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Competition Law's Role in Health Care Quality

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When dangerous medical practices threaten patients' lives, Americans expect government to act. This expectation survives evolving attitudes regarding the proper balance of government, professional and market control of health care delivery. Over the past 30 years, regulatory philosophy has vacillated between direct "command and control" regulation and the maintenance of efficient markets. We may not regulate less, but we regulate differently.

Regulatory innovation is not, however, smooth or gradual. Government often acts in response to dramatic events, whether natural or man-made. Government reacts to terrorist attacks, hurricanes, oil spills and floods. Theoretical preferences for big or small government diminish in salience in the face of a sufficiently substantial threat to public safety. The 1999 report of the Institute of Medicine ("IOM") on medical error\(^1\) reported findings that had hallmarks of a disaster demanding government action. The IOM, extrapolating from two large studies, estimated that 44,000 to 98,000 Americans die each year as a result of medical errors.\(^2\) As the IOM pointed out, this mortality rate places medical error ahead of motor vehicle accidents, breast cancer, and AIDS as a cause of death.\(^3\) The scale of this problem has elicited attention and response from Congress and commentators.

The flurry of activity in response to the IOM report is not unprecedented. Following years of documented poor-quality care in nursing homes, Congress commissioned a study into the

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1. INSTITUTE OF MEDICINE, COMM. ON QUALITY CARE IN AMERICA, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (1999) [hereinafter "*To Err is Human*"].
2. *Id.* at 1.
3. *Id.*
issue by the IOM.⁴ The resulting report, published in 1986, described a wide range of quality problems in the industry, and suggested a range of regulatory responses.⁵ Many of these recommendations were translated into law and regulation.⁶ Similarly, an increasing drumbeat of discontent with perceived quality concerns in the managed care industry during the 1990s led to the consideration and passage of a wide variety of laws, loosely referred to as "patient protection acts," regulating managed care organizations.⁷ The governmental reaction to these two examples of health care quality concerns differed sharply, reflecting preferences for varying mixes of market-enhancing and non-market solutions, depending upon the circumstances.

This essay will first briefly review various modes of regulation of health quality.⁸ It will then discuss the concerns raised by the IOM's 1986 nursing home study and the current controversy over managed care quality, and the regulatory responses to both.⁹ It will then discuss the recent IOM report on medical error, and the range of available regulatory responses.¹⁰ It concludes by arguing for a regulatory response to the problem of medical error that relies to only a limited extent on command and control regulation. Instead, it argues that the significant causes of medical error are complex and not readily amenable to direct correction. Regulatory oversight to ensure professional development and adoption of remedial action, and to per-

⁴ Institute of Medicine, Improving the Quality of Care in Nursing Homes 2-4 (1986) [hereinafter "Improving the Quality of Care in Nursing Homes"].
⁵ See id.
⁸ See infra Part I.
⁹ See infra Part II.
¹⁰ See infra Part III.
mit effective marketplace incorporation of quality information is appropriate. Pragmatic assessment of failures of professionalism and markets should drive limited but attentive governmental intervention to protect the welfare of patients at risk.

I. THE RELATIONSHIP BETWEEN HEALTH QUALITY AND REGULATION

Defining health care quality such that the good can be distinguished objectively from the bad is difficult. The task requires a melding of the scientific, the customary, and the normative to permit an evaluation against both technical standards and the achievement of social goals.11 Avedis Donabedian described the task of judging health quality as requiring an assessment of "the application of medical science and technology in a manner that maximizes its benefits to health without correspondingly increasing its risks."12 But technical competence is merely instrumental, and has value only when serving "socially defined values and norms."13

A working definition of quality is necessary in order to evaluate and improve health care. The definition employed by the IOM describes quality as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."14 This short definition does not avoid the complexity of the concept. Quality assessment includes the normative (i.e., "desired health outcomes"), the objective (i.e., measuring "outcomes") and the customary (i.e., "consistent with professional knowledge").15

In institutional settings, these principles are often translated into assessment of structure, process and outcomes of health care delivery.16 Assessment of structure considers the resources - human and otherwise - available for care; assessment of pro-

11. See Avedis Donabedian, The Definition of Quality and Approaches to its Assessment 4-6 (1980).
12. Id. at 5.
cess considers the routine means by which the resources are applied; assessment of outcomes considers the results of care, against some objective metric. In physician services, the assessment of quality is closely dependent on observing deviance from a customary norm. Once the application of normative principles permits a determination as to the appropriateness of a procedure, performance quality is usually determined in comparison with professional standards of care. These professional standards may be derived informally, through observation of a sufficiently large cohort of practitioners, or more formally, by reference to norms produced by professional organizations.

The informal development of many important norms thus renders quality assessment in health care unavoidably imprecise and subject to varying interpretations.

The technical, even arcane, analysis of health quality is extremely important. Consumers care a great deal about the quality of health care, but without some technical assistance, they cannot meaningfully evaluate the quality of care. For minor gradations of quality, the marketplace may well be the best vehicle for the provision of such technical assistance. But major deviations from acceptable quality norms threaten the health and safety of consumers, and therefore more readily support the need for regulatory intervention. Such major deviations arise, for example, when people in nursing homes suffer unnecessary pressure ulcers, or when people with apparently comprehensive health coverage are denied access to undeniably appropriate care. The IOM's report that 44,000 to 98,000 Americans die from preventable medical error each year is such a major deviation. The health care delivery system ought not function so as to subject people to serious avoidable injury. Under such cir-

17. Id.; See also Maria A. Friedman, supra note 15, at 6.
18. CROSSING THE QUALITY CHASM supra note 14, at 244-45.
19. Id. at 245.
20. See John V. Jacobi, supra note 13, at 767; Timothy Stolzfus Jost, Oversight of the Quality of Medical Care: Regulation, Management or Market?, 37 ARIZ. ST. L. REV. 825, 843-44 (1995).
21. See IMPROVING THE QUALITY OF LONG-TERM CARE, supra note 6, at 80-82.
22. See John E. Ware et al., Differences in 4-Year Health Outcomes for Elderly and Poor, Chronically Ill Patients Treated in HMO and Fee-for-Service Systems, 276 J. AM. MED. ASS'N 1039, 1042 (1996).
23. I do not mean to glide over the point that, as the IOM pointed out, "to err is human." To ERR IS HUMAN, supra note 1. Mistakes occur in every human endeavor. In this context I mean "preventable" as does the IOM — subject to possible correction through system modifications. Id. at 28.
cumstances, quality assessment and regulation properly have been grist for the government mill.

