OVERSIGHT OF THE QUALITY OF MEDICAL CARE: REGULATION, MANAGEMENT, OR THE MARKET?

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I. INTRODUCTION

The great health care reform debate of 1993 and 1994 was driven by two primary concerns—the high and rising cost of health care and increasing difficulties experienced by Americans in securing access to health insurance.[1] Dramatic increases in the cost of health care have severely burdened the federal and state governments and alarmed employers that have traditionally provided health insurance as a benefit. As employers have dropped or limited insurance coverage, an ever-growing number of Americans have become uninsured. For these Americans, the ever-present risk of illnesses or accidents that might require expensive health care poses a continuing threat to financial security, indeed to life itself.

Though these problems continue largely unabated, Congress failed to enact health care reform in 1994. The reasons for this failure are complex. One factor that certainly contributed to the public's anxiety with regard to health care reform was the potential threat that health care reform posed, at least in the public imagination, to the quality of health care received by Americans.[2] Though Americans express high levels of dissatisfaction with their health care system, most continue to believe that it provides high quality care.[3] Public fear that quality would suffer if tough actions were taken to control cost while

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1. *See* THE WHITE HOUSE DOMESTIC POLICY COUNCIL, HEALTH SECURITY, iii (1993).

2. Gordon D. Schiff et al., *A Better-Quality Alternative: Single-Payer National Health System Reform*, 272 JAMA 803 (1994); *Poll Finds Public Fears Fallout From Health Reform, Wants More Debate*, U.S. NEWSWIRE, Sept. 9, 1994 (60% of persons polled in national opinion poll feared that health care reform would diminish quality of care); Surveys and Polls CBS/NYT, American Political Network, American Health Line, Sept. 13, 1994 (55% answered yes to the question "Do you worry that, in order to provide health care for all, the quality of your care will be diminished?")

3. SYSTEM IN CRISIS: THE CASE FOR HEALTH CARE REFORM 76, 77, 176, 177 (Robert J. Blendon & Jennifer Edwards eds., 1991).

expanding access undoubtedly led to much of the resistance to health care reform.[4]

Future attempts to reform the health care system must therefore seriously address the need to continue to assure the quality of medical care in a reformed health care system. The task of quality oversight has long been assigned in the first instance to the regulatory boards that license and discipline health care professionals. These bodies were scarcely mentioned in President Clinton's Health Security Act or by its competitors.[5] Instead, the reform proposals evidence a belief that health care quality is the responsibility of those who manage health care plans and institutions and the markets to which they respond.[6]

This article questions this assumption. In particular, it explores the continuing role of regulation in assuring quality of care. In pursuing this inquiry, it begins with an account of the history of legal oversight of the medical profession. This examination documents two trends. First, over time the focus of regulation has changed from assurance of minimal professional competence (competence being defined to include the structural capacity to practice appropriately and the avoidance in actual practice of consistent error), to consideration of quality as more globally defined, including concern for the continual improvement of the process and the outcome of actual practice.[7] Second, control over quality oversight has tended to move from regulatory (primarily self-regulatory) bodies to management and to the market. This historical account raises a second order of questions: Are these trends salutary? And what residual role, if any, remains for regulation (including professional licensure) in a system in which management and the market dominate quality oversight? To answer these questions, the article examines the texture of medical practice, and the mechanisms that might be useful for improving the quality of practice. It then evaluates the relative merits of the market, management, and regulation as means to accomplishing the task of quality oversight. The article concludes that a residual role remains for regulation, and attempts to define the nature of this role.

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4. Dana Priest, *Democrats Pull the Plug on Health Care Reform,* WASH. POST, Sept. 27, 1994, at A1.

5. Timothy S. Jost, *Health System Reform: Forward or Backward with Quality Oversight?* 271 JAMA 1508, 1508 (1994).

6. *Id.*; Alan Hillman et al., *Safeguarding Quality in Managed Competition,* HEALTH AFF., Supp. 1993, at 110.

7. Throughout this article reference will be made to the Donabedian typology of quality assessment, which recognizes three different approaches to assessing the quality of health care: analysis of structure, process, and outcome. Structure refers to the basic resources that must be present as a prerequisite to the provision of quality care: professionals, equipment, educational attainments, etc. Process refers to the manner in which care is provided, utilizing the structural elements that are available. Outcome refers to the results of process. While the ultimate goal of health care is always a good outcome, outcomes are often difficult to assess or to attribute to particular interventions. Quality is often, therefore, assessed on the basis of the acceptability of processes followed. Finally, structure is generally regarded as the least reliable, but most easily measured, indicia of quality. I. AVEDIS DONABEDIAN, THE DEFINITION OF QUALITY AND APPROACHES TO ITS ASSESSMENT 79–84 (1980).

II. A HISTORY OF THE LEGAL OVERSIGHT OF MEDICAL PRACTICE

A. The Nineteenth Century Origins

A little more than a century ago the United States Supreme Court considered a case involving a medical practitioner named M. H. Dent.[8] Dent, a graduate of the American Medical Eclectic College of Cincinnati, Ohio, had practiced in West Virginia for six years, but was refused a license by the West Virginia State Board of Health.[9] The Board determined that Dent had not practiced long enough to qualify under the licensure act's grandfather clause and was not a graduate of a reputable school.[10] He was subsequently convicted of the unlicensed practice of medicine.[11] Dent argued before the Court that, having established a successful medical practice, he had a property interest that the state could not take from him.[12] Mr. Justice Field, writing for the unanimous Supreme Court, rejected Dent's claim. Justice Field took note of the arcane and complex body of knowledge that physicians must master, and then asserted:

> Every one may have occasion to consult [the physician], but comparatively few can judge of the qualifications of learning and skill which he possesses. Reliance must be placed upon the assurance given by his license, issued by an authority competent to judge in that respect, that he possesses the requisite qualifications.[13]

In this passage the Supreme Court articulated, at the dawn of modern professional regulation in the United States, both a justification for professional licensure and an understanding of its purpose. The justification was market failure, in particular, a failure caused by lack of information in the hands of consumers and the inability of consumers to understand such information as was available to them. The Court endorsed the belief that consumers lack expertise to identify competent medical practitioners. Regulatory intervention was thus necessary to protect them. Second, the Court defined the purpose of licensure: assuring the competence of practitioners by confirming that they "possesse[d] the requisite qualifications."[14] The rationale of market failure continues to be relied upon today to justify external regulation of health care professionals. The purpose of external oversight has been expanded, however, beyond simply assuring competence.[15]

Today's regulation of health care professionals in the United States is primarily a product of the late nineteenth century. Physician licensure appeared first in the United States in the seventeenth century and was nearly universal by the beginning of the nineteenth.[16] During this early period licensure authority

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8. Dent v. West Virginia, 129 U.S. 114 (1889).
9. *Id.* at 117–18.
10. *Id.* at 118.
11. *Id.*
12. *Id.* at 118–20.
13. *Id.* at 122–23.
14. *Id.* at 123.
15. *See infra* notes 69–79 and accompanying text.
16. *See* ROBERT C. DERBYSHIRE, MEDICAL LICENSING AND DISCIPLINE IN THE UNITED STATES 1–7 (1969); RICHARD H. SHRYOCK, MEDICAL LICENSING IN AMERICA, 1650–1965, at 3–42 (1967).

was often delegated by statute to the medical societies and was generally guild-like in nature.[17] As the nineteenth century progressed, however, occupational licensure was largely abandoned, and by 1850 the medical profession had been almost totally deregulated.[18] Accompanying and perhaps contributing to this deregulatory trend was the proliferation of medical colleges (many of them proprietary and of very low quality) that permitted virtually anyone who desired to practice the healing arts to enter the profession.[19] The mid-nineteenth century also saw the spread of a variety of schools of healing theory (homeopathic, Thompsonian, eclectic, spiritualist), and an increase in the number of healers not attached to any particular school of practice.[20]

Licensure was reborn in 1873 with the adoption of the Texas licensure statute.[21] Over the next thirty years all of the existing states adopted physician licensure statutes.[22] The *Dent* decision was the culmination of this movement. While early statutes grandfathered those already in practice and permitted admission to practice on the basis of a medical diploma, the licensure statutes became more restrictive over time, requiring that applicants attend recognized schools, meet specified standards with respect to duration and nature of training, and pass an examination.[23] Fulfillment of these requirements was intended to assure that the physician had the capacity to practice medicine competently.

The nineteenth century origins of physician licensure have been thoroughly studied, and a variety of theories have emerged as to why licensure was in fact adopted. Some commentators argue that "regular" allopathic physicians lobbied for medical licensure in order to defend their dominance against the rise of competing schools of medicine, such as the Thompsonians or eclectics.[24] Other scholars contend that qualified physicians, regardless of school of practice, fought for licensure laws to protect themselves from competition from graduates of substandard medical schools or from untrained lay healers.[25] At the time, however, the advocates of licensure argued simply that licensure would protect the public from practitioners of the healing arts who could not demonstrate competence to practice.[26] The articulated purpose of

17. JEFFREY L. BERLANT, PROFESSION AND MONOPOLY: A STUDY OF MEDICINE IN THE UNITED STATES AND GREAT BRITAIN 203–16 (1975); JOSEPH F. KETT, THE FORMATION OF THE AMERICAN MEDICAL PROFESSION: THE ROLE OF INSTITUTIONS, 1780–1860, at 14–30 (1968); SHRYOCK, *supra* note 16, at 24–25.

18. BERLANT, *supra* note 17, at 218–20; DERBYSHIRE, *supra* note 16, at 6; SHRYOCK, *supra* note 16, at 30–31; ROSEMARY STEVENS, AMERICAN MEDICINE AND THE PUBLIC INTEREST 26–27 (1971).

19. JAMES G. BURROW, ORGANIZED MEDICINE IN THE PROGRESSIVE ERA: THE MOVE TOWARD MONOPOLY 15, 31–32 (1977); SHRYOCK, *supra* note 16, at 28, 60; PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 40–44 (1982); STEVENS, *supra* note 18, at 26–28.

20. STARR, *supra* note 19, at 47–54, 93–102.

21. DERBYSHIRE, *supra* note 16, at 6–7.

22. DERBYSHIRE, *supra* note 16, at 8.

23. STARR, *supra* note 19, at 104.

24. BURROW, *supra* note 19, at 58; DERBYSHIRE, *supra* note 16, at 7.

25. BURROW, *supra* note 19, at 58, 61; SHRYOCK, *supra* note 16 at 57; STARR, *supra* note 19, at 102–03. One commentator has argued that the laws were enacted to protect doctors holding local economic power against dominant national corporations that could have taken over the provision of health care. BERLANT, *supra* note 17, at 238–40.

26. While a great deal has been written about the growth of medical licensure in the late 19th century, most of it is speculative and based largely on anecdote. One of the few thorough

licensure as recognized in *Dent* was to assure the competence of practitioners, with competence defined structurally in terms of the possession of the basic skills and knowledge necessary to practice medicine.

Two important characteristics of licensure in the late nineteenth and early twentieth century must be noted. First, licensure was not concerned with the quality of medical care as that term is commonly understood today. A widely quoted modern source defines quality as follows,. "Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[27]

Licensure was concerned with the capacity to deliver minimally adequate care, not with the actual delivery of optimal care. It was not concerned with improving practice to increase the likelihood of desired outcomes and contributed only indirectly to this end.

A second characteristic of public regulation of physicians in the late nineteenth century is that it was largely self-regulation of the profession by the profession.[28] The late nineteenth century statutes created public licensure boards appointed by state government rather than delegating licensure responsibilities to the medical societies, as had their eighteenth century predecessors.[29] Nevertheless, organized medicine continued to dominate the appointment process, and as recently as the late 1960s statutes in a third of the states required that medical board members be appointed from persons nominated by medical societies.[30] Appointed members of the board were inevitably physicians.

Licensure was merely the most "legal" manifestation of a broader structure of self-regulation that physicians constructed beginning in the nineteenth century. Perhaps the most important of these self-regulatory initiatives was reform of medical education. Through the efforts of medical reformers, including ultimately the Flexner Report,[31] a large number of deficient medical colleges were closed during this period.[32] The length of the

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studies of a particular (in this case unsuccessful) state campaign to establish licensure concludes that the campaign is much better understood as an attempt by a group of reformers to "bring public affairs under the sway of certified expertise" to promote a concern for public health than as an attempt to monopolize practice to promote economic interests. Samuel L. Baker, *A Strange Case: The Physician Licensure Campaign in Massachusetts in 1880*, 40 J. HIST. MED. & ALLIED SCI. 286, 306 (1985).

27. I INSTITUTE OF MEDICINE, MEDICARE: A STRATEGY FOR QUALITY ASSURANCE 3 (Kathleen N. Lohr ed., 1990).

28. MICHAEL MORAN & BRUCE WOOD, STATES, REGULATION AND THE MEDICAL PROFESSION 38–41 (1993).

29. Samuel L. Baker, *Physician Licensure Laws in the United States, 1865-1915*, 39 J. HIST. MED. & ALLIED SCI. 173, 181–84 (1984).

30. BURROW, *supra* note 19, at 58–60; DERBYSHIRE, *supra* note 16, at 33.

31. The Flexner Report, written by Abraham Flexner for the Carnegie Foundation for the Advancement of Teaching and published in 1910, documented the serious problems in medical education at the beginning of the 20th century and helped set the course for its reform. STARR, *supra* note 19, at 118–23.

32. STARR, *supra* note 19, at 112–27; STEVENS, *supra* note 18, at 68.

medical course of education was expanded from two to four years and eventually to eight years beyond high school.[33]

The profession also took steps to organize and to improve specialty practice under its own control. The license to practice medicine in the United States was from the outset a "license to practice medicine and surgery in all of its branches."[34] By the late nineteenth century, however, it was becoming clear that no one physician could master all of medical practice and that many particular medical problems were best addressed by specialists. The first specialty board, The American Board for Ophthalmic Examinations, was formally created in 1916.[35] Though licensure by specialty was considered briefly in the late 1920s,[36] it was rejected in favor of exclusive control over specialization by self-regulatory specialty boards. The system of private specialty boards that exercised this control was firmly established by the time the Advisory Board for Medical Specialties was formed in 1933.[37]

Though the late nineteenth and early twentieth centuries witnessed a number of initiatives directed at self-improvement of the practice of medicine, true external control over the medical profession was largely absent during this period. Attempts by corporations or workers' cooperatives to employ or to contract with physicians, and thus to control medical practice, were rebuffed first by fierce professional opposition[38] and then by the legislatures and courts, which codified and enforced the corporate practice of medicine doctrine.[39] The American hospital, unlike its European counterparts, did not employ physicians. Rather, physicians within hospitals practiced as independent contractors, "privileged" by other physician members of the medical staff.[40] It was the physicians, in fact, who oversaw the quality of hospitals rather than the hospitals that supervised the quality of physicians.[41] Most physicians, moreover, conducted their office practice as sole practitioners, their practices largely hidden from external view.[42] And even those physicians who practiced in group practices were subject to only minimal oversight.[43]

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33. STARR, *supra* note 19, at 114–15, 118. The American Medical Association's Council on Medical Education, established in 1904, played a major role in this process. *Id.* at 117; STEVENS, *supra* note 18, at 63–66.

34. *See, e.g.*, N.J. STAT. ANN. § 45:9–5.1 (West 1991); FRANK P. GRAD & NOELIA MARTI, PHYSICIAN LICENSURE AND DISCIPLINE 70 (1979).

35. STEVENS, *supra* note 18, at 113.

36. *See* STEVENS, *supra* note 18, at 164–67.

37. STEVENS, *supra* note 18, at 212–15.

38. *See* STARR, *supra* note 19, at 200–32.

39. *See generally*, Mark A. Hall & Justin G. Vaughn, *The Corporate Practice of Medicine*, *in* HEALTH CARE CORPORATE LAW FORMULATION & REGULATION § 3.3 (Mark A. Hall ed., 1993).

40. For the history of this system, see STARR, *supra* note 19, at 162–69.

41. This was accomplished first through the Hospital Standardization Program of the American College of Surgeons and then through the Joint Commission on Accreditation of Hospitals. *See* Timothy S. Jost, *The Joint Commission on Accreditation of Hospitals: Private Regulation of Health Care and the Public Interest*, 24 B.C. L. REV. 835, 848 (1983).

42. In 1946 only 2.6% of active, non-federal physicians were in group practices. MEDICAL CARE CHARTBOOK 177 (Leon Wyszewianski & Stephen S. Mick eds., 1991) (hereinafter CHARTBOOK).

43. This continued to be true as late as the second half of the 20th century. *See* ELIOT FREIDSON, DOCTORING TOGETHER: A STUDY OF PROFESSIONAL SOCIAL CONTROL 118–19, 123, 163, 166, 216, 232, 241 (1975).

