitudes toward dietary advice and to actually give dietary advice); Erica Frank et al., *Personal and Professional Nutrition-Related Practices of US Female Physicians*, 75 AM. J. CLINICAL NUTRITION 326, 328-30 (2002) (finding that while 23.5% of female physicians reported discussing diet with their patients at every visit and 43.4% reported doing so at least yearly, physicians were more likely to give dietary advice if they were vegetarians, had tried to change their own eating habits, or had a personal history of obesity). The study by Frank et al. may suggest that female physicians are somewhat more likely to give dietary advice than male physicians; however, Frank et al. referenced no comparison with male physicians, and this author was unable to find other studies even distinguishing between male and female physicians.

117. Flocke et al., *supra* note 103, at 418 tbl.2 (finding that physicians initiated the discussion of diet 82% of the time); Moore & Adamson, *supra* note 108, at 533 (follow-up survey of 251 English primary care patients who discussed diet with their doctors found that patients had raised the subject in 29% of cases, physicians in 37%, and nurses or other health professionals in the remaining cases).

118. See Gowani et al., *supra* note 106, at 3 (study of Pakistani cardiologists finding that 58.4% would prescribe fish oil to a hypothetical patient after a heart attack, but that figure jumped to 92.6% if the patient specifically requested advice about fish); Oh, Beresford & Lafferty, *supra* note 104, at 461 (in the very similar study of Washington primary care physicians, the fish oil prescriptions jumped from 57% to 93% with a specific request).

119. See Flocke et al., *supra* note 103, at 419 tbl.4 (in the study directly observing patient-physician office visits, 93% of physician-initiated discussions resulted in some advice to the patient, whereas just 53% of patient-initiated discussions resulted in any advice).

120. Honda, *supra* note 101, at 372, 373 (respondents more likely to receive dietary advice from their physician if they were middle-aged, had at least some college, had some health insurance coverage, and had a usual place of care other than an ER); Mellen et al., *supra* note 102 (finding patients more likely to receive dietary counseling in the hospital setting, if they were under seventy-four years old, or if they belonged to a racial or ethnic minority); Sinclair, Lawson & Burge, *supra* note 107, at 407, 409 (finding that Canadian patients were more likely to report often or always receiving dietary advice if they were middle-aged (thirty-five to fifty-four) or male).

121. Sinclair, Lawson & Burge, *supra* note 107, at 409.

B. Physicians Giving Poor Advice

Even if a physician discusses diet, it might not be a very helpful discussion for the patient. There are two basic reasons why: (1) the counseling may not be very intensive, limiting the likelihood the patient will change his or her habits; and (2) the diet advocated may not be helpful even if the patient complies.

1. Low intensity counseling

Even if diet is generally discussed, the physicians may not actually recommend dietary changes. For example, a 2001 follow-up survey of 251 English primary care patients who discussed diet with their physicians found that just 40% of patients were actually asked to change what they eat, and just 67% of those patients were given advice on how to make those changes (although 90% still thought they could make the changes they were asked to).¹²²

Physicians might also spend very little time discussing diet and nutrition. For example, a 1993 study found that an average time of just one minute and fifty-one seconds was spent discussing diet, an average of just 9% of the total visit time.¹²³ A 1995 study of over one thousand physicians found that 68% of physicians reported spending five minutes or less discussing dietary changes with their patients; none spent more than fifteen minutes.¹²⁴ A five-minute chat is hardly likely to lead to life-altering dietary changes.¹²⁵

Physicians may also rarely give out written information reinforcing their advice. The 2001 follow-up survey of 251 English primary care patients who discussed diet with their physicians found that only 12% were given written information to reinforce their discussion.¹²⁶ Similarly, a 2005 study

122. Moore & Adamson, *supra* note 108, at 533-34. See also Flocke et al., *supra* note 103, at 418-19 tbl.3 and tbl.4 (finding that 13% of diet discussions included no advice at all, and while 93% of physician-initiated discussions resulted in some advice to the patient, just 53% of patient-initiated discussions did so); Nancy K. Russell & Debra L. Roter, *Health Promotion Counseling of Chronic-Disease Patients During Primary Care Visits*, 83 AM. J. PUB. HEALTH 979, 979-81 (1993) (study of 439 office visits finding that diet was discussed 43% of the time, a fairly high percentage, but on a scale of one ("brief mention") to five ("extensive counseling"), dietary advice scored only an average of 2.7).

123. Russell & Roter, *supra* note 122, at 980 tbl.1.

124. Kushner, *supra* note 103, at 549 (also noting that physicians in a private office setting were more likely to spend at least six minutes with a patient compared to those in a hospital, university, or HMO setting).

125. See, e.g., M.L. Burr et al., *Lack of Benefit of Dietary Advice to Men with Angina: Results of a Controlled Trial*, 57 EUR. J. CLINICAL NUTRITION 193, 198 (2003) (concluding that men with angina receiving initial advice to eat more fish and/or fruits and vegetables—but no training or follow-up assistance—were no less likely to die from any cause or from a heart attack).

126. Moore & Adamson, *supra* note 108, at 534 tbl.4.

found that, when discussing diet, just 12% of physicians provided educational materials.¹²⁷

Further, physicians rarely even offer to help patients make behavioral changes suggested. A 2005 study found that 83% of the time when discussing diet with a patient, the physician provided no assistance at all.¹²⁸

Finally, even if physicians make a recommendation, they may not schedule a follow-up appointment to monitor the patient's progress. The follow-up survey of English primary care patients found that just 32% of patients were asked to make a follow-up appointment regarding their diet.¹²⁹ Similarly, a 2005 study involving the direct observation of three hundred office visits found that the physician arranged a follow-up interview to discuss diet just 10% of the time.¹³⁰

2. Ineffective diets advocated

It does not appear that physicians advise patients to follow diets shown to prevent heart attacks and reverse heart disease. A 2006 study found that, of forty-four responding cardiologists, just 7% preferred to order and recommend very low-fat vegetarian diets for their inpatient cardiac patients, while 86% preferred the "standard low-fat cardiac diet."¹³¹ Similarly, 80% preferred to recommend the standard diet when discharging patients, compared to 14% who preferred the low-fat vegetarian diet.¹³² When it came to their actual practice, 63% reported rarely or never ordering or recommending the diet, 23% sometimes ordered or recommended the diet, and just 13% often or always did.¹³³ Fifty-seven percent of the cardiologists further reported that the hospitals or institutions they worked in rarely or never offered the diet.¹³⁴

Other diets advocated by physicians may not be very helpful for a couple reasons. First, the diet may be confusing. If the patient cannot

127. Flocke et al., *supra* note 103, at 418 tbl. 2.

128. *Id.* (One percent of physicians helped patients set goals, 4% made referrals, 7% provided prescriptions, and 1% helped in other ways.)

129. Moore & Adamson, *supra* note 108, at 534 tbl.4.

130. Flocke et al., *supra* note 103, at 418. The authors note, however, the possibility that follow-ups were implied, given that "nearly 20% of discussions were in the context of a prior discussion of the health behavior topic." *Id.* at 419.

131. KEITH RAFAL, AMY JOY LANOU & NEAL D. BARNARD, PHYSICIANS COMM. FOR RESPONSIBLE MED., NUTRITIONAL APPROACHES FOR CORONARY ARTERY DISEASE: SURVEY OF CARDIOLOGISTS REVEALS INSUFFICIENT RECOMMENDATION OF VERY LOW-FAT DIETS 3 (2006), available at http://www.pcrm.org/health/reports/pdfs/cardiochemist_survey.pdf. This study was not peer-reviewed, and it suffered from an extremely low response rate (44/1,135=3.87%). *Id.*

132. *Id.*

133. *Id.*

134. *Id.*

understand what she may or must eat or not eat, then she cannot follow the diet. If she cannot follow the diet, then she cannot enjoy its benefits. Second, the diet may have very few, if any, benefits. In that case, even if the patient can and does follow the diet, she may not be much better off.

The advice that physicians tend to offer likely suffers from both problems. Many if not most physicians are likely providing patients information about the diet advocated by the AHA.¹³⁵ For example, a 1993 survey reported that 55% of surveyed physicians usually or always prescribed the AHA's diet in order to control CVD risk factors,¹³⁶ and in a 1995 survey, authors reported that cardiac patients received information on the AHA's diet.¹³⁷

Many cardiac patients find the information about the AHA diet confusing. In the 1995 study, while 50.7% found the information completely or highly understandable, the remaining 49.4% found the information just somewhat understandable or not understandable at all.¹³⁸ One likely reason for the confusion was that the information seemed to contradict itself at several points. For example, one AHA guide on dining out encouraged eating more fruits and vegetables, but "warned patients that health foods and vegetarian meals may be high in fat, and that 'steakhouses, like seafood restaurants, may be a good choice.'"¹³⁹ It even contained recipes that exceeded the recommendations for saturated fat intake.¹⁴⁰ The information the AHA provides to the public is still likely confusing. The basic recommendation is to "[eat] a diet rich in vegetables and fruits, with whole grains, high-fiber foods, lean meats and poultry, fish at least twice a week, and fat-free or 1 percent fat dairy products [and which is] low in saturated fat, *trans* fat[,] and cholesterol."¹⁴¹ It then advises people that "[t]hese fats are usually found in meat and dairy foods Cutting back on these foods can reduce your risk for cardiovascular disease."¹⁴² In other words, the AHA tells people to both eat and not eat

135. The AHA's official dietary guidelines, along with scientific support, are found in Ronald M. Krauss et al., *AHA Dietary Guidelines: Revision 2000: A Statement for Healthcare Professionals from the Nutrition Committee of the American Heart Association*, 102 CIRCULATION 2284 (2000).

136. Levine et al., *supra* note 116, at 118 tbl.5.

137. S. Plous, Robert B. Chesne & Arthur V. McDowell III, *Nutrition Knowledge and Attitudes of Cardiac Patients*, 95 J. AM. DIETETIC ASS'N 442, 443, 444 (1995).

138. See *id.* at 444.

139. *Id.* at 445-46.

140. *Id.*

141. *Eat a Heart-Healthy Diet*, AM. HEART ASS'N, <http://www.americanheart.org/presenter.jhtml?identifier+1510> (last visited Sept. 6, 2009).

142. *Eat Less of the Nutrient-Poor Foods*, AM. HEART ASS'N (Jan. 2010), <http://www.americanheart.org/presenter.jhtml?identifier=3040349>.

meat and dairy products. This results in no real advice at all, as people can eat whatever they want and comply with the diet, which is utterly confusing.

Even the AHA's 2000 scientific review supporting its recommended diet is confusing. For example, the AHA recommends consuming "lean meats" in addition to foods from other groups.¹⁴³ However, while the AHA supports *all* of its other recommendations with many scientific studies,¹⁴⁴ *at no point* does it cite to any studies supporting the recommendation to eat lean meats.¹⁴⁵ This is confusing, especially since the recommendations are designed to be "based on the best available scientific evidence."¹⁴⁶ It is not that the AHA just forgot to support its recommendation; rather, *there is no* scientific support for the recommendation, in which case it is not clear why the AHA is recommending it.¹⁴⁷

143. Krauss et al., *supra* note 135, at 2286 ("The AHA strongly endorses consumption of a diet that contains a variety of foods from all the food categories and emphasizes fruits and vegetables; fat-free and low-fat dairy products; cereal and grain products; legumes and nuts; and fish, poultry, and lean meats. Such an approach is consistent with a wide variety of eating patterns and lifestyles."). See also Lori Mosca et al., *Evidence-Based Guidelines for Cardiovascular Disease Prevention in Women*, 109 CIRCULATION 672, 676 (2004) (advocating essentially the same diet for preventing cardiovascular disease specifically in women: "Consistently encourage an overall healthy eating pattern that includes intake of a variety of fruits, vegetables, grains, low-fat or nonfat dairy products, fish, legumes, and sources of protein low in saturated fat (e.g., poultry, lean meats, plant sources).").

144. The AHA's report contains 205 citations, most of which are scientific studies supporting the recommendations made therein. See Krauss et al., *supra* note 135, at 2295-99.

145. See *id.*

146. *Id.* at 2284.

