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# FROM THE DOCTOR TO THE SYSTEM: THE NEW DEMANDS OF HEALTH LAW

*Barry R. Furrow*<sup>†</sup>

## INTRODUCTION

**HEALTH LAW HAS GROWN** from the topic of an occasional seminar to a new academic cottage industry, with courses proliferating as new casebooks pour from the publishers' presses. Major law firms now have health law sections, and boutique health law firms are also common in many cities. What has fueled this growth? And what does the future hold for this maturing specialty? I will take a brief historical look at the forces that have changed the American health care system, and the role of lawyers in it; and then venture some predictions—and hopes—about the future shape of health care law in the United States.

What is health law? Health law is the legal domain that addresses the health care industry in all of its component parts, including providers, insurers, patients, drug companies, and researchers. The field of health law is a specialized response to the increased complexity of relationships in the health care field and the intense fragmentation of the American health care delivery system. Health care delivery is an unruly domain, characterized by the lack of a comprehensive national health policy and an untidy morass of state and federal regulatory schemes. Lawyers represent various constituencies in this health care system, from injured patients to physician groups trying to work out agreements with large insurers; from drug manufacturers to pharmacies to universities conducting human subjects research. In a German or Italian health care system, the concept of health law is not well developed. In most European systems, because of the centrality of a national health system with strong central management, there is less play for private institutions, and lawyers simply have less to do. They are social security specialists rather than health lawyers. Our system, by contrast, has thousands of private insurers, hundreds of both non-profit and for-profit hospitals, large managed care companies, and a

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large and powerful pharmaceutical industry. The cat-and-mouse game between regulators trying to control the extreme tendencies of a hyper-entrepreneurial system and the stakeholders trying to profit from it requires lawyers, lots of lawyers, to handle the deals, the disputes, and the regulatory battles. Health care is a classic lawyer's playground, and it will continue to be one.

The heart of a private lawyer's work is protecting her client's interests, as that client defines them. Transactional work involves innovation in deal making, and mastery of a complex set of rules so that a business can operate without fear of regulatory backlash. Health law work is more intensely prophylactic than many areas of law practice, given the pervasive regulation of many features of the health care environment.

The government lawyer may represent entities with one of many goals: promoting quality, access to health care, or cost control in publicly financed programs, or all three. Typically outgunned by the private bar, it is clear that in some areas, like fraud and abuse, government health lawyers have gained considerable powers in their struggle with health care entrepreneurs.

The academic health lawyer stands at a remove from the regulators and the deal makers, and tries to understand the features of this fragmented system and evaluate its performance by contrast to existing models. Our health system can do better, by any number of measures, and it is the job of the academic to probe, provide sharp criticism and empirical information, and argue for paths to improvement and the merits of alternative pathways. I have been an academic lawyer for almost thirty years, teaching health law in several different forms in a variety of settings, and the field is more complex and challenging than it has ever been.

## I. THE EFFECT OF HEALTH CARE RELATIONSHIPS ON HEALTH LAW PRACTICE: A BRIEF HISTORY<sup>1</sup> (WITH ACRONYMS)

### A. The Doctor - Patient Relationship

Physician + Availability + Cash + Treatment = PACT

The health care world in the late nineteenth century was dominated by solo practitioners. The compact between doctor and patient defined the health care universe. Doctors delivered care in their offices or in a patient's home, on a cash basis. They also gave charity care in hospitals. Patients avoided hospitals, which were known as breeding grounds for infection.<sup>2</sup> The cash basis of most of their relationships with patients constrained the ability of the health care system to expand rapidly. We trusted our doctors, and the pact was a simple one: we would pay in cash for the few minimal treatments that were available and they would provide care even if cash was short at times.

Pockets of prepaid care could be found in Kaiser's industrial co-operative health care arrangements in California and the Puget Sound Health Cooperative in the Northwest, which were precursors of today's managed care. Physicians who worked in these plans or physicians who practiced were either salaried employees of large plans, or were paid on a per patient basis.

Hospitals existed as bastions of care for the poor until the 1870s in the United States, subsidizing such care through their charitable status and income, and protected through charitable immunity laws against litigation for medical harms.

The physician-patient relationship provided the framework for most health law issues. The historical evolution of the field of health law starts with this central focus on the physician-patient relationship. The courts nipped and tucked the edges of the provider-patient relationship, developing legal doctrines in malpractice cases, with informed consent doctrine as an important development. Judicially developed general legal and ethical principles governed the dyadic relationship of a sole practitioner and patient.<sup>3</sup> What were the doctor's

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<sup>1</sup> I have based much of the historical discussion on the superb historical examination of American medicine in PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* (1982).

<sup>2</sup> *Id.* at 75.

<sup>3</sup> See generally BARRY R. FURROW ET AL., *HEALTH LAW* §§ 4-32 to 4-34.

obligations to patients? Under what circumstances was a doctor responsible to patients for his errors? The ethical and legal discussions assumed the simple doctor-patient relationship.

### B. The Institutional Provider - Patient Relationship

Hospital + Open access to insurance + Patient + Expansion = HOPE

The hospital began to develop into a powerful scientific institution around the turn of the last century. Hundreds of new hospitals sprang into being; in the words of Rosemary Stevens, they became "a manifestation of modern America."<sup>4</sup> Stevens wrote that "[b]etween 1900 and 1917, patterns of influence, financial and political incentives, and expectations about the hospital's function were created that we still see today, both at the local and national levels."<sup>5</sup> The professionalization of nursing and the advent of antiseptic surgery speeded the reorganization of the hospital into a bureaucratic entity.<sup>6</sup> One could see the ideological underpinnings of a classically American view of health care regulation: "[t]he ideal role for the hospitals, from their own perspective, was governmental subsidy (or purchase of service) with little or no government supervision."<sup>7</sup>

The laws of charitable immunity and vicarious liability protections were part of the indirect subsidies to hospitals, protecting them from liability at the same time they were relieved of tax burdens. Courts slowly began to whittle away some of the legal protections by the 1950s, as courts became aware of the reality that hospitals were big businesses with little need for such a range of legal protections.<sup>8</sup>

The Depression had enhanced ordinary citizens' anxieties about how to pay hospital bills, and it became clear that a working class individual could not save enough to cover the high costs of extended hospitalization. The American Hospital Association pushed for hospi-

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(West, Hornbook Series, 2000) (explaining the legal duties of a health care provider to maintain confidentiality and to disclose patient information); *see also id.* at §§ 3-1 to 3-24 (discussing the law governing the regulation and licensure of physicians).

<sup>4</sup> ROSEMARY STEVENS, IN *SICKNESS AND IN WEALTH: AMERICAN HOSPITALS IN THE TWENTIETH CENTURY* 17 (1989).