In fact, despite movement toward self-regulation of the structure of quality in the late nineteenth and early twentieth centuries, in the end it was the individual professional, and not organized medicine or external institutions, who bore primary responsibility for assuring the quality of the process and outcome of medical practice during this period.[44] While the emergence of the scheme of self-regulation described above was an important historical development, encounters between the average physician and this system were infrequent and fleeting. As late as the middle of the twentieth century, the typical physician would attend a professionally-accredited medical school, be licensed by a physician-dominated medical board, and perhaps be certified in a specialty by a self-governing specialty board.[45] If he was unfortunate, he might have to respond at some point in his career to a complaint that he had deviated from the ordinary standard of medical practice and thus committed malpractice.[46] In ordinary day to day life, however, the physician answered to no one but himself. His practice was largely invisible to his peers, incomprehensible to his patients, and unconstrained by external institutions.

B. The Era of Accountable Regulation: 1960—1990

The system of self-regulation that emerged at the end of the nineteenth century has not, of course, remained undisturbed. The practice of medicine itself has changed radically and continually as the twentieth century has progressed. First, health care financing has changed dramatically. The federal government has become ever more engaged in paying for health care, first tentatively through the Hill-Burton program in the late 1940s,[47] and then to a much greater extent through the Medicaid and Medicare programs enacted in the 1960s.[48] The emergence of the Blue Cross-Blue Shield plans in the 1930s, followed closely by the rise of commercial health insurance, transformed medical care into an employment benefit. This in turn intensified the interest of employers and insurers in the cost, and to a lesser extent the quality, of medical care.[49]

Changes in the law have also affected medical practice. The demise of charitable immunity,[50] the birth of the corporate negligence doctrine,[51] and the malpractice crises of the mid 1970s and early 1980s intensified the interest of hospitals in policing the work of the physicians who practiced within them.

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44. Physicians themselves see their own character and their concern for their reputation as the primary factors producing quality work. *See id.* at 123–24, 188–93. *See also*, Timothy S. Jost, *The Necessary and Proper Role of Regulation to Assure the Quality of Health Care*, 25 HOUS. L. REV. 525, 536–37 (1988).

45. As recently as 1949, over 60% of physicians were in general or family practice. CHARTBOOK, *supra* note 42, at 175.

46. As recently as 1956, only about 19% of physicians in active private practice were sued for medical malpractice during their lifetime. PATRICIA M. DANZON, MEDICAL MALPRACTICE 59 (1985).

47. Pub. L. No. 79-725, 60 Stat. 1040 (Codified at 42 U.S.C. §§ 291–291n (1946)).

48. Pub. L. No. 89-97, 79 Stat. 290 (1965).

49. For the history of these developments, see CONGRESSIONAL RESEARCH SERVICE, HEALTH INSURANCE AND THE UNINSURED: BACKGROUND DATA AND ANALYSIS 14–19 (1988).

50. *See, e.g.*, Bing v. Thunig, 143 N.E.2d 3 (N.Y. Ct. App. 1957).

51. *See* Darling v. Charleston Community Memorial Hosp., 211 N.E.2d 253 (Ill. 1965), *cert. denied*, 383 U.S. 946 (1966).

Finally, the institutional structure of medical practice has changed. As the twentieth century draws to a close, the sole practitioner has begun to fade from the scene as the group practice and the employed physician have become more common.[52]

These changes in the financing and structure of medical practice have been accompanied by a growing challenge to the self-regulatory structures that formerly governed the practice of medicine. Increasingly during the 1960s and 1970s, critics ranging from consumer activists to conservative economists questioned self-regulation in the health care industry.[53] The surprising growth in the cost of medical care during this period led to calls for bringing external controls to bear on medical costs.[54] Physician complaints about the malpractice crisis of the 1970s were met with consumer demands that issues of physician competence be attended to.[55] Consumer groups demanded reform of and representation on the self-regulatory institutions like the Joint Commission.[56]

In response to these challenges, new programs were created to regulate the quality of medical care and existing regulatory programs changed their nature and focus. Among the most important of the new programs was the Professional Standards Review Organization program established by the Social Security Amendments of 1972,[57] and replaced by the Peer Review Organization ("PRO") program in the 1980s.[58] These programs created regional and then statewide entities that would, among other functions, review the medical records of discharged Medicare patients to determine whether the patient had received necessary and appropriate care of acceptable quality. Though these programs were always concerned particularly with utilization issues, they also from the outset addressed quality concerns and as time went on became increasingly focused on quality issues. At the height of the PRO program in the late 1980s, the hospital records of one out of every four Medicare discharges was reviewed by PRO reviewers and over one hundred doctors were sanctioned because of quality concerns.[59]

This was also a period of particular growth in programs intended to regulate the institutions in which health care is delivered. These included requirements that institutional providers that participated in Medicare be

52. By 1991, 32.6% of non-federal physicians were located in group practices of three or more and 33.1% were employees or contractors. In total, 61.5% were in non-solo practices. Howard Larkin, *Welcome to the Machine: Doctors Will More Likely be Employees than Sole Proprietors as Medicine Shifts from a Cottage Industry to a Major Corporate Enterprise*, AM. MED. NEWS, Jan. 4, 1993, at 43.

53. *See, e.g.*, MILTON FRIEDMAN, CAPITALISM AND FREEDOM 149–60 (1962); William Worthington & Laurens H. Silver, *Regulation of Quality of Care in Hospitals: The Need for Change*, 35 L. & CONTEMP. PROBS. 305 (1970). This trend was also part of a larger rethinking of the benefits of regulation generally. EUGENE BARDACH & ROBERT A. KAGAN, GOING BY THE BOOK: THE PROBLEM OF REGULATORY UNREASONABLENESS 3–29 (1982).

54. STARR, *supra* note 19, at 381–83.

55. *See* SIDNEY M. WOLFE ET AL., MEDICAL MALPRACTICE: THE NEED FOR DISCIPLINARY REFORM, NOT TORT REFORM 4–5 (1985).

56. Jost, *supra* note 41, at 855, 856.

57. Pub. L. No. 92-603, § 249F, 86 Stat. 1329, 1429–45 (1972).

58. Pub. L. No. 97-248, § 143, 96 Stat. 324, 382 (1982).

59. OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH AND HUMAN SERVICES, THE SANCTION REFERRAL AUTHORITY OF PEER REVIEW ORGANIZATIONS 1–3 (1993); Timothy S. 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, 8, 33 (1989).

certified as meeting various Medicare certification requirements;[60] federal nursing home regulatory requirements;[61] and the Clinical Laboratories Improvement Act of 1988,[62] which brought under federal purview almost 200,000 clinical laboratories including tens of thousands of small laboratories in doctors' offices.[63]

New oversight programs appeared during this period not just nationally, but also at the institutional level. Most hospitals established risk management and quality assurance programs. While a few states required these programs by law,[64] it was more common for states to encourage these programs by providing evidentiary and liability immunities to protect persons who participate in them.[65] The strongest impetus for the creation of quality assurance and risk management programs, however, was probably the Joint Commission, which began to require quality assurance programs in the 1970s.[66] While quality assurance and risk management programs are internally directed, they are subject to external oversight through the corporate negligence doctrine, which holds hospitals liable for negligent credentialing and supervision,[67] and through the federal Health Care Quality Improvement Act, which requires reporting of adverse credentialing actions to a federal data bank and lays the ground rules for credentialing programs.[68]

The focus of existing regulatory programs also changed dramatically during this period. Medical boards responded to pressure for change by turning their attention to the on-going competence of licensed physicians to practice medicine. Continuing medical education requirements became common.[69] Several medical licensure boards added token consumer members, increasing marginally their accountability to the public.[70] They also began to take

60. BARRY FURROW ET AL., HEALTH LAW, § 13–9 (1995).

61. Timothy S. Jost, *Legal Characteristics of the Extended Care Facility*, *in* HEALTH CARE FACILITIES LAW 993, 1007–08 (Anne M. Dellinger ed., 1991).

62. Codified at 42 U.S.C. § 263a. *See*, discussing CLIA, *From the Centers for Disease Control: Regulations for Implementing Clinical Laboratory Improvement Amendments of 1988: A Summary*, 267 JAMA 1725 (1992); Hope S. Foster, *Federal Regulation of Clinical Laboratories*, *in* 1991 HEALTH LAW HANDBOOK 325, 326 (Alice G. Gosfield ed., 1991).

63. *See* David H. Frankel, *USA: CLIA Laboratory Changes*, 340 LANCET 962 (1992).

64. *See, e.g.*, MD. CODE ANN., HEALTH-GEN. § 19-319(g)(2). U.S. GENERAL ACCOUNTING OFFICE, HEALTH CARE: INITIATIVES IN HOSPITAL RISK MANAGEMENT 20–37 (1989); Arlene J. Diosegy, *Risk Management*, *in* HEALTH CARE FACILITIES LAW 389, 391 n.4 (Anne M. Dellinger ed., 1991).

65. *See* AMERICAN MEDICAL ASSOCIATION, A COMPENDIUM OF STATE PEER REVIEW IMMUNITY LAWS (1988) (hereinafter AMA COMPENDIUM) (a comprehensive review of all state immunity laws).

66. R. Heather Palmer & Mary M. E. Adams, *Quality Improvement/Quality Assurance Taxonomy: A Framework*, *in* PUTTING RESEARCH TO WORK IN QUALITY IMPROVEMENT AND QUALITY ASSURANCE 13, 17 (Mary L. Grady et al. eds., 1993).

67. *See, e.g.*, Darling v. Charleston Community Memorial Hosp., 211 N.E.2d 253 (Ill. 1965), *cert. denied*, 383 U.S. 946 (1966).

68. The Act requires hospitals to report disciplinary actions their state medical licensure board, which must in turn report them to a National Practitioner Data Bank (42 U.S.C.A. § 11,133 (West Supp. 1995)) and to consult the Data Bank at the time they initially grant privileges to a physician and every two years thereafter (42 U.S.C.A. § 11,135 (West Supp. 1995)).

69. *See* 1 FEDERATION OF STATE MEDICAL BOARDS, 1992-1993 EXCHANGE: FLEX AND M.D. LICENSING REQUIREMENTS 69 (1991).

70. Andrew K. Dolan & Carolyn A. Watts, *Adding Public Members to Governing Boards: A Critique*, 9 J. CONTEMP. BUS. 87, 88 (1980).

responsibility for investigating consumer complaints.[71] Consumer groups began to keep track of licensure actions and to prod boards to greater activity.[72]

These innovations and modifications represented important developments in both the structure and focus of regulation. Structurally, most of these developments represent an attempt to create regulatory programs that are answerable to the public, rather than only to the profession. The programs that emerged during this period have been described as embodying "bureaucratic" as compared to "professional" controls over professional practice.[73] In the bureaucratic model, described in its classic form by Max Weber,[74] organizations are structured hierarchically and work is governed by specific, impersonal rules.[75] Others have contrasted the bureaucratic model with the collegial control, personal responsibility, and relative absence of formal rules that characterize professionalism.[76]

This description is only partially apt when applied to oversight programs that emerged during this period. Doctors remained largely free from hierarchical control. The programs that imposed external regulatory controls upon doctors also retained important elements of self-regulation—PROs and medical boards were still dominated by physicians and applied standards prescribed by physicians.[77] But the description is accurate insofar as it

71. *See* Jost, *supra* note 59, at 55–60. The most ambitious attempts to impose lay oversight over the health care system were found in the consumer representation requirements of the Health Planning and Resource Development Act of 1974. *See* JAMES A. MARONE, THE DEMOCRATIC WISH: POPULAR PARTICIPATION AND THE LIMITS OF AMERICAN GOVERNMENT 253–321 (1990).

72. In particular, the Public Citizens Health Research Group, headed by Dr. Sidney Wolfe, began to publicize annual medical board disciplinary statistics on a state by state basis.

73. This movement is consistent with the often noted general decline in professional power in recent years. The nature and extent of the power of the professions, both historically and currently, has been much debated. Descriptively, some have argued that the professions in general, and particularly the medical profession, are dominating forces in their spheres of practice. This position has been identified primarily with the sociologist Eliot Freidson, though his views have evolved over time. *See* ELIOT FREIDSON, PROFESSIONAL DOMINANCE (1970); ELIOT FREIDSON, PROFESSIONAL POWERS (1986); Eliot Freidson, *The Reorganization of the Medical Profession*, 42 MED. CARE REV. 11 (1985) (hereinafter *Reorganization*). Others maintain that professionals have become "proletarianized," that they have become workers and the servants of capital. *See* John B. McKinlay & Joan Arches, *Towards the Proletarianization of Physicians*, 15 INT. J. HEALTH SERV. 161 (1985); John B. McKinlay & John D. Stoeckle, *Corporatization and the Social Transformation of Doctoring*, 18 INT. J. HEALTH SERV. 191 (1988). Still others argue that professionals have become "deprofessionalized," that professionals have ceased to be distinguished by the classic characteristics of the professions: esoteric knowledge, autonomy in work performance, and authority over clients. Marie R. Haug, *A Re-examination of the Hypothesis of Physician Deprofessionalization*, 66 MILBANK Q. 48 (Supp. 2, 1988); Marie R. Haug, *Deprofessionalization: An Alternative Hypothesis for the Future*, 20 SOC. REV. MONOGRAPH 195 (1973). Finally, some argue that professional power has never been as great as has commonly been believed. Vicente Navarro, *Professional Dominance or Proletarianization?: Neither*, 66 MILBANK Q. 57, 61 (Supp. 2, 1988). All, however, even Freidson, agree that individual practitioners no longer possess the independence from external oversight that they once enjoyed.

74. MAX WEBER, THE THEORY OF SOCIAL AND ECONOMIC ORGANIZATIONS 329–36 (1947).

75. *See* FREIDSON, *supra* note 43, at 7–9; Palmer & Adams, *supra* note 66, at 15–17.

76. FREIDSON, *supra* note 43, at 7–9; Palmer & Adams, *supra* note 66, at 13–17.

77. *See* Freidson, *Reorganization*, *supra* note 73, at 26; Fredric D. Wolinsky, *The Professional Dominance, Professionalization, Proletarianization, and Corporatization Perspectives: An Overview and Synthesis*, *in* THE CHANGING MEDICAL PROFESSION: AN

emphasizes the fact that these programs began to impose external regulatory controls on professionals.

Second, the focal concern of these programs diverged subtly from that of their predecessors. While licensure had previously been concerned primarily with capacity to practice medicine at the time of entry to the profession and with professional ethics, the new and modified programs conceptualized quality in broader terms. They were more globally concerned with the on-going capacity of professionals to practice their professions and the ability of institutions to deliver care competently.[78] Whereas formerly regulation had been concerned almost exclusively with structure, the new and reformed programs began to consider also the process of care delivery and the outcome of that process.[79] Regulation began to deal more comprehensively with quality, though its capacity to deal with process and outcome issues was still quite primitive.

While these changes were significant, the continuity between the programs that emerged during this period and those that preceded them is also striking. The new programs continued to be based on the persistent belief that health care is not subject to normal market controls because consumers lack the capacity to identify quality health care.[80] They also continued to rely on professionals to regulate professionals, though now through bureaucratic controls rather than simply through classical professional self-discipline.[81] Thus, in the second half of the twentieth century only incremental change was evident.

C. The Coming of Management and the Market

At the close of the twentieth century the continuities that have long existed in health care regulation seem to be giving way to radical change. Innovations in information technology and transformations in the structure of the health care industry, combined with dramatic erosion in the public's confidence in professional self-regulation, are facilitating significant changes in the oversight of health care quality. The market is pushing to replace external bureaucratic regulation while management is beginning to displace professional self-regulation.

INTERNATIONAL PERSPECTIVE 11, 16–17 (Frederic W. Hafferty & John B. McKinlay eds., 1993).

78. The PRO program, for example, reviewed patient records looking for substantial deviations from professional standards, while the nursing home inspection program under OBRA 1987 was reoriented to examine actual residents and their care, rather than just looking at the facility and its procedures. *See* Jost, *supra* note 59, at 34–37; Jost, *supra* note 61, at 1101–13.

79. *See* Smith v. Heckler, 747 F.2d 583 (10th Cir. 1984) (ordering the federal government to devise a nursing home certification system that considered process and outcome as well as structural quality issues).

80. The classic examination of this issue is found in Kenneth Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 951–52 (1963). For a fuller exploration of the problem, see Jost, *supra* note 44, at 558–72; Alan D. Wolfson et al., *Regulating the Professions: A Theoretical Framework, in* OCCUPATIONAL LICENSURE AND REGULATION 180, 190–93 (Simon Rottenberg ed., 1980).