147. The AHA is not alone in this regard: both the Report of the Dietary Guidelines Advisory Committee and the European Guidelines recommend lean meats but cite no supportive scientific literature. The Report of the Dietary Guidelines Advisory Committee states that scientific support for "[t]he other basic food group (meat, poultry, fish and legumes) is covered in Section 1." DIETARY GUIDELINES ADVISORY COMM., U.S. DEP'T OF HEALTH & HUMAN SERVS. & U.S. DEP'T OF AGRIC., REPORT OF THE DIETARY GUIDELINES ADVISORY COMMITTEE ON THE DIETARY GUIDELINES FOR AMERICANS, 2005 pt. D, § 6, at 1 (2005), available at http://www.health.gov/dietaryguidelines/dga2005/report/PDF/D6_SelectedFood.pdf. However, Section 1 contains very little discussion of the health consequences of eating meat. See *id.* pt. D, § 1 at 9, 17, available at http://www.health.gov/dietaryguidelines/dga2005/report/PDF/D1_Adequacy.pdf (noting that higher-fat meats can be accommodated in the food pattern as "discretionary calories" and that meat can provide much-needed iron for adolescent females). Even when discussing a National Cancer Institute report that found diets high in both red and white meat increase the risk of colorectal cancer, the Committee completely ignores that particular finding. See *id.* pt. D, § 4, at 7, available at http://www.health.gov/dietaryguidelines/dga2005/report/PDF/D4_Fats.pdf ("[e]pidemiologic, experimental (animal), and clinical investigations suggest that diets high in total fat, protein, calories, alcohol, and meat (both red and white) and low in calcium and folate, are associated with an increased incidence of colorectal cancer." (emphasis removed) (quoting the National Cancer Institute)). See also Ian Graham et al., *European Guidelines on*

Also, the recommendations in the scientific report are just as inconsistent as the public information. After making its unsupported recommendation to eat lean meats, the report later gives several strong reasons for people to eat less meat:

Most Americans consume protein in excess of their needs. Extra protein is not efficiently utilized by the body and provides a burden for its degradation. Furthermore, meat protein is the most expensive source of calories in the food budget. Protein foods from animal sources . . . are also generally higher in fat, saturated fat, and cholesterol. When diets high in protein severely limit carbohydrates, food choices become restrictive and overall nutrient adequacy, long-term palatability, and maintenance of the diet are major concerns Sustained high protein intake also may lead to renal damage and a reduction in bone density.¹⁴⁸

It is hard to make sense of a recommendation that is both unsupported and contradicted by other recommendations that are scientifically supported.

The second general problem with the AHA diet is that it is far less capable of helping those who follow it, compared to the diets in the Ornish and Esselstyn studies. A 1992 study put eighteen patients with heart disease in an experimental group and another eighteen in a control group.¹⁴⁹ Those in the experimental group ate a diet based on the AHA's recommendations at the time, exercised at least thirty minutes a day at their target heart rate, and participated in two group exercise training sessions a week.¹⁵⁰ The control group followed their doctors' usual advice.¹⁵¹ After one year, heart disease had reversed in seven patients in the experimental group compared to just one in the control group, a significant difference.¹⁵² However, heart disease *still progressed* in five patients in the experimental group—including three patients with excellent adherence to the program—almost identical to the six patients in the control group whose heart disease

Cardiovascular Disease Prevention in Clinical Practice: Full Text, 14 EUR. J. CARDIOVASCULAR PREVENTION & REHABILITATION (Supp. 2) S1, S26-S36 (2007) (containing the basic recommendations, and supporting each recommendation with extensive citations to the literature, except for the recommendations to consume lean meats and low-fat dairy products, for which there are no supportive discussions or citations).

148. Krauss, *supra* note 135, at 2292 (internal citations omitted).

149. See Gerhard Schuler et al., *Myocardial Perfusion and Regression of Coronary Artery Disease in Patients on a Regimen of Intensive Physical Exercise and Low Fat Diet*, 19 J. AM. C. CARDIOLOGY 34, 36 (1992).

150. *Id.* The diet was nutrient-based, not food-based, and recommended: 15% of calories come from protein, 65% from carbohydrates, and less than 20% from fat, as well as under two hundred milligrams of dietary cholesterol a day and a ratio of polyunsaturated to saturated fat greater than one. *Id.*

151. *Id.*

152. *Id.* at 37 tbl.1.

progressed, resulting in no net benefit from the AHA's diet.¹⁵³ In other words, patients following the diet were just as likely to get worse as they were to get better. In contrast, *no one's* heart disease progressed in those following the Ornish and Esselstyn programs.¹⁵⁴ Further, the rate of reversal in the Ornish study was *more than double* the rate of reversal in the AHA study (among patients experiencing reversal).¹⁵⁵ So, the AHA diet may be a little better than the typical diet, but it cannot completely prevent the progression of heart disease, and there was no showing that it prevented heart attacks at all.¹⁵⁶

The AHA diet is also not very good at reducing cholesterol. Many studies examined whether the AHA's Step 1 and Step 2 diets (which were replaced with a single diet in 2000)¹⁵⁷ could reduce cholesterol. A 1998 review of nineteen trials showed that these diets lead to reductions in total cholesterol of only about 3 to 6%.¹⁵⁸ A 1991 review of sixteen trials similarly found that the AHA's Step 1 diet leads to reductions in total cholesterol of only about 2%, which were clinically insignificant.¹⁵⁹ However, the problem might not have been the quality of the diets advocated; rather, the participants in the trials may not have adhered to the diets very well.¹⁶⁰

Doctors advising patients to follow the AHA diet are recommending a confusing, sometimes unsupported, and often contradicting diet that has never been shown to reduce the risk of heart disease or death from heart disease, when there are diets shown to completely prevent heart attacks and reverse or completely stop the progression of heart disease. This makes no sense.

153. *Id.* at 40.

154. See *supra* notes 84-100 and accompanying text (Ornish study); *supra* note 75-83 and accompanying text (Esselstyn study).

155. Schuler et al., *supra* note 149, at 41.

156. *Id.* The authors report as a side note that two patients in the control group had heart attacks, but do not say if or how many patients in the experimental group had heart attacks. *Id.* at 36.

157. See Krauss et al., *supra* note 135, at 2286-92.

158. J.L. Tang et al., *Systematic Review of Dietary Intervention Trials to Lower Blood Total Cholesterol in Free-Living Subjects*, 316 BRIT. MED. J. 1213, 1218 (1998).

159. L.E. Ramsay, W.W. Yeo & P.R. Jackson, *Dietary Reduction of Serum Cholesterol Concentration: Time to Think Again*, 303 BRIT. MED. J. 953, 956 (1991).

160. *Id.* ("These small responses could be due to inadequate intervention effort in some studies, but not others, or to incomplete adherence, but above all reflect an insufficiently rigorous diet" (internal citations omitted).); Tang et al., *supra* note 158, at 1217 ("The most plausible explanation for the modest effects of these diets in our overview is incomplete compliance with dietary advice.").

C. Heart Patients Lack Dietary Knowledge and Lead Unhealthy Lifestyles

Heart patients lack basic dietary knowledge that could help them. A 2008 study surveyed 803 people in Poland with known CVD.¹⁶¹ Out of nine questions of basic information, just one was correctly answered by more than half of men and women, concerning the benefits of more intense physical activity.¹⁶² Just 23% of both men and women were aware of the benefits of regular fruit and vegetable consumption.¹⁶³ Overall, just 2.6% of men and 3.0% of women could correctly answer questions in all categories.¹⁶⁴ Similarly, a 1995 study quizzed 543 cardiac patients in the US.¹⁶⁵ Out of ten questions, the average was just 3.5 correct answers; less than 5% got more than six correct, and less than one-third got more than four correct.¹⁶⁶ For example, just 43.6% of patients knew that plant foods do not contain cholesterol, just 7.3% knew that chicken and beef contain about the same amount of cholesterol, and just 36.6% knew that animal products contain no fiber.¹⁶⁷ In addition to those questions, 50.3% of patients did not know that women's arteries can harden before menopause.¹⁶⁸ Overall the patients scored no better than if they had just randomly guessed.¹⁶⁹

The diets of cardiac patients are also very poor. A 2008 study analyzed the diets of 555 Americans one year after having been diagnosed with heart disease.¹⁷⁰ Their diets were measured using the Alternate Healthy Eating Index, which creates scores between zero and eighty, eighty being the best.¹⁷¹ The average total score was just 30.8,¹⁷² significantly worse than

161. Anna Waskiewicz et al., *Quality of Nutrition and Health Knowledge in Subjects with Diagnosed Cardio-Vascular Diseases in the Polish Population – National Multicentre Health Survey (WOBASZ)*, 66 KARDIOL. POL. 507, 508 tbl.II (2008).

162. *Id.* at 509 tbl.II.

163. *Id.* (noting that the other questions concerned weight reduction, stopping or reducing cigarette smoking, reduced alcohol consumption, reduced salt intake, reduced fat intake, and getting proper rest and avoiding hyperanxiety).

164. *Id.*

165. Plous, Chesne & McDowell, *supra* note 137, at 444.

166. *See id.*

167. *Id.* tbl.2

168. *Id.* at 445.

169. *See id.*

170. Yunsheng Ma et al., *Dietary Quality 1 Year After Diagnosis of Coronary Heart Disease*, 108 J. AM. DIETETIC ASS'N 240, 241 (2008).

171. *Id.* at 242. The Index score was based on a person's consumption of (1) fruits, (2) vegetables, (3) nuts and soy, (4) cereal fiber, (5) trans fat, and (6) alcohol, as well as (7) the ratio of white meat to red meat consumed, and (8) the ratio of polyunsaturated fat to saturated fat consumed. *Id.* A ninth category measuring multivitamin use was excluded from the Index calculation. *Id.* at 241.

172. *Id.* at 241.

the average scores previously found for healthy men (45.0) and women (38.4).¹⁷³ Only 12.4% of cardiac patients ate the recommended servings of vegetables a day; less than 8% ate the recommended amounts of fruit and cereal fiber; and only 5.2% limited their intake of trans fats to the recommended amount.¹⁷⁴ Just under 70% of the patients were overweight or obese.¹⁷⁵ The 2008 study of adult Polish cardiac patients reached very similar results.¹⁷⁶ Even children with congenital heart disease have very poor diets. A 2007 survey of 329 Belgian children with heart disease found that just 31.6% ate fruit about everyday and 39.4% ate fruit twice a week or less.¹⁷⁷ Just 40.4% ate vegetables every day and 30.7% ate vegetables twice a week or less.¹⁷⁸ In comparison, 28.6% had sugary drinks about every day.¹⁷⁹

Heart patients also suffer from other risk factors that are modifiable through diet and lifestyle. For example, a survey of 973 Americans with heart disease for an average of 11.5 years found that 85.8% were overweight or obese, 87.2% were abdominally obese, 84.6% had high blood pressure, 11.8% still smoked, and 85.1% were physically inactive or minimally active.¹⁸⁰ The six hundred patients with both heart disease and Type 2 diabetes fared no better.¹⁸¹

Perhaps most alarming, cardiac patients as a group are in many ways getting sicker, not healthier. A 2009 study examined trends in eight European countries across three versions of the EUROASPIRE survey, which collected data from 1995-96, 1999-2000, and 2006-07, respectively.¹⁸²

173. *Id.* at 243. (citing Marjorie L. McCullough et al., *Diet Quality and Major Chronic Disease Risk in Men and Women: Moving Toward Improved Dietary Guidance*, 76 AM. J. CLINICAL NUTRITION 1261, 1263 (2002)).

174. *Id.* at 242.

175. Ma et al., *supra* note 170, at 242.

176. For example, just 23.0% of men and 36.2% of women limited their intake of total fat to the recommended amount; 24.2% of men and 30.8% of women limited their intake of saturated fat to the recommended amount; and 40.7% of men and 43.2% of women ate the recommended amount of fruits and vegetables. Waskiewicz et al., *supra* note 161, at 510. Overall, no person surveyed met all the recommended daily intakes. *Id.*

177. Martial M. Massin, Hedwig Hövels-Gürich & Marie-Christine Seghaye, *Atherosclerosis Lifestyle Risk Factors in Children with Congenital Heart Disease*, 14 EUR. J. CARDIOVASCULAR PREVENTION & REHABILITATION 349, 349-50 tbl.1 (2007).

178. *Id.*

179. *Id.*

180. S.J. Lewis, K.M. Fox & S. Grandy, *Self-Reported Diagnosis of Heart Disease: Results from the SHIELD Study*, 63 INT'L J. CLINICAL PRAC. 726, 729 tbl.1 (2009).

181. See *id.*

182. Kornelia Kotseva et al., *Cardiovascular Prevention Guidelines in Daily Practice: A Comparison of EUROASPIRE I, II, and III Surveys in Eight European Countries*, 373 LANCET 929, 929 (2009) [hereinafter Kotseva et al., *Comparison*]. EUROASPIRE stands for European Action on Secondary and Primary Prevention by Intervention to Reduce Events. *Id.* See also

Between the first and third surveys, greater percentages of people had diabetes (up 9.3%), were obese (up 13.1%), were overweight and obese (up 5.1%), and had high blood pressure (up 3.4%).¹⁸³ This occurred despite massive increases in the percentages of people taking pharmaceutical drugs designed to treat CVD.¹⁸⁴ For example, between the first and third surveys, greater percentages of people took statins (up 67.8%), other lipid-lowering drugs (up 54.3%), ACE inhibitors (up 42.8%), and blood pressure-lowering drugs (up 11.6%).¹⁸⁵ Thus, even though our knowledge about how to prevent heart disease through diet and lifestyle is increasing, cardiac patients are adopting healthy dietary and lifestyle changes at decreasing rates, and are instead relying on drugs, which produce only modest benefits. Unfortunately, this is essentially "[treating the disease] without addressing the underlying causes . . . ; [instead,] we need to invest in prevention."¹⁸⁶

But it is not as if these patients are not willing and trying to change. The EUROASPIRE III survey interviewed and collected medical information from 8,966 patients with heart disease in twenty-two European countries.¹⁸⁷ Nearly all patients—92%—tried to change their diet in some way, for example by eating less fat (82.1%), eating more fruits and vegetables (77.9%), changing types of dietary fat (73.5%), eating less salt (71.3%), eating more fish (64.9%), eating less sugar (61.8%), eating fewer calories (61.3%), and drinking less alcohol (54.9%).¹⁸⁸ They tried to make non-dietary lifestyle changes, too, such as increasing physical activity (59.1%).¹⁸⁹ Similarly, in a 1995 study of 606 American cardiac patients, patients

Seungmin Lee et al., *Trends in Diet Quality for Coronary Heart Disease Prevention Between 1980-1982 and 2000-2002: The Minnesota Heart Survey*, 107 J. AM. DIETETIC ASS'N 213, 213 (2007). Overall the authors found that dietary quality improved significantly from 1980 to 1995 for both men and women, then leveled off and, on some measures, declined in 2000. *Id.* at 219. For example, compared to men in 1995, men in 2000 were eating fewer fruits and vegetables and getting more dietary cholesterol. *Id.* at 218 (the authors do not report if this change is statistically significant; they only report the significance of the overall trend). In every survey since 1980, both men and women increasingly consumed more calories than they needed, and their average body mass index ("BMI") increased. *Id.* at 218, 220. Women also showed a trend toward consuming increasing amounts of sodium. *Id.* at 220.

