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Patient Safety, Risk Reduction, and the Law

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ARTICLE

PATIENT SAFETY, RISK REDUCTION, AND THE LAW

*Larry I. Palmer**

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"When you go into a hospital, you should be safer than when you step onto an airplane."¹

I. INTRODUCTION

David Lawrence is not the first member of the medical establishment to compare the risks of being a patient in a hospital to the risks of being a passenger on an airplane flight.² The chief operating officer of the Veterans Administration's vast health care system recently made similar public statements.³ In

1. Tom Abate, *Kaiser CEO Warns About Drug Errors*, S.F. CHRON., June 30, 1999, at B1 (quoting David Lawrence, CEO, Kaiser Permanente). David Lawrence's comments in his speech to biotechnology industry executives were repeated the next month at a National Press Club Newsmaker Luncheon, where he was quoted as saying, "[O]ne can conclude that the third-leading cause of death in the United States are [sic] fatal accidents that result from [medical errors]. These accidents are responsible for over 400,000 deaths each year, more than tobacco, stroke, diet, alcohol, drugs, firearms or automobile accidents . . ." *National Press Club Newsmaker Luncheon with Dr. David Lawrence, CEO, Kaiser Permanente*, FED. NEWS SERVICE, July 14, 1999, available in LEXIS, News Library, Transcripts File.

2. At a hearing addressing Veterans Administration medical care, Lucian Leape of the Harvard School of Public Health asked, "Why is it that when you enter a hospital, your chances of dying from an accident are 1 in 200, but when you climb on an airplane, your chances of dying in an accident are 1 in two million[?]" *VA Medical Care: Hearing of the Health Subcomm. of the House Veterans' Affairs Comm.*, 105th Cong. (1997) (statement of Lucian Leape, Harvard School of Public Health) [hereinafter *Hearing*, statement of Lucian Leape], available in LEXIS, News Library, Transcripts File (discussing the VA's efforts to prevent patient injury).

3. In 1997, Kenneth W. Kizer, then Under Secretary for Health, Department of Veterans' Affairs, in testimony before Congress spoke of systems redesign as a means of increasing patient safety. See *Prepared Statement of Kenneth W. Kizer, M.D., M.P.H., Under Secretary for Health, Dep't of Veterans' Affairs Before the House Veterans' Affairs Comm. Health Subcomm. on VA's Risk Management Policies*, FED. NEWS SERVICE, Oct. 8, 1997, available in LEXIS, News Library, Transcripts File (describing the VA's new error prevention systems, including the creation of a Risk Management Oversight Committee and increased evaluative functions of the existing Office of the Medical Inspector). On May 14, 1999, Leape; Kizer; Robert Simon, Ed.D., C.P.E., Chief Scientist, Crew Performance Group, Dynamics Research Corporation; and Senator Bill Frist (R-Tenn.) participated in a discussion of the National Health Policy Forum, which addressed opportunities for a systems-based approach to error reduction and considered how the aviation approach of "restructuring the delivery environment and retraining" might be applied to improve patient safety. See *Reducing Medical Error: Can You Be as Safe in a Hospital as You Are in a Jet?*, NAT'L HEALTH POL'Y F., May 14, 1999, at 2.

1998, a Presidential Commission suggested that the Federal Aviation Safety Reporting System⁴ was a possible model for developing a “blame-free system of error reporting” that would identify and help prevent the reoccurrence of errors in the health care system.⁵ With this new emphasis on preventing patient injury and the metaphor of “safe” airline travel has come a new way of conceptualizing the causes of patient injury: “systems errors” and “systems thinking.”

The “systems” approach to patient injury grew out of a seminal multidisciplinary study of malpractice in New York State in the 1980s,⁶ when “no fault” was thought to be one possible solution to the “malpractice crisis.”⁷ The most significant

4. The Aviation Safety Reporting System (ASRS) is an “incident reporting program designed to identify issues and hazards existing or emerging in the national aviation system . . . [and] is administered by the National Aeronautics and Space Administration (NASA) for the Federal Aviation Administration (FAA) under a management and funding agreement initiated in 1975.” *FAA Wake Vortex Regulations: Hearings Before Subcomm. on Technology, Environment and Aviation of the House Comm. on Science, Technology and Space*, 103d Cong. (1994) (statement of William Reynard, Director, Aviation Safety Reporting System), available in 1994 WL 14190976. The reports are analyzed by a contractor, Battelle Memorial Institute, which is a research institution that employs retired aviation professionals. *See id.*

5. *See* THE PRESIDENT’S ADVISORY COMM’N ON CONSUMER PROTECTION AND QUALITY IN THE HEALTH CARE INDUSTRY, QUALITY FIRST: BETTER HEALTH CARE FOR ALL AMERICANS, FINAL REP. TO THE PRESIDENT OF THE UNITED STATES 155 (1998) [hereinafter PRESIDENT’S COMM’N REP.] (calling for a national effort by federal, state, and local governments, health care professionals and workers, employers, health plans, consumers, unions, and others to improve and sustain the quality of health care in the United States).