81. *See* Freidson, *Reorganization*, *supra* note 73; Eliot Freidson, *The Reorganization of the Professions by Regulation*, 7 L. & HUM. BEHAV. 279 (1983); David Mechanic, *Sources of Countervailing Power in Medicine*, 16 J. HEALTH POL., POL'Y & L. 485 (1991).

The most important factor driving change has been an ever quickening reorganization of the health care industry, a reorganization that is becoming revolutionary rather than simply evolutionary in nature. The prevalence of the sole practitioner mode that dominated medical practice until the last two decades continues to decline as group practices and physicians employed by health care institutions or managed care organizations or allied with hospitals in integrated delivery systems become ever more common.[82] The large health care corporation, whose power was long resisted by the medical profession, seems now to have carried the day.[83] Both institutions that provide health care, such as hospitals or nursing homes, and entities that pay for health care, including insurers or self-insured employers, have become much more interested in overseeing the work of the professionals who practice within them or whose care they purchase.[84] The emergence of managed care organizations that both pay for and provide care, moreover, gives lay managers even greater control over medical practice.[85]

In tandem with this change, and perhaps driven by it, has come a revolution in information processing. Developments in information processing technology in the second half of the twentieth century have dramatically enhanced the ability of the health care industry to collect, process, and analyze data.[86] These advances create the possibility of engaging in analysis of the outcomes of health care processes.[87] Data describing large numbers of patients can be studied to determine the efficacy of alternative diagnostic and treatment modalities.[88] This information in turn contributes to the construction of practice guidelines, which describe best practices.[89] These practice guidelines

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82. *See* Mark A. Hall, *Managed Competition and Integrated Health Care Delivery Systems*, 29 WAKE FOREST L. REV. 1 (1994); Larkin, *supra* note 52.

83. This transformation was noted early on by STARR, *supra* note 19, at 420–49 and Arnold S. Relman, *The New Medical-Industrial Complex*, 303 NEW ENG. J. MED. 963 (1980), and has continued at an accelerating pace. It is also at the heart of the proletarianization literature cited in note 73 above. *See, e.g.*, McKinlay & Stoekle, *supra* note 73. It has also been noted in the legal literature, where some welcome it, Mark Hall, *Institutional Control of Physician Behavior: Legal Barriers to Health Care Cost Containment*, 137 U. PA. L. REV. 431 (1988), and others decry it, David Frankford, *Creating and Dividing the Fruits of Collective Economic Activity: Referrals Among Health Care Providers*, 89 COLUM. L. REV. 1861 (1989).

84. *See* Palmer & Adams, *supra* note 66, at 17–19; Robert J. Panzer & Carol Cronin, *Using Information in Quality Improvement and Quality Assurance*, *in* PUTTING RESEARCH TO WORK IN QUALITY IMPROVEMENT AND QUALITY ASSURANCE 85, 91–95 (Mary L. Grady et al. eds., 1993).

85. *See*, regarding the quality management activities of HMOs, Lawrence K. Gottlieb et al., *Clinical Practice Guidelines at an HMO: Development and Implementation of a Quality Improvement Model*, QRB, Feb. 1990, at 80; Phyllis Malamud, *Practice Parameters may Benefit Employers*, BUS. & HEALTH, June 1992, at 34.

86. *See generally*, INSTITUTE OF MEDICINE, HEALTH DATA IN THE INFORMATION AGE: USE, DISCLOSURE, AND PRIVACY (Molla S. Donaldson & Kathleen N. Lohr eds., 1994). In her remarkably prescient article, *Computer Technology and the Obsolescence of the Concept of Profession*, *in* WORK AND TECHNOLOGY (Marie R. Haug & Jacques Dofny eds., 1977), Marie Haug predicted this development nearly two decades ago. It seems finally to be coming to pass.

87. *See, e.g.*, Paul M. Ellwood, *Shattuck Lecture—Outcomes Management: A Technology of Patient Experience*, 318 NEW ENG. J. MED. 1549 (1988); Arnold Relman, *Assessment and Accountability: The Third Revolution in Medical Care*, 319 NEW ENG. J. MED. 1220 (1988).

88. *See* J. Jarrett Clinton, *Outcomes Research—A Way to Improve Medical Practice*, 266 JAMA 2057 (1991).

89. *See* INSTITUTE OF MEDICINE, CLINICAL PRACTICE GUIDELINES (1990); David M. Eddy, *Practice Policies—What Are They?* 263 JAMA 877 (1990).

can in some instances be reduced to algorithms that can be used to enable computer review of the quality of the practices of individual practitioners or institutions.[90] Outcome data can also be used to support pattern analysis, comparing the outcome of the care provided by individual practitioners or institutions with average or optimal practice as revealed by outcome analysis.[91]

Two implications of these developments in information technology and industry structure are particularly important for the purposes of this article. First, as practitioners and institutions are organized into a manageably small number of health care provider or managed care entities, and as it becomes possible to describe and evaluate physician practice and institutional performance through outcomes data and practice patterns, the construction of "quality report cards" becomes feasible.[92] Report cards comparatively scoring the quality of a number of health care providers can empower consumers (or other purchasers) to make choices among providers based on the quality information the report cards disclose.[93]

Several attempts have been made in recent years to enable consumers to comparatively evaluate quality in health care markets. From 1986 until 1992 the federal Health Care Financing Administration published annual data comparing the mortality experience of hospitals for certain procedures.[94] Several states, most notably Pennsylvania, New York, and California, have begun to assemble and release comparative outcome data, permitting prospective patients to compare the performance of various health care institutions and professionals.[95] Voluntary programs like the Greater Cleveland Health Quality Choice Project have also begun to assemble such data.[96] Other information initiatives have also been proposed, such as the Joint Commission's new disclosure policy, which includes hospital report cards.[97]

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90. *See* William L. Roper et al., *Effectiveness in Health Care: An Initiative to Evaluate and Improve Medical Practice*, 319 NEW ENG. J. MED. 1197 (1988) (describing HCFA's interest in outcomes research).

91. This is the goal of the Uniform Clinical Data Set project of the Health Care Financing Administration. Stephen F. Jencks & Gail R. Wilensky, *The Health Care Quality Improvement Initiative: A New Approach to Quality Assurance in Medicare*, 268 JAMA 900, 900–01 (1992). The Joint Commission also intends to use outcomes analysis to evaluate the quality of care in hospitals. *See* JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, THE MEASUREMENT MANDATE (1993).

92. *See* Charles Marwick, *Using High-Quality Providers to Cope with Today's Rising Health Care Costs*, 268 JAMA 2142 (1992); Panzer & Cronin, *supra* note 84, at 91–95.

93. Consumer report cards were the key method for regulating health care under President Clinton's proposed health security act, see H.R. 3600/S. 1757, 103d Cong., 1st. Sess. §§ 1325(a)(2)(D), 5003, 5004, 5005, 5012(1),(2), 5013(1),(2) (1993), and one of the least controversial provisions of that proposal. *See* Arnold M. Epstein, *Changes in the Delivery of Care Under Comprehensive Health Care Reform*, 329 NEW ENG. J. MED. 1672, 1674–75 (1993); Jost, *supra* note 5.

94. Bruce Goldfarb, *Making the Grade: Validity of Scoring System for Doctors and Hospitals Under Fire*, MED. WORLD NEWS, Aug. 15, 1993, at 46.

95. U.S. GENERAL ACCOUNTING OFFICE, HEALTH CARE REFORM, "REPORT CARDS" ARE USEFUL BUT SIGNIFICANT ISSUES NEED TO BE ADDRESSED (1994) (hereinafter GAO); Linda Oberman, *Rating Doctors; Pennsylvania Joins Trend in Releasing Physician Specific Mortality Data*, AM. MED. NEWS, Dec. 7, 1992, at 2; Douglas P. Shuit, *State Health "Report Card" to List Top Hospitals Only*, L.A. TIMES, Dec. 9, 1993, at A3.

96. Marwick, *supra* note 92.

97. *See* Timothy S. Jost, *Confidentiality and Disclosure in Accreditation*, 57 L. & CONTEMP. PROBS. 171 (1994).

Second, information processing technology and industry reorganization permit much greater oversight of health care by lay managers. Once it is possible to describe the quality of physician practices in terms that lay managers can apply or in algorithms that computers can manipulate, the genie is out of the bottle and physician dominance of quality oversight has been broken. In the last half-decade, health care institutions have begun to move from traditional physician-led quality assurance to a new management-led and data-driven philosophy of quality oversight: continuous quality improvement or total quality management.[98]

The continuous quality improvement or total quality management movement is based on quality improvement strategies developed in the industrial setting. The ideas of Demming, Juran, Schewhart and others had a significant impact on Japanese, and then American industrial production. Within the past few years these ideas have begun to be applied widely in health care as well.[99] Lay managers (sometimes in conjunction with physicians) are using their new-found power within reorganized health care institutions and their new and greatly enhanced access to and ability to manipulate data to improve the quality of medical care delivered in institutional settings.[100]

The quality improvement philosophy is based on several principles:

1) Quality is defined in terms of meeting the needs of "customers," defined broadly to include not only patients but also others who consume the services of the institution, including physicians themselves.[101] This orientation is immediately appealing to managers, who are increasingly oriented toward regarding patients as consumers. While this definition short-circuits debates over the true nature of quality, as quality is viewed as what consumers want, it is inherently problematic. If patients as consumers cannot recognize or assess the quality of medical care, as the law has assumed since *Dent*, how can they define quality?[102]

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98. *See* Palmer & Adams, *supra* note 66, at 19–31; Roy Penchansky & Carol L. Macnee, *Ensuring Excellence: Reconceptualizing Quality Assurance, Risk Management, and Utilization Review*, QRB, June 1993, at 182.

99. *See, e.g.*, DONALD M. BERWICK ET AL., CURING HEALTH CARE: NEW STRATEGIES FOR QUALITY IMPROVEMENT (1991); ELLEN J. GAUCHER & RICHARD J. COFFEY, TOTAL QUALITY IN HEALTHCARE: FROM THEORY TO PRACTICE (1993); MARA M. MELUM & MARIE K. SINIORIS, TOTAL QUALITY MANAGEMENT: THE HEALTH CARE PIONEERS (1992). One recent survey found that more than two thirds of the hospitals surveyed were adopting a TQM/CQI program. Linda Oberman, *Quality Quandary: Little Clinical Impact Yet*, AM. MED. NEWS, Apr. 25, 1994, at 3.

100. Though writing on TQM/CQI normally advocates physician involvement in TQM/CQI programs, the settled impression that emerges from the literature is that these programs are usually initiated by lay managers, and that physicians must be drawn in, sometimes reluctantly. *See* BERWICK ET AL., *supra* note 99, at 151–53; Al Lewis, *Reinvigorating Stalled CQI Efforts Through Physician Involvement*, PHYS. EXEC., July/Aug. 1993, at 32; Brian McCormick, *AMA not Ready for New Quality Philosophy*, 34 AM MED. NEWS, July 21, 1991, at 5; Oberman, *supra* note 99. The marginal role of physicians is illustrated by the fact that TQM/CQI manuals frequently have distinct chapters on physician involvement. *See* GAUCHER & COFFEY, *supra* note 99, at 181–216; MELUM & SINIORIS, *supra* note 99, at 129–58.

101. GAUCHER & COFFEY, *supra* note 99, at 27–28; Donald M. Berwick, *Controlling Variation in Health Care: A Consultation from Walter Shewart*, MED. CARE, Dec. 1991, at 1212, 1214.

102. *See infra* notes 222–28 and accompanying text.

2) Energy is better directed toward improving the system through which care is delivered than toward looking for "bad apples."[103] Most quality deficiencies are caused by faulty systems, not by incompetents working within those systems.[104] One can accomplish more, therefore, by raising the mean of the performance curve than by chopping off the tail.[105] This emphasis on improving the average performance rather than punishing the bad actor is perhaps the clearest distinction between quality improvement and traditional quality assurance, which has tended to be preoccupied with looking for "bad apples." This orientation gives quality improvement a more positive tone than quality assurance, thus making it more palatable to hospital employees and medical staff.[106] It also results in a heavy emphasis on process and on systems.

3) Data are very important for driving and shaping systems improvement.[107] Outcomes data are particularly useful for identifying areas where improvement is possible or necessary. Not only must systems be monitored continuously, but improvements in systems must also be monitored to assure that they are in fact effective.[108] Much of the arcanity of the quality improvement movement (Ishikawa diagrams, Pareto diagrams, histograms, etc.) results from attempts to organize, make sense out of, and devise rational responses to patterns revealed by data.[109]

4) Management and staff must be involved at all levels in the process of improvement.[110] This is a particular focus of total quality management. The culture of the organization must be molded to emphasize quality.[111]

5) Quality improvement is never finished. This is the primary insight of continuous quality improvement. There is always room for further progress. This should be reassuring, however, and not lead to discouragement.

This newfound confidence in the market and in internal management has been accompanied by a decline in confidence in external public regulation. The

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103. Mary T. Koska, *Discard "Bad Apple" Theory of Quality Assurance*, HOSP., June 20, 1990, at 64.

104. GAUCHER & COFFEY, *supra* note 99, at 62–63.

105. GAUCHER & COFFEY, *supra* note 99, at 60–61; Stephen B. Kritchevsky & Bryan P. Simmons, *Continuous Quality Improvement: Concepts and Applications for Physician Care*, 266 JAMA 1817 (1991).

106. *See* Richard E. Thompson, *From Quality Assurance to Continuous Quality Improvement*, PHYSICIAN EXECUTIVE, Sept./Oct. 1991, at 3.

107. *See* BERWICK ET AL., *supra* note 99, at 46–66; Kathryn L. Coltin & David B. Aronow, *Quality Assurance and Quality Improvement in the Information Age*, *in* PUTTING RESEARCH TO WORK IN QUALITY IMPROVEMENT AND QUALITY ASSURANCE 51 (Mary L. Grady et al. eds., 1993); Kritchshevsky & Simmons, *supra* note 105; Panzer & Cronin, *supra* note 84, at 86–91.

108. BERWICK ET AL., *supra* note 99, at 134–43; Kritchshevsky & Simmons, *supra* note 105.

109. *See* BERWICK ET AL., *supra* note 99, at 177–219.

110. *See* GAUCHER & COFFEY, *supra* note 99, at 99–180, 217–45; Robert F. Casalou, *Total Quality Management in Health Care*, 36 HOSP. & HEALTH SERV. ADMIN. 134 (1991).

111. BERWICK ET AL., *supra* note 99, at 1214; GAUCHER & COFFEY, *supra* note 99, at 148–80.

cost of health care quality regulation programs has long been recognized, and criticism of the high cost of regulation has become increasingly shrill. The whole range of federal and state regulatory programs, including the PRO program, CLIA, nursing home regulation, and even professional licensure have been criticized for their direct costs and for the costs they impose on the industry.[112] Increasingly, the benefits of traditional forms of regulation that focus on competence and error have been questioned. The continuous quality improvement/total quality management program poses a serious challenge to traditional regulatory programs that focus on "bad apples." The view of TQM is that such programs depress morale, discourage innovation, and do little to improve the care provided in the vast majority of instances.[113]

Self-regulation by professionals has been particularly criticized by economists, commentators, and the consumer advocates, who have perceived it as inefficient or untrustworthy, or both.[114] Though peer review of medical judgment technically makes a great deal of sense, professionals are notoriously and understandably reticent to discipline colleagues with whom they must maintain a daily working relationship.[115] When peers are also competitors, there is also the risk that peer discipline might be a cover for anticompetitive conduct.[116] When professionals are empowered to discipline members of other professions, there is the potential of peer review masking interprofessional rivalries.[117] Deputizing peer reviewers as government officials does not necessarily overcome these problems. Finally, the philosophy of professionalism that grounds peer review seems to be diminishing in strength as medical practitioners increasingly view themselves as businessmen engaging in commerce rather than as professionals and gentlemen.[118]

The approach to health care quality regulation of the Clinton administration's Health Security Act (HSA) as it was introduced into Congress in 1993 is a clear indication of the diminished respect enjoyed by traditional health care regulation and self-regulation programs. The Clinton proposal illustrates the philosophy that has come to dominate quality oversight: regulation is no longer necessary and is indeed pernicious, especially insofar as it involves sanctions for poor quality. Thus the HSA would have abolished the PRO program.[119] State licensure and the Joint Commission had no role in the HSA. On the other hand, the HSA would have required consumer report cards

112. *See, e.g.*, CAROLYN COX & SUSAN FOSTER, FEDERAL TRADE COMMISSION, THE COSTS AND BENEFITS OF OCCUPATIONAL REGULATION (1990) (licensure); Diane M. Gianelli, *Some Lab Rules Relaxed, But Many Doctors say "Enough" and Close*, AM. MED. NEWS, Feb. 1, 1993, at 1 (CLIA); Andrew A. Skolnick, *After Long Delay, Federal Regulations for Enforcing Nursing Home Standards May Be Issued this Year*, 269 JAMA 2348 (1993) (nursing homes). *See generally*, considering the costs of regulation, BARDACH & KAGAN, *supra* note 53.

