

Saint Louis University Law Journal

Volume 49
Number 1 *Administrative Law Meets Health
Law: Inextricable Pairing or Marriage of
Convenience? (Fall 2004)*

Article 3

12-1-2004

Health Law and Administrative Law: A Marriage Most Convenient

Timothy Stoltzfus Jost

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



Part of the [Law Commons](#)

Recommended Citation

Timothy S. Jost, *Health Law and Administrative Law: A Marriage Most Convenient*, 49 St. Louis U. L.J. (2004).

Available at: <https://scholarship.law.slu.edu/lj/vol49/iss1/3>

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

**HEALTH LAW AND ADMINISTRATIVE LAW:
A MARRIAGE MOST CONVENIENT**

TIMOTHY STOLTZFUS JOST*

This symposium explores the complex relationship between health law and administrative law. It is based on the observation that these two fields of law are peculiarly intertwined. It attempts to understand why this is so, as well as whether it is necessary and whether it is desirable. Would we as a society, that is, be better off if health law were less permeated by administrative law? Even if we would be better off, is it indeed possible to extricate health law from administrative law?

This essay begins by defining health law and administrative law. It then proceeds to describe the function of law, the institutions through which law is made and applied, and how law is made and applied in the health-care industry, demonstrating the prominent role of administrative entities in health care. It next examines why the close relationship between health law and administrative law exists. In particular, it considers and rejects the thesis that this close relationship is an artifact of history. The article goes on to develop an alternative hypothesis that administrative entities play a major role in overseeing the delivery and finance of health care because of the need for such oversight and the lack of superior institutional alternatives. This essay concludes by considering why this permeation of health law by administrative law is likely to continue, and why this may not be such a bad result.

I. WHAT IS HEALTH LAW? WHAT IS ADMINISTRATIVE LAW?

To begin this exploration, we must define our terms. Health law and administrative law describe domains of law, but they represent different approaches to classification. Health law encompasses law as it affects a

* Robert Willett Family Professor, Washington and Lee University School of Law. The author wishes to thank the Saint Louis University School of Law and Health Law Program (including Sandra Johnson, Tim Greaney, and Nick Terry), which sponsored this symposium; Eric Claeys, who dreamed it up; John Griesbach and Robert Schwartz for their commentary; the participants in the Washington and Lee University Lewis Law Center Faculty Enclave who vetted an early version of it (and in particular Blake Morant, Mark Grunewald, Brian Murchison, David Super and Lash LaRue); and the Francis Lewis Law Center for a summer research grant that funded my work on this paper.

particular industry—the health-care industry.¹ For the purposes of this article, I define health law to include law that governs the relationships among health-care providers, professionals, patients, and the government with respect to the organization, provision, and financing of health care. It is, therefore, neither a distinct body of substantive law nor of procedural law, but rather a very broad and disparate category, tied together only by the fact that it includes law that governs a particular industry. Because that industry, however, is our largest industry,² encompassing nearly one-seventh of our economy,³ and intimately affecting each of our lives on a regular basis—occasionally literally in matters of life and death—the law that governs this industry is of vital importance.

The emergence of health law as a distinct body of law is relatively recent. The study of medical law—forensic medicine and medical negligence—dates back to the nineteenth century, while bioethics emerged as a field of study in the 1970s.⁴ Health law, as broadly defined above, began to appear as a distinct area of practice in the 1960s and 1970s, and health law as a self-conscious academic discipline in the 1970s and 1980s.⁵ The first casebook designed to teach health law appeared in 1987.⁶ At the present time, most major law firms have a health law department, while virtually every law school has at least one health law course and many law schools have several such courses.

While health law is defined in terms of the industry that it addresses, administrative law is commonly defined in terms of the nature of the entities that it governs. Black's Law Dictionary defines administrative law as "the law governing the organization and operation of the executive branch of government (including independent agencies) and the relations of administrative agencies with the legislature, the executive, the judiciary, and the public."⁷ A leading administrative law text offers a similar definition: "[A]dministrative law consists of those legal principles that define the authority and structure of administrative agencies, specify the procedural formalities that agencies use, determine the validity of administrative

1. BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* xvii (1987).

2. BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 497 (5th ed. 2004) ("In 2000, Americans spent \$1173.9 billion on personal medical care compared to \$958.8 billion on housing, \$928.5 billion on food and tobacco, and \$784.9 billion on transportation.").

3. Uwe E. Reinhardt et al., *U.S. Health Care Spending in an International Context*, 23 *HEALTH AFF.* 10, 11 (2004). In 2001, health spending accounted for 13.9% of the gross domestic product of the United States. *Id.*

4. PETER D. JACOBSON, *STRANGERS IN THE NIGHT: LAW AND MEDICINE IN THE MANAGED CARE ERA*, 27–30, 49–55 (2002).

5. *Id.* at 46–47; Timothy Stoltzfus Jost, *The Uses of the Social Transformation of American Medicine: The Case of Law*, 29 *J. HEALTH POL. POL'Y & L.* 799 (2004).

6. See FURROW ET AL., *supra* note 1.

7. BLACK'S LAW DICTIONARY 48 (8th ed. 2004).

decisions, and outline the role of reviewing courts and other organs of government in their relation to administrative agencies.”⁸

These broad definitions obviously encompass the law that governs or emerges from traditional regulatory agencies that oversee private conduct through traditional command-and-control regulation.⁹ They could indeed include all of public law, except for criminal law, which is traditionally carved out as a separate domain. Even an understanding of administrative law this broad, however, might be too narrow to serve our purposes. This is because of the nature of health-care administrative law.

In fact, traditional command-and-control regulation plays a relatively small role in health-care law. Certainly, several of the classic federal command-and-control regulatory agencies do have jurisdiction over the health-care industry. The Federal Trade Commission, for example, polices trade restraints within the health-care industry,¹⁰ while the National Labor Relations Board oversees collective bargaining within health-care institutions.¹¹ Several federal executive departments also have regulatory jurisdiction over the health-care industry, including the Labor Department, which regulates ERISA health benefits plans.¹² Regulatory law also imposes general prohibitions that set the backdrop for licensing or certification requirements. Unauthorized practice of medicine, for example, is prohibited by state law, and medical licensing boards have the authority to interpret and enforce these prohibitions.¹³ Similarly, the sale of drugs that have not been approved by the federal Food and Drug

8. STEPHEN G. BREYER ET AL., *ADMINISTRATIVE LAW AND REGULATORY POLICY: PROBLEMS, TEXT, AND CASES* 3 (5th ed. 2002).

9. The term “command-and-control regulation” is commonly used as though its meaning were self-evident. Perhaps the closest one can come to a definition of it, however, is Cass Sunstein’s descriptions of it:

Congress has often employed command-and-control strategies to accomplish various regulatory goals, most notably to clean the air and water. Command-and-control strategies seek to direct private behavior through centralized national bureaucracies. Often they require all or most industries to adopt inflexible, legally identified methods of achieving compliance within specified times.

CASS R. SUNSTEIN, *AFTER THE RIGHTS REVOLUTION: RECONCEIVING THE REGULATORY STATE* 87 (1990).

10. Although the jurisdiction of the FTC only extends to for-profit corporations, 15 U.S.C. §§ 44–45 (2000), this limitation has been interpreted so as to recognize jurisdiction over trade associations that operate as non-profits but that confer economic benefits on their members. *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 765–69 (1999).

11. BARRY R. FURROW ET AL., *HEALTH LAW* §§ 4-14 to -19, at 115–19 (2d ed. 2000). Certain special rules apply to health care institutions, however, such as NLRB rules governing bargaining units in acute-care hospitals. 29 C.F.R. § 103.30 (2003).

12. *See, e.g.*, 29 C.F.R. § 2560.503–1 (2003) (providing the Labor Department’s rules on ERISA claims determinations and appeals).

13. FURROW ET AL., *supra* note 11, § 3-3, at 62.

Administration (FDA) is prohibited by the Food and Drug and Cosmetic Act.¹⁴ And much of modern environmental and health and safety legislation grows out of state and local public health laws, one of our earliest forms of command-and-control regulation. But the exercise of command-and-control regulatory authority, independent of licensing requirements or payment conditions, is not characteristic of modern health-care law.

Much more common in health-care law are three other approaches to regulation. First, there are health-care financing and tax subsidy programs, which use administrative entities to assure the quality of services, oversee proper billing and utilization, and deter and punish fraud and abuse. The Center for Medicare and Medicaid Services exercises tremendous power over the health-care industry through the certification, coverage, and payment rules that it enforces in connection with its administration of the hundreds of billions of dollars spent by the Medicare and Medicaid programs on services provided by health-care professionals, suppliers, and providers.¹⁵ The Office of Inspector General of the Department of Health and Human Services and Department of Justice, moreover, enforce additional rules against the same professionals, providers, and suppliers under their authority to enforce compliance with the fraud and abuse laws, including the false claims and anti-kickback prohibitions. The Internal Revenue Service exerts considerable authority over the operation of hospitals and other health-care institutions through its interpretation of the laws granting tax-exempt status to “charitable” institutions,¹⁶ and over employee benefit plans through its administration of laws offering tax subsidies to employers who offer and employees who enroll in such plans.¹⁷ These regulatory interventions are not imposed under the Commerce Power, like antitrust laws or ERISA, but rather are imposed under the taxing or spending powers on private entities that choose to participate in federal health-care financing and subsidy programs. Some of these regulatory provisions, such as Medicare payment rules, are necessary adjuncts of government spending programs; others, such as the Emergency Medical

14. 21 U.S.C. § 355 (2000).

15. The President’s budget for FY 2005 projects Medicare expenditures at \$290 billion and the federal share of the Medicaid program at \$182 billion. KAISER COMM’N ON MEDICAID AND THE UNINSURED, THE PRESIDENT’S FY 2005 BUDGET PROPOSAL: OVERVIEW AND BRIEFING CHARTS, 1–2 (June 2004), available at <http://www.kff.org/medicaid/7115.cfm>.

16. See 26 U.S.C. § 501(c)(3) (2000); FURROW ET AL., *supra* note 11, ch. 2, § 2-1 to -16, at 38–50.

17. See, e.g., 26 U.S.C. § 105(h) (2000) (limiting the ability of self-insured plans to discriminate in favor of highly compensated individuals). The expansion of tax subsidies for new health-care financing vehicles, such as Health Savings Accounts created by the Medicare Modernization Act, 26 U.S.C.A. § 223 (2004), portends a greater regulatory role for the I.R.S.

Treatment and Active Labor Act (EMTALA)¹⁸ and the former federal health planning laws, are much more tangentially related to federal spending programs but are enforced through these spending programs.

