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REGULATING PATIENT SAFETY: TOWARD A FEDERAL MODEL OF MEDICAL ERROR REDUCTION

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I. INTRODUCTION

The American healthcare system is under attack. Critics point out that access is limited for millions of citizens¹ and that costs are higher on a perpatient basis than in any other developed country.² We have assumed however that at least the system offers high quality care — at least for those able to pay for it. It is only since 1999, with the Institute of Medicine (“IOM”) report, *To Err is Human*,³ that we have begun to pay attention to the lethality of the American health care system. Books with titles such as *Internal Bleeding: The Truth Behind America’s Terrifying Epidemic of Medical Mistakes* and *Wall of Silence: The Untold Story of the Medical Mistakes that Kill and Injure Millions of Americans* lambast American medicine from a medical insider’s perspective,⁴ or a patient’s perspective,⁵ while medical journalists attack in books like *Demanding Medical Excellence*.⁶ It has become clear that patients suffer unnecessary injuries and death at the hands of healthcare providers, both because they receive substandard care, and because they fail to get necessary and effective treatments. The IOM’s now familiar 1999 projection of up to 98,000 deaths per year,⁷ and hundreds of thousands of avoidable injuries and extra days of hospitalization,⁸ has been enlarged by more recent analyses. A recent HealthGrades analysis of Medicare data projected a casualty rate more than twice the Institute of Medicine figures, or approximately 241,000 deaths per year attributable to adverse medical events.⁹ The CDC has estimated that medical errors, if ranked as a disease, would be the sixth leading cause of death in the United States, outranking deaths due to diabetes, influenza, pneumonia,

1. TIMOTHY S. JOST, DISSENTLEMENT? THE THREATS FACING OUR PUBLIC HEALTH-CARE PROGRAMS AND A RIGHTS-BASED RESPONSE (2003).

2. Uwe E. Reinhardt, *Is There Hope for the Uninsured?*, HEALTH AFF. 376 (2003), available at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.376v1.pdf>.

3. INSTITUTE OF MEDICINE, TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (Linda T. Kohn et al. eds., 2000) [hereinafter IOM report].

4. ROBERT M. WACHTER & KAVEH G. SHOJANIA, INTERNAL BLEEDING: THE TRUTH BEHIND AMERICA’S TERRIFYING EPIDEMIC OF MEDICAL MISTAKES (2004).

5. ROSEMARY GIBSON & JANARDAN PRASAD SINGH, WALL OF SILENCE: THE UNTOLD STORY OF THE MEDICAL MISTAKES THAT KILL AND INJURE MILLIONS OF AMERICANS (2003).

6. MICHAEL L. MILLENSON, DEMANDING MEDICAL EXCELLENCE: DOCTORS AND ACCOUNTABILITY IN THE INFORMATION AGE (1997).

7. This projection has been criticized as based on a methodology that is likely to overstate the death rate. See Rodney A. Hayward & Timothy P. Hofer, *Estimating Hospital Deaths Due to Medical Errors: Preventability is in the Eye of the Reviewer*, 286 JAMA 415 (2001).

8. IOM report, *supra* note 3.

9. HEALTHGRADES, HEALTHGRADES QUALITY STUDY: SECOND ANNUAL PATIENT SAFETY IN AMERICAN HOSPITALS REPORT 3 (2005), available at <http://www.healthgrades.com/media/DMS/pdf/PatientSafetyInAmericanHospitalsReportFINAL42905Post.pdf>.

Alzheimer's disease and renal disease.¹⁰ Others rank health care, more generally defined, as the third leading cause of death in this country.¹¹

This article will provide an overview of some of the regulatory and market-based strategies now in place to alter the landscape of patient injury and medical errors, and then look at approaches to strengthening the regulatory hand of the federal government in order to accelerate change in the nation's hospitals and providers.

II. THE MAGNITUDE OF MEDICAL MISADVENTURES: IT'S WORSE THAN YOU THINK

It may seem a strange principle to enunciate as the very first requirement in a Hospital that it should do the sick no harm.
—Florence Nightingale, *Notes on Hospitals*, 1859.

We are proud of the technological prowess of the American healthcare system. We measure progress by the degree to which technology appears to grow more sophisticated and more prevalent. We have more machinery and hospital beds available than any other country, and new medical discoveries receive air time and media attention every week. We also love our providers—we must, given how much they earn and how much access they have to state legislatures and the halls of Congress. Yet, far too many patients receive ineffective treatment, and far too many suffer avoidable injury and death for a multitude of reasons—from drug dosing errors to deficiencies in surgical techniques; from hospital infections that prove lethal to system failures to manage patient care.¹²

The studies catalogue a growing chorus of patient harms. Medicare patients are experiencing an increasingly high level of errors.¹³ Patient infection studies have found astonishing levels of preventable and often deadly infections. “Hospital-acquired infection rates worsened by approximately 20 percent from 2000 to 2003 and accounted for 9,552 deaths and \$2.60 billion, almost 30 percent

10. CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL VITAL STATISTICS SYSTEM (2005), <http://www.cdc.gov/nchs/nvss.htm>.

11. Bruce Spitz & John Abramson, *When Health Policy is the Problem: A Report From the Field*, 30 J. HEALTH POL. POL'Y & L. 327, 329 (2005).

12. I have discussed this problem, using case law for examples. See Barry R. Furrow, *Medical Mistakes: Tiptoeing Toward Safety*, 3 Hous. J. HEALTH L. & POL'Y 181 (2003).

13. MEDICARE PAYMENT ADVISORY COMMISSION, Report to the Congress: Medicare Payment Policy (2005), http://www.medpac.gov/publications/congressional_reports/Mar05_EntireReport.pdf (suggesting higher Medicare spending as of late without improvements in quality).

of the total excess cost related to the patient safety incidents.”¹⁴ Unnecessary surgery, by one estimate, kills 12,000 people each year.¹⁵ The accumulating data on patient injury continues to startle the outside observer.¹⁶ Approximately three to four percent of all hospitalizations give rise to adverse events. Provider-caused injury is a predictable and substantial feature of hospital care.¹⁷ A survey of patients by the Commonwealth Fund concludes that twenty-two percent of patients have experienced a medical error, with adverse drug events the largest contributor to these errors, leading the Fund to project a much higher rate of patient injury caused by medical errors and adverse drug events than previously thought.¹⁸ It has been estimated that the average patient in an intensive care unit experiences 1.7 errors during his or her hospital stay, some of them life-threatening.¹⁹

Serious quality problems are widespread throughout American medicine, in spite of the technological prowess of the system.²⁰ Standards of effectiveness are violated, leading to poor patient outcomes, just as unsafe practices endanger patients. Spitz and Abramson write,

What other industry would tolerate such disregard for professional standards? Who would buy their products? What would happen if we learned that defense contractors failed to follow production protocol 45 percent of the time and that

14. HEALTHGRADES, *supra* note 9, at 3.

15. Barbara Starfield, *Is US Health Really the Best in the World?*, 284 JAMA 483, 483 (2000).

16. The Agency for Healthcare Research and Quality (“AHRQ”) recently developed and released a set of Patient Safety Indicators (“PSIs”) specifically designed for screening administrative data for incidences of concern related to patient safety. AHRQ is the lead agency for the U.S. government on quality in health care, sponsoring research that examines the frequency and cause of medical errors and tests techniques designed to reduce these mistakes. AHRQ identified the rates of, and excess length of stay and mortality associated with, these specific patient safety indicators. Extrapolating from AHRQ’s sample data, representing approximately twenty percent of all U.S. hospitals (2000 Healthcare Cost and Utilization Project Nationwide Inpatient Sample), researchers estimated that the eighteen patient safety indicators evaluated contributed to \$9.3 billion excess charges and 32,591 deaths in the United States annually. HEALTHGRADES, *supra* note 9, at 2. *See generally*, AHRQ, <http://www.ahrq.gov/> (last visited Nov. 20, 2005).

17. David M. Studdert, Troyen A. Brennan & Eric J. Thomas, *Beyond Dead Reckoning: Measures of Medical Injury Burden, Malpractice Litigation, and Alternative Compensation Models from Utah and Colorado*, 33 IND. L. REV. 1643, 1662 (2000). The Utah-Colorado Medical Practice Study (“UCMPS”) found that adverse events connected to surgery accounted for about half (44.9%) of adverse events across both states, with only 16.9% of the surgical adverse events involving negligence. *Id.* at 1660.

18. *See* Karen Davis et al., *Room for Improvement: Patients Report on the Quality of Their Health Care* 3-4 (2002), available at http://www.cmwf.org/usr_doc/davis_improvement_534.pdf. For an excellent summary of studies of medical errors, *see* SHEILA LEATHERMAN & DOUGLAS MCCARTHY, *QUALITY OF HEALTH CARE IN THE UNITED STATES: A CHARTBOOK* (2002).

19. CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* 10.

20. Mark R. Chassin, Robert W. Galvin & the National Roundtable on Health Care Quality, *The Urgent Need to Improve Health Care Quality*, 280 JAMA 1000 (1998).

ninety-eight thousand soldiers died annually because of the low quality of their equipment.²¹

System failures account for the vast majority of these harmful errors in hospitals. Almost eighty percent of hospital adverse drug events are traceable to a system malfunction, broadly defined.²² Institutional short-staffing is often the culprit in patient injury, and long working hours may also contribute.²³ Adverse drug events are a major contributor to iatrogenic (provider-induced) illness in hospitals and may account for as much as ten percent of hospitalizations. Errors in the administration of drugs by nurses are often a primary cause of these adverse events.²⁴ Most of these drug errors are due to information failures occurring at the time of treatment. In spite of this level of error, it has been difficult to move quality of care onto the agenda of most health care institutions. Serious quality problems are widespread throughout American medicine.²⁵ In spite of the evidence, health care executives have failed to make patient safety a clear priority and commit the resources needed (money and staff) to improve safety in their institutions.²⁶ Leape and Berwick have bemoaned the failure of health care to move safety to a central concern:

A truly national response to the IOM's call to reduce preventable patient injuries by 90% requires that every health care board, executive, physician, and nurse make improving safety an absolutely top strategic priority—fully equal to the corporate priority of financial health. At a national level, such a commitment has yet to emerge; indeed, it is not in sight.²⁷

In spite of the studies and the magnitude of the problem, we pay surprisingly little attention to what, in any other industry, would be a crisis. Why the lack of response? It has been argued that a variety of impediments thwart recognition of medical errors and system failures—from causal complexity to attribution errors, trust in authority, wishful thinking, and defensiveness.²⁸ Milstein and Adler note that these impediments are powerful forces holding back real acknowledgment of the severity of the problem and a strong response. “When considered together with the large magnitude of quality failure and our collective

21. Spitz & Abramson, *supra* note 11, at 329.

22. Lucien L. Leape et al., *Systems Analysis of Adverse Drug Events*, 274 JAMA 35 (1995).

23. David I. Orton & John H. Gruzelier, *Adverse Changes in Mood and Cognitive Performance of House Officers After Night Duty*, 298 BMJ 21 (1989).

24. VIRGINIA A. SHARPE & ALAN I. FADEN, *MEDICAL HARM: HISTORICAL, CONCEPTUAL, AND ETHICAL DIMENSIONS OF IATROGENIC ILLNESS* 188 (1998).

25. Chassin et al., *supra* note 20.

26. See Lucian L. Leape & Donald M. Berwick, *Five Years After TO ERR IS HUMAN: What Have We Learned?*, 293 JAMA 2384, 2384 (2005).

27. *Id.* at 2388-89.

28. This is developed in an excellent article by Arnold Milstein & Nancy E. Adler, *Out Of Sight, Out of Mind: Why Doesn't Widespread Clinical Quality Failure Command Our Attention?*, HEALTH AFF., Mar./Apr. 2003, at 119.

tepid response to the IOM's unambiguous alarms, these impediments constitute a strong rationale for vigorous policy intervention to strengthen detection and correction of health care quality failure."²⁹ And yet we see few recommendations for tough new federal regulation, as even the critics continue to hope that industry leaders will develop a strong response.