183. Kotseva et al., *Comparison*, *supra* note 182, at 934 tbl.3.

184. *Id.*

185. *Id.*

186. *Id.* at 938.

187. Kornelia Kotseva et al., *EUROASPIRE III: A Survey on the Lifestyle, Risk Factors and Use of Cardioprotective Drug Therapies in Coronary Patients from 22 European Countries*, 16 EUR. J. CARDIOVASCULAR PREVENTION & REHABILITATION 121, 124-25 (2009) [hereinafter Kotseva et al., *EUROASPIRE III*].

188. *Id.* at 127.

189. *Id.*

overwhelmingly viewed diet as very important in both the treatment and prevention of heart disease,¹⁹⁰ and 67% of those who had suffered a heart attack believed their diet was a contributing cause.¹⁹¹ While physicians have highly motivated patients willing to make changes, doctors themselves are proving to be of little help.

Recognizing the poor state of health evident in the EUROASPIRE studies, two authors suggested that physicians and health authorities should be required to give higher priority to helping cardiac patients achieve healthy lifestyles,¹⁹² and that the dangerous trends would have to be addressed through political action.¹⁹³

III. THE CAUSES

When surveyed, physicians generally pay almost unanimous lip service to the importance of diet and their role in giving dietary advice. For example, a 2006 survey of about 230 Washington State physicians found that 99.1% agreed that nutrition is important in the prevention of CVD, and 91.9% believed “[t]he primary care physician has an essential role in giving dietary advice.”¹⁹⁴ Similarly, a 2009 study of Pakistani cardiologists found that 93.9% believed “[n]utrition has an important part to play in the prevention of CVD,” 91.4% believed that cardiologists have “an essential role in giving dietary advice,” 95.3% believed their advice would impact what people eat, and 90.8% believed the dietary advice would be effective at reducing CVD.¹⁹⁵ Many other studies show similar attitudes.¹⁹⁶

190. Plous, Chesne, & McDowell, *supra* note 137, at 444. Specifically, on a scale of 1 (unimportant) to 9 (extremely important), patients on average gave diet a score of 7.7 with respect to the treatment of heart disease (52.8% scored it a 9) and a 7.6 with respect to the prevention of heart disease (51.8% scored it a 9). *Id.*

191. *Id.*

192. Mette Brekke & Bjørn Gjelsvik, Comment, *Secondary Cardiovascular Risk Prevention—We Can Do Better*, 373 LANCET 873, 874 (2009).

193. *Id.* (“Political action is needed to reverse the negative trends of obesity and sedentary habits, ranging from fighting against the fast food and sugar industries to safe bicycle paths and healthy school meals.”).

194. Oh, Beresford & Lafferty, *supra* note 104, at 462 tbl.3.

195. Gowani et al., *supra* note 106, at 5 tbl.2.

196. Kushner, *supra* note 103, at 549 tbl.2 (finding that 79% of physicians agreed that nutrition counseling is a high priority, and 72% agreed that nutrition counseling is the physician’s responsibility); Levine et al., *supra* note 116, at 116 tbl.2 (finding that more than 75% of 3,416 surveyed physicians agreed that diet has an important role in the prevention of heart disease and disease prevention, and that nutrition education is the responsibility of the physician); Moore & Adamson, *supra* note 108, at 533 tbl.3 (2001 survey of eighty-four English primary care practitioners found that 99% believed nutrition is important in the prevention of disease, and 99% believed that “[t]he primary care team has an essential role in giving dietary advice”); Colleen E. O’Keefe, Donna F. Hahn & Nancy M. Betts, *Physicians’*

As shown in section II, however, the right advice is not getting to the patients, despite these favorable physician attitudes. There are several reasons why, including: (A) a lack of knowledge, training, and confidence; (B) a lack of sufficient time for advice; (C) a belief that the patient is unable or unwilling to comply with the advice; and (D) others, including insurance reimbursement issues.¹⁹⁷

A. *Lack of Knowledge, Training, and Confidence (Medical Education)*

A physician cannot relay information he or she does not have, so it should be no surprise that physicians who know about the benefits of diet are more likely to give dietary advice. For example, a 2006 study found that primary care physicians aware of the preventive effects of fish oil on sudden cardiac death were almost three times more likely than other physicians to be high prescribers of fish oil.¹⁹⁸ Similarly, a 2009 study found that cardiologists aware of the effect of fish oil on sudden cardiac death were about six times more likely than other cardiologists to be high prescribers of fish oil.¹⁹⁹ Other studies reach similar results.²⁰⁰

Unfortunately, both primary care physicians and cardiologists tend to not know very much about diet and nutrition. For example, a 2003 survey of 120 cardiologists and 517 general internists found that large majorities of both lacked basic knowledge about the effects of low-fat diets on triglycerides and HDL levels (the “good” cholesterol).²⁰¹ Similarly, a 1999

Perspectives on Cholesterol and Heart Disease, 91 J. AM. DIETETIC ASS'N 189, 191 (1991) (finding that 99.3% of physicians agreed or strongly agreed that nutrition is an essential part of total healthcare, and 98.4% agreed that physicians should know the basics of dietary therapy and how to apply them).

Wechsler et al., *supra* note 103, at 996, 997 tbl.1 (finding physicians were less enthusiastic in some older surveys. For example, a survey of general internists and family physicians in Massachusetts in 1994 found that less than half (47%) considered “eating a balanced diet” to be “very important for the average person,” and—even more strangely—that percentage had actually declined from 58% in 1981.).

197. Kushner, *supra* note 103.

198. Oh, Beresford & Lafferty, *supra* note 104, at 462.

199. Gowani et al., *supra* note 106, at 7.

200. Frank et al., *supra* note 116, at 329 tbl.2 (finding that female physicians were more likely to give dietary advice if they had extensive training in nutrition counseling, were highly confident in their training, and felt their training was highly relevant); Kushner, *supra* note 103, at 548 (survey of over one thousand physicians finding that about 75% of those who counseled their patients about diet more than 40% of the time had received nutrition training, while only about 50% of those who counseled their patients less had received training).

201. Mary Flynn, Christopher Sciamanna & Kevin Vigilante, *Inadequate Physician Knowledge of the Effects of Diet on Blood Lipids and Lipoproteins*, NUTRITION J., Dec. 1, 2003, at 1, 20 (Specifically, 84% of cardiologists and 96% of internists did not know a low-fat diet would increase blood triglycerides, and 70% of cardiologists and 77% of internists did not know that a low-fat diet would decrease blood levels of HDL. Twenty-two percent of

survey found that eighty-four Canadian physicians averaged 63.1% correct responses on a sixteen-question quiz covering basic dietary and nutrition information.²⁰² The physicians were more likely to correctly answer questions that had received a lot of media exposure.²⁰³ Primary care physicians have also shown a lack of knowledge about the benefits of fish oil.²⁰⁴ As a result, it is no wonder that physicians report agreeing that they are not very knowledgeable about or well-prepared to give dietary advice,²⁰⁵ and that this lack of knowledge is a significant barrier to providing dietary counseling.²⁰⁶

Cardiologists may be more knowledgeable than primary care doctors, however. In a 2006 survey, of forty-four responding cardiologists, 91% reported being somewhat or very familiar with research supporting the use of very low-fat vegetarian diets.²⁰⁷ Of course, they still rarely recommended those diets,²⁰⁸ so there were other reasons they did not do so.

Physicians also do not have much training in giving dietary advice and counseling patients to make changes. For example, a 1995 study found that 67% of over one thousand physicians cited lack of training in counseling skills as a barrier to providing nutrition education.²⁰⁹ Similarly, in a 1985 study, 27.5% of primary care physicians reported that a lack of

cardiologists and 53% of internists did not know that rising triglycerides are most likely to be caused by carbohydrates.). See also Moore & Adamson, *supra* note 106, at 533-34 (2001 survey of eighty-four English primary care practitioners finding that 65% of questions were answered correctly by more than half of respondents, but about one-third of the questions were answered incorrectly by more than half of respondents. The questions answered incorrectly were more likely to contain complex nutritional terms, such as "monounsaturates" and "non-starch polysaccharides."). But see Lentzner, Connolly & Phoon, *supra* note 110, at 555 (just 5% of pediatric cardiologists cited lack of knowledge as a reason for not discussing diet).

202. Norman J. Temple, *Survey of Nutrition Knowledge of Canadian Physicians*, 189 J. AM. C. NUTRITION 26, 27 (1999).

203. *Id.* at 28.

204. See Oh, Beresford & Lafferty, *supra* note 104, at 462 tbl.3 (finding that primary care physicians incorrectly answered questions about fish oil and CVD 43.5% of the time, questions about fish oil and triglycerides were incorrectly answered 57% of the time, while questions about fish oil and sudden cardiac death were incorrectly answered 73.5% of the time).

205. See Levine et al., *supra* note 116, at 116 tbl.3.

206. Kushner, *supra* note 103, at 549 tbl.2 (finding that 62% of over one thousand physicians surveyed reported lack of nutrition knowledge as a barrier to providing nutrition counseling).

207. RAFAL, LANOU & BARNARD, *supra* note 131, at 3 (59% were somewhat familiar with the research, while 32% were very familiar).

208. See *supra* notes 136-139 and accompanying text (responding cardiologists and institutions rarely or never recommending or preferring the diet).

209. Kushner, *supra* note 103, at 549.

training to treat lifestyle risks was an obstacle to providing advice on diet and lifestyle.²¹⁰

This lack of knowledge and training gives rise to a lack of confidence in the ability to give dietary advice or counsel patients about diet.²¹¹ For example, a 2001 survey of English primary care physicians found that just 32% rated their personal knowledge of diet and CVD as good or excellent.²¹² In a 1999 survey of Canadian physicians, none described their nutrition knowledge as excellent; 42% described it as weak, and 47% described it as satisfactory.²¹³ A 1994 study of Massachusetts physicians found that "[l]ess than half. . . felt very prepared to counsel patients about diet."²¹⁴ Other studies reach similar results.²¹⁵

Likely the main reason that physicians lack knowledge, training, and confidence is that they received inadequate nutrition education in medical school. In 1992, just thirty-four of 139 North American medical schools had a required course in nutrition, decreasing to just twenty-seven in 1995.²¹⁶ Overall, the number of schools requiring courses on nutrition (about thirty) or teaching some nutrition as part of another required course (about eighty) remained stable between 1984 and 1995.²¹⁷ In 1998-99,

210. Orleans et al., *supra* note 114, at 642.

211. Temple, *supra* note 202, at 28 (As a result of their poor knowledge, "many physicians do not have the expertise to properly advise their patients on important aspects of the role of nutrition in the causation, prevention, and [treatment] of disease."). See also O'Keefe, Hahn & Betts, *supra* note 196, at 191 (1991 study, finding that 78% of Midwest physicians felt unprepared to address their patients' nutrition problems, yet 83% would still provide dietary advice to reduce cholesterol, likely leading to the provision of bad advice).

212. Moore & Adamson, *supra* note 108, at 533 tbl.2.

213. Temple, *supra* note 202, at 27-28.

214. Wechsler et al., *supra* note 103, at 997.

215. Kushner, *supra* note 103, at 549 (finding that 50% of physicians surveyed agreed or strongly agreed that lack of confidence in the ability to counsel patients about diets was a barrier to nutrition counseling); Karen V. Mann & R. Wayne Putnam, *Physicians' Perceptions of Their Role in Cardiovascular Risk Reduction*, 18 PREVENTIVE MED. 45, 49 fig.1, 51 tbl.4 (1989) (finding that just 2% of fifty physicians surveyed were very confident in their ability to help patients reduce their cholesterol, and 44% were only moderately confident, and just 18% of the physicians felt they were very skilled at counseling). See Femke Visser et al., *Longitudinal Changes in GPs' Task Perceptions, Self-Efficacy, Barriers and Practice of Nutrition Education and Treatment of Overweight*, 25 FAM. PRAC. i105, i109 tbl.3 (2008) (finding that Dutch general practitioners' perceived capacity to give dietary advice to treat CVD significantly declined from 1992 to 2007).