The means by which government regulates health care has shifted over time and has varied among the health care settings to which regulation is applied. At an ideological level, commentators advocate for means that range from comprehensive governmental control of health care delivery to free market principles governing health transactions. Scholarly and political thinking has shifted several times in past decades, and a range of strong regulatory positions are well represented in the discourse. As is often the case, most discussion tends toward a mixed view between the two extremes; the question is not whether, but how much government will regulate health care delivery.

Toward one end of the regulatory spectrum, governmental judgment replaces that of the industry with regulators making direct instrumental decisions about how care should be delivered. This “command and control” regulation springs from the position that market forces cannot assure safety, and that governmental judgment should therefore supplant private judgment. Toward the opposite end of the spectrum, government operates under different assumptions. In regulating to enhance competition, the government regards aspects of the health care system as properly driven by market forces, but sees imperfections in the market sufficient to justify some governmental interference. Examples of the former are licensure and certification requirements requiring staffing levels and modes of treatment. Examples of the latter are regulations facilitating the gathering and distribution of information, antitrust regulations protecting consumers from anti-competitive arrangements, anti-fraud regulations protecting market participants from devious conduct impeding comparative evaluation, and regulations creating opportunities for the fair and open resolution of disputes.

II. NURSING HOMES AND MANAGED CARE: PRIOR REGULATORY RESPONSES

On two recent occasions, one in the 1980s and one in the 1990s, substantial concern surfaced regarding the quality of nursing home care. Concerns arose in the 1980s about the quality of care provided in the Nation's nursing homes, and a study by the IOM addressed this concern at length. Comprehensive statutory and regulatory measures consistent with the IOM study have been produced steadily since the release of its study. Later, in the 1990s, concerns about the practices of managed care organizations ("MCOs") resulted in a somewhat less systematic review of the health quality implications. A range of statutory and regulatory responses followed, and major federal statutory intervention also may be in the offing. This section will examine the nature of the quality concerns in the above two instances and the shape of the regulatory response that followed.

A. Nursing Home Quality

In the late 1970s and early 1980s, the quality of care provided in nursing homes was questioned in a series of Congressional hearings.26 Some impetus for these hearings was provided by Colorado litigation on behalf of nursing home residents who challenged the lack of federal oversight in the arena of long term care.27 After recounting the recent explosion in need for long-term care services,28 the trial court noted that:

The evidentiary record . . . supports a general finding that all is not well in the nation's nursing homes and that the enormous expenditures of public funds and the earnest efforts of public officials and public employees have not produced an equivalent return in benefits. That failure of expectations has produced frustration and anger among those who are aware of the realities of life in some nursing homes which provide so little service that they could be characterized as orphanages for the aged.29

26. See Schneider, supra note 6, at 109 (citing reports from Congressional hearings).
29. Id. at 293.
In the Colorado litigation, plaintiffs argued that the poor quality of care provided in many nursing homes was in part traceable to a failure of federal oversight.\textsuperscript{30} As a dominant funder of nursing homes through the Medicaid program, the Department of Health and Human Services ("HHS") exercises substantial power over nursing homes through its quality regulations.\textsuperscript{31} Plaintiffs argued that the means by which HHS enforced these regulations violated the Medicaid Act\textsuperscript{32} by focusing on the "theoretical capability of the facility to provide high quality care rather than . . . the care actually provided."\textsuperscript{33} The court found that plaintiffs had established both that the Medicaid Act requires HHS to police nursing homes to assure that quality services are provided, and that the failure of HHS to "promulgate regulations which will enable [it] to be informed as to whether the nursing facilities receiving federal Medicaid funds are actually providing high quality medical care" violated a statutory duty. Consequently, the court permitted the remedy of mandamus.\textsuperscript{34}

As this judicial evaluation of nursing home oversight proceeded, HHS proposed regulations easing the annual inspection and certification requirements for nursing homes participating in Medicaid.\textsuperscript{35} The regulations were "strongly opposed" by state nursing home regulators and consumer groups because they seemed a move in the wrong direction, lessening regulatory oversight at a time when long term care services were judged as deficient, and the regulatory system was judged as too lax.\textsuperscript{36} Under pressure from Congress, HHS requested a review of nursing home regulation by the IOM, which released its report in 1986.\textsuperscript{37} The report reached three essential conclusions. First, it concluded that applying "reasonably objective measures" of quality to nursing homes established that care was frequently "seriously inadequate."\textsuperscript{38} Second, it concluded that quality can

\begin{itemize}
  \item \textsuperscript{30} \textit{Id.} at 290.
  \item \textsuperscript{31} \textit{747 F.2d} at 587 (describing the regulatory requirements regarding, \textit{e.g.}, "the frequency and general content of patients' attending physician evaluations," nursing requirements and personal care requirements).
  \item \textsuperscript{32} Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 \textit{et seq.}
  \item \textsuperscript{33} \textit{747 F.2d} at 587.
  \item \textsuperscript{34} \textit{Id.} at 591.
  \item \textsuperscript{35} \textit{See Improving the Quality of Care in Nursing Homes, supra} note 4, at 1.
  \item \textsuperscript{36} \textit{Id.} at 2.
  \item \textsuperscript{37} \textit{Id.}
  \item \textsuperscript{38} \textit{Id.} at 21.
\end{itemize}
be improved through strengthened regulatory oversight, particularly on the part of the federal government. And third, it found that regulatory reform alone would not correct the quality problems that existed in nursing homes. Instead, improvements in the management and training of staff and effective community and consumer involvement were also required to remedy the deficits.