We face a regulatory vacuum in terms of quality regulation, in spite of the accumulation of evidence that medicine is dangerous. Serious measures to improve quality are only slowly and reluctantly being adopted. Quality improvement means that providers—physicians and hospitals—will have to learn which of their behaviors causes patient injury, and then change these practices. Providers resist these efforts.³⁰ The culture of physicians—autonomous and craft oriented—repels talk of systems re-engineering; the management of hospitals is obsessed with financial health as a priority, and patients remain largely unaware of the failures of the system and the risks they might encounter upon entering a doctor's office or a hospital emergency room. Most interventions have focused on controlling costs. It has simply been easier than trying to change health care quality, given difficulties in monitoring, evaluating, and changing provider behavior.³¹

III. CURRENT REGULATORY APPROACHES TO QUALITY: CLAMPS

The attitude of physicians involved in quality improvement toward malpractice and medical injuries is quite similar to that of physicians generally; most understand accidents as random events that cannot be prevented. Thus risk management tends to lead a quiet, somewhat isolated life in institutions that have tried to incorporate modern methods of quality improvement into their work.³²

The current approach to patient safety is piecemeal: a classical American mix of incrementalism and pluralism; private initiatives blending with mild regulatory approaches. Lacking a holistic regulatory model for coping with a too often lethal health care system, researchers and advocates argue the merits of a mixed market/regulatory strategy that is allowed to develop slowly (and like evolution, it appears that effective regulation may take eons).³³ Health care imposes

29. Milstein & Adler, *supra* note 28, at 125.

30. Joseph White, *Three Meanings of Capacity: Or, Why the Federal Government is Most Likely to Lead on Insurance Access Issues*, 28 J. HEALTH POL. POL'Y & L. 217 (2003).

31. Miriam J. Laugesen & Thomas Rice, *Is the Doctor in? The Evolving Role of Organized Medicine in Health Policy*, 28 J. HEALTH POL. POL'Y & L. 289, 310 (2003).

32. TROYEN A. BRENNAN & DONALD M. BERWICK, *NEW RULES: REGULATION, MARKETS, AND THE QUALITY OF AMERICAN HEALTH CARE* 315 (1996).

33. Michelle M. Mello et al., *Fostering Rational Regulation of Patient Safety*, 30 J. HEALTH POL. POL'Y & L. 375, 418 (2005) (arguing that regulation has not matured into "rational regulation" and that regulatory pluralism is needed at present in light of evidence shortfalls).

enforcement difficulties. It is a fragmented industry with many producers, its highly technical underpinnings discourage explicit controls, and it has a strong tradition of self-regulation.

A. Cozy Self-Regulation: Provider Licensing, JCAHO, and QIOs.

Health care regulation has never been truly comprehensive. Self-regulation has been the primary tool, with licensing and discipline under the control of doctors on state medical boards, and regulation of health care facilities by the Joint Commission on Accreditation of Healthcare Organizations (“JCAHO”), to whom both state and federal authorities typically defer with respect to hospital oversight.

Provider licensing scrutiny is improving, but all too often from a very mild regulatory starting point in many states. At the same time, JCAHO accreditation of hospitals is finally using an outcome-based sentinel events approach.³⁴ But, it is still providers regulating providers, and such self-regulation too often lacks real bite. JCAHO is a private accreditor, granted authority by federal and state governments to accredit hospitals.³⁵ JCAHO, to whom both state and federal authorities typically defer with respect to hospital oversight, has its origin in surgical self-regulation and remains responsive to the priorities of organized medicine.³⁶

Private accreditation like that provided by JCAHO is notoriously gentle in its approach, slow to develop meaningful standards and reluctant to develop enforcement mechanisms other than the unlikely threat of withdrawal of accreditation.³⁷ The use of organizations like JCAHO has advantages for the federal and state governments, saving money and offering a collaborative model of negotiated standard-setting.³⁸ JCAHO’s oversight has, however, had limited effects on hospital quality, in spite of continued cheerleading for its newer quality-based standards. It is not clear that Medicare should continue to rely on

34. Mello et al., *supra* note 33, at 382.

35. See generally Timothy Stoltzfus Jost, *Medicare and the Joint Commission on Accreditation of Healthcare Organizations: A Healthy Relationship?*, 57 LAW & CONTEMP. PROBS. 15 (1994); Timothy Stoltzfus Jost, *The Joint Commission on Accreditation of Hospitals: Private Regulation of Health Care and the Public Interest*, 24 B.C.L. REV. 835 (1983); see also Eleanor D. Kinney, *Private Accreditation as a Substitute for Direct Government Regulation in Public Health Insurance Programs: When Is It Appropriate?*, 57 LAW & CONTEMP. PROBS. 47, 52-55 (1994); Douglas C. Michael, *Federal Agency Use of Audited Self-Regulation as a Regulatory Technique*, 47 ADMIN. L. REV. 171, 218-22 (1995).

36. James S. Roberts, Jack G. Coale & Robert R. Redman, *A History of the Joint Commission on Accreditation of Hospitals*, 258 JAMA 936 (1987).

37. Barry R. Furrow, *Regulating the Managed Care Revolution: Private Accreditation and a New System Ethos*, 43 VILL. L. REV. 361, 397-99 (1998); see also Michael J. Astrue, *Health Care Reform and the Constitutional Limits on Private Accreditation as an Alternative to Direct Government Regulation*, 57 LAW & CONTEMP. PROBS. 75, 79 (1994).

38. See Michael, *supra* note 35, at 221-22.

JCAHO accreditation as satisfying its conditions of participation for hospitals.³⁹ A higher accreditation status under JCAHO, for example, does not necessarily mean that the care provided is of higher quality nor that outcomes are better.⁴⁰ In spite of these doubts, federal hospital quality regulation continues to depend on JCAHO as a baseline for hospital quality of care.

Another significant federal quality effort that developed in 1992 is the Quality Improvement Organization (“QIO”) program, which has begun to replace peer review organizations. These QIOs, under contract to the Medicare program, partner with hospitals to improve their overall quality of care.⁴¹ The organizations provide educational materials, use data collection and feedback to track performance on quality indicators, and help hospitals to change their systems by implementing promising new approaches such as clinical pathways.⁴² A recent study evaluated hospitals that partnered with QIOs compared to those that did not, in order to determine the effectiveness of the QIOs. The authors concluded that “. . . [t]he findings from this study do not support the hypothesis that the QIO program improves the quality of care for Medicare beneficiaries in the inpatient setting.”⁴³ The authors cautioned that the data was several years old, and noted that more recent QIO partnerships have had more success in quality improvement.⁴⁴

So, we are left with the modest gains of various gentle forms of self-regulation. No doubt state medical boards detect and sanction some bad physicians; JCAHO has certainly refocused hospital care on near misses and adverse events; and QIOs may indeed offer useful information to partner hospitals. But, one is left with the sense that most of the universe of errors, adverse events, and system failures are largely side-stepped by these regulatory approaches.

39. CAROLYN L. WEINER, *THE ELUSIVE QUEST: ACCOUNTABILITY IN HOSPITALS* (2000); COMMITTEE ON ENHANCING FEDERAL HEALTH CARE QUALITY PROGRAMS, *LEADERSHIP BY EXAMPLE: COORDINATING GOVERNMENT ROLES IN IMPROVING HEALTH CARE QUALITY* (Janet M. Corrigan et al. eds., 2002).

40. Jersey Chen et al., *JCAHO Accreditation and Quality of Care for Acute Myocardial Infarction*, HEALTH AFF., Mar./Apr. 2003, at 243.

41. See Stephen F. Jencks & Gail R. Wilensky, *The Health Care Quality Improvement Initiative: A New Approach to Quality Assurance in Medicare*, 268 JAMA 900 (1992).

42. See generally Claire Snyder & Gerard Anderson, *Do Quality Improvement Organizations Improve the Quality of Hospital Care for Medicare Beneficiaries?*, 293 JAMA 2900 (2005).

43. *Id.* at 2906.

44. *Id.*

B. Litigation: Malpractice As Economic Pressure

The tort system for medical accidents is surprisingly accurate in ascertaining negligent physician conduct. It does provide compensation for more serious injuries but not generally for smaller ones and it makes a crude and clearly inefficient trade-off between an effective level of deterrence of future provider error and levels of compensation.⁴⁵ The tort system is, therefore, far from perfect, but the issue is always whether an alternative system will function any better, or instead trade too much deterrence for more compensation, or exchange administrative savings for accurate fact-finding.⁴⁶ Malpractice suits, for all their inefficiencies, serve a range of functions in promoting medical accountability. They are a form of “bottom up” regulation of quality.⁴⁷

First, liability judgments—and the costs of settling such cases—impose an “error tax” on providers that cause medical errors. While this tax may be imposed infrequently, just as an Internal Revenue Service audit of a tax return is infrequent, the specter of suit limits certain kinds of conduct and adds financial pressures to other forces that reinforce good medical practice. Case law states minimum principles of generally accepted medical practice, based on the medical consensus on a standard of practice, and rarely looks closely at the limits of the standards. But tort law nonetheless influences medical practice by imposing financial burdens on providers and their malpractice insurers for medical errors

45. See Marc Galanter, *Real World Torts: An Antidote to Anecdote*, 55 MD. L. REV. 1093 (1996). [H]eavier reliance on the tort system signifies not only what the United States has more of, but also what it has less of. Compared to our industrialized counterparts, we do not have an administrative state with intensive governmental regulation of risks, nor do we have a comprehensive welfare state . . . In short, our greater reliance on tort reflects not greater generosity to victims, but less reliance on administrative controls and social insurance. *Id.* at 1141.

Galanter argues that by dulling the tort signal to physicians, they will alter their behavior less, thus reducing potentially beneficial defensive medicine and resulting in medicine with less clinical value. *Id.* at 1151.

46. See also Michael J. Trebilcock, *Incentive Issues in the Design of “No-Fault” Compensation Systems*, 39 U. TORONTO L.J. 19, 53 (1989).

[T]he notion that the consequences of accidents, and perhaps other classes of misfortunes, should be solely a community rather than an individual responsibility ignores the fact that accident (or misfortune) rates are often significantly influenced by the conduct of individuals, which targeted pricing and benefit policies and a residual role for the tort system are likely to influence significantly. In short, it is assumed, without justification, that economic incentives do not influence individual behaviour. Neither theory nor empirical evidence supports this assumption.

47. Mello et al., *supra* note 33, at 386.

where good practice was ignored or sloppy practices tolerated. Providers, as consumers of lawyers and insurance, are sensitive to increases in price, which heightens their sensitivity to bright-line rules of practice. We may not want to dull the tort signal to physicians, but rather fine-tune it to provide a better error-taxing system. In some areas, like products liability, it is clear that the risk of suit has promoted innovation in products in response to the judicial costs imposed.⁴⁸ Hospitals clearly will respond to system flaws that lead to liability, although individual physicians often overreact to the risk of suit for a variety of psychological and financial reasons.⁴⁹

The proliferation of clinical guidelines, easily accessible to lawyers through internet research, provides bright-line rules that have been previously lacking in malpractice cases.⁵⁰ This availability adds to the institutional pressure toward convergence on validated standards of practice. Lawyers can introduce evidence of emerging clinical practice guidelines as a way of arguing for a standard of care that the defendant failed to satisfy. Proof of malpractice thus slowly moves from elastic expert opinion toward more empirically validated clinical practices. This means the defense has less wiggle room in the average malpractice case, and as a result, the law indirectly forces hospitals and physicians toward evidence-based patterns of practice. A malpractice suit may be little more than a mirror, reflecting back onto providers the new face of medical practice—practice guidelines, research findings, and new technologies of diagnosis and treatment. But the reflection is always changing. Providers are forced to keep up or risk suit for not reflecting what is expected of them. The generalized threat of suit therefore operates as part of a bundle of market forces that spur the evolution of medical practice toward more effective and convergent modes of practice.