216. Elaine B. Feldman, *Networks for Medical Nutrition Education—A Review of the US Experience and Future Prospects*, 62 AM. J. CLINICAL NUTRITION 512, 513 (1995).

217. *Id.* at 513 fig.1.

38 of 127 US medical schools had a required nutrition course, and 112 included nutrition as part of a separate required course.²¹⁸

Even where it gets attention, however, the content of nutrition education may be very poor due to conflicts of interest. For example, food and drug companies sponsor entire departments at universities²¹⁹ and even sponsor and help create the content for an interactive compact disc series used by seventy-six American medical schools to teach medical students about diet and nutrition.²²⁰ The food industry is also a large sponsor of medical conferences attended by students and educators.²²¹ Recently, the American Academy of Family Physicians decided to have its consumer education website concerning the relationship between beverages and disease sponsored by Coca-Cola,²²² a decision that was heavily criticized²²³ and

218. ASS'N AM. MED. C., CURRICULUM DIRECTORY 1998-1999 12 tbl.5 (Kimberly S. Varner ed., 27th ed. 1998).

219. MARION NESTLE, FOOD POLITICS: HOW THE FOOD INDUSTRY INFLUENCES NUTRITION AND HEALTH 120-22 (2d ed. 2007) (noting that the number of university partnerships with industry reached 4,800 by 1998).

220. The interactive CD series is called "Nutrition in Medicine" ("NIM"), designed for primary or supplemental instruction in nutrition in medical schools. *About Us: Overview*, POGO HEALTH EDUCATION, <http://pogohealtheducation.com/series/overview.jsp> (last visited Sept. 14, 2010). NIM is funded by sixteen organizations, including the National Cattlemen's Beef Association, the National Dairy Council, the Dannon Institute, the Kellogg Co., Nestle, the Quaker Oats Foundation, and six pharmaceutical companies. *Series History: Sponsors*, POGO HEALTH EDUCATION, <http://pogohealtheducation.com/series/sponsors.jsp> (last visited Sept. 14, 2010). Each food association and company is represented on NIM's advisory board, along with a French food company, Eridania Baghin-Say. *Series History: Advisory Board*, POGO HEALTH EDUCATION, http://pogohealtheducation.com/series/advisory_board.jsp (last visited Sept. 14, 2010). At least seventy-six U.S. medical schools currently use NIM. *Reviews: Nutrition in Medicine Users*, POGO HEALTH EDUCATION, <http://pogohealtheducation.com/reviews/schools.jsp> (last visited Sept. 14, 2010).

221. Nestle, *supra* note 219, at 115-16. See also Feldman, *supra* note 216, at 514 (mentioning that the National Livestock and Meat Board funded a symposium for medical students in 1993).

222. *American Academy of Family Physicians Launches Consumer Alliance with First Partner: The Coca-Cola Company*, AM. ACAD. FAM. PHYSICIANS (Oct. 6, 2009), <http://www.aafp.org/online/en/home/media/releases/newsreleases-statements-2009/consumeralliance-cocacola.html>.

223. See Associated Press, *Outrage as Doctors' Group Allows Coca-Cola to Sponsor Health Advice*, FOXNEWS.COM, Nov. 5, 2009, http://www.foxnews.com/printer_friendly_story/0,3566,571930,00.html (for example, one critic—Dr. Walter Willett at Harvard—stated that "Coca-Cola, like other sodas, causes enormous suffering and premature death by increasing the risks of obesity, diabetes, heart attacks, gout, and cavities. . . . [T]he academy should be a loud critic of these products and practices, but by signing with Coke their voice has almost surely been muzzled."); Jerry LaMartina, *Doctors Resign from American Academy of Family Physicians Over Coca-Cola Alliance*, KAN. CITY BUS. J., Oct. 30, 2009, <http://kansascity.bizjournals.com/kansascity/stories/2009/10/26/daily59.html?t=printable> (for example, one doctor stated that "[h]aving the soda industry create materials about making the right choices

even caused some physicians to withdraw from the organization.²²⁴ For medical schools, the temptation of inexpensive teaching tools for cash-strapped nutrition programs may be too difficult to resist,²²⁵ but it likely comes at the cost of compromising the content of medical education, as these interests are unlikely to sponsor programs if they could not influence the advice provided.²²⁶

Given the poor coverage in medical school, graduating medical students consistently report they receive inadequate nutrition education. The percentage of graduating medical students who agreed or strongly agreed that their "[n]utrition-related experiences were adequate" was 23.4 in 2000,²²⁷ 28.7 in 2001,²²⁸ and 30.0 in 2002.²²⁹ Thus, roughly 70% of medical students believe they received inadequate nutrition education. Also, the percentage of graduating medical students believing that inadequate time was devoted to clinical nutrition training was 64.4 in 1998,²³⁰ 65.7 in 2001,²³¹ 62.7 in 2002,²³² 51.8 in 2003,²³³ 51.8 in 2004,²³⁴ and 51.1 in 2005.²³⁵ While the time devoted is apparently

is like having the fox guard the hen house. . . . This is reminiscent of when the tobacco industry enlisted doctors to endorse cigarette brands as 'mild.'").

224. LaMartina, *supra* note 223 (describing how ten to twenty physicians from a particular health center withdrew in response, and the Academy's response).

225. See Feldman, *supra* note 216, at 515 (suggesting that funds for a network-based nutrition education program should be sought from "the food or pharmaceutical industries," in addition to the government and other resources).

226. See Nestle, *supra* note 219 (discussing the influence corporations wield in academic research departments where they sponsor the programs).

227. See DIV. MED. EDUC., ASS'N AM. MED. C., 2000 MEDICAL SCHOOL GRADUATION QUESTIONNAIRE: ALL SCHOOLS REPORT 13 (2000), available at <http://www.aamc.org/data/gq/allschoolsreports/2000.pdf> [hereinafter AAMC QUESTIONNAIRE 2000].

228. See DIV. MED. EDUC., ASS'N AM. MED. C., 2001 MEDICAL SCHOOL GRADUATION QUESTIONNAIRE: ALL SCHOOLS REPORT 16 (2001), available at <http://www.aamc.org/data/gq/allschoolsreports/2001.pdf> [hereinafter AAMC QUESTIONNAIRE 2001].

229. See DIV. MED. EDUC., ASS'N AM. MED. C., 2002 MEDICAL SCHOOL GRADUATION QUESTIONNAIRE: ALL SCHOOL REPORT 19 (2002), available at <http://www.aamc.org/data/gq/allschoolsreports/2002.pdf> [hereinafter AAMC QUESTIONNAIRE 2002] (this was the last year this information was collected).

230. S. Edwards Dismuke & Alicia M. McClary, *Putting It All Together: Building a Four-Year Curriculum*, ACAD. MED., July 2000, at S90, S91 tbl.1 (citing ASS'N AM. MED. C., GRADUATING STUDENT QUESTIONNAIRE (1998)).

231. AAMC QUESTIONNAIRE 2001, *supra* note 228, at 20.

232. AAMC QUESTIONNAIRE 2002, *supra* note 229, at 24.

233. DIV. MED. EDUC., ASS'N AM. MED. C., 2003 MEDICAL SCHOOL GRADUATION QUESTIONNAIRE: ALL SCHOOLS REPORT 27 (2003), available at <http://www.aamc.org/data/gq/allschoolsreports/2003.pdf>.

234. DIV. MED. EDUC., ASS'N AM. MED. C., 2004 MEDICAL SCHOOL GRADUATION QUESTIONNAIRE: ALL SCHOOLS REPORT 24 (2004), available at <http://www.aamc.org/data/gq/allschoolsreports/2004.pdf>.

improving, still less than half of students thought it was adequate. However, medical schools do the best at teaching nutrition for heart disease. The percentage of students agreeing or strongly agreeing they “were adequately taught to nutritionally assess and treat patients at risk for coronary heart disease” was 57.9 in 2000,²³⁶ 58.6 in 2001,²³⁷ and 58.0 in 2002.²³⁸ That is better than general attitudes, but still about 42% of students felt they were *not* adequately taught how to treat risk factors for heart disease, and it does not tell us anything about the *content* of that education.

Surveys of practicing physicians reinforce the surveys of graduating students. A 2003 study of Washington State physicians found that just 22.1% of those who received nutrition training in medical school thought it was adequate, and 75.2% thought the quality of their nutrition education in medical school was fair or poor.²³⁹ The perceived quality of nutrition education was associated with a physician’s self-perceived nutrition proficiency.²⁴⁰ A 1999 survey of eighty-four Canadian physicians found that 43% had received under five hours of nutrition instruction in medical school, 28% had received five to ten hours, 23% had received ten to twenty hours, and just 6% had over twenty hours.²⁴¹ The authors concluded that this lack of training was clearly reflected in the physicians’ poor scores on basic nutrition knowledge.²⁴²

Not only do medical schools not teach it, states may do a poor job of testing it. To be granted a license to practice medicine in any state, a medical student must take and pass the United States Medical Licensing Examination (USMLE).²⁴³ Medical schools will by necessity teach students what they need to know to pass the exam. In 1985, the National Academy of Sciences criticized the exam for its poor coverage of basic nutrition knowledge.²⁴⁴ Following this, the percentage of questions relating to

235. DIV. MED. EDUC., ASS’N AM. MED. C., 2005 MEDICAL SCHOOL GRADUATION QUESTIONNAIRE: ALL SCHOOLS REPORT 24 (2005), available at <http://www.aamc.org/data/gq/allschoolsreports/2005.pdf>.

236. See AAMC QUESTIONNAIRE 2000, *supra* note 227.

237. See AAMC QUESTIONNAIRE 2001, *supra* note 228.

238. See AAMC QUESTIONNAIRE 2002, *supra* note 229, at 20.

239. Tanis V. Mihalynuk, Craig S. Scott & John B. Coombs, *Self-Reported Nutrition Proficiency is Positively Correlated with the Perceived Quality of Nutrition Training of Family Physicians in Washington State*, 77 AM. J. CLINICAL NUTRITION 1330, 1332-33 tbl.3 (2003).

240. *Id.* at 1333.

241. Temple, *supra* note 202, at 27.

242. *Id.* at 28.

243. See *About USMLE*, U.S. MED. LICENSING EXAMINATION, http://www.usmle.org/General_Information/general_information_about.html (last visited Aug. 28, 2010) (state medical boards set their own criteria, but all utilize the USMLE).

244. Lisa A. Hark et al., *Nutrition Coverage on Medical Licensing Examinations in the United States*, 65 AM. J. CLINICAL NUTRITION 568, 568 (1997).

nutrition increased from 9% to 11% on the first part of the exam, and from 6% to 12% on the second part.²⁴⁵ While this is a significant improvement, the content of the questions was not examined.²⁴⁶ It is unknown if—and seems doubtful that—the USMLE requires students to know that programs based on diet and lifestyle can reverse heart disease and prevent heart attacks, and the content of those programs.²⁴⁷

Even after licensure, physicians receive inadequate training in residency programs.²⁴⁸ Any nutrition education needs to be reinforced in postgraduate training.²⁴⁹ A 1998 survey identified just twenty-two active clinical nutrition training programs for physicians in the entire country, down from thirty-eight in 1993.²⁵⁰ One of the largest obstacles to residency training in diet and nutrition may be the lack of physicians with expertise in nutrition who can teach residents and act as role models.²⁵¹

The American College of Cardiology and the AHA recommend that all cardiovascular specialists be trained in the prevention of cardiovascular diseases, including in all cases “[f]amiliarity with appropriate cardiovascular dietary choices and interventions for change in dietary habits.”²⁵² Unfortunately, medical education is not appropriately organized to achieve this goal.

245. *Id.*

246. *Id.*

247. See *id.* at 570 (noting that such topics as lifestyle choices and reversing heart disease, and preventing heart attacks through diet were absent from the list of nutritional items by topic on the USMLE).

248. Ruth A. Bruer, Richard E. Schmidt & Howard Davis, *Commentary: Nutrition Counseling—Should Physicians Guide Their Patients?*, 10 AM. J. PREVENTIVE MED. 308, 309 (1994) (U.S. Public Health Service noting that one significant barrier to physician knowledge is the lack of emphasis on nutrition knowledge on certification and accreditation exams after graduation).

249. Nancy F. Krebs & Laura E. Primak, *Comprehensive Integration of Nutrition into Medical Training*, 83 AM. J. CLINICAL NUTRITION 945S, 948S-49S (2006).

250. Douglas C. Heimbarger, Virginia A. Stallings & Lisa Routzahn, *Survey of Clinical Nutrition Training Programs for Physicians*, 68 AM. J. CLINICAL NUTRITION 1174, 1175 (1998).

251. Roland L. Weinsier et al., *Nutrition Training in Graduate Medical (Residency) Education: A Survey of Selected Training Programs*, 54 AM. J. CLINICAL NUTRITION 957, 957 (1991) (“[A] shortage of nutrition-oriented physician role models is probably the major constraint in teaching nutrition to residents.”); John R. Boker et al., *Components of Effective Clinical-Nutrition Training: A National Survey of Graduate Medical Education (Residency) Programs*, 52 AM. J. CLINICAL NUTRITION 568, 568 (1990) (“An important identified need is to train and involve more clinical-nutrition faculty members in residency programs.”).