Congress responded to the IOM report with the passage of the Nursing Home Act of 1987. The Act and regulations promulgated between 1989 and 1991 addressed such fundamental quality issues as patient assessment and care plans, minimum facility staffing, patient privacy, decisional and visitation rights, and patient evaluation and screening requirements. Subsequent regulations established the survey and certification mechanisms by which a nursing homes' compliance with substantive obligations may be measured, and set out the remedial tools available to regulators, including directing plans of correction, imposing training requirements, placing a state monitor in the facility, imposing civil money penalties, and terminating participation in Medicaid.

The regulation of nursing homes that followed the 1986 IOM report is best described as "command and control" regulation. The regulations avowedly intrude into the daily activities of nursing homes, prescribing in detail the conduct of care providers, thereby substituting the judgment of regulatory officials for that of treatment professionals in many aspects of care. These regulations are consistent with the IOM's 1986 findings which rejected free market mechanisms of quality assurance. The IOM's advocacy of command and control regulation over a market-oriented approach followed naturally from its assessment of the ability of nursing home residents to protect themselves through free market methods:

39. Id. at 21-22.
40. Id. at 24.
41. See Improving the Quality of Long-Term Care, supra note 6, at 21; Marshall B. Kapp, Quality of Care and Quality of Life in Nursing Facilities: What's Regulation Got To Do With It?, 31 McGeorge L. Rev. 707, 711-12 (2000); Schneider, supra note 6, at 107.
42. See Kapp, supra note 41, at 712.
43. See Improving the Quality of Long-Term Care, supra note 6, at 153-56; Kapp, supra note 41, at 712-13.
44. See Improving the Quality of Care in Nursing Homes, supra note 4, at 21-22.
Persons needing nursing home care generally suffer from a large array of physical, functional, and mental disabilities. A significant portion of all residents are mentally impaired. The average resident’s ability to choose rationally among providers and to switch from one provider to another is therefore very limited even if bed occupancy rates are low enough to make such choices feasible. Moreover, some who reside in nursing homes lack close family to act as their advocates. Even if they have family the choice of a nursing home is usually made relatively hastily in response to a new illness or disability level; once in an institution, the opportunities for transfer to another nursing home are very limited.\footnote{45}

Market mechanisms for quality control work poorly for such patients; nursing home residents are rarely able to “vote with their feet.”

Have the regulations worked? The answer appears to be a qualified “yes.” In its 2001 report on long-term care, the IOM concluded that the regulatory changes responding to its 1986 report have resulted in improvements in many areas, including the overuse of restraints and psychoactive drugs and in the adoption of “more consumer-centered approaches to care.”\footnote{46} It cautioned, however, that improvements lagged in other areas, such as the prevention of pressure sores, incontinence care, and assuring patient privacy.\footnote{47} Marshall Kapp considered these question in a recent article. Kapp surveyed the opinions of regulators, health care providers, and advocates.\footnote{48} From these sources, he found general agreement that the regulatory structure flowing from the Nursing Home Reform Act of 1987 have resulted in better patient care.\footnote{49} Objective measurements also seem to point to improvements in clinical care, survey and certification measures have facilitated improved quality assurance procedures, and physicians are more involved in patient care and institutional quality concerns.\footnote{50}

Significant problems remain. The IOM describes the three central elements of the post-1987 federal regulatory structure as:

- establishing quality and related \textit{standards} for service providers;

\footnotesize
\begin{itemize}
  \item Id. at 5-6.
  \item Improving the Quality of Long-Term Care, \textit{supra} note 6, at 108.
  \item Id.
  \item Kapp, \textit{supra} note 41 at 719-29.
  \item Id. at 718-19.
  \item Id.
\end{itemize}
designing survey processes and procedures to measure and monitor actual conditions of residents or clients and to assess compliance; and

- specifying and imposing remedies or sanctions for noncompliance.¹

A recent report from the General Accounting Office suggests that HHS and the states are failing in their execution of at least a third of these factors.² An examination of the regulatory treatment of California nursing homes whose surveys revealed substantial quality shortfalls established that regulators have failed to impose sanctions, permit extensive grace periods for remediation, forgive sanctions, and reinstate facilities terminated for quality reasons.³ The report concluded that the laxness of the system for imposing sanctions on nursing homes has given operators "little incentive to sustain compliance" with regulatory requirements.⁴ The report’s point is a common-sense one: Regulatory standards are ineffective if the regulated community knows they will not be enforced.

Both the IOM (in its 2001 report) and Kapp point to means other than command and control regulation for improving the quality of nursing home care. The IOM points to the potential benefits of an organized effort to enhance professional coordination of quality improvement efforts through methods similar to those it proposed in its recent report on medical error.⁵ In addition, the IOM reiterated a common-sense point first articulated in its 1986 study: Payment policy affects health care, and HHS and the states should set reimbursement rates that permit appropriate care to be provided to vulnerable nursing home residents.⁶

¹ Improving the Quality of Long-Term Care, supra note 6, at 137 (italics in original).
³ Id. at 22-28; See Comment, Angela Snellenberger Quin, Imposing Federal Criminal Liability on Nursing Homes: A Way of Deterring Inadequate Health Care and Improving the Quality of Care Delivered?, 43 St. Louis U. L.J. 653, 667-69 (1999).
⁴ United States General Accounting Office, supra note 52, at 30.
⁵ Improving the Quality of Long-Term Care, supra note 6, at 233-34 (proposing the establishment of Centers for the Advancement of Quality in Long-Term Care). Compare To Err is Human, supra note 1, at 59 (recommending the creation of a Center for Patient Safety).
⁶ Improving the Quality of Long-Term Care, supra note 6 at 235-47. Compare Improving the Quality of Nursing Homes, supra note 4, at 193-96.
Kapp cautions against over-reliance on command and control methods and advocates for consideration of other means of improving nursing home quality, including "market mechanisms, professional education, different payment systems, private accreditation and privately initiated QA interventions." An additional mechanism mentioned by Kapp that is consistent with his advocacy of alternative regulatory mechanisms is the use of ombudsman programs. Long-term care ombudsman programs have proven capable of allowing independent, well-informed agents to act on behalf of patients who have limited direct ability to advocate for themselves.

The vulnerability of nursing home patients dictates substantial reliance on command and control regulation of quality. While shifts in regulatory theory may push the discussion toward market-oriented mechanisms, a firm grounding of direct regulation of the delivery of long term care continues to be essential.