Secondly, tort rules set moral standards for some kinds of provider behavior, giving voice to patients who have been patronized, ignored, actively manipulated at times, or cruelly treated by physicians.⁵¹ Some cases have articulated legal rules that force distinct changes in provider behavior. For example, the informed consent doctrine has forced medical recognition of patients' informational needs; duties to warn and other disclosure obligations have built on the physician's fiduciary duty toward patients. Courts have at times been impatient with provider irresponsibility, pushing new duties on providers.⁵² These duties

48. Evidence exists in the product area that liability promotes innovation, at least for firms with lower liability costs. See W. Kip Viscusi & Michael J. Moore, *Rationalizing the Relationship between Product Liability and Innovation*, in *TORT LAW AND THE PUBLIC INTEREST: COMPETITION, INNOVATION AND CONSUMER WELFARE* 123 (Peter H. Schuck ed., 1991).

49. Furrow, *supra* note 12, at 185-86.

50. See generally Barry R. Furrow, *Broadcasting Clinical Guidelines on the Internet: Will Physicians Tune In?* 25 *AM. J.L. & MED.* 403 (1999).

51. I made this point earlier in Barry R. Furrow, *Pain Management and Provider Liability: No More Excuses*, 29 *J.L. MED. & ETHICS* 28, 30 (2001).

52. See cases discussed in Furrow, *supra* note 12.

become part of the overhead of treating patients with care and respect. Physicians not only must pay attention to emerging practices, but must also disclose risks to third parties created by a patient, candidly make a referral to a more skilled specialist, be honest with patients, and watch out for patients' interests over those of the provider. These new duties force providers to focus on the patient. As Mark Galanter has written,

American tort law manages to be an expensive and inefficient way to deliver compensation, a risk regulator of uneven and largely unknown efficacy, an influential register of our moral concerns, and a remarkable enclave of individualized treatment that has survived in a world in which the ascendancy of organizations over natural persons is ever more pronounced.⁵³

It is this "register of our moral concerns" that is valuable as a way to illuminate rude, thoughtless, or dangerous conduct by providers. Medical errors are not purely driven by systems and their deficiencies, but providers, as failed moral agents, also treat patients badly at times. Tort suits can also shed light on poorly designed institutional systems.

C. Absorption of Losses: No Gain, Some Pain

Excess patient treatment costs induced by errors and adverse events ideally should be internalized to providers, providing further economic incentives for them to improve patient safety. But most excess costs are either covered by insurance or absorbed by patients, families, insurers, employers, or state or private disability and income-support programs.⁵⁴ This means these adverse outcomes are underpriced to providers. Feeling no extra financial pain, they lack the incentive to track down the source of the patient injury. The added costs of a failed intervention caused either by error or by a failure to use an effective approach include added acute care costs, lost income, lost household production, and extra pain.⁵⁵ As Leape and Berwick note,

... [P]layers often subsidize unsafe care quite well, although unknowingly. In most industries, defects cost money and generate warranty claims. In health care, perversely, under most forms of payment, health care professionals receive a premium for a defective product; physicians and hospitals can bill for the additional services that are needed when patients are injured by their mistakes.⁵⁶

Only a tort suit seeks to impose these excess costs on the hospital or provider

53. Galanter, *supra* note 45, at 1160.

54. Mello et al., *supra* note 33, at 396.

55. Michele M. Mello, David M. Studdert, Eric J. Thomas, C. Yoon & Troyen A. Brennan, *Is There a Business Case for Patient Safety? An Analysis of Hospital Adverse Event Costs and Where They Fall* (2005) (unpublished manuscript, cited in Mello et al., *supra* note 33).

56. Leape & Bernick, *supra* note 26, at 2388. See also R. Lamb, *Open Disclosure: The Only Approach to Medical Error*, 13 QUALITY & SAFETY HEALTH CARE 3 (2004).

that was responsible for the patient's injury. Ironically, the movement to a system of "offer and apology," by the Veteran's Administration system ("VHA") is clearly an initiative that will force a reflective internalization of accident costs.⁵⁷ The VHA's National Ethics Committee endorses a general policy requiring the routine disclosure of adverse events to patients.⁵⁸ Likewise, the requirement of some states that hospitals admit to their patients that they suffered a medical injury will force some extra costs onto providers, as more claims are filed than might otherwise have been the case.⁵⁹

The system needs enough data moving rapidly from providers to payors, comparing institutions to their own past records and that of other providers, so payment structures can be calibrated to below average and above average outcomes, and payments varied yearly based on variations in patient outcomes. If both private and public payers moved in this direction, it would be more than sufficient to get the attention of every hospital in the country.

D. Monitoring Error Rates: Sentinel Events, Near Misses, and Feedback

One of the difficult issues to emerge from the IOM report, *To Err Is Human*, has been how to achieve provider disclosure of medical errors and adverse events (including near misses). States have adopted a variety of error disclosure approaches, with Pennsylvania's Patient Safety Authority the most demanding in its requirements of a range of mandatory disclosures.⁶⁰ The Federal approach has expanded over the past few years, continuing its reliance on JCAHO, but also developing a new Center for Medicare and Medicaid Services ("CMS") Error Rule, and new legislation to promote voluntary disclosure of errors by providers.⁶¹

1. JCAHO Sentinel Events Policy

The JCAHO Sentinel Event Policy has adopted the view of medical errors from the IOM report, *To Err is Human*.⁶² It requires reporting on two levels: first to JCAHO of serious events, and second to patients. It defines a sentinel event as "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof," including unanticipated death or major

57. Michael D. Cantor et al., *Disclosing Adverse Events to Patients*, 31 J. QUALITY & PATIENT SAFETY 5 (2005).

58. *Id.*

59. *See* Medical Care Availability and Reduction of Error ("MCARE") Act, 40 PA. STAT. ANN. §1303.308 (West 2002).

60. *Id.* I have discussed this act in more detail in Furrow, *supra* note 12.

61. *Id.*

62. *See* JCAHO, Sentinel Event Policy and Procedures (2005), http://www.jcaho.org/accredited+organizations/sentinel+event/se_pp.htm.

loss of functioning unrelated to the patient's condition, patient suicide, wrong-site surgery, infant abduction/discharge to the wrong family, rape, and hemolytic transfusion reactions.⁶³ Hospitals must report serious events to JCAHO, and if they do not, and JCAHO learns of the events from a third party, the hospital must conduct an analysis of the root cause or risk loss of accreditation.⁶⁴ Loss of accreditation is rarely exercised, however, leaving accreditation as a modest tool to promote uniformity of hospital systems.

The JCAHO disclosure standard also requires that “[p]atients, and when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes.”⁶⁵ The intent statement provides: “The responsible licensed independent practitioner or his or her designee clearly explains the outcome of any treatments or procedures to the patient and, when appropriate, the family, whenever those outcomes *differ significantly from the anticipated outcomes.*”⁶⁶

The JCAHO standard unfortunately suffers from several infirmities. First, the use of “significantly” is not self-defining, and hospitals are likely to adopt a very conservative interpretation to reduce their disclosure obligations.⁶⁷ JCAHO indicates that they are the same as “sentinel events” or “reviewable sentinel events.” A “sentinel event” is defined by JCAHO standards as: “. . . an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase ‘or the risk thereof’ includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.”⁶⁸

The second problem is the locus of the disclosure obligation. The intent statement specifies “the responsible licensed independent practitioner or his or her designee”, who must clearly explain “the outcomes of any treatments or procedures.”⁶⁹ This practitioner is someone with clinical privileges, typically the patient’s attending physician.⁷⁰ Since the attending physician typically has the informed consent responsibility, he or she is the logical person to conduct such a conversation. But physicians are not subject to JCAHO requirements, and are likely to resist such disclosures out of fear of liability, stigma or other

63. See JCAHO, *supra* note 62.

64. *Id.*

65. JCAHO, REVISIONS TO JOINT COMMISSION STANDARDS IN SUPPORT OF PATIENT SAFETY AND MEDICAL/HEALTH CARE ERROR REDUCTION (2001), *available at* http://www.premierinc.com/all/safety/resources/patient-safety/downloads/12_JCAHO_Strds_05-01-01.doc.

66. *Id.* (emphasis added).

67. See, e.g., Nancy LeGros & Jason D. Pinkall, *The New JCAHO Patient Safety Standards and the Disclosure of Unanticipated Outcomes*, 35 J. HEALTH L. 189, 191 (2002).

68. JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, HOSPITAL ACCREDITATION STANDARDS 53 (2001).

69. LeGros & Pinkall, *supra* note 67, at 191.

70. *Id.*

motivations. The disclosure of errors that leads to an increased number of small claims increases the risks to physicians. So the design of the rule is likely to lead to undertreating and resistance by physicians.

The third problem is, lacking real regulatory muscle, the level of actual disclosure of errors has been very low. If errors are not disclosed and diagnosed, the goal of system improvement is thwarted.

2. CMS Rules on Error

CMS has issued a final rule that requires hospitals to develop a quality assessment and performance improvement (“QAPI”) program.⁷¹ This QAPI program is intended to push providers to look at the care delivered to their patients and hospital performance. It mandates systematic examination of a hospital’s quality and the undertaking of improvement projects on an ongoing basis in order to maintain the hospital’s quality of care at what CMS calls “acceptable” levels. The Rules list the requirements as including the identification and verification of quality problems and their causes, acting to correct these deficiencies, determining the success of an intervention, and detecting new problems. CMS states that: “[p]erformance improvement activities aim to improve overall performance assuming that there is no permanent threshold for good performance. Under performance improvement framework, hospitals will continuously study and improve the processes of healthcare and delivery of service.”⁷²

CMS notes in the summary of the Rules and review of the comments to the Proposed Rules that medical error in hospitals has become a major concern for patients and payors.

While both the public and the private sectors have made notable contributions to reducing preventable medical errors, additional and aggressive efforts are needed to further reduce these types of incidents. Therefore, we are publishing this final rule, with some modification in response to comments, to guide improved patient safety in the hospital setting.⁷³

The comments note that medical errors are sometimes hard to recognize due to patient variation, and providers may not notice that a product or procedure has caused a problem, given an already sick patient. Detection is difficult since “medical errors usually affect only a single patient at a time, they are treated as isolated incidents and little attention, if any, is drawn to these problems.”⁷⁴

71. 42 C.F.R. §482.21 (2005).

72. Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement, 68 Fed. Reg. 3435 (Jan. 24, 2003) (codified at 42 C.F.R. 482.21).

73. *Id.*

74. *Id.*

Errors are also underreported. “All of these factors explain the ongoing invisibility of medical errors despite the existence of research that documents their high prevalence.”⁷⁵

CMS has promulgated this new rule to follow up the IOM recommendations in their previous reports: reduction of preventable medical errors, a system of public accountability, a knowledge base system regarding medical errors, and a change in the culture of healthcare organizations to ferret out errors and improve patient safety.⁷⁶ CMS notes that accreditation surveys for deemed status performed by national accrediting organizations such as JCAHO are performed under the authority of CMS and may provide grounds for enforcement by CMS in some cases. During accreditation surveys, CMS intends that its QAPI program will be evaluated for its hospital-wide effectiveness on the quality of care provided. If a hospital, for example is “significantly out of compliance with the QAPI CoP requirements, the hospital will be scheduled for termination from the Medicare and Medicaid programs.”⁷⁷ A plan of correction could then be submitted and a follow-up survey conducted to see if the hospital can bring itself into compliance. QIOs (formally known as Peer Review Organizations (“PROs”)) are intended to be CMS’s “quality improvement agents.”⁷⁸

What is the role of medical error reporting? Is a mandatory system required? CMS writes in the comments:

*We agree that hospitals should consider adverse events in the development of its QAPI strategy. We expect hospitals to implement an internal error reduction system. Adverse event tracking and analysis of underlying causes are an effective way to determine issues involving medical errors. We emphasize the need for hospitals to assess processes and systems that affect patient care and quality. Section 482.21(c) requires the hospital(s) to establish priorities, and identify areas of risk that affect patient safety. We believe that the identification of adverse events and analyses of events must be an integral part of the hospital’s QAPI program, as the analyses will lead to better protections for patients.*⁷⁹

JCAHO standards are consistent with the CMS Rule, according to the comments. Section 482.21(c) of the Rules requires hospitals to “consider prevalence and severity of identified problems and to give priority to improvement activities that affect clinical outcomes, patient safety, and quality of care.”⁸⁰ JCAHO’s sentinel events could be one such source, along with external

75. Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement, 68 Fed. Reg. at 3435.