252. Roger S. Blumenthal et al., *Task Force 10: Training in Preventive Cardiovascular Medicine*, 51 J. AM. C. CARDIOLOGY 393, 394-95 (2008).

B. Lack of Time

One of the most frequent complaints of physicians is that they have inadequate time to provide dietary advice and counseling. For example, the 2006 study of Washington State primary care physicians found that just 18.8% agreed they have sufficient time to give adequate dietary advice.²⁵³ The physicians who perceived sufficient time were more likely to prescribe fish oil to patients.²⁵⁴ Similarly, a 1995 study of over 1,000 physicians found that while just 34% spent more than six minutes discussing diet with their patients, and just 14% spent more than nine minutes, 58% *wanted* to spend more than five minutes, and 28% *wanted* to spend more than nine minutes.²⁵⁵ Not surprisingly, 75% of all physicians surveyed agreed or strongly agreed that lack of time was a barrier to dietary counseling, the most commonly cited reason.²⁵⁶ Many other studies have reached similar results.²⁵⁷

However, it is possible that cardiologists perceive more time as available time than primary care physicians. A 2009 survey of Pakistani cardiologists found that just 35% agreed or strongly agreed that they had insufficient time to adequately advise patients.²⁵⁸ Pediatric cardiologists' most frequently cited reason for not discussing risk factors such as diet with children and their families was lack of time, at 35%, which is still comparatively a good result.²⁵⁹

C. A Belief That the Patient Is Unwilling or Unable to Comply

Physician beliefs about patient compliance are somewhat contradictory. On one hand, physicians believe their dietary advice is likely to have a

253. Oh, Beresford & Lafferty, *supra* note 104, at 462 tbl.3.

254. *Id.* at 464.

255. Kushner, *supra* note 103, at 549.

256. *Id.*

257. See, e.g., Mann & Putnam, *supra* note 215, at 53 tbl.6 (72% of fifty physicians surveyed in 1989 reported lack of time as a barrier to providing cardiovascular disease prevention, by far the most frequently cited barrier); Moore & Adamson, *supra* note 108 (survey of eighty-four English primary care practitioners finding that 76% believed they have insufficient time to adequately advise patients about diet); O'Keefe, Hahn & Betts, *supra* note 196, at 191-92 (finding that nearly 84% of physicians surveyed reported having insufficient time to give adequate dietary advice); Orleans et al., *supra* note 114, at 642 tbl.2 (study of primary care physicians finding that lack of time was cited as an obstacle to promoting healthy diets and lifestyles by 47.7% of physicians). See also Visser et al., *supra* note 215 (study of the same Dutch general practitioners in 1992 and 2007 found that those perceiving lack of time as a barrier to nutrition counseling significantly increased over the years, suggesting that time constraints are becoming more of a problem, not less).

258. Gowani et al., *supra* note 106, at 6.

259. Lentzner, Connolly & Phoon, *supra* note 110, at 555.

significant impact on the patient's behavior. For example, a 2001 survey of eighty-four English primary care practitioners found that 70% believed their advice would have some impact on what people would eat.²⁶⁰ In a 1991 survey, 81.3% of physicians reported believing they were successful in helping patients lower their cholesterol through dietary changes.²⁶¹

On the other hand, one of the main reasons physicians give for not discussing diet is a belief that patients will not comply. For example, in 2006, when forty-four cardiologists explained why they did not routinely order or recommend diets shown to reverse heart disease, in spite of their knowledge of the research, the two most common reasons cited were the beliefs that patients would not want to follow it, or that patients could not comply with the diet even if they wanted to.²⁶² Similarly, in a 1985 survey of primary care physicians, the most frequently cited obstacle to dietary and lifestyle advice was "[p]essimism about people's abilities to change their lifestyles."²⁶³

Physicians may seriously underestimate the ability of people to change their diets, especially when faced with a life-threatening illness and receiving adequate training and assistance. The Agency for Healthcare Research and Quality (AHRQ) conducted a large systematic review of the scientific evidence and concluded that dietary counseling by health care practitioners "produce[s] modest reductions in the consumption of dietary total and saturated fat and modest increases in the consumption of fruits and vegetables."²⁶⁴ Counseling tended to have a larger effect when the patient

260. See Moore & Adamson, *supra* note 108, at 533 tbl.3. See also Levine et al., *supra* note 116, at 116 tbl.3 (1993 survey finding that more than 75% of physicians disagreed with the statement that dietary advice "is a waste of time because people don't change their habits anyway"); RAFAL, LANOU & BARNARD, *supra* note 131, at 3 (of forty-four cardiologists surveyed in 2006, 52.2% believed they were highly influential over what patients ate after being discharged from the hospital).

261. O'Keefe, Hahn & Betts, *supra* note 196.

262. RAFAL, LANOU & BARNARD, *supra* note 131 (cited by 48% and 52% of respondents, respectively).

263. Orleans et al., *supra* note 114, at 642 tbl.2. Ultimately, a physician may just skip diet and discuss something he or she knows the patient is sure to comply with: prescription drugs. Linda Van Horn & Rae-Ellen Kavey, *Diet and Cardiovascular Disease Prevention: What Works?*, 19 ANNALS BEHAV. MED. 197, 202 (1997) ("The Step I and II Diets encompass the dietary factors shown to be helpful in improving risk status, but the challenge of achieving adherence may seem unreasonably daunting, thereby prompting the decision to skip to one of the more consistently reliable pharmacologic approaches instead."). In a 1989 survey, 84% of fifty physicians reported believing their advice to lower cholesterol would be ineffective or only somewhat effective, Mann & Putnam, *supra* note 215, at 49 fig.1, and zero physicians felt they were very skilled at helping patients achieve behavior change, *id.* at 51 tbl.4.

264. ALICE AMMERMAN ET AL., SYSTEMATIC EVIDENCE REVIEW NUMBER 18: COUNSELING TO PROMOTE A HEALTHY DIET 55 (2002), available at <http://www.ahrq.gov/downloads/pub/prevent/pdfser/dietser.pdf>. Thirty-three studies were included in the review. *Id.* at 40. To

had a major illness like heart disease or cancer, and when the counseling intervention was more intense.²⁶⁵ Similarly, in Ornish's original study, twenty-five out of twenty-seven people with severe heart disease were able to completely adhere to a low-fat vegetarian diet for a year.²⁶⁶ Compared to the control group, the diet group enjoyed their food just as much and exerted no more effort to stay on the diet.²⁶⁷ These patients both had severe heart disease and received intensive dietary training and assistance, which included family involvement, group support, and the provision of some prepared meals.²⁶⁸ Another study found that 74% of participants in the Ornish program adhered to the diet after three months.²⁶⁹ Participants with prior heart attacks adhered to the diet significantly better than others, suggesting that "patients with greater disease severity may be more motivated to change their lifestyle, perhaps because they fear worse health outcomes than their relatively healthier counterparts."²⁷⁰ Other studies reach similar results.²⁷¹ Just giving simple advice without training and

illustrate, one study found that patients who received brief counseling and a self-help book from a physician were, compared to a control group, more likely to eat less fat and get more dietary fiber after one year. Shirley A.A. Beresford et al., *A Dietary Intervention in Primary Care Practice: The Eating Patterns Study*, 87 AM. J. PUB. HEALTH 610, 613-14 (1997).

265. Ammerman et al., *supra* note 264, at 46-47, 124.

266. Barnard, Scherwitz & Ornish, *supra* note 96.

267. *Id.* at 429 tbl.7.

268. *Id.* at 430. See also Van Horn & Kavey, *supra* note 263, at 206 (listing practical steps to improve dietary compliance, including: stricter limits on fat intake; frequent monitoring; an initial "[r]esidential" component, i.e., having participants reside in a facility initially where they receive intense education and demonstrations; vegetarian diets; family involvement; group support; providing food; and symptomatic patients).

269. Daubenmier et al., *supra* note 96, at 64 (adherence measured by whether 10% of calories or less came from dietary fat intake).

270. *Id.* at 65-66. Further, both diabetics and those with smoking histories spent more time a week on average practicing stress management. *Id.* at 65.

271. This study included ten patients in North Carolina with heart disease: none completely adhered to a vegetarian diet after twenty-eight weeks or one year, and five were following the AHA Step 1 diet after one year. Terry L. Franklin et al., *Adherence to Very-Low-Fat Diet by a Group of Cardiac Rehabilitation Patients in the Rural Southeastern United States*, 4 ARCHIVES FAM. MED. 551, 552-53 tbl.2 (1995). Still, after twenty-eight weeks, all but one were following a near-vegetarian diet with less than 20% of calories coming from fat. *Id.* at 553 tbl.2. Weekly support and counseling stopped at twenty-eight weeks, showing that constant support is a significant factor in adherence. *Id.* at 553. Some surveys show that people are more likely to engage in healthy behaviors after receiving physician advice to do so. For example, in the very large study using data from the BRFSS survey, 82.8% of individuals receiving physician advice reported they were eating fewer high-fat and high-cholesterol foods, compared with just 55.6% of those who received no physician advice. CDC, *Cardiovascular Disease Risk Reduction*, *supra* note 103, at 76. Similarly, a 2002 study found that 85.4% of stroke victims who received physician advice changed their diet, compared to just 56.0% of stroke victims who received no advice. Kurt J. Greenlund et al., *supra* note

follow-up assistance is not likely to lead to strong adherence or produce many benefits.²⁷²

Ultimately, if the patient is motivated to change and received some intensive training and assistance in making those changes, he or she is more than capable of adhering to a strict diet.

D. Other Barriers

Lack of or low insurance reimbursement may be a significant barrier. A 2000 survey of eighty-two health insurers found that just forty-three (52%) covered medical nutrition therapy.²⁷³ Surveys of physicians have also found that insurance reimbursement was a major obstacle to dietary advice and counseling.²⁷⁴ Similarly, in 1994, the U.S. Public Health Service noted that a significant barrier to physician education was the lack of reimbursement for dietary counseling, since reimbursement drives physician education and practice time.²⁷⁵

However, the situation may be improving; consider the Dean Ornish Program for Reversing Heart Disease. The Centers for Medicare and Medicaid Services (CMS) made the decision to provide Medicare coverage of the program in 2006.²⁷⁶ Congress, not to be outdone, passed the Medicare Improvements for Patients and Providers Act of 2008,²⁷⁷ which expressly provides coverage of "intensive cardiac rehabilitation programs"

114. Almost identical results were found among non-stroke victims. *Id.* (the figures were 80.8% and 54.9%, respectively).

272. See, e.g., Burr et al., *supra* note 125 (men with angina receiving initial advice to eat more fish and/or fruits and vegetables—but no training or follow-up assistance—are no less likely to die from any cause or from a heart attack).

273. Cynthia L.N. Baranoski & Sondra L. King, *Insurance Companies Are Reimbursing for Medical Nutrition Therapy*, 100 J. AM. DIETETIC ASS'N 1530, 1531 (2000). See also Adam Gilden Tsai, David A. Asch & Thomas A. Wadden, *Insurance Coverage for Obesity Treatment*, 106 J. AM. DIETETIC ASS'N 1651, 1652 (2006) (survey of sixteen health insurers, finding that all sixteen covered bariatric surgery for obesity, but just nine covered dietary counseling, and just five covered intensive counseling).

274. Kushner, *supra* note 103, at 549 (1995 study finding that 61% of physicians surveyed agreed that insufficient insurance reimbursement was a barrier to dietary counseling); O'Keefe, Hahn & Betts, *supra* note 196, at 192 (1991 study finding that, of those physicians reporting having insufficient time to give adequate dietary advice, 65.4% also reported lack of insurance coverage as a barrier to giving dietary advice). But see Orleans et al., *supra* note 114, at 642 tbl.2 (1985 study found that just under 24% of primary care physicians cited insufficient insurance reimbursement as an obstacle to promoting healthy diets and lifestyles).

275. Bruer, Schmidt & Davis, *supra* note 248.

276. Hilary E. MacGregor, *Endorsing a Lifestyle*, L.A. TIMES, June 12, 2006, at F3, available at <http://articles.latimes.com/2006/jun/12/health/he-ornish12>.

277. Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110-275, 122 Stat. 2494 (2008).

such as the Ornish Program for qualifying Medicare enrollees.²⁷⁸ Many private insurers now cover the program as well, citing the benefits to patients and the savings to insurers.²⁷⁹ Not all insurers are on board, however: the Ornish program has been designated by Aetna as “experimental and investigational” and thus not covered.²⁸⁰

There are a number of other possible barriers that contribute to the lack of dietary advice, including: (1) some physicians may believe the patient’s disease or condition is just a matter of genetics, rather than diet and lifestyle, notwithstanding the evidence to the contrary;²⁸¹ (2) some physicians

278. § 144(a)(1)-(2), 122 Stat. 2494, 2544-47 (defining “Intensive Cardiac Rehabilitation Program,” determining who is eligible, establishing coverage, and providing for the determination of an appropriate fee schedule; codified as amended at 42 U.S.C. 1395x).

