

HEALTH CARE'S "THIRTY YEARS WAR": THE ORIGINS AND DISSOLUTION OF MANAGED CARE

THOMAS R. MCLEAN* & EDWARD P. RICHARDS**

INTRODUCTION

In 1618, Reformation and the Catholic Church's Counter-Reformation engulfed Europe in a complex war that lasted until the Treaty of Westphalia in 1648. In a similar manner, the passage of the Employee Retirement Income Security Act (ERISA)¹ in 1974, and the ensuing growth of managed care, have engulfed health care in a holy war between insurers, physicians, and patients over the control of medical decisionmaking. This fight is driven by the increasing cost of health care, both in absolute terms and as a percentage of the Gross National Product (GNP). Private and governmental health care insurers, who pay for almost all health care in the United States, argue that traditional fee-for-service medicine created incentives that increase cost and lead to substandard medical care through over-treatment and inappropriate treatment. Many patients and health care providers counter that insurers want to cut costs without regard to quality of care. The battleground is state legislatures and state courts, where opponents of managed care initiate tort lawsuits and draft state insurance regulations.

Initially, courts ruled that ERISA's preemption clause² prevents states from regulating ERISA-qualified plans, either directly or indirectly through tort litigation. These rulings gave ERISA managed

* Medical Director, Third Millennium Consultants, LLC, Shawnee, Kansas (www.firms.findlaw.com/TMCLLC); Clinical Assistant Professor of Surgery, University of Kansas School of Medicine; Attending Surgeon, Dwight D. Eisenhower Veterans Administration Medical Center, Leavenworth, Kansas. Address correspondence to Tom McLean at Third Millennium Consultants, LLC, 4970 Park, Shawnee, Kansas 66216, or via email at tmclean@dnamail.com.

** Harvey A. Peltier Professor of Law, Director, Program in Law, Science, and Public Health, Paul M. Hebert Law Center, Louisiana State University, Baton Rouge, LA 70803-1000. richards@lsu.edu, <http://biotech.law.lsu.edu>.

1. Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, 88 Stat. 829 (codified as amended at 29 U.S.C. §§ 1001-1461 (2000)).

2. Employee Retirement Income Security Act of 1974 § 514(a), 29 U.S.C. § 1144(a) (stating that ERISA provisions "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan," barring certain exemptions).

care plans a significant economic edge in the market: ERISA plans could control physician decisionmaking with impunity, while non-ERISA plans faced state benefit mandates and mounting medical malpractice litigation.³ As ERISA plans became the dominant deliverers of health care, however, managed care horror stories began to appear on the nightly news and in the courts. Over time, these horror stories caused the courts to re-examine ERISA preemption, culminating in a series of United States Supreme Court cases between 2000 and 2003 that have dramatically changed the legal landscape for managed care. This article reviews the rise and fall of ERISA preemption and its impact on managed care, and considers how this developing issue will affect health care in the United States.

Part I of this article reviews the pre-ERISA landscape of medical care delivery and how it was shaped by the issues associated with traditional health insurance. This section further explains how medical inflation arises both from a very real expansion of medical needs and from medical imperialism—the failure of the medical care paradigm in the United States. Part II of this article examines the rise of ERISA-protected Managed Care Organizations (MCOs)⁴ and their effects on medical care delivery. Part III of this article analyzes the Supreme Court's retrenchment on ERISA preemption, beginning with *Pegram v. Herdrich*⁵ and culminating with *Kentucky Ass'n of Health Plans v. Miller*.⁶ While *Kentucky Ass'n of Health Plans* may not be the health care Treaty of Westphalia, it will have profound effects on health care insurance. Finally, Part IV of this article discusses how the erosion of ERISA protections and the ever increasing cost of health care will drive market consolidation in health insurance,⁷ shifting health insurer management of medical decisionmaking towards a system run in accordance with national

3. See, e.g., *Fox v. Health Net*, 1993 WL 794305 (Cal. Super. Ct., Riverside Cty., Dec. 23, 1993) (state court jury awarded \$89,128,153 in damages, including punitive damages, against a plan that delayed the patient's receiving what was then considered an experimental treatment).

4. This is the umbrella term for health insurance plans that impose controls on physician decisionmaking, either directly or through financial incentives. Courts, including the United States Supreme Court, tend to use "health maintenance organization" (HMO) as a generic term, but this is an incorrect usage. "HMO" implies a particular type of organizational structure, usually with a captive physician group providing care on a fixed cost basis.

5. 530 U.S. 211 (2000).

6. 123 S. Ct. 1471 (2003).

7. For additional information, see Thomas R. McLean & Edward P. Richards, *ERISA Pre-Emption: High Court's Road Map*, NAT'L L.J., June 9, 2003, at 39.

guidelines that define “medical necessity” and appropriate medical procedure.⁸ We argue that this brave new world of standardized medical care may improve care in some situations and can lower costs while preserving or improving the quality of care. On the other hand, we argue that the construction and mass utilization of clinical guidelines does not address the failure of the United States to examine the underlying social welfare and environmental issues that lead to poor health and increase the cost of medical care. Moreover, we assert that guideline-driven protocols fail to address universal access to care and the tragic choices implicit in a system based on a paradigm that promises cures and miracles for aging and death itself.⁹

I.

THE DEVELOPMENT OF MODERN MEDICINE

The most important constant in medical care and the medical care delivery system is change: medicine is not a stable industry, and its development is shaped by economic and political factors as much as by science. Medical insurance does not just pay for medical care—it shapes the medical care delivery system, determines what treatments are developed, and formulates our view of what constitutes medical care. Medical care is a hybrid industry based on applied technology and services. The technology component is global and subject to global market forces. Medical care in France, Germany, and the United States is based on the same science, but medical care in European countries is very different from care in the United States. For instance, compared to the rest of the world, the United States is much more likely to expend resources to apply high-tech solutions to commonplace medical conditions, even when such expenditures may not improve medical care in any significant fashion.¹⁰ The service component of medicine in the United States (its personal aspect) remains very local and is shaped

8. For additional information, see Thomas R. McLean, *The Implications of Patient Safety Research & Risk Managed Care*, 26 S. ILL. U. L.J. 227 (2002) [hereinafter *Implications*]; Thomas R. McLean, *The Institute of Medicine and the Risk Managed Care Revolution*, GREATER KAN. CITY MED. BULL. Apr., 2001, at 16–19.

9. See *infra* notes 52–54; see also GUIDO CALABRESI & PHILIP BOBBITT, *TRAGIC CHOICES* (1978).

10. For example, consider coronary artery bypass grafting (CABG) surgery. Approximately 600,000 CABG procedures are performed annually in the United States, only two-thirds of which may have been medically appropriate. David A. Hyman & Charles Silver, *You Get What You Pay For: Result-Based Compensation for Health Care*, 58 WASH. & LEE L. REV. 1427, 1437, 1487 (2001). Per capita, the United States performs far more CABGs than any other country in the world.

by state and federal laws and norms. To understand how these two components interact, it is necessary to consider the development of modern medicine from a historian's perspective.

A. *Pre-World War II*

While modern medicine has some roots in the systematic observations of the alchemist Paracelsus,¹¹ it is best dated to the work of Ignaz Semmelweis, a French obstetrician who introduced controlled observations and statistical analysis with his studies of childbed fever in the mid 1800s.¹² While few of Semmelweis' contemporaries took heed of his observation that physicians' dirty hands spread disease, his work was fundamental to the later work of Pasteur and Koch, who developed the germ theory of disease, and Lister, who showed how to clean medical equipment and personnel to prevent infection. Coupled with the discovery of anesthesia, the germ theory transformed surgical practice from a mostly unsuccessful and extremely unpleasant process to a life-saving intervention.

In the late 1800s, for the first time in history, a patient's chances of survival were improved by seeing a physician and going to a hospital. This fueled both medical licensing movements and the expansion of hospitals and medical practice.¹³ At the same time, the sanitation movement in public health began to dramatically reduce the death rate associated with infectious diseases. In aggregate, the innovations of the latter years of the nineteenth century led to a rapid increase in life expectancy and the beginnings of a public expectation of life-long health rather than disease and death.

In contrast, innovation and regulation came slowly to the non-surgical fields of medicine.¹⁴ Non-surgical medicine changed little

Hans G. Brost, Address at the Annual Meeting of the Society of Thoracic Surgeons (Jan. 2000).

11. Early 16th Century alchemist and mystic. See William Osler, *The Evolution of Modern Medicine, A Series of Lectures Delivered at Yale University on the Silliman Foundation in April, 1913*, available at http://biotech.law.lsu.edu/Books/osler/modern_medicine.htm (on file with the NYU Annual Survey of American Law) (last visited Oct. 23, 2003).

12. IGNAZ PHILIPP SEMMELWEIS, *THE ETIOLOGY, CONCEPT, AND PROPHYLAXIS OF CHILDBED FEVER* (K. Codell Carter ed., trans., The Univ. of Wisc. Press 1983).

13. PAUL STARR, *SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 156-57 (1982).

14. For a more detailed discussion of health care and the regulation of health care prior to 1930, see Edward P. Richards, *The Police Power and the Regulation of Medical Practice: A Historical Review and Guide for Medical Licensing Board Regulation of Physicians in ERISA-Qualified Managed Care Organizations*, 8 *ANNALS HEALTH L.* 201,

until the 1930s and 1940s, when the introduction of antibiotics allowed the successful treatment of common infections such as pneumonia and tuberculosis. As medicine became more effective, there was more concern about providing access to medical care. In the 1930s, medical insurance was introduced in two forms: the Kaiser-Permanente and Blue Cross plans.

When the Grand Coulee Dam was being built, construction was hampered by a logistic problem: how to provide health care workers to care for the employees at the remote dam construction site? George Kaiser introduced a model whereby his company would make arrangements with physicians to provide health care for a fixed-maximal fee.¹⁵ While many believe that capitated medical care was not invented until Health Maintenance Organizations appeared in the late 1960s, the history of MCOs can actually be traced to Kaiser's Grand Coulee Dam plan. However, because MCOs did not reap the financial rewards of fee-for-service (FFS)¹⁶ medicine, they were relegated to the sidelines of medical care until the 1970s.

The first Blue Cross plan was developed in Baylor, Texas. In 1929, Baylor University Hospital offered to provide hospital care for up to twenty-one days for teachers who were willing to purchase insurance coverage for six dollars a year.¹⁷ At first, the purpose of this type of plan was not so much to provide health benefits as to keep cash flowing into hospitals.¹⁸ Over time, though, Baylor's plan for hospital insurance evolved into an indemnity insurance scheme. The resulting Blue Cross/Blue Shield insurance system¹⁹ became the quintessential FFS health insurance plan in that it provided first dollar coverage for all medical expenses that were "usual, customary and reasonable."²⁰

202-20 (1999); Thomas R. McLean, *Crossing the Quality Chasm: Autonomous Physician Extenders Will Necessitate a Shift to Enterprise Liability Coverage for Health Care Delivery*, 12 HEALTH MATRIX 239, 244-46 (2002) [hereinafter *Quality Chasm*].

15. See Edward P. Richards & Thomas R. McLean, *Physicians In Managed Care: A Multidimensional Analysis of New Trends in Liability and Business Risk*, 18 J. LEGAL MED. 443, 447 n.20 (1997).

16. Also called indemnity insurance, this is traditional health insurance that pays for what the physician orders without trying to manage the physician's medical decisionmaking.

17. GEORGE D. LUNDBERG & JAMES STACY, *SEVERED TRUST: WHY AMERICAN MEDICINE HASN'T BEEN FIXED* 24 (2000).

18. *Id.* at 25.

19. Ten years after the Blue Cross hospital insurance was introduced, Blue Shield, a physician insurance scheme that was analogous to Blue Cross, was introduced. *Id.* at 82.

20. See Uwe E. Reinhardt, *Columbia/HCA: Villain Or Victim?*, HEALTH AFF., Mar./Apr. 1998, at 30, 31 (Medicare, set up in 1964, adopted the same "usual,

Blue Cross plans (which cover hospital services) and Blue Shield plans (which cover physician services) were organized and run by physicians and hospitals, so it is not surprising that they paid what providers charged. Indeed, Blue Cross/Blue Shield plans became emblematic of FFS health insurance because they rewarded physicians for providing medical services, and lacked mechanisms whereby negative feedback could be used to inhibit the over-prescription of medical services. Accordingly, in a FFS incentive environment, physicians overutilize (i.e., over-prescribe) health care treatment.²¹ Additionally, FFS lacks a mechanism to define “medical necessity,” as it relies on physicians to make all medical decisions.²² This was not a significant problem prior to 1960, when efficacious medical treatment was largely limited to the prescription of antibiotics and some straightforward surgical procedures, and when physicians were limited in their capacity to over-treat patients. During the 1960s, however, high technology found the medical field, and physicians began to offer patients such expensive items as transplantation,²³ coronary artery bypass surgery, and chemotherapy.

B. Post-World War II—Medical Imperialism and Medical Inflation

In the decades following World War II, medical care in the United States, and its costs, have been shaped by three economic factors: third-party payment for medical care, FFS reimbursement, and the expansion of the nation’s capacity to provide high-tech

customary, and reasonable” standard developed by the private health insurance plans.)