76. *Id.*

77. *Id.*

78. *Id.*

79. *Id.*

80. Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement, 68 Fed. Reg. at 3435.

industry data, or government data.⁸¹ The current rules do not yet require evidence-based performance measures, which are left to a future rule-making process.⁸² Nor is mandatory reporting required, other than through acknowledgment of JCAHO and its requirements of error reporting.

CMS is a reluctant regulator, and the error rule reflects the culture and history of CMS (previously the Health Care Financing Administration, HCFA). This CMS rule is quite modest in its ambitions, tracking the JCAHO standards closely, and sounding more aspirational than compulsory in its tone. The Rule mentions in a mildly threatening way the possibility that a hospital's Medicare status might be denied if a hospital does not implement proper error detection systems; however, the lack of explicit mandates for error reporting remove teeth from the Rule.

CMS, like HCFA before it, has traditionally viewed itself as a funding agency, not a regulatory one.⁸³ This rule reflects that tradition of a timid regulatory stance and reliance on the parallel efforts of private accreditation. As Michael Astrue has described CMS and its historical roots, it is a reluctant regulator. "HCFA [now CMS] has attempted to minimize its role as regulator through liberal use of private contractors and private accrediting agencies."⁸⁴ The regulatory approach of the federal government in both JCAHO and the CMS error rule is a gradualist approach that fails to reflect the urgency of the patient safety problem.

3. Patient Safety and Quality Improvement Act

The tension between voluntary and mandatory disclosure has resulted in a new federal statute that subsidizes a largely voluntary system.⁸⁵ The Patient Safety and Quality Improvement Act is a new federal patient safety bill passed in 2005.⁸⁶ It

81. The Agency for Healthcare Research and Quality ("AHRQ") has been funding research and developing evaluative criteria on effectiveness and errors. See AHRQ Portfolios of Research, <http://www.ahrq.gov/fund/portfolio.htm> (last visited Nov. 21, 2005).

82. In this final rule, we are not setting a requirement for using and reporting on a core set of evidence-based performance measures. Once the evidence and methodologies to support a set of performance measures that can be used nationwide are available, we will assess issues such as commonality of data elements, standardization, and reporting systems. We will inform hospitals and the public of the specifics of and the methods for reporting these performance measures via future rulemaking. This will give the public the opportunity to comment on the core measures before implementation. Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement, 63 Fed. Reg. at 3435.

83. Astrue, *supra* note 37, at 75.

84. *Id.* at 77.

85. Lucian L. Leape, *Reporting of Adverse Events*, 347 NEW ENG. J. MED. 1633 (2002).

86. Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424

authorizes the creation of “patient safety organizations” that will conduct “patient safety activities” within hospitals and other health care institutions.⁸⁷ Such patient safety work product is any data, reports, records, memoranda, analysis or written or oral statements “which could result in improved patient safety, health care quality, or health care outcomes.”⁸⁸

The heart of this new legislation is the federal certification of patient safety organizations (“PSOs”) governed by the Agency for Healthcare Research and Quality, good for three years.⁸⁹ These PSOs would collect reports of medical errors voluntarily submitted by healthcare providers for inclusion in a patient safety network of databases. Results would be analyzed and disseminated to providers including recommendations—protocols or other guidelines describing best practices. The Act creates a new and strong federal privilege for patient safety work product, preempting state laws governing civil or administrative procedures that would require the disclosure of information by a healthcare provider to a certified PSO. Providers could report voluntarily and confidentially all errors through a Patient Safety Work Product (“PSWP”) to a certified PSO. Such work products are not subject to discovery, to disclosure under the Freedom of Information Act, to admissibility in any federal, state or local government proceeding, or to disciplinary proceedings under state law. They are also confidential and may not be disclosed. Exceptions to confidentiality include disclosure to carry out patient safety activities, nonidentifiable patient safety work product, disclosure to grantees for research, demonstration projects and so on. JCAHO is specifically considered, as §922(c)(2)(E) allows “[v]oluntary disclosure of patient safety work product by a provider to an accrediting body that accredits that provider.”⁹⁰

Subsection (d)(4)(A)(i) provides that “[a] patient safety organization shall not be compelled to disclose information collected or developed under this part whether or not such information is patient safety work product unless such information is identified, is not patient safety work product, and is not reasonably available from another source.”⁹¹ Subsection (d)(4)(B) specifies that

An accrediting body shall not take an accrediting action against a provider based on the good faith participation of the provider in the collection, development, reporting, or maintenance of patient safety work product in accordance with this part. An accrediting body may not require a provider to reveal its communication with any patient safety organization established in accordance with this part.⁹²

(2005).

87. 119 Stat. at 424.

88. 119 Stat. at 426.

89. 119 Stat. at 426.

90. 119 Stat. at 428.

91. Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. at 428-429 (2005).

92. 119 Stat. at 429.

In addition, adverse employment actions may not be based on an employee reporting to such organizations.

The new Act offers increased comfort to providers in terms of a new federal peer review immunity. The federal law, however, adds virtually nothing to the real needs of a proper regulatory approach to medical errors—it provides no mandate for systematic data collection by providers nor any reimbursement for it; it does not compel use of data in any kind of national reporting system, and it fails to make a serious and systematic attempt to tie performance to solid measurements and reimbursement.⁹³ Providers still will be likely to resist disclosure of their mistakes. State mandatory reporting systems, in place in twenty-two states, may also cause inconsistencies and result in confusing procedures and inaccurate data, or no data collected at all. It is likely that hospitals or their medical staffs will establish their own PSOs for their own confidential and privileged safety program.⁹⁴

Reporting of adverse events and near misses is an essential part of an information infrastructure, yet efforts to obtain good data on performance continues to founder on the shoals of system and provider resistance.⁹⁵ Does the new Patient Safety Act federalize medical error reporting or quality management generally? No, but it is now one of a multiplicity of incentives, part of a pluralistic approach to move hospitals in this direction. Providers are confronted with varying regulatory forces that relate to medical errors and their discovery. No coordination of reporting is currently mandated in our complex state-federal system, with its market-driven insurance component and its powerful civil litigation system existing in parallel. Modest JCAHO and CMS reporting requirements and audits strive to create a state of “forced mindfulness” by providers, as the data allows for feedback as to sources of bad outcomes and the resulting ability to fix problems.

E. Paying for Quality: “Pay for Performance” and the Market

Quality does not pay at present. It costs money to generate and mine data, produce useful feedback, and implement new quality measures. Computer software is needed, new personnel must be hired or retrained, and an institution would like to be able to recapture those costs from its payors or through greater efficiencies. But perverse incentives dominate, and poor care is reimbursed at the

93. See American Medical Association, *Summary of S. 544*, <http://www.ama-assn.org/ama/pub/category/15341.html> (last visited Oct. 16, 2005).

94. For various approaches to improving patient safety, see Agency for Healthcare Research and Quality, Patient Safety Network, <http://psnet.ahrq.gov/> (last visited Oct. 16, 2005).

95. Elizabeth A. McGlynn & Robert H. Brook, *Keeping Quality on the Policy Agenda*, HEALTH AFF., May/June 2001, at 86.

same level as high quality care. It has been suggested that

[g]overnment and private purchasers of care ought to consider moving “optional” aspects of quality into the expected “core” of care, creating a stronger need for providers to decide how, not whether, to provide an improvement. This would apply especially to the care of chronic conditions, in which the current payment mechanisms allow, and even reward, defective and fragmented care because they are unable to reward future benefit.⁹⁶

The current regulatory ideology in the United States today is use of market power through purchasing concentrations to increase consumer and purchaser knowledge about providers. The Leapfrog Group is the most visible current example of this manifestation.⁹⁷ Leapfrog members are encouraged to refer patients to hospitals with the best survival odds, to staff intensive care units with doctors having credentials in critical care, and to use error prevention software to prescribe medications. The goal is prevention of medical mistakes through the power of the marketplace rather than the threat of a lawsuit. Economists argue for payment mechanisms that would better help physicians respond to quality incentives. Result-based compensation is moving into the mainstream of academic debate as a way to move quality to the forefront of provider decision-making.⁹⁸ The alignment of payment and quality may prove to be the biggest challenge for health care in the next decade. The use of computer databases to track error and patient outcomes and the importation of corporate techniques such as continuous quality improvement, point to a system in which a health enterprise can more completely integrate patient injuries into its reimbursement structure. Such integration could, for example, be achieved through the use of a health accounting system, a pay-for-performance approach in which debits as well as credits are tallied for patient outcomes. Reimbursement by private payers, government programs, or companies would be based on patient outcomes, providing a powerful incentive for providers to constantly improve the quality of care offered.⁹⁹ But, even if this translates to improved quality, can insurers be induced to market quality care as well as cost-effective care to their purchasers?

96. Sheila Leatherman et al., *The Business Case for Quality: Case Studies and An Analysis*, HEALTH AFF., Mar./Apr. 2003, at 25.

97. The Leapfrog Group, <http://www.leapfroggroup.org/> (last visited Oct. 21, 2005).

98. See J.W. Winkelman et al., *Cost Savings in a Hospital Clinical Laboratory with a Pay-for-Performance Incentive Program for Supervisors*, 115 ARCHIVES PATHOLOGY & LABORATORY MED. 38 (1991). For an earlier discussion of such an idea, see Barry R. Furrow, *The Changing Role of the Law in Promoting Quality in Health Care: From Sanctioning Outlaws to Managing Outcomes*, 26 HOUS. L. REV. 147 (1989).

99. See David A. Hyman & Charles Silver, *Just What the Patient Ordered: The Case for Result-Based Compensation Arrangements*, 29 J.L. MED. & ETHICS 170 (2001). For a critique of the effectiveness of such arrangements, see E. Haavi Morreim, *Result-Based Compensation in Health Care: A Good, But Limited, Idea*, 29 J.L. MED. & ETHICS 174 (2001).

The results have not been encouraging.¹⁰⁰

Another pricing approach is one in which high quality costs more. As Elise Becher and Mark Chassin argue, “purchasers of health care need to develop payment methods that reward excellence in quality. Purchasers should pay more for high-quality care.”¹⁰¹ This is a daunting challenge empirically—defining high quality, pricing it in a tiered fashion that is not confusing to shoppers, and, more practically, convincing providers to accept differential pay based on quality distinctions.

Medicare has begun some moves in this direction with CMS’s modest changes to its payment structure for hospitals. CMS has taken a long time to move in this direction, apparently letting the market forces move first.¹⁰² In 2002, CMS launched a national Quality Initiative that started with the Nursing Home Quality Initiative. In 2003, the Home Health Quality Initiative and Hospital Quality Initiative were added.¹⁰³

The Hospital Quality Initiative has several components. First, the Hospital Quality Alliance was created to improve and standardize hospital data, data transmission, and performance measures. The goal was to create and validate one set of standardized quality measures with which to evaluate hospital quality that would be reported to the public.¹⁰⁴ The Voluntary Reporting Initiative had an initial starter set of ten measures related to three common medical conditions treated in hospitals, Acute Myocardial Infarction, Heart Failure, and Pneumonia. Twelve more measures were added in 2005 with three specific to surgical infection prevention. The HQA mission is to continuously work to incorporate measures in the reporting system to achieve a “robust and comprehensive set of hospital performance measures.”¹⁰⁵

The HQA Voluntary Reporting Initiative is buttressed by Section 501(b) of

100. See Morreim, *supra* note 99, at 177-179.

101. Elise C. Becher & Mark R. Chassin, *Improving Quality, Minimizing Error: Making It Happen*, HEALTH AFF., May/June 2001, at 78. See also James C. Robinson, *Blended Payment Methods in Physician Organizations Under Managed Care*, 282 JAMA 1258 (1999); D.A. Kindig, *Purchasing Population Health: Aligning Financial Incentives to Improve Health Outcomes*, 33 HEALTH SERVS. RES. 223 (1998).