Second, there are licensure and certification programs. In general, health-care professionals cannot practice their profession within a state unless they are licensed (or in some instances certified) by the proper board or agency, and, once licensed, health-care professionals must comply with the rules of these boards or agencies or risk disciplinary action.¹⁹ Any pharmaceutical company that wants to market a new drug or medical device manufacturer that wants to introduce a new device must obtain approval from the FDA.²⁰ To obtain and retain this license or approval, the applicant must conform to certain statutory and regulatory requirements, which are not imposed as general “commands” upon society, but rather as conditions of licensure, certification, or approval with respect to particular professionals, providers, or manufacturers.

The third regulatory model that pervades health care is regulation through private entities. While private regulation has recently been discovered by administrative law scholars,²¹ those of us who work with health law have known about it for decades.²² Although the theme of private regulation will be explored in detail below,²³ a few illustrative examples demonstrate this point. The Medicare program is governed by the Center for Medicare and Medicaid Services (CMS), a large government agency located within an executive department and subject to a complex body of statutes and regulations, but the day-to-day operation of the program is carried out by private Medicare contractors, which make their own rules (Local Medicare Review Policies) under “rulemaking” procedures specified by statute.²⁴ Medicare contractors

18. 42 U.S.C. § 1395dd (2000). *See also* Dean M. Harris, *Beyond Beneficiaries: Using the Medicare Program to Accomplish Broader Public Goals*, 60 WASH. & LEE L. REV. 1251, 1273–82 (2003).

19. Timothy S. Jost, *Oversight of the Competence of Healthcare Professionals*, in REGULATION OF THE HEALTHCARE PROFESSIONS 17, 21–26 (Timothy S. Jost ed., 1997).

20. 21 U.S.C. § 355 (2000).

21. *See, e.g.*, Symposium, *Public Values in an Era of Privatization*, 116 HARV. L. REV. 1211 (2003); Jack M. Beermann, *Administrative-Law-Like Obligations of Private[Ized] Entities*, 49 UCLA L. REV. 1717 (2002); Jody Freeman, *Extending Public Law Norms Through Privatization*, 116 HARV. L. REV. 1285 (2003); Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543 (2000).

22. *See, e.g.*, Timothy Stoltzfus Jost, *The Joint Commission on Accreditation of Hospitals: Private Regulation of Health Care and the Public Interest*, 24 B.C. L. REV. 835 (1983).

23. *See infra* text accompanying notes 46–59.

24. CENTER FOR MEDICARE AND MEDICAID SERVICES, MEDICARE PROGRAM INTEGRITY MANUAL: LOCAL MEDICAL REVIEW POLICY, available at http://www.cms.gov/manuals/108_pim/pim83toc.asp (last modified Sept. 16, 2004). *See* Timothy S. Jost, *The Medicare Coverage Determination Process in the United States*, in HEALTHCARE COVERAGE DETERMINATIONS: AN INTERNATIONAL COMPARATIVE STUDY 207, 212–13 (Timothy S. Jost ed., 2005).

also make coverage adjudications, subject to review by separate private “qualified review organizations,” whose determinations are in turn subject to administrative and judicial review.²⁵ Clinical research can only be approved for federal funding in the United States, and clinical trials can only be approved as adequate to support Food and Drug Administration new drug approvals, if the clinical research or trials are approved by Institutional Review Boards (IRBs), which are private entities constituted in accordance to federal regulations that must follow procedures established by federal regulations.²⁶ Hospitals that are accredited by the private Joint Commission on Accreditation of Healthcare Organizations can participate in the Medicare program by meeting only minimal additional requirements,²⁷ while managed care organizations that are accredited can escape certain regulatory requirements in some states.²⁸ Hospitals that make staff privilege decisions²⁹ or ERISA plans that make coverage decisions³⁰ are required by the courts to follow procedures that are essentially administrative, and the courts treat their decisions with much the same deference afforded the decisions of administrative agencies.

A comprehensive definition of administrative law, therefore (at least with respect to health law), must include not only the law that emerges from or governs public agencies that engage in command-and-control regulation, or even all public governmental agencies (including licensing and certification agencies and agencies that oversee health-care financing or tax-subsidy programs), but also the law that controls all “tools of government,” including private or quasi-public entities that carry out government functions.³¹ I define “administrative law,” therefore, idiosyncratically for this article to include law that emerges from or governs entities (public or private) other than the courts or legislatures that are rather created or sanctioned by law to carry our public regulatory functions or to collect and expend public resources.

Common salient characteristics of such entities, explored further below, are that they are usually designated to carry out public functions because of special claims to competence or expertise; their acts and decisions are supposed to serve (at least in part) the public interest; their adjudicatory

25. 42 U.S.C. § 1395ff(b)(1), (c)–(d) (2000).

26. 21 C.F.R. §§ 56.101(a), 56.103 (2004); 45 C.F.R. § 46.109(a) (2003).

27. 42 U.S.C. § 1395bb (2000); 42 C.F.R. § 488.5 (2003).

28. See Barry R. Furrow, *Regulating the Managed Care Revolution: Private Accreditation and a New System Ethos*, 43 VILL. L. REV. 361, 396–99 (1988) (describing managed care accreditation).

29. See FURROW ET AL., *supra* note 11, § 4-5 to -6, at 101–105.

30. See Mark D. DeBofsky, *The Paradox of the Misuse of Administrative Law in ERISA Benefit Claims*, 37 J. MARSHALL L. REV. 727, 727–32 (2004).

31. See generally THE TOOLS OF GOVERNMENT: A GUIDE TO THE NEW GOVERNANCE (Lester M. Salamon ed., 2002) (describing many of the administrative tools utilized by government).

decisions are usually subject ultimately to judicial review; that judicial review is generally deferential because of the entities' special claims to competence; these entities are usually authorized to promulgate rules, standards, or guidelines formally or informally; the "rules" that they promulgate are often made through processes that include some element of public participation; their "rules" are usually afforded some deference by the courts; and their acts are often subject to some level of public scrutiny. These characteristics, of course, are those described in the federal and state administrative procedure acts,³² even though those laws may not apply to all of the entities swept within our broad definition of administrative law.

II. LAW AS MAKING RULES AND DECIDING DISPUTES AND THE INSTITUTIONS THAT MAKE RULES AND DECIDE DISPUTES IN HEALTH CARE

The understanding of what is meant by administrative entity and by administrative law that is adopted here is based on an underlying understanding of the nature of law and of how law functions. To grossly oversimplify matters that jurists debate endlessly, law serves two basic purposes in society. First, it establishes (or recognizes) enforceable rules by which individuals and entities order their relationships with each other and with society.³³ These rules may be based on the underlying norms under which private and public relationships are in fact conducted, they may reflect a misunderstanding or distortion of those norms,³⁴ or they may be shaped by a conscious attempt to create new norms or change existing norms to serve a particular public purpose.³⁵ Second, law provides institutions that serve to settle disputes among individuals and entities and between those individuals and entities and the state.³⁶ These two purposes are, of course, closely interrelated, as rules may emerge from the settlement of disputes, while the settlement of disputes presupposes rules with reference to which those disputes can be resolved. But it is sometimes useful to recognize these two functions as separate.

32. See 5 U.S.C. §§ 553, 554, 702, 706 (2000).

33. See H. L. A. HART, *THE CONCEPT OF LAW*, 79–99 (2d ed. 1994); Frederick Schauer, *Formalism*, 97 *YALE L.J.* 509, 510 (1988) (describing the rule-setting function of law).

34. See ROBERT C. ELLICKSON, *ORDER WITHOUT LAW: HOW NEIGHBORS SETTLE DISPUTES*, 280–86 (1991); Robert C. Ellickson, *A Critique of Economic and Sociological Theories of Social Control*, 16 *J. LEGAL STUD.* 67 (1987) (describing the relationship between law and norms).

35. The possibility of law serving a "meliorative function," striving to achieve a more just society, can be understood as a third role of law. See Steven D. Smith, *Reductionism in Legal Thought*, 91 *COLUM. L. REV.* 68, 73–75 (1991).

36. K.N. LLEWELLYN, *THE BRAMBLE BUSH: ON OUR LAW AND ITS STUDY* 11–12 (3d prt. 1960); see also Smith, *supra* note 35, at 69–71.

Given common notions of institutional competence, we primarily think of the elected legislative bodies as laying down rules by enacting laws (usually with some participation from the executive) and of the courts as settling disputes by deciding cases. However, rules are laid down and disputes resolved generally in our society through four different types of institutions. First, legislatures establish rules through enacted legislation. In doing so they often also incidentally settle disputes, as when a local city council imposes a final resolution on a contentious re-zoning dispute. Second, courts do indeed resolve disputes in both civil disputes among private individuals and institutions as well as disputes between government and individuals that are litigated in criminal or civil enforcement cases. In our common law legal system, courts also articulate rules, interpret and apply statutes and constitutions, and find the common law when there is no statute or constitutional provision on point.³⁷

Third, rules are articulated and disputes settled through private arrangements. Private individuals, through contracts and by the formation of private entities such as partnerships and corporations, create rules that are legally enforceable among themselves. These generally reflect the norms that govern society and are shaped by the market forces affecting commercial transactions. Private individuals and entities also reach legally binding resolutions of disputes through negotiation, mediation, and arbitration.

Finally, a great many rules are laid down and disputes resolved by administrative entities, as broadly defined above. These entities make rules that govern private conduct (as well as their own conduct) through formal or informal rulemaking procedures.³⁸ These entities also formally and informally decide disputes. These disputes usually involve regulatory enforcement (or the raising or expenditure of public funds), but can also include disputes among private parties (for example, where the NLRB decides a collective bargaining dispute or the Office of Civil Rights of the Department of Housing and Urban Development decides a housing discrimination claim).

Health law offers many examples of rules made and disputes resolved through each of these mechanisms. Congress has enacted a host of statutes affecting the organization and finance of health care, sometimes as freestanding legislation, but often as part of omnibus budget bills. Some of the better-known examples of this legislation are the Employee Retirement Income Security Act of 1974 (ERISA),³⁹ the Emergency Medical Treatment and Active Labor Act (EMTALA),⁴⁰ and the Health Insurance Portability and

37. LLEWELLYN, *supra* note 36, at 12.

38. *See* 5 U.S.C. § 553 (2000) (governing rulemaking by federal agencies).

39. 29 U.S.C. §§ 1001–1411 (2000).

40. 42 U.S.C. § 1395bb (2000).

Accountability Act (HIPAA).⁴¹ State legislatures also regularly enact new legislation affecting health care.

The state and, to a lesser degree, federal courts are continually resolving disputes involving health-care issues. Important sectors of health law, notably malpractice and informed-consent law and much of bioethics, are governed by the common law that the courts have established.⁴² Criminal prosecutions and civil penalty proceedings brought in the courts have also taken on an increasingly important role in health care in recent years.