279. See, e.g., UPMC HEALTH PLAN: POLICY AND PROCEDURE MANUAL, UPMC HEALTH PLAN, available at http://www.upmchealthplan.com/pdf/PandP/PAY_059_LifestyleModificationProgramHeartDiseaseMay10.pdf (last visited Sept. 4, 2010) (determining that the program will be covered, as it is “appropriate and consistent with good medical practice when performed for the indications listed in this policy.”); *Dr. Dean Ornish Program for Reversing Heart Disease*, BLUE ADVOCACY, BLUECROSS BLUESHIELD ASS’N, http://www.blueadvocacy.org/plans/program/dr_dean_ornish_program_for_reversing_heart_disease (last visited Sept. 5, 2010) (offered since 1997 to “promote healthy lifestyle habits that can slow, stop and reverse the damage caused by this chronic condition,” and noting that “78 percent of participants avoid[ed] bypass surgery or angioplasty,” there were “statistically significant reductions in all risk categories, including angina, blood pressure, cholesterol levels, weight and body fat,” and “a 2003 cost analysis estimated that program participation saved an average of more than \$17,000 per patient from avoided invasive procedures, heart attacks, medication use and cardiac rehabilitation.”)

280. *Clinical Policy Bulletin: Ornish Cardiac Treatment Program*, AETNA, http://www.aetna.com/cpb/medical/data/200_299/0267.html (last visited Sept. 5, 2010). Compare with UPMC HEALTH PLAN: POLICY AND PROCEDURE MANUAL, *supra* note 279 (determining that the program should be covered because it is “appropriate and consistent with good medical practice.”). See also Ornish, *Avoiding Revascularization*, *supra* note 8, at 75T (noting that, at the time of the study in 1998, about forty private health insurers were covering the costs of training patients to make comprehensive lifestyle changes, while likely all covered the costs of drugs and surgical interventions); Ben A. Shaberman, *An Update on the Ornish Program: Studies Provide Evidence that it Reverses Heart Disease, but are Insurance Companies and Hospitals Coming on Board?*, VEGETARIAN J., 2004, at 12-13, available at http://www.thefree library.com/_/print/PrintArticle.aspx?id=124418821 (discussing the uphill battle to get private insurance to cover Ornish’s program).

281. Van Horn & Kavey, *supra* note 263 (discussing the possibility “that certain genetic polymorphisms influence [a person’s] lipid response.” “For some patients with elevated triglycerides and lower levels of HDL-C and without markedly elevated LDL-C, a very low-fat, high-carbohydrate diet may have an adverse effect by further reducing HDL-C It is not possible to predict what percent of the population may have inherited genetic traits that limit lipid response to diet, but it appears that qualitative adjustments to the diet may even benefit some of these patients. More data are needed to determine whether more precise dietary recommendations can be targeted to certain phenotypes that will more accurately predict lipid response even in these individuals.”).

may feel threatened by a system of prevention and treatment they lack expertise in, and which gives the patient more control;²⁸² and (3) some physicians may feel dietary advice is the responsibility of other physicians or health care professionals.²⁸³

IV. THE CURE?

The law can be used to improve the treatment and prevention of heart disease by helping to get information about diet and lifestyle from physicians to their patients. Four possible strategies are: (A) reforming medical education; (B) requiring insurers to cover dietary and lifestyle counseling and intensive training; (C) requiring physicians to disclose the information by statute; and (D) holding physicians accountable through tort law.

A. *Reforming Medical Education*

Changing medical education would address physicians' lack of knowledge, training, and confidence, as well as patient compliance. Doctors will be more likely to give accurate, optimal advice, and more capable of helping patients adhere to that advice. Benefits might not be felt for some time, however, as physicians and cardiologists adequately trained in dietary counseling would not immediately replace others lacking such training.

There are at least five things the government can do to reform medical education. First, state medical schools can directly reform their curricula by requiring more extensive courses in diet and nutrition, *particularly* with respect to heart disease, since this area stands to produce the greatest individual and societal benefits.²⁸⁴ Many ways of reforming medical school curricula have been suggested.²⁸⁵

282. T. COLIN CAMPBELL & THOMAS M. CAMPBELL II, *THE CHINA STUDY: THE MOST COMPREHENSIVE STUDY OF NUTRITION EVER CONDUCTED AND THE STARTLING IMPLICATIONS FOR DIET, WEIGHT LOSS AND LONG-TERM HEALTH* 334, 338 (2004).

283. *E.g.*, Lentzner, Connolly & Phoon, *supra* note 110, at 554-55 (2003 study of pediatric cardiologists finding that, while 59% thought it was extremely important for a child's primary care physician to discuss diet in relation to cardiovascular health, just 19% thought it was extremely important for pediatric cardiologists to do so).

284. Krebs & Primak, *supra* note 249, at 945S (describing the need for nutrition coursework in medical schools as an "essential component of medical education. . ."). See *supra* Section I.A-C (discussing heart disease, its human and financial toll, as well as surgical, pharmaceutical, dietary, and lifestyle interventions).

285. See, *e.g.*, Dismuke & McClary, *supra* note 230, at S90-91 (suggesting how to reform the four-year curriculum to emphasize health promotion and disease prevention); Feldman, *supra* note 216, at 512 (suggesting pooling resources from multiple schools to create nutrition education networks that provide training for the students at all included schools); Linda Kinsinger, *Teaching Prevention in Internal Medicine Clerkships*, ACAD. MED., July 2000, at

Second, states can indirectly influence medical school curricula through their licensing examinations, by ensuring that medical students are tested on detailed nutrition knowledge with respect to heart disease, as well as the limits of surgical and pharmaceutical interventions. If the USMLE does not test this knowledge, then states and the federal government can try to change the content of the exam.²⁸⁶ The National Academy of Sciences was able to improve the *amount* of nutrition coverage on the USMLE through a 1985 report,²⁸⁷ so a concerted effort should similarly be able to improve the *content* of nutrition coverage. Alternatively, states could go outside the USMLE. For instance, states might require that the student has either taken and passed a class that specifically covered this information, or that the student takes and passes a short supplemental examination that covers this information.²⁸⁸ Regardless, if the information is tested or otherwise required for licensure, it will almost certainly be taught, as students are paying for this assurance.

Third, state governments can seek to eliminate or address conflicts of interest to improve the content of nutrition education. They can try to eliminate conflicts at state institutions by ensuring that medical nutrition programs receive adequate state funding, and prohibiting them from accepting funds and materials from organizations, businesses, and people with conflicts of interest, such as food, beverage, and pharmaceutical companies.²⁸⁹ This will help ensure there are no financial incentives to base the nutrition education on something other than science. States can also provide disincentives at both public and private medical schools to accept

S60, S61-63 (discussing how to use clerkships to teach students about prevention); Krebs & Primak, *supra* note 249, at 945S-49S (describing the operation of a successful and comprehensive nutrition education program at the University of Colorado School of Medicine); Judith K. Ockene & Jane G. Zapka, *Provider Education to Promote Implementation of Clinical Practice Guidelines*, CHEST, Aug. 1, 2000, at 33S, 33S-36S (2000) (discussing how continuing medical education can be used to improve compliance with clinical practice guidelines); Ajit K. Sachdeva, *Faculty Development and Support Needed to Integrate the Learning of Prevention in the Curricula of Medical Schools*, ACAD. MED., July 2000, at S35, S37-S41 (discussing how to get faculty assistance and leadership needed to change the medical school curriculum to emphasize prevention).

286. The two organizations responsible for the content of the USMLE are the Federation of State Medical Boards and the National Board of Medical Examiners. 2011 USMLE Bulletin – Overview, U.S. MED. LICENSING EXAMINATION, http://www.usmle.org/General_Information/bulletin/2007/overview.html (last visited Sept. 5, 2010).

287. See *supra* note 252 and accompanying text.

288. Another option—an entirely separate and independent examination—would not be very appealing to individual states. It would be burdensome to create and would provide graduating students significant disincentives to practice in that state, since that test would permit licensure in far fewer states than the USMLE.

289. See *supra* note 229 and accompanying text.

funds or materials from sources that have real or potential conflicts. For instance, the state could require that schools fully disclose to all students the nature and extent of any conflicts with respect to the funding of a nutrition education program, or the source of its materials. If students and the public are aware of these conflicts, they may demand change, and the schools may respond.

Fourth, the federal government can indirectly improve physician training in nutrition through its subsidization of residency training. Medicare makes direct and indirect payments to teaching hospitals to subsidize the training of residents after graduation (aka, "graduate medical education" or "GME").²⁹⁰ In 2005 alone, this subsidy gave teaching hospitals about \$3.2 billion, accounting for up to 21% of individual hospitals' total expenditures.²⁹¹ It is a tremendous source of untapped influence. Noting that "[t]he nearly \$10 billion spent annually on GME. . . is [currently] neither monitored nor regulated by the Federal government," the Advisory Council on Graduate Medical Education²⁹² made several recommendations to help create a more cost-effective delivery system, including: (1) "[m]andate accountability for GME funding in order to reshape the incentives [of] teaching hospitals and academic medical centers to improve the health of the nation"; and (2) "[m]ake Graduate Medical Education sites laboratories for innovations in primary care delivery and responsible for producing the next generation of physicians who will work in them."²⁹³ Using funds to encourage residency programs in primary care and cardiology to include training in dietary and lifestyle advice and counseling would promote both

290. For an overview of direct subsidization, see *Medicare Direct Graduate Medical Education (DGME) Payments*, ASS'N AM. MED. C., https://www.aamc.org/advocacy/gme/71152/gme_gme0001.html (last visited Dec. 24, 2010). For an overview of indirect subsidization, see *Medicare Indirect Graduate Medical Education (IME) Payments*, ASS'N AM. MED. C., https://www.aamc.org/advocacy/gme/71150/gme_gme0002.html (last visited Dec. 24, 2010). The statutory authority for these payments is found at 42 U.S.C. § 1395ww(h) (2006).

291. ELICIA J. HERZ & SIBYL TILSON, CONG. RESEARCH SERV., RS22842, *MEDICAID AND GRADUATE MEDICAL EDUCATION* CRS-3 (2008), available at <http://aging.senate.gov/crs/medicaid8.pdf>.

292. Congress created the Council to make recommendations regarding GME payments to the Secretary of Health and Human Services, the Senate Committee on Labor and Human Resources, and the House Committee on Energy and Commerce. 42 U.S.C. § 294o(a) (2010); Letter from The Council on Graduate Med. Educ. (COGME) to Kathleen Sebelius, Sec'y, Dep't of Health & Human Servs.; Dr. Mary Wakefield, Adm'r, Health Res. Serv. Admin.; Senate Health, Educ., Labor, & Pensions Comm.; House Energy & Commerce Comm.; Medicare Payment Advisory Comm'n; Senate Fin. Comm.; and House Ways & Means Comm. 2 (May 5, 2009) [hereinafter Letter from COGME], available at <ftp://ftp.hrsa.gov/cogme/cogmeletter.pdf>.

293. Letter from COGME, *supra* note 292.

goals. It is the most cost-effective strategy for addressing the deadliest and costliest disease in the country and it is an innovation in the delivery of cardiovascular care that the next generation of physicians needs to be trained in. It is time that Congress tried to get the most benefit for its vast GME expenditures.

There are at least three ways to use this influence over GME. First, Congress could decrease payments to institutions that do not provide this training. That might not go over too well with institutions that are not at all prepared to make this transition. Second, Congress could increase payments to institutions that do provide this training. Institutions would likely find a positive incentive more appealing and less threatening. Third, if Congress wanted to be cautious, it could authorize demonstration programs to determine how best to use this influence and determine what specific elements it should be encouraging.²⁹⁴

Finally, both the federal government and state governments can try to educate the public about the benefits of lifestyle interventions for heart disease, as well as the risks and limited benefits of the alternatives. This could be done, for example, by improving the nation's dietary advice to better reflect the science.²⁹⁵ As a result, people might choose to follow these diets or at least ask their physicians about them, creating a demand for dietary knowledge and training. Practicing physicians will thus be motivated to become educated about the research and/or provide appropriate referrals.

B. Insurance Coverage Mandates

Insurance coverage mandates would address a lack of time and the belief that patients will not or cannot comply. If physicians are getting paid enough to provide advice and counseling, they will make the time. Further, if intensive training for dietary changes is covered, the patient is far more likely to comply with the program and experience its benefits.²⁹⁶ Further, insurance coverage will probably make patients more likely to know about dietary interventions in the first place. For example, they may find out from

294. For example, it may wish to require a series of lectures on diet and nutrition, reinforced by clinical training. See Rebecca K. Kirby, Katherine B. Chauncey & Betsy Goebel Jones, *The Effectiveness of a Nutrition Education Program for Family Practice Residents Conducted by a Family Practice Resident-Dietitian*, 27 FAM. MED. 576, 579 (1995) (residents significantly improved their nutrition knowledge after attending up to four lectures on diet and nutrition).

295. For a discussion of how the Dietary Guidelines for Americans are not consistent with current scientific knowledge and how to improve them, see generally Jeff Herman, *Saving U.S. Dietary Advice From Conflicts of Interest*, 65 FOOD & DRUG L.J. 285 (2010).