<sup>5</sup> *Id.* at 19.

<sup>6</sup> *See id.* at 18-19 ("Doctors and nurses combined to make the hospital a 'hygienic machine' in which the patient's body could be restored, recalibrated, and repaired.").

<sup>7</sup> *Id.* at 46.

<sup>8</sup> *See, e.g.,* *Bing v. Thunig*, 143 N.E.2d 3 (N.Y. 1957) (discussing the evolution of the charitable immunity doctrine and disavowing its applicability to the modern hospital).

tal services plans (Blue Cross plans) and through the 1930's, regional Blue Cross plans were developed to offer hospitalization insurance in prepayment plans open to everyone on a community-rated basis. Such plans did more than relieve the anxieties of ordinary Americans; they also created a new source of payment for hospitals and, therefore, a new source of nutrient for growth.<sup>9</sup>

The Blue Cross plans blossomed during WWII, as the federal government agreed that unions could bargain for health care benefits without violating the wage freeze. The federal tax code fertilized growth by granting tax breaks for such fringe benefits. Hospital spending was unconstrained, since the plans typically paid ordinary and reasonable charges without much scrutiny. Prior to World War II, health care's share of the Gross Domestic Product was about 4%. By 2001 it was 14.1%, and it is now estimated to reach 17.7 % by 2012.<sup>10</sup>

World War II was a turning point for hospital capacity to treat. The antibiotic revolution had produced penicillin, sulfonamides, and other drugs. The Army and the Navy had made major advances in surgery during the war, including use of blood products to prevent shock in soldiers, mobile MASH units, and other technologies of organization that delivered care swiftly and effectively. These tools and technologies were transferable to the domestic hospital setting, and they enhanced the hospitals' abilities to treat patients successfully.<sup>11</sup> With such capacity came the desire of patients to have access to these treatments, and this required insurance to cover hospital costs.

The development of the Salk polio vaccine in 1953, and later the Sabin vaccine in 1956, was a major public health development. I remember standing in line in elementary school in rural South Dakota to drink a small cup of the Sabin polio vaccine. In the 1950s in South Dakota we were well aware of the effects of polio, seeing parents of our friends crippled by the disease and forced to use leg braces, crutches and other aids to move around. The polio vaccine was a harbinger of the increased power and pervasiveness of medicine. Doctors were becoming an important feature of life; they gave comfort and pain relief to the elderly with chronic diseases or terminal illnesses. Annual checkups were still uncommon, however, and even

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<sup>9</sup> See STEVENS, *supra* note 4, at 171-99, for a description of the genesis of Blue Cross and hospitalization insurance.

<sup>10</sup> Stephen Heffler et al., *Health Spending Projections for 2002-2012*, HEALTH AFF.: WEB EXCLUSIVE W3-54, W3-54 (Feb. 7, 2003), at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.54v1.pdf>.

<sup>11</sup> Cf. ELI GINZBERG, *THE MEDICAL TRIANGLE: PHYSICIANS, POLITICIANS, AND THE PUBLIC* 42 (1990) (discussing how these medical technologies brought about funding for their domestic application and for more medical research).

trips to the dentist were unlikely for children unless cavities developed. My only contact with a physician as a child was the result of stepping into a pan of boiling water and getting third degree burns to my foot. The skin grafts for several weeks were done in the doctor's office, since hospitals were few and far between outside major urban centers. And penicillin ensured that the foot was not infected. Medicine was gaining clinical power.

The role of lawyers in this era grew as they represented the growing numbers of insurers offering both hospital and physician insurance. And hospital law began to develop with the rapid growth of the hospital industry—staff privilege disputes, contract and employment issues, and other institutional legal work came to characterize the work of the slowly developing health law practice. As medicine came to be practiced in the hospital, the law of medical staff privileges, restrictions on practice, and antitrust law developed as a major source of health law advising. As more money poured into the system, the legal issues surrounding reimbursement rules and controversies grew as a source of legal specialization.

### C. The Insurer-Provider relationship

Commercial Insurance + Access Exclusions + Patients = CAP

Nongovernmental insurance proliferated in the 1950s and 1960s through aggressive selling by commercial health insurance companies who offered employers a better deal than Blue Cross by quoting a premium rate based on the employer's individual experience, rather than the Blues' community rating. As these insurers skimmed off the healthier patients, the Blues were forced to gradually raise rates and change their rating practices, setting the stage for the problems of coverage for the elderly, chronically ill, and others at high risk.<sup>12</sup>

Employment-based health insurance became the norm, providing even more revenue to fuel health care growth.<sup>13</sup> It also foreshadowed future problems with health care coverage, since insurance as a fringe benefit of work meant that those who stopped working were in trouble. Employment-based health insurance was an accident of wartime collective bargaining, not a thoughtful design choice for a health care

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<sup>12</sup> See STARR, *supra* note 1, at 327 (observing the paradox of commercial insurers' increased market share driving the system toward eventual government intervention on behalf of high-risk groups).

<sup>13</sup> See STARR, *supra* note 1, at 311 (noting that the expansion of employee health plans after the war "took on new implications when in the late forties labor unions gained the right to bargain collectively for health benefits").

payment system. This is an example of the characteristic American approach in which the path to health care policy is the end result of a zigzag path among the landmines in the political landscape of the era. The combination of Blue Cross and commercial insurance may have increased the velocity of dollars moving through the health care system, but the lack of federal money still meant that the health care system was constrained prior to the passage of Medicare in 1965.

Drugs were becoming central as a treatment modality, and drug product liability cases began to appear in the case law as large pharmaceutical companies developed new mass-produced drugs that replaced the compounded prescriptions that pharmacies traditionally had supplied.<sup>14</sup> The power of the hospital to revive patients through the use of cardiopulmonary resuscitation (CPR), new in its routine use for the resuscitation of patients, raised interesting issues in the new field of bioethics.<sup>15</sup> Patients began to fear being kept alive against their wishes, as a byproduct of the use of CPR. Fears about control over death and dying began to be expressed by patients and ethicists, and cases began to appear, including the landmark decisions Quinlan<sup>16</sup> and Brother Fox cases.<sup>17</sup> Lawyers began to handle cases on behalf of patients, not only for malpractice claims, but in termination of life cases like that of Karen Ann Quinlan. And, of course, they represented the commercial insurers whose market share was growing.

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<sup>14</sup> See, e.g., *Randall v. Goodrich-Gamble Co.*, 70 N.W.2d 261 (Minn. 1955) (products liability action against a liniment manufacturer); see generally Annotation, *Liability of Manufacturer or Seller for Injury Caused by Drug or Medicine Sold*, 79 A.L.R.2d 301, 369-77 (1961) (summarizing cases in which successful causes of action were asserted against manufactures of drugs and medicines).