Private contracts and institutional arrangements governing relationships between professionals, providers, and patients are ubiquitous in health care.⁴³ The use of private alternative dispute resolution approaches, including mediation, arbitration, and negotiation has also become common in health care.

But, much of health law is administrative law, created and applied by administrative entities as described above. These include traditional federal regulatory agencies and commissions, as well as the federal entities that oversee federal health-care financing and tax-expenditure programs. They also include a host of state boards and agencies that license and regulate health-care professionals and health-care institutions, such as hospitals or nursing homes. States are primarily responsible for regulating health insurance as recognized by the McCarran-Ferguson Act.⁴⁴ States actively exercise this power to guarantee the capacity of insurers to meet their obligations and supervise insurance claims practices, while at the same time attempting to regulate insurance underwriting to expand access to insurance.⁴⁵

As noted above, federal and state regulatory authority, exercised through command-and-control regulation or federal spending authority, tax subsidies, and licensing and certification authority, does not begin to exhaust the scope of administrative oversight over the health-care industry. A complete description must also include the private and quasi-private entities that either exert public authority over the health-care industry or are overseen by public law in their private oversight of the health-care industry.

First, and most obviously, there are private entities essentially created by federal or state law to extend public oversight over the health-care industry. A prime example are Institutional Review Boards (IRBs), whose membership

41. Pub. L. No. 104-191, 110 Stat. 1936 (1996).

42. See Lawrence Gostin, *The Formulation of Health Policy by The Three Branches of Government*, in *SOCIETY'S CHOICES: SOCIAL AND ETHICAL DECISION MAKING IN BIOMEDICINE* 335, 339-345 (Ruth Ellen Bulgaer et al. eds., 1995) (describing the role of the courts in healthcare policy-making).

43. Indeed, private arrangements have arguably become more important in recent years as "transactional" work, arranging relationships between health-care professionals and institutions, has become a major focus of health law practice. See FURROW ET AL., *supra* note 2.

44. 15 U.S.C. §§ 1011, 1012, 1015 (2000).

45. FURROW ET AL., *supra* note 2, ch. 9, at 566-643.

and function are specified by federal law.⁴⁶ These IRBs possess authority primarily because their approval is necessary if research is to be funded by the federal government or will result in regulatory approvals issued by the federal Food and Drug Administration.⁴⁷

Second, there are pre-existing private entities that contract with the government to carry out regulatory responsibilities of the government. In this category must be placed Medicare contractors, who are generally insurers and data processors who make local coverage and medical review policies and process and pay Medicare claims.⁴⁸ Also included are Medicare and Medicaid HMOs that are often commercial insurers that administer public managed-care plans in addition to their private business, but which, in doing so, act in the place of the state in administering public insurance programs.⁴⁹ Finally there are Medicare Quality Review Organizations, which are private entities carrying out public quality and utilization review responsibilities under contract with the Medicare program.⁵⁰

Third, there are private entities that have effectively been commandeered by the government to carry out public regulatory responsibilities even though they do not necessarily do this under contract. The prime example of this phenomenon is private accreditation bodies. The Joint Commission on Accreditation of Healthcare Organizations was established more than a decade before the Medicare program and grew out of the Hospital Standardization Program that antedated Medicare by at least a half-century.⁵¹ When the Medicare program was created, however, it incorporated JCAHO (then Joint Commission on Accreditation of Hospitals or JCAH) accreditation, extending Medicare certification to accredited hospitals.⁵² State hospital licensure laws have also incorporated JCAHO accreditation; indeed, in some states, accredited hospitals are effectively licensed automatically.⁵³ In more recent years, both federal and state regulatory authorities have turned to other accreditation programs, including JCAHO and the National Committee for Quality Assurance (NCQA), to oversee the quality of health insurers and

46. See 45 C.F.R. §§ 46.101–124 (2003) (describing the role of IRBs in approving research involving human subjects, their composition and procedures).

47. 21 C.F.R. §§ 56.101–124 (2004).

48. See 42 U.S.C. §§ 1395h, 1395u (2000).

49. See *Grijalva v. Shalala*, 152 F.3d 1115 (9th Cir. 1998), *vacated by* 526 U.S. 1096 (1999) (recognizing Medicare HMOs as public actors subject to the Constitution).

50. 42 U.S.C. §§ 1320c-1 to -12 (2000); See Timothy Stoltzfus Jost, *Administrative Law Issues Involving the Medicare Utilization and Quality Control Peer Review Organization (PRO) Program: Analysis and Recommendations*, 50 OHIO ST. L.J. 1 (1989) (analyzing administrative law issues with respect to Medicare Peer Review Organizations).

51. Timothy Stoltzfus Jost, *Medicare and the Joint Commission on Accreditation of Healthcare Organizations: A Healthy Relationship?*, 57 LAW & CONTEMP. PROBS. 15, 16 (1994).

52. *Id.* at 18.

53. See, e.g., OHIO REV. CODE ANN. § 3727.02 (1998).

health-care institutions. These programs create a symbiotic relationship between the public entity and the private accreditor, under which the public agency is spared the trouble of devising its own standards and gains the flexibility and credibility of the private agency, while the private accreditor gains market share from the public regulatory endorsement as well as enhanced authority to enforce its regulatory decisions.⁵⁴

Finally, administrative procedures or judicial review have in some instances been imposed upon private entities by the courts or legislature.⁵⁵ Although employee benefit plans are created by private contracts between employers and insurers or plan administrators for the benefit of employees, their administrators are treated much like administrative entities under ERISA. The Department of Labor Regulations, for example, requires ERISA plans to follow certain claims and appeals procedures that look like those followed by public agencies.⁵⁶ The courts have assumed an oversight relationship towards ERISA plans that resembles judicial review of administrative decisions. Courts generally require exhaustion of plan remedies before reviewing plan coverage decisions and generally review those decisions following an arbitrary and capricious standard.⁵⁷

Hospital staff privilege decisions offer another example of private decisions coming under the influence of something that resembles administrative law. Even though staff privilege decisions essentially govern the relationship between professionals and private hospitals, courts in a number of states have required hospitals to follow “fair procedures” that closely resemble administrative procedures in making staff privilege decisions and have subjected privileging decisions to something resembling administrative review.⁵⁸ The Health Care Quality Improvement Act goes one step further, essentially requiring hospitals to follow administrative procedures in exchange for antitrust immunity.⁵⁹

In sum, health law is thoroughly permeated by administrative law. Throughout health law one finds entities that are not popularly elected, that are not courts, and that either are in fact public administrative agencies or are private entities that resemble administrative agencies making rules and deciding disputes. Some of these entities are established by statute and are

54. See Jost, *supra* note 51, at 25–38 (exploring these mutual benefits).

55. See generally DeBofsky, *supra* note 30.

56. See 29 C.F.R. § 2560.503-1 (2003).

57. See *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 109 (1989) (courts should show deference to discretionary judgments of ERISA plans); *Amato v. Bernard*, 618 F.2d 559, 566–68 (9th Cir. 1980) (exhaustion required before filing suit in ERISA cases).

58. See, e.g., *Ende v. Cohen*, 686 A.2d 1239, 1242–43 (N.J. Super. Ct. App. Div. 1997); *Christenson v. Mount Carmel Health*, 678 N.E.2d 255, 260 (Ohio Ct. App. 1996); *Rosenblit v. Fountain Valley Reg'l Hosp. & Med. Ctr.*, 282 Cal. Rptr. 819, 825 (Cal. Ct. App. 1991).

59. 42 U.S.C. § 11112(a) (2000).

required by statute to follow specified administrative procedures; others are the product of private arrangements but have had administrative procedures imposed upon them by a legislature, the courts, or by regulatory agencies. All, however, are subject to administrative law or something that closely resembles it.

III. WHY IS ADMINISTRATIVE LAW SO PERVASIVE IN HEALTH-CARE LAW? THE HISTORICAL EXPLANATION EVALUATED

Why is administrative law so pervasive in health-care law? One possible explanation, put forth by Professor Claeys in his article in this symposium, is historical. In particular, from the 1960s to the 1980s, there was extraordinary growth in the health-care industry and the emergence of health law as a distinct area of practice and academic discipline. It was also a time of extraordinary ferment in administrative law. It would not be surprising if there was some cross-fertilization between the two legal domains during this fertile time, if there was not some degree of “peer pressure” promoting the adoption of administrative entities and law as health law emerged.⁶⁰

What was happening in administrative law during this time? Most noteworthy, there was a dramatic expansion of government regulation. Beginning with President Johnson’s Great Society, and continuing through much of the Nixon administration, a host of new regulatory programs were initiated. The programs focused on the environment and public health and safety. Federal control over air pollution regulation was established through a series of laws adopted between 1963 and 1977. The Occupational Safety and Health Act, creating a sizeable regulatory bureaucracy, was adopted in 1970, while the Federal Consumer Products Safety Commission was established in 1972. Responsibilities of existing agencies and departments during the 1960s and early 1970s were also expanded as new regulatory programs were created.⁶¹

There were other trends under way in administrative law at this time as well. One was a dramatic expansion of the use of rulemaking. The Administrative Procedures Act had recognized the power in administrative agencies to regulate through quasi-legislative rules.⁶² For the two decades following its enactment, however, agencies continued to establish policy

60. Eric R. Claeys, *The Food and Drug Administration and the Command-And-Control Model of Regulation*, 49 ST. LOUIS U. L.J. 105 (2005).

61. See CASS R. SUNSTEIN, *AFTER THE RIGHTS REVOLUTION: RECONCEIVING THE REGULATORY STATE* 24–31 (1990) (exploring the expanding responsibilities of existing agencies and departments in the 1970s); Robert L. Rabin, *Federal Regulation in Historical Perspective*, 38 STAN. L. REV. 1189, 1272–1315 (1986).

62. 5 U.S.C. § 553 (2000).

primarily through adjudication.⁶³ As the scope of regulatory authority expanded in the “rights revolution” of the 1960s and 1970s, the agencies increasingly turned to rulemaking as a more expeditious and efficient means of setting policy.⁶⁴ Two Supreme Court decisions, *United States v. Florida East Coast Railway*,⁶⁵ and *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*,⁶⁶ undoubtedly encouraged this trend. As a result, there was more emphasis on agencies’ rulemaking (quasi-legislative powers) as opposed to the dispute resolution functions (quasi-judicial powers).⁶⁷

Many key health law regulatory initiatives date from this period. Medicare and Medicaid were created in 1965. The Professional Standards Review Organization program was established in 1972. ERISA was enacted in 1974, as was the National Health Resources Planning and Development Act, which, though later repealed, established the state certificate of need programs, many of which still exist. In general, the agencies created by these statutes proceeded to adopt rules using the newly invigorated informal rulemaking process, though many of these rules served to establish agency procedures rather than to impose regulatory requirements.⁶⁸ The regulatory output of some of these entities was, however, quite modest.⁶⁹

When examined more closely, however, the hypothesis of “administrative peer pressure” goes only so far. First, though social and environmental command and control regulation blossomed in the 1960s and 1970s, federal administrative law has much deeper roots, as does health law. Calls for increased government regulation emerged from the Populist movement in the second half of the nineteenth century and from the Progressives at the end of the nineteenth century and the beginning of the twentieth.⁷⁰ Responding to this

63. Thomas W. Merrill, *Capture Theory and the Courts: 1967–1983*, 72 CHI.-KENT L. REV. 1039, 1092–93 (1997).

64. *Id.*; see also BREYER ET AL., *supra* note 8, at 665–667.