296. See discussion *supra* Section III.C (discussing research showing that patients are more likely to comply with dietary advice if they receive intensive training).

literature their insurer provides them, or from their doctor, who may be more likely to know about the program and to recommend it if coverage is available.

Medicare coverage of "intensive" programs for heart disease is a huge step, but a potentially large gap in private health insurance remains. While over 82% of people who die of heart disease are age sixty-five or over,²⁹⁷ many younger people are affected. For example, in 2005, over 150,000 Americans died of CVD who were under sixty-five.²⁹⁸ State coverage mandates can fill this gap. It would not be unusual, either: states already impose numerous coverage mandates designed to promote public health.²⁹⁹ Further, even if some private health insurance plans were to eventually become governed primarily by federal law, Congress or the Department of Health and Human Services could require coverage of physician dietary advice and intensive dietary counseling as part of the comprehensive mandatory benefits package. Medicare could also influence the amount which a physician is paid for providing in-office dietary advice and counseling, through its own payment system.³⁰⁰

Insurance companies should be in favor of such changes. It makes no sense for them to want to fund what are extremely expensive and ineffective therapies for heart disease, when they can save lots of money and cover a healthier population by encouraging enrollees to make dietary and lifestyle changes. This is a win-win situation.

C. Mandated Physician Disclosure

Requiring physicians to disclose the risks and limits of drugs and surgery, and the benefits of diet and lifestyle, is the most direct way to get information from physicians to patients. The physicians would have to make the time for these discussions or face state discipline and/or civil liability. Further, doctors have to know the information to disclose it; practicing

297. *Understand Your Risk of Heart Attack*, AM. HEART ASS'N (Dec. 3, 2010), http://www.heart.org/HEARTORG/Conditions/HeartAttack/UnderstandYourRiskofHeartAttack/Understand-Your-Risk-of-Heart-Attack_UCM_002040_Article.jsp (in the table labeled "Risk Factors and Coronary Heart Disease," select the arrow labeled "Major Risk Factors that Can't Be Changed.>").

298. Lloyd-Jones et al., *supra* note 6, at e22.

299. See VICTORIA CRAIG BUNCE & J.P. WIESKE, COUNCIL FOR AFFORDABLE HEALTH INS., HEALTH INSURANCE MANDATES IN THE STATES 2009 4 tbl.1 (2009), available at http://www.cahi.org/cahi_contents/resources/pdf/HealthInsuranceMandates2009.pdf (providing a comprehensive list of coverage mandates in each state).

300. For an overview of Medicare's physician fee schedule, see *Physician Fee Schedule: Overview*, CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T OF HEALTH & HUMAN SERVS. (Nov. 2, 2010), <http://www.cms.hhs.gov/PhysicianFeeSched/>.

physicians would have to learn it and medical schools would almost certainly have to teach it.

California already has such a bill up for vote in 2010.³⁰¹ Assembly Bill 1478 would require that:

Prior to the delivery to a patient of nonemergency health care for the treatment for diabetes or heart disease, a physician and surgeon licensed pursuant to this chapter shall:

(1) Inform the patient or the patient's legal representative of the option of medical nutrition therapy treatment for diabetes or heart disease, respectively, including a description of the potential risks, consequences, and benefits of this treatment relative to other medical treatment options.

(2) Obtain written acknowledgment from the patient or the patient's legal representative confirming that the patient received this information and discussed it with the physician and surgeon, or his or her designee, and that the patient or the patient's legal representative understands this information.³⁰²

Advocates hope the bill will provide patients with true freedom of choice by getting doctors to go beyond ineffective traditional treatments and allow patients to make the "diet[ary] and lifestyle changes that are the first line of defense."³⁰³ Critics, such as the California Medical Association, complain that the bill intrudes on the patient-physician relationship.³⁰⁴

Such a statute would not be unusual. For example, many states already have disclosure mandates for women with breast cancer,³⁰⁵ in effect requiring the physician to tell the patient that a radical mastectomy (total removal of the breast) will not increase the patient's chance of survival compared to a lumpectomy (which saves the breast).³⁰⁶ These statutes have

301. See A.B. 1478, 2009-10 Leg., Reg. Sess. (Cal. 2009).

302. *Id.* at § 1. See also John A. McDougall, *Urgent: Support the Proposed New Law in California Requiring Doctors to Provide Patients with Information on Diabetes and Heart Disease*, MCDUGALL NEWSLETTER, Mar. 2009, available at <http://www.drmcDougall.com/misc/2009nl/mar/urgent.htm> (advocating for the bill by discussing the scientific research regarding surgery, drugs, and diet and lifestyle).

303. Matt Perry, *Legislating Diet: Assembly Bill 1478 Would Require Doctors to Discuss Nutrition Options with Patients, but Powerful Medical Interests Balk*, SACRAMENTO NEWS & REV., Aug. 13, 2009, at 9, available at <http://www.newsreview.com/sacramento/PrintFriendly?oid=1080621> (quoting Dr. Clare Hasler).

304. *Id.* at 11.

305. "Twenty-two states have enacted informed consent [mandates for] breast cancer" See Rachael Andersen-Watts, Comment, *The Failure of Breast Cancer Informed Consent Statutes*, 14 MICH. J. GENDER & L. 201, 211 n.65 (2007) (listing the statutes).

306. *Id.* at 202-03.

been criticized,³⁰⁷ but ultimately they require a physician to provide a patient relevant information that cannot cause harm, but may help the patient reach her most-preferred decision. This is worthwhile when severe consequence might be prevented, like the loss of a breast. Preventing a heart attack or death with respect to heart disease is equally worthwhile despite any inconvenience to the physician.

D. Tort liability

Tort liability is another way to create and enforce a legal duty for physicians to tell their patients about preventing and reversing heart disease through diet, and the limitations of drugs and surgery. However, unlike a statutory mandate, here, no legislative action is needed. Recently, some have suggested that physicians could be liable for medical malpractice for failing to give up-to-date dietary advice to patients.³⁰⁸ This section assesses the potential viability of a malpractice claim based on negligence. After introducing the basic legal standards at issue in section 1, the remaining sections discuss the viability of claims at two distinct points: before diagnosis in section 2; and after diagnosis in section 3.

1. The legal standards

Medical malpractice is just a negligence claim against a physician. It has four elements: (1) duty; (2) breach; (3) causation; and (4) damages.³⁰⁹ A physician's basic legal duty is to act as a reasonable physician would in the same clinical circumstances.³¹⁰ However, a physician also has a more specific duty to disclose material information to a patient when obtaining

307. See *id.* at 221-22 (arguing that these statutes do not work and actually are contrary to the meaning of informed consent).

308. See JOEL FUHRMAN, CHOLESTEROL PROTECTION FOR LIFE 5 (2006) ("Tragically, most patients are not given the facts they need to truly protect themselves against heart attacks. Instead, they are told that it is okay to eat the heart disease-causing American diet as long as they sprinkle a few drugs on top to try to lessen the risk a bit. *I consider this to be bad medicine and predict that in the future, failure to give patients the up-to-date scientific information they need will be considered malpractice*") (emphasis added); Elisabeth Rosenthal, *In Europe It's Fish Oil After Heart Attacks, but Not in U.S.*, N.Y. TIMES, Oct. 3, 2006, at F5 (the Chief of Cardiology at San Filippo Neri Hospital in Rome stated that "it would be considered tantamount to malpractice in Italy to omit [fish oil or omega-3 fatty acids for patients who have survived a heart attack]").

309. See 57A AM. JUR. 2D Negligence § 71 (2004) (stating the elements and citing cases from many jurisdictions).

310. See, e.g., Michael D. Greenberg, *Medical Malpractice and New Devices: Defining an Elusive Standard of Care*, 19 HEALTH MATRIX: J. L.-MED. 423, 426-30 (2009) (discussing the basic standard of care for physicians).

informed consent for a course of treatment.³¹¹ Material information includes the nature of the proposed treatment,³¹² such as its “probability of success”³¹³ and its risks, as well as the benefits and risks of feasible alternatives.³¹⁴

The materiality of information is governed by either the reasonable physician standard or the reasonable patient standard, depending on the jurisdiction.³¹⁵ The reasonable physician standard holds that information is material if it is customarily disclosed by physicians, or if a reasonable physician would disclose the information under the same or similar circumstances.³¹⁶ In such a jurisdiction, the existence of a duty to disclose particular information will be determined as a result of expert testimony.³¹⁷ The reasonable patient standard holds that information is material if a reasonable person, in what the physician knows or should know to be the patient’s position, would be likely to attach significance to the information in deciding to undergo the therapy or not.³¹⁸ This standard is generally more favorable to plaintiffs.³¹⁹

The more specific informed consent standard,³²⁰ rather than the general negligence standard,³²¹ would almost certainly govern any negligence action based on a failure to disclose information, here. Courts have held

311. See Laurent B. Frantz, *Modern Status of Views as to General Measure of Physician’s Duty to Inform Patient of Risks of Proposed Treatment*, 88 A.L.R.3d 1008, 1010-11 (1978) (collecting cases).

312. W.M. Moldoff, *Malpractice: Physician’s Duty to Inform Patient of Nature and Hazards of Disease or Treatment*, 79 A.L.R.2d 1028, 1029-35 (1961).

313. *Goodman v. U.S.*, 298 F.3d 1048, 1058 (9th Cir. 2002) (quoting *Sard v. Hardy*, 379 A.2d 1014, 1020 (Md. 1977)).

314. *Patient-Physician Relationship Topics: Informed Consent*, AM. MED. ASS’N, <http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/patient-physician-relationship-topics/informed-consent.shtml>. See also Moldoff, *supra* note 312, at 1030 (“A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment.”) (emphasis added) (citing *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 317 P.2d 170, 181 (Cal. 1957)).

315. Rebecca Walker, *Governing Physician-Associated Risk Disclosure by Adopting the ADA “Direct Threat” Approach: Doctors, Pack up Your Stethoscopes and Get Out Your Checkbooks*, 1997 U. ILL. L. REV. 1199, 1208 (1997).

316. See Frantz, *supra* note 311, at 1012 (discussing two views of materiality generally). The geographic region in which medical custom or reasonableness is measured could be limited to the community, the locality, the area, or not be limited at all. *Id.* at 1013.

317. See *id.* at 1012-13.

318. See *id.* at 1013 (collecting cases).

319. See Walker, *supra* note 315, at 1208.

320. See *Backlund v. Univ. of Wash.*, 975 P.2d 950, 955 (Wash. 1999) (discussing the distinction between a common negligence action and a breach of informed consent action).

321. *Id.*

the informed consent standard governs physicians' disclosures when beginning preventive treatment before a diagnosis, when beginning new treatment after a diagnosis, and even continuing the same treatment following diagnosis or other material changes.³²²

An important preliminary issue under the informed consent doctrine is whether a physician can defend a suit on the ground that he or she had no *actual* knowledge of the research being argued should have been disclosed.³²³ Two important points can be made about this potential argument. First, a physician should *not* be able to argue a lack of actual knowledge if the failure to have such knowledge is a breach of the physician's general duty to not act unreasonably.³²⁴ Thus, courts have held that a physician "is charged with knowledge and foresight to the degree of learning and skill possessed by practicing physicians."³²⁵ While physicians will not be charged with anything and everything,³²⁶ they have been charged with knowledge of such things as rabies research when that research reasonably should have been possessed by a physician in the same elite

322. See, e.g., *McQuitty v. Spangler*, 976 A.2d 1020, 1030 (Md. 2009) (holding that a physician can be liable for breach of informed consent when failing to disclose information material to the *continuation* of a course of treatment, not just the start of a new course of treatment, *id.*, and rejecting a requirement that the patient suffer some physical invasion as a result of the breach, *id.* at 1038.).

323. The plaintiff here will likely argue that the physician should have disclosed any or all of the following: research showing the limited benefits of bypass surgery and drugs, the ineffectiveness of stents in non-emergencies, and the ability to reverse heart disease and prevent heart attacks through diet and lifestyle. See *Perry*, *supra* note 303, at 2 (discussing prevention of heart attacks through diet and lifestyle).

324. Phyllis Forrester Granade, *Medical Malpractice Issues Related to the Use of Telemedicine—An Analysis of the Ways in Which Telecommunications Affects the Principles of Medical Malpractice*, 73 N.D. L. REV. 65, 88 (1997).

325. See *Agnew v. Larson*, 185 P.2d 851, 854 (Cal. Dist. Ct. App. 1947) ("The physician is chargeable with knowledge and foresight, to the degree of learning and skill possessed by physicians of good standing practicing in the same locality . . ."). See also *Rothman v. Silber*, 199 A.2d 86, 90 (N.J. Super. Ct. Law Div. 1964).