<sup>15</sup> See generally STEFEN TIMMERMANS, *SUDDEN DEATH AND THE MYTH OF CPR* (1999) (presenting a historical review of CPR in the hospital setting); cf. Norman L. Cantor, *Twenty-Five Years After Quinlan: A Review of the Jurisprudence of Death and Dying*, 29 J.L. MED. & ETHICS 182, 185 (2001) (raising the point that similar to a patient's right to refuse life-sustaining medical treatment, a patient can request that CPR not be performed in the event of cardiac or respiratory arrest).

<sup>16</sup> *In re Quinlan*, 355 A.2d 647 (N.J. 1976) (holding that a guardian could assert, on behalf of a patient in a persistent vegetative state, the privacy right to withdraw life-sustaining medical intervention).

<sup>17</sup> *In re Storar*, 420 N.E.2d 64, 67-68 (N.Y. 1981) (affirming the trial court's decision to permit the removal of life support from a patient in a persistent vegetative state who had previously expressed his wish to avoid medically prolonged life with no hope of recovery).



## D. Government-Provider Relationships I: Pouring in Dollars

Medicare + Opened Spigot + Technology + Health Free = MOTH

Providers are drawn to health care dollars as moths are to light. The federal government became the dominant payer for many classes of patients, including the poor and the elderly, starting in 1966 with the Medicare program. When I began the practice of law in 1972 in Boston, the issues facing me as a young lawyer in a large firm with several health clients were primarily related to reimbursement by private and public payers. I handled coverage disputes between patients and Blue Cross-Blue Shield and advised the Blues on insurance coverage of novel or experimental new therapies. But the Blues generally paid what physicians and hospitals asked, only fighting with subscribers over coverage issues.

A large percentage of the American population was Medicare and Medicaid eligible in the mid 1960s as the two large federal programs grew. Kennedy had made Medicare in 1960 a plank of his platform.<sup>18</sup> By 1965, Johnson, having trounced Goldwater, had a mandate to get Medicare passed, and Medicaid as well, in 1965 (effective in 1966).<sup>19</sup> Liberals thought that next would be universal coverage for women and children, and then for all adult men. But no one else could or did agree.

Between 1966 and 1983, when the prospective payment or diagnosis related group (DRG) system was put in place to control Medicare hospital costs, one could argue that the health care system was free of financial restraints, the result of what Starr terms "the politics of accommodation."<sup>20</sup> National health expenditures increased by a factor of 10, from \$26.9 billion in 1960 to \$248 billion in 1980, in constant dollars.<sup>21</sup> The increased quantity of money in the health care system was a magnet for device and drug manufacturers and entrepreneurs of all sorts. Health care regulation began in earnest, defined as

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<sup>18</sup> See STARR, *supra* note 1, at 369.

<sup>19</sup> See STARR, *supra* note 1, at 366-70 (discussing the Democrats' political opportunity to create an "unconditional war on poverty in America," which came to include support for Medicare and Medicaid. *Id.* at 366 (quoting President Johnson's Jan. 8, 1964 speech to both houses of Congress)).

<sup>20</sup> STARR, *supra* note 1, at 374-78 (noting the importance of "buffers" between health care providers and federal bureaucracy and the favorable cost calculations for the hospital industry).

<sup>21</sup> See Kenneth E. Thorpe and James R. Knickman, *Financing for Health Care*, in *HEALTH CARE DELIVERY IN THE UNITED STATES* 32,34 (Anthony R. Kovner & Steven Jones eds., 1999).

a set of strategies to control costs: in 1973, the HMO Act,<sup>22</sup> in 1974, the Health Planning and Resource Development Act<sup>23</sup> with its Certificate of Need requirements. Employers were also looking for solutions—cost-shifting from themselves to the employees through deductibles on coverage, dropping of dependents—a pattern that has intensified in recent years.

By 1995, the federal share of health coverage was 45%<sup>24</sup> Medicare was the spigot that few foresaw at the time of its passage. The consequence of the opening of this federal spigot was a seesaw battle between providers and their lawyers, and the government, its lawyers, and accountants, to control costs by finding ways to limit reimbursement. The cat-and-mouse game had begun.

### E. Government - Provider II: Cost Panic

Physician + Insurance + Government + Patient + Escalating Use of  
Technology + Naysaying on Spending = PIGPEN

The money still flowed into the system, but pressures mounted as the players fought over the tightening resources, like pigs at the trough in their pigpen. Blue Cross had become a fiscal intermediary, in effect managing the flow of federal dollars from the Medicare program. The Blue Cross plans and hospitals proved adept at shifting hospital costs onto Medicare through a range of apportionment techniques.<sup>25</sup> The federal government was aware of the problem.

In 1973, I handled a Medicare reimbursement hearing for a large Boston hospital under attack by the Government Accounting Office for purported overcharges to the Medicare program for a range of services. The amount of money at stake, around \$300,000, seems like small change compared to today's disputes, but it was the opening shot in a long term battle over proper use of Medicare dollars. The federal government had already begun to lose patience with hospitals by the early 1970s. Medicare had only been in place since 1966, but

<sup>22</sup> Health Maintenance Organization Act of 1973, Pub. L. No. 93-222, 87 Stat. 914 (codified as amended at 42 U.S.C. §§ 300e to 300e-17 (2000)) (amending the Public Health Service Act to promote the establishment of HMOs).

<sup>23</sup> National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (codified as amended at 42 U.S.C. §§ 300q to 300t-14 (2000)) (promoting the development of both national and state planning for health services and authorizing financial assistance toward that end).

<sup>24</sup> Thorpe and Knickman, *supra* note 21, at 35.

<sup>25</sup> See SYLVIA A. LAW, BLUE CROSS: WHAT WENT WRONG? 59-114 (1974) (describing some of the techniques for cost-shifting to Medicare and the failure of HEW, now HHS, to properly regulate this practice).

as health care cost inflation heated up, the government had begun to tighten its reimbursement policy and improve its auditing procedures out of a rapidly growing unease about fraud and waste in the Medicare program. Regulation by contract became the norm for federal-provider relationships, and the proliferation of reimbursement rules for Medicare gave rise to a new subspecialty of practice within health law. Health law practice was still classified under the rubric of law and medicine in the 1970s, and most lawyers thought of such a practice as mostly bringing or defending medical malpractice cases, handling an occasional staff privilege dispute, or working on a bond issue for hospital construction. But those who had hospital clients could see that reimbursement disputes were going to become a larger and larger percentage of the practice.

The mid-1970s saw renewed interest in health reform by three administrations: Nixon, Ford and Carter. The rapid growth in health care cost inflation was fed by forces set free in earlier stages: a federal decision to fund biomedical research at a high level,<sup>26</sup> rapid expansion of the physician supply,<sup>27</sup> funding for construction and upgrading of hospitals through the Hill-Burton Program,<sup>28</sup> and restructuring of health care financing.<sup>29</sup> Hospitalization costs grew, so private health insurance grew to fit this need.