6. *See* HARVARD MED. PRAC. STUDY, PATIENTS, DOCTORS, AND LAWYERS: MEDICAL INJURY, MALPRACTICE LITIG. AND PATIENT COMPENSATION IN NEW YORK (1990) (providing empirical data under contract for the State of New York in order to inform the debate surrounding the malpractice liability system). The study had four main components: a measure of the incidence of injuries resulting from medical intervention, an estimate of the number of claims borne of such injury, a calculation of the costs suffered by injured victims, and an estimate of the extent to which a threat of litigation affected patient injury. *See id.* at 1-2; *see also* Troyen A. Brennan et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I*, 324 NEW ENG. J. MED. 370, 383 (1991); Lucian L. Leape et al., *The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II*, 324 NEW ENG. J. MED. 377, 377, 383 (1991) [hereinafter Leape et al., *The Nature of Adverse Events*].

7. *See, e.g.*, Larry M. Pollack, *Medical Maloccurrence Insurance (MMI): A First-Party, No-Fault Insurance Proposal for Resolving the Medical Malpractice Controversy*, 23 TORTS & INS. L.J. 552, 552-53 (1988) (proposing a “patient-derived (first-party) ‘no-fault’ insurance system to compensate victims of iatrogenic maloccurrence, regardless of negligence,” that would require patients to buy an insurance policy for a particular course of treatment or operation and under which the patient would be covered for any treatment-related adverse medical outcome regardless of negligence or fault on the part of the health care providers); *see also, e.g.*, Randall R. Bovbjerg & Frank A. Sloan, *No-Fault for Medical Injury: Theory and Evidence*, 67 U. CIN. L. REV. 53, 56, 82-113 (1998) (reporting on “no fault” as “a

finding of that study was that patient injuries deemed by health care professionals to be caused by substandard care resulted in almost no malpractice litigation.⁸ With special legislation authorizing the study,⁹ the researchers were able to examine the records of patients in nonpsychiatric hospitals in the entire state of New York.¹⁰ Based upon “chart reviews” performed by nurses, medical-records analysts, and physicians, the researchers were able to estimate the medical error rate among hospitalized patients.¹¹ The principal investigator of the study, Lucian Leape of the Harvard Public Health School, has become the leading spokesman for the patient safety movement in the media,¹² professional journals,¹³ and other public forums.¹⁴ Leape testified

leading alternative to today’s liability systems for resolving medically caused injuries” and discussing the Virginia and Florida no-fault legislation enacted in the late 1980s for medical injuries).

8. See A. Russell Localio et al., *Relation Between Malpractice Claims and Adverse Events Due to Negligence: Results of the Harvard Medical Practice Study III*, 325 NEW ENG. J. MED. 245, 247 (1991) (reporting that the probability that injuries caused by medical negligence would lead to litigation was only 1.53%).

9. See Act of July 8, 1986, ch. 266, 1986 N.Y. Laws 2021, 2046.

10. See Brennan et al., *supra* note 6, at 370.

11. See *id.* at 370, 372.

12. See, e.g., Sandra G. Boodman, *Diagnosing Medical Errors*, WASH. POST., Nov. 19, 1996 (Health Magazine), at 12 (quoting Leape and referring to him as a “nationally respected expert on the problems of medical errors”); Richard A. Knox, ‘Collegial’ Monitoring of Hospitals Hit, BOSTON GLOBE, July 21, 1999, at A1, available in LEXIS, News Library, Bglobe File (quoting Leape and referring to him as “perhaps the most prominent advocate nationally of a non-punitive approach to quality improvement”); Patricia Neighmond, *Sounds Like Science: Study Shows Drug Errors in Hospitals Could Be Drastically Reduced If Pharmacists Were Made Part of Medical Teams* (National Public Radio broadcast, July 24, 1999), available in LEXIS, Nexis Library, Newsgroup File (discussing a study conducted by Leape, “a longtime analyst of medical mistakes,” in which he concluded that adding a pharmacist to a hospital medical team resulted in a two-thirds drop in prescription error).

13. See, e.g., Lucian L. Leape, *Error in Medicine*, 272 JAMA 1851, 1852 (1994) [hereinafter Leape, *Error in Medicine*] (stating that “if physicians, nurses, pharmacists, and administrators are to succeed in reducing errors in hospital care, they will need to fundamentally change the way they think about errors and why they occur”); Lucian L. Leape et al., *Promoting Patient Safety by Preventing Medical Error*, 280 JAMA 1444, 1445, 1447 (1998) (critiquing error analysis, presenting four examples of current efforts to promote patient safety, and calling for the conversion of a “culture of blame that hides information about risk and error into a culture of safety that flushes information out and enables us to prevent or quickly recover from mistakes before they become patient injury”).