65. 410 U.S. 224 (1973) (limiting the application of ponderous, formal, on-the-record rulemaking).

66. 435 U.S. 519 (1978) (limiting the judicial imposition of additional burdensome rulemaking requirements on agencies).

67. The late 1960s and early 1970s also saw an extraordinary burst of activity on the part of the courts, generally opening up agency procedures, expanding opportunities for the public to participate in regulatory programs, and engaging in more energetic oversight of administrative proceedings. See Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1669 (1975); Merrill, *supra* note 63, at 1059–1067. This development is not directly relevant to our subject, however, and will not be explored here.

68. See, e.g., Imposition of Sanctions on Health Care Practitioners and Providers of Health Care Services by a Quality Improvement Organization, 42 C.F.R. pt. 1004 (2003) (governing Peer Review Organization sanction proceedings).

69. As of 1980, the Department of Labor regulations governing ERISA plan claims processes filled only four pages. See 29 C.F.R. § 2560.503-1 (2003).

70. See Rabin, *supra* note 61, at 1197–243.

pressure, the Interstate Commerce Commission was created in 1887, and the Federal Trade Commission in 1914.⁷¹ Administrative law flourished during the New Deal of the 1930s, when the power of the federal bureaucracy was expanded dramatically to cope comprehensively with the crisis of the Depression.⁷² Many agencies created during that time (the National Labor Relations Board, the Securities and Exchange Commission, and the Federal Deposit Insurance Corporation) continue to play an important role in regulation of our economy. The Administrative Procedures Act (APA), adopted in 1946, recognized and confirmed (even as it formalized and restrained) the power that administrative agencies had gained during the New Deal.⁷³ The APA formalized the models of notice-and-comment rulemaking and on-the-record adjudication that form the basis for subsequent administrative law. It is these models that still predominate in health-care law, though, as elsewhere in administrative law, they have been modified and expanded during the intervening half-century.⁷⁴

Similarly, health law, including health-care administrative law, has roots that long antedate the 1960s and 1970s. State and local public health regulation existed before the founding of the Republic and constitutes one of our oldest forms of administrative law.⁷⁵ State medical licensure boards were established in the second half of the nineteenth century.⁷⁶ State programs providing care for the mentally ill were well-developed by the end of the nineteenth century, while state and local programs for aiding the medically indigent were widespread even before the New Deal.⁷⁷ At the federal level, the Food and Drug Administration began to oversee the safety of drugs in the early twentieth century, and federal medical assistance for welfare recipients began to appear in 1950.⁷⁸ There was, therefore, a considerable administrative

71. *Id.* at 1206–07, 1223–24.

72. *Id.* at 1243–62; BREYER ET AL., *supra* note 8, at 21–24.

73. Rabin, *supra* note 61, at 1265–66; *see also* JERRY L. MASHAW et al., *ADMINISTRATIVE LAW: THE AMERICAN PUBLIC LAW SYSTEM* 9 (5th ed. 2003).

74. *See* Timothy Stoltzfus Jost, *Governing Medicare*, 51 *ADMIN. L. REV.* 39, 92–96 (1999). The use of informal guidelines and agency opinions has become common in administrative law, and an even greater extent in health law. *Id.*

75. *See* Wendy E. Parmet, *Health Care and the Constitution: Public Health and the Role of the State in the Framing Era*, 20 *HASTINGS CONST. L.Q.* 267, 285–302 (1992); *see also* 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, 203–08 (1999).

76. Timothy S. Jost, *Oversight of the Quality of Medical Care: Regulation, Management, or the Market?*, 37 *ARIZ. L. REV.* 825, 827–31 (1995).

77. TIMOTHY STOLTZFUS JOST, *DISSENTLEMENT?: THE THREATS FACING OUR PUBLIC HEALTH-CARE PROGRAMS AND A RIGHTS-BASED RESPONSE* 67–79 (2003).

78. *Id.* at 80–82.

infrastructure in place in health law by the time the expansions of the 1960s arrived.

The reach of health-care administrative law continued to expand, moreover, long after the activist 1960s and 1970s had faded into the deregulatory 1980s and 1990s. Certainly, in health-care law, as elsewhere, there was some regulatory retrenchment during this period. The National Health Resources Planning and Development Act was repealed in 1986 (though many states retained their certificate of need programs (CON) after repeal, and some still remain).⁷⁹ The Professional Standards Review Organization Program was reborn in 1982 as the Peer Review Organization program and soon lost much of its regulatory bite.⁸⁰ Since then it has morphed into the Quality Review Organization Program, which eschews aggressive regulation in favor of educational interventions.⁸¹

But other significant health-care regulatory programs were created or continued to expand during the 1980s and 1990s. The federal nursing home reform program—one of our most prescriptive federal regulatory programs (though one tied to a financing program rather than a general command-and-control program)—was initiated with new legislation in 1987.⁸² EMTALA, adopted as part of the Consolidated Omnibus Budget Reconciliation Act of 1985, imposed an obligation on every hospital in the country that participates in Medicare and has an emergency room to screen and stabilize every patient who came to the hospital in an emergency, including active labor.⁸³ The Medicare program moved in the 1980s from cost and charge-based payment systems that mimicked the private sector to administered price systems (DRGs for hospitals in 1983 and RBRVS for physicians in 1989) that required a much higher level of administrative intervention.⁸⁴ Finally, and perhaps most dramatically, the Health Insurance Portability and Accountability Act of 1996 (HIPAA)⁸⁵ exponentially expanded federal regulation of health insurance and of the privacy of health-care information. Although the 1960s and 1970s,

79. Laretta Higgins Wolfson, *State Regulation of Health Facility Planning: The Economic Theory and Political Realities of Certificates of Need*, 4 DEPAUL J. HEALTH CARE L. 261, 269–73 (2000–2001).

80. JOST, *supra* note 51, at 27–28.

81. See, e.g., OFFICE OF CLINICAL STANDARDS AND QUALITY, CTRS. FOR MEDICARE & MEDICAID SERVS., QUALITY IMPROVEMENT GROUP PROPOSED SUMMARY OF DRAFT 8TH STATEMENT OF WORK (May 13, 2004), available at <http://www.cms.hhs.gov/qio/2s.pdf>.

82. The Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, §§ 4201, 4214 (codified at 42 U.S.C. §§ 1395i-3, 1396r (2000)). This program has in fact been relatively successful in improving conditions within nursing homes. See John V. Jacobi, *Competition Law's Rule in Health Care Quality*, 11 ANNALS HEALTH L. 45, 50–55 (2002).

83. 42 U.S.C. § 1395dd (2000).

84. See, e.g., David M. Frankford, *The Complexity of Medicare's Hospital Reimbursement System: Paradoxes of Averaging*, 78 IOWA L. REV. 517 (1993).

85. Pub. L. No. 104-191.

therefore, certainly were a period of growth for health-care administrative law, the link between health law and administrative entities and programs both antedates and postdates this period, calling into question the proposition that it resulted from developments that occurred during this period.

The most significant challenge to the thesis that health-care administrative law is a product of the activism of the 1960s and 1970s, however, is the fact that the classic command-and-control model of administrative law that characterized that period is not the predominant model of administrative regulation in health law. The Environmental Protection Agency, the Occupational Safety and Health Administration, and the Consumer Products Safety Commission all promulgate rules with which all affected industries must comply.⁸⁶ If entities fail to obey the commands of these agencies, they face sanctions. In this way, these agencies attempt to control the activities of subject industries to promote the purposes of their enabling statutes. Some of these regulatory programs are focused on particular industries or actors, but their prohibitions are usually general and directed to all affected persons.

But, as noted earlier, although examples of command-and-control regulation can certainly be found in health-care law, they do not predominate. Rather, the prevailing models in health care tie regulation to licensure and certification, to financing, or to tax subsidies.⁸⁷ Moreover, while the command-and-control regulatory agencies created in the 1960s and 1970s were public agencies (primarily federal), private regulation is very common in the health-care industry. If the predominant examples of administrative law in health law were a product of “administrative peer pressure,” it would seem logical that it would look more like the prevailing models of regulation that emerged elsewhere during this time period.

IV. AN ALTERNATIVE EXPLANATION OF THE LINK BETWEEN HEALTH LAW AND ADMINISTRATIVE LAW: INSTITUTIONAL COMPETENCE

But if the historical peer pressure explanation does not work, how does one explain the entwinement between health law and administrative law? How does one explain the fact that entities that are administrative agencies, or function like them, and that apply and are bound by administrative law or something that resembles it, are ubiquitous in health care?

One place to begin is with notions of institutional competence. Recognition that particular legal institutions have particular competencies or limitations for carrying out legal tasks was one of the key insights of the legal

86. See SUNSTEIN, *supra* note 9, at 87.

87. Professor Claeys identifies the licensure and certification model with the New Deal, though it goes back beyond the New Deal at least to the beginnings of professional licensure in the 19th century. See Claeys, *supra* note 60; see also, Jost, *supra* note 76, at 827–31.

process school of jurisprudence.⁸⁸ Although legal process theory has passed from fashion in jurisprudence, this approach remains in fact useful for understanding the allocation of responsibilities among institutions.⁸⁹ Earlier in this article, four different institutions were identified that contribute to establishing rules and resolving conflicts—legislatures, courts, private ordering, and administrative entities. Examining the capabilities, and the disabilities, of each of these sets of institutions sheds light on the question of why we end up with administrative entities playing a central role in governing health care.

Congress and the state legislatures lay down the basic laws that govern health care. These laws, in fact, establish most of the administrative entities that we consider in this essay and set the tasks that they are to pursue and sketching out the procedures that they must follow.