113. GAUCHER & COFFEY, *supra* note 99, at 151; Koska, *supra* note 103, at 64.

114. *See* COX & FOSTER, *supra* note 112, at 36–40.

115. *See, e.g.*, FREIDSON, *supra* note 43, at 241–44; Robert C. Derbyshire, *How Effective is Medical Self-Regulation*, 7 L. & HUM. BEHAV. 193, 198 (1983).

116. COX & FOSTER, *supra* note 112, at 38–39.

117. Daniel B. Hogan, *The Effectiveness of Licensing: History, Evidence, and Recommendations*, 7 L. & HUM. BEHAV. 117, 126–33 (1983).

118. *See* Relman, *supra* note 87. *See also* JOSEPH M. JACOB, DOCTORS AND RULES: A SOCIOLOGY OF PROFESSIONAL VALUES 109–42 (1988) (on the doctor as gentleman).

119. H.R. 3600/S. 1756, 103d Cong., 1st Sess. § 4031 (1993).

to facilitate market oversight[120] and would have experimented with enterprise liability, which would have strengthened the hand of management.[121] The continuing role of government under the HSA would have been to fund research and collect data, not to enforce norms. Self-regulation would have been marginalized, and would not have been relied on to assure quality. Though the HSA was not adopted into law, these aspects of the proposal were not generally controversial and enjoyed widespread support.

In the end, however, are market- and management-based strategies adequate to assure the quality of health care? More particularly, can the quality of professional services in general and of health care in particular be reduced to data that computers can process, managers can manipulate, and consumers can understand? If so, is professional peer review expendable? If, on the other hand, government or the profession—or government through the profession—has a continuing role in quality oversight, how should this role be defined and how should it be carried out? To begin to answer these questions we turn next to an examination of the nature of medical practice.

III. THE TEXTURE OF MEDICAL PRACTICE

In considering the design of a system for regulating health care quality, it is useful to distinguish between two components of the provision of medical care. First, the provision of medical care includes in most instances the application of professional judgment and skill. This includes, first and foremost, judgments involving the diagnosis and the prescription of treatment for disease. It also includes, however, the exercise of professional skill in carrying out medical procedures. In our system of medical practice it is the physician who normally bears initial responsibility for articulating a diagnosis and plan of treatment for a patient, but the judgment and skills of numerous other professionals—nurses, physician therapists, social workers—often are called upon in complex or prolonged episodes of illness.[122]

The second component of medical care is the health care production process.[123] Health care production processes are most clearly evident in complex health care institutions such as the hospital, in which patients are admitted, fed, cleaned, toileted, moved about from place to place (for X-rays or surgery, for example), connected to and disconnected from various machines, medicated, observed and monitored, discharged, and billed.[124] Machines are purchased, calibrated and maintained;[125] records of all sorts are created, filed, and retrieved;[126] drug orders are received and filled; tests are ordered and

120. *Id.* §§ 1325(a)(2)(D), 5003, 5004, 5005, 5012(1)(2), 5013(1)(2).

121. *Id.* § 5311.

122. Strauss notes that the physician is the central figure in planning treatment, but that the head nurse is the key actor in implementation of medical work. ANSELM STRAUSS ET AL., SOCIAL ORGANIZATION OF MEDICAL WORK 151 (1985).

123. Strauss notes that this second component can be further divided into the higher order work of organizing, setting up, supervising and monitoring work requested or ordered by the physician, and the lower level of actually doing the work. STRAUSS ET AL., *supra* note 122, at 156. The higher of these two levels of "articulation work" often involves aspects of professional judgment.

124. This dense complexity is best described by Anselm Strauss. STRAUSS ET AL., *supra* note 122, *passim* and 5–7, 53–59 (1985).

125. *See* STRAUSS ET AL., *supra* note 122, at 40–68 on "machine work."

126. *See* STRAUSS ET AL., *supra* note 122, at 255–57.

analyzed and their results transmitted; venues and things are cleaned and disinfected. Less complex production systems exist in other institutions such as nursing homes, home health agencies, or ambulatory surgical centers—or even in doctors' offices and pharmacies.

While these processes support and implement professional judgment, they are analytically independent of it. A rough analogy can be drawn to the distinction between design and manufacturing processes. Professional judgment conceptualizes the goal and specifies the nature of the process just as a designer or engineer specifies the nature of a product and how it is to be produced. The production process then implements the professional judgment, much as the manufacturing process realizes the design specified by design and engineering.[127] At the margins the distinction is hard to discern. For example, is the laboratory technician who analyzes a specimen applying professional skill or engaged in a production process? In most instances, however, the distinction is relatively clear.

An acceptable quality oversight system must monitor and promote the improvement of quality and detect error and encourage its correction in both of these dimensions of health care provision. It must foster the accuracy of professional judgment while stimulating the appropriateness, efficacy, and efficiency of production processes.[128] To design such a system, we must first better understand these dimensions of health care provision. Only then can we accurately identify and describe quality problems and design solutions to those problems.

A. The Nature of Professional Judgment

In the popular imagination, medicine is considered a science.[129] The doctor, it is believed, gathers information by taking a medical history, observing and probing the patient, and analyzing the results of laboratory tests or the revelations of imaging devices. Through this process of information gathering, the physician identifies the nature of the disease (or traumatic injury) that afflicts the patient. The physician then proceeds mechanically to prescribe the treatment or execute the procedure known to be appropriate for the particular diagnosis.

Under this paradigm, quality can be defined in terms of consistently identifying the nature of the disease and prescribing or executing its treatment correctly. Error consists of an incorrect diagnosis or treatment. The entire process can be described in practice guidelines or expert systems computer algorithms. Errors can be readily identified by those trained to understand the nature of disease or trauma and their treatment.[130]

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127. STRAUSS ET AL., *supra* note 122, at 24.

128. *See* on the latter, JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE, *supra* note 91.

129. *See* ERIC J. CASSELL, THE NATURE OF SUFFERING AND THE GOALS OF MEDICINE (1991).

130. For a critique of this vision of science, and of a more sophisticated vision in which medicine is conceived of as a probabilistic enterprise that can approximate reality through statistical analysis even if it cannot establish precise causal relationships, see David Frankford, *Managing Medical Clinicians' Work Through the Use of Financial Incentives*, 29 WAKE FOREST L. REV. 71, 84–88 (1994). Frankford notes that this image of science is now "fairly quaint," long abandoned by philosophy of science.

Sociologists, anthropologists, and philosophers who have observed and described the operation of medical judgment uniformly recount a much more complex process.[131] Disease is often highly enigmatic and infinitely variable; knowledge of disease is idiographic. Much about disease processes remains poorly understood. Diseases reveal themselves in individual patients in very particular ways and multiple disease processes often interact within particular patients.[132] In a very fundamental sense, "Doctors do not treat diseases, they treat patients."[133] Diseases are manifested in patients over a period of time, and metamorphize over the course of their "trajectory."[134] Diseases must often be interpreted—"narrated"—rather than comprehended.[135] Often the professional must treat what is perceived, without fully comprehending the underlying causative processes.[136]

Diagnostic decisions are probabilistic—the physician often must decide what is most likely to be the problem.[137] Even after a diagnosis is reached, the course of treatment appropriate to the diagnosis will often vary depending on the patient's characteristics.[138] The entire process is characterized by judgments that are uncertain and highly contingent.[139]

Within this context, diagnosis and treatment decisions are made by individual professionals or small groups of professionals, each with their own individual limitations. No one physician can comprehend the totality of what is

131. CHARLES BOSK, FORGIVE AND REMEMBER 174 (1979); JOHN M. EISENBERG, DOCTORS' DECISIONS AND THE COST OF MEDICAL CARE 62–63 (1986); KATHRYN M. HUNTER, DOCTORS' STORIES: THE NARRATIVE STRUCTURE OF MEDICAL KNOWLEDGE 3-48 (1991); Stephen Daniels, *The Pragmatic Management of Error and the Antecedents of Disputes Over the Quality of Medical Care, in* QUALITY AND REGULATION IN HEALTH CARE: INTERNATIONAL EXPERIENCES 112, 114–23 (Robert Dingwall & Paul Fenn eds., 1992); David Eddy, *Variations in Physician Practice: The Role of Uncertainty*, 3 HEALTH AFF. 74 (1984). *But see* MARCIA MILLMAN, THE UNKINDEST CUT: LIFE IN THE BACKROOMS OF MEDICINE 129–30 (1977) (criticizing this account of medicine).

132. HUNTER, *supra* note 131, at 28–29; JEROME P. KASSIER & RICHARD I. KOPELMAN, LEARNING CLINICAL REASONING 9 (1991); MARIANNE A. PAGET, THE UNITY OF MISTAKES: A PHENOMENOLOGICAL INTERPRETATION OF MEDICAL WORK 23–26, 29–30 (1988); Daniels, *supra* note 131, at 119.

133. CASSELL, *supra* note 129, at 20.

134. PAGET, *supra* note 132, at 75; STRAUSS ET AL., *supra* note 122, at 8, 23.

135. HUNTER, *supra* note 131, at 5–26; Eric. B. Beresford, *Uncertainty and the Shaping of Medical Decisions*, 21 HASTINGS CENTER REP. 6, 7 (July/Aug. 1991), citing William Osler, *On the Need of a Medical Reform in Our Methods of Teaching Medical Students*, 82 MED. NEWS 49 (1904).

136. HUNTER, *supra* note 131, at 35; Deborah R. Gordon, *Clinical Science and Clinical Experience: Changing Boundaries Between Art and Science in Medicine, in* BIOMEDICINE EXAMINED (Margaret Lock & Deborah R. Gordon eds., 1988). These perceptions are in turn often based in part on information harvested from laboratory tests, imaging equipment, or monitoring machines through processes that are in turn subject to potential error. *See* STRAUSS ET AL., *supra* note 122, at 65–66.

137. BOSK, *supra* note 131, at 23; EISENBERG, *supra* note 131, at 18–21, 63; KASSIER & KOPELMAN, *supra* note 132, at 17–27. Alternatively, the doctor may rely on categorical judgments (clinical heuristics) as a tool for dealing with uncertainty. EISENBERG, *supra* note 131, at 64.

138. HUNTER, *supra* note 131, at 38–39; KASSIER & KOPELMAN, *supra* note 132, at 34; Eddy, *supra* note 131, at 78–79.

139. BOSK, *supra* note 131, at 61–62; CASSELL, *supra* note 129, at 229–31; HUNTER, *supra* note 131, at 40–41.

known; each must act based on his or her limited base of knowledge and experience.[140] Experience is at least as valuable as knowledge.[141]

In such an environment, defining and identifying quality and error are highly problematic. Some diagnoses or procedures are relatively straightforward and amenable to description in practice protocols. There is often, however, no single correct approach to a particular condition, but rather a range of options of diagnosis and treatment. The results of each of these options might turn out better, worse, or identical to those of other options.[142] Judgments are continually made that in retrospect were erroneous, or at least were not the best choices.[143] In some instances it can never be known whether or not the right decision was made.[144]

Failure—as evidenced by undesired outcomes—is common, and often occurs even though the diagnosis and treatment seem to have been appropriate when judged by conventional process standards.[145] Indeed, the "best" physicians may fail the most frequently, as they are willing to take the greatest risks to help their patients in the most heroic situations.[146]

Treatment may not just fail to help, it may affirmatively harm the patient.[147] The Harvard Medical Practice Project determined that 3.7% of patients hospitalized in New York during 1984 were injured by medical treatment.[148] Many of these injuries were quite serious: 13.6% resulted in death and 6.5% in permanent disability.[149]

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140. Beresford, *supra* note 135, at 7.

141. BOSK, *supra* note 131, at 86; CASSELL, *supra* note 129, at 214–36; ELIOT FREIDSON, PROFESSION OF MEDICINE 166 (1970); KASSIER & KOPELMAN, *supra* note 132, at 10; Gordon, *supra* note 136, at 269. A related point is made by Bosk in citing the aphorism "Excellent surgery makes dead patients." The mark of a good surgeon is not the ability to follow textbook principles, but rather to comprehend and respond appropriately to the immediate situation. BOSK, *supra* note 131, at 46. One corollary of this is that styles of practice vary considerably among physicians, depending on their experience and how they interpret it. *See* EISENBERG, *supra* note 131, at 38–45. Another is that conflict is inevitable when physicians with different experiences share responsibility for the care of a patient or group of patients. Daniels, *supra* note 131, at 127.

142. FREIDSON, *supra* note 43, at 134–37; PAGET, *supra* note 132, at 48–57; STRAUSS ET AL., *supra* note 122, at 25, 79–81.

143. PAGET, *supra* note 132, at 45, 56.

144. Bosk notes the power of attending physicians to define reality (and the corresponding impotence of house staff to contest the attending's definition of reality). BOSK, *supra* note 131, at 85.

145. BOSK, *supra* note 131, at 68–70, identifies four sources of medical failure other than physician error: failures due to the inexorable course of the disease process, failures due to patient procrastination or non-cooperation, failures due to the errors of nurses or other support staff, and failures due to machine error.

146. The Harvard study, for example, found that teaching hospitals had higher rates of adverse events, but lower rates of negligent errors, than non-teaching hospitals. HARVARD MEDICAL PRACTICE STUDY, *infra* note 148, at 6–44.

147. For an extreme statement of this position, see IVAN ILLICH, MEDICAL NEMESIS 26–27 (1976).

148. HARVARD MEDICAL PRACTICE STUDY, PATIENTS, DOCTORS AND LAWYERS 6–1 (1990). There is reason to believe that this study may have undercounted adverse events, as it attempted to error in favor of false negatives rather than false positives and it relied on medical records, which may not have revealed all incidences of error. Michael J. Saks, *Medical Malpractice: Facing Real Problems and Finding Real Solutions*, 35 WM. & MARY L. REV. 693, 707–09 (1994). *See also* Lucien Leape, *Error in Medicine*, 272 JAMA 1851 (Dec. 21, 1994) (recounting other studies identifying high error rates in medical treatment).

149. HARVARD MEDICAL PRACTICE STUDY, *supra* note 148, at 6–21.

In summary, there is a large universe of medical failures, including any medical intervention that fails to heal a disease or injury or to meliorate the consequences of disease or injury. Error—diagnosis or treatment that turns out in hindsight to have been in some way less than optimal—is a subset of this universe. Negligent error, which not only turns out to have been less than optimal, but also would have been avoided prospectively by a careful practitioner, is an even smaller subset.[150]

Competency is defined in this context not only in terms of avoiding error, but also in terms of managing error, compensating for error, and learning from error.[151] But true incompetents—those who repeatedly make negligent errors because of an inability or unwillingness to learn from error[152]—are responsible for only a tiny proportion of all treatment failures. Even the most competent fail often.

If this understanding is correct, regulation cannot eliminate failures. Even elimination of error through regulation is highly problematic. Error is inevitable and ubiquitous; everyone errs.[153] Error can often not be foreseen, perhaps not even be recognized retrospectively except through careful examination.[154] It cannot always be avoided, only managed.[155] Moreover, error is an integral part of both the formal educational process and of the informal lifetime learning process.[156] Error is a necessary step in the process of gaining experience and is thus the foundation of informed judgment.[157]

In this environment, normative failures—violations of professional responsibility—are perceived by professionals to be more serious than errors of judgment or of application of skill.[158] Errors of judgment and of technique are inevitable and are expected.[159] If technical errors and errors of judgment are often random events, then all practitioners are subject to error; but for the grace of God, anyone may err.[160] Normative failures, however, such as laziness, obstinacy, arrogance, or quarrelsomeness, indicate an unwillingness to learn and enhance the likelihood of repeated technical or judgment errors.[161]

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150. PAGET, *supra* note 132, at 133–37. A corollary of this is that only unexpected failure is problematic. Expected failure is non-threatening. BOSK, *supra* note 131, at 120.

151. PAGET, *supra* note 132, at 98.

152. PAGET, *supra* note 132, at 136.

153. *See* FREIDSON, *supra* note 43, at 128; PAGET, *supra* note 132, at 5–7, 94–101.

154. FREIDSON, *supra* note 43, at 134–37; Daniels, *supra* note 131, at 131–32.

155. Daniels, *supra* note 131, at 121.

156. BOSK, *supra* note 131, at 72. In this context, Bosk notes the pedagogic use of the horror story, the recounting of medical treatment that went radically wrong, as a component of medical education. *Id.* at 103–10.

157. Eisenberg notes that as clinicians mature they prescribe services more appropriately and at a lower volume, supporting this notion of a learning curve. EISENBERG, *supra* note 131, at 45.