B. Managed Care Quality

Like the public concern for quality of care in nursing homes, a concern over quality in managed care gathered in an increasing stream of commentary. Beginning in the early 1980s, newspaper accounts began to describe anecdotes of quality shortfalls — usually either the denial of necessary care or the provision of substandard care — allegedly attributable to the financing of managed care. These newspaper accounts reflected a managed care "backlash" deeply ingrained in public perception. Surveyed populations reported that they believed the "horror stories" to be "fairly common occurrences" for managed care plan members. A majority of respondents in a large survey believed that people covered by managed care "may not receive the services they need when they are very sick," that people in managed care have a harder time gaining access to specialists when they are sick, and that "managed care has decreased the quality of care."

The actual measure of quality in managed care is less certain. Several analyses have found that the quality of care provided by

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57. Kapp, supra note 41, at 716-17 (footnotes omitted).
58. Id. at 723-24.
59. See Improving the Quality of Long-Term Care, supra note 6, at 174-176.
60. See Mark A. Peterson, Introduction: Politics, Misperception, or Apropos?, 24:5 J. HEALTH POL., POL'Y & LAW 873, 877-80 (1999); Jacobi, supra note 13, at 711-17.
61. Robert J. Blendon, et al., supra note 7, at 84.
62. Id.
managed care organizations is no worse than that provided by other financing systems.\textsuperscript{63} However, there is some evidence that this is not the case for those managed care participants most in need of care — those with chronic illness.\textsuperscript{64} Adding to the uncertainty was the lack of confidence in plan performance measures which one leading commentator described as "blunt, expensive, incomplete and misleading."\textsuperscript{65} Currently, much effort is being expended to improve quality measurements in managed care, but comprehensive objective measurements will be unpersuasive in the near term. Under conditions of evaluative uncertainty, consumer concerns about managed care are understandable and rational.

The fee-for-service system famously incorporated incentives to overuse resources, and in particular failed to provide incentives for the efficient use of resources. Increases in the absolute cost of health care strongly suggested that some constraint was necessary, and, in the absence of more comprehensive systemic reform market-based managed care mechanisms presented themselves as a ready and available option. Managed care partially reverses the incentives of health care providers, reducing moral hazard in health expenditures and discouraging wasteful spending.\textsuperscript{66} In the absence of reassuring objective evaluative data, however, consumers are rationally concerned about quality of care. In the absence of either direct (command and control) or market-based (competition-enhancing) regulations, providers have incentives to skimp on care and to shun patients when they most need care.\textsuperscript{67} But under conditions of evaluative uncertainty, the law of unintended consequences looms, and care must be taken not to do more harm than good.\textsuperscript{68}

\textsuperscript{63} See Paul M. Ellwood, Jr. & George D. Lundberg, Managed Care: A Work in Progress, 276 J. AM. MED. ASS'N 1083 (1996); Robert H. Miller & Harold S. Luft, Managed Care Plan Performance Since 1980: A Literature Analysis, 271 J. AM. MED. ASS’N 1512 (1994).


\textsuperscript{65} David M. Eddy, Performance Measurement: Problems and Solutions, 17:4 HEALTH AFFAIRS 7, 16 (1998).


\textsuperscript{68} See Alice A. Noble & Troyen A. Brennen, The Stages of Managed Care Regulation: Developing Better Rules, 24 J. HEALTH POL., POL’Y & LAW 1275, 1275-1277 (1999).
There has been no defining blockbuster study driving the regulation of managed care. Instead, legislators and regulators act within a swirl of input, including self-interested and self-protected lobbying from providers, dramatic but isolated anecdotes of harm resulting from managed care errors, and thoughtful commentary from divergent expert sources. Unlike the regulatory response to nursing home quality failures, the response to managed care concerns has not focused on command and control regulation, but has ranged across the spectrum of regulatory tools. Several commentators have recognized a temporal progression in this regulation, as it has moved from disjointed and reactive forms to more structural mechanisms.69 The regulatory palate has, and will continue to have, a mix of forms incorporating both command and control and competition-enhancing strategies.

Much of the regulatory response to managed care has been motivated by a concern that cost containment efforts by managed care organizations ("MCOs") would result in the denial of medically necessary, high-quality care. The need to address cost pressures, particularly in the absence of health systems reform, was appreciated by all. It was feared, however, that MCOs' financial incentives might lead to a cost/quality balance unacceptable to consumers or regulators. In short, the market for health coverage was seen as sufficiently dysfunctional that intervention was required. Imbalances in information, choice and power between consumers and MCOs were viewed as negating the possibility that quality could be preserved through private ordering.70

Initial efforts at managed care regulation were reactive to anecdotes suggesting that MCOs imperiled consumers by denying access to specific services or providers. In response, states specified the regulatory "rules of the game" in increasing but uneven detail.71 State statutes and regulations set minimum coverage for hospital procedures including labor and delivery and mastectomies, mandate access to certain treatments and providers, and set out rules governing coverage of emergency

69. See Richard Sorian & Judith Feder, Why We Need a Patients' Bill of Rights, 24 J. HEALTH POL., POL'Y & LAW 1137, 1139-43 (1999); Russell Korobkin, supra note 7, at 7; Noble & Brennan, supra note 68, at 1281-95.

70. See Thomas Rice, Can Markets Give Us the Health System We Want?, 22 J. HEALTH POL., POL'Y & LAW 383 (1997).

room visits. These regulatory measures are similar to those adopted in the nursing home context in one important sense: they assumed that competition among plans would fail to produce the preferred or "correct" menu of services and providers for MCO members, and that command and control regulation is necessary to define the basic product.

A second type of managed care regulation is somewhat more complex. These measures, sometimes scoffingly referred to as "physician protection acts," limited the power of MCOs over physicians. MCOs had developed a series of inducements and punishments to reverse the perceived profligacy flowing from the moral hazard inherent in the fee for service system. MCOs provided monetary incentives for more cost effective practices, and penalties for less cost effective practices, and exercised varying degrees of veto power over specific care choices. In addition, they employed the powerful tool of panel selection to choose among physicians on the basis of their practices' compatibility with the MCOs' business plan. That is, MCOs retained physicians practicing consistent with MCO standards and "deselected" physicians who did not. As deselection excluded physicians from the pool of the MCO's insureds, its threat could be a powerful motivation.