Legislative bodies have long agendas, however, and cannot begin to attend to the details that are dealt with by administrative agencies.⁹⁰ Their processes are often cumbersome and time-consuming, and they lack that agility and flexibility that is ideally possessed by administrative entities.⁹¹ Legislators are also generalists and cannot specialize in particular problems to the extent that administrative entities can. Legislatures are particularly dependent on political contributors and exposed to lobbyists for powerful interests and thus may not always be best positioned to carry out the public interest.⁹² Because legislatures are exposed politically to an extent that administrative agencies are not, legislatures are sometimes content to shape the broad outlines of administrative programs, giving themselves cover with policy advocates but leaving the contentious details to administrators.⁹³ Finally, many administrative programs, such as health-care financing programs, require millions of individualized determinations and could not possibly be run by a legislature.⁹⁴ In sum, legislatures can and do establish and set the broad policy

88. William N. Eskridge, Jr. & Philip P. Frickey, *Introduction* to HENRY M. HART, JR. & ALBERT M. SACKS, *THE LEGAL PROCESS: BASIC PROBLEMS IN THE MAKING AND APPLICATION OF LAW* li, lx–lxii (1994); Keith Werhan, *The Neoclassical Revival in Administrative Law*, 44 ADMIN. L. REV. 567, 577–79 (1992).

89. Legal Process Theory has also been adopted by commentators working in the law and economics tradition. See generally NEIL K. KOMESAR, *IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY* (1994).

90. HART & SACKS, *supra* note 88, at xciii.

91. See LOUIS L. JAFFE, *JUDICIAL CONTROL OF ADMINISTRATIVE ACTION* 36–37 (1965).

92. GOSTIN, *supra* note 42, at 347–48.

93. See David B. Spence & Frank Cross, *A Public Choice Case for the Administrative State*, 89 GEO. L.J. 97, 138 (2000). This phenomena of legislative buck passing has also been noted by scholars in the public choice and positive political theory traditions. David B. Spence, *Administrative Law and Agency Policy-Making: Rethinking the Positive Theory of Political Control*, 14 YALE J. ON REG. 407, 426–27 (1997).

94. HART & SACKS, *supra* note 88, at 846; JAFFE, *supra* note 91, at 37.

parameters for programs for administering health-care oversight programs, but they are not adept at running them.

Many of the functions of health-care administrative entities are also beyond the capacity of the courts. In our legal system, courts decide disputes between individuals or entities and are largely dependent on those individuals and entities to provide them with the information necessary to decide those disputes.⁹⁵ They lack the capacity for independent fact-finding and, in particular, are not very adept at identifying and consulting all of the interest groups affected by particular decisions. The courts, like legislatures, are usually generalists and lack specialized knowledge about complex fields, except insofar as the parties to the litigation before them provide them with this information. The courts also have short attention spans, limited by the duration of litigation, and cannot take on responsibility for the ongoing implementation of policy decisions.⁹⁶ Finally, the courts are even limited in their capacity for covering their area of core competency—deciding disputes. Courts would, for example, be quickly overburdened if they had to decide the literally millions of reconsiderations and appeals that arise in the Medicare program.⁹⁷

In sum, legislatures and the judiciary can make only a limited (though very important) contribution to setting the rules for governing the health-care industry or for resolving disputes that arise within it. That leaves the two other approaches identified at the outset for carrying out these tasks—private ordering and administrative oversight. However, while earlier discussion was concerned with approaches that were available generally to society when looking specifically at health care, a fifth institution comes into focus: professionalism and the use of professional networks and their institutions.

95. Gostin, *supra* note 42, at 339–40 (discussing the limitations of the courts in making health law policy). For classic explorations of the limited ability of courts to determine “polycentric” issues in traditional civil litigation, see Abram Chayes, *The Role of the Judge in Public Law Litigation*, 89 HARV. L. REV. 1281, 1292–98 (1976); see also Lon L. Fuller, *The Forms and Limits of Adjudication*, 92 HARV. L. REV. 353, 394–405 (1978).

96. The exception from this generalization, of course, is institutional reform litigation involving structural injunctions. For a time, structural injunctions were seen as affording the courts a significant role in policy-making and administration. See Chayes, *supra* note 95, at 1288–1304. In recent years, however, the courts have been generally hostile to institutional litigation, which has taken on a rather marginal role. See Myrian Gilles, *An Autopsy of the Structural Reform Injunction: Oops . . . It’s Still Moving*, 58 U. MIAMI L. REV. 143, 161–63 (2003).

97. U.S. GENERAL ACCOUNTING OFFICE, DISPARITY BETWEEN REQUIREMENTS AND RESPONSIBLE AGENCIES’ CAPABILITIES 1 (2003) (reporting 3.7 million Medicare Part B appeals filed at the first level in FY 2001). By contrast, in FY 2003, 252,962 civil cases were filed in the federal district courts. News Release, Administrative Office of the U.S. Courts, *Judicial Business of the Federal Courts in FY 2003: Substantial Caseloads Continue to Fill Courts* 2 (Mar. 16, 2004), available at http://www.uscourts.gov/Press_Releases/judbus03.pdf.

Health care is delivered by professionals. These professionals relate to one another, to their patients, to institutions, and to governments as private individuals operating within markets and subject to ordinary social norms. The terms under which health-care professionals deliver their services are to some extent governed by the general laws of supply and demand⁹⁸ and are subject to the social norms that govern society, such as prohibitions against killing or stealing. Professionals are also subject to oversight by a host of administrative entities, as we have already noted.

Beyond societal norms and the laws of supply and demand, health-care professionals also function within professional networks and are subject to their own norms and institutions.⁹⁹ Professionals often belong to professional associations, which have their own codes of conduct that may or may not be sanctioned by law.¹⁰⁰ Some professional associations also assist in peer review or peer dispute resolution,¹⁰¹ a function that is often carried on informally in networks.

Sociologists have long noted the unique characteristics of professionals as opposed to other occupational or social groups.¹⁰² In particular, they have observed that professionals have been able, to a considerable extent, to govern themselves through their own institutions, establishing their own ethical standards, entry requirements, and training programs, as well as the internal divisions and external boundaries of their professions.¹⁰³ Although some economists have been highly skeptical about the claims of the professions to special treatment,¹⁰⁴ Kenneth Arrow, in his famed essay, *Uncertainty and the Welfare Economics of Medical Care*, speculated that some degree of self-governance within the health-care professions might make sense in the face of

98. See generally THOMAS RICE, *THE ECONOMICS OF HEALTH RECONSIDERED* (1998) (taking the position that the laws of economics apply only imprecisely to health care). The extent to which health-care professionals are or are not governed by these laws is a complex topic, which will be discussed further below.

99. See, e.g., ELIOT FREIDSON, *PROFESSIONALISM: THE THIRD LOGIC* (2001); see also Deborah A. Savage, *Change and Response: An Economic Theory of Professions with an Application to Pharmacy* 32–33, 99–100, 140 (1993) (unpublished Ph.D. dissertation) (on file with Homer Babbidge Library, Storrs, CT).

100. See, e.g., *Pons v. Ohio State Med. Bd.*, 614 N.E.2d 748, 751–52 (Ohio 1993) (recognizing that a doctor may be disciplined by a medical disciplinary board under Ohio law for violating the ethical standards of a professional association regarding sexual behavior).

101. See AM. HEALTH LAWYERS' ASS'N, *ALTERNATIVE DISPUTE RESOLUTION SERVICE* (offering alternative dispute resolution services since 1992), at <http://www.healthlawyers.org/adr> (last visited on Oct. 4, 2004).

102. ELIOT FREIDSON, *PROFESSIONAL POWERS: A STUDY OF THE INSTITUTIONALIZATION OF FORMAL KNOWLEDGE* 1–62 (1986); ANDREW ABBOTT, *THE SYSTEM OF PROFESSIONS: AN ESSAY ON THE DIVISION OF EXPERT LABOR* 35–58 (1988).

103. See, e.g., FREIDSON, *supra* note 99.

104. See MILTON FRIEDMAN, *CAPITALISM AND FREEDOM* 137–60 (1962).

failures that attended the market for medical services, most particularly those caused by problems of uncertainty.¹⁰⁵ More recently, economist Deborah Savage has contended that professionals produce services neither as atomistic individual participants in markets defined by competition, nor as employees in hierarchically organized firms, but rather within professional networks that are largely self-governing.¹⁰⁶

Professionalism presents a distinct alternative to general private ordering. Professional norms, for example, are not identical to those that govern society in general. Norms respecting honesty, for example, can be interpreted somewhat idiosyncratically in the professional-patient relationship,¹⁰⁷ while professionals in relationship to their patients are held to a higher standard of propriety in sexual conduct than the standards that may govern relationships outside of a professional context.¹⁰⁸ Even norms relating to killing may be bent when terminal care of a patient in terrible pain is at stake.¹⁰⁹ Professional networks also result in behavior that can be characterized as market restraints. Professional ethical constraints, for example, have long limited physician advertising.¹¹⁰

Both Deborah Savage and Eliot Freidson focus on the unique characteristics of professional knowledge as explaining the unique institutions of professionalism. Professional knowledge (as opposed to other forms of knowledge) is complex, theoretical, largely tacit (unverbalized and often unverbalizable),¹¹¹ and both routine, in the sense that services are performed similarly by the same professionals everywhere, and nonroutine (discretionary in Freidson's language¹¹²), because it is applied differently in the situation of

105. Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 966–67 (1963).

106. Savage, *supra* note 99, at 32–33; *see also* Deborah A. Savage, *Professional Sovereignty Revisited: The Network Transformation of American Medicine*, 29 J. HEALTH POL. POL'Y & L. 661, (2004).

107. While a doctor is generally obligated to reveal information to a patient honestly regarding the risks and alternatives of a medical procedure, the doctor may be free from an obligation of full disclosure under the therapeutic privilege when full disclosure might itself harm the patient. *Canterbury v. Spence*, 464 F.2d 772, 789 (D.C. Cir. 1972).

108. A doctor, for example, is not permitted to have a sexual relationship with a patient, even if both of them consent to the relationship. *See* COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, AM. MED. ASS'N, CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS, Op. 8.14 at 230 (2002–2003).

109. *See* *Washington v. Glucksberg*, 521 U.S. 702, 736–37, 780 (1997) (O'Connor, J., & Souter, J., concurring) (accepting the position that terminal sedation may be acceptable under extenuating circumstances).

110. FURROW ET AL., *supra* note 11, § 14–10, at 693–96.

111. FREIDSON, *supra* note 99, at 24–27.

112. *Id.* at 31–35.

each individual patient. Professional knowledge is shared among professional networks. To quote Savage:

I define professions as networks of shared competence. . . . For the purposes of this discussion, it will suffice to think of networks as non-hierarchical governance modes that manage shared capabilities. Professional networks identify core competences, build capabilities, and institutionalize knowledge flows. That is, professions store, acquire, develop, transmit, protect, and earn rents from their capabilities. They compete with other professions and other organizations by attempting to take advantage of their capabilities more quickly and ably than others.