158. BOSK, *supra* note 131, at 37–61.

159. BOSK, *supra* note 131, at 38–39; FREIDSON, *supra* note 43, at 134–37; Daniels, *supra* note 131, at 133.

160. BOSK, *supra* note 131, at 173; FREIDSON, *supra* note 141, at 179. *See* BOSK, *supra* note 131, at 138–40, 145 (discussing "putting on the hairshirt," a ritualized public acknowledgment of fallibility and error in the peer group context as a means of seeking—and obtaining—expiation for this type of error from peers similarly subject to fallibility. "By this practice surgeons excuse their mistakes by admitting them," claims Bosk.)

161. BOSK, *supra* note 131, at 51–61. Freidson makes a similar distinction between "normal mistakes," to which every practitioner is subject, and "deviant mistakes," violations of clear rules. FREIDSON, *supra* note 43, at 128–29. The former are excusable, the latter are not.

The ultimate obligation of the physician is to do everything possible for the patient (subject, of course, to resource constraints and to the patient's choices and preferences). This is a moral, not a technical requirement.[162] Technical and judgment error must be forgiven, but normative error must be sanctioned.[163]

Because of the ubiquity of technical or judgment error, regulatory systems that sanction them are suspect. Anyone might make a single error, and even clusters of error might be random events. Systems that attempt to enforce uniformity of practice are also not to be trusted.[164] Patients are unique individuals with distinct conditions in particular contexts. The physician treats them based on his own judgment and experience.[165] Physicians resist supervision by those who are not familiar with the individual patient or possessed of the experience on which their judgments are based.[166] Those who are not in direct contact with the individual patient cannot fully comprehend the contingencies of the case and should not dictate treatment choices.[167] Finally, outcome measures are problematic.[168] Failures happen without error, and errors happen without fault.[169] Negligent error can be reinterpreted as error, and error as failure.[170] Bad outcomes do not necessarily indicate that the underlying care is of poor quality.

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162. BOSK, *supra* note 131, at 170. "It is not the patient dying but the patient dying when the doctor on call fails to answer his pages that makes it impossible to sustain a case of acting in the client's interest." *Id. See also* PAGET, *supra* note 132, at 58–66.

163. Bosk notes that this forgiveness is important to both the pedagogic process and the protection of the patient, because it removes the stigma from uncertainty and makes it more likely that doctors-in-training will reveal their errors in time for the error to be corrected. The forgiven physician is also more likely to be vigilant in the future to demonstrate that the error was an aberration and that the forgiveness was warranted. BOSK, *supra* note 131, at 178. Frequent and repeated technical or judgment errors may indicate an underlying lack of competence, however, and may be as serious as normative errors. *Id.* at 163. Freidson notes that deviant mistakes are considered culpable conduct in themselves, regardless of their outcome, but that only deviant mistakes that result in bad patient outcomes become the basis for disciplinary actions. FREIDSON, *supra* note 43, at 132. He also notes that self-criticism for technical and judgment errors is normal, but criticism of others is not acceptable. FREIDSON, *supra* note 141, at 179. For a more sinister view of the tendency of the medical profession to excuse error, see MILLMAN, *supra* note 131, at 90–95.

164. FREIDSON, *supra* note 43, at 136; HUNTER, *supra* note 131, at 42. Gordon makes the related point that expert clinicians who create expert systems construct formal systems that are poor abstract approximations of the much richer and more complex systems of judgment and understanding that they apply in practice. Gordon, *supra* note 136, at 278. Though clinicians object to protocols designed to be imposed upon them, they themselves devise protocols to be followed by their staff as one approach to managing uncertainty, and in this context insist that the protocols be followed. Daniels, *supra* note 131, at 121.

165. FREIDSON, *supra* note 141, at 172.

166. FREIDSON, *supra* note 141, at 180.

167. BOSK, *supra* note 131, at 189; FREIDSON, *supra* note 43, at 241; Beresford, *supra* note 135, at 8. Blame is readily shifted to external persons and institutions, however, when error occurs. Daniels, *supra* note 131, at 134–35.

168. Eddy, *supra* note 131, at 80–82.

169. The extent to which this statement is true may be specialty specific. Bosk notes that, "When the patient of an internist dies, the natural question his colleagues ask is 'What happened?' When the patient of a surgeon dies his colleagues ask, 'What did you do?'" BOSK, *supra* note 131, at 30. Nevertheless, even when a surgeon's patient dies, he is not necessarily considered to be at fault.

170. *See* BOSK, *supra* note 131, at 129–35 (discussing the mortality and morbidity conference as a forum for accomplishing this).

B. The Health Care Production Process

The processes through which health care is produced in many respects resemble production processes in other industries. Health care institutions, like factories, organize personnel and machines around production tasks. Much of the work at this level is controlled by protocols and policies laying out in considerable detail how situations are to be handled.[171] Approaches that have been designed for engineering and for measuring quality in other industries are to a considerable extent applicable to the health care delivery context. This is, of course, the message of the quality improvement/quality management movement.[172]

The health care production process, however, is not identical to the processes of producing automobiles or computers.[173] First, and most obviously, every patient is different from every other not just in terms of his or her disease (the reason for being in the hospital) but also in many other respects as well (psychologically, socially, intellectually, physically).[174] Each patient changes over time as he or she progresses through her disease trajectory.[175] Thus, the level of standardization possible in the assembly line where a single product is repeatedly and regularly produced is not possible in a health care institution.[176] Effective quality management programs must stress innovation at least as much as standardization.

Second, the health care production process is highly labor intensive. Human error, which can be largely engineered out of other production processes, is inherent in most health care enterprises.[177] The patient—the object of health care—is of course a human being as well as a human body, and the human interactions between the patient and the persons who are treating him is a further occasion for complexity.[178] For example, the patient must often remember and be willing to take his medication; it cannot simply be inserted like a memory chip into a computer on the assembly line.

Third, health care institutions face unusual problems in allocating resources.[179] While health care is primarily a market good, it is also often perceived to be a right. It is generally believed that health care institutions should provide urgently needed health care regardless of whether compensation is received for this care. Indeed, the law requires this in many situations.[180] Thus institutions and professionals must allocate resources not just in

171. Daniels, *supra* note 131, at 129. These protocols are often idiosyncratic to a particular unit, however, and are based on the experience of the head of the unit and his or her approach to managing uncertainty and error. *Id.* at 130.

172. BERWICK ET AL., *supra* note 99, at 21–23, 29–32.

173. *See* STRAUSS ET AL., *supra* note 122, at 19–20.

174. STRAUSS ET AL., *supra* note 122, at 151–53.

175. STRAUSS ET AL., *supra* note 122, at 23.

176. *See, e.g.*, STRAUSS ET AL., *supra* note 122, at 158–60 (discussing the difficulties of applying standard operating procedures).

177. Daniels, *supra* note 131, at 121. It is important, nonetheless, to structure the production process so as to obviate the likelihood of human error and its effects whenever possible. *See* Leape, *supra* note 148.

178. STRAUSS ET AL., *supra* note 122, at 9, 154.

179. STRAUSS ET AL., *supra* note 122, at 37, 153–54.

180. The Emergency Medical Treatment and Active Labor Act of 1986, 42 U.S.C. § 1395dd (1988), requires that all hospitals that participate in Medicare and have an emergency department provide stabilizing treatment to emergency patients regardless of their ability to pay. *See* FURROW ET AL., *supra* note 60, at ch. 12.

accordance with where they will yield the most profit, but also to where they are most "needed."[181] In this context, negotiating and persuasion become key strategies for resource allocation.[182] Additionally, demand for health care is more difficult to predict than demand for other products. Institutions may thus have inefficient excess capacity at one point in time, insufficient resources to deliver quality care a short time later.[183] The level of efficiency in allocation of resources possible in other industries is simply not possible in health care.

Finally, the task of rationally organizing the production process is further complicated by the peculiar division of the American hospital between the medical staff—an organized group of independent contractors, which is responsible for medical judgments—and the rest of the hospital—subject to the administrator but responsible for fulfilling the orders of the medical staff.[184] Similarly, the semi-autonomous status of physician-led wards and departments within the hospital further confounds the organizational task.[185]

Because of these complexities, the forms of quality evaluation and improvement that have been applied in other industries may not always exactly fit the health care industry. Nevertheless, the health care production process is, in spite of these qualifications, much more manageable than is professional judgment. Solutions to production process problems are often technical.[186] Examples of such solutions cited by Berwick in his text on quality improvement include changing from 8.4 volt to 9 volt batteries to make oxygen analyzers run more dependably, implementing procedures to improve preoperative charting to reduce operative delays, and improving procedures for obtaining Medicare data to facilitate billing.[187] Identifying defects in the production process and designing strategies for curing those defects is thus generally an easier task for management than is the task of rationalizing professional judgment.[188]

Given this understanding of how health care is delivered, how can its quality be improved? To answer this question, the article first considers the levers that can be manipulated to improve health care quality. Next, it considers the capacity of the market and of management to improve health care quality. Finally, it discusses the continuing role of legal regulation.

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181. *See* EISENBERG, *supra* note 131, at 79–85 (exploring this problem); Beresford, *supra* note 135, at 7, 8.

182. STRAUSS ET AL., *supra* note 122, at 189; Daniels, *supra* note 131, at 125.

183. *See* STRAUSS ET AL., *supra* note 122, at 74 (discussing the problems hospitals encounter in maintaining adequate staffing levels for safety).

184. FREIDSON, *supra* note 141, at 117; Hall, *supra* note 83, at 505–07.

185. *See* STRAUSS ET AL., *supra* note 122, at 71–73 (discussing the implications of these phenomena for safety regulation in the hospital). One commentator describes this situation as "organized anarchy." Daniels, *supra* note 131, at 124.

186. *See* Leape, *supra* note 148, at 1854–55 (discussing the lessons to be learned about health care delivery from the engineering approaches of other industries to limiting errors).

187. BERWICK ET AL., *supra* note 99, at 111–31.

188. The production process is also more amenable to the forms of regulation developed for assuring the quality of production in other industries. In particular, audited self-regulation strategies, where firms regulate themselves subject to public regulatory oversight, seem well-suited to regulation of the production of health care services. *See* IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION, TRANSCENDING THE DEREGULATION DEBATE 101–32 (1992) (proposing a model of enforced self-regulation); DOUGLAS C. MICHAEL, FEDERAL AGENCY USE OF AUDITED SELF-REGULATION AS A REGULATORY TECHNIQUE (1994).

IV. ASSURING THE QUALITY OF MEDICAL CARE

A. Factors That Contribute to Quality

Any program directed at improving or assuring quality—be it private, public, or some combination of the two—will have to find a means to affect the behavior of individuals or institutions. A key question that must be answered, therefore, before turning to a consideration of the comparative strengths of various institutions that might address quality problems, is what levers are available to improve the quality of professional judgment and of health care production processes.

The first such lever is the generation and dissemination of information. General information on outcomes and best practices generated from research involving large databases, particularized feedback based on small numbers of cases involving particular practitioners or institutions, and pattern analysis comparing the two, are all useful toward informing judgment and guiding improvement of production processes.[189] Even if experience rather than analysis guides many decisions, experience can be improved through dissemination of information.[190] As harvesting of data becomes ever more feasible and cost-effective, it should be encouraged and supported as an important tool of quality improvement. For reasons related above, however, expectations as to what can be accomplished through data collection and dissemination for influencing medical judgment should be modest. In the final analysis, medical practice cannot be reduced to statistics.[191]

Second, an essential insight of the total quality management program is the importance of culture and environment for fostering quality.[192] Most of us have probably had the experience of working or studying both in settings where everyone worked together (or in competition) to do the best possible job and in settings where many of those present were just putting in time and getting by with minimal effort. A significant difference in quality between the work produced in these two environments is usually apparent. A culture where quality is valued and encouraged stimulates the continuous improvement of production processes. It could also be expected to encourage increased accuracy of medical judgment and more appropriate management of inevitable error.

Historically, the culture of professionalism has played an important role in stimulating quality.[193] The professional was a gentleman who rose above the crass concerns of merchants to dedicate himself to serving the needs of his patients with clear and undivided judgment.[194] The concern that licensure boards have traditionally shown for professional ethics and for unprofessional

189. *See generally* Coltin & Aronow, *supra* note 107; Panzer & Cronin, *supra* note 84; Institute of Medicine, *supra* note 86.

190. A cautious endorsement of the use of information to improve physicians' practice based on a thorough review of the research is found in EISENBERG, *supra* note 131, 99–124.

191. *See* Sandra J. Tanenbaum, *Knowing and Acting in Medical Practice: The Epistemological Politics of Outcomes Research*, 19 J. HEALTH POL. POL'Y & L. 27 (1994).

192. *See, e.g.*, GAUCHER & COFFEY, *supra* note 99, at 148–80.

193. Jost, *supra* note 44, at 536–42.

194. *See* JACOB, *supra* note 118, at 109–42 (developing this notion of professionalism).

conduct can be understood in part as an attempt to suppress normative error, and thus to sustain a culture in which quality was valued and promoted.[195]

Third, incentives have an obvious role to play in encouraging quality. The market stimulates quality in other sectors of the economy by directing business toward those merchants who can deliver value for money. Incentives such as money, recognition, power, independence, or anything else of value can be used to encourage professionals or institutions to improve production processes or to be more attentive in making professional judgments and applying professional skills.[196]

Fourth, sanctions have a legitimate role, however marginal, in encouraging quality. Sanctions can be used to exclude from the market practitioners or institutions that totally lack the capacity to make appropriate professional judgments or to carry out effective production processes.[197] Corrective or educative sanctions can improve the performance of those who have the basic capacity to do well but need information or direction.[198] Punitive and deterrent sanctions may be appropriate for normative deficiencies that result in technical or judgment errors or for careless production processes.

Fifth, wherever possible systems should be designed and implemented to identify errors where they occur, to replace fallible humans with more reliable technology, to standardize and simplify tasks, and to absorb errors so as to minimize their effect.[199]

B. Can the Market Assure Quality?

Functioning markets provide natural incentives to stimulate the provision of quality work. Market incentives can prompt organizations to foster a culture of quality, which can in turn support work of high quality. The key issue is whether the market for health care quality can be made to work like markets for other products.

The traditional judgment, noted at the outset of this article, was that the market for health care does not work; consumers are not capable of making appropriate judgments as to health care quality.[200] In particular, it has been widely believed that consumers are not capable of evaluating professional judgment. The explication of the nature of professional judgment set out above demonstrates the plausibility of this belief. The consumer has neither the knowledge nor experience in most instances to evaluate *ex ante*, or even *ex post*, the judgment of the professional.[201] It is, of course, not necessary that

195. *See supra* text accompanying notes 174–78. Of course, the dark side of professional "ethics" must also be recognized. More often than not ethical prohibitions have historically been aimed at competitive behavior within the profession (*e.g.*, advertising) or at competitors from without (*e.g.*, ethical prohibitions against cooperating with chiropractors).

196. *See* EISENBERG, *supra* note 131, at 132–34 (discussing the limited evidence of the use of rewards for altering physician behavior); GAUCHER & COFFEY, *supra* note 99, at 281–315 (discussing use of rewards in quality management).

197. This, of course, has always been a function of licensure. *See supra* text accompanying note 26.

198. *See* OFFICE OF INSPECTOR GENERAL, DEP'T OF HEALTH & HUMAN SERVICES, STATE MEDICAL BOARDS AND QUALITY-OF-CARE CASES: PROMISING APPROACHES 21-22 (1993) (describing innovative approaches to corrective discipline by medical boards).

199. Leape, *supra* note 148, at 1856–57.

200. Arrow, *supra* note 80, at 966; Wolfson, *supra* note 80, at 190–92.

201. *See* Jost, *supra* note 44, at 560–64.

consumers understand the process of professional judgment, only that they be able to evaluate its product. Even here, however, the ability of consumers is limited. The consumer may be able to recognize a failure of professional action (and even this may not always be true), but as was noted above, failure may or may not indicate a quality deficiency.

The consumer may be more capable of evaluating production processes. Waiting times, cleaning schedules, or billing procedures, for example, are readily accessible to consumer evaluation. Even with respect to many production processes, however, consumers will lack sufficient information to make a useful quality judgment with respect to the particular process, similar or comparative processes generally, or both.

Some commentators believe that the information processing revolution, aided by market restructuring, offers the promise of overcoming the traditional deficiencies of health care markets.[202] If consumers have information about the comparative outcomes of professional care—it is contended—they can evaluate the quality of that care without needing to understand the professional judgments that produced those outcomes. If consumers possess comparative information about patient satisfaction with health care institutions, they need not understand the production processes that produced patient satisfaction in one institution or dissatisfaction in another. In the final analysis, we are told that if consumers can be given "report cards," the market will produce quality.[203] But has the information revolution solved the market failures that originally justified regulation?