102. Donald M. Berwick et al., *Paying for Performance: Medicare Should Lead*, HEALTH AFF., Nov./Dec. 2003, at 8.

103. CENTERS FOR MEDICARE & MEDICAID SERVICES, HOSPITAL QUALITY INITIATIVE OVERVIEW (2005), <http://www.cms.hhs.gov/HospitalQualityInits/downloads/HospitalOverview200512.pdf> [Hereinafter HOSPITAL QUALITY INITIATIVE]. The program also contains a physician-focused quality initiative and an End-Stage Renal Disease management demonstration project.

104. *Id.* The Hospital Quality Alliance was formerly known as the National Voluntary Hospital Reporting Initiative and is a collaboration between CMS and the American Hospital Association, the Federation of American Hospitals, the Association of American Medical Colleges, JCAHO, AHRQ, and the National Quality Forum. *Id.*

105. See, e.g., CENTERS FOR MEDICARE & MEDICAID SERVICES, REPORTING HOSPITAL QUALITY DATA FOR ANNUAL PAYMENT UPDATE (2004), <http://www.cms.hhs.gov/HospitalQualityInits/downloads/HospitalfactsheetAP.pdf>.

the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), which provides modest financial incentives for hospitals to report.¹⁰⁶ However, the MMA is different from the HQA in two important respects: hospitals need only to report data on the initial starter set of ten measures created by the HQA, and the legislation sunsets after three years. If hospitals that are paid under the Prospective Payment System do not report this data, they will be ineligible to receive a 0.4% payment increase for the FY2005. The same thing applies to the FY2006 and FY2007 payment updates.¹⁰⁷ These incentives, while small, have proved significant enough to increase reporting by hospitals. CMS announced in September of 2004 that 98.3% of hospitals had reported the data required by the MMA by the August 15, 2004 deadline. CMS also stated that this quality data will be available to consumers beginning in the Spring of 2005 on their website.¹⁰⁸

Second, the Hospital Quality Initiative includes a three-state pilot program. Arizona, New York, and Maryland are collaborating with CMS in two projects designed to assess the most effective ways to report hospital quality information (Three-State Pilot Program) and the most effective ways to collect information about patient perspectives on hospital care (“HCAHPS”). The states in the Three State Pilot Program report hospital quality data using the same method and measures as the voluntary reporting effort of the HQA.¹⁰⁹ The study will help the HQA in terms of knowing its impact on hospitals, its impact on consumer behavior towards hospitals and their quality improvement activities, in identifying and reporting essential components of high quality performance, and in studying the relationship between hospital leadership, public reporting, and quality improvement.¹¹⁰

HCAHPS is a survey instrument used to measure patient perspectives on hospital care and is being tested to provide a national standard for the collection of this information. A standardized survey instrument and data collection methodology will allow consumers to compare hospitals nationwide and make an “apples to apples” comparison of quality.¹¹¹ A national implementation of HCAHPS is planned for 2006 by incorporation into the HQA reporting initiative. The first full public reporting will occur later that year and will be

106. *Id.*

107. *Id.*

108. Press Release, Centers for Medicare & Medicaid Services, Nearly All Eligible Hospitals Are Reporting Quality of Care Data (2004), <http://63.241.27.79/media/press/release.asp?Center=1188>.

109. HOSPITAL QUALITY INITIATIVE OVERVIEW, *supra* note 103, at 3.

110. CENTERS FOR MEDICARE & MEDICAID SERVICES, CMS HOSPITAL THREE-STATE PILOT FACT SHEET 1-2 (2005), http://www.aamc.org/quality/jointinitiative/hcahps_joint_fact_sheet_feb0219042.pdf

111. CENTERS FOR MEDICARE & MEDICAID SERVICES & AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, HOSPITAL CAHPS (“HCAHPS”) FACT SHEET 1 (2005), <http://www.cms.hhs.gov/quality/hospital/HCAHPSFactSheet.pdf>.

posted on the CMS website.¹¹²

Finally, the HQI has a Premier Hospital Quality Incentive Demonstration, which will reward hospitals that perform well on certain quality measures with monetary bonuses and public recognition of their performance on the CMS website. Thirty-four measures relating to five medical conditions common to the Medicare population; Acute Myocardial Infarction, Coronary Artery Bypass Graft, Heart Failure, Pneumonia, and Hip and Knee Replacement, are the criteria of this initiative.¹¹³ These measures are evidence-based and have been extensively validated through research.¹¹⁴

The hospitals participating in the Premier Hospital Quality Incentive Demonstration will be separated into deciles by performance. The top performers will be in the first and second decile (top ten and twenty percent). Those hospitals that perform in the top decile will receive a two percent bonus payment from CMS (two percent of the Diagnosis Related Group-based prospective payment). Those that perform in the second decile will receive a one percent bonus payment. Those hospitals in the third through eighth deciles will not receive any bonus payment. The baseline performance level (the payment adjustment threshold) is defined by the performance of the lowest two deciles in the first year. Hospitals in the ninth and tenth deciles will not be penalized in the first and second year of the initiative. However, if hospital performance falls below the payment adjustment threshold by year three, the hospital will receive a reduced Medicare reimbursement. The Medicare payment can be reduced by one or two percent. If all hospitals improve by year three above the payment adjustment threshold, then no hospital will receive a reduced payment. The average quality performance of all of the hospitals is expected to increase each year.¹¹⁵

Hospitals performing in the top fifty percent will have their name and rank published on the CMS website. Those hospitals performing in the top two deciles will be recognized for superior quality. The performance and rank of all other hospitals will not be reported.¹¹⁶ It is clear that as the percentage of payments rises, the interest of providers in developing better quality care will increase. Money does talk, and CMS is moving in the right direction.

The new CMS initiatives represent further movement in the right direction, particularly by providing incentives for hospitals in a variety of ways. But CMS continues to lack intensity, not putting sufficient dollars at risk for hospitals to move seriously and rapidly toward a central focus on patient safety.

112. *Id.* at 2.

113. HOSPITAL QUALITY INITIATIVE OVERVIEW, *supra* note 103, at 4.

114. CENTERS FOR MEDICARE & MEDICAID SERVICES, REWARDING SUPERIOR QUALITY CARE: THE PREMIER HOSPITAL QUALITY INCENTIVE DEMONSTRATION FACT SHEET 1 (2005), <http://www.cms.hhs.gov/quality/hospital/PremierFactSheet.pdf>.

115. *Id.* at 2.

116. *Id.*

F. Shopping For Quality: Information for Consumers

Will consumers pay for quality? Should employers as well as consumers shop on the basis of evidence of higher quality care? Can consumer choice be based on different levels of care, representing different levels of resources?¹¹⁷ The New York Cardiac Surgery reports appear to be effective: information about a surgeon's quality published in the reports influences provider selection by patients and referring physicians.¹¹⁸ Hospitals also take public reporting seriously, often changing their practices to improve their rank.¹¹⁹ Critics note, however, that physicians and hospitals may seek to avoid sicker and more complicated patients in order to improve their ratings. This adverse selection is a real risk of public reporting.¹²⁰

A healthy skepticism toward consumer shopping is needed. Can we expect individual consumers to shop for their care on the basis of quality? A RAND review of healthcare report cards, provider profiles, and consumer reports concluded that few are influenced by this information: "consumers' choice of hospitals relied more on anecdotal press reports of adverse events than on the comparative assessments that were available."¹²¹ Is the public simply discounting this information on the theory, so often probably true, that health information is usually aimed to sell a product?

In other words, in an information environment that is awash with advertisements masquerading as scientific truth, where medical journals have difficulty parsing the marketing from the research, intelligent and conscientious laymen—as well as doctors and health policy experts—may never be able to distinguish the hype from information they need to act in their own best interests.¹²²

However, it may also be that quality information—presented in terms of what a patient might reasonably expect—might create a new set of pressures on providers to guarantee their work. As Leatherman et al. argue, "organizations, both providers and payers, that want a robust business case for quality need to play a stronger role in teaching consumers how good care can be and what to ask

117. See, e.g., E. HAavi MORREIM, *HOLDING HEALTH CARE ACCOUNTABLE: LAW AND THE NEW MEDICAL MARKETPLACE* (2001).

118. Dana B. Mukamel et al., *Quality Report Cards, Selection of Cardiac Surgeons, and Racial Disparities: A Study of the Publication of the New York State Cardiac Surgery Reports*, 41 *INQUIRY* 435, 443-44 (2004).

119. Rachel M. Werner & David A. Asch, *The Unintended Consequences of Publicly Reporting Quality Information*, 293 *JAMA* 1239, 1241 (2005).

120. Z.G. Turi, *The Big Chill—The Deleterious Effects of Public Reporting on Access to Health Care for the Sickest Patients*, 45 *J. AM. C. CARDIOLOGY* 1766 (2005).

121. Rand Corporation, *Report Cards for Health Care*, <http://www.rand.org/publications/RB/RB4544/> (last visited Oct. 17, 2005).

122. Spitz & Abramson, *supra* note 11, at 347.

for that they may not now be getting.”¹²³ One recent study concluded that “there is limited evidence that public report cards improve quality through this mechanism, and there is some evidence that they paradoxically reduce quality.”¹²⁴ It may be best for physicians to be the only audiences for such report cards to avoid the problem of adverse selection of higher-risk patients. For example, another study of hospital ratings found, to the contrary, that quality improvement can be stimulated by the publication of performance information.¹²⁵

Shopping by employers is not likely to fare much better. As employers face large and escalating premium increases over the next few years, it is likely to continue to be cost containment, and not quality, that is again the primary concern of purchasers. In 2003, only six percent of employers in small firms (<200 employees) and twenty-four percent of employers in large firms (200-5,000 employees) were familiar with Health Plan Employer Data and Information Set (“HEDIS”), the national benchmark for measuring and comparing managed care plans.¹²⁶ Less than five percent even thought quality, as scored by HEDIS, was very important.¹²⁷ Should we even expect employers to make judgments about quality of care? Should they now have to play complex private contractual compliance games with providers to protect their workers? *LeapFrog* and other corporate quality groups hope so, but others note that only five percent of employers in small firms and only eighteen percent in large firms were even aware of the *LeapFrog* Group’s national quality effort.¹²⁸

Informed consumerism is therefore harder than it looks, and it may be that generating more information will have little effect on quality. Patients may not use the information, and employers are likely to disregard it.¹²⁹ It provides a market-driven ideological justification for shifting responsibility from government oversight to the forces of the market, although the consequences are that bad practices increase and patients suffer. Let the consumers suffer the consequences of their bad choices, the free marketeers argue. And government agencies are let off the hook from developing tough new rules to govern a complex health care system that will fight back, tooth and claw.

IV. A Tougher Federal Approach to Safety: Mandating Flawless Execution: BITE

123. Leatherman et al., *supra* note 96, at 25.

124. Werner & Asch, *supra* note 119, at 1242.

125. Judith H. Hibbard, Jean Stockard & Martin Tusler, *Does Publicizing Hospital Performance Stimulate Quality Improvement Efforts?*, HEALTH AFF., Mar./Apr. 2003, at 84.

126. Jon Gabel et al., *Health Benefits In 2003: Premiums Reach Thirteen-Year High As Employers Adopt New Forms Of Cost Sharing*, HEALTH AFF., Sept./Oct. 2003, at 123

127. *Id.*

128. *Id.* at 122-23.