What is a shared competence? The locus of professional production is a well-defined community of practitioners possessing an esoteric knowledge core (citation omitted). Since this knowledge is tacit, or perhaps esoteric, it is hard to specify in explicit terms what it is that practitioners know. We can, however, observe what they do. Within a profession, the routines of individual practitioners exhibit certain similarities. For example, lawyers evaluate whether a particular problem falls within the expertise of both the legal system and their own legal abilities. That is, they select and evaluate problems using the same criteria, even if they reach different conclusions. One source of their ability to do this is a shared background, usually because they have completed similar education and training programs and have shared work experiences (“practice”).

This means that the decisions of professionals, bringing to bear skills and knowledge in solving a production problem, follow what in the engineering profession is called “next bench design.” What professionals can and will do depends on what the professional system can do. Each professional’s decisions are constrained by the capabilities of the network as a whole, and their decisions must be implemented within the system.¹¹³

In this sense, professional competences are routines shared among individual practitioners. In performing a routine, the individual professional wants to be sure that her activities “interface” with the routines of others.¹¹⁴ Each individual practitioner represents embodied or human capital, often in the form of tacit knowledge, but the products and services that each produces require integration of this esoteric knowledge base across practitioners.¹¹⁵

Savage argues that the creation, transmission, enhancement and application of such professional knowledge optimally takes place neither in markets composed of individual and atomistic competitors, nor in hierarchically organized firms, but in networks composed of independent yet linked

113. Savage, *supra* note 99, at 23–24.

114. *Id.* at 30.

115. *Id.* at 30–31.

professionals.¹¹⁶ These networks, in turn, develop their own self-governing institutions that assure the transmission and enlargement of tacit and formal knowledge by controlling entrance into the profession and exit from the profession, boundaries of the profession, and ethical behavior within the profession.¹¹⁷

The relatively benign explanation of the development of professional power by Freidson, Savage, Arrow and others is far from universally accepted. Critics such as Milton Friedman,¹¹⁸ Jeffrey Berlant,¹¹⁹ Paul Starr,¹²⁰ Clark Havighurst,¹²¹ and others see professional autonomy and authority as the result of the exercise of political and economic power, largely lacking in legitimate economic or social justification. For our purposes, however, it is not necessary to resolve this argument. In fact, professionalism and professional networks have been accepted and continue to be accepted in the United States as a legitimate approach to making rules and resolving disputes. The Supreme Court recently held that professional restraints on advertising by dentists must be handled differently than restraints on advertising would be handled elsewhere in the economy because of the unique characteristics of professional services.¹²² Congress and state legislatures continue to recognize professional certification and accreditation as acceptable alternatives to external regulation.¹²³ Professionalism, legitimate or not (or, most probably, as partially legitimate and partially not) must be considered as yet another approach to legal ordering.

Adding, then, the possibility of regulation of conduct through professional networks, we are left with three alternative approaches to governing the health-care industry: private ordering through market forces and social norms,

116. *Id.* at 16–57; *see also* FREIDSON, *supra* note 99, at 1–2 (making the same point from the perspective of a sociologist).

117. Savage, *supra* note 99, at 99–141.

118. *See generally* FRIEDMAN, *supra* note 104, at 149–160.

119. *See generally* JEFFREY LIONEL BERLANT, *PROFESSION AND MONOPOLY: A STUDY OF MEDICINE IN THE UNITED STATES AND GREAT BRITAIN*, 177–308 (1975).

120. *See generally* PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* (1982).

121. *See, e.g.*, Clark C. Havighurst, *The Professional Paradigm of Medical Care: Obstacle to Decentralization*, 30 *JURIMETRICS J.* 415, 419–21 (1990); Clark C. Havighurst, *Decentralizing Decision Making: Private Contract versus Professional Norms*, in *MARKET REFORMS IN HEALTH CARE: CURRENT ISSUES, NEW DIRECTIONS, STRATEGIC DECISIONS* 22, 23–26 (Jack A. Meyer ed., 1983).

122. *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 771–74 (1999).

123. *See* Medicare Modernization Act, 42 U.S.C.A. § 1395w–104(j) (West 2004) (deeming accredited prescription drug plans and Medicare Advantage plans to be in compliance with certain regulatory requirements); *see also* 42 U.S.C.A. § 1395m(a)(20) (West 2004) (identifying quality standards governing supplemental medical insurance benefits for the aged and disabled).

administrative regulation and dispute resolution, and regulation and dispute resolution through professional networks.

As a general matter in our liberal American society, we leave most matters to private ordering, i.e. to private contracts, firms, and associations operating within the framework of social norms and markets, unless there is a good reason to do otherwise. However, no country in the world leaves health-care organization and finance purely to private ordering, and the United States is no exception. There are several reasons for this phenomenon.

First, and most basically, private arrangements cannot assure universal access to health care. I have fully explained the reasons for this elsewhere and will only sketch them out here.¹²⁴ The need for health-care services varies dramatically across our population, with a small percentage of the population consuming most of our nation's health-care resources in any given year while half of the population uses virtually no resources at all.¹²⁵ Those who use the most health-care resources, however, are not necessarily those who have the most financial resources; indeed, the contrary is often the case.¹²⁶ To some extent this unequal distribution of resources and need is evened out through private insurance, but private insurers must necessarily steer away from those who can be predicted to have the highest health-care costs unless an insurer is able to charge rates that cover the increased risk, rates that would be unaffordable to many high-need persons.¹²⁷ Even the rates charged persons presenting "normal" risks, however, are unaffordable to many low-income persons. Unaffordability is one of the primary reasons one-sixth of our population is uninsured, and far more would be were it not for public insurance.¹²⁸

Some form of public health insurance is the most common response to this conundrum. But public health insurance programs require eligibility, coverage, and payment rules; institutions to decide disputes involving these rules; and fraud and abuse enforcement mechanisms for dealing with those who do not play by the rules. Under some circumstances, public insurance programs also rely on private claims processors or managed-care organizations in an attempt to appropriate the supposed efficiencies of private ordering for

124. See JOST, *supra* note 77, at 8–18.

125. See Marc L. Berk & Alan C. Monheit, *The Concentration of Health Care Expenditures, Revisited*, HEALTH AFF., Mar.–Apr. 2001, at 9, 12–13. In any given year, 1% of the population accounts for 27% of health care costs, 5% for more than 50%. *Id.* The least expensive 50% of the population accounts for only 3% of health-care expenditures. *Id.*

126. See, e.g., Michael Marmot, *The Influence of Income on Health: Views of an Epidemiologist*, HEALTH AFF., Mar.–Apr. 2002, at 31.

127. JOST, *supra* note 77, at 11–14.

128. See KAISER COMM'N ON MEDICAID AND THE UNINSURED, KAISER FAMILY FOUNDATION, THE UNINSURED: A PRIMER 2 (2003), available at <http://www.kff.org/uninsured/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=29345>.

the benefit of public programs.¹²⁹ In the United States, there have been attempts to maximize private insurance coverage in lieu of establishing public coverage.¹³⁰ At the federal level, we have primarily pursued a carrot strategy, trying to encourage employment-related health insurance coverage by offering employers tax incentives and protection from state lawsuits (and to some extent regulation) through ERISA.¹³¹ The states have pursued more of a stick strategy, regulating individual and small group insurance markets to extend coverage through coverage mandates, preexisting condition bans, guaranteed issue and renewal requirements, and community rating requirements or other limitations on underwriting.¹³² Even putting aside the use of regulatory power to expand coverage, moreover, private insurance must in any event be regulated to assure solvency and fair claims practices.¹³³ Insuring access to health care, therefore, inevitably requires some form of regulation.

Though health insurance solves, to some extent, the problem of access to care within markets, it inevitably brings with it the problem of moral hazard.¹³⁴ The marginal cost of health care to insured patients is essentially the amount of cost-sharing obligations (plus transportation costs and the value of time spent receiving health care). For some services and some patients, these costs may be very low. Patients have an incentive, therefore, to consume insured health care regardless of whether the benefits of that health care exceed its costs. Professionals and providers also have an incentive to order, prescribe, refer for, or provide insured health-care products and services without carefully weighing the true cost and benefits because the products and services cost so little to the individual patient (and often produce a considerable benefit to the provider).¹³⁵

Insurers, public and private, attempt to combat moral hazard by changing the incentives of providers or by screening claims or the utilization of services.¹³⁶ Medicare contractors, for example, screen against the provision of

129. This is true with the Medicare program in the United States. *See supra* text accompanying notes 48-50.

130. *See* Timothy Stoltzfus Jost, *Public or Private Approaches to Insuring the Uninsured, Lessons from International Experience with Private Insurance*, 76 N.Y.U. L. REV. 419, 463-68 (2001).

131. JOST, *supra* note 77, at 184-85.

132. FURROW ET AL., *supra* note 11, § 9-4, at 474-82. In recent years, the federal government has also begun to use command-and-control regulation imposing coverage mandates for persons who lose employment-related insurance, (COBRA), and limiting the use of preexisting condition clauses. *Id.* at §§ 9-6 to 9-7, at 486-91.

133. *Id.* at § 9-4(a), at 474.

134. RICE, *supra* note 98, at 82-84.

135. *See id.* at 107-15. Though there is widespread belief that physician-induced demand is a problem in health care, its extent is quite controversial. *Id.*

136. *See* FURROW ET AL., *supra* note 11, § 9-8, at 492, § 7-12, at 409.

excess services.¹³⁷ Fraud and abuse enforcement is another response to extreme manifestations of moral hazard. However, aggressive utilization review may deny access to needed services or worsen inequities in access to health-care services.¹³⁸ For this reason the state and federal governments mandate the provision of some services, limit the use of some forms of provider incentives, and impose internal and external appeal procedures on health plans.¹³⁹

Another commonly identified limitation of private ordering in health care is the lack of, or asymmetric availability of, information about health care.¹⁴⁰ The human body is infinite in its complexity, and when it malfunctions or is injured, patients often have little idea as to what is wrong or how to address the problem. Patients seek out health-care professionals and providers for help, but they are rarely in a position to judge the competency of the professionals or providers whom they consult or to evaluate the information and assistance that those professionals and providers offer. Even following an episode of treatment, a patient may not be able to evaluate retrospectively the quality, or even efficacy, of services received.¹⁴¹ The patient's condition may well have improved without the treatment, or it may have gotten worse no matter what was tried. Moreover, even professionals are often uncertain about what is wrong with a patient or how to treat the patient's symptoms, though they are usually better informed than are their patients. In this environment of information deficits, private ordering is problematic.¹⁴²

Patients in health-care markets not only lack quality of service information, but often price information as well. Health-care treatment is often complex, involving a number of products and services and a variety of product and service providers. It is rare that a patient can know beforehand exactly what a treatment will cost, even when it is provided by a single professional. Indeed, a professional may not have any idea what a complex service is going to cost. Comparison shopping, therefore, is often difficult if not impossible.¹⁴³

137. 42 U.S.C. § 1395y(a)(1)(A) (2000).