There are reasons to believe that it has not, or at least not totally.[204] The report card is not a concept without problems. To begin with, report cards will not be easy to implement. The idea of comparison shopping for health care raises a host of methodological questions with respect to data collection and presentation.

First, at what level should data be collected and aggregated? Ideally consumers should be given comparative information regarding health plans, institutions that participate in those plans, or professionals who practice in those institutions, facilitating consumer choice at all three levels. But as information is aggregated in smaller and smaller units, it becomes less likely that the number of observations will be sufficiently large to generate meaningful data.[205] Data collection also becomes more expensive and presentation of data more cumbersome at lower levels of aggregation.

Second, what information should be collected? Though structure and process measures are often used because they are relatively easy to maintain, their relationship to quality is problematic.[206] It is generally thought that outcome data is a better measure of quality, but one must determine which outcomes to measure. Mortality data was one of the earliest types of outcome

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202. *See* Mark V. Pauly, *The Public Policy Implications of Using Outcome Statistics*, 58 BROOK. L. REV. 35 (1992).

203. *See* Epstein, *supra* note 93, at 1674.

204. The material in the next several paragraphs appeared previously in Jost, *supra* note 5, copyright American Medical Association, 1994. *See also*, GAO, *supra* note 95.

205. Barbara J. McNeil et al., *Current Issues in Profiles: Potentials and Limitations*, *in* PHYSICIAN PAYMENT REVIEW COMMISSION, CONFERENCE ON PROFILING 46–70 (1992).

206. GAO, *supra* note 95, at 39.

information to become available to consumers. For most health conditions, however, mortality is a relatively infrequent result, and survival is less an indication of success than other outcome measures might be.[207] Indeed, for some conditions an early death might be the best result. Defining and measuring other indicators of quality, such as improvement of quality of life or of functioning, is far more problematic and costly than measuring mortality. It will be tempting to limit report cards to data that are already readily available and to areas of performance that are easily measured, regardless of the usefulness of these data.

Third, there is the problem of quality of data. Available data is often incomplete, misleading, or inaccurate.[208] It was often created for other purposes, such as payment, and is of limited value for measuring quality. While better quality data could be created through review of medical records, it would still be far from perfect and very expensive to obtain.[209]

Fourth, a host of "noise" problems must be overcome. Outcomes data are meaningless or misleading unless they are adjusted for severity of illness, the presence of do not resuscitate orders or comorbidities, and other factors not under the control of providers.[210] The history of the Health Care Financing Administration (HCFA) mortality surveys shows how devilishly difficult it can be both to adjust adequately for the host of exogenous factors that can affect mortality and to quell suspicions that attempted adjustments are not adequate.[211] HCFA ultimately dropped its reporting because it determined that a high percentage of the lowest performing hospitals were institutions that served the poorest and most needy patients and because it could not solve intractable problems with its measurement methodology.[212] Similarly, California's outcome assessment program found that some of the state's most sophisticated hospitals rated poorly on outcome indices because they had been most aggressive in reporting complications of surgery to maximize Medicare Diagnosis Related Group reimbursement.[213] Adjusting for risk, on the other hand, permits providers to play games with outcome reporting systems by inflating risk data about their patients, thus improving risk adjusted performance.[214] Risk adjustment requires the use of additional data, which itself may be incomplete or inaccurate.[215] Risk adjustment also may potentially mask quality problems. Adjusting for age, for example, may mask problems in treatment of the elderly.[216] Finally, even if perfect risk adjustment could be

207. Eric J. Topol & Robert M. Califf, *Scorecard Cardiovascular Medicine: Its Impact and Future Directions*, 120 ANNALS INTERNAL MED. 65 (1994).
208. GAO, *supra* note 95, at 35–37.
209. GAO, *supra* note 95, at 37–38.
210. Jesse Green, *Problems in the Use of Outcome Statistics to Compare Health Care Providers*, 58 BROOK. L. REV. 55 (1992).
211. Donald M. Berwick & David L. Wald, *Hospital Leaders' Opinions of the HCFA Mortality Data*, 263 JAMA 247 (1990).
212. Jesse Green et al., *Analyzing Hospital Mortality: The Consequences of Diversity in Patient Mix*, 265 JAMA 1849, 1849–53 (1991); Rolla Edward Park et al., *Explaining Variations in Hospital Death Rates*, 264 JAMA 484 (1990).
213. Shuit, *supra* note 95.
214. Topol & Califf, *supra* note 207.
215. GAO, *supra* note 95, at 42.
216. GAO, *supra* note 95, at 42.

achieved, some providers are still likely to appear as outliers simply because of random variation, a factor unlikely to be appreciated by consumers.[217]

Accurate measurement of patient satisfaction will also prove difficult. Reported levels of satisfaction diverge depending both on variables in data collection (such as response rates and the timing and manner of surveying) and on reporter characteristics, such as gender, age, ethnicity, health status, income, and whether the reporter is a patient or proxy (family member or friend).[218] Devising either a simplified description of consumer satisfaction that accurately corrects for these variables or a complex representation that fully accounts for their diversity will be very difficult.

A related concern is assurance of measurement uniformity. To make certain that data are comparable, not only must the same units and instruments of measuring be used, but timing and scope of measurement must also be identical. Since data are likely to be drawn from a number of different sources, including self-reporting by plans or institutions, this may be difficult to achieve. Uniformity of reporting systems is also important. Currently, national standards do not exist for report cards,[219] and absent some form of national health care reform, such standards are unlikely to be adopted.

Timeliness of data will also be very important. Some time lag between data collection and use will be inevitable. By the time information on health plans or institutions becomes available, the professionals that were affiliated with an institution or the professionals and institutions that were affiliated with a plan at the time the data were collected may have left the institution or plan and been replaced by others.

Finally, validation of the integrity of the data will also be a major concern. Significant incentives exist for plans and providers to manipulate or even misrepresent results. Even in an area as objective as clinical laboratory proficiency testing, substantial opportunity has been found for manipulation of results.[220] Assuring unbiased patient satisfaction, access, and outcome data will prove even more demanding a task. If the data are to be of any use at all, a system for auditing of data and for monitoring of data reporting will need to be put in place.[221]

How consumers will use the report card is also problematic. The assumption that underlies consumer report card proposals is that consumers will make what is called in the consumer behavior literature a "compensatory" choice.[222] It is presumed that each consumer evaluating a set of plan or institution report cards will: 1) consider each of the scores that each plan or institution achieved for each of the quality measures that the consumer considers salient: 2) weight these measures by the intensity of their salience; and 3) combine the information gained from this process with information

217. Green, *supra* note 210.

218. Lea Aharony & Stephen Strasser, *Patient Satisfaction: What We Know About and What We Still Need to Explore*, 50 MED. CARE REV. 49 (1993); Haya R. Rubin, *Can Patients Evaluate the Quality of Hospital Care?*, 47 MED. CARE REV. 267 (1990).

219. GAO, *supra* note 95, at 43–46.

220. D. Joe Boone, *Literature Review of Research Related to the Clinical Laboratory Improvement Amendments of 1988*, 116 PATHOLOGY LAB. MED. 681, 681–85 (1992).

221. GAO, *supra* note 95, at 47.

222. Denis A. Lussier & Richard W. Olshavsky, *Task Complexity and Contingent Processing in Brand Choice*, 6 J. CONSUMER RES. 154 (1979).

regarding price, cost-sharing, and the identity of participating providers and professionals; to 4) on the basis of this information pick the "best" plan or institution, *i.e.*, the plan or institution that achieves the highest "score" once the products of the weight and grades for each measure are totaled, with low grades on some measures compensating for high scores on others.

In fact, this result is very unlikely. If a report card covers a dozen plans or institutions, each with fifty quality measures, consumers would be dealing with six hundred discrete bits of information—many of which might be continuous rather than binary variables—and a nearly infinite variety of combinations of variables. One potential result in this information-rich environment would be "information overload."[223] Consumers might simply be overwhelmed by the quantity of information, and make choices randomly related to their actual optimal choice.

A more likely result is that consumers will pursue a conjunctive search strategy. The consumer will begin by identifying one or two highly important product attributes and screening available plans or institutions based on these attributes to eliminate all but a few plans or institutions. The consumer will then switch to the compensatory search strategy described above for evaluating the small subset of plans or institutions so identified.[224] The initial screening search for health plans will in all likelihood be based on factors such as price, cost-sharing, or access to providers with whom the consumer has an established relationship, with quality comparisons only playing a marginal role at the final cut. For institutions, ease of access and professional affiliations may be key characteristics.

It is also likely that consumer decision-making will be affected by biased heuristics and framing effects. A consumer who has just seen a television program on breast cancer may focus unduly on a mammography screening rate measure. Even so trivial a factor as the order in which quality information or plans or institutions are presented will probably influence some decisions.[225]

In fact, distinctions among plans will in most instances be much finer and less determinate than is commonly imagined. Patient satisfaction surveys tend to be skewed toward the high end and are often quite insensitive, particularly if the consumer is merely asked to rank in order the global acceptability of care.[226] State and local consumer information projects currently underway tend to reveal quite small differences in performance among most hospitals, particularly in the area of patient satisfaction.[227] It is thus possible that consumer decisions will be based on statistically meaningless differences, especially if consumers are not carefully educated in the use of the reported material.

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223. Kevin L. Keller & Richard Staelin, *Effects of Quality and Quantity of Information on Decision Effectiveness*, 14 J. CONSUMER RES. 200 (1987); Naresch K. Malhotra, *Information Load and Consumer Decision Making*, 8 J. CONSUMER RES. 419 (1982).

224. David M. Grether et al., *The Irrelevance of Information Overload: An Analysis of Search and Disclosure*, 59 S. CAL. L. REV. 277 (1986).

225. INSTITUTE OF MEDICINE, *supra* note 86.

226. Rubin, *supra* note 218.

227. Steven Findlay, *Cleveland Health Quality Initiative Bears its First Fruit*, 11 BUS. & HEALTH 30 (June 1993); Dan Wascoe, Jr., *Guide to Choosing Health Plans May Cure Indecision*, MINN. STAR TRIB., Nov. 28, 1993, at 3D.

Finally, it is quite probable that many consumers will not understand what the report cards are measuring. The fact that many hospital administrators seem to have misunderstood HCFA's methodology for analyzing mortality data gives little confidence that average consumers will understand the much more sophisticated report cards that have recently been proposed.[228]

Although it is difficult, indeed probably impossible, to predict exactly how all of these factors will affect consumer decisionmaking, it takes a mighty leap of faith to believe that consumers will in fact choose the plan or institution that is in some absolute sense either the highest quality or the most appropriate for their needs. While one can predict with confidence that consumers will eschew plans or institutions that are clear low-end outliers, why rely on consumers to boycott clearly inadequate plans or institutions rather than simply excluding them from the market? If we cannot be certain that consumers will make the right choice, why not at least protect them through regulation from making choices that are clearly wrong?

One can argue, however, that the real goal of report cards is not to control quality directly, but rather to encourage and empower management to improve quality. Before we turn to the regulatory alternative, therefore, we must consider the potential for management to manage quality.

C. Management of Quality

Managers have available to them all of the levers noted above for addressing quality issues. They can generate and disseminate information, provide leadership to create a culture of quality, manipulate incentives, impose sanctions, and improve systems. Management is clearly necessary to insure quality, but is it sufficient?

Let us begin answering this question by returning to the professional judgment/production process distinction. Managers have considerable control over production processes. Given adequate information, resources, and technology, they should be able to do much toward improving the production process. Quality improvement and total quality management are particularly useful for addressing production process problems. Production process problems, as noted above, often closely resemble difficulties in industrial production processes and are therefore amenable to the quality improvement solutions worked out in industrial settings. Quality improvement strategies take a positive and collegial approach to these problems, addressing them without the finger pointing and scapegoating that characterizes investigatory punishment-driven strategies for dealing with problems. Thus, they are also more readily acceptable to the managed than are more traditional quality assurance approaches.[229] Anecdotes abound in the literature regarding quality improvement programs that have solved production process problems.[230] Even here, however, caution is necessary. For the reasons related above,[231]

228. Berwick & Wald, *supra* note 211.

229. GAUCHER & COFFEY, *supra* note 99, at 149–51; BERWICK ET AL., *supra* note 99, at 32–37.

230. *See, e.g.*, GAUCHER & COFFEY, *supra* note 99, at 397–440; BERWICK ET AL., *supra* note 99, at 111–31; David C. Kibbe, *Continuous Quality Improvement for Continuity of Care*, 36 J. FAM. PRAC. 304 (1993); Mary T. Koska, *Using CQI Methods to Lower Postsurgical Wound Infection Rate*, HOSPITALS, May 5, 1992, at 62.

231. *See supra* notes 171–88 and accompanying text.

production processes in health care are not completely fungible with industrial processes, and are not as fully subject to management control.[232]

While managers can directly affect production processes, they can only affect professional judgment indirectly. This is not to say that managers cannot have a positive impact in this arena. Managers can track outcomes and errors in much greater detail than can consumers, and can institute corrective actions when errors or negative outcomes become too prevalent.[233] They can attempt to use pattern analysis to help physicians improve clinical practice.[234] They can implement practice guidelines through critical pathways programs to cabin professional discretion.[235] Managers can facilitate peer review, which can look more closely at professional judgment in particular cases. They can do much to support a culture of quality and professionalism. They can often manipulate the incentive structure (perhaps including financial incentives, but certainly including rewards in terms of power and recognition) to compensate those who maximize good outcomes and minimize errors.

There are, however, limitations to the power of managers to affect professional judgment.[236] Even where managers are medical professionals, they are unlikely to have the specialized knowledge or experience necessary to evaluate most particular instances of professional judgment. While there is some potential for improving the judgments of physicians by studying the patterns formed by the outcomes of these judgments, the discussion presented above of failure and error, and of physician perception of failure and error, demonstrates the limitations of this strategy. As noted above,[237] physicians generally view patients as individuals, not as points in a pattern, and bad outcomes as largely random events.[238] The uncertainty at the core of the process of professional judgment limits the capacity of pattern analysis to fully capture the quality, or lack thereof, of professional practice.

There are also more pervasive limitations on the ability of managers to bring about or cause quality in health care. First, much that has been said above about the limitations of the data on which the market must depend is also true of the data to which managers must look when making quality judgments.[239] Second, successful completion of quality improvement or management projects

232. *See supra* text accompanying notes 173–85.

233. *See* Coltin & Aronow, *supra* note 107.

234. *See, e.g.*, AMERICAN HOSPITAL ASSOCIATION, PRACTICE PATTERN ANALYSIS: A TOOL FOR CONTINUOUS IMPROVEMENT OF PATIENT CARE QUALITY (1991); David Blumenthal, *Total Quality Management and Physicians' Clinical Decisions*, 269 JAMA 2775 (1993); David A. Snyder, *TQM: A Paradigm for Physicians*, PHYSICIAN EXECUTIVE, Mar.–Apr. 1993, at 39.

235. *See* Karen Zander, *Critical Pathways, in* MELUM & SINIORIS, *supra* note 99, at 305.

236. It should also be noted that external constraints on hospitals make it difficult to fully embrace quality improvement strategies to the exclusion of traditional quality assurance. Kritchevsky & Simmons, *supra* note 105, at 1822. Hospitals are still required by Joint Commission accreditation requirements, statute in many states, and negligence doctrine to credential their staff. Denial or withdrawal of credentials will generally require review of individual cases, and will normally be perceived as punitive. The fact that adverse credentialing action must be reported to the National Practitioner's Data Bank or to licensure boards under state and federal law makes these actions even more patently punitive.

237. *See supra* notes 129–70 and accompanying text.

238. *See also* Sandra Tanenbaum, *What Doctors Know*, 329 NEW ENG. J. MED. 1268 (1993).

239. *See supra* text accompanying notes 204–21.

will often require the cooperation of physicians, who are often suspicious of management initiatives and resistant to being co-opted.[240] A recent survey found that although two thirds of the 3,303 responding hospitals had implemented TQM programs, "only 10% of their active staff physicians have or are participating in a quality improvement project."[241] Third, the power of managers to take action against incompetent practitioners is also limited. The application of antitrust law to professional practice has led to a torrent of litigation challenging medical staff privilege denials or revocations.[242] The Health Care Quality Improvement Act,[243] intended to protect legitimate professional peer review from the antitrust threat, has imposed stultifying procedural requirements on the staff privileging process.[244] Fourth, managers vary in their abilities, and bottom-tier managers are probably no more competent in stimulating quality than bottom-tier physicians are in providing it. Both bottom-tier groups may, moreover, end up in the same institutions.