Health care presented a perverse economic market. For several decades, payment was available for relatively unlimited care through both private and public insurance. Hospitals did not compete based on price; they had access to bond funding at subsidized rates for construction and expansion. They competed for physicians who could fill their beds. Physicians had a monopoly on the practice of medicine and were not subject to any manpower policy requirements that seriously confronted geographic shortages, so that low income urban and rural residents were underserved or not served at all. This market had become the health lawyer's playground, a nightmarishly complex and fragmented system of overlapping nonprofit, for-profit, and government sectors, without a counterpart in any other area of the American economy.

Technology was becoming a cost driver in a big way. Investment in medical research was reflected in a growth in the National Institute of Health (NIH) budget from \$81 million in 1955 to \$400 million five years later in 1960.<sup>30</sup> Hospitals and physicians were avid users of the

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<sup>26</sup> STARR, *supra* note 1, at 338-347.

<sup>27</sup> *Id.* at 421-422.

<sup>28</sup> *Id.* at 348-49.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.* at 347.

newest technology, which was hawked by the makers, sought by doctors and hospitals to maximize their prestige and cutting edge reputations, and paid for without sufficient reflection by private and public payers—a formula for inflation and harm to patients.

#### F. Corporate - Provider Relationships

Systems + Knuckle under + Integration + Management + Patients =  
SKIMP

Cost pressures continued to mount, and everyone in the system, from employers to the federal government, looked for a way to skimp on health care payments. The late 1980s and early 1990s saw a period of hyper-entrepreneurship, with for-profit hospitals beginning to acquire non-profits, and for-profit managed care plans expanding rapidly.<sup>31</sup> The hospital as the hub of healthcare began to fade. One of the secondary consequences of the DRG program and its set prices for diagnosis-related groups within the hospital was to move many procedures out of the hospital to unregulated settings. The result by now is that most medical encounters occur in non-hospital settings,<sup>32</sup> and outpatient surgery as a percent of total surgical procedures has gone from 16.4% in 1980 to 54.9% by 1993, and the percent continues to increase.<sup>33</sup> Between 1985 and 1995 alone, 538 community hospitals closed.<sup>34</sup> During the same period, there was an absolute decline in admissions from nearly 3345 million to 3094.5 million and a 16% decline in inpatient days from 236.6 million to 199.9 million.<sup>35</sup> Group practices, ambulatory care centers, home health agencies, subacute units, and hospices grew in part as a response to this shift in location of patient care. The hospital had become less central to the delivery of many surgical services. The delivery of health care became corporatized in the 1980s, the direct result of a desire by the government to provide a method for cost control without using regulatory tools such as price controls. Managed care was chosen as the market tool to bring inflation under control, coming to dominate the market by the

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<sup>31</sup> See ROBERT KUTTNER, *EVERYTHING FOR SALE: THE VIRTUES AND LIMITS OF MARKETS* 134 (1997) (describing the “hyper-entrepreneurial environment of the 1990s”).

<sup>32</sup> Andrew P. Mezey, *Ambulatory Care*, in *HEALTH CARE DELIVERY IN THE UNITED STATES* 183, 186 (Anthony R. Kovner & Steven Jones eds., 1999).

<sup>33</sup> *Id.* at 196.

<sup>34</sup> Anthony R. Kovner, *Hospitals*, in *HEALTH CARE DELIVERY IN THE UNITED STATES* 157, 161 (Anthony R. Kovner & Steven Jones eds., 1999) (using American Hospital Association statistics).

<sup>35</sup> *Id.*

1980s and 1990s.<sup>36</sup> The 1973 HMO Act was passed to counter health care cost inflation in the 1960s and early 1970s with the discipline of private plans that would “manage” doctors and hospitals to keep costs under control.<sup>37</sup> Managed care began to develop, spurred by federal policy and by a marketplace appetite for better cost controls from the employers’ perspective. The use of capitation by the modern managed care organization, and its focus on cost-effective treatment, is a modern update of the early history of health maintenance organizations.<sup>38</sup> During this period the Medicare and Medicaid programs were facing rapidly growing costs, while critics noted that American health care was badly mal-distributed, limiting access by the poor and rural resident, and was inefficiently administered and inferior in many of its delivery components.<sup>39</sup> The country was perceived to face a national “crisis” in health care in 1970, driven by escalating costs of “usual, customary, and reasonable” reimbursement and fee-for-service medicine. Under the Nixon administration, the Department of Health, Education and Welfare (HEW) consulted with Paul M. Ellwood, Jr., a Minnesota physician, founder of Interstudy, and an advocate of the restructuring of financial incentives in the private medical sector. Ellwood argued that the financing system should reward health maintenance through prepayment for comprehensive care.<sup>40</sup> This health maintenance strategy was viewed as self-regulating, not needing a new federal bureaucracy to manage it. The strategy appealed to a Republican administration hostile to big government. President Nixon adopted the HMO strategy as a cornerstone of his new national health policy, as did then Governors Ronald Reagan and Nelson

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<sup>36</sup> For the origins of the managed care strategy, see STARR, *supra* note 1, at 394-98.

<sup>37</sup> *Id.* at 396-97.

<sup>38</sup> “[T]hroughout the 1800s, [various immigrant groups and their employers] pioneered capitated health care and organized delivery of services.” Emily Friedman, *Capitation, Integration, and Managed Care Lessons from Early Experiments*, 275 JAMA 957, 957 (1996). Businesses such as railroads, sugar plantations, and lumbering companies wanted to attract immigrant labor and retain it, often in isolated locations in an undeveloped United States. The provision of health services was an important way of attracting new labor and reducing labor turnover. Three of the major organizing principles that underpin managed care were visible early: security to the employee that all necessary care would be provided so long as the employment status continued; financial risk-bearing by employers and/or providers, through salary as the mode of payment instead of fee-for-service; and a focus on prevention or wellness in many of the programs, as part of business goals of maintaining a healthy workforce, and as a way of reducing the costs of chronic illnesses to the plan. See generally *id.*

<sup>39</sup> STARR, *supra* note 1, at 381 (citing *It’s Time to Operate*, FORTUNE, Jan. 1970, at 79).

<sup>40</sup> *Id.* at 395.

Rockefeller for their states.<sup>41</sup> Congress passed the 1973 HMO Act, which required employers to offer at least one qualifying HMO as an alternative to conventional insurance in their health benefit plans, if a qualifying HMO was in the vicinity.<sup>42</sup> By 1976, momentum toward HMO growth increased as Congress amended the law to increase federal aid to HMOs. HMO enrollment began to increase more rapidly.<sup>43</sup> Managed care, in all its myriad forms, became the insurance mechanism of choice in many places.