138. See FURROW ET AL., *supra* note 11, § 7-12, at 409.

139. See *id.* § 9-8, at 493.

140. See MARK A. HALL, MAKING MEDICAL SPENDING DECISIONS: THE LAW, ETHICS, AND ECONOMICS OF RATIONING MECHANISMS 41-47 (1997); see also RICE, *supra* note 98, at 68-74; Gail B. Agrawal, *Resuscitating Professionalism: Self-Regulation in the Medical Marketplace*, 66 MO. L. REV. 341, 383 (2001); Jost, *supra* note 76, at 850-51.

141. RICE, *supra* note 98, at 73-74.

142. The problematic character of professional knowledge, is, of course, the justification for professionalism, professional networks, and professional self-regulation. See *supra* text accompanying notes 111-15.

143. See Jost, *supra* note 76, at 853-55 (discussing how consumers manage health-care information). Recent treatments of the problems of information and agency in health-care markets have also taken into account the effects of decision-making heuristic shortcuts applied to process information when consumers are presented with large bodies of complex information and

Patients often rely on their physicians to make health-care purchasing decisions for them.¹⁴⁴ Professionals also often have some power over the resources of health-care institutions.¹⁴⁵ Health-care professionals are rarely single-minded in their allegiance to either the patient or the institution. They must often keep in mind the interests of the patient, a health-care institution, an insurer or managed-care organization and last, but often far from least, their own financial and professional interests. Simple ordering through private agreements in this context of conflicted agency is highly problematic.

The traditional response to these problems of information and agency has been regulation. Professional licensure and certification reduce the patient's risk in information poor and interest conflicted situations by putting a floor under the competency of and imposing ethical obligations on those who act as health care professionals.¹⁴⁶ FDA approval of drugs and devices similarly helps to assure that prescribed drugs and devices available to consumers are at least for some conditions safe and effective. Regulation has increasingly been used to encourage disclosure of information to consumers, increasing the ability of consumers to function in information-poor markets.¹⁴⁷ Programs rating institutions or insurers are directed at improving the environment in which patients act as consumers.¹⁴⁸ Institutional review boards play a dual role here, both making certain that research proposals meet requirements of scientific validity before human research participants are asked to sign up for them and also making sure that the information that participants receive prior to signing up for the research provides enough information to make a meaningful choice.¹⁴⁹

must cope with this information limited by "bounded rationality." Thus, for example, consumers may focus on information received most recently or presenting the most dramatic risk. *Id.*; see also Russell Korobkin, *The Efficiency of Managed Care "Patient Protection" Laws: Incomplete Contracts, Bounded Rationality, and Market Failure*, 85 CORNELL L. REV. 1, 48–59 (1999) (examining ramifications of bounded rationality for managed care contracting). The problem of "bounded rationality" limits to some extent the standard response to information-poor markets—the production of more information through, among other things, disclosure requirements. *Id.*

144. HALL, *supra* note 140, at 45–47; see also, Agrawal, *supra* note 140, at 383. For example, physicians prescribe medications, order durable medical equipment or physical therapy, refer to specialists, and admit to hospitals.

145. By their control over the hospital medical staff, doctors have some control over the number and specialty of physicians practicing at a hospital.

146. See Arrow, *supra* note 105, at 966–67.

147. *But see supra* notes 140–42 (discussing information poor markets); see also Jost, *supra* note 76, at 850–55 (describing limitations with "report card" solutions).

148. See Deborah Haas-Wilson, *Arrow and the Information Market Failure in Health Care: The Changing Content and Sources of Health Care Information*, 26 J. HEALTH POL. POL'Y & L. 1031, 1040–41 (2001).

149. See FURROW ET AL., *supra* note 2, at 1473–90.

Health-care markets arguably fail in other ways, further limiting the viability of private ordering. Health-care purchasing decisions, for example, are attended by externalities that limit the effectiveness of consumer choice as the sole means of allocating resources. My decision to forgo having my child vaccinated, for example, may result in the spread of an infectious disease to my neighbor's child.¹⁵⁰ My neighbor's decision to seek medical attention for a serious, but treatable, medical problem may increase my welfare by relieving me from the burden of observing him in constant pain.¹⁵¹ Vaccination and other public health requirements, on the one hand, and public health insurance, on the other, may thus prevent negative or create positive externalities. Artificial constraints on the supply of health-care services can result in artificially high prices or low supply of products or services.¹⁵² These forms of market failure have been used to justify other regulatory interventions, notably the use of the antitrust laws.

Although the most obvious alternative to private ordering through the use of markets is government regulation, defects in private ordering have also been addressed through professional self-governance. Kenneth Arrow's seminal article *Uncertainty and the Welfare Economics of Medical Care* observed that many of the organizational characteristics of the health-care industry—the nonprofit organization of health-care institutions, subsidization of medical education, and professional certification and licensure, make sense in terms of professionals attempting to maintain trust in the face of consumer uncertainty.¹⁵³ Additional common examples of self-regulation by professionals include peer review of staff privileges in hospitals, accreditation programs, and Medicare Peer Review Organizations.¹⁵⁴

Professional self-regulation has continued unabated in the face of the growth of external regulation of health care in recent years.¹⁵⁵ Indeed, it has recently received a boost from the Institute of Medicine's work on quality of health care, which has been read as criticizing licensure agency discipline or tort liability-based approaches to quality oversight.¹⁵⁶ Recent literature on "trust-enhancing" regulation also questions the value of external command-and-control regulation as opposed to professional ethics.¹⁵⁷ Although the worst

150. See RICE, *supra* note 98, at 23–24.

151. *Id.* at 33–38.

152. See *id.* at 115–18 (discussing the movement towards more monopoly power in hospitals and health plans).

153. Arrow, *supra* note 105, at 964–67.

154. See *supra* text accompanying notes 21–30, 46–59.

155. See Peter D. Jacobson, *Regulating Health Care: From Self-Regulation to Self-Regulation?*, 26 J. HEALTH POL. POL'Y & L. 1165 (2001).

156. See COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, INSTITUTE OF MEDICINE, *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* 78 (2001).

157. Mark A. Hall, *Arrow on Trust*, 26 J. HEALTH POL. POL'Y & L. 1131, 1140–42 (2001).

excesses of self-regulation, such as peer review of fees or absolute ethical prohibitions on advertising, have been squelched by the antitrust laws, the Supreme Court's recent decision in *California Dental Association v. Federal Trade Commission* recognized an ongoing role for professional self-regulation, indeed regulation of advertising, because of the unique characteristics of health-care markets.¹⁵⁸

The problem is that while professional self-regulation can be understood as serving the public interest by responding to information deficit and agency problems in health care, it can also be seen as restraining trade and facilitating the preservation and consolidation of professional power. Indeed, Paul Starr's *The Social Transformation of American Medicine* became the most influential vision of the history of American health care in the twentieth century because of its convincing description of how physicians had been able to parlay the control over medical knowledge afforded to them by the scientific revolution to gain political and economic control over health care as well.¹⁵⁹ The scope the law had granted them for self-regulation played a key role in this rise of physician power.¹⁶⁰

One response to professional self-regulation could have been simply to outlaw it. However, this response, though frequently debated, has never caught on. In the end, the arguments of Freidson, Savage and others that health-care professionals have the best knowledge base for judging one another's work has carried the day. There is also a benefit to society in maintaining among professionals a sense of responsibility for self-criticism and peer oversight.¹⁶¹ As noted above, recent considerations of quality oversight have endorsed a continuing key role for peer review. Moreover, given the political power of organized medicine, it would probably not be politically possible to replace peer review with external regulation.¹⁶²

The alternative that we have ended up with is a fourfold response. First, the worst excesses of professional self-regulation, as has already been noted, have been outlawed, often as violations of antitrust laws.¹⁶³ Second, professional regulation has been supplemented by external regulation. The

158. 526 U.S. 756 (1999).

159. Starr, *supra* note 120; see also *Special Issue: Transforming American Medicine: A Twenty-Year Retrospective on the Social Transformation of American Medicine*, 29 J. HEALTH, POL., POL'Y & L. 557-1023 (2005).

160. See STARR, *supra* note 120, at 20, 28, 102-107.

161. See David Orentlicher, *The Role of Professional Self-Regulation*, in REGULATION OF THE HEALTHCARE PROFESSIONS 129, 130-33 (1997).

162. The health-care industry spent more on lobbying in 2003 than any other industry. The AMA alone spent \$17.3 million. *American Political Network*, 10 AM. HEALTH LINE 9 (June 15, 2004) at <http://www.americanhealthline.com>. The AMA is rated twelfth on Fortune Magazine's list of most powerful lobbying groups. See *The Power 25, Top Lobbying Groups*, FORTUNE (July 20, 2004), at <http://www.fortune.com/fortune/power25>.

163. See FURROW ET AL., *supra* note 11, § 14-10, at 693-96.

Stark self-referral laws, for example, were adopted because professionals had failed to address an obvious, indeed embarrassing, problem of conflicts of interest in the medical profession.¹⁶⁴ Third, the courts and legislatures have imposed upon peer review processes the harness of administrative procedure. In a number of states, the courts require bodies that credential hospital medical staff, for example, to provide “fair procedure.”¹⁶⁵ The Health Care Quality Improvement Act goes even further, offering protection to hospitals that offer full administrative due process in staff privileging procedures.¹⁶⁶ Finally, courts afford judicial review to those who are aggrieved by peer review proceedings.¹⁶⁷ This form of review, however, resembles closely judicial review of administrative decisions, requiring exhaustion of in-hospital remedies and deferring to peer review findings of fact and application of decision-making discretion.¹⁶⁸

In sum, however, what has happened is that professional self-governance in health care has become subject to administrative law. That is to say, professional self-governance has been recognized as a viable and legitimate alternative to public regulation, but the legislatures and courts have subjected professional self-regulation, to a considerable degree, to the same administrative law constraints imposed on public regulatory entities. This has also been true when private organizations have been used to achieve other public ends, such as the administration of public health-care financing programs.¹⁶⁹ The result has been the phenomenon that is the subject of this paper—the dominance of administrative law in health care.

At the outset we identified three types of health-care programs in which administrative law was found: financing tax-subsidy programs, licensure and certification programs, and private regulation. The discussion just concluded suggests why these three types of programs exist and persist. First, private ordering cannot assure universal access to health-care finance, and public regulation exists to oversee public financing, to expand private financing, to control moral hazard, and to police private insurer responses to moral hazard. Second, public licensing and certification programs exist to address

164. *Id.* § 13-8, at 648–50.

165. *See supra* text accompanying notes 58–59.

166. 42 U.S.C. § 11112 (2000).

167. FURROW ET AL., *supra* note 11, § 4-5, at 101–02.

168. *Id.* §§ 4-3, at 98, 4-6, at 104–05.