21. Nor was there any informal brake on our health care system. After the government determined that health insurance was an “ordinary and necessary” business expense, health care was increasingly provided by business as an employee benefit. See 26 U.S.C. § 162 (2000). Thus, because employers ultimately bore the cost of insurance, the employee-patients had an incentive to demand all the health care they could get.

22. Thomas R. McLean & Edward P. Richards, *Managed Care Liability for Breach of Fiduciary Duty After Pegram v. Herdrich: The End of ERISA Preemption for State Law Liability for Medical Care Decision Making*, 53 FLA. L. REV. 1, 34 (2001) (“Traditionally, treating physicians have been proud of their individual autonomy . . .”). Under FFS reimbursement, physicians like to tell patients that everything possible is being done (physicians have “seen themselves as being the patient’s advocate”), *id.*, but doing everything possible may not be best when it leads physicians to provide treatment in fields in which they are inadequately trained and more likely to commit error.

23. Organ transplants are especially expensive because they have a large initial surgical cost, require life-long treatment with dangerous, expensive drugs, and have high long-term complication rates.

medical care. These factors are interrelated and inseparable. Wartime price and wage controls encouraged employers to recruit scarce workers by offering them non-wage benefits. As it became increasingly popular for workers to receive health insurance benefits, more individuals were covered by third-party insurance, which further fueled the public's desire for medical care.²⁴ The federal government responded to this desire by subsidizing the construction of community hospitals through the Hill-Burton program.²⁵ With more hospitals going up, medical training programs expanded and, by 1980, it was clear that this expansion would soon lead to a surplus of physicians.²⁶ Lurking behind all of these developments was medical research, increasingly facilitated by new developments in electronics and radioisotopes²⁷ that seemed to improve the efficacy of the practice of medicine on a daily basis.

Health insurance grew problematic during this period, as these new treatments (and their related hospital care) proved to be much more expensive than prior forms of care. Most individuals could not pay for high-tech health care without insurance, but because the probability of any given patient needing care was relatively low, the cost of the insurance remained reasonable for a time. FFS reimbursement encouraged a "do everything" mentality. Just as the legal profession's requirement of zealous advocacy drives lawyers to do everything the client can afford to win cases, the medical profession, drawing on essentially unlimited insurance resources, did everything it could do to save patients' lives. This meant more procedures, which soon included sophisticated laboratory tests;

24. Employer-paid FFS insurance means that the employee pays little or nothing for health care. Accordingly, employees have an incentive to demand all possible medical care, i.e., patients have no incentive to ask their physicians if the medical treatment prescribed is cost-effective. Thus, the third-party insurance served as a financial incentive to over-utilize care, independent from the FFS incentive to physicians to over-prescribe care.

25. Hospital Survey and Construction (Hill-Burton) Act, Pub. L. No. 79-725, 60 Stat 1040 (1946) (providing federal grants to modernize hospitals that had become obsolete due to lack of capital investment throughout the period of the Great Depression and World War II).

26. See Eli Ginzburg, *Ten Encounters With the US Health Sector, 1930-1999*, 282 J. AM. MED. ASS'N 1665, 1667 (1999) (observing that a 1980 Graduate Medical Education National Advisory Committee report had concluded that by the year 2000 there would be a surplus of over 150,000 physicians based on the then-current medical school graduation rate).

27. Radioisotopes allow a chemical to be traced as it transverses the enzymatic machinery of a cell. Thus, radioisotopes, which arose from research on the atomic bomb, served to elucidate the principles of biochemistry in the 1950s and 1960s, and biomolecular engineering a generation later.

however, medical training did not stress the careful selection or understanding of diagnostic tests—instead, physicians were encouraged to order every possible test and sort out the results later.²⁸ Additionally, physicians were encouraged to confer with specialists and to refer patients for specialist care. Although such practice patterns resulted in escalating health care costs, they generally did not harm patients, unless they resulted in unnecessary medical procedures.

We term this model medical imperialism. Historically, its practitioners have sought to treat conditions aggressively, to develop new and better treatments, and to expand medical facilities and medical technology. Medical imperialism worked very well for the twenty-five years between 1945 and 1970, but the passage of Medicare²⁹ and continued technological innovation ensured that health care costs would soon explode.

Prior to 1970, the most significant reductions in morbidity and mortality were due to public health practices (such as water purification) and effective antimicrobial treatment. Because such measures led to clear benefits (such as significant gains in life expectancy) between 1900 and 1970, no one questioned the cost of health care. In 1968, after the Surgeon General declared that infectious diseases had been conquered, medicine turned increasingly to treatment of chronic diseases such as coronary artery disease and cancer. Unlike acute infectious diseases, chronic medical conditions proved to be much more resistant to medical therapy, even with the application of high-tech practices. Accordingly, medical imperialism began to become an increasingly problematic paradigm—the country was spending more on health care, but life expectancy no longer increased as rapidly. This era was typified by President Nixon's war on cancer. Modeled on the space program

28. This uncritical habit of ordering diagnostic tests, without a clear rationale for each test, also drove "defensive medicine" because physicians who do not understand which tests to order also do not know how to reduce the ordering of tests without jeopardizing patient care. Although physicians rightly worried about not ordering enough tests, much diagnostic testing done under the rubric of defensive medicine was really driven by ignorance and by the income it generated for labs. The managed care problem aggravated physicians' litigation anxiety by forcing them to reduce the level of diagnostic testing.

29. Medicare, by expanding FFS health insurance to a segment of the population that could not otherwise afford health care, increased the demand for health care. See *HEALTH CARE DELIVERY IN THE UNITED STATES* 160 (Anthony R. Kovner & Steven Jonas eds., 6th ed. 1999). Initially, this was not a problem because only a small percent of the population reached age sixty-five; today, however, thirteen percent of the population is over age sixty-five, and that percentage will double over the next twenty years. See *id.* at 511.

started by President Kennedy, the war on cancer was based on the assumption that cancer was just one more technological problem that could be solved if the government put enough money into research and treatment.³⁰ More than thirty years later, the benefits of this program are still questionable. While we have learned much about the biology of cancer, what we have learned is that cancer is thousands of different diseases that have proved very resistant to cure. There have been major breakthroughs in the treatment of some relatively rare cancers, but little progress in treating the major killers.³¹ The result of this is that ever more money is spent on treatments yielding little incremental improvement.³² Ironically, however, expenditure of monetary and political capital on the prevention of smoking (the leading cause of preventable cancer) is tiny compared to the money spent for the treatment of its related illnesses.

Another model for chronic disease raises an even greater specter of medical inflation. Unlike coronary artery disease or cancer, patients with diabetes can live for a long time with their disease.³³ Type I diabetes occurs in childhood or early adolescence and manifests without regard to dietary or other environmental causes. Prior to the development of insulin, children with diabetes died at an early age. Indeed, insulin has totally changed the natural history of this disease because type I diabetics can easily live forty or fifty years with their condition if it is treated with insulin. This lengthened life expectancy means that most patients will develop one or more costly-to-treat complications over the course of the disease.³⁴ A type II diabetic is at risk to develop all of the complications of type I diabetes. Like type I diabetes, type II has a multifactorial etiology. However, type II diabetes has its onset later in life, and the major factor triggering type II diabetes in susceptible persons is

30. National Cancer Act of 1971, Pub. L. No. 92-218, 85 Stat. 778.

31. Much of the improvement in cancer treatments comes from simple efforts to better educate patients: as patients are now much better aware of the sign and symptoms of cancer, and have access to health care, they present for treatment at an earlier stage. Fifty years ago, it was not unusual for a woman with breast cancer to present only when the cancer had grown through her skin and developed a malodorous secondary infection. Today most women present with a painless small breast mass, which is much easier to treat.

32. Much of Medicare spending accrues during the final months of a patient's life.

33. Obesity is another chronic medical condition that is compatible with a long life.

34. The primary complications of diabetes are renal failure, retinopathy, and neuropathy.

obesity. Over the past twenty-five years the prevalence of obesity has nearly doubled in the United States,³⁵ and in the coming years, the prevalence of type II diabetes can also be expected to double. This has important implications if America attempts to control medical inflation by the use of guideline-driven protocols. The Institute of Medicine (IOM), is undoubtedly correct that care guidelines will help control cost today. However, as the total population increases, and the percentage of obese individuals within the total population increases, health care costs will continue to rise because there will be many more individuals with the complications of diabetes. This is a major reason why the United States is poised to invest \$100 million dollars per year on the prevention of diabetes, obesity, and such similarly preventable chronic conditions as asthma.³⁶

Medical imperialism also drives the pharmaceutical industry. Total spending on prescription drugs increased by over three hundred percent between 1991 and 2001.³⁷ Drugs are developed based on their potential market, which is a combination of the number of affected persons and their willingness and ability to pay for relief. Most drugs are very cheap to manufacture, their main costs being the initial research and clinical trials necessary to get FDA approval. This means that drug companies depend on patent law to protect their profits. Once a drug is no longer under patent protection, it can be cheaply manufactured by a competitor, and its price and profitability will fall rapidly. Because the clock begins to run on new drugs even before they are in the marketplace, drug companies often have as few as ten years of patent exclusivity. For many years this system worked very well, producing new drugs that worked dramatically better than those that they replaced, reducing both patient suffering and overall health care costs. Currently,

35. Approximately twenty percent of the U.S. population is obese.

36. Brook Raflo, *Bush's Budget to Fund Shift to Home Care*, HOME CARE, Feb. 2003, at 10. Of course, many in the preventive medicine industry are poised to take advantage of the coming preventive healthcare market. See Susan Orenstein, *The Pill that Will Make You Thin*, Business 2.0 (Mar., 2004), available at <http://www.business2.com/b2/web/articles/1,17863,591634,00.html> (describing attempts by pharmaceutical manufacturers to develop and market a pill that reduces the desire for calorie consumption) (on file with the NYU Annual Survey of American Law).

37. PRICEWATERHOUSECOOPERS, COST OF CARING: KEY DRIVERS OF GROWTH IN SPENDING ON HOSPITAL CARE 6 (2003), available at [http://www.pwcglobal.com/Extweb/service.nsf/8b9d788097dff3c9852565e00073c0ba/bf4b112134b51ce785256cd300754249/\\$FILE/Final%20Executive%20Summary%2021903.pdf](http://www.pwcglobal.com/Extweb/service.nsf/8b9d788097dff3c9852565e00073c0ba/bf4b112134b51ce785256cd300754249/$FILE/Final%20Executive%20Summary%2021903.pdf) (reporting an increase in national spending on prescription medication from 5.9% of \$761 billion in 1991 to 9.9% of \$1.42 trillion in 2001) (on file with the NYU Annual Survey of American Law).

many new drugs offer marginal or no benefits to most patients when compared with existing remedies; however, these new drugs cost much more than existing drugs.³⁸ To be profitable, drug manufacturers must persuade physicians to prescribe these new drugs for patients who would be better served by cheaper, better, and safer older drugs.³⁹ Now, biotechnology is promising drugs tailored to an individual's own genetic makeup, but at astronomical costs and with no assurance that benefits will be significantly better than existing therapy's. At the same time, private foundations are left to satisfy the critical need for public-health drugs in the developing world, and for the poor in the United States, as there is no one to pay drug manufacturers for drugs that they might develop to address these needs.

There are three key failings of medical imperialism. First, it applies a "cost is no object to cure the patient" model to chronic diseases that have no cure and that can only be managed and prevented.⁴⁰ This model evolved from an earlier, unconstrained, fee-for-service system. The increase in the number and costs of treatments for chronic diseases, coupled with the dramatic rise in per-

38. Claritin, which recently went off-patent, offers only minor benefits over generic antihistamines, but costs one dollar a day versus a few pennies. Similarly, a recent study has demonstrated that the most cost-effective treatment for essential hypertension is a cheap diuretic, rather than the many patented antihypertensive agents on the market that sell for substantially more money. See Lawrence J. Appel, *The Verdict From ALLHAT—Thiazide Diuretics Are the Preferred Initial Therapy for Hypertension*, 283 J. AM. MED. ASS'N, 3039-42 (2002).

39. The general scheme of inducing a physician to prescribe a new drug is sending a good-looking sales person to call on the physician and supply the physician with a gift. While these gifts for years were only to have token value, the sales representatives have proven that they can adroitly disguise the value of the gift. Accordingly, the Office of Inspector General (OIG) has recently issued new pharmaceutical regulations intended to prevent the abuse of this relationship. See COMPLIANCE PROGRAM GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS, available at <http://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf> (Apr. 2003) (on file with the NYU Annual Survey of American Law).