A still greater problem, however, is the motivational mix that managers must balance. The ultimate job of the health care manager is to keep the institution afloat financially, or if it is a for-profit institution, to make a profit for the shareholders. Quality is always one among many concerns that managers must address. Quality improvement normally depends on the availability of resources, and resources are always more or less scarce and subject to many demands. Quality improvement programs in particular require the commitment of substantial resources to training and to committee work.[245] Though this investment may pay off in the end, the current financial status of American hospitals makes it difficult up front. The limited ability of consumers to recognize true quality[246] relieves the pressure to provide quality that managers might feel in fully functioning markets, thereby freeing up managers to be more attentive to other concerns, such as cost.

There is considerable evidence that many hospitals have adopted quality improvement programs without fully embracing the quality improvement philosophy, and that quality improvement programs are experiencing a high rate of failure.[247] In the end some managers may find it easier to manipulate data to indicate quality than to achieve actual quality. Similarly, some may find it easier to cover up error than to correct it.

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240. *See* GAUCHER & COFFEY, *supra* note 99, at 182–91; Lewis, *supra* note 100; McCormick, *supra* note 100.

241. Oberman, *supra* note 99.

242. *See, e.g.*, Weiss v. York Hosp., 745 F.2d 786 (3d Cir. 1984), *cert. denied*, 470 U.S. 1060 (1985). *See also* 2 JOHN J. MILES, HEALTH CARE AND ANTITRUST LAW § 10 (1992) (for a compilation of these cases).

243. 42 U.S.C. §§ 11,101–11,152 (1988).

244. *See* FURROW ET AL., *supra* note 60, at ¶ 10–25; M. Elizabeth Gee, *Health Care Quality Improvement Act Immunity: An Antitrust Help or Hinderance?*, *in* ABA, ANTITRUST AND HEALTH CARE: CUTTING EDGE ISSUES (1992).

245. Jack Zusman, *Moving from Quality Assurance to Continuous Quality Improvement*, PHYSICIAN EXECUTIVE, July–Aug. 1992, at 3.

246. *See supra* notes 200–02 and accompanying text.

247. Lewis, *supra* note 100; Oberman, *supra* note 100.

V. THE CONTINUING ROLE OF PUBLIC INSTITUTIONS IN OVERSEEING THE QUALITY OF MEDICAL CARE

Even after the information and organizational restructuring revolutions, neither markets nor management, nor both together, can fully bear the burden of assuring the quality of health care. A residual role remains for oversight programs that are accountable to the public. This role should be carefully circumscribed, however, recognizing the potential problems and limitations that attend regulation. This article now turns to the role of government and the law.

A. Support for the Market and for Management

Let us begin with the assumption that the primary task of encouraging quality must be accomplished by the market and management. For markets to function effectively, comparative information is necessary. Although there are a few examples of coalitions of businesses that purchase group health insurance banding together to produce comparative quality information,[248] comparative information is likely to be under-supplied absent government intervention.[249] Information is by nature a public good. Although private entities will produce it under some circumstances, there is often an under-supply because of the difficulty private entrepreneurs encounter in recovering their costs of production.[250] Even when providers voluntarily make quality information available for marketing purposes, oversight of some sort is necessary to assure that this information is accurate and not misleading. Government intervention might also be necessary to assure that information provided by various providers is comparable. Some states have already begun to collect comparative quality information, and a few have even begun to disseminate it.[251] Many of the proposals for health care reform considered by Congress in the summer of 1994 included a legitimate role for government in organizing quality markets.[252] Dissemination of information to consumers is certainly an appropriate public endeavor even if it is not sufficient to fully assure quality for the reasons given above.[253]

Management also requires information to address quality issues effectively. Management needs information regarding best production practices and practice guidelines to channel professional judgment. This information also is a public good. The federal government has recently assumed a major role in funding research in health care outcomes and practice guidelines through the

248. Panzer & Cronin, *supra* note 84 at 91–95; Kathleen Day, *Hastening Health Care's Consumer Era; An Industry Emerges to Collect, Compare Price and Quality Data*, WASH. POST, June 6, 1993, at H1; Joan M. Mazzolini, *Report Grades Cleveland Hospitals: Businesses Hope Innovative Plan Will Keep Costs Down, Improve Quality*, THE PLAIN DEALER, Apr. 29, 1993, at 1A.

249. This is true because such information is costly to produce and because recovery of the production costs are impeded by the public goods nature of quality information. *See* Howard Beales et al., *The Efficient Regulation of Consumer Information*, 24 J.L. & ECON. 491, 502–03 (1981); Hayne E. Leland, *Quacks, Lemons, and Licensing: A Theory of Minimum Quality Standards*, 87 J. POL. ECON. 1328, 1343 (1979).

250. *See* Jost, *supra* note 41, at 863.

251. *See supra* note 95.

252. Jost, *supra* note 5.

253. *See supra* notes 204–28 and accompanying text.

Agency for Health Care Policy Research.[254] Continued public funding of research directed both toward informing professional judgment and toward improving the processes of physician judgment is necessary.

The government can also stimulate management activity by requiring quality improvement and quality management programs, either as a condition of institutional licensure or as a requirement for certification for participation in publicly administered health care programs.[255] To the extent that powerful professionals within institutions resist quality improvement or management programs, management is in a stronger position if it can point to legal requirements mandating such programs.[256]

Finally, the government can support management by minimizing barriers to legitimate peer review. This is what is attempted, of course, by state peer review evidentiary and liability immunity laws,[257] and by the federal Health Care Quality Improvement Act.[258] There is always a delicate balance that must be struck between shielding legitimate peer review, on the one hand, and preventing anticompetitive activity or secretive attempts to cover-up errors on the other. It is important, however, that fear of liability not be used as an excuse for eschewing legitimate peer review.

B. Public Regulation as a Guarantor of Competence

1. Competence as Capacity: The Role of Licensure

Assisting in organizing the market for health care quality and supporting management quality initiatives do not exhaust the role of government in overseeing health quality. The deficiencies of the market and of management[259] insure the existence of a continuing legitimate role for quality regulation. There is general support for continued independent regulation of health care quality in the United States.[260] The costs of government intervention point, however, to a limited rather than an expansive government role.

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254. Charles Marwick, *Federal Agency Focuses on Outcomes Research*, 270 JAMA 164 (1993).

255. The Joint Commission already requires quality improvement programs through its hospital accreditation guidelines. JOINT COMMISSION, 1994 ACCREDITATION MANUAL FOR HOSPITALS 51-58.

256. It might be best, however, to impose these requirements through professional accreditation programs rather than directly. Legislative and administrative rulemaking processes are often cumbersome and driven by politics rather than technological developments. They characteristically react slowly and often inadequately to change. Professional accreditation agencies are more flexible and have in the past been much more responsive to developments in quality oversight technology. In an area such as quality improvement, where the interests of the industry do not appear to diverge remarkably from those of the public, it is probably wise for the government to encourage private accreditation (as does the Medicare program and the licensure programs of many states) and allow accreditation agencies to impose quality improvement or assurance requirements. It is also important that quality management or improvement programs supplement rather than supplant traditional medical staff credentialing programs. *See* Timothy S. Jost, *Medicare and the Joint Commission on Accreditation of Healthcare Organizations: A Healthy Relationship?*, 57 L. & CONTEMP. PROBS. 15 (1994).

257. AMA Compendium, *supra* note 65.

258. 42 U.S.C.A. § 11,112 (West Supp. 1994).

259. *See supra* notes 200–47 and accompanying text.

260. Fifty-nine percent of the respondents to a recent poll on quality issues stated that independent quality oversight was important to guaranteeing quality medical care; only 26%

First, public regulation should return to its original focus on competence, but rely on advances in technology that make the identification of competence (and incompetence) more accurate. While the government may be able to contribute little to driving or shaping management quality improvement initiatives, advocates of quality improvement and management freely admit that their task does not include dealing with the outlying incompetent practitioners.[261] The job of management is to improve the performance of those in the middle.[262] Dealing with the tail is ultimately the job of regulation.

The first task of public regulation in this arena is to assure competency in terms of possession of the basic knowledge and minimal experience necessary to practice a profession. Whatever form of health care reform we eventually adopt, it is unlikely to abrogate basic state licensure requirements. The most important contribution of professional licensure programs to professional competence is establishment of educational and examination requirements that must be met before a person can enter professional practice. Before a person may be licensed as a physician, for example, he or she must complete an educational program leading to a Medical Doctor or Doctor of Osteopathy degree, complete a period of postgraduate clinical training of from one to three years (depending on the state), pass an examination, and satisfy a screening for "character."[263]

These requirements provide some assurance of capacity to render competent professional judgment, though the assurance is not absolute. Entry to American and presumably to most foreign medical schools is competitive, and persons admitted to medical school are generally quite bright.[264] American medical schools must meet uniform accreditation standards, and presumably offer fairly consistent and high quality medical education. The one to three years of residency that state licensure laws require for admission to practice assures that licensed physicians have some clinical experience. While the quality of these residencies is not assessed independently by the licensure boards,[265] they are reviewed by a private accreditation body.[266] Even though licensure is based on objective written examinations,[267] considerable effort has been put

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stated that requiring independent quality oversight would just create another expensive bureaucracy. Coalition for Consumer Protection and Quality News Release, Sept. 14, 1993.

261. Kritchevsky & Simmons, *supra* note 105, at 1822.

262. GAUCHER & COFFEY, *supra* note 99, at 57.

263. OFFICE OF INSPECTOR GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERV., MEDICAL LICENSURE AND DISCIPLINE: AN OVERVIEW 2 (1986) [hereinafter OIG 1986]; American Medical Association Council on Medical Education, *Report on Medical Licensure*, 259 JAMA 1994, 1995 (1988) [hereinafter AMA].

264. Only about one-half of applicants for medical school in the United States were accepted in 1991-92. ELI GINZBERG ET AL., THE ECONOMICS OF MEDICAL EDUCATION 27–28 (1993).

265. OIG 1986, *supra* note 263, at 9–10.

266. *See* U.S. DEPT. HEALTH & HUM. SERV'S, COUNCIL ON GRADUATE MEDICAL EDUCATION, THIRD REPORT 49 (1992).

267. Historically, many states admitted applicants to licensure on the basis of either successful completion of the sequence of examinations offered to U.S. medical students by the National Board of Medical Examiners or on the basis of the state's own examination. In 1968 the Federation of State Medical Boards developed the Federated Licensing Exam (FLEX) which by 1979 achieved universal acceptance as an alternative to the NBME sequence. The FLEX exam was taken by international medical graduates and by U.S. medical graduates who had chosen not to take the NBME sequence or had failed some part of it. As of 1994, a single medical exam, the three-part United States Medical Licensing Exam (USMLE) is replacing both

into devising examinations that probe clinical skills and not just scientific knowledge.[268]

The licensure process does not give perfect assurance of competence. Licensure boards do not independently assess the quality of domestic medical education programs and have only a very limited ability to assess the quality of foreign medical schools, from which about one fifth of the physicians practicing in the United States have graduated.[269] The objective questions found in licensure exams cannot begin to encompass the range of complexity and the degree of uncertainty encountered in practice.[270] Moreover, the judgment processes that examinations are designed primarily to evaluate—those learned in medical schools—seem to differ from the judgment processes physicians use in practice, as is evidenced by the fact that many successful practicing physicians do poorly on licensure examinations.[271] Finally, the high percentage of examination-takers that usually pass licensure examinations,[272] and the fact that persons who fail can in most instances retake the examination, underscore the fact that if an incompetent physician is not screened out by the educational process, he or she is unlikely to be kept from licensure by the examination. Nevertheless, licensure does assure in most instances that persons who present themselves as physicians possess the basic qualifications for practicing medicine.[273]

2. *Competence as Ability to Avoid Persistent Error: The Role of Disciplinary Action*

Another task of regulation is to deal with practicing professionals that cease to be competent. Competence requires not only the initial education and knowledge necessary to practice a profession, but also the ongoing ability to avoid avoidable error and manage the results of unavoidable error. In recent years licensure boards have attempted to exercise greater oversight over the

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the FLEX and NBME exams as the exclusive path to licensure. Henry C. Cramblett, *The United States Medical Licensing Examination (USMLE): Background and Structure of the Examination*, 77 FED. BULL. 205 (1990).

268. *See, e.g.*, Anthony LaDuca & Donald E. Melnick, *Status of the USMLE Step 3 Examination*, 80 FED. BULL. 38 (1993).

269. As of 1988 only 10 licensure boards attempted to maintain lists of approved foreign medical schools. AMA, *supra* note 263, at 1995. *See also* OIG 1986, *supra* note 263, at i, 5–6, 12.

270. *See* Michael T. Kane, *The Assessment of Professional Competence*, 15 EVAL. & HEALTH PROF. 163, 177–80 (1992).

271. *See* Gordon H. Deckert, *Will Certifying Examinations Ever Predict Physician Performance*, 78 FED. BULL. 355 (1991).

272. Ninety-eight percent of the first-time takes and 82% of repeat takes passed the NBME Part III in 1993. THE NATIONAL BOARD EXAMINER, Winter 1994, at 4.

273. Licensure of professionals also presupposes delineation of scope of practice for licensed practitioners and proscription of unlicensed practice. While this protects the public from the untrained, it also bars the public from receiving services from the unorthodox. It also limits the possibilities of health care institutions engaging in "cross training" or "patient centered care." *See* Patricia Brider, *The Move to Patient Focused Care*, 92 AM. J. NURSING 26 (Sept. 1991). The Clinton HSA would have prohibited states from adopting scope of practice laws that would restrict medical professionals from offering services which they are trained to offer. H.R. 3600/S. 1757, 103d Cong., 1st Sess. § 1161 (1993). This provision portended frequent challenges in federal court to state licensure laws, a costly and unproductive possibility. A better idea might be to create a federal commission to consider scope of practice issues and to provide information to the states on appropriate scope of practice definitions.

ongoing competence of medical practitioners through their disciplinary function. The boards' influence has been modest.

The number of physicians disciplined by medical boards, though growing in recent years, is still only a tiny fraction of practicing physicians.[274] Disciplinary actions still predominantly involve the "mad and the bad." The most common ground for medical discipline is misuse of controlled substances, usually involving either impairment or criminal violations of the controlled substances laws.[275] Other common grounds involve abuse of alcohol, mental impairment, or criminal convictions. While practitioners who exhibit this kind of behavior are likely to be providing care of less than optimal quality, these categories certainly do not include all incompetent practitioners.

Though disciplinary actions specifically based on incompetence have become more common in recent years, they are still unusual.[276] There are a number of reasons for this. Medical boards have heretofore had no systematic means for surveillance of medical practice to detect errors. Board actions are still largely complaint-driven, and in particular are based on patient complaints.[277] Yet patient complaints appear to be largely ineffective in identifying incompetent physicians.[278] Though the health care industry is becoming more organized, medicine has traditionally been practiced by isolated practitioners.[279] Even now, medicine continues to be practiced in the context of numerous, usually brief professional/patient encounters. Most of these contacts take place in private, indeed in secret.[280] The regulated behavior is ephemeral; its only enduring existence is in the medical record.[281] It is usually not possible to review the conduct, therefore, only the record of the conduct. If no record has been kept or if the record is inadequate or altered,.it is difficult to discover what in fact happened.[282]

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274. In 1994, 3,685 of the 615,854 physicians licensed to practice medicine in the United States were disciplined. *Punishing of Doctors Increased in 1994*, N.Y. TIMES, Apr. 6, 1995, at A8.

275. *Id.* at 15; Richard P. Kusserow et al., *An Overview of State Medical Discipline*, 257 JAMA 820 (1987).

276. The Office of Inspector General found that only 11.5% of the cases it sampled for 1988 involved "incompetence." OFFICE OF INSPECTOR GENERAL, U.S. DEP'T OF HEALTH AND HUMAN SERV., STATE MEDICAL BOARDS AND MEDICAL DISCIPLINE 15 (1990) [hereinafter OIG 1990]. The difficulties involved in determining the proportion of incompetent physicians who are actually disciplined is discussed in Andrew K. Dolan and Nicole D. Urban, *The Determinants of the Effectiveness of Medical Licensure Boards: 1960-1977*, 7 L. & HUM. BEHAV. 203 (1983).

277. OIG 1986, *supra* note 263, at 15; OIG 1990, *supra* note 276, at 6. In investigating complaints, boards also mediate between the public and the professions. The extent of the resources that boards invest in responding to consumer complaints is in many instances difficult to understand except as an attempt to maintain professional accountability (or the illusion of professional accountability) to the public. Timothy S. Jost et al., *Consumers, Complaints, and Professional Discipline: A Look at Medical Licensure Boards*, 3 HEALTH MATRIX 309, 337 (1993).

278. Jost, *supra* note 277, at 330–33.

279. This problem is thoroughly explored in FREIDSON, *supra* note 43, at 138–66. Freidson concludes that even in the group practice doctors have difficulty gaining access to information about their colleagues' practices and that critical information is largely kept secret.