169. Thus, as noted above, privately insured ERISA employee-benefit plans are subject to external review under state law, internal review of ERISA plans are regulated by Labor Department regulations, and ERISA plan decisions are subject to (deferential) judicial review. *See supra* text accompanying notes 56–57. Federal rules provide for review of the decisions of Medicare contractors, subjecting them to administrative law controls. Reconsiderations and Appeals, 42 C.F.R. pt. 478 (2003); *see also* Grievances, Organization Determinations and Appeals, 42 C.F.R. pt. 422(M) (2004) (relating to Medicare Advantage plans).

information deficiencies, real or perceived, in health-care markets. Third, private regulatory programs exist to facilitate the functioning of professional networks. These private regulatory programs are often brought under the sway of public administrative law, or something closely resembling it, to enhance the likelihood that they will serve the public interest.

V. HEALTH-CARE LAW AND ADMINISTRATIVE LAW: MARRIAGE MADE IN HEAVEN OR ILL-ADVISED?

Having identified explanations as to the predominance of administrative law in health-care law, we must still address the final question presented, at least implicitly, by this symposium: Would we be better off without this dominance? Are health law and administrative law inextricably entwined, or is their combination a marriage of convenience that can be disentwined when it results in inconvenience?

This question can be usefully separated into two subsidiary questions. First, would our health-care system be better off without the pervasive presence of administrative entities—public and private? Second, would it be better off without the influence of administrative law as such?

The first question we have already discussed at some length. What alternatives are superior to administrative oversight? One answer is greater use of legislation and of the courts. Private *qui tam* litigation in the courts enforcing a broad statutory prohibition against false claims offers one example of how this might work.¹⁷⁰ The Civil False Claims Act,¹⁷¹ and in particular its *qui tam* provisions,¹⁷² has had a huge impact on the health-care industry. The same could be said to a lesser extent of private antitrust legislation,¹⁷³ or private RICO suits.¹⁷⁴

Our experience here, however, does not offer a great deal of encouragement for moving in this direction. Private enforcement of public law has been criticized as distorting enforcement priorities, encouraging expensive litigation, and diminishing the predictability of the law.¹⁷⁵ Its effectiveness has,

170. See Pamela H. Bucy, *Private Justice*, 76 S. CAL. L. REV. 1, 43–54 (2002) (describing the use of *qui tam* litigation to prosecute health-care fraud).

171. 31 U.S.C. § 3729 (2000).

172. See 31 U.S.C. § 3730 (2000).

173. 15 U.S.C. § 15(a) (2000).

174. 18 U.S.C. § 1864 (2000). See generally Bucy, *supra* note 170 (describing the variety of private mechanisms used for law enforcement).

175. Joan H. Krause, *A Conceptual Model of Health Care Fraud Enforcement*, 12 J.L. & POL'Y 55, 137–141 (2003) (describing problems with private enforcement under *qui tam*); see Bucy, *supra* note 170, at 62–68.

in most instances, been enhanced when the effect of the governing statute has been clarified and magnified by the actions of an administrative agency.¹⁷⁶

A more challenging response is that we should rely on private ordering, and in particular markets, to take the place of administrative oversight. This assertion enjoys broad support among politicians and considerable support among academics, though it is contested by others. How one evaluates the capacities of private ordering depends in part on how seriously one takes market failures in health care. If the problems of information and agency described above are in fact intractable, then internal and external administrative review are necessary to assure high quality and appropriate utilization in health care. However, if information and agency problems in health care are in fact surmountable (if, for example, they can be solved by increased disclosure or by application of the internet), then administrative oversight may be superfluous, even harmful. Even if one views market failures in health care as serious, it is arguable that administrative intervention makes things worse rather than better. External bureaucratic oversight may create additional inefficiencies, exacerbating rather than solving problems.

A great deal of ink has been spilled on this topic, and we cannot resolve it or even exhaustively describe it here.¹⁷⁷ Suffice it to say, however, that it is not conceivable that we are going to completely abandon quality oversight regulation in the foreseeable future. Professional licensure has been criticized for years and at the margins has been subjected to sunset legislation, but there is no significant political appeal to the idea of abolishing it and to letting anyone practice medicine who believes he or she can do it.¹⁷⁸ Similarly, there is no political traction behind the idea of abolishing the FDA. Alternative and complementary medicine remains largely unregulated, but even here there has been movement in the recent past toward more regulatory control.¹⁷⁹

176. The HHS Office of Inspector General (OIG) regulates false claims. The Federal Trade Commission (FTC) and Department of Justice (DOJ) regulate antitrust laws. The compliance guidelines of the OIG are available at <http://www.oig.hhs.gov/fraud/complianceguidance.html> (last visited Nov. 7, 2004). See Krause, *supra* note 175, at 91–110 (describing the variety of informational tools available to the OIG for effecting compliance with the fraud and abuse laws).

177. One of the most intelligent and persuasive proponents of the position that health-care markets are not that different is Mark Pauly. See, e.g., Mark V. Pauly, *Is Medical Care Different?*, in *COMPETITION IN THE HEALTH CARE SECTOR: PAST, PRESENT, AND FUTURE* 19 (Warren Greenberg ed., 1978). In law, the most consistent and persuasive free-market advocates have been Clark Havighurst and James Blumstein. See Clark C. Havighurst, *I've Seen Enough! My Life and Times in Health Care Law and Policy*, 14 *HEALTH MATRIX: J.L. MED.* 107 (2004); James Blumstein, *Health Care Law and Policy: Whence and Whither?*, 14 *HEALTH MATRIX: J.L. MED.* 35 (2004).

178. Timothy S. Jost, *Introduction—Regulation of the Healthcare Professions*, in *REGULATION OF THE HEALTHCARE PROFESSIONS* 1, 3–4 (Timothy S. Jost ed., 1997).

179. See for example the FDA's recent move to regulate Ephedra. Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an

Regardless of how this debate is resolved, administrative oversight of health care is likely to continue, indeed probably to increase, because of the inescapable public role in health-care financing. For reasons explained briefly above, and at length elsewhere,¹⁸⁰ a public role in insuring the public, or segments of it, for health care is inevitable. If public money is going to be spent on health care, some control over the utilization of publicly financed products and services and protection against fraud and abuse is inescapable, and some public oversight of the quality and quantity of publicly purchased care is likely. As long as we rely primarily on private health insurance to finance health care, regulation of private insurance to assure solvency and fair claims practices is necessary, and attempts to control underwriting to expand access to care are likely.¹⁸¹

We can, of course, attempt to privatize public systems, and conservative commentators and health insurers and managed-care organizations that are likely to profit from privatization, will continue to push for this.¹⁸² Our experience with the Medicare+Choice program, however, demonstrates that privatization makes no sense in terms of efficiency and raises serious equity problems as well.¹⁸³ The true cost of the Medicare Advantage program, which is also leaking out, underlines the high cost of privatization of public programs.¹⁸⁴ In any event, privatization is likely to expand rather than contract regulation because it enhances the need to regulate participating insurers and managed-care organizations while not wholly obviating the need for regulating providers. In sum, the pervasive involvement of administrative entities in health care is likely to remain for the foreseeable future.

The final alternative that we have considered to public administrative regulation is private regulation through professional networks. Peer review and self-regulation are likely to continue to play an important role in the health-care industry for the foreseeable future. Indeed, professional power seems to be reasserting itself as managed care has receded.¹⁸⁵ But professional

Unreasonable Risk; Final Rule, 69 Fed. Reg. 6788 (Feb. 11, 2004) (to be codified at 21 C.F.R. pt. 119).

180. JOST, *supra* note 77.

181. *See* Jost, *supra* note 130, at 472–483.

182. *See, e.g.*, TRUDY LIEBERMAN, SLANTING THE STORY: THE FORCES THAT SHAPE THE NEWS (2000) (documenting the campaign of the Heritage Foundation pushing the privatization of public health care provision).

183. GERALDINE DALLEK ET AL., THE COMMONWEALTH FUND, LESSONS FROM MEDICARE+CHOICE FOR MEDICARE REFORM, POLICY BRIEF 5–7 (June 2003), available at http://www.cmwf.org/programs/medfutur/dallek_mcleasonsforreform_pb_658.pdf.

184. *See* BRIAN BILES ET AL., THE COMMONWEALTH FUND, THE COST OF PRIVATIZATION: EXTRA PAYMENTS TO MEDICARE ADVANTAGE PLANS, ISSUE BRIEF (May 2004), available at http://www.cmwf.org/programs/medfutur/biles_extrapayments_ib_750.pdf.

185. *See* David E. Grembowski et al., *Managed Care and the US Health Care System: A Social Exchange Perspective*, 54 SOC. SCI. & MED. 1167 (2002).

self-regulation is unlikely to replace public regulation any time soon. Its usefulness is limited by its particular competencies. There are some functions such as oversight of enforcement of the antitrust or fraud and abuse laws to which self-regulation is peculiarly unsuited, while oversight of other functions,¹⁸⁶ such as approval of new drugs and devices is likely to require resources unavailable to professional networks. Moreover, as noted above, transfer of authority from public to private regulatory entities does not necessarily mean that there will be less administrative law.

In sum, our examination of institutional alternatives for governing health care leaves us with the conclusion that a prominent role for public or private administrative entities is going to continue indefinitely. This leads us to our second and final question, however: Should administrative law continue to dominate health-care law?

If the answer to the first question is that administrative entities, public and private, will continue to play a major role in overseeing health-care organization and finance, then the answer to this question would seem self-evident. Administrative law was developed, at least in part, to assure that administrative entities serve the public interest. One can argue how well it does this, and one can certainly contend that it could be improved. At its best, however, administrative law promotes principles of fairness, transparency, reflectiveness, non-discrimination, and accountability that are basic values in our legal system. Administrative law offers the hope of making professional self-regulation more attentive to public values and making public and private regulation of health-care financing more equitable. As long as administrative entities continue to play a major role in health care, administrative law will continue to oversee them.

VI. CONCLUSION

Administrative law, therefore, will continue to be inextricably entwined with health law. We will continue to argue about whether this should be so, but we are unlikely to ever totally eliminate the sway of administrative law in this area. In the short term, indeed, the application of administrative law may increase rather than decrease, as we continue to struggle to expand access to health care, reduce its cost, and improve its quality. We need to focus, therefore, on how we might improve the application of administrative law to health care, or even how we might improve administrative law. What the marriage between administrative law and health care may need, that is to say, is not a divorce, but rather marriage counseling. This is one of the potential contributions of this symposium, and it is a worthwhile enterprise.

186. The reluctance of the AMA to take on physician conflicts of interest prior to the Stark legislation illustrates this point. See MARC A. RODWIN, *MEDICINE, MONEY, AND MORALS: PHYSICIANS' CONFLICTS OF INTEREST*, 31–45 (1993).