40. FFS reimbursement encourages physicians to over-treat, to be uncritical about the drug company claims for new and expensive drugs, and to do surgical procedures with questionable indications. For example, coronary artery bypass surgery has been shown to improve longevity and quality of life for certain middle-aged patients. It is now widely used in elderly patients even though there is no evidence that it improves either longevity or quality of life. End-state renal disease (ESRD), which requires dialysis to prolong the patient's life, was a rare but serious condition in the 1960s. The federal government set up a special program to pay for dialysis and within 20 years it was paying dramatically more patients than were predicted to exist. Kidney disease did not become more common, but physicians, who made huge profits from dialysis centers, became very creative in expanding the diagnosis of ESRD.

sons with chronic diseases, accounts for most of medical inflation. Second, medical imperialism draws political and financial support from prevention efforts that can reduce the incidence of medically costly diseases. Alcoholism, HIV, and gun violence account for a huge financial burden on urban hospitals. Obesity and smoking affect all segments of health care. Yet America has expended minimal effort in preventing these problems—instead, we wait until a patient has acquired an advanced disease from these factors, at which time we apply costly and technologically complex solutions to the exacerbated problem.⁴¹ Third, medical imperialism attempts to “medicalize” all social problems so that they are treated with medications. This practice expands the umbrella of treatable conditions and thereby increases the cost of health care for everyone.⁴²

Medicalizing psycho-social problems is a phenomenon well-illustrated by the current treatment of alcohol and drug abuse. Only a few generations ago, these problems were classified as personal moral failures; today, alcoholism and drug abuse are classified as treatable conditions. While treatment for such problems can be beneficial to individuals, it is also costly, and adds to the health care budget. Moreover, some have argued that medicalizing a condition may reduce people’s fear of that condition, and cause them to be less interested in preventing its onset.⁴³ Interestingly, when society does benefit from providing medical treatment for social conditions, the avoidance of future medical treatment, and hence costs, is never contemplated. Any benefits to society in rehabilitating drunks or drug addicts are not subtracted from the medical budget, so the net result is always more costs with no credit for the benefits.

Nursing homes are another manifestation of the nation’s desire to “fix” societal problems that stem from cultural changes.

41. Diabetes illustrates a further problem because its complications are much less severe if the disease is carefully managed in the early stages. Many health plans and most indigent care systems make it difficult for patients to get this careful care, increasing the rate of complications such as kidney and heart disease and disability, which are much more expensive to treat.

42. For example consider the prescription of Ritalin to “hyperactive” children. While there is no doubt that some children benefit from being on this medication, many children are placed on Ritalin as a means of treating a dysfunctional family. Not only does the Ritalin have to be paid for, but so does the medical monitoring cost associated with long-term medication of children.

43. Harvey Fierstein, noted gay writer and actor, makes a powerful argument that the medicalization of HIV has led gay men to think that it is treatable and does not need to worry them, that it may even be seen as cool to have HIV. See Harvey Fierstein, *The Culture of Disease*, N.Y. TIMES, July 31, 2003, at A25.

Nursing home care, one of the largest components of Medicaid, is as much a reflection of the breakdown of the traditional family and the one-income household as it is a medical care issue. However, the consequential cost of providing custodial care for the elderly is substantial, especially when America's health care costs are compared with those of other countries.⁴⁴

C. *The Introduction of Managed Care*

Medical inflation first appeared in the late 1960s,⁴⁵ touching off approximately two decades during which general inflation and medical inflation in particular skyrocketed.⁴⁶ General inflation may have been driven by the need to pay for the Vietnam War and the Arab oil embargo, but the origins of medical inflation are more complex. Medical inflation is not merely the result of providers overutilizing expensive high-tech medical procedures to maximize their own self-interest.⁴⁷ Instead, six factors drive medical inflation: (1) health care providers offer new services that greatly improve outcomes but either cost more than existing treatments or have no existing analog; (2) demographic shifts increase the number of elderly persons needing medical services;⁴⁸ (3) lifestyle and environmental diseases increase the number of persons needing medical services; (4) health care providers charge more for the same services; (5) health care providers offer new services to gain market

44. While the United States spends much more on health care than European countries such as Germany, Germany spends much more on the total social welfare bundle, including health care, than does the United States. People in the United States, especially those in the lower socio-economic strata, are much less healthy than they could be if they were better educated, had access to social welfare services designed to improve health and prevent disease, and if the environmental causes for disease states such as obesity were better controlled. To a significant extent, the U.S. health care system is much more expensive than comparable European countries' because we do not properly allocate social welfare spending and social costs in other sectors.

45. See *Quality Health Care Coalition Act of 1999: Hearing on H.R. 1304 Before the House Comm. on the Judiciary*, 106th Cong. 122, 124 (1999) (statement of Don Young, M.D., Chief Operating Officer and Medical Director of the Health Insurance Association of America).

46. Mark A. Hall, *Institutional Control of Physician Behavior: Legal Barriers to Health Care Cost Containment*, 137 U. PA. L. REV. 431, 435 (1988).

47. Physicians certainly thrived under FFS, and continued to do so even under managed care. During the decade of 1986 to 1996, physician income increased seventy-seven percent to a median net income of \$ 166,000, while the average worker's income increased only forty-three percent to a median net income of \$ 25,480. LARRY LEVITT & JANET LUNDY, HENRY J. KAISER FAM. FOUND., TRENDS AND INDICATORS IN THE CHANGING HEALTH CARE MARKETPLACE 65 (1998).

48. Examples include the increasing number of obese and elderly persons.

share or increase profits that are more costly but have little benefit over existing services, or offer unnecessary services;⁴⁹ and (6) more services are put under the medical umbrella.

That managed care alone would not be able to control medical inflation is obvious, in hindsight, because managed care cannot address factors one through three without denying individuals necessary care. This problem is addressed in a thoughtful article by David Orentlicher, who argues that managed care failed because the American public will not stand for rationing health care:

Managed care has failed not because of market imperfections, a bad design, or because its design was poorly executed. Rather, the United States' experience with managed care illustrates what happens when society tries to ration health care resources, regardless of the mechanism used for rationing. In this view, problems with the health care market or the design and implementation of managed care might have affected how quickly managed care failed, but they did not affect *whether* managed care would fail.⁵⁰

Professor Orentlicher draws on the classic work *Tragic Choices*, by Guido Calabresi and Phillip Bobbitt. The theme of Orentlicher's article is that Americans will not stand for rationing life-saving medical care, and that managed care was doomed to fail because it was a rationing system⁵¹ that could succeed only as long as it could hide the rationing behind the rhetoric of reducing unnecessary care and improving quality of care. Orentlicher concludes on the bleak note that the future will only see a continuing shifting between subterfuges for rationing, with the public rejecting each approach as its injustices become widely appreciated.⁵² For example, Orentlicher posits that practice guidelines are only a rationing subterfuge that disguises value choices about the proper way to spend medical care dollars behind a façade of scientific detachment.

We believe that this bleak analysis is fundamentally correct as concerns factors one and two. We believe that the United States Supreme Court shifted its views on ERISA preemption because it recognized the political and social implications of allowing health

49. The drug industry provides many examples, such as new hypertension drugs that are very expensive but not as effective as older agents in most patients. *See supra* note 38.

50. David Orentlicher, *The Rise and Fall of Managed Care: A Predictable "Tragic Choices" Phenomenon*, 47 ST. LOUIS U. L.J. 411, 412 (2003).

51. *See id.* at 413.

52. *Id.* at 420.

care rationing decisions to be made without public recourse. This shift is chronicled in Parts II and III of this article.

We differ with Professor Orentlicher as to his opinions on factors four and five, which we believe can be addressed by managing physician decisionmaking, and which we believe will make a significant difference in medical inflation. Factor three, which is the most critical of these problems, is beyond the reach of managed care and must be addressed through state and federal political action. (Factor six just demands honesty in political debate, which makes it the least likely to be addressed.) Thus the dilemma in managed care: how do you sort out areas where costs can be contained without hurting the quality of care—factors four and five—from areas where cost containment must hurt the quality of care—factors one and two?

II. THE RISE OF ERISA MCOS

By 1970, medical inflation was a political issue. The Federal Health Maintenance Organization Act of 1973⁵³ was passed to stimulate the development of managed care insurance products that would, ideally, help to control health care cost by decreasing medical imperialism's overutilization of high-tech health care. The key feature of the Federal MCO Act was its formal recognition that cost-containment measures can be an appropriate part of health insurance.⁵⁴

Managed care uses two fundamental strategies to control costs.⁵⁵ One strategy is to leave the actual care decisions to physicians and other health care providers, but cap the amount of money they would be paid for the care of individual patients or groups of patients. Providers who deliver care for less than the pay-

53. 42 U.S.C. §§ 300e–300e-17 (2000).

54. See Brooks Richardson, *Health Care: ERISA Preemption and HMO Liability—A Fresh Look at ERISA Preemption in the Context of Subscriber Claims Against HMOs*, 49 OKLA. L. REV. 677, 687–88 (1996) (The “basic premise in every state and federal HMO Act remains the same: HMOs should be encouraged to operate within the health care market to promote efficiency and economy.”).

55. Managed care is enforced through physician financial incentives and economic credentialing. An HMO, for example, would withhold up to twenty percent of a physician's income until that physician reached his or her utilization targets. Economic credentialing is reserved for those recalcitrant physicians who repeatedly do not meet their utilization goals in spite of the financial incentives: under such circumstances the physician contract is simply not offered to the physician at the time of annual renewal.

ment make money, and those whose care costs more lose money.⁵⁶ The second strategy is to intervene directly in medical care decisions by requiring pre-authorization for any but the most routine care, and by excluding some treatments from policy coverage.⁵⁷ Both of these strategies create conflicts of interest for health care providers that differ from those of FFS, and both result in claims that plans are directly or indirectly responsible for patients being denied medically necessary care.⁵⁸ Initially, states attempted to control these strategies by mandating health benefits, while private attorneys filed medical malpractice suits against plans for injuries allegedly caused by denial of care.

A year after the passage of the Federal MCO Act, Congress enacted ERISA. The intent of ERISA was to provide a uniform national set of laws governing pension plans so that national employers such as General Motors could bargain with local unions and have uniform national contracts. ERISA achieves this goal by providing comprehensive and detailed guidance for pension plans, and explicitly preempting any state regulation of ERISA-sheltered activities. However, there is virtually no mention of health plans in ERISA.⁵⁹ The only sentence in ERISA that mentions health plans is found in the Act's preamble, which defines the scope of the coverage of ERISA.⁶⁰

When the courts began to consider cases involving ERISA health plans, they looked to pension plan rules and to ERISA's preemption of any state law that "relates to" an ERISA plan.⁶¹ Without

56. One strategy, used extensively by Medicare for controlling hospitalization costs, was fixed-cost budgeting based on diagnosis-related groups (DRG). Hospitals were paid a fixed amount based on the patient's diagnosis. If the care they provided exceeded the DRG payment, they lost money. If it was less than the DRG payment, they made money. Some private insurers used a similar fixed budget system for physician services, paying physician groups a capitation payment—a fixed payment per patient. If the group could treat the patients for less than the capitation payment, they made money. Since health insurance requires large numbers of patients in the pool to average out costs, most medical groups did not have large enough pools with the same insurer, and consequently lost money on these arrangements.

57. A concise summary of prospective utilization review can be found in *Danca v. Private Health Care Systems, Inc.* 185 F.3d 1, 1–6 (1st Cir. 1999).

58. See McLean & Richards, *supra* note 22, at 17–19.

59. Because medical inflation was not an issue prior to 1970, it is not surprising that Congress provided little guidance for health plans.

60. Employee Retirement Income Security Act of 1974 § 2, 29 U.S.C. § 1001(b) (stating that a purpose of the Act is to protect interests of "participants in employee benefit plans").

61. See Employee Retirement Income Security Act of 1974 § 514(a), 29 U.S.C. § 1144(a).

more to flesh out Congressional intent, the courts concluded that any state law remotely related to ERISA health plans was preempted.⁶² This expansive view of ERISA preemption was confirmed in the early 1980s by two Supreme Court cases.

The first of these cases was *Metropolitan Life Insurance v. Massachusetts*,⁶³ which concerned state-mandated mental health coverage. Specifically, the State of Massachusetts set out minimal mental health coverage requirements that all insurers were expected to provide in their contracts of insurance, but Metropolitan Life Insurance argued that it did not need to provide this mandated mental health coverage in insurance contracts sold to ERISA plans. The Massachusetts Supreme Judicial Court found that the state law was not preempted by ERISA, and the U.S. Supreme Court took the case on appeal. The U.S. Supreme Court found that the state law was one that regulated the business of insurance and thus was saved from ERISA preemption by the ERISA saving clause.⁶⁴ However, the Court was careful to note that this law applied only to the contracts of insurance purchased by ERISA plans, not to the ERISA plans themselves. As the Court recognized, this decision would create a double standard, with “plans that purchase insurance” (insured plans) subject to the state mandated benefits laws, but plans that self-insured, and thus did not purchase insurance, exempt from the benefits mandate.⁶⁵ Thus, while the *Metropolitan Life* Court found that the specific state statute was not preempted by ERISA, it cleared the way for ERISA plans to avoid such mandates by self-insuring, rather than by purchasing insurance contracts from third party insurers.

The second of these two cases, *Massachusetts Mutual Life Insurance v. Russell*,⁶⁶ involved a woman who was temporarily denied disability benefits due to a dispute with her disability insurer over the nature of her illness. While her benefits were eventually restored,

62. ERISA actually contemplates two forms of preemption: complete preemption under § 502 and conflict preemption under § 514. See, e.g., *Roark v. Humana, Inc.*, 307 F.3d 298, 305 (5th Cir. 2002); *Giles v. NYLCare Health Plans, Inc.*, 172 F.3d 332, 336–37 (5th Cir. 1999). Although this distinction is important to ERISA litigation, further discussion is beyond the scope of this article.

63. 471 U.S. 724 (1985).

64. *Id.* at 744.

65. *Id.* at 724 (“We are aware that our decision results in a distinction between insured and uninsured plans, leaving the former open to indirect regulation while the latter are not. By so doing we merely give life to a distinction created by Congress in the ‘deemer clause,’ a distinction Congress is aware of and one it has chosen not to alter.”).