Physicians, of course, objected to this new and disturbing intrusion into their professional autonomy, and federal and state regulators created a variety of responsive regulatory measures. To varying degrees, regulators placed limits on physician incentives, created limited due process rights for physicians facing deselection, and passed any willing provider rules. These regulations have been dismissed as mere rent-seeking behavior on the part of physicians, and there is power in this assertion. An alternative explanation, however, is that consumers are hopelessly unable (due to information deficits, limited time and attention, and/or limitations on choice) to respond in the classic market sense, and physicians (although self-interested as well) serve as a roughly effective proxy. In any event, physicians appear to have gained little real power though these measures.

72. See Korobkin, supra note 7, at 17-24; Sorian & Feder, supra note 7, at 1140; Noble & Brennan, supra note 68, at 1283-85.
73. See Peter Kongstvedt, Compensation of Primary Care Physicians in Open Panel Plans in ESSENTIALS OF MANAGED CARE 115 (2d ed. 1997).
74. See Noble & Brennan, supra, note 68, at 1285-86; Korobkin, supra note 7, at 16.
75. See Hyman, supra note 7, at 272-73.
Other aspects of the regulatory response are intended to improve the function of the market rather than supplant it. These regulations enhance a consumer's ability to use markets to improve quality both directly (by improving consumer access to information) and indirectly (by enhancing private law contract and tort remedies). They are premised on the belief that consumers' market power can enforce quality improvement, either through "voting with their feet" or demanding changes in MCO conduct, if they are armed with better information on the relative merits of plans. These regulatory measures gather and distribute information that purports to describe plan quality directly (through "report cards" based on process and patient satisfaction surveys) and indirectly (through reporting modes of operation such as physician compensation terms). However, the questionable validity of the reported information, the limits on consumers' ability to process the information, and consumers' limited ability to choose their MCO have cast some doubt on the power of these regulations.

All else being equal, efficient and effective markets contemplate the keeping of promises and the adherence of market participants to well-established societal norms. The market literally disciplines participants to keep promises and meet background expectations by disfavoring unreliable or unpredictable participants. Dispute resolution mechanisms play an important role in markets by providing a trustworthy means of determining whether a breach of faith or standards has occurred. Although common law actions for fraud, breach of contract, and tort (including medical malpractice) have been available to members of MCOs, the utilization of these mechanisms has been limited by a judicial reluctance to recognize tort and quasi-contractual responsibilities of the plans. In addition, courts have interpreted ERISA as preempting large swaths of common law as applied to the relationship between health insurers (including MCOs)


78. See Korobkin, supra note 7, at 50-56; Herzlinger, supra note 77, at 1081; Enthoven & Singer, supra note 71, at 102-03.

and insureds. While this reluctance has abated in recent years, legislators and regulators have nevertheless intervened to ensure the availability of dispute resolution mechanisms to members of MCOs. The two principle forms of regulation have been: (1) legislative action to permit civil litigation against MCOs for denial of medically appropriate care; and (2) the creation of administrative appeals to independent medical review organizations, in order to challenge a denial of services.

The first of these process measures has been intended to open traditional civil litigation remedies to MCO members, correcting the limitations imposed by slow common law development and ERISA preemption barriers. At least eight states have adopted legislation permitting members to sue their MCO for a failure to meet quality standards, and these standards are often borrowed from tort law. A pioneering statute from Texas, for example, permitted recovery against a health maintenance organization if it "fail[ed] to use ordinary care when deciding whether to pay for a medical procedure." Pending federal legislation would similarly permit tort litigation against a managed care organization if it failed to use ordinary care in denying coverage for services and if such denial caused injury to a member. In brief, this enacted and pending legislation extends members' rights to enforce contractual and common law quality and access rights against plans. The state statutes attempt to avoid ERISA preemption by defining the new rights as the regulation of insur-


81. See In re U.S. Healthcare, Inc., 193 F.3d 151 (3d Cir. 1999) (recognizing the diminishing sweep of ERISA preemption in tort actions against MCOs); Barry R. Furrow, Managed Care Organizations and Patient Injury: Rethinking Liability, 31 Georgia L. Rev. 419 (1997) (describing broader recognition of common law actions against MCOs).


and the proposed federal legislation simply aims to amend ERISA in order to permit the new remedies.\textsuperscript{86}

The second process measure, the creation of a right of appeal to an independent medical organization, has now been adopted by a majority of states and is included in the pending federal legislation.\textsuperscript{87} This process is less formal than civil litigation, and is therefore easier for a plan member to employ. It usually permits review of decisions to deny coverage, and in some jurisdictions extends to quality of care complaints.\textsuperscript{88} Like civil litigation, the independent review provisions provide a formal mechanism for the disclosure of information on coverage, exposes decision-making within plans to public scrutiny, and designates a forum for enforcing the bargain embodied in the insurance contract.\textsuperscript{89}

A couple of caveats. First, in some respects, discussion of these process measures is a bit far afield in the context of health care “quality,” as many of the disputes concern payment for care, and not the quality of care. The procedures do, however, contemplate resolution of some quality disputes. Second, there is vigorous debate over the extent to which process measures, including medical malpractice actions, actually affect health care quality.\textsuperscript{90} Imperfect though it may be, however, medical malpractice litigation (and by natural implication any administrative mechanism that mimics it) provides some measure of deterrence, thereby inclining future health care providers to avoid in-

\textsuperscript{85} See Corporate Health Insurance, Inc. v. Texas Department of Insurance, 215 F.3d 526 (5th Cir.) petition for cert. filed 69 USLW 3317 (October 24, 2000); Moran v. Rush Prudential HMO, 230 F.3d 959 (7th Cir. 2000) cert. granted 121 S. Ct. 2589 (2001).