Solo practice, once the norm in American medical practice, began to disappear as managed care spread. By one prediction, the percentage of patient-care physicians in group practice will increase from 46% in 1996 to around 60% by 2005.<sup>44</sup> Physicians have lost workplace autonomy as a result, even as they have gained a stable and predictable guarantee of patients to treat. Institutions that provide health care, such as hospitals or nursing homes, and entities that pay for health care, including insurers and self-insured employers, now oversaw the work of the medical professionals who practice within them or whose care they purchase. The emergence of managed care organizations that both pay for and provide care gave lay managers even greater control over medical practice, in the name of both cost containment and quality of care.

Shifting loci of market power in health care created new tasks for health lawyers. As physicians struggled to adopt new methods for dealing with powerful systems, they needed lawyers to improve their negotiations, draft their agreements, and help them sort out the complexities of reimbursement. Likewise, as physicians went from control of the old hospital model, through the staff privileging system, to a need to aggregate to gain power to deal with integrated systems and economic credentialing modern hospitals used to improve their revenues. In response, during the 1990s, Independent Practice Associations (IPAs), Physician Hospital Organizations (PHOs), Management Service Organizations (MSO), and foundation, staff, and equity models developed, as transactional lawyers worked to create new corporate forms for the new health care economy.

The corporatization movement also took the form of a management paradigm of continuous quality improvement and clinical re-

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<sup>41</sup> *Id.* at 396.

<sup>42</sup> *Id.* at 400-01 (for businesses with more than twenty-five employees).

<sup>43</sup> *Id.* at 415 (stating that enrollment increased 1.4 million over the year before and by mid-1979, total enrollment was 7.9 million people, which was double that in 1970).

<sup>44</sup> INST. FOR THE FUTURE, HEALTH AND HEALTH CARE 2010, at 80 (2d ed. 2003).

engineering, concepts borrowed from industry. The concept of continuous quality improvement (CQI) was touted to identify variation from desired outcomes and correct it through protocols, pathways, and clinical information systems.<sup>45</sup> Outcomes measurement began to be developed in a cost-sensitive, consumer-oriented health care marketplace. Purchasers began to look at risk-adjusted mortality and morbidity rates, functional health status post-hospitalization for procedures such as hip replacement surgery, and at community health status measures such as immunization rate and levels of domestic violence. Health maintenance organizations came to pay for more comprehensive preventive care than traditional fee-for-service plans did, as HMO managers understood that an HMO is responsible for the health of a defined population, rather than for a series of individuals with individual health problems. Unfortunately, the pressures of competition in local markets drove managed care to compete primarily on price, with a shift away from population health and prevention.

The United States has resisted centralized arrangements for health care.<sup>46</sup> We have ended with this shift to more and more for-profit health care, but without visible evidence of either strong cost control or quality improvement. Instead, we have achieved a very high level of administrative overhead, reflecting a competitive market for insurers and providers with their inherent marketing and administrative costs.

Lawyers work for these private companies doing regulatory and transactional work, for hospitals now subject to a variety of both market and regulatory constraints, for the vast drug industry, and for physicians as they struggle to maintain office practices and negotiate contracts with managed care companies.

## **II. THE (PROBABLY?) PREDICTABLE FUTURE ENVIRONMENT OF HEALTH CARE DELIVERY: MORE**

Forecasting is notoriously difficult, and our health care future is complicated to predict, given the confluence of enormous amounts of

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<sup>45</sup> See generally Timothy Stoltzfus Jost, *Oversight of the Quality of Medical Care: Regulation, Management, or the Market?* 37 ARIZ. L. REV. 825 (1995) (exploring the continued role of regulation of quality of care in an industry dominated by management and the market).

<sup>46</sup> E.g. Uwe E. Reinhardt, *Is There Hope for the Uninsured?*, HEALTH AFF.: WEB EXCLUSIVE W3-376 (Aug. 27, 2003), at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.376v1.pdf> (predicting that universal health insurance coverage in the U.S. is unlikely to occur).

money in the system, intense political pressures, and high status professionals.<sup>47</sup>

#### A. Managed Care Will Retreat and New Models Will Emerge

Managed care will continue to dominate the delivery of care, but in a looser, less physician- and patient-constraining form, and without many of the tools of effective cost management with which it began. Employers will be more demanding about quality as well as price, given that by 2007 over two-thirds of the American population will be enrolled in HMOs and PPOs.<sup>48</sup> Health care costs will, however, continue to increase for employees. Per employee premium growth is expected to be at around 11 %.<sup>49</sup> Employers are struggling with whether to absorb costs or shift them to employees. Managed care may be less managed, but the form will continue to dominate.

The newest model to emerge, as yet unproven as to efficacy or consumer acceptance, will be defined contribution health insurance. Benefits managers in corporations are more willing to experiment with these plans that use the Internet to market their products. They appear to give employees greater choice in health care decisions, although the choices are often complicated. These products suit the ideology of the moment, allowing employers to shift costs and creating the appearance of control on the part of employees frustrated with managed care.<sup>50</sup>

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<sup>47</sup> See generally Theodore R. Marmor, *Forecasting American Health Care: How We Got Here and Where We Might Be Going*, 23 J. HEALTH POL. POL'Y & L. 551 (1998) (reviewing conditional forecasting of the past and exploring alternative scenarios for the future of American health care policy).

<sup>48</sup> INST. FOR THE FUTURE, *supra* note 44, at 72.

<sup>49</sup> Stephen Hefler et al, *supra* note 10, at W3-54-56.

<sup>50</sup> See generally Jon B. Christianson et al., *Defined-Contribution Health Insurance Products: Development and Prospects*, HEALTH AFF., Jan.-Feb. 2002, at 49 (explaining defined-contribution health insurance products and their impact on the health care market). These products have the following attributes:

(1) A portion of the employer's contribution toward employee health benefits is placed in an account from which the employee purchases services with tax-advantaged dollars. (2) A major medical . . . insurance policy is purchased with a portion of the employer's contribution. (3) Employees could, in any given year, need to spend their own dollars to cover an "actuarial gap" between the cost of services purchased using dollars in the "health spending account" . . . and the services covered by the insurance policy. (4) The Internet is used to facilitate and support employees' purchasing decisions. *Id* at 51.