66. 473 U.S. 134 (1985).

she sued the plan fiduciary for damages arising from the period during which the benefits were stopped, arguing that the fiduciary breached its duty to her by conducting an improper review of her medical condition. The Supreme Court held that the duty of the plan's fiduciary ran to the plan, not to the insureds, and thus ERISA preempted the plaintiff's claim for money damages from the plan fiduciary.⁶⁷

Russell is a pivotal case in medical ERISA jurisprudence, and its holding was extended in subsequent cases to ban money damages for prospective utilization review.⁶⁸ After *Russell*, many assumed that states could not individually regulate an ERISA MCO's prospective utilization review. Unfortunately, prospective utilization can be easily manipulated by creating incentives for physicians to misclassify a patient's conditions so that expensive care is not classified as medically necessary under the plan's guidelines.⁶⁹ Such incentives became commonplace because MCOs are not required to disclose provider incentive packages,⁷⁰ and because physicians had little power to bargain over these incentives once MCOs captured a majority of insured lives where the physician practiced.⁷¹

Similarly, *Russell's* holding on the nature of allowable damages, while technically correct, created havoc. ERISA only contemplates equitable relief as it is defined within the statute,⁷² through language that has increasingly been interpreted as referring only to such "categories of relief" as "injunction[s], mandamus, and restitu-

67. *Id.* at 140–44.

68. *See infra* note 94 and accompanying text.

69. For example, a CT scan is generally not medically indicated for headaches. Thus, a prospective utilization review decision that denies a head CT scan as a benefit unless the headache is severe/acute or else persistent is entirely appropriate. But, if the HMO provides incentives for a physician not to properly take notice that a patient's headache is severe/acute or persistent so as to cut its cost for providing treatment, the HMO is abusing the utilization review as a method to determine eligibility for benefits. *See, e.g., Lancaster v. Kaiser Found. Health Plan*, 958 F. Supp. 1137, 1139–40 (E.D.Va. 1997).

70. *Peterson v. Conn. Gen. Life Ins.*, 2000 WL 1708787, at *7 (E.D.Pa. Nov. 15, 2000) (failing to find in the Third Circuit any "'ringing endorsement' of such a universal, automatic duty upon all HMOs to disclose every aspect of their physician financial incentives without a request from the participant or without any other special circumstance"); *Maio v. Aetna*, 221 F.3d 472, 493 (3d Cir. 2000) (rejecting RICO claim for failure to disclose).

71. Under such situations, it is financially impossible for physicians to refuse to deal with the MCO.

72. Employee Retirement Income Security Act of 1974 § 502(a)(3), 29 U.S.C. § 1132(a)(3) (authorizing parties to seek injunctions or "other appropriate equitable relief" as necessary).

tion, but not compensatory damages”⁷³ On the other hand, a breach of contract action, as in *Russell*, is “‘quintessentially an action at law,’”⁷⁴ and cannot be characterized under ERISA as “an injunction to compel the payment of money past due under a contract, or specific performance of a past due monetary obligation.”⁷⁵

Russell's engraftment of pension plan-style analysis onto an investigation into health plan administrative malfeasance remains the standard legal approach to such issues, even though the calculus often produces perverse outcomes.⁷⁶ These perverse legal outcomes were made worse where participants in non-ERISA MCOs were able to recover damages if their plan's prospective utilization review process wrongfully denied care.⁷⁷ The presumption that prospective utilization review was protected under ERISA provided ERISA HMOs with a competitive advantage in the marketplace, thereby fostering the development of many other forms of managed care products.⁷⁸

In short, *Metropolitan Life* and *Russell* prevent states from either defining minimal benefits or regulating prospective utilization review of ERISA qualified HMOs, and plaintiffs' attorneys have had only mixed success in re-characterizing prospective utilization review as medical malpractice.⁷⁹ The problem with re-characterizing

73. *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 256 (1993).

74. *Wal-Mart Stores, Inc. Assocs.' Health & Welfare Plan v. Wells*, 213 F.3d 398, 401 (7th Cir. 2000) (“A claim for money due and owing under a contract is ‘quintessentially an action at law.’”) (citing *Hudson View II Assoc. v. Gooden*, 644 N.Y.S.2d 512, 516 (App. Div. 1996)).

75. *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 210–11 (2002).

76. *See, e.g., Corcoran v. United Healthcare, Inc.*, 965 F.2d 1321, 1324, 1337–38 (5th Cir. 1992) (ERISA preemption precludes emotional distress claim for parents whose unborn child died as a result of employee disability plan's use of prospective utilization review).

77. *See, e.g., Fox v. Health Net*, 1993 WL 794305 (Cal. Super. Ct., Riverside Cty., Dec. 23, 1993) (state court jury awarded \$89,128,153 in damages, including punitive damages, against a plan that delayed the patient's receipt of what was considered at the time to be an experimental treatment).

78. MCOs include other types of organizations, such as Preferred Provider Organizations (PPOs). There are many distinctions between PPOs and HMOs: for example, HMOs wield much greater control over the health care providers that are available to patients. HMOs are discussed in greater detail in this article because they provide the clearest examples.

79. *Compare* *State Bd. of Reg. for the Healing Arts v. Fallon*, 41 S.W.3d 474, 476–77 (Mo. 2001) (finding that MCO medical director's decision to override physician's medical decision was not entitled to ERISA preemption), *and* *Murphy v. Bd. of Med. Exam'rs*, 949 P.2d 530, 536 (Ariz. Ct. App. 1998) (finding that review by insurance company employee of physician's medical decisions is itself a medical

an administrative malfeasance action predicated on prospective utilization review as a medical malpractice action⁸⁰ is that state tort law can be viewed as a form of state regulation⁸¹ related to ERISA. Specifically, this created the perception that ERISA health plans were beyond state statutory and common law, leading ERISA MCOs to conclude that they could deny care without fear of subsequent litigation (provided that the plan itself was not delivering medical services, so as to open the door to a potential vicarious liability action).⁸² Early ERISA MCOs had an additional financial edge because they did not need to acquire insurance for either malpractice or omissions and errors related to medical care.⁸³ Accordingly, a number of MCOs regularly denied medical care to patients under the assumption that they could not be found liable for a wrongful decision.

III. THE END OF ERISA PREEMPTION

Soon, there began to be horror stories of MCOs ordering mothers out of the hospital within twenty-four hours of delivering a child, or middle-age males with atypical chest pain undergoing cardiac arrest after their MCOs refused to authorize appropriate medical workups.⁸⁴ Although it took the Supreme Court over fifteen years after *Russell* to revisit its medical ERISA jurisprudence, the Court did so with a vengeance in a series of three cases.

decision, rather than an insurance decision), *with* United Healthcare Ins. Co. v. Levy, 114 F. Supp. 2d 559, 564 (N.D. Tex. 2000) (finding that medical board's attempt to discipline physician based on coverage decision was preempted by ERISA as de facto attempt by state to mandate benefits).

80. *Dukes v. U.S. Healthcare, Inc.*, 57 F.3d 350, 351–52 (1995) (successfully stating such a claim and avoiding ERISA preemption).

81. *See, e.g., Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 524 (1992) (characterizing certain health-related state laws as preempted regulation).

82. *See, e.g., Lancaster v. Kaiser Found. Health Plan of Mid-Atlantic States, Inc.*, 958 F.Supp. 1137, 1149–50 (E.D. Va. 1997) (refusing to grant motion to dismiss claim of vicarious liability against MCO, where there was an agency relationship between the MCO and an allegedly negligent physician).

83. *See Quality Chasm, supra* note 14, at 279.

84. *See, e.g., In re U.S. Healthcare, Inc.*, 193 F.3d 151, 156 (3d Cir. 1999) (MCO rule encouraged discharge of mother and child from hospital within twenty-four hours of birth); *Shea v. Esenstein*, 107 F.3d 625, 626 (8th Cir. 1997) (MCO failed to refer patient to heart specialist despite a number of symptoms suggesting heart disease, resulting in patient's death several months later).

A. *Pegram v. Herdrich: State Authority over Individual Prospective Utilization Review Decisions*

The first Supreme Court medical ERISA case after *Russell* was *Pegram v. Herdrich*.⁸⁵ After Cynthia Herdrich had recovered from an appendectomy, she brought suit against her MCO for wrongful denial of care, alleging that her MCO had breached its fiduciary duties to her by denying authorization for the appendectomy for over a week, thereby complicating her recovery. The MCO responded that because it was an ERISA-qualified plan, ERISA preempted state review of its prospective utilization review decision to deny authorization of the appendectomy. Justice Souter's unanimous opinion narrowly defined the ERISA health plan:

Thus, when employers contract with an HMO to provide benefits to employees subject to ERISA, the provisions of documents that set up the HMO are not, as such, an ERISA plan; but the agreement between an HMO and an employer who pays the premiums may, as here, provide elements of a plan by setting out rules under which beneficiaries will be entitled to care.⁸⁶

Still, even under a narrow definition of an ERISA plan, prospective utilization review, because it defines eligibility for benefits, is related to the plan. In this case, as in most cases of MCO administrative malfeasance, a physician's judgment was potentially corrupted by the MCO's financial incentive package—e.g., if Dr. Pegram denied needed medical care to enough patients, she would receive a bonus.⁸⁷ In a non-ERISA MCO, there is a check against prospective utilization review abuse: the threat of a medical malpractice action against both the physician and the MCO. *Pegram* did nothing to curb physician financial incentive packages; to the contrary, the Supreme Court specifically indicated that prospective utilization review and physician incentive plans were integral components of an ERISA MCO because they were necessary to control health care costs.

Pegram did, however, create a set of rules that can be used to identify when an ERISA MCO is abusing—by any mechanism—the prospective utilization review process. According to Justice Souter, an ERISA MCO can make only three types of decisions concerning

85. 530 U.S. 211 (2000).

86. *Id.* at 223.

87. Prior to this case, the plaintiff's bar had, at the appellate level, been chipping away at the ERISA preemptive shield of prospective utilization review using a theory that the MCO had breached either its statutory or common law fiduciary duties to the patient-beneficiary. *See also* McLean & Richards, *supra* note 22, at 12.

beneficiaries: (1) a pure eligibility decision; (2) a pure medical treatment decision; or (3) a mixed eligibility-medical decision.⁸⁸ As it has done since the time of *Metropolitan Life*, the Court held that where an MCO makes a pure eligibility decision—whether the plan provides coverage for the treatment regardless of the patient’s medical condition—that decision is entitled to preemption protection from state law because the decision is related to the plan.⁸⁹ The characteristics of a pure eligibility decision are that the decision is categorical, applicable to all beneficiaries, and one that can be answered “yes” or “no” without any patient-specific information.

On the other hand, if any part of the MCO decision involves a medical decision—a decision that required patient-specific knowledge—the decision must be characterized as either a mixed eligibility/treatment decision or a pure medical treatment decision. From a practical point of view, it does not matter whether the MCO’s decision is deemed a mixed eligibility treatment decision or a pure medical decision: both decisions are unrelated to ERISA plans and therefore are not entitled to ERISA preemption protection, as they occur outside of the scope of ERISA. In short, when an MCO makes either a mixed eligibility treatment decision or a pure medical decision, that decision is subject to regulation by state law, rather than ERISA.⁹⁰ Therefore, *Pegram* made it clear for the first time that some prospective utilization review decisions may expose MCOs to medical malpractice liability.⁹¹

88. 530 U.S. at 228–30.

89. *Id.* at 230 (using as an example a scenario in which the question is simply “whether a plan covers an undisputed case of appendicitis”); see *Pryzbowski v. U.S. Healthcare, Inc.*, 245 F.3d 266, 279 (3rd Cir. 2001).

90. *Id.* at 237 (“We hold that mixed eligibility decisions by HMO physicians are not fiduciary decisions under ERISA.”).

91. This can be seen in subsequent cases, such as *Pappas v. Asbel*, 768 A.2d 1089, 1096 (Pa. 2001) (holding that prospective utilization review decisions involving individual patient medical information are mixed processes not entitled to ERISA preemption). Moreover, cases decided subsequent to *Pegram* suggest that the threshold for finding liability is lower when denial of care is determined by the party responsible for payment. See *Lazorko v. Pa. Hosp.*, 237 F.3d 242, 250 (3d Cir. 2000) (finding potential liability where financial incentives may affect the quality, rather than simply existence, of care provided by MCO employees); *Berger v. Livengrin Found.*, 2000 U.S. Dist. LEXIS 3832, *11–*12 (E.D. Pa. Mar. 27, 2000) (failing to find complete preemption where MCO referred patient to program with which it had financial dealings, and which proved unsuccessful at treating patient’s condition). *But see* *HCA Health Servs. of Ga., Inc. v. Employers Health Ins. Co.*, 240 F.3d 982, 1000 n.38 (11th Cir. 2001) (suggesting that *Pegram*’s rules apply only if there is bodily injury clearly eligible for treatment); *Rubin-Schneiderman v. Merit Behavioral Care Corp.*, 163 F. Supp. 2d 227, 231 (S.D.N.Y. 2001)

From a regulatory point of view, although *Pegram* made it clear that MCOs could no longer engage in prospective utilization review with impunity, the case also points out a way for MCOs to obtain freedom from liability for their decisions. Specifically, to the extent that MCOs can shift the responsibility for making mixed decisions and pure medical care decisions to independent physicians, they may be able to avoid liability.⁹² This explains why, in the wake of *Pegram*, some MCOs started advertising that they were leaving medical decisions to doctors—MCOs were not giving doctors a blank check; they were merely shifting their means of control over medical decisionmaking from direct review to the implementation of indirect financial incentives. *Pegram* recognized that ERISA contemplates that MCOs will try to reduce the cost of medical care, and that they may use incentives to achieve such cost reductions. Many MCOs used “hold-back” pools, which retained a certain fraction of the payments due to their plan physicians, and paid the retained funds only if an end-of-year audit showed that physicians had met the plan’s goals for limiting medical care expenses. In addition to financial incentives designed to reward physicians who met cost control goals, MCOs also used economic credentialing to remove physicians from their rolls who consistently missed their cost control targets.