129. Gabel et al., *supra* note 126, at 122-123.

Patient safety has generated much attention since the IOM published *To Err Is Human* in 1999, with new market and regulatory initiatives developing at a rapid rate. The eclecticism and pluralism of these forces might mean that they are pulling in tandem and making patients safer day by day.¹³⁰ The regulator must confront the claim that “there is presently very little evidence of measures that can give rise to patient safety regulation. This nearly ensures that the regulation will be a complicated story, as the enthusiasm of regulators exceeds the range of tools available to them.”¹³¹ This argument is both true and an excuse. A strong federal approach can use the tools and goals currently achievable, along with constant improvement of knowledge toward a standard-setting approach to federal regulation. Consider the British, for example, who have established a National Patient Safety Agency under the National Health Service to coordinate safety efforts throughout the British system.¹³² It is easy to feel that the variety of initiatives means real progress, while our look at the current regulatory picture suggests that the admirable efforts are glacial in nature in terms of real culture change in hospitals in particular. Unfortunately, as Brennan and Berwick observe, “the defects persisted, and persist today. Variation in practice runs rampant—beyond the bounds of common sense. Hospitals and doctors continue to perpetrate harms in their work, albeit unintended ones. And it is no easier now to cause an alcoholic surgeon to stop operating than it was forty years ago.”¹³³ Patient safety regulation needs to provide relentless pressure toward a goal of “flawless execution,” the healthcare equivalent of zero defects.¹³⁴ Regulators used to talk about “technology-forcing” regulation in the environment protection arena, a way to move companies into newer, more effective emissions controls through a variety of strategies from markets for pollution credits to tax breaks.¹³⁵

How about safety-forcing regulation in health care? Safety has been rising into the regulatory cross hairs of state and federal regulators. States have adopted medical error disclosure mandates for hospitals and have begun to regulate

130. See generally Mello et al., *supra* note 33.

131. *Id.* at 380-81.

132. National Patient Safety Agency, <http://www.npsa.nhs.uk/> (last visited Oct. 17, 2005).

133. BRENNAN & BERWICK, *supra* note 32, at 339.

134. The phrase “flawless execution” is used in Robert M. Wachter, *The End of the Beginning: Patient Safety Five Years After TO ERR IS HUMAN*, HEALTH AFF., Nov. 2004, at w4-534, <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.534v1.pdf>. He notes that as medicine has grown more complicated and sophisticated, the need for coordination has grown. “It should come as no surprise, then, that without a culture, procedures, and technology focused on flawless execution, errors would become commonplace. One study found that the average ICU patient experiences 1.7 errors per day, nearly one-third of which are potentially life-threatening. Most involve communication problems.” *Id.* at W4-535.

135. See, e.g., ALYSON WARHURST, *MINING AND THE ENVIRONMENT: CASE STUDIES FROM THE AMERICAS* (1998).

outpatient practice. The federal government, through CMS, has supported data collection as to errors and offered modest incentives for performances through its Performance programs.

The gentleness of regulation is in sharp contrast to the ferocity of cost regulation through the Fraud and Abuse regulations, Stark I and II, and even The Health Insurance Portability and Accountability Act (“HIPAA”), with its complex mandates and drop-dead dates for compliance.¹³⁶ Are the excuses sufficient grounds for going slowly on patient safety regulation? Thinking about regulatory strategies is all too often bounded by what is viewed as possible within the constraints of the regulated party, resources, and ideas. We do have to think about provider resistance versus compliance, so-called buy-in strategies. We also have to look at the often unexpected effects of regulation in imposing high costs while stifling innovation.

Consider the federal Diagnosis Related Group (“DRG”) program, which sets limits on federal reimbursement for hospital treatment.¹³⁷ The DRG categories have forced providers to think about budgets and face limits about what a hospital does well and less well. The program does not tell a hospital what to do; it simply sets a boundary based on Medicare history for 559 diagnostic groups, a modest form of price control over charges to Medicare.¹³⁸ How about fraud and abuse regulation? It sets up prohibited classes of economic activity, so that all is prohibited which is not allowed.¹³⁹ The regulatory scheme is intolerant of conflicts of interest and suspicious of the abuses easily induced by high-velocity federal money zooming through the health care system. It carves out careful exceptions or safe harbors for non-suspect activity, but only after a strong principle is established for the regulatory system prohibiting economic conflicts of interest.¹⁴⁰

HIPAA is also a potentially demanding regulatory approach, closer to a command and control regime full of mandates, but with the broad goals in mind of medical privacy protections and consistency and uniformity in data sets, and with apparent regulatory flexibility in making compliance possible.¹⁴¹ It

136. Civil Money Penalties for Referrals to Entities and for Prohibited Arrangements and Schemes, 60 Fed. Reg. 16580 (March 31, 1995) (to be codified at 42 C.F.R. pt. 1003); Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 856 (Jan. 4, 2001) (to be codified at 42 C.F.R. pts. 411 and 424); Health Insurance Portability and Accountability Act of 1996, (HIPAA) 104-191, 110 Stat. 1936 (1996).

137. Social Security Amendments of 1983, Pub. L. No. 98-21, 97 Stat. 65 (1983).

138. 97 Stat. at 65.

139. Civil Money Penalties for Referrals to Entities and for Prohibited Arrangements and Schemes, 60 Fed. Reg. at 16580. Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. at 856.

140. Civil Money Penalties for Referrals to Entities and for Prohibited Arrangements and Schemes, 60 Fed. Reg. at 16580. Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. at 856.

141. 110 Stat. at 1936.

internalizes compliance through a medical privacy officer, whose job, in part, is to educate providers as to the requirements of the federal rule.¹⁴² Patient safety requires a regulatory approach that forces a more integrated bureaucratic structure and reduces the damage caused by too often fragmented organizational structures.

A. Boundary Setting: Of Guidelines and Teams

Practice guidelines aim at effectiveness in medicine and therefore operate as well to reduce the risk that a patient will suffer an adverse event because something is not done. Medicine is complicated, and this complexity is often argued to excuse poor quality care. Yet we know a great deal about what works in terms of medicines and interventions for sets of standard problems. One study looked at 439 indicators of quality for care provided to 18,000 adult patients in twelve metropolitan areas and found that only fifty-five percent of the patients received the recommended procedures for their conditions.¹⁴³ We are learning about best practices as organizations like the National Quality Forum (“NQF”) and the Veteran’s Health Administration develop evidence-based best practices.¹⁴⁴ The problem is that clinicians don’t follow practice guidelines: they may not trust the evidence or resist for cultural or other reasons. Guidelines are too often ignored even when the underlying science has become well established.¹⁴⁵ While physicians have often led through their specialty societies as well as individually in developing clinical practice guidelines, little progress is made in the practice setting.

Providers may have to be forced to adopt the new information technologies and other systems that improve drug prescribing accuracy, inform physicians as to new practice guidelines, and provide feedback on physician practices, both good and bad.¹⁴⁶ Federal regulation needs to impose requirements for these technologies with sanctions at every step in the regulation of health care, e.g., as

142. 110 Stat. at 1936.

143. Elizabeth A. McGlynn et al., *The Quality of Health Care Delivered to Adults in the United States*, 348 NEW ENG. J. MED. 2635, 2641 (2003).

144. Chassin et al., *supra* note 20. J. R. Heget et al., *John M. Eisenberg Patient Safety Awards. System Innovation: Veterans Health Administration National Center for Patient Safety*, 28 JOINT COMMISSION ON QUALITY IMPROVEMENT 660 (2002); Jonathan B. Perlin, Robert M. Kolodner, & Robert H. Roswell, *The Veterans Health Administration: Quality, Value, Accountability, and Information as Transforming Strategies for Patient-Centered Care*, 10 AM. J. MANAGED CARE 828 (2004).

145. Michael D. Cabana et al., *Why Don't Physicians Follow Clinical Practice Guidelines? A Framework for Improvement*, 282 JAMA 1458 (1999); S. H. Woolf, *Changing Physician Practice Behavior: The Merits of a Diagnostic Approach*, 49 J. FAM. PRAC. 126 (2000); AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (“AHRQ”), TRANSLATING RESEARCH INTO PRACTICE (TRIP)—II FACT SHEET (2001), <http://www.ahrq.gov/research/trip2fac.pdf>.

146. *See, e.g.*, Catarina I. Kiefe et al., *Improving Quality Improvement Using Achievable Benchmarks for Physician Feedback: A Randomized Controlled Trial*, 285 JAMA 2871 (2001).

a condition of physician licensing, hospital accreditation, government reimbursement, and malpractice insurance coverage.¹⁴⁷ Such technologies as computerized clinical decision support systems (“CDSSs”) must be developed and hospital adoption of them mandated as soon as they prove cost effective.¹⁴⁸

Individual deficiencies, such as momentary lapses or long-term failures of technique or education in the health care setting, are often the cause of adverse events. Psychological or educational deficits may be the culprit.¹⁴⁹ Not surprisingly, studies have found that physicians are generally more often responsible for such errors than are nurses, pharmacists, or other hospital personnel.¹⁵⁰ The response, at least to drug-related errors, has been individual strategies such as computerized order entry to eliminate errors from poor handwriting. Individual deficiencies are an important aspect of error reduction, since education and training can eliminate some of these problems. A system focus still means professional reeducation, training, and dissemination of clinical guidelines and evidence-based medicine.

B. *Information: Tracking Patient Outcomes and Provider Performance*

Hospital organizational systems are highly resistant to change and linear fixes. Hospitals have to commit financial and staff resources to error prevention, and they have competing pressures on them. As Howard Burde writes:

[h]ealthcare providers generally dislike data collection and submission because it is a time-consuming, expensive, and unproductive exercise with no discernable direct benefit. The challenge for governments is to limit the cost and potential liability inherent in the collection and submission of data, and to ensure the narrow focus and utility of the data to be collected.¹⁵¹

Certainly hospital administrators dislike state mandatory reporting systems, fearing that they discourage internal reporting of errors and expose hospitals to

147. See generally Becher & Chassin, *supra* note 101.

148. Amit X. Garg et al., *Effects of Computerized Clinical Decision Support Systems on Practitioner Performance and Patient Outcomes: A Systematic Review*, 293 JAMA 1223 (2005); Jonathan C. Javitt et al., *Using a Claims Data-Based Sentinel System to Improve Compliance With Clinical Guidelines: Results of a Randomized Prospective Study*, 11 AM. J. MANAGED CARE 93 (2005) (studied a system “that scans administrative claims information and clinical data to detect and mitigate errors in care and deviations from best medical practices,” a sentinel system in that it both constantly monitors patient information and spontaneously contacts physicians (as distinguished from point-of-care support)). *Id.* at 93.

149. Kenneth L. Melmon, *Preventable Drug Reactions - Causes and Cures*, 284 NEW ENG. J. MED. 1361, 1362 (1971).

150. David W. Bates, Lucien L. Leape & S.L. Petrycki, *Incidence and Preventability of Adverse Drug Events in Hospitalized Patients*, 8 J. GEN. INTERN. MED. 289 (1993).

151. Howard Burde, *The Implementation of Quality and Safety Measures: From Rhetoric to Reality*, 35 J. HEALTH L. 263, 274 (2002).

a greater risk of lawsuits.¹⁵² The failure of the federal government to implement a national system of mandatory error reporting has meant the spawning of a range of state systems that often lack clarity and use different language to describe the reporting requirements.¹⁵³ A standardized approach, either based on a uniform model adopted by the states or federal in nature, would create standardization and allow for comparisons across states and regions over time.¹⁵⁴

Government must first mandate data collection and reporting of both outcomes and medical mistakes of all kinds, so that all hospitals have incentives to respond to errors and face similar risks for failing to do so. The goal of mandating collection and disclosure of errors is the primary one, with data for comparing outcomes over time a secondary goal. Many errors are simply never reported.¹⁵⁵ Reasons may include failure to recognize that an error occurred, liability worries, concerns about job security (particularly relevant for nurses), and concerns about personal and professional reputation. One study found that twenty-nine percent of observed errors were not reported.¹⁵⁶ Organizational embracing of error disclosure is essential through rewarding disclosure of errors by teams.