### B. Organizations Will Fight Back

Hospitals will continue to be the emergent winners in their battle with managed care, having gained negotiating leverage and higher reimbursement rates. In his discussion of the recent shift in power away from managed care, Jacobson notes that “[u]nder pressure to close unneeded beds and to streamline operations, the number of hospitals has declined by nine percent (9%) since 1990, even as the population has increased.”<sup>51</sup> The consolidation of hospitals into larger chains, equivalent in size and power to large managed care plans, has allowed them to receive a higher price for their services.<sup>52</sup> Short term at least, hospitals will recapture some lost income. Over the longer term, it appears that power will shift to newer models of delivery, as intermediaries will become much more important. Disease management companies, case managers, and health plans will take a more active—and profitable role—in directing patient care.<sup>53</sup> Physicians on the other hand will continue to lose autonomy as the result of a surplus, a change to employee status, and continued pressures on their incomes.<sup>54</sup>

### C. Reimbursement Will Continue to Tighten

The use of maintenance drugs is increasingly important for treating chronic illness. Protease cocktails for AIDS, Lipitor and other statins for lowering cholesterol, Fosamax for osteoporosis, and psychotropic drugs for mental illnesses are all part of a rapidly growing list. But the powerful products of pharmaceutical innovation are also an escalating cost for state and federal budgets, as the battle in Congress over prescription drug benefits in the Medicare program demonstrates. The revenue losses of recession and the costs of war mean continued reimbursement battles, as the budgetary pie is divided into more pieces. Patients will end up with more of the costs imposed on them through co-payments, deductibles, and large premium costs for workplace insurance.

### D. Errors in Medicine Will be Spotlighted

The Institute of Medicine, in its reports, has put medical error at the forefront of the national debate on medicine, its costs as well as its

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<sup>51</sup> Peter D. Jacobson, *Who Killed Managed Care? A Policy Whodunit*, 47 ST. LOUIS U. L.J. 365, 388 (2003).

<sup>52</sup> *Id.*

<sup>53</sup> INST. FOR THE FUTURE, *supra* note 44, at 67-80.

<sup>54</sup> *Id.* at 68.

benefits.<sup>55</sup> The patient safety movement is gathering momentum, and the drug delivery system and its flaws is gaining attention. Pharmacists will become more important as a first line of defense in detecting drug problems, since the doctor's office and ambulatory care setting generally lacks a checks and balance system: no one checks dosage, frequency, or duration. Reporting of medical errors and near misses, the sentinel events of error detection, will be demanded of hospitals and other institutions as the level of errors begins to be understood by consumers. And the tort system may finally be altered in experiments with enterprise liability, placing liability on the institutions that deliver care rather than just on the physicians at the front lines of that care.

These predictions are based on the status quo and its most probable evolution. I do not predict big changes in the mode of delivery of health care or its financing, or significant improvements in funding for improving access for the poor. But the future is subject to the forces of health lawyers as well as other players in the health care system. Below I suggest some roles for lawyers that may have an effect on the evolution of the health care system.

### III. THE FUTURE OF HEALTH LAW: PROTECT

I use the acronym PROTECT advisedly, for protection can be a problem for the goals of the health care system. Whom are we protecting, we health lawyers? And what are the primary and secondary consequences of the kinds of protection that good lawyering provides? I will offer here a range of positive protective functions that health lawyers can serve.

#### A. Promoting Quality

Quality and its mirror image of error reduction have moved into the limelight with the Institute of Medicine report, particularly *To Err*

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<sup>55</sup> See generally COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., 2000) (discussing current research on medical errors and the implications for American health care); COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., *CROSSING THE QUALITY CHIASM: A NEW HEALTH SYSTEM FOR THE 21<sup>ST</sup> CENTURY* (2001) (discussing methods for improving the quality of the current health care system); COMM. ON RAPID ADVANCE DEMONSTRATION PROJECTS: HEALTH CARE FINANCE AND DELIVERY SYSTEMS, INST. OF MED., *FOSTERING RAPID ADVANCES IN HEALTH CARE: LEARNING FROM SYSTEM DEMONSTRATIONS* (Janet M. Corrigan et al. eds., 2003) (describing demonstration projects that could aid in health system change or redesign).

is Human.<sup>56</sup> This report brought to the attention of the public and policymakers the high level of patient injury in our health care system, and how chaotic and uncoordinated much health care is. As a result, patient safety programs are being developed, and pressure from the Centers for Medicare and Medicaid Services (CMS), the Joint Commission on Accreditation of Health care Organizations (JCAHO) and states have spurred incident reporting requirements for hospitals. Private industry, through organizations such as the LEAPFROG Group, is attempting to force providers to provide more cost-effective “quality” care through the use of some fairly simple principles.<sup>57</sup> The National Committee for Quality Assurance (NCQA) continues to accredit managed care plans, and its requirements provide useful information for consumers about the relative merits of various plans.<sup>58</sup> CMS has also issued new rules and has demonstration projects underway, as it moves to adopt the values of the patient safety movement.

Malpractice suits will continue, as erosion of ERISA preemption has opened the door to suits against managed care plans. Lawyers are suing more, finding solid clinical practice guidelines to set the standard of care, and finding ways to make plans pay for their errors that harm patients. The countercurrent here is the temptation by state legislatures to provide varying degrees of protection for providers, through immunity legislation, caps on the amount of possible recovery in suits, and other strategies for limiting the efficacy of tort litigation. But perhaps the time is finally coming for effective reform of the malpractice system to improve its workings, not as the AMA would like, to make it go away.

### B. Restraining Conflicts of Interest in Research

The scare stories of research gone bad—the deaths of Jesse Geisinger at the University of Pennsylvania and Ellen Roche at Johns Hopkins—have sensitized us to the risks of research. Both government scrutiny and tort liability now exist for research that is poorly

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<sup>56</sup> TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM, *supra* note 61.

<sup>57</sup> See The Leapfrog Group, *Fact Sheet*, at [http://www.leapfroggroup.org/FactSheets/LF\\_FactSheet.pdf](http://www.leapfroggroup.org/FactSheets/LF_FactSheet.pdf) (Oct. 2003) (focusing on comparing health care provider information, rewarding providers for protecting patients from preventable errors, utilizing accountability mechanisms, and creating favorable purchasing environments for all clients as ways to improve patient safety).

<sup>58</sup> See National Committee for Quality Assurance, *NCQA Overview: Measuring the Quality of America's Health Care*, at <http://www.ncqa.org/Communications/Publications/overviewncqa.pdf> (June 2003).

designed and /or exposes subjects to conflict of interest situations.<sup>59</sup> New regulatory initiatives have been proposed for reducing conflicts of interest, from the Association of American Medical Colleges, the Association of American Universities, and the Department of Health and Human Services (DHHS). New accreditation actions are also being developed by the Association for Accreditation of Human Research Protection Programs (AAHRPP) and the National Council for Quality Assurance (NCQA).<sup>60</sup> The Office of Human Research Protections is moving from a compliance focus to a prevention focus.<sup>61</sup> The FDA is hunting for conflicts of interest under its existing rules.<sup>62</sup> In other words, more pervasive regulatory efforts are developing, requiring lawyers to interpret them for institutional clients to insure compliance with state and federal laws. This is a positive development, a counterbalance to the corruptive power of money in a research environment where hopes for biotechnology and other new scientific developments are primary.