States recognized these attempts to influence physician decisionmaking without triggering the *Pegram* factors that subject plans to liability, and they sought to prospectively regulate medical decisions made by MCOs. Rather than having plaintiffs’ lawyers sue to overturn individual denial-of-care decisions, a more efficient system would provide states with a safe harbor to regulate the impact of MCO incentives on medical decisionmaking. That is, a more efficient state regulatory system for MCOs would involve a bright-line test demarcating ERISA’s preemptive shield of prospective utilization review. If the state regulated within the boundaries of the safe harbor, ERISA preemption would not be an issue. Not surprisingly, states increasingly tried to regulate prospective utilization review under ERISA’s saving clause,⁹³ a safe harbor to ERISA preemption.

(finding *Pegram* inapplicable to a Preferred Provider Organization (PPO), although it “features aspects of an HMO”).

92. See *Rubin-Schneiderman*, 163 F. Supp. 2d at 231 (suggesting that claims are not preempted only because MCO acts as both medical provider and decisionmaker).

93. Employee Retirement Income Security Act of 1974 § 514(b)(2)(A), 29 U.S.C. § 1144(b)(2)(A) (“saving” state laws regulating insurance from preemption by ERISA).

The next ERISA Supreme Court case examined whether such a law could circumvent ERISA preemption.

B. Rush Prudential HMO v. Moran: *Regulation by the Saving Clause*

In *Rush Prudential HMO v. Moran*, the Supreme Court examined whether an insurance code regulation could be applied to an ERISA MCO.⁹⁴ State insurance code regulations have always occupied a special niche under ERISA. Because insurance is considered to be a traditional state function, the McCarran-Ferguson Act, which preempted federal antitrust regulation, allowed states to regulate the business of insurance (i.e., reserve requirements, aspects of the business side of insurance, and the identity of those permitted to buy and sell policies). ERISA also authorizes the states to regulate the business of insurance,⁹⁵ through the Act's saving clause, which "saves" the business of insurance, and its regulation, from ERISA preemption.⁹⁶ Under this clause, state insurance regulations are applicable to all MCOs, regardless of ERISA status.⁹⁷

At issue in *Rush Prudential HMO* was whether an ERISA MCO had to comply with an Illinois insurance code regulation that mandated external review of adverse prospective utilization review decisions, if challenged by the patient-beneficiary.⁹⁸ Justice Souter, writing for a 5-4 majority, began his discussion by observing that a state regulation having "the effect of [regulating] an integral part of the policy relationship between the insurer and the insured" is saved from ERISA preemption. In *Union Labor Life Ins. Co. v. Pireno*, the Court had announced a three factor test for determining whether a state law regulates the business of insurance.⁹⁹ Specifi-

94. 536 U.S. 355, 359 (2002) ("The issue in this case is whether the statute, as applied to health benefits provided by a health maintenance organization under contract with an employee welfare benefit plan, is preempted by [ERISA]."); see also *Corporate Health Ins. v. Tex. Dep't of Ins.*, 215 F.3d 526, 534-35 (5th Cir. 2000) (earlier case permitting non-malpractice forms of state regulation over MCOs via professional organizations).

95. 15 U.S.C. §§ 1011-1015 (2000).

96. Employee Retirement Income Security Act of 1974 § 514(b)(2)(A), 29 U.S.C. § 1144(b)(2)(A).

97. An important limitation of the saving clause, however, is the "deemer clause." ERISA § 514(b)(2)(B), 29 U.S.C. § 1144(b)(2)(B). The deemer clause prevents a self-insured ERISA plan from being deemed an insurance company and hence subject to state regulation. A more detailed discussion of the deemer clause follows, *infra* Part III.D.

98. See 215 ILL. COMP. STAT. 125/4-10 (2000).

99. 458 U.S. 119, 129 (1982).

cally, a state law regulates the business of insurance if the regulation:

- (1) “has the effect of transferring or spreading a policyholder’s risk;”
- (2) “is an integral part of the policy relationship between the insurer and the insured;” and
- (3) “is limited to entities within the insurance industry.”¹⁰⁰

Subsequently, the Court made it clear that a state law could regulate the business of insurance without all three *Pireno* factors being present.¹⁰¹

In *Rush Prudential HMO*, Justice Souter found that two of the three *Pireno* factors were present.¹⁰² First, the Illinois statute regulated an integral part of the policy relationship between the insurer and the insured because the statute addressed how the terms of the insurance contract were to be interpreted. Second, because the external review statute was only applicable to the insurance industry, it was limited to entities within the insurance industry.¹⁰³ Accordingly, because two out of the three *Pireno* factors were present, the Illinois statute was considered to regulate the business of insurance and was therefore saved from ERISA preemption.¹⁰⁴

The importance of *Rush Prudential HMO* is that the Supreme Court made it clear that MCO insurance procedures, including prospective utilization review, could be regulated under a state’s insurance code regardless of ERISA status. Although the Court had not budged on its position that states cannot mandate benefits, *Rush Prudential HMO* continued where *Pegram* left off: *Pegram* granted the states the authority to retrospectively determine whether an MCO wrongfully denied care on a case-by-case basis, while *Rush Prudential HMO* extended the states’ authority to prospectively regulate

100. *Id.*

101. *UNUM Life Ins. Co. of Am. v. Ward*, 526 U.S. 358, 373 (1999) (considering “as a matter of common sense” whether a rule regulates insurance, and noting that the factors are “relevant” but not “required”). In the wake of the *UNUM* opinion some courts adapted a “common sense” approach to the business of insurance, rather than applying the *Pireno* factor analysis. *See, e.g., Conn. Gen. Life Ins. Co. v. Ins. Comm’r*, 810 A.2d 425, 432–33 (Md. 2002). This derogation of the *Pireno* factor analysis was later addressed by the Court in *Ky. Ass’n of Health Plans*. *See* discussion *infra* Part III.C.

102. 536 U.S. 355, 373 (2002).

103. The nature of the state statute mandating external review of an HMO is significant. One of the key facts that distinguished *Cicio v. Does*, 321 F.3d 82, 95 (2d Cir. 2003), from *Rush Prudential HMO* was that the New York statute in question in *Cicio* was part of the public health code.

104. 536 U.S. at 375–87.

MCO medical decisionmaking. The key to this authority is that the state regulation must be “specifically directed toward” the insurance industry if it is to be saved from ERISA preemption.¹⁰⁵

Rush Prudential HMO gives the states broad latitude to regulate prospective benefit decisions by regulating prospective utilization review, pointing to a major problem with state regulation: assuming that MCOs by their very nature are going to control costs,¹⁰⁶ the rule in *Rush Prudential HMO* could be used to allow states to mandate benefits for an ERISA plan—something the Supreme Court has steadfastly refused to do. Hence, for treatments that are not specifically excluded from the plan, a state can use the third party review process as a surrogate for a law mandating the benefit. Mandated benefit laws are often driven by noisy interest groups rather than medical science; in many cases, they mandate that plans pay for treatments (such as bone marrow transplants for breast cancer) which have not been proven to work. In other cases, the mandated treatment is for a social condition that has been medicalized by medical imperialism. Thus, *Rush Prudential HMO* conflicts with the dicta in *Pegram* that recognized cost-containment as a legitimate pursuit of an ERISA medical plan.¹⁰⁷

C. *Kentucky Ass’n of Health Plans v. Miller: A New Test for the Business of Insurance*

The third and most recent medical ERISA Supreme Court case is *Kentucky Ass’n of Health Plans v. Miller*.¹⁰⁸ While both *Pegram* and *Rush Prudential HMO* turn on what can best be termed mixed eligibility-treatment decisions, *Kentucky Ass’n of Health Plans*, which focuses on a state’s “any willing provider” (AWP) statute, is the first Supreme Court case to reach beyond medical decisionmaking to address factors that limit state regulation of ERISA plans. Specifically, the statute at issue in *Kentucky Ass’n of Health Plans* stipulated: “A health insurer shall not discriminate against any provider who is located within the geographic coverage area of the health benefit plan and who is willing to meet the terms and conditions for partici-

105. See *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 50 (1987).

106. In *Rush Prudential HMO*, the HMO was willing to pay for Ms. Moran to undergo the standard operation to treat Thoracic Outlet Syndrome, but Ms. Moran wanted it to pay for an “unconventional” operation. 536 U.S. at 360. Thus, the facts of *Rush Prudential HMO* are similar to those of *Russell*. The key distinction is that saving state insurance regulations was not an issue in *Russell* because state HMO regulations were still at a rudimentary stage.

107. *Rush Prudential HMO* will also undermine efforts to improve quality of care by plans that want to base care decisions on evidence-based medical research.

108. 123 S. Ct. 1471 (2003).

pation established by the health insurer, including the Kentucky state Medicaid program and Medicaid partnerships.”¹⁰⁹ The MCO industry frowns upon such AWP statutes because they frustrate MCOs’ ability to control the cost and the quality of health care service, since the statutes require an MCO to contract with cost-inefficient and potentially incompetent providers. Both the trial and appellate courts found that Kentucky’s AWP statute was related to the ERISA health plans. However, following the lead of the Supreme Court in *Rush Prudential HMO*, the Sixth Circuit ruled that Kentucky’s AWP statute regulated the business of insurance and was therefore saved from ERISA preemption.¹¹⁰ The insurer then appealed.

Justice Scalia began the analysis of a unanimous Court by considering the MCOs’ argument that the AWP statute could not be protected from ERISA preemption by the saving clause because AWP statutes are not “specifically directed toward” the insurance industry as required by *Pilot Life*.¹¹¹ The MCOs argued that AWP statutes were directed at health care providers, and placed in Kentucky’s insurance code only as an end-run around ERISA preemption. In support of this position, the MCOs cited *Group Life & Health Insurance v. Royal Drug* for the proposition that if agreements between insurers and third parties can be seen as outside of the “business of insurance” under the McCarran-Ferguson Act, then regulation of similar agreements should not be saved from ERISA preemption under § 2(b) of the Act.¹¹² The Court rejected this argument and found that the AWP statute did not impose “any prohibitions or requirements on health-care providers,”¹¹³ and accordingly did not regulate the industry. Moreover, even when a state law affects parties outside the insurance industry, it does not automatically follow that a state law is not specifically directed at the insurance industry: “Regulations ‘directed toward’ certain entities

109. KY. REV. STAT. ANN. § 304.17A-270 (Michie 2001).

110. Ky. Ass’n of Health Plans v. Nichols, 227 F.3d 352, 372 (6th Cir. 2000).

111. 123 S. Ct. at 1475.

112. *Id.* at 1476–77; *see also* Group Life & Health Ins. v. Royal Drug, 440 U.S. 205, 232 n.40 (1979) (claiming that there would be no “principled basis” for distinguishing between direct and indirect effects).

113. 123 S. Ct. at 1475. The Court also noted that *Royal Drug* did not involve a state law regulating the agreements in question but the private agreements themselves, and that it was therefore unhelpful as precedent for purposes of ERISA. *Id.* at 1475–76 (“ERISA’s savings clause, however, is not concerned (as is the McCarran-Ferguson Act provision) with how to characterize *conduct* undertaken by private actors, but with how to characterize *state laws* in regard to what they ‘regulate.’”).

will almost always disable other entities from doing, with the regulated entities, what the regulations forbid; this does not suffice to place such regulation outside the scope of ERISA's savings clause."¹¹⁴

Justice Scalia's summary dismissal of the "directed toward" language argument of the MCO, and the Court's narrow construction of the saving clause, suggests that the Supreme Court does not want saving clause litigation to generate a torrent of litigation in a manner analogous to that which followed the expansive interpretation of the preemption clause's "related to" language.

The Court next examined the *Pireno* factor that it had avoided in *Rush Prudential HMO*: the "risk pool." According to the Court, an "AWP prohibition substantially affects the type of risk pooling arrangements that insurers may offer,"¹¹⁵ implying that such statutes regulate the business of insurance. However, Justice Scalia observed that the Court's prior cases concerning the saving clause turned "to varying degrees, on our cases interpreting §§ 2(a) and 2(b) of the McCarran-Ferguson Act," noting that this reliance was misdirected because it "failed to provide clear guidance to lower federal courts, and, as this case demonstrates, added little to the relevant analysis. That is unsurprising, since the statutory language of § 1144(b)(2)(A) differs substantially from that of the McCarran-Ferguson Act."¹¹⁶ Rather than being concerned with health care and benefits, Justice Scalia opined, the focus of the McCarran-Ferguson Act was limited to issues of antitrust and litigation conducted "by private actors, not state laws."¹¹⁷ The Court also acknowledged that its holdings in *UNUM* and *Rush Prudential HMO*, both of which were predicated on McCarran-Ferguson analysis, were problematic because they did not specify how many *Perino* factors had to be present, or the relative weight of the factors.¹¹⁸ Accordingly, *Kentucky Ass'n of Health Plans* held that it would "make a clean break from the McCarran-Ferguson factors" for interpretation of the saving

114. *Id.* at 1476.