\textsuperscript{87} See Butler, supra note 82, at 2 (“Over three-quarters of states now require ‘external’ review under which MCO enrollees can appeal a denial of coverage on grounds of medical necessity (or sometimes other grounds) to an organization outside of the MCO . . .”); Shirley Eiko Sanematsu, Taking a Broader View of Treatment Disputes Beyond Managed Care: Are Recent Legislative Efforts the Cure?, 48 U.C.L.A. L. REV. 1245, 1260 (2001) (“As of March 2000, thirty-two states had some form of an [independent medical review] procedure mandated in state law.”); S. 1052, § 104; H.R. 2563, § 104.

\textsuperscript{88} See Corporate Health Insurance, 215 F.3d at 536-39 (discussing the Texas statute); Moran, 230 F.3d at 966-97 (discussing Illinois statute); Sanematsu, supra note 87, at 1263-1271 (discussing California statute).

\textsuperscript{89} See Sanematsu, supra note 87, at 1268 (describing California statute).

\textsuperscript{90} See, e.g., PATRICIA DANZON, MEDICAL MALPRACTICE: THEORY, EVIDENCE AND PUBLIC POLICY (1985); PAUL WEILER et al., MEDICAL MALPRACTICE ON TRIAL (1991); PAUL WEILER et al., A MEASURE OF MALPRACTICE: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION (1993).
This deterrence effect is achieved by increasing the level of information available in the marketplace about the quality of care and about the meaning of contract and tort terms imposing liability when quality lags. Certainly health care providers are better able to arm themselves with information in order to conform their conduct to quality norms, in theory, at least, consumers could also learn about the quality judgments of these tribunals. The process remedies in managed care regulation, then, bolster private ordering arrangements for health quality and improve the distribution of quality information.

The response to nursing home concerns concentrated on command and control regulation, apparently because nursing home residents and their families were seen as having sharply limited ability to obtain and understand quality information, and as having little or no meaningful choice even if they were armed with excellent information. In contrast, the regulatory response to quality concerns in managed care have been varied. Indeed, it is artificial to suggest that a coherent legislative intent unifies the field. Instead, it seems that a variety of regulations have responded to a variety of concerns. As is true with nursing homes, there is concern that consumers will not have access to quality information that either accurately captures the distinctions among plans or is readily intelligible, and that consumer choice of plans is quite limited. These observations about managed care, as with nursing homes, inclines government to supplant markets and impose command and control regulations on plans. On the other hand, much regulatory attention has been paid to gathering and distributing information as though consumers can process the information and make real choices.

The explanation for this divergence may be that compared to nursing home patients, a larger percentage of managed care consumers can process the information, while also having some measure of freedom to make choices. Some consumers are em-

92. See John V. Jacobi & Nicole Huberfeld, Quality Control, Enterprise Liability and Disintermediation in Managed Care, 29 J. LAW, MED. & ETHICS 305, 308 (2001).
93. See Donald W. Moran, Federal Regulation of Managed Care: An Impulse in Search of a Theory?, 16:6 HEALTH AFFAIRS 7, 20 (1997) ( suggesting that the array of regulatory models does not “match up well against the essence of the problem that any meaningful policy needs to address.”).
ployers or HR directors who choose for a group; some are members of state employee purchasing systems who are permitted very wide choice; and some participate in either public (Medicare or Medicaid) or private markets for individual coverage. As Regina Herzlinger has pointed out, "[t]he fundamental lesson of Economics 101 is that [market] equilibrium is determined by marginal participants, not the average ones." If some managed care consumers are able and motivated, their activities may complement the command and control regulation; the market-enabling regulations producing consumer information may foster that ability and motivation. Further, the participants in independent medical reviews and civil litigation may be among the able and motivated marginal group, and regulations fostering this quasi-private dispute resolution may affect the quality equilibrium as well. The disparate nature of the regulation of managed care, therefore, may simply reflect the mixed nature of the problem. To some extent regulators have concluded that markets fail; they therefore direct plans with respect to certain minimum quality indicators such as plan design and terms of participation. To some extent, however, the market, suitably supplemented by regulation, may produce quality improvement even without more direct government involvement.

III. REGULATING MEDICAL ERROR: ENFORCING COMPETITION

Today, government is faced with a new health quality concern. The concerns raised in the IOM's 1986 report on nursing homes are in some ways similar to those raised by its recent report on medical error. The former reported nursing home patients who "receive very inadequate - sometimes shockingly deficient - care that is likely to hasten the deterioration of their physical, mental and emotional health." The new report estimates that up to 98,000 hospital patients per year die from medical error and suggests that hospital-based injuries may be only the tip of the iceberg, "since hospital patients represent only a small portion of the total population at risk," as many people receive "increasingly complex" care in settings other than hospitals. The
IOM’s recommended response to the nursing home crisis was heavily regulatory:

A freer market was not considered by the committee to be a serious alternative to more effective government regulation. . . . Regulation is essential to protect these vulnerable consumers. Although regulation alone is not sufficient to achieve high-quality care, easing or relaxing regulation is inappropriate under current circumstances. 98

Similarly, the 1999 report also highlighted a basic regulatory response:

The committee believes that a basic level of safety should be assured for all who use the health system and a strong regulatory component is critical to accomplishing this goal. In most industries, safety is a traditional role of public policy, enforced through regulation. A regulatory authority generally defines minimum levels of capability or expected performance. Through some type of monitoring mechanism . . . problems can be identified and corrective action taken to maintain the minimum levels of performance. 99

The IOM, then, recommended command and control standard setting and monitoring regulations similar to those applicable to nursing homes. But its recommendations on how to address the problem of medical error were broader. The committee advocated a mixture of responses in addition to the regulatory suggestions, encouraging the employment of economic and professional incentives. 100 Two questions then arise in connection with the 1999 IOM report: What types of regulatory responses are available in this setting, and, of that assortment of responses, which can best facilitate the “[c]areful alignment of regulatory, economic, professional and other incentives [necessary] if significant improvements in safety are to occur”? 101 Preliminarily, it is useful to survey the steps government has taken thus far in reaction to the problem.