### C. Orchestrating Medical Information Protections

The Health Insurance Portability and Accountability Act's (HIPAA) medical privacy regulations are now fully in effect.<sup>63</sup> These regulations have several goals. They aim to improve patient trust in the health care system by removing the risks that private confidential health care information will be leaked or circulated widely to those outside the limited treatment team.<sup>64</sup> The regulations aim to protect proper treatment, while allowing providers full discretion in determining when sending patient records to other providers for treatment purposes.<sup>65</sup>

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<sup>59</sup> See, e.g., Sherman, Silverstein, Kohl, Rose & Podolsky Law Offices, Clinical Trials Litigation, at <http://www.sskrplaw.com/gene> (last visited Nov. 16, 2003) (listing some recent high profile clinical research litigation cases).

<sup>60</sup> See [www.aahrpp.org/index.html](http://www.aahrpp.org/index.html) for information on the activities of AAHRPP and [www.ncqa.org/Programs/Accreditation/PHRP/phep.hrm](http://www.ncqa.org/Programs/Accreditation/PHRP/phep.hrm) for the NCQA's initiative, the Partnership for Human Research Protection, Inc. Accreditation Program.

<sup>61</sup> See generally OFFICE OF HUMAN RESEARCH PROTECTIONS, D.H.H.S., QUALITY IMPROVEMENT PROGRAM, at <http://ohrp.osophs.dhhs.gov/humansubjects/qip/qip.htm> (last visited Dec. 29, 2003).

<sup>62</sup> See, e.g., F.D.A., POLICIES AND PROCEDURES FOR HANDLING CONFLICTS OF INTEREST WITH FDA ADVISORY COMMITTEE MEMBERS, CONSULTANTS, AND EXPERTS, at [www.fda.gov/oc/advisory/conflictinterest/guidance.html](http://www.fda.gov/oc/advisory/conflictinterest/guidance.html) (July 14, 2003).

<sup>63</sup> 45 C.F.R. §§ 164.500-164.534 (2003).

<sup>64</sup> See Preamble, 65 Fed. Reg. 82,462.

<sup>65</sup> See generally HHS, FACT SHEET: PROTECTING THE PRIVACY OF PATIENTS' HEALTH INFORMATION, at <http://aspe.hhs.gov/admsimp/final/pvcfact2.htm> (May 9, 2001).

The administrative obligations of health care entities are substantial under the medical privacy rules of HIPAA. Entities must establish and implement policies, procedures and enforcement activities that govern their use and disclosure of individually identifiable health information.<sup>66</sup> The law requires a privacy compliance officer in each institution to develop policies.<sup>67</sup> This officer is to receive complaints and provide further information regarding patient privacy notice materials; provide training for all existing and future members of the provider's workforce; establish a complaint process for noncompliance; and implement and enforce sanctions.<sup>68</sup> HIPAA is a large mandate, requiring a new generation of health law specialists to interpret and apply the law in the hospital and office practice settings. Its goal is to reform one aspect of the often chaotic operation of health care institutions: record keeping. It is part of a larger effort to produce uniform electronic medical records in order to better integrate the fragmented American institutional delivery system, a goal which should produce quality benefits for patients.

The computerized patient record has hardly followed inexorably on the heels of the major new set of regulatory mandates that the HIPAA regulations have brought. The United States lags other countries in this area, which is not surprising considering the lack of a national health service or single payor, which means the government lacks muscle to drive providers rapidly toward a uniform system. Once again, the drawbacks of an antiquated and fragmented system are clear.<sup>69</sup>

#### D. Thrashing Bad Ideas

Health care policy is no different from any other subject of debate in our country. The facts often are obscured by the carefully crafted campaigns of vested interests of all kinds, and at times the facts, and good ideas, are simply not being broadcast for lack of a broadcaster. And these bad ideas can too easily become conventional wisdom with enough repetition on talk radio and in newspaper editorials. This is where the academic health lawyer has the largest role to play as analyst and surveyor of the academic literature in the field. Consider some of our most dearly held beliefs. We believe we have a great

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<sup>66</sup> *Id.*

<sup>67</sup> 45 C.F.R. § 164.308(a)(2).

<sup>68</sup> *Id.*

<sup>69</sup> See Jeff Goldsmith et al., *Federal Health Information Policy: A Case of Arrested Development*, HEALTH AFF., July-Aug. 2003, at 44 (discussing the problems of inaccessibility, fragmentation, and cost associated with the present, technologically inadequate system for maintaining patient records).

health care system, and yet by the measures of the World Health Organization, many other countries score higher on multiple criteria even though we spend almost twice as much as most of these countries.<sup>70</sup> We think that we are a generous people, and yet as Paul Krugman writes, we are a Scrooge nation when it comes to foreign aid for poorer countries for their health needs.<sup>71</sup> We believe the rhetorical railings of the American Medical Association about the evils of malpractice litigation, while the reality is far more complicated and the problems more scattered.<sup>72</sup> We believe that uninsured Americans always manage to get care when they need it through hospital emergency rooms and free care. This is not true most of the time, and even when care is given, it is often too little too late.<sup>73</sup>

One of the tasks of the academic health lawyer is to promote accuracy in debates over health care—to ensure that the facts are correct, the data meaningful, and the ideas meritorious. The power of the various lobbies in health care demands strong countervailing power to detect the errors in argument and help guide policymakers away from legislating based on misinformation.

### E. Energizing Public Health

The anthrax attacks of 2001 brought public health concerns back into the limelight briefly, as the public was suddenly reminded about this backwater of health practice.<sup>74</sup> Public health is a large area, encompassing assessment of community health status and needs; policy development based on scientific knowledge and government leadership; and access to health services. The federal government provides leadership and accountability, while much public health is handled at

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<sup>70</sup> *E.g.* WORLD HEALTH ORG., THE WORLD HEALTH REPORT 2000: HEALTH SYSTEMS: IMPROVING PERFORMANCE 200 (2000) (providing statistical information and rankings for health care systems in different nations).

<sup>71</sup> PAUL KRUGMAN, THE GREAT UNRAVELING 379 (2003); Microsoft founder Bill Gates, to his credit, is single-handedly more generous than the U.S. government in his AIDS grants in Africa.

<sup>72</sup> *See* G.A.O., MEDICAL MALPRACTICE: IMPLICATIONS OF RISING PREMIUMS ON ACCESS TO HEALTH CARE 20, 26-27, 38-41 (2003) (questioning the results of a recent AMA member survey), available at <http://www.gao.gov/new.items/d03836.pdf> (Aug. 8, 2003).