115. *Id.* at 1478.

116. *Id.*

117. *Id.*

118. *Id.* ("Our holdings in *UNUM* and *Rush Prudential*—that a state law may fail the first McCarran-Ferguson factor yet still be saved from pre-emption under § 1144(b)(2)(A)—raise more questions than they answer and provide wide opportunities for divergent outcomes. May a state law satisfy *any* two of the three McCarran-Ferguson factors and still fall under the savings clause? Just one? What happens if two of three factors are satisfied, but not 'securely satisfied' or 'clearly satisfied,' as they were in *UNUM* and *Rush Prudential*?").

clause of ERISA.¹¹⁹ The court then announced a new two-prong test for whether a state law is to be deemed a law that “regulates insurance”: “[f]irst, the state law must be specifically directed toward entities engaged in insurance,” and second, “the state law must substantially affect the risk pooling arrangement between the insurer and the insured.”¹²⁰ Because “Kentucky’s law satisfies each of these requirements,” it was saved from ERISA preemption.¹²¹

D. Caveat: The Deemer Clause

ERISA’s deemer clause prohibits a state from deeming that a self-funded ERISA plan is an insurer subject to state regulation under the saving clause.¹²² The ERISA saving clause, which was the subject of both *Rush Prudential HMO* and *Kentucky Ass’n of Health Plans*, and which allows states to regulate plans, is limited by the deemer clause, which says that if a plan is purely self-funded, then the saving clause does not apply. The key to understanding the deemer clause is remembering that Congress was thinking of pension plans, not health plans, when it wrote ERISA. The deemer clause says that although a self-funded and administered pension plan is doing something that looks like what an insurance company does, this does not make it an insurance company. For example, while pensions take special expertise to administer, the expertise required is the same sort of financial expertise that many corporations use in their core businesses. Indeed, it is not unusual for a company to fund and run its own pension plan. Such a plan invests its reserves and pays benefits, closely resembling involvement in the business of insurance. Without the deemer clause, these plans would be subject to state regulation because they do the same business as insurance companies.

The deemer clause is more complicated for health plans because employers cannot run health plans internally in the way that they can run pension plans. Administration of a health plan requires knowledge of medicine and the services of many health care providers, something that is outside the usual business expertise.¹²³

119. *Id.* at 1479.

120. *Id.*

121. *Id.*

122. Employee Retirement Income Security Act of 1974 § 514(b)(2)(B), 29 U.S.C. § 1144(b)(2)(B); *see also, e.g.*, *FMC Corp. v. Holliday*, 498 U.S. 52, 61 (1990) (“We read the deemer clause to exempt self-funded ERISA plans from state laws that ‘regulat[e] insurance’ within the meaning of the saving clause.”).

123. Almost all states banned the corporate practice of medicine when ERISA was written. These bans generally prevented physicians from being employed by non-physicians, so that employers that wanted to retain physicians to provide gen-

While a health plan may be completely self-funded, it is almost never run exclusively by the employer. *Rush Prudential HMO* and *Kentucky Ass'n of Health Plans* involved employers whose plans were run by external companies, called third party administrators (TPAs). The opinions in both decisions contained footnotes referring to the deemer clause. In *Kentucky Ass'n of Health Plans*, the Court stated, "The deemer clause presents no obstacle to Kentucky's law, which reaches only those employee benefit plans 'not exempt from state regulation by ERISA'"¹²⁴ Similarly, the Court in *Rush Prudential HMO* stated, "Illinois's Act would not be 'saved' as an insurance law to the extent it applied to self-funded plans."¹²⁵ Had the medical plans been pure self-funded or self-administered plans (like pension plans), these cases would have been decided differently: neither plan would be subject to state regulation, because the deemer clause would trump the saving clause. To understand how the Court's decision would be altered if these plans had been self-funded and self-administered, it is useful to contrast *Rush Prudential HMO* and *Kentucky Ass'n of Health Plans* with *Pegram*.

In *Pegram*, the Court distinguished medical decisionmaking from decisions regarding plan benefits. *Pegram* draws a bright line by holding that individualized medical decisionmaking—making decisions about an individual's care that depend on the specific facts of the individual's medical condition rather than on a generic reading of the contract of insurance—is completely outside ERISA. Thus neither the saving clause nor the deemer clause is relevant: medical decisionmaking is not covered by ERISA, and it does not matter how a plan is structured or administered. In contrast, although the statutes at issue in *Rush Prudential HMO* and *Kentucky Ass'n of Health Plans* affected how plan administrators make decisions that are within the ambit of ERISA, both statutes were permissible because the saving clause allows states to regulate plans involving the business of insurance.¹²⁶

The difficult question, and one that has not been directly answered by courts or the ERISA statute, is how much of a health

eral care to employees would have had to treat them as independent contractors. While a company could employ a physician as medical director to administer a health plan, the corporation would then be exposed to medical malpractice liability for the physician's actions and omissions.

124. 123 S.Ct. at 1476 n.1.

125. 536 U.S. 355, 371 n.6 (2002).

126. The key difference between *Rush Prudential HMO* and *Kentucky Ass'n of Health Plans* is that the latter refines the definition of "business of insurance" so as to clear up some of the ambiguities created by *UNUM*.

plan's operations can be contracted out before the deemer clause no longer blocks state regulation. As an example, assume that an employer sets up a self-insured health plan and runs it directly, perhaps as Kaiser did in the 1930s. The employer contracts with physicians to provide care, sets the terms of the care, but makes no medical decisions. While the self-funded employer is providing both medical and insurance services, in a manner analogous to an HMO, the deemer clause prevents the state from declaring the employer's plan an insurance company subject to state regulation. This is consistent with the purpose of ERISA, which was to create a special legal niche protecting self-funded health and pension plans.

In contrast, while large employers may have enough employees to justify running a plan in-house, few do it because of the complexity (created by the need to have medical expertise and providers) of running an MCO system. Running a plan entirely in-house also limits the options for managing care: if the employer starts making medical-necessity decisions, *Pegram* will allow the beneficiaries to sue the employer in its role as plan administrator for medical malpractice. No employer wants the potential legal liability and bad publicity that such state court claims would bring, given that there are no reported cases in which a court found that a health plan with a TPA was governed by the deemer clause.¹²⁷

If the employer does not give the third party administrator any medical discretion in the administration of benefits, then the deemer clause would logically extend to the administrator. Given the cost of health care claims, however, it would be expected that the employer would want the administrator to have both the authority and the duty to find ways to ensure that the care was provided in a cost effective manner. The more authority the employer gives the administrator, the less likely the deemer clause will apply. The right to make medical-necessity decisions, as was at issue in *Rush Prudential HMO*, would be another powerful reason for the courts to find that the administrator was outside the deemer clause. Moreover, because *Kentucky Ass'n of Health Plans* found that an AWP law affected risk sharing, it could also be argued that an administrator who sets up a physician panel rather than letting patients seek care from any physicians they wanted is outside the deemer clause because it is acting as an insurer.

127. See, e.g., *Marks v. Watters*, 322 F.3d 316, 323, 326–27 (4th Cir. 2003) (finding that claims against administrative actor making only non-medical decisions were appropriately removed to federal court under ERISA § 502 rather than through § 514 analysis).

In short, because health plans are distinctly different from pension plans, it is impossible to predict the real impact of the deemer clause in health plan regulation. The language about the deemer clause in *Rush Prudential HMO*, *Kentucky Ass'n of Health Plans*, and other health plan cases is dicta. It is impossible to tell from the case record whether the court is going to be strict about its standards for applying the deemer clause, or whether the nature of health plans causes employers to contract out so much of the plan administration that the deemer clause is irrelevant. Clear financial benefits result when an expert TPA administers a self-insured health plan lacking comparable internal expertise. Moreover, in hiring a TPA, a self-insured plan would insulate itself from exposure to medical malpractice claims. The price of the third party administration of the plan would be that the decisionmaking that is delegated to the TPA becomes subject to state insurance code regulation. If a court were to attempt to extend deemer clause protection to third-party administrator actions that are dictated by the plan (i.e., to decisions where the third-party administrator has no discretion), the court will be faced with a line-drawing issue analogous to the "related to" problem that has plagued ERISA preemption.

E. Implications: MCOs Face Increased Exposure

Collectively, *Pegram*, *Rush Prudential HMO*, and *Kentucky Ass'n of Health Plans* increase liability exposure for MCOs when they engage in medical decisionmaking. In the days before *Pegram*, MCO medical directors routinely second-guessed treating physicians and made de facto medical decisions under the guise of prospective utilization review without the MCO acquiring any liability. Given that there was little downside at that time to denying medical care, MCOs operated in an environment where strong incentives existed to deny even necessary medical care. Thus, while horror stories of the consequences of under-prescription of medical care occasionally leaked into the press and written appellate opinion, what is surprising is that there were not more.

Pegram, however, made it clear that if medical care was wrongfully denied by prospective utilization review, and if a medical decision was involved, that decision was subject to judicial review. After *Pegram*, when an MCO either intentionally or negligently harmed a patient, the patient could sue the medical director for malpractice. This meant that the MCO accrued liability for medical decisions made by its medical director under *respondeat superior* theory. Thus, for the first time, ERISA MCOs needed to contemplate either giving up medical decisionmaking power or purchasing medical mal-

practice insurance. Given the huge awards in cases brought successfully against non-ERISA MCOs, managing medical decisions would have to be very cost-effective to be worth doing under *Pegram*. Many plans had already begun to question the effectiveness of prospective utilization review before *Pegram* because it is very costly to do—*Pegram* just provided one more powerful incentive to shift to different cost-control strategies.¹²⁸ *Rush Prudential HMO* and *Kentucky Ass'n of Health Plans* further undermined the ability of MCOs to control care through plan-driven strategies to manage medical decisionmaking, in that they confirm that the state may regulate some aspects of ERISA health plans.

Allowing the states to regulate MCO medical decisionmaking under their insurance codes and their tort laws creates an interesting situation. Arguably, each state could set its own quality standards, which would thereby defeat an express purpose for enacting ERISA: to provide national employers with a uniform set of laws to govern the administration of employee health plans. Wealthy states, or those with powerful plaintiffs' lawyer lobbies, could set the quality-of-health-care bar higher than less-endowed states that cannot afford equally luxuriant medical care.¹²⁹ Such a crazy quilt of health care regulations would increase the cost of health insurance in national plans, in addition to defeating this express purpose of ERISA. Thus, we soon may see national businesses and labor unions lobbying Congress to provide a unified set of health care regulations as ERISA is undermined by the courts.¹³⁰

128. A recent Aetna settlement agreement is a good example of such alternative cost-control strategies. *Settlement Agreement* (May 21, 2003), available at http://www.aetna.com/legal_issues/pdf_documents/settlement.pdf (on file with the NYU Annual Survey of American Law).

129. To some extent this is already happening. Louisiana, a poor state, has the nation's most draconian tort reform laws, putting very stringent limits on medical malpractice awards. Whether this is cause or effect is hard to say, but the quality of care in many of Louisiana's charity hospitals is very low.

130. Even before Justice Scalia's opinion in *Kentucky Ass'n of Health Plans* was handed down, America had become increasingly concerned over the rising cost of health insurance. See, e.g., David Stires, *The Breaking Point*, FORTUNE, Mar. 3, 2003, at 104–08. Given the current cost of health insurance, many employers can no longer afford to provide such coverage as a benefit. Consequently, between 2001 and 2002, nearly four out of five individuals without health insurance were employed or actively looking for employment. FAMILIES USA, GOING WITHOUT HEALTH INSURANCE: NEARLY ONE IN THREE NON-ELDERLY AMERICANS 5 (Mar. 2003), available at http://www.familiesusa.org/site/DocServer/Going_without_report.pdf?docID=273 (on file with the NYU Annual Survey of American Law). *Kentucky Ass'n of Health Plans* will likely aggravate this situation.

IV.
THE FUTURE OF THE HEALTH
INSURANCE INDUSTRY

A. *Health Insurance After Pegasus, Rush Prudential HMO, and
Kentucky Ass'n of Health Plans*

At the time of its introduction, managed care was a logical reaction to rampant medical inflation that was driven by the nexus of fee-for-service medicine and the medical imperialism model of care. Before the limitations and perverse consequences of managed care dominated the public discourse, there were grave concerns about the unintended consequences of fee-for-service medicine: these included unnecessary surgery, unneeded and even dangerous drug prescriptions, ever more splintered medical care driven by super-specialization, increasing lengths of hospital stays with rising levels of iatrogenic injuries, and most critically, rapidly rising costs that were seen as unsupportable. Managed care, in its initial form of closed-panel HMOs with one-stop shopping for medical care, theoretically offered better-coordinated care, the elimination of unnecessary and dangerous care, more patient convenience (achieved by offering more services in the office), and better quality of care (through modern management). To a great extent, these promises were fulfilled, and patients in these early HMOs (such as Kaiser in California) were very satisfied with their care.