One of the IOM’s principle recommendations called for the creation of a federal Center For Patient Safety to serve as a hub of research into measures necessary to achieve a “50% reduction in errors over five years.” 102 Shortly after the report’s re-

98. IMPROVING THE QUALITY OF CARE IN NURSING HOMES, supra note 4, at 4-6.
99. To ERR IS HUMAN, supra note 1, at 18.
100. Id.
101. Id.
102. Id. at 60.
lease, the Center for Quality Improvement and Patient Safety was funded within the Agency for Healthcare Research and Quality.\textsuperscript{103} Shortly after the 2000 elections, the Bush administration formed an interagency Patient Safety Task Force, with the IOM's goal of "reducing the number for medical errors by 50 percent over 5 years."\textsuperscript{104} More recently, HHS has announced the award of $50 million (described as "the first phase of a multi-year effort") to researchers engaged in the enterprise set out by the IOM.\textsuperscript{105} The grantees fell into six categories, including those investigating reporting of medical error data, studying the use of computers and other "innovative approaches" to improve patient safety, and examining the relationship between working conditions and patient error.\textsuperscript{106} The projects are intended to:

address key unanswered questions about how errors occur and provide science-based information on what patients, clinicians, hospital leaders, policymakers and others can do to make the health care system safer. The results of this research will identify improvement strategies that work in hospitals, doctors' offices, nursing homes and other health care settings across the nation.\textsuperscript{107}

These efforts to advance the research into the rate, cause, and means of prevention of medical error appear to comprise the regulatory response to the IOM report to date. Should there be more?

One way of answering this question is to consult history by examining the health and safety concerns and regulatory responses associated with the nursing home and managed care "crises" described above for guidance.\textsuperscript{108} That is, assuming that

\begin{itemize}
  \item \textsuperscript{107} HHS Press Release, \textit{supra} note 105.
  \item \textsuperscript{108} There are, of course, other ways to answer this question. Formal and extensive examinations of regulatory theory in general and as applied to the health care delivery system are available. See, e.g., BRENNAN \& BERWICK, \textit{supra} note 24; JOST, \textit{supra} note 25; SUNSTEIN, \textit{supra} note 25; BRYER, \textit{supra} note 25. As is described above, the goal in this essay is to compare the treatment of two prior instances of
\end{itemize}
the research efforts described in the 1999 IOM report on medical error bear fruit, and the IOM's dream of at least some level of acceptance of systemic, process-oriented correctives to the circumstances causing medical error are developed, can regulatory response be guided by the experience with previous health quality regulatory responses? Drawing from the nursing home and managed care cases, a variety of regulatory responses are possible, both those that are intended to protect consumers through command and control regulation in the absence of market mechanisms on which they can rely, and those that facilitate or enhance market mechanisms for consumer protection.

In the command and control category, regulatory responses may include requiring licensure, certification, and certificates of need. All would serve a similar role here: if one assumes that some objectively valid steps for the amelioration of risks of medical error are developed, command and control regulation could ensure that these steps are taken by health care providers. Suppose, as is likely, that the research now being undertaken establishes that computerized drug prescription and/or administration systems can significantly reduce the risk of human error in drug administration at a reasonable cost. Traditional command and control regulation can induce reluctant providers to adopt these promising new methods. The mechanism for this inducement is similar. Licensure requirements could mandate the consideration and/or adoption of the new quality control methods, much as nursing home licensure now requires the implementation of some process for error analysis and continuous quality improvement. Certification programs, by which regulators adopt the assessment of trusted independent surveyors on quality assurance, could include as a measure of compliance the surveyed institution's adoption of the quality tool. And certification of need programs could select among providers on the basis of their adoption of quality tools, and condition the award

health care quality concern with that presented by the 1999 IOM report, and suggest an inference from the respective regulatory responses.

109. HHS Press Release, supra note 105, identifying $5.3 million in funding for research on the “use of computers and information technology to reduce medical errors, improve patient safety, and improve quality of care.”

110. CROSSING THE QUALITY CHASM, supra note 14, at 162-63 (describing extensive positive research on the use of software to prevent drug error).

111. IMPROVING THE QUALITY OF LONG-TERM CARE, supra note 6, at 220-34.

112. See BRENNEN & BERWICK, supra note 24, at 159-62 (describing the certification function of the National Committee on Quality Assurance in the managed care arena).
of a certificate on their maintenance of up to date methods of reducing drug error.\textsuperscript{113}

Market-oriented regulatory mechanisms are, of course, premised on a different mechanism for quality assurance. These mechanisms assume some viable market in health care services, and attempt to facilitate informed choice by consumers and their proxies, so that "good" products succeed and "bad" products fail. Regulators intervene in markets to increase the possibility that choice is available, informed and effective in selecting as among competitors.

For example, antitrust law seeks to protect competition, thereby permitting actual choice to drive the market. At some point in the aggregation of market power, an entity or combination of entities may become practically immune to market pressure through the elimination of meaningful competitors. In recent years, a consolidation movement has increased the size of health care institutions, and has tended to reduce the number of competitors.\textsuperscript{114} Consolidation and cooperation among competitors is often seen as harmful to competition, and therefore to consumers. In the health care industry, however, such consolidation and cooperation is often asserted to be advantageous to consumers, as peculiarities in the health care market allegedly limit the price effects of such cooperation, and as consolidation and cooperation are sometimes seen as enhancing the quality of care. Both of these assertions are contested, but do render complex any assertion that aggregation of market share is contrary to consumer interests.\textsuperscript{115}

Frustration of competition is one means by which markets could be rendered ineffective in ensuring quality in health care. Unremedied fraud is another. In nearly perfect markets, the failure of a health care provider to provide services at the quality level explicitly or implicitly promised would cause competitive disadvantages for that provider, and the market would discipline it away from that behavior. The health care market is

\textsuperscript{113} See Robert B. Hackey, Commentary, New Wine in Old Bottles: Certificate of Need Enters the 1990s, 18 J. HEALTH POL., POL'Y & LAW 927, 929-30 (1993).