326. See, e.g., *Arpin v. U.S.*, 521 F.3d 769, 774 (7th Cir. 2008) (stating in dictum that "[p]hysicians are not charged with knowledge of every disease, however rare," but finding such knowledge irrelevant where the physicians failed to even conduct an adequate examination in search of the cause of the patient's symptoms).

position,³²⁷ knowledge of relevant facts about a patient's history,³²⁸ and knowledge of the nature and effect of using anesthesia on a patient.³²⁹

The second important point is that cardiologists will likely be charged with knowledge of the Ornish and Esselstyn studies, but general practitioners may not be. Recall that in a recent study, 91% of reporting cardiologists reported being somewhat or very familiar with research supporting the use of very low-fat vegetarian diets for treating heart disease.³³⁰ Hopefully, cardiologists are aware of the research, so it will not be an issue. But if not, it is hard to imagine a cardiologist—who is supposed to be a specialist at treating heart disease—successfully arguing it is reasonable to not know about the only studies showing how to reverse heart disease, completely prevent heart attacks, and drastically improve cardiovascular risk factors. All cardiologists, according to the AHA and the American College of Cardiology, are supposed to be have “[f]amiliarity with appropriate cardiovascular dietary choices and interventions for change in dietary habits.”³³¹ The results of several studies showing the benefits of the Ornish and Esselstyn diets, both large and small, have been published in many major medical journals.³³² Dean Ornish even wrote a *New York Times* best-selling book called *Dr. Dean Ornish's Program for Reversing Heart Disease: The Only System Scientifically Proven to Reverse Heart Disease Without Drugs or Surgery*,³³³ and Caldwell Esselstyn wrote a popular book called *Prevent and Reverse Heart Disease: The Revolutionary, Scientifically Proven, Nutrition-Based Cure*.³³⁴ It is almost impossible to miss. A general practitioner or internist, however, may be acting reasonably by relying on the scientific advice provided by the AHA. It is (mostly)³³⁵ a well-cited discussion of the scientific research, and it may be unreasonable to generally require physicians to scrutinize this research and conduct an independent review of the scientific research; after all, the clear purpose of

327. See *Andrulonis v. U.S.*, 724 F.Supp. 1421, 1434-35, 1490 (N.D.N.Y. 1989) (physicians conducting rabies research for the Centers for Disease Control and Prevention).

328. *Naidu v. Laird*, 539 A.2d 1064, 1073 (Del. 1988) (“Dr. Naidu was chargeable with knowledge that Putney had twice been involved in automobile accidents while in a psychotic state, possessed a driver's license at the time of his release, and could be expected to drive a motor vehicle on public roadways.”).

329. *Rothman*, 199 A.2d at 92.

330. See *supra* note 250 and accompanying text.

331. Blumenthal et al., *supra* note 252, at 395.

332. See discussion *supra* Section I.D (discussing the studies).

333. ORNISH, *supra* note 5.

334. ESSELSTYN, PREVENT AND REVERSE HEART DISEASE, *supra* note 75.

335. Recall that it cites no studies regarding the consumption of “lean meats.” See *supra* notes 152-56 and accompanying text. Neither does it cite the Ornish and Esselstyn studies. See Krauss et al., *supra* note 135, at 2295-99 (listing citations).

the review and recommendations is to conduct the research so others do not have to do so. Ultimately, however, the issue will come down to testimony by expert physicians, so any conclusion is tentative at best.

2. Liability before diagnosis

Consider a person at-risk for heart disease, but not yet diagnosed. In these circumstances, a physician may wish to begin prevention using drugs, and will need to obtain informed consent. It is likely the physician must disclose the limited ability of drugs to prevent heart attacks or death in those without diagnosed heart disease, the side effects associated with these drugs, and the ability to prevent heart attacks and death through diet and lifestyle, without side effects. The first two types of information concern the nature of the proposed treatment; specifically, its probability of success and its risks, which must be disclosed.³³⁶ Drugs are successful if they prevent heart disease or the occurrence of cardiac events, like heart attacks and death. But statins do not prevent heart disease, and they only have a very small effect on the occurrence of cardiac events.³³⁷ This should be material information under either standard of materiality.

The physician must also discuss with the patient the benefits and risks of diet and lifestyle, a feasible alternative (or supplement) to drug therapy. Here, a patient could rely on several authorities to establish a duty. For example, the U.S. Preventive Services Task Force recommends "intensive behavioral dietary counseling for [all] adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease."³³⁸ Similarly, European Guidelines state that "[a]ll patients with cardiovascular disease and individuals at high risk should be given recommendations on the food and dietary options which reduce the cardiovascular risk."³³⁹ The AHA even expressly notes that diet and lifestyle are the best prevention method available for heart disease.³⁴⁰ Courts have relied on AHA guidelines before when determining the existence of a

336. See *supra* notes 320-22 and accompanying text.

337. See discussion *supra* Section I.C (discussing pharmaceutical interventions).

338. U.S. PREVENTIVE SERVICES TASK FORCE, AGENCY FOR HEALTHCARE RESEARCH & QUALITY, BEHAVIORAL COUNSELING IN PRIMARY CARE TO PROMOTE A HEALTHY DIET: RECOMMENDATIONS AND RATIONALE 1 (2003), available at <http://www.uspreventiveservicestaskforce.org/3rduspstf/diet/dietrr.pdf> (adding that "[i]ntensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians."). Similarly, the Department of Health & Human Services, in its *Healthy People 2010* report, set as a goal that 75% of physician office visits by patients with high cholesterol, diabetes, or known cardiovascular disease include dietary counseling or education. HEALTHY PEOPLE 2010, *supra* note 100, at 19-42.

339. Graham et al., *supra* note 147, at S34.

340. See *supra* note 104 and accompanying text.

duty.³⁴¹ Further, a physician or cardiologist should have a duty to discuss the Ornish and Esselstyn diets, which have been shown to reverse heart disease and prevent heart attacks, as opposed to diets that have not been shown to have any significant benefits.³⁴²

Together, information about the limits of drugs and the benefits of diet and lifestyle is very powerful. Essentially, the patient hears that drugs have no benefit for women and a very slight benefit for men, while diet and lifestyle is very close to a cure. It is no wonder that “many men presented with this evidence *do not choose to take a statin*.”³⁴³ A patient afraid of heart disease and heart attacks may readily prefer the immediate and substantial benefits of diet and lifestyle rather than accepting the uncertain and meager benefits of statins.

Even if a plaintiff can show duty and breach, however, proving causation at this stage may be difficult. The plaintiff/patient would have to show *both* that a reasonable person in her position would have made a different choice had the information withheld been disclosed (decisional causation), *and* the risk that was not disclosed materialized and caused the plaintiff’s injury (injury causation).³⁴⁴ A plaintiff could likely prove decisional causation.³⁴⁵ It is hard to imagine a court finding that it is unreasonable for a patient to choose the only actual preventive therapy with a significant likelihood of actually working, even though it is easier to take a pill rather than change one’s lifestyle. To hold otherwise, a court would basically be

341. See, e.g., *Mobile Infirmary Ass’n v. Tyler*, 981 So.2d 1077, 1099 (Ala. 2007) (“Based on the testimony of Dr. Korn, including his testimony regarding the 1993 article from the [AHA], there was sufficient evidence from which the jury could conclude that a patient suffering from acute mesenteric ischemia is characterized by an ‘acute, unrelenting abdominal cramping’ that is ‘so dramatic’ that a reasonable cardiologist ‘should not . . . miss’ its diagnosis.”); *Berry v. Cardiology Consultants*, 909 A.2d 611, 616-19 (Sup. Ct. 2006) (upholding verdict finding no medical malpractice, based in part on joint guidelines by the AHA, the American College of Cardiology, and the European Society of Cardiology); *Hinlicky v. Dreyfuss*, 848 N.E.2d 1285, 1287, 1289 (N.Y. 2006) (holding that joint AHA/American College of Cardiology guidelines admissible as evidence of standard of care on behalf of the defendant-physician); *Scallly v. Veterans Admin.*, 2006 WL 294789, *4 (S.D. Ill. Feb. 2, 2006) (relying on expert medical testimony based on joint AHA/American College of Cardiology guidelines); *Bond v. U.S.*, 2008 WL 655609, *4 (D. Or. Mar. 10, 2008) (discussing the joint AHA/American College of Cardiology guidelines regarding bypass surgery and their consistency with an expert’s medical testimony).

342. But see discussion *supra* Section IV.D.1 (discussing whether a cardiologist or physician can be charged with this knowledge).

343. *Abramson & Wright*, *supra* note 70, at 168 (emphasis added).

344. *Moldoff*, *supra* note 312, at 1029-30 (Supp. 2010).

345. See Jon F. Merz, *An Empirical Analysis of the Medical Informed Consent Doctrine: Search for a “Standard” of Disclosure* 2 RISK ISSUES IN HEALTH & SAFETY 27, 38, 50 (1991).

saying that people at risk for heart disease are hopeless, unable to make the best decision for their health; that seems unlikely.

Showing injury causation may be more difficult. A plaintiff would likely need to show that he or she would not have suffered a heart attack or death if the information had been properly disclosed.³⁴⁶ This means: (1) the plaintiff would have followed the diet; and (2) the diet would have prevented the event that caused the injury. The first is the most difficult, and will depend on the particular plaintiff's ability and willingness to change and, possibly, the plaintiff's health insurance, as that affects whether the plaintiff would have received intensive dietary counseling, which affects the likelihood of making dietary changes.³⁴⁷ The second would be easy enough to show through expert medical testimony regarding the Ornish and Esselstyn programs. It could not likely be shown regarding the AHA's diet, however, as studies have not shown that a person who follows the diet can prevent heart attacks, reverse heart disease, or even create a clinically significant reduction in cholesterol.³⁴⁸

3. After diagnosis

A potential plaintiff has the best chance of succeeding on a medical malpractice claim after diagnosis. After diagnosis, a physician or cardiologist may wish to continue drug therapy or try surgery, either one of which implicates informed consent. At this point, the situation is more dire for the patient and the risk of dying more real. This means two things for a negligence cause of action. First, it will be easier to prove the materiality of information regarding the dangers and limited benefits of drugs and surgery

346. Note that the general standard for injury causation assumes that it is a material *risk* of the therapy that was not disclosed; it is not immediately clear how a court would reframe decisional causation when the *probability of success*, and/or the *availability of a feasible alternative*, is not disclosed. However, a court may recognize that the standard is about finding an appropriate causal relationship between the information withheld and the plaintiff's injury. Such an appropriate relationship exists if the information, had it been disclosed, would more likely than not have prevented the injury from occurring. This burden could be met by showing by a preponderance of the evidence that: (1) the plaintiff would have followed the strict diet and lifestyle; and (2) that medical evidence shows this would have prevented the injury at issue (e.g., heart attack or death). See *Hodges et al. v. Brannon*, 707 A.2d 1225, 1227-29 (R.I. 1998) (demonstrating the difficulty in proving causation in an informed consent case where "finding[s] of no proximate cause torpedoed all these failure-to-disclose theories of liability.").

347. In other words, a physician could defend the action by arguing that the plaintiff had poor health insurance coverage, and thus would have been unable to change his or her diet and lifestyle, since intensive dietary counseling significantly improves the likelihood of a patient actually changing. AMMERMAN ET AL., *supra* note 264 (discussing findings which suggest counseling interventions result in meaningful dietary changes).

348. See discussion, *supra* Section II.B (discussing studies).

and the ability to reverse the disease and prevent a future heart attack on the Ornish and Esselstyn programs. A patient is likely to attach profound significance to such information when a premature death seems possible or even close to inevitable.

Second, both decisional and injury causation will be easier to prove. It is clearly reasonable to do the only thing practically guaranteed to save one's life in the face of the world's deadliest disease. Further, the patient will also be far more capable of showing he or she would have followed the diet, since patients are more likely to make drastic changes the sicker they are; the risk of death or heart attack provides great motivation to change.

If duty, breach, and causation could be met, then there remain only damages to prove.³⁴⁹ If the patient is injured or dies, damages could include, for example, medical bills, loss of income, and pain and suffering.³⁵⁰ These could be substantial.³⁵¹

V. CONCLUSION

We already know how best to combat the deadliest disease in the world. Unfortunately, this information is not getting from physicians to their patients. This needs to change. It will benefit individual patients and their families by hopefully saving their lives, and it will help the healthcare system as a whole by reducing costs associated with the most expensive disease in the country. If we ever hope to reduce the devastating human and financial toll of heart disease, patients must receive adequate advice and counseling regarding the most effective and cost-effective intervention. The law can be an effective tool for improving the treatment and prevention of the disease, by improving the scope and content of nutrition education in medical school, requiring insurers to cover the costs associated with dietary and lifestyle interventions, and requiring physicians to discuss this information with their patients, either through statutes or medical malpractice actions.

JEFF HERMAN*

349. Greenberg, *supra* note 310, at 426; 57A AM. JUR. 2D *Negligence* § 71 (2004).

350. *Alexander v. Univ. of Pittsburgh Med. Ctr. Sys.*, 185 F.3d 141, 145 (3d Cir. 1999); *Canterbury v. Spence*, 464 F.2d 772, 778 (D.C. Cir. 1972).

351. See *Alexander*, 185 F.3d at 145.

* J.D. Saint Louis University School of Law 2010, M.A. University of Missouri-Columbia 2007. Jeff Herman is the Health Policy Fellow at the Missouri Foundation for Health, the largest nongovernmental funder of community health activities in the State. You may contact the author at herman.jeffa@gmail.com.