The idea of systematically collecting information of all kinds on patient progress through a healthcare institution is nothing new or remarkable. Over eight decades ago, Dr. Ernest Codman was one of the first to advocate a hard headed approach to data collection and error reduction.¹⁵⁷ Codman was a Boston doctor who wanted hospitals and doctors to track their practices and evaluate outcomes of their patients, an ideal he developed around 1920. He offered an “end-result system” based “on the common-sense notion that every hospital should follow every patient it treats, long enough to determine whether or not the treatment has been successful, and then to inquire ‘if not, why not?’ with a view to preventing similar failures in the future.”¹⁵⁸ Codman’s central idea was a complete patient record that included assessments of why a treatment was unsuccessful, including discussion of errors of technical knowledge or risk, lack of surgical judgment, lack of care or equipment, lack of diagnostic skill, unconquerable disease, patient’s refusal of treatment, calamities of surgery or

152. Joel S. Weissman et al., *Error Reporting and Disclosure Systems: Views From Hospital Leaders*, 293 JAMA 1359, 1362 (2005).

153. *Id.* at 1360.

154. *Id.* at 1364-65.

155. Dorothea Wild & Elizabeth H. Bradley, *The Gap Between Nurses and Residents in a Community Hospital’s Error-Reporting System*, 31 JOINT COMMISSION ON QUALITY & PATIENT SAFETY 13 (2005) (and notes cited).

156. See generally Margaret H. Applegate, *Diagnosis-Related Groups: Are Patients in Jeopardy?*, in HUMAN ERROR IN MEDICINE 349 (Marilyn Sue Bogner ed., 1994).

157. SHARPE & FADEN, *supra* note 24, at 29.

158. SHARPE & FADEN, *supra* note 24, at 29. See generally Susan Reverby, *Stealing the Golden Eggs: Ernest Amory Codman and the Science and Management of Medicine*, 55 BULL. HIST. MED. 156 (1981).

accidents, and complications over which doctors had no control. This detailed record was to serve an auditing function to evaluate, compare, and establish benchmarks for the performance of physicians and hospitals. His idea was revolutionary, aiming to assess a hospital's efficiency in therapeutic, outcome-based terms. To Codman, patient harm due to infections or unnecessary or inappropriate operations was a hospital "waste product."¹⁵⁹ His comparison of bad outcomes to waste products was brilliant; a tough analogy for hospitals and their public and private payers.¹⁶⁰

Current systems approaches attempt to draw our attention to the broader framework for errors within the delivery system. A broader definition is needed to capture the reality of modern health care delivery: drugs, devices, hospital infections, nurses, support staff, technicians, and all those other factors that support the ultimate doctor-patient treatment. Diffusion of responsibility among members of a health care team means often that instead of no one being responsible for harms from system failures, everyone is—everyone who could have prevented the error. And sometimes poor outcomes are not readily visible until data is screened over time and tracked against external benchmarks.

Hospital staff privilege disputes increasingly reveal problems caught by the use of computer analyses. Hospitals may then take steps to reduce patient harm based on the data. One example is the case of *Unnamed Physician v. Bd. of Trustees of Saint Agnes Med. Ctr.*¹⁶¹ "For the period of January 1, 1999, to September 30, 1999, appellant had a 14 percent infection rate for one procedure and a 7.9 percent overall infection rate. This is apparently quadruple the national rate for physicians with his specialty[.]" based on a review of fifteen patient charts.¹⁶² This review began as a result of the Reappointment Review Committee, which suggested that the physician's charts be flagged for further review.¹⁶³ The hospital used a Midas reappointment program that generated a statistical analysis of outliers in physician performance, including infection rates, and flagged outliers.¹⁶⁴ The physician's staff privileges were limited as a result of this flagging and further peer review.¹⁶⁵

A second example of use of statistical analysis to reduce patient risk is *Lo v.*

159. SHARPE & FADEN, *supra* note 24, at 31.

160. Unfortunately, the threat to physicians from such performance measurement was clear, and when the American College of Surgeons ("ACS") developed its error reporting system, the analysis of patient outcomes and error reporting was omitted—these were Codman's most central ideas for error reduction. His work led eventually to the Joint Commission on Accreditation of Health Care Organizations ("JCAHO") which has slowly moved toward a more outcome-based accreditation system. *See generally* Reverby, *supra* note 158.

161. *Unnamed Physician v. Bd. of Trustees of Saint Agnes Med. Ctr.*, 113 Cal. Rptr. 2d 309 n.2 (Cal. Ct. App. 2001).

162. *Id.* at 313 n.2.

163. *Unnamed Physician*, 113 Cal. Rptr. 2d at 313.

164. *Id.* at 313, 317.

165. *Id.* at 313.

*Provena Covenant Med. Ctr.*¹⁶⁶ A review of patient statistics from the hospital's cardiovascular-surgery program revealed that Dr. Lo, one of two cardiovascular surgeons on the medical staff, had a high rate of mortality compared to national norms (5.3% compared to three percent) and a high complication and readmission rate.¹⁶⁷ The President of the medical center, faced with apparent unwillingness by the medical staff to get involved in the various limitations imposed on Dr. Lo, met with the executive committee of the board of directors.¹⁶⁸ "[T]he committee authorized Friedman to summarily suspend plaintiff's clinical privilege to perform open heart surgery."¹⁶⁹ When Dr. Lo challenged this decision, the court held that if danger to patients is genuine and imminent, the hospital governing board has a duty to protect patients by summarily suspending the privilege of a physician where data shows that a mortality rate is well above the norm.¹⁷⁰

C. Transparency: Making Quality Information Available

Quality information and comparative data can be invaluable to both patients and payers as they evaluate care. Transparency is a virtue, one that creates a market for information that is properly presented. Providers could make quality a marketing and business tool by "[s]howcasing quality differences."¹⁷¹ Providers are confronted with varying regulatory forces that relate to medical errors and their discovery. Hospital report cards have had only modest success. Their goals to allow comparisons of quality of care across providers are admirable.¹⁷² Hospitals, however, when surveyed, say they must recoup their investment in safety in quality improvement.¹⁷³ It is important that both reimbursement and liability link to quality improvement to provide the financial motivation for rapid change.

The candidates for data reporting and public availability are many. One example is infection control report cards.¹⁷⁴ It may be that a graphic depiction of a hospital's progress over time is more useful than cross-institution

166. *Lo v. Provena Covenant Med. Ctr.*, 796 N.E.2d 607 (Ill. App. Ct. 2003).

167. *Id.* at 611.

168. *Id.* at 611-12.

169. *Id.* at 612.

170. *Id.* at 614.

171. Leatherman et al., *supra* note 96, at 25.

172. Martin N. Marshall et al., *The Public Release of Performance Data: What Do We Expect to Gain? A Review of the Evidence*, 283 JAMA 1866 (2000); see generally Eric C. Schneider & Arnold M. Epstein, *Use of Public Performance Reports: A Survey of Patients Undergoing Cardiac Surgery*, 279 JAMA 1638 (1998).

173. Ateev Mehrotra, Thomas Bodenheimer & R. Adams Dudley, *Employers' Efforts To Measure And Improve Hospital Quality: Determinants of Success*, HEALTH AFF., Mar./Apr. 2003, at 70.

174. See Robert A. Weinstein, Jane D. Siegel & P. J. Brennan, *Infection-Control Report Cards -- Securing Patient Safety*, 353 NEW ENG. J. MED. 225 (2005).

comparisons.¹⁷⁵ However, generating the reports in a graphic way so hospital providers can clearly see baselines and improvement is a goal worth mandating.

It is not easy to evaluate and compare institutions.¹⁷⁶ The goal of data transparency, however, may be valuable as much for internal learning and staff privileging decisions as for consumer and shopping, in the short term at least.¹⁷⁷

D. *Expectations: Warranting Zero Defects*

The high level of patient injury violates a patient's reasonable expectations of care within a health care system. It is not high quality care when the level of errors, some extremely destructive, is so high. One suggestion has been a regulatory approach that rewards institutional guarantees of safe health care, in order to motivate hospitals to provide high quality care. Brennan and Berwick propose a regulatory policy that requires providers to guarantee a safe level of care, with the accompanying promise of "prompt, easily claimed redress when that promise is broken."¹⁷⁸ The guarantees might encompass "timely access, information exchange, modernity of therapy, and outcomes that are well within the reach of all providers of care."¹⁷⁹ Codman's idea of the end result report foreshadowed this idea of a warranty to patients, and required a baseline to measure defects. Patterns of defects can be analyzed in order to design improvements.

Incentive bonuses could be provided for hospitals and physicians who can show progress in providing safe care, such as reducing the level of pneumonia,

175. *Id.* at 225

We have also learned that we must select denominators carefully in order to avoid artificial inflation or deflation of rates; that sophisticated information technology is required; and that it can be difficult to define useful benchmarks, especially for small hospitals, so that reporting a trend for a particular hospital may provide more useful information than does comparing hospitals.

176. Lisa I. Iezzoni, *The Risks of Risk Adjustment*, 278 JAMA 1600, 1600 (1997).

177. See Ashish K. Jha et al., *Care in U.S. Hospitals – The Hospital Quality Alliance Program*, 353 NEW ENG. J. MED. 265 (2005).

Our findings indicate that quality measures had only moderate predictive ability across the three conditions. Although a high quality of care for acute myocardial infarction predicted a high quality of care for congestive heart failure, the former was only marginally better than chance at identifying a high quality of care for pneumonia. These data do not provide support for the notion that "good" hospitals are easy to identify or consistent in their performance across conditions. Our data suggest that evaluations of hospitals' performance will most likely need to be based on a large number of conditions. *Id.* at 272.

178. BRENNAN & BERWICK, *supra* note 32. "Responsive regulation need not always specify the content of guarantees, but it can encourage a culture of ambition by ensuring that some guarantees exist and can be invoked easily when violated." *Id.* at 355.

179. *Id.* at 354.

surgical site infections, or central line infections to zero. There are rapidly growing lists of goals and practices that could be implemented if payment incentives were provided.¹⁸⁰ Improvement could be measured by comparing a patient outcome against a scale of measurement that accounts for the patient's preexisting conditions and other personal factors. Since patient care is tied directly to the treatment delivered, reducing plan profit and physician income for substandard care and providing financial incentives for good practice would be warranted. In an explicit outcome-based system, bonus payments are forthcoming only if patients improve.¹⁸¹

Negative financial consequences and disincentives for unsafe practices should also be provided. Hospitals would not be paid for serious preventable adverse events.¹⁸² Patients who suffer a medical mishap, whose period of recovery substantially exceeds a statistical norm, or who are outliers from a benchmark, will receive compensation through scheduled benefits, like the schedules developed for an accelerated-compensation events system. This system, which defines a set of injuries that are deemed to be avoidable under good medical care, is designed to promote good outcomes and reduce the level of iatrogenic injury.¹⁸³

E. Systems: Forcing Quality Assurance to the Front of the Line

Most medical errors can be prevented by applying systems thinking to the often fragmented and chaotic health care environment. As Wachter and Shojania write, “[m]ost errors are made by good but fallible people working in

180. See, e.g., Agency for Healthcare Research and Quality, Buy-Rights for HealthCare Quality: Evidence and Indicator (2004), <http://www.ahrq.gov/news/ulp/buyright/>.

181. The health accounting proposal of John Williamson requires that doctors and other professionals identify important areas of weakness in their programs, as judged by a perceived failure to achieve improvements in health status that the program should be capable of achieving. An acceptable level of health outcomes is then set for each problem selected and, after the lapse of a period of time, the degree of success in meeting the standards is determined. JOHN W. WILLIAMSON, *ASSESSING AND IMPROVING HEALTH CARE OUTCOMES: THE HEALTH ACCOUNTING APPROACH TO QUALITY ASSURANCE* (1978); John W. Williamson, H. Braswell & S. D. Horn, *Validity of Medical Staff Judgements in Establishing Quality Assurance Priorities*, 17 *MED. CARE* 331 (1979); John W. Williamson et al., *Priority Setting in Quality Assurance: Reliability of Staff Judgments in Medical Institutions*, 16 *MED. CARE* 931 (1978).