As cost control became an issue in the 1970s and 1980s, these early HMOs, which had not marketed themselves as money-saving entities, shifted their marketing and organization to use their administrative structures to cut costs. They were soon joined by many other forms of managed care, all seeking to control costs by controlling medical decisionmaking.¹³¹ Unfortunately, while there was money to be saved by reducing the charges for services, and by reducing unnecessarily expensive services or unneeded services, it is often difficult to determine what can be cut without harm and what is a necessary service. Physicians who uncritically ordered unnecessary tests and procedures under FFS did not have the skills or clinical information to make good decisions about tests and procedures that could be eliminated under managed care. More troublingly, as the courts recognized ERISA preemption of both state tort lawsuits and state regulation dealing with MCO control of medical decisionmaking, ERISA MCOs became more ruthless in their cost cutting and less concerned about the quality of care. This was exac-

131. See Richards & McLean, *supra* note 15, at 447 (noting that the rise of MCOs paralleled the generally "rising cost of health care").

erbed by economic factors: many MCOs did not make money and employed ever more desperate strategies to cut costs.¹³²

In response to this situation, patients, plaintiffs' lawyers, and state regulators pushed the courts to rethink ERISA preemption. This push was also supported by physicians, who took the brunt of the legal fallout from ERISA preemption. Even into the late 1990s, while the courts were holding that ERISA plans could not be sued for interfering with medical decisionmaking, treating physicians enjoyed no preemption and were the sole available targets of plaintiffs' ire.¹³³ Thus, while physicians were forced to deliver lower quality care or risk losing their jobs or contracts with the insurer, they could not use the insurer's policies as a defense when they were sued for medical malpractice.¹³⁴

Ultimately, the Supreme Court responded to these concerns with its *Pegram*, *Rush Prudential HMO*, and *Kentucky Ass'n of Health Plans* decisions. These cases carved out regulation of medical decisionmaking from ERISA preemption (at least, for plans run by third party insurers not covered by the deemer clause).¹³⁵ Plans that continue to directly control medical decisionmaking are subject to tort lawsuits and to state regulation of their decisions. However, *Rush Prudential HMO* and *Kentucky Ass'n of Health Plans* also undermined the Court's recognition in *Pegram* that cost control is not an illegitimate goal of managed care, and may be necessary if health care is going to be broadly available.¹³⁶ One can argue that *Pegram* is about malpractice and that plans should not commit malpractice.¹³⁷ Even if plans are willing to accept the medical malpractice risks, *Rush Prudential HMO* still imposes state regulatory controls on ERISA plans. *Rush Prudential HMO* itself is a good ex-

132. Robert Lowes, *We Nailed an HMO for \$6 Million*, MED. ECON., Dec. 23, 2002, at 60, 65–66 (stating that defunct HMOs' losses "weren't produced by runaway medical costs," but from "administrative costs").

133. See *Lancaster v. Kaiser Found. Health Plan*, 958 F. Supp. 1137, 1149–50 (E.D. Va. 1997) (finding that medical malpractice claims against physicians—and vicarious liability for insurers—are not preempted by ERISA, while direct negligence claims against insurers are preempted).

134. McLean & Richards, *supra* note 22, at 12.

135. The authors believe that because the excesses of managed care drove the U.S. Supreme Court to reconsider ERISA in *Pegram*, *Rush Prudential HMO*, and *Kentucky Ass'n of Health Plans*, it is unlikely that the Court will then undermine these cases by allowing the same excesses under plans sheltered by the deemer clause.

136. See *Pegram v. Herdrich*, 530 U.S. 211, 219–22 (2000).

137. Anyone familiar with medical malpractice litigation against MCOs will recognize that it is very difficult to defend a proper medical decision to deny care if a consequence of that decision is to save money.

ample of the problem: the plan that prompted the litigation rightfully, per its written policies, denied payment for an expensive, dangerous, unconventional, and unproven treatment for a condition that arguably does not require treatment at all. Unfortunately, a state regulation allowed the patient to have the decision reviewed by a third party reviewer,¹³⁸ who overturned the plan's denial based on the reviewer's own criteria for treating the patient's condition.¹³⁹ The problem with outside review of denial-of-care decisions is that the reviewer has no incentive to deny care¹⁴⁰ and every reason to approve the treatment,¹⁴¹ as under the traditional FFS model of care.

B. *Rethinking the Tragic Choices*

At the beginning of this article we listed six factors that affect the cost of health care in the United States:

- (1) health care providers offer new services, which appear to improve outcomes but either cost more than existing treatments or have no existing analog;
- (2) demographic shifts increase the number of elderly persons needing medical services;
- (3) lifestyle and environmental diseases increase the number of persons needing medical services;
- (4) health care providers charge more for the same services;

138. Certain administrative decisions may still qualify as medical decisions subject to state review. *See* *Corporate Health Ins., Inc. v. Tex. Dep't of Ins.*, 215 F.3d 526, 534 (5th Cir. 2000); *Murphy v. Bd. of Med. Examiners*, 949 P.2d 530, 536 (Ariz. Ct. App. 1997); *State Bd. of Registration for the Healing Arts v. Fallon*, 41 S.W.3d 474, 476-77 (Mo. 2001).

139. The development of objective guidelines for treatment and precise definition of "medical necessity" will go a long way to eliminating *Rush*-type litigation. *See generally* Thomas R. McLean, *Medical Rationing: The Implicit Result of Leadership by Example*, 36 J. HEALTH L. 325 (2003) (discussing the "medical necessity" standard and reviewing INSTITUTE OF MEDICINE, *LEADERSHIP BY EXAMPLE: COORDINATING GOVERNMENT ROLES IN IMPROVING HEALTH CARE QUALITY* (2002)).

140. Bone marrow transplants for advanced breast cancer are a good example. They never had good scientific backing, yet health plans were sued for not providing them and some states passed laws mandating that they be covered. Ironically, while later medical research has shown them to be ineffective, expensive, and very detrimental to the patient's quality of life, these state mandates are still in place.

141. The plan is also subject to fraud by its own physicians, who may manipulate patient medical information to justify unnecessary treatments. *See* Matt O'Connor, *Transplant Scandal Hits 3 Hospitals*, CHI. TRIB. July, 29, 2003, at 1 (describing how several physicians manipulated diagnoses in order to perform unindicated liver transplants).

- (5) health care providers offer new services to gain market share or increase profits, which are more costly but have little benefit over existing services, or offer unnecessary services; and
- (6) more services are put under the medical umbrella.

1. The Pitfalls of Legislative Reforms

We then asked whether it is possible to sort out factors four and five from factors one and two, so as to avoid Professor Orentlicher's tragic choices. We now return to this analysis in the light of the U.S. Supreme Court's restructuring of ERISA's preemption of state requirements on managed care plans. Controlling factors four and five and distinguishing them from factors one and two requires that there be some system for controlling medical decisionmaking.

Chelation therapy for cardiac disease provides a good example of how these factors play out in the real world. Chelation therapy is being offered by health care providers in many communities as a new and miraculous treatment. However, not only is documentation of the therapy's efficacy lacking,¹⁴² chelation therapy may be detrimental if used in place of effective treatments, and it costs the health care system more than \$400,000,000 a year, perhaps much more.¹⁴³ While providers of this treatment would call it a factor one treatment—one that is valuable and must be paid for even though it is costly—an MCO would rightly term it a factor five—a worthless and costly treatment. Thus, the question is which classification would prevail under the new rules of *Rush Prudential HMO* and *Kentucky Ass'n of Health Plans*.

The U.S. Supreme Court's recent ERISA preemption cases greatly limit the ability of MCOs to control the care that is delivered to their patients.¹⁴⁴ While *Rush Prudential HMO* and *Kentucky Ass'n of Health Plans* are ostensibly about the right of the state to regulate health plans to ensure the protection of the public, their results will likely be paradoxical. *Rush Prudential HMO* authorizes states to impose administrative due process (e.g., third-party review of the MCOs' decisions) on MCOs, but sets no standards for review. Accordingly, MCOs' costs will rise after *Rush Prudential HMO* because the cost of administering an HMO with cost-effective providers will increase. For example, it is likely that an independent reviewer in Illinois would approve chelation therapy—the treatment is some-

142. Merrill L. Knudtson et. al, *Chelation Therapy for Ischemic Heart Disease: A Randomized Controlled Trial*, 287 J. AM. MED. ASS'N 481, 484 (2002).

143. *Id.* at 481.

144. McLean & Richards, *supra* note 7, at 39.

thing that the patient wants and that some physician says is both a good idea and one that is worth performing (the only discernable requirement for approval in *Rush Prudential HMO*).¹⁴⁵

The fundamental problem with state regulation of MCOs is that such regulation is driven by patient and health care provider groups that seek only to deal with the denial-of-care aspects of MCO decisionmaking. The most common manifestations of this problem are statutory mandates for insurance coverage that are driven by media storms rather than good science.¹⁴⁶ The costs of care are further ratcheted up when such mandated coverage is sometimes unnecessary or dangerous.¹⁴⁷ Prior to *Rush Prudential HMO*, such mandates did not apply to ERISA plans, unless enacted as federal law. However, after *Rush Prudential HMO*, states will be able to bypass the prohibition against mandated benefits by recasting them as quality-of-care mandates. This is an example of the “tragedy of the commons” phenomenon that afflicts most state regulation of private health care:¹⁴⁸ the immediate individual benefit from increased care is perceived to outweigh the more global problem of cost-of-care increases. As mandates are increased, care becomes more expensive and more people are excluded from coverage.

This is not a new problem. In 1974, the federal government gave states regulatory power over the development of new health care facilities.¹⁴⁹ The centerpiece of this legislation was the certificate of need (CON) process, which was intended to lower costs of health care by preventing the construction of new health care facilities in areas where there was already adequate capacity.¹⁵⁰ In most communities, however, the citizen boards overseeing the CON pro-

145. In fact this is exactly what happened in *Rush Prudential HMO*, but rather than approving chelation therapy, *Rush Prudential HMO* concerned the approval of a costly surgical procedure that the patient wanted, but that had not yet been demonstrated to be efficacious.

146. David A. Hyman, *Regulating Managed Care: What's Wrong With a Patient Bill of Rights*, 73 S. CAL. L. REV. 221, 222–24 (2000).

147. Laws limiting insurance companies' ability to deny questionable care may also be used in insurance fraud schemes that depend on claims being paid with little or no review. See Vanessa Furhman, *FBI Raids Surgery Clinics in Probe—Investigators Say Patients Were Paid to Have Surgery in a \$300 Million Scam*, WALL ST. J., Mar. 19, 2004, at A7.

148. See generally Garrett Hardin, *The Tragedy of the Commons*, 162 SCI. 1243 (1968).

149. National Health Planning and Resource Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (1976).

150. See Patrick John McGinley, *Beyond Health Care Reform: Reconsidering Certificate of Need Laws In a “Managed Competition” System*, 23 FLA. ST. U. L. REV. 141, 148–50 (1995).

cess did not limit construction, because they saw the value of a new facility in their community as outweighing its effect on the global cost of health care.

2. The Institute of Medicine and National Standards

The only supportable antidote to these problematic state or federal insurance mandates is a national set of evidence-based medicine standards. For the past several years, the Institute of Medicine (IOM) has been publishing reports on medical errors. These reports paint a grim picture of needless patient suffering and death. While these reports have been controversial and may dramatically overstate the consequences of medical mistakes,¹⁵¹ they do identify a key problem in medicine—the lack of good information on what are the best treatment options for common medical conditions. There are now major research programs in place to develop standard protocols for the treatment of common medical conditions. While the rationale behind such protocols is improving care, it is assumed that reducing costs is also a main objective. Such protocols are already available for asthma and are proven to greatly improve patient care and cut costs by reducing severe complications which require hospitalization.¹⁵² Applied to our chelation therapy example, it is clear that evidence-based clinical-care guidelines would improve care and save money.

The IOM envisions that these protocols will replace managed care with a system of risk managed care.¹⁵³ The key features of risk managed care will be increased: (1) utilization of guideline-driven protocols; (2) monitoring of providers' practices; and (3) financial incentives to induce provider compliance with the guideline protocols.¹⁵⁴ As envisioned by the IOM, risk managed care will be an improvement over managed care because medical decisionmaking will be above board and subject to increased scrutiny and scientific validation. This would make it much easier to manage factors four and five and to tell when a purportedly beneficial new treatment is

151. See Troyen A. Brennan, *The Institute of Medicine Report on Medical Errors—Could It Do Harm?*, 342 NEW ENG. J. MED. 1123 (2000); Clement J. McDonald et. al, *Deaths Due to Medical Errors Are Exaggerated in Institute of Medicine Report*, 284 J. AM. MED. ASS'N 93–94 (2000).

152. McLean, *supra* note 139, at 329, 355 n.40 (discussing the time-line for implementation of guideline-driven medicine to treat conditions such as asthma).

153. *Implications*, *supra* note 8, at 229.

154. See McLean, *supra* note 139, at 327. See also INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH CARE SYSTEM* 1–15 (Linda T. Kohn et al., eds. 2000) (stating that the current health care system has failed consumers and suggesting broad routes to improvement).

really yet another unproven treatment that will raise costs without improving care. However, the IOM's system of health care delivery shares, in common with managed care, the fault that it only addresses the delivery of medical care, not the primary prevention of illness.¹⁵⁵ Because IOM's system does not tackle the other causes of medical inflation, it will have only a limited effect as a cost control device,¹⁵⁶ although it may be effective at improving quality of care and reducing malpractice litigation against doctors who follow the protocols.