<sup>73</sup> *See, e.g.*, COMM. ON THE CONSEQUENCES OF UNINSURANCE, INST. OF MED., HIDDEN COSTS, VALUE LOST: UNINSURANCE IN AMERICA (2003) (discussing the ultimate costs to American society, including lack of workforce productivity and financial stress on families and institutions, stemming from the lack of health insurance).

<sup>74</sup> *See generally* BARBARA HATCH ROSENBERG, FED’N AM. SCIENTISTS, ANALYSIS OF THE ANTHRAX ATTACKS, (2002), at <http://www.fas.org/bwc/news/anthraxreport.htm> (last modified May 12, 2003) (outlining the chronology of events relating to the anthrax attacks).

the local and state levels. AIDS infections, ground water contamination, epidemics, bioterrorism, West Nile disease, gun violence—the list of public health issues is a long one.<sup>75</sup> Public health is, therefore, a major aspect of health policy. Few lawyers specialize in public health law, since there are few government jobs in this specialty. And for good reason—the federal government's social vision has narrowed over the past three decades, as the safety net has been privatized, and we have spent less on infrastructure, education and research, dropping spending from 24% at its peak in the 1980s to 14% of the budget in 1999.<sup>76</sup>

#### F. Controlling Provider Avarice

One of the real growth areas in health law has been the area of fraud and abuse. Medicare and Medicaid fraud and abuse costs federal and state governments tens of billions of dollars per year.<sup>77</sup> The billions of dollars paid by the federal government entitle it to enforcement by contract. As a result, health care providers are subject to a large body of law governing their financial arrangements with each other and with payors. These state and federal laws cover many practices that amount to fraud, bribery, or stealing. They also prohibit many contractual relationships, investments, and marketing and recruitment practices that are perfectly legal in other businesses. These laws seek to rectify a number of serious flaws in the health care financing system, save the government money, and prevent conflicts of interest that taint the physician-patient relationship. HIPAA<sup>78</sup> expanded federal enforcement powers substantially. The law expands certain criminal sanctions, such as the anti-kickback law, to cover all federal and state financed health care programs (except the federal employee benefits program); creates new criminal health care offenses that apply to abuses affecting private as well as public payment plans; broadens the authority of the Office of the Inspector General (OIG), Federal Bureau of Investigation (FBI), and the Department of Justice

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<sup>75</sup> See generally LAW IN PUBLIC HEALTH PRACTICE (Richard A. Goodman et al. eds., 2003).

<sup>76</sup> INST. FOR THE FUTURE, HEALTH AND HEALTH CARE: 2010: THE FORECAST, THE CHALLENGE 169 (Charles Grosel et al. eds., 2d ed. 2003).

<sup>77</sup> E.g. Jerry L. Mashaw & Theodore R. Marmor, *Conceptualizing, Estimating, and Reforming Fraud, Waste, and Abuse in Healthcare Spending*, 11 YALE J. ON REG. 455, 488 (1994) (stating that a consensus has developed that fraud and abuse contributes 10%, or \$80 billion, to total health care spending, although "no one really knows what the correct number is").

<sup>78</sup> Pub. L. No. 104-191, § 110 Stat. 1936 (1996) (codified as amended in scattered sections of 42 U.S.C.).

(DOJ) to investigate all health care fraud, regardless of payment; establishes health care fraud, theft or embezzlement and other conduct not limited to federal programs as federal offenses; increases the OIG's administrative penalty authority by increasing fines, prescribing new minimum periods of exclusion, and authorizing exclusions of investors, officers and directors of sanctioned entities; and provides enhanced funding to finance and coordinate federal and state enforcement as well as establishing a trust fund into which criminal and civil penalties are paid and used to finance future fraud and abuse efforts.

The fraud and abuse laws have been used to bring to justice a large number of providers, including some major corporate entities, engaged in systematic fraud. The rules are extremely complicated, generating confusion and the resulting need for legal interpretation. These laws have had a profound impact on the health care industry and have created an enormous amount of work for health care lawyers designing organizational structures that must comply with their strictures. The powerful regulatory reach of the fraud and abuse laws are a direct response by the federal government to the size of the American system, its fragmentation, and the opportunities for avarice and corner-cutting in health care institutions.

#### G. Turning the Tide

The United States lacks universal health insurance, and that goal is sliding farther and farther away as the federal deficit grows. Income inequality in the country continues to increase, as does lack of access to health coverage.<sup>79</sup> Is there a way to persuade the nation's political leadership that it is, in Uwe Reinhardt's words, "a moral imperative to provide every American family with the physical and fiscal protection that comes with health insurance, as it was in Taiwan, whose political leadership introduced universal coverage in that country in 1995"?<sup>80</sup> Reinhardt makes compelling arguments that universal health insurance is not only a morally compelled policy, but also makes good economic sense. Health lawyers, from transactional to governmental to academic, may not agree on the shape or nature of such universal coverage, but they could be united behind the merits of such a concept. In an economic period when even professionals are afraid to retire for fear of losing employment-based insurance, we are all beginning to empathize with the plight of the poor in our society.

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<sup>79</sup> See generally COMM. ON THE CONSEQUENCES OF UNINSURANCE, INST. OF MED., *supra* note 73.

<sup>80</sup> Reinhardt, *supra* note 46, at W3-383.



Health care needs to be a central part of the debate in local and national elections again. The failure of Clinton's Health Security Act has stalled political debate of universal coverage for too long.<sup>81</sup> It is time for health lawyers to energize this national discussion, with a goal of making this country one to be proud of, instead of apologetic for. Politicians are influenced by their more affluent constituents far more than by the poor.<sup>82</sup> What can be more effective than for health lawyers to ask their congressmen to make health care access a central concern of state and national lawmakers? Health lawyers have fiduciary roles to play as professionals, and expanding health care coverage is at the heart of what such a fiduciary duty can mean.

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<sup>81</sup> Cf. Robert J. Blendon et al., *Where Was Health Care in the 2002 Election?*, HEALTH AFF.: WEB EXCLUSIVE W2-426, W2-431 (Dec. 11, 2002), at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.426v1.pdf> (explaining the modest role that health affairs played in the 2002 congressional elections).

<sup>82</sup> See Reinhardt, *supra* note 46, at W3-388 (citing to a paper by Larry Bartels, *Economic Inequality and Political Representation*, in which Bartels concludes from a statistical analysis of senators' roll-call behavior that they "'appear to be much more responsive to the opinions of affluent constituents than to the opinions of constituents with modest incomes . . . . The preferences of constituents near the top of the income distribution are even more influential, while those at the bottom fifth receive little or no weight'").