\textsuperscript{115} See Hammer, supra note 114; William M. Sage, Judge Posner's RFP: Antitrust Law and Managed Care, 16:6 HEALTH AFFAIRS 44 (1997); Thomas L. Greaney, Quality of Care and Market Failure Defenses in Antitrust Health Care Litigation, 21 CONN. L. REV. 605 (1989).
famously imperfect, however; information flow is bad and its comprehensibility even worse. Common law fraud is the intentional misrepresentation of a material fact that is intended to and does cause a person to reasonably rely to his detriment, resulting in damages. Statutory versions of fraud, in particular the False Claims Act, embody similar elements, and have to a large degree replaced common law fraud in the health care arena. In recent years, health care providers who injure patients by falling below accepted quality standards are sometimes taken to task through the mechanism of fraud actions. The pursuit of actionable misrepresentations has the potential benefit of both increasing the information available to consumers (through publicity surrounding the action) and disciplining market participants to say what they mean and do what they say.

Finally, regulation that disseminates (or requires the dissemination of) information could assist consumers and their proxies in understanding which health care providers have progressively adopted emerging error reduction technologies. Borrowing from the managed care regulations described above, government could directly or indirectly cause adoption of such measures and the publication of the results in order to facilitate informed choice based on quality. As outcomes research proceeds, it may one day be bundled with this process information to permit consumers and their proxies to review both the means by which providers seek to avoid error, and their rate of success in that endeavor.

Private law, in the form of medical malpractice litigation, will undoubtedly affect the development of discipline such that it complies with sound quality-control mechanisms within the health care industry. In this sense, it will be arguably adjunctive to the actions that may pursued under the False Claims Act

116. See Korobkin, supra note 7.
(or is it the other way around?). In any event, purely private medical malpractice law is beyond the scope of this essay.

Assuming that the development of systemic error reduction follows the infusion of research funding that followed the IOM report, both non-market (command and control) and market-oriented regulatory interventions are supported by history. Will the application of these tools be necessary to reduce error? Only two arguments would support a negative answer. First, it could be argued that the professionalism of health care providers is a force of sufficient strength so that the error-reduction mechanism will be adopted upon production without any outside urging. Second, it could be argued that the free market, unfettered by government, will naturally favor providers adopting such mechanisms, and will therefore provide incentives sufficient to do the job. Neither of these arguments is persuasive. The nursing home quality problems have demonstrated that shortfalls in professional practice do not arise only when technical information on quality is lacking. Rather, quality suffers even in the presence of adequate understanding of error-reduction methods when poor care is to the economic advantage of health care providers, and when outside regulators fail to intervene. Moreover, the managed care quality problems of more recent vintage suggest that market forces alone are inadequate to ensure quality, for reasons including imperfections in health care markets and cognitive limits on market participants' ability to gather and process information.

Some regulation, therefore, will be necessary to ensure the implementation of systemic error-reduction mechanisms that will flow from ongoing research efforts. History suggests two constraints on that regulatory impulse. First, government is a flawed micro-manager of health systems, and command and control regulation is therefore proper only in limited circumstances in the health care setting. Second, markets have the power to regulate well when nearly perfect, but can readily fail when imbalances of information, choice, and power go unremedied. These constraints suggest two appropriate categories of regulation.

Command and control regulation should set and enforce a threshold level of adoption of error-reduction technologies.

121. See Improving the Quality of Care in Nursing Homes, supra note 4, at 2-7.

122. See Rice, supra note 25; Korobkin, supra note 7.
Through licensure and certification standards, regulators can mandate that providers participate in the implementation of error-reduction technologies as they emerge, as regulators now mandate a process of continuous quality improvement. This requirement would be a process requirement only, mandating the formal consideration of the developing error-reduction field unless and until a set of technologies reaches the status of state of the art. Surveying against licensure and certification would ascertain the degree to which providers meaningfully consider and selectively adopt appropriate methods. More intrusive command and control regulation seems unwise; innovation is hoped to flow continually from the ongoing research, and the actual selection of error-reduction methods by regulators is sure to suffer from time-lag and other problems.

In light of the inappropriateness of direct command and control regulation in this area, the role of competition-enhancing regulation rises. As described above, the market is not likely to operate sufficiently well to maximize the adoption of new error-reduction technologies. In such circumstances, market-enhancing regulations can complement limited command and control regulation by correcting market imperfections traceable to imbalances in information, choice, and power. The least intrusive and most clearly appropriate mechanism would be the facilitation of the gathering and distribution of information on market participants' adoption of error-reduction methods, thereby facilitating choice. Choice is possible, however, only where competition exists, and anti-trust enforcement, even in the face of claims that consolidation benefits consumers, is therefore essential. Furthermore, choice is meaningful only if market participants are not permitted to short-circuit the process by defrauding consumers and their proxies by promising quality services in the absence of meaningful error-reduction efforts. Fraud enforcement provides discipline for accurate information flow.

IV. CONCLUSION

The intensive research now being undertaken into the causes of medical error will bear fruit, most likely in the form of systems-based protocols, to correct the human tendency to error. These protocols are not likely to permeate the health care delivery system unaided by government. Both professional aspirations to excellence and market pressures toward efficiency have been inadequate in past quality crises and will not correct the
problem unaided. Instead, government regulation is called for now, as it was called for then.

Two factors should limit the move to regulation. First, the complexity of the causes of error in health care delivery does not lend itself to comprehensive command and control regulation. Second, the somewhat plodding nature of regulatory reaction meshes poorly with the rapid pace of innovation anticipated in this area. Regulation therefore should be limited in scope but substantial where applied. Command and control regulation of providers should be limited to ensuring their participation in the process of reviewing and selectively adopting novel methods of improving quality. The balance of the regulatory effort should be devoted to enhancing market forces, which more quickly and responsively may encourage adoption of new technologies. These market-enhancing regulations should be of three types. First, information on adoption of, and, where possible, success with new methods of error reduction on the part of providers should be gathered and made available to consumers and their proxies. Second, antitrust limits on consolidation and cooperation should be enforced, even in the face of assertions that large-scale cooperative behavior facilitates error-reduction. The power of competition to encourage and maintain quality assurance methods is sufficiently significant to cause regulators to eye warily claims of consumer benefits in monopoly. Third, fraud actions should be employed to identify those who subvert the competitive system with misinformation, thereby frustrating attempts to employ informed choice to ensure quality. Information flows too poorly in the health care marketplace to expect frauds and cheats to be exposed without governmental oversight.