280. FREIDSON, *supra* note 43, at 150–66; FREIDSON, *supra* note 141, at 91.

281. *See supra* note 131, at 84–93 (describing the hospital chart as narrative, its strengths and limitations).

282. *See* FREIDSON, *supra* note 43, at 167–85, discussing the potential and limitations of medical record review for evaluating quality of care. A recent study had researchers observe the

Medical Boards historically have also had limited options for responding to proven deficiencies. Traditionally, the power of boards was limited because the few sanctions they could impose for responding to disciplinary offenses—revocation and suspension, for example—were too draconian to use in response to many quality issues. Modern boards generally possess a range of possible responses to error and incompetence. Boards increasingly have access not only to incapacitating sanctions like revocation and suspension, but also to rehabilitative sanctions such as remedial continuing medical education or structured probations.[283] Prosecution of an incompetent physician still requires a tremendous commitment of resources, however, it is the equivalent of proving up several malpractice cases simultaneously.[284] Licensure boards are usually strapped for resources, and are often dependent on whatever legal personnel are made available by an attorney general's office that usually has other priorities.[285] In many states disciplinary actions, including those based on competence, must be proved by clear and convincing evidence.[286] Disciplinary actions are vigorously contested and wear down the resolve of even the most resolute boards.

Perhaps the most important factor limiting the effectiveness of medical boards in addressing incompetence is the fact that most licensure boards are still composed predominantly of physicians.[287] Physicians are reluctant to criticize each other for technical and judgment errors.[288] Unless a physician has violated professional norms as well as technical norms, it is difficult for many physicians to find it within themselves to support disciplinary action. If

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performance of doctors at a hospital and then compare the negligent injuries they actually observed with those recorded in the medical record and incident reports. The study found that the observed incidence of negligent injuries was four times that of the recorded incidence. Lori Andrews, *Medical Error and Patient Claiming in a Hospital Setting* 10 (May 30, 1993) (unpublished paper *cited in* Saks, *supra* note 148, at 708–09). The easiest conduct to regulate is prescribing, where transparent and accessible records are kept, usually both by the physician and pharmacy. This may explain in large part why prescribing practices are such a focal point for professional discipline.

283. 3 FEDERATION OF STATE MEDICAL BOARDS OF THE UNITED STATES, EXCHANGE, PHYSICIAN LICENSURE BOARDS AND PHYSICIAN DISCIPLINE 54 (1992).

284. OIG 1990, *supra* note 276, at 8–10. Although some disciplinary cases have involved a single act of incompetence, see Blanchad v. Michigan State Bd. of Examiners in Optometry, 40 Mich. App. 320 (1972), courts are reluctant to uphold disciplinary actions unless multiple acts are proved. *See* Kearl v. California Bd. of Medical Quality Assurance, 189 Cal. App. 3d 1040 (1986).

285. OIG 1990, *supra* note 276, at 7–8; Kusserow et al., *supra* note 275.

286. OIG 1990, *supra* note 276, at 9–10; David A. Swankin & Rebecca A. Cohen, *A Resource Guide for Responding to Attempts to Weaken State Medical Licensing Boards by Legislating a Higher Standard of Evidence*, 79 FED. BULL. 206 (1992).

287. One recent study found that physicians compose 63.3% of the boards studied. R. John Kinkel & Norma C. Josef, *Disciplining Doctors: How Medical Boards are Dealing with Problem Physicians in the Midwest*, 9 RES. SOC. HEALTH CARE 207, 209 (1991).

288. *See supra* notes 158–70 and accompanying text; Robert C. Derbyshire, *How Effective is Medical Self-Regulation?*, 7 L. & HUM. BEHAV. 193, 197–99 (1983); Robert C. Derbyshire, *Medical Discipline in Disarray*, 19 HOSP. PRAC. 136A (June 1984); Kusserow et al., *supra* note 275; Charlotte L. Rosenberg, *Why Doctor-Policing Laws Don't Work*, MED. ECON., Mar. 5, 1984, at 84, 89. A recent study found that while physician members of medical boards believe that they do reasonably well at sanctioning negligent physicians, non-physician members are less confident in this evaluation. Kinkel & Josef, *supra* note 287, at 221. The study also found that non-physician members were much more supportive of the idea of automatically reviewing malpractice judgments for possible disciplinary action than were physicians. *Id.* at 225.

rehabilitative sanctions are available, these may be more palatable,[289] as may be disciplinary actions not disclosed to the public.[290] But physicians are clearly unenthusiastic about the use of serious licensure actions to sanction medical errors.

In the past two decades, professional competence has become an issue of federal as well as state concern. Issues of on-going competence to practice fall within the responsibility of the federal Medicare Utilization and Quality Peer Review (PRO) program (formerly the Professional Standards Review Organization (PSRO) program).[291] The strength of the PRO program has always been its surveillance capacity: literally millions of episodes of medical treatment are reviewed annually by the PROs. When the PRO program has identified problems through this surveillance process its interventions have primarily been educational in nature.[292] PRO attempts to actually sanction doctors for quality deficiencies in the late 1980s met with considerable resistance, and ultimately ended with a retreat from these efforts.[293] Though PROs retain statutory authority to sanction violations of quality of care, the PRO program is now focused almost exclusively on data collection and education as it begins to implement the Health Care Quality Improvement Initiative.[294]

To effectively oversee the on-going competence of physicians, the disciplinary authority of the state physician licensure boards should be combined with the data-gathering and analysis capacity of the PROs. As health care data gathering in general becomes more routine, this data-gathering function will become less intrusive and burdensome. Once medical records are computerized, for example, it will no longer be necessary to physically photocopy stacks of medical records to review medical care, as the information will simply be transmitted electronically. This data can then be submitted to pattern analysis, and professionals that seem persistently to have bad outcomes or to violate practice guidelines may be sought out.

The same quality data that are used for creating markets and facilitating management should be made available to regulatory agencies. Regulatory agencies possess advantages over both consumers and managers. Regulators possess or have access to expertise that should permit them to understand quality data as well as its potential and limitations much better than can consumers. Regulators can also handle far greater quantities of data than consumers can digest. Though regulators will probably have less ability to understand data pertaining to any particular institution than will its manager, the regulator has a significant advantage over the manager from the standpoint of assuring quality: the regulator is accountable to the public rather than to the

289. Boards have been quite active in dealing with physician impairment, where rehabilitation is the goal of disciplinary action.

290. There is some evidence that use of non-public actions is increasing, at least with some boards. OIG 1990, *supra* note 276, at 17.

291. 42 U.S.C. §§ 1320c–1320c–12 (1988).

292. OFFICE OF INSPECTOR GENERAL, U.S. DEP'T OF HEALTH & HUM. SERV'S, EDUCATING PHYSICIANS RESPONSIBLE FOR POOR QUALITY CARE: A REVIEW OF THE PEER REVIEW ORGANIZATIONS' EFFORTS (1991).

293. OFFICE OF INSPECTOR GENERAL, U.S. DEP'T OF HEALTH & HUM.. SERV'S, THE SANCTION REFERRAL AUTHORITY OF PEER REVIEW ORGANIZATIONS (1993).

294. Jencks & Wilensky, *supra* note 91, at 900–01.

bottom line.[295] The regulator can thus focus single-mindedly on quality concerns. The regulator should also have a better grasp of the context of the data of one institution or professional, as he or she has access to data regarding the performance of professionals or institutions throughout the whole system subject to the regulator's jurisdiction.

It is unlikely that data will be sufficiently available or manageable in the immediate future to permit regulators to review comprehensively patterns of practice of all practitioners. In the interim, licensure agencies should focus on those practitioners who are relatively free from managerial or market oversight. These might include the semi-retired and sole practitioners who do not have privileges in health care institutions.[296] Professionals rejected by managers (for example, those who have had their staff privileges revoked or have been rejected by managed care plans for quality related reasons) should receive special attention.[297] These may be persons, unfortunately, for whom practice data is least available. It may be necessary for the near future to engage in practice audits, reviewing a representative sampling of patients, to assure competence.

Our consideration of the nature of professional judgment, above,[298] cautions us against excessive trust in data analysis. A record of bad outcomes is merely evidence of possible underlying incompetence, it does not prove it. To make a more definitive diagnosis of incompetence, medical boards must have the capacity to carry out peer audits to look at the process of judgment itself. This could be a two step process, beginning with record review and followed by clinical observation.[299] An examination such as the SPEX, designed to evaluate the clinical competency of practicing physicians, may also be useful.[300] The process should be conducted as part of the investigative process prior to initiation of discipline rather than as part of a disciplinary sanction.[301] It would need to be conducted confidentially, therefore, as public disclosure of the investigation might well seriously affect the reputation of the provider. Once a chart or practice audit revealed serious defects in medical judgment, however, the licensure board would already be well on its way to proving up its case. It would also be on its way to discerning an appropriate sanction for the professional, which could range from revocation (where total incapacitation of the professional was necessary to protect the public) to focused continuing

295. This point is obviously a modest one. A sophisticated explanation of the motivations of regulatory behavior is beyond the scope of this article, but it is well established that regulators serve the industry they regulate as well as the public.

296. This strategy is followed by the Canadian Provinces of British Columbia and Ontario. OFFICE OF INSPECTOR GENERAL, U.S. DEP'T OF HEALTH & HUM. SERV'S, STATE MEDICAL BOARDS AND QUALITY-OF-CARE CASES, PROMISING APPROACHES 24 (1993).

297. Physicians whose staff privileges have been revoked will be reported to the Boards under the Federal Health Quality Improvement Act, 42 U.S.C.A. § 11,133 (West Supp. 1995).

298. *See supra* notes 131–50 and accompanying text.

299. *See* Candice S. Rettie, *Evaluating the "At Risk" Physician*, 78 FED. BULL. 365 (1991).

300. *See* John H. Marton, *The Current Status of SPEX*, 80 FED. BULL. 257 (1993).

301. As an investigative process it could perhaps be initiated with less extensive procedural protections than disciplinary processes. *See* Smith v. Bd. of Medical Quality Assurance, 248 Cal. Rptr. 704 (Cal. Ct. App. 1988).

medical education (where the physicians problem seemed readily definable and correctable).[302]

The goal of this process should be modest: to identify and address the deficiencies of the truly incompetent. It should be conducted without illusions as to the ability of regulators to do much to improve the quality of professional care generally or to prevent all error. Furthermore, expansion of responsibility in this area should come with expanded resources and with contraction of other responsibilities. Simply attempting to address the problems of the truly incompetent would strain the resources of most of the nation's licensure boards. Perhaps if licensure boards were freed of the responsibility of investigating all consumer complaints, as advocated below,[303] they would have more resources for the task of quality oversight. Perhaps federal assistance could be made available for state boards if they took over some of the responsibilities formerly pursued by the PROs.

Competence review of this sort should find widespread support across the profession and among professional leaders. Since the process would begin with unintrusive data review and only lead to the more intrusive chart review and clinical observation phases once potential problems could be identified, professional resistance to the program should be less than would be met by universal surveillance chart review programs like the PRO program has been until recently. The fact that disciplinary action would only be brought after intensive peer review of practice should also overcome some of the traditional resistance to professional discipline. This form of competency review is also a task that the public should support, since it would allow consumers to enter the market with some confidence that all of their available choices are potentially acceptable.

C. Sustaining the Foundations for Quality by Sanctioning Unprofessional Conduct.

The primary concern of professional discipline has historically not been quality, or even competence, but rather "professionalism." Since professionalism has often been interpreted to mean not competing against fellow professionals, this fact has supported the arguments of those who believe that the main goal and effect of licensure has been cartelization of professional services.[304] An alternative understanding of at least part of medical licensure boards' concern with professional conduct is that by enforcing the norms of the profession the boards were ultimately protecting the integrity of professional judgment.

The concern of licensure boards with disciplining criminals and substance abusers is understandable in this context. Physicians who are convicted of crimes are regarded as having committed normative errors and can expect little sympathy from their peers.[305] Physicians who are mentally or physically

302. *See* Thomas C. Meyer, *The Role of Remedial CME*, 77 FED. BULL. 182 (1990) (describing remedial CME).

303. *See infra* notes 308–10 and accompanying text.

304. *See* COX & FOSTER, *supra* note 112, at 36–40.

305. Richard J. Feinstein, *The Ethics of Professional Regulation*, 312 NEW ENG. J. MED. 801, 804 (1985). In fact, even in these cases some boards have had a difficult time imposing sanctions. *See* Robert C. Derbyshire, *Offenders and Offenses*, 19 HOSP. PRAC. 98A, 98L–

impaired or substance abusers are more commonly thought by their peers as sick and in need of treatment.[306] Placing them under supervision, however, also contributes to maintaining the integrity of the profession. Punishing those who violate their allegiance to their patients by accepting kickbacks for referrals or profits from self-referrals also bolsters the norm of fiduciary duty, which in turn supports professional judgment. Similarly, those who take sexual advantage of their patients have clouded their professional judgment and violated professional norms.

Professional self-regulation, be it independent or state-sponsored, carries with it risks of anticompetitive conduct. The ideal of the professional as the selfless agent of the client, however, is still an important factor motivating the delivery of quality care. It is still worth defending. One function of professional regulation, therefore, ought to be sanctioning those found to have violated seriously those professional norms that support the fiduciary relationship to the patient.

D. Public Accountability: Complaint Investigation

A final function that licensure boards have traditionally assumed is investigation of public complaints. This role should also be taken from licensure boards.

It is necessary that there be some entity to which members of the public can bring complaints about professionals. Licensed professionals must ultimately be accountable to the public, and consumers should have someone who will take their grievances seriously. Yet if the ultimate responsibility of professional regulation is to assure the competence of professionals, consumer complaints are as much a distraction as they are an aid.

Consumer complaints have many causes. Some are the result of poor interpersonal skills of professionals, some the result of poor interpersonal skills of complainants.[307] Some stem from misunderstandings or unrealistic expectations. Some in fact identify unprofessional conduct or errors. Some identify errors that have had truly horrific consequences. Rarely, however, do consumer complaints identify professionals subsequently determined to be truly incompetent.[308]

It is important that consumers have a place they can go with complaints about care they receive from professionals. Voice as well as exit need to be available as routes for expressing consumer grievances.[309] In a reformed health care system there should be ombudspersons available at the institution, health plan, health alliance, and state level. These ombudspersons should have adequate

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98M (Mar. 1984). In my experience, some physicians also have an easier time forgiving their colleagues for tax evasion or medicaid fraud than for other sins.

306. *See* Feinstein, *supra* note 305, at 804; Carol Klaperman Morrow, *Doctors Helping Doctors*, 14 HASTINGS CTR. REPT. 32 (Dec. 1984). Some state programs for helping impaired physicians have been very successful. *See* Antony C. Gualtieri et al., *The California Experience with a Diversion Program for Impaired Physicians*, 249 JAMA 226 (1983); James H. Shore, *The Impaired Physician: Four Years After Probation*, 248 JAMA 3127 (1982).

307. Jost et al., *supra* note 277, at 318–26; Linda Mulcahy & Sally L. Bostock, *Complaining—What's the Use?*, *in* QUALITY AND REGULATION IN HEALTH CARE: INTERNATIONAL EXPERIENCES 51, 54–55, 64–65 (Robert Dingwall & Paul Fenn eds., 1992).

308. Jost et al., *supra* note 277, at 330–33.

309. *See* ALBERT O. HIRSCHMAN, EXIT, VOICE AND LOYALTY (1970).

resources to assure that consumers get a response to their grievances, and, if necessary, redress. This may often be an apology, sometimes perhaps a payment of cash or the forgiveness of a bill.

On occasion this complaint investigation system will identify an incompetent professional. The ombudsperson should freely refer these to the body that regulates the relevant profession.[310] The record of the complaint investigation could then form a basis for further action by the regulatory body. But only at this point should the complaint enter the regulatory system.

VI. CONCLUSION

Professional licensure and discipline is not obsolete, even though the ability of management and the market to address quality issues has grown. The task of professional regulation needs to be refocused on assuring initial and ongoing competency and the professionalism that supports it. Prevention of error should by and large be left to management, and accountability to consumers be assured through the market and through an independent ombudspersons' office responsible for investigating consumer complaints. All the resources of modern technology must then be brought to bear on the residual tasks of regulation.

The job of professional regulation will continue to be arduous and perplexing. If that job is done well, however, a more secure environment might be created that will lay the foundation for the aggressive actions that must be taken to address the immediately pressing problems of access and cost.

310. This system would be roughly equivalent to the Swedish system, where local complaint boards investigate patient complaints, referring serious cases to the Medical Responsibility Board. TIMOTHY S. JOST, ASSURING THE QUALITY OF MEDICAL PRACTICE: AN INTERNATIONAL COMPARATIVE STUDY 40 (1990).