3. Prevention

Factor three—lifestyle decisions that increase illness—is the most important factor to manage. Lifestyle, perhaps more than any other factor, is subject to manipulation. Changing lifestyles and environmental factors to prevent the development of disease is called primary prevention. It is the most cost-effective way to manage diseases and also creates the greatest gains for individuals because it is always better to avoid developing an illness than to receive good treatment for it.¹⁵⁷ Smoking is the most important preventable cause of premature death and chronic illness, and it is on the decline because of decades of efforts to make it more difficult for people to smoke. Eliminating cigarette machines, making it difficult to smoke at work, raising the cost of cigarettes, and other strategies are gradually convincing people that smoking is not worth the trouble. Over the next several decades, it is hoped that smoking will decrease to levels that will not greatly impact health care.

Obesity is the number two preventable health risk. Obesity, which increases the risk from smoking and genetic predispositions

155. The IOM's publications make it clear that it is aware of the entire breadth of medical imperialism. We also recognize that the IOM's techniques could be used to address medical imperialism issues that are beyond the control of health care providers. Still, to date, it seems that the government and the business communities are interested only in IOM's recommendations to control provider autonomy. Whether the payors of health care adopt effective preventive medicine technology—which leverages current assets against only potential future liabilities—remains to be seen.

156. However, if the IOM does implement an effective preventive medicine system, it would be a substantial improvement over managed care. Moreover, to the IOM's credit, it has a long but underappreciated track record of publishing articles on preventive medicine. See INST. OF MED., PUBLICATION LIST, at <http://www.iom.edu/file.asp?id=7458> (last visited Jan. 19, 2004) (on file with the NYU Annual Survey of American Law).

157. Diet, exercise, and eliminating smoking could dramatically reduce diabetes, cancer, kidney disease, and other chronic conditions that require the most expensive and least successful treatments.

to heart disease and diabetes, is rising rapidly in this country, with 20.9% of the population classified as clinically obese, a dramatic increase from over thirty years ago.¹⁵⁸ Obesity and its major secondary complication, type II diabetes, already account for significant health care expenditures, and these costs will increase dramatically as current trends develop through time.

Shifting the medical care system toward preventive medicine is a key part of an overall strategy to control factors such as smoking, obesity,¹⁵⁹ AIDS, gun violence,¹⁶⁰ and accidents,¹⁶¹ all of which increase health care costs. The medical role in prevention is called secondary prevention. The best examples are hypertension treatment and the careful management of diabetes. Treating these diseases, which often occur together, reduces the development of heart and kidney disease, blindness, nerve damage leading to am-

158. The core cause of obesity is too much food relative to the individual's physical activity. There are many individual genetic and metabolic factors that affect the exact need for calories and exercise, but at the societal level, the problem is too much food and too little exercise. This is the result of two trends. First, over the past fifty years, the United States and most other developed countries have established farm policies that encourage the production of large amounts of cheap food. These policies have been wildly successful, making food cheap in historical terms and so abundant that it is difficult to dispose of the excess production. Government policy encouraged the consumption of more food, and individuals and private businesses responded with larger portion sizes and more calorically dense foods.

During the same period, employment and household tasks have become much less physically demanding, and changes in living and transportation patterns resulted in most people getting much less exercise in their daily lives. Schools allowed children less time for play, and the shift to organized sports left out the children who did not have the family resources and transportation to participate in structured activities outside school time. Passive entertainment such as television and computer games became a substitute for active outside play for most children and young adults.

159. Medical care providers have an important role in reducing smoking and obesity and managing diabetes to reduce long term complications and medical costs. Yet these are activities that pay off only in the long term, and health insurance is rated and paid for on yearly cycles. Thus there is no incentive for a health plan to encourage preventive care because it cannot recapture the ultimate savings within its financial planning horizon.

160. See *generally* Edward P. Richards, Book Review, 21 J. POL'Y ANALYSIS & MGMT. 166 (2002) (considering various proposals to prevent the costly effects of gun violence) (reviewing PHILIP J. COOK & JENS LUDWIG, GUN VIOLENCE—THE REAL COSTS (2000)).

161. AIDS, gun violence, and serious accidents, especially automobile accidents, are a tremendous burden on urban emergency rooms and hospitals, perhaps the most fragile component in the health care system.

putation, and other tragic and expensive complications.¹⁶² These treatments are not expensive, but pose one of the most difficult problems in the U.S. health care system: ensuring that patients have consistent access to quality medical care.

Chronic disease treatment is very difficult if patients cannot see the same physicians over time, and if those physicians do not use standardized care plans to ensure that the chronic diseases are treated in the most effective manner possible.¹⁶³ As employers change health plans, as health plans shift patients between different physicians based on the latest bids for services, as those same often over-worked physicians rush their schedules, it becomes difficult for most patients to see their physicians on a regular basis, and impossible for diabetic patients with problems that need immediate care to get that care before the problems become more serious. Prevention is very sensitive to inconvenience and delay because patients ripe for preventive care usually do not have severe enough symptoms to drive them to get care despite these barriers. Unfortunately, although it is hard to get patients to worry about asymptomatic diseases such as early diabetes or hypertension, getting them consistently treated in the early stage of disease is the key to prevention.¹⁶⁴ Many health plans are further complicating this goal by shifting more of the cost of care to the insured through higher co-payments and up-front charges when they want to see their doctors. These shifts are intended to make patients better shoppers for health care, but they really encourage patients to not go to the doctor unless they are really sick. Unfortunately, this is the worst possible strategy for preventing the complications of chronic diseases. When such plans include preventive medicine coverage, such coverage relates to patients getting a check-up, not having their diabetes or hypertension managed.

Since preventive medicine and injury prevention require present-day expenditures that only save money in the longer term, health insurance must be restructured to have a longer financial

162. See The CDC Diabetes Cost-effectiveness Group, *Cost-effectiveness of Intensive Glycemic Control, Intensified Hypertension Control, and Serum Cholesterol Level Reduction for Type 2 Diabetes*, 287 J. AM. MED. ASS'N 2542, 2547 (2002).

163. Christopher D. Saudek, *Progress and Promise of Diabetes Research*, 287 J. AM. MED. ASS'N 2582, 2583 (2002) (concluding that the "US health care system is undeniably built around acute, episodic illness, providing a care model that does not deal well with chronic disease").

164. CDC Diabetes Cost-Effectiveness Study Group, *The Cost-effectiveness of Screening for Type 2 Diabetes*, 280 J. AM. MED. ASS'N 1757, 1757 (1998) (suggesting that screening, even while subjects are asymptomatic, could prove helpful in terms of disease prevention and would most likely be cost-effective).

time horizon.¹⁶⁵ As with all statistics-based insurance strategies, this first demands that the risk pools be as large as possible. Additionally, insurers and employers should be given incentives to use standard policies that group together as many patients as possible.¹⁶⁶ While the health care insurance industry is already dominated by large corporations, they write thousands of separate plans, thus fragmenting the risk pools. The more difficult problem is that plans, or the employers who buy them, need to have an incentive to aggressively promote preventive medical services. This means that rate decisions need to be made on large pools over a multi-year time horizon. From a health policy perspective, health insurance should be written on multi-year contracts with limits on rate increases. This has been unpopular because it implies also that the insureds would have to be locked into a single plan. However, if the pools of insureds were large enough and spanned enough employers, and if all plans faced the same requirements, then there would be little incentive to switch plans.

4. Muting the Demographics of Aging

The most important factor increasing health care costs is the relentless push of demographics. As the population increases, which it is slated to do for many years to come, the total cost of health care increases. As the number of elderly persons increases as a percentage of the population, the cost of health care per capita again increases. As the number of unhealthy persons, either through lifestyle choices or now-survivable genetic diseases, increases, the cost of care increases further still. Like lifestyle changes, a burgeoning aged and ill population increases medical cost in a way that cannot be controlled by the IOM's guidelines. For example, using guidelines, surgical intervention for coronary artery disease can be limited to individuals with three-vessel disease. But, because the incidence of coronary artery disease increases with age, we will soon be paying for more coronary intervention regard-

165. See Thomas R. McLean, *Medicine v. Health Insurance: A Tale of Two Industries* 24 (forthcoming 2004) (manuscript, on file with the NYU Annual Survey of American Law).

166. The IOM chides the practice of medicine for being variable, overly complex, and needlessly inefficient. The truth is that all of these terms apply to the medical insurance industry. See *id.* at 4 (“[O]ur health insurance system is also a complex and inefficient system”).

less.¹⁶⁷ Finally, as medical science develops more treatments for previously poorly treatable conditions, the cost of care will increase.

The increase of elderly in the population is overloading the Medicare system, a problem that, while hardly new, will only get worse as the baby boom population ages. When people retire, the cost of their care shifts to the federal government at the same time that most of them stop paying taxes. The burden of paying for their care, as well as for their social security payments, shifts to the remaining working population. When sixty-five was adopted as the retirement age, approximately three percent of the population reached sixty-five. Now, life expectancy is more than seventy-seven years, and a significant number of persons are surviving well beyond that age. While current literature shows that most of these older people are healthier than their counterparts in previous generations, they are still not as healthy on average as younger persons, and will dramatically raise the cost of care over a comparable number of persons in middle age. This means that the real health care economics problem is retirement, not age.

Shifting the retirement age to seventy would have a profound effect on the finances of the social security system and the Medicare system, as well as increasing state and federal tax revenues. While this would not reduce health care costs, it would make many more of them pay-as-you-go, and take the burden off other workers and the government. This would free up state and federal money which could be used to broaden access to care for those who are unemployed or working in jobs without health insurance. Increasing the retirement age to seventy would be perhaps the most intellectually honest and straightforward solution to controlling Medicare and Social Security expenditures, which would raise the GNP and defray rising health care costs.

C. Conclusions

Ultimately, society must confront the question of how much it spends on health care. While economists worry about health care being too large a part of the GNP, this fear is based on old-fashioned notions of an industrial economy dominated by manufacturing.¹⁶⁸ Health care is a very diverse service industry based on

167. Other countries take a more direct approach to controlling health care cost and do not pay for coronary intervention over a certain age. See McLean, *supra* note 139, at 343, 361 n.130.

168. This statement is made with the assumption that health care is not paid for by employers. If employers pay for health care and then add it to the cost of goods sold, a nation's economy is disadvantaged in the global market place as

knowledge, high technology, and personal services. It is also a very local industry. Health care jobs, unlike manufacturing jobs and even software engineering jobs, are in no danger of being exported to foreign countries.¹⁶⁹ The problem with health care spending is not that it is too large a part of the GNP, but that it is paid for in ways that distort the job market and make it unavailable for many persons in society. Many Americans are horrified by European tax rates, yet when all the costs of privately paid-for benefits such as health care are added to the tax bill, middle class tax payers probably pay as much or more than their European counterparts, and get less for it.¹⁷⁰ As we discussed earlier in this paper, a key reason why health care is more expensive in the United States is that it includes many direct and indirect social welfare costs that would either be reduced in Europe or paid under a different umbrella. There is no

health care will make up a larger portion of its spending. Thomas R. McLean, *Cybersurgery: Innovation or a Means to Close Community Hospitals and Displace Physicians*, 20 J. MARSHALL J. COMPUTER & INFO. L. 495, 511 (2002) (“Simply put, health care benefits . . . act like a tax on U.S. products and services thereby making these products and services less desirable in the global market place.”) [hereinafter *Cybersurgery: Innovation*]; Tom McLean, *Deep Pockets: The Liability of Risk Managed Care Organizations for Medical Malpractice*, in MEDICAL MALPRACTICE UPDATE 231 (Aspen Law & Business 2003); Thomas R. McLean, *Stealth v. Health: The Complexity of Tort Reform*, 12 LEGAL MED. PERSP. (Mar.–Apr. 2003), available at http://www.aclm.org/publications/Impvol.12_4supplement.asp (discussing need to cut medical spending in order to “make American business more competitive in the global market place”) (on file with the NYU Annual Survey of American Law).

169. As telemedicine and cybersurgery improve, this statement may not be true in five to ten years. See *Cybersurgery: Innovation*, *supra* note 168, at 514–15 (discussing the economic arguments for “outsourcing” surgery to foreign doctors); Thomas R. McLean, *Cybersurgery: An Argument for Enterprise Liability*, 23 J. LEGAL MED. 167, 168 (2002) (“[I]n the not too distant future, physicians will use advanced telemedicine technology in heretofore unintended ways to perform cybersurgery, that is, physicians will use telemedicine and computer-assisted robotics to perform surgery on remote patients.”).

170. An important subject that is beyond the scope of this article is insurance administrative costs. Europeans have cheaper health care because a single payor system is much more efficient than the polymorphic health insurance system of America. It has been estimated that America could cut its health care costs by approximately fifty percent if America adopted a single payor national health insurance system. Steffie Woolhandler & David U. Himmelstein, *Paying For National Health Insurance—And Not Getting It*, HEALTH AFF., July-Aug. 2002, at 94; see also McLean, *supra* note 165, at 16–18 (suggesting that, even if Woolhandler and Himmelstein’s fifty percent projected reduction is unrealistic, “consolidation of the U.S. health insurance market down to a single payor system . . . offers some distinct advantages for the United States”).

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free lunch, and if the United States does not address its social welfare problems directly, it is not surprising that associated costs ultimately surface in the only program that the United States does support: medical care.