14. See, e.g., *Hearing*, statement of Lucian Leape, *supra* note 2 (presenting his error-reduction methodology and evaluating the VA’s new risk management policy); see also Peter Mayberry, *Medication Errors: Is Unit-Dose Packaging the Solution?*, PHARMACEUTICAL & MED. PACKAGING NEWS MAG. (Feb. 1998) <<http://www.devicelink.com/pmpn/archive/98/02/003.html>> (reporting that Leape testified at a public hearing of the Federal Drug Administration on the issue of medication error and the roles of government and industry in solving the problem).

before the recent President's Commission on Consumer Quality, and the Commission's Final Report cited his work as evidence of "unacceptably high error rates" in health care.¹⁵ Within the last decade, "patient safety" has truly come of age.¹⁶

This Article does not propose to argue that the medical liability system, criminal prosecution of health care professionals, or even disciplinary actions against professionals will in fact make health care safer. This Article suggests that there is no evidence to prove that the mere threat of civil or criminal liability or disciplinary action is the key vector inhibiting new approaches to injury prevention under the rubric of "systems thinking." There is in fact a disconnect between the new rhetoric of systems thinking about medical error and legal scholarship on the health care system that remains preoccupied with the issue of medical liability.

To develop a new framework for the role of law in enhancing patient safety, this Article proposes a different paradigm than the liability model. An examination of how law interacts with public health should be the starting point for framing the legal analysis of patient safety.¹⁷ This framing of the issues

15. See PRESIDENT'S COMM'N REP., *supra* note 5, at 23.

16. In late November 1999, the Institute of Medicine issued its report on medical error. See COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, INSTITUTE OF MEDICINE, *To Err Is Human: Building a Safer Health System* (Linda Kohn et al. eds., National Academy Press, Advance Copy, Nov. 1999) [hereinafter *To Err Is Human*]. Lucian Leape and David Lawrence were both members of the committee issuing the report. See *id.* at iii. Not surprisingly, aviation safety was viewed as the standard. See *id.* at 4. On December 7, 1999, President Clinton asked the Quality Interagency Coordination Task Force to develop recommendations regarding patient safety within sixty days. See Memorandum on Improving Health Care Quality and Ensuring Patient Safety, 35 WEEKLY COMP. PRES. DOC. 2530-31 (Dec. 7, 1999), available at <<http://frwebgate5.access.gpo.gov>>. Several members of Congress have already introduced bills to promote patient safety. See Marilyn Webber Serafini, *To Err Is . . . Reason for a New Law*, 32 NAT'L J. 45 (Jan. 1, 2000), available at <<http://web.lexis-nexis.com/congcomp>>.

17. Donald A. Schön has written extensively about the general problem of how professionals and policy makers frame issues. See generally DONALD A. SCHÖN, *THE REFLECTIVE PRACTITIONER: HOW PROFESSIONALS THINK IN ACTION* (1983) [hereinafter SCHÖN, *REFLECTIVE PRACTITIONER*] (suggesting that professionals know more about their practice than they are at times able to articulate and analyzing and systematizing these intuitive acts with the goal of promoting a "reflective practice"); DONALD A. SCHÖN & MARTIN REIN, *FRAME REFLECTION: TOWARD THE RESOLUTION OF INTRACTABLE POLICY CONTROVERSIES* (1994) (challenging the prevailing notion that contemplative, reflective thinking is out of place in the "common sense" arena of policy making and advocating "design rationality," a rational approach to concrete problems that includes "higher-level" reflection). For an application of a Schön-like analysis to a problem of law and medicine, see Joseph J. Fins & Matthew D. Bacchetta, *Framing the Physician-Assisted Suicide and Voluntary Active Euthanasia Debate: The Role of Deontology, Consequentialism, and Clinical Pragmatism*, 43 J. AM. GERIATRIC SOC'Y 563, 563

acknowledges that the liability model may have a role to play in error reduction, but that this role should be determined by more empirical study of the law and legal institutions as part of the overall emerging system of patient safety.

In proposing a new framework for the legal debate of patient safety, this Article does not offer a single solution to the patient safety problem. Hidden behind any proposed solution is a host of questions that have not yet been answered: What is "patient safety"? What is "systems thinking" about patient injury? And most important, what role, if any, do legal institutions need to play in promoting systemic approaches to injury prevention within health care organizations?

Part II of this Article defines the concepts or constructs that frame the debate: patient safety, systems thinking, medical liability, and public health law. Part III explores "comparative institutional analysis"¹⁸ and proposes that systems thinking about injury prevention creates new kinds of professional knowledge. Surprisingly, this type of knowledge is embedded in organizations, not individuals, as assumed by the model of professional liability for patient injury.¹⁹ Part IV uses the dual lens of public health law and comparative institutional analysis to resolve problems in regulation, disciplinary procedures