182. Both private and government payers would have to agree on the baseline for measuring adverse events. See, e.g., R. Kazel, *Minnesota Insurer Won't Pay Hospitals for "Never Events,"* *AM. MED. NEWS*, Nov. 8, 2004.

183. Andreas Laupacis and colleagues proposed a “yardstick” by which to assess measures of the consequences of treatment: “the reciprocal of the absolute risk reduction (i.e., the number of patients with a given disorder that a physician must treat in order to protect one of them from the disorder's potential consequences).” Andreas Laupacis, D. L. Sackett & R. S. Roberts, *An Assessment of Clinically Useful Measures of the Consequences of Treatment*, 318 *NEW ENG. J. MED.* 1728 (1988).

dysfunctional systems, which means that making care safer depends on buttressing the system to prevent or catch the inevitable lapses of mortals.¹⁸⁴ A robust safety system is hard to create, requiring a culture that values safety first and worries about it constantly.¹⁸⁵ The question is how to force hospitals and other providers to develop more integrated bureaucratic structures that involve physicians. Aligning payment with quality improvement, mandating the adoption of information technology systems, and developing performance measures are three of the central challenges of regulatory policy.¹⁸⁶

The current debate over medical errors has shifted critical discussion toward the healthcare delivery system, typically the hospital, and away from individual providers.¹⁸⁷ One problem with the current enthusiasm for systems fixes is that hospital organizational systems are highly resistant to change and linear fixes. Limiting the cost and liability is a proper regulatory consideration, but the goal of mandating collection and disclosure of errors is the primary one.

Teams in health care are increasingly recognized as a source of good delivery. In *Monzingo v. Pitt Cty. Mem'l. Hosp., Inc.*,¹⁸⁸ a case of on-call supervision of obstetrics residents at a teaching hospital, the court noted the role of teams:

The modern provision of medical care is a complex process becoming increasingly more complicated as medical technology advances. Large teaching hospitals . . . care for patients with teams of professionals, some of whom never actually come in contact with the treated patient but whose expertise is nevertheless vital to the treatment and recovery of patients.¹⁸⁹

Unlike the traditional personalized delivery of health care, where the patient seeks out and obtains the services of a particular physician, the institutional environment of large hospitals incorporates a myriad of complex and attenuated relationships. Here, the presenting patient enters a realm of full-service coordinated care in which technical agreements and affiliations proliferate the specialized functions and obligations of various allied health professionals.¹⁹⁰

A federal approach should include a set of expectations that hospitals will develop a team approach to a range of medical problems, mandating, for example, rapid response teams in emergency rooms as a way to improve

184. WACHTER & SHOJANIA, *supra* note 4, at 20-21.

185. KARL E. WEICK & KATHLEEN M. SUTCLIFFE, *MANAGING THE UNEXPECTED: ASSURING HIGH PERFORMANCE IN AN AGE OF COMPLEXITY* 127-29 (2001). They argue that a safety culture is an informed culture, where everyone is in a constant state of wariness.

186. Rushika Fernandopulle et al., *A Research Agenda For Bridging the 'Quality Chasm'*, *HEALTH AFF.*, Mar./Apr. 2003, at 187.

187. See CHARLES PERROW, *NORMAL ACCIDENTS: LIVING WITH HIGH-RISK TECHNOLOGIES* (1999); Neville Moray, *Error Reduction as a Systems Problem*, in *HUMAN ERROR IN MEDICINE* (Marilyn Sue Bogner ed., 1994).

188. *Monzingo v. Pitt Cty. Mem'l Hosp., Inc.*, 415 S.E.2d 341 (N.C. 1992).

189. *Id.* at 345.

190. *Monzingo*, 415 S.E. 2d at 345.

outcomes.¹⁹¹

Hospitals are not top-down hierarchical bureaucracies. Hospitals have been described as one of the most complex organizations possible, integrating hierarchal bureaucracy and informal professional decision-making under one roof.¹⁹² They are loosely coupled in several ways: the medical staff has authority independent of the hospital administration, nurses and other allied providers are employees of the hospital, and hospital pharmacies have often been poorly integrated into patient care. The process by which physicians and other providers learn—about new clinical findings, sources of error, and other technologies—is not a straightforward one.¹⁹³ One suggestion therefore has been to focus on teams within organizations and view them as “self-correcting performance units.”¹⁹⁴ Edmondson describes a “superb team” as one that has the ability to “perform as a seamless whole.”¹⁹⁵ Error rates vary across such units even within the same hospital.¹⁹⁶ In one drug complication study, unit error rates ranged from 2.3 to 23.7 errors per 1,000 patient days.¹⁹⁷ The study found that “a primary influence on detected error rates is unit members’ willingness to discuss mistakes openly.”¹⁹⁸ Edmondson writes that:

These perceptions influence willingness to report mistakes, and may contribute to a climate of fear or of openness that is likely to endure and further influence the ability to identify and discuss problems.¹⁹⁹

It is even more complicated than this. Errors in the operating room “have their roots in the backgrounds of the participants, the dynamics of the group, and the environment in which the activity occurs. To understand the causes of error,

191. Rinaldo Bellomo et al., *Prospective Controlled Trial of Effect of Medical Emergency Team on Postoperative Morbidity and Mortality Rates*, 32 CRITICAL CARE MED. 916 (2004).

192. See ODIN W. ANDERSON, *HEALTH SERVICES AS A GROWTH ENTERPRISE IN THE UNITED STATES SINCE 1875* 309 (2d ed., Health Admin. Press 1990).

193. See Martin Wood, Ewan Ferlie & Louise Fitzgerald, *Achieving Clinical Behavior Change: A Case of Becoming Indeterminate*, 47 J. SOC. SCI. & MED. 1729, 1729 (1998) (noting that transfer of evidence-based medical research is not linear and “may underestimate the impact of other confounding circumstances.”).

194. Amy C. Edmondson, *Learning From Mistakes is Easier Said Than Done: Group and Organizational Influences on the Detection and Correction of Human Error*, 40 J. APPLIED BEHAV. SCI. 66, 70 (2004) (surfacing of medical errors depends on the team leaders’ attitudes; the primary influence on detected errors in the health-care setting is the unit members’ willingness to discuss mistakes openly, and more accessible and open managers seem to elicit error disclosure at higher levels. More authoritarian leaders inhibit candid discussions and willingness of staff to reveal and discuss mistakes openly.) *Id.* at 86.

195. *Id.* at 70.

196. *Id.* at 72.

197. *Id.*

198. Edmondson, *supra* note 194, at 86.

199. *Id.* at 86.

it is necessary to consider the organizational, physical, and social context as well as the specific behavior.”²⁰⁰

Factors that foster the making of errors in the health care setting are most likely different from factors that foster detecting, correcting, discussing and learning from errors. The leader of teams and units within hospitals have a critical role in error reduction.²⁰¹ Edmondson observes that “willingness to report errors varies systematically with perceived openness of unit leaders, and we can speculate that these attributes may overwhelm differences in actual error rates.”²⁰²

The language of Continuous Quality Improvement and Total Quality Management²⁰³ of business management and the new JCAHO rules on hospitals suggest that the good aspects of the industrial model can be applied to hospitals as systems. The problem with healthcare delivery is not just that patient care is complicated, even though that is a truism, but rather that institutional inertia seizes hospitals as they struggle for revenue in tough healthcare markets, and this makes change difficult. A range of safety technologies is available, however, that can reduce errors, and that should become the standard of care for practice in all institutions. Bar coding, for example, will reduce levels of drug prescribing errors by nurses. Physicians make the most mistakes with drug orders, accounting for thirty-nine percent of all adverse drug events traceable to incorrect orders.²⁰⁴ Half are caught, however, and corrected by nurses and pharmacists.²⁰⁵ Nurses contribute to thirty-eight percent of all drug errors, but only two percent are caught, since there are fewer checkpoints between nurses and patients.²⁰⁶ Bar coding is a way to reduce nursing errors.²⁰⁷ One VA hospital documented a twenty-four percent decrease in the rate of medication-administration errors after implementing bar coding.²⁰⁸ Yet only five percent of U.S. hospitals currently use bar coding, in spite of studies that found more than a fifty percent reduction in drug errors.²⁰⁹ Why doesn't Medicare or JCAHO mandate bar coding as a condition of participation?

200. Robert L. Helmreich & Hans-Gerhard Schaefer, *Team Performance in the Operating Room*, in HUMAN ERROR IN MEDICINE 226 (Marilyn Sue Bogner ed., 1994).

201. Amy C. Edmondson, Richard M. Bohmer & Gary P. Pisano, *Disrupted Routines: Team Learning and New Technology Implementation in Hospitals*, 46 ADMIN SCI. Q. 685 (2001) (importance of team leaders in the successful implementation of new medical technologies).

202. Edmondson, *supra* note 194, at 86.

203. See Timothy Stoltzfus Jost, *Oversight of the Quality of Medical Care: Regulation, Management, or the Market?*, 37 ARIZ. L. REV. 825, 838-39 (1995).

204. Alexi A. Wright & Ingrid T. Katz, *Bar Coding for Patient Safety*, 353 NEW ENG. J. MED. 329, 330 (2005).

205. *Id.*

206. Wright & Katz, *supra* note 204, at 330.

207. *Id.*

208. *Id.* at 330.

209. Wright & Katz, *supra* note 204, at 330.

Computerized physician order entry (“CPOE”) is another new system device with potential for reducing prescription errors, as well as costs.²¹⁰ Like other new technologies that are powerful, it can create its own errors and must be monitored as part of ongoing system reviews.²¹¹ Nonetheless, its potential for error reduction is great enough to justify the requirement that CPOE systems be standardized and installed in all hospitals.

Linking good and bad outcomes to reimbursement is a logical extension of payment system reform, and Medicare has already begun modest initiatives in this direction. Enterprise liability, which imposes on healthcare institutions a centralized responsibility for bad outcomes, is a logical outgrowth of the emergence of corporate negligence and the vicarious liability doctrine.²¹² Some form of experience rating combined with incentive payments has never been systematically applied to medical practice, although it would establish a meaningful link between outcomes and the individual providers.²¹³

V. CONCLUSION

It has been too easy to excuse regulatory inertia in health care—the problem is multi-faceted, providers are full of excuses, and clinical studies about what works in medicine are constantly amending the previous standard of care. Unfortunately, the status quo has not proved to be effective in improving patient safety. The federal effort, while praiseworthy for its earnestness, has been slow, overly reliant on private bodies like JCAHO, and focused more on protecting providers from the consequences of error disclosure than really demanding change. It is time for a tougher federal regulatory approach.

My use of the acronym BITES is intended to convey the need for increasing the intensity of federal action to reduce medical errors. Reporting of all medical outcomes and patient errors needs to be mandated, collected, and tracked, as Codman suggested decades ago. A regulatory system can demand that hospitals and other providers aspire to zero defects and promise patients a level of care that meets standards of general acceptability. Reimbursement, using data as to

210. Ross Koppel et al., *Role of Computerized Physician Order Entry Systems in Facilitating Medication Errors*, 293 JAMA 1197 (2005).

211. *Id.* at 1202.

212. One of the interesting early proposals, Medical Adversity Insurance, used the hospital as the basis for the compensation scheme for malpractice reform, since the authors observed that it was the best central authority to manage such a system. See C. C. Havighurst & L. R. Tancredi, “*Medical Adversity Insurance*” - *A No-Fault Approach to Medical Malpractice and Quality Assurance*, 51 MILBANK MEM’L FUND Q.: HEALTH & SOC. 125 (1973).

213. Frank A. Sloan, *Experience Rating: Does It Make Sense for Medical Malpractice Insurance?*, 80 AM. ECON. REV. 128 (1990). “‘Experience rating’ refers to a variety of plans that base future premiums on past claims or loss experience of insureds.” *Id.* at 128.

performance, can increasingly reflect performance improvements of providers against their own baselines, as well as comparatively against other providers. And patients can be assured that if something goes wrong, they will be treated with respect—compensated fairly, and promised that the system will learn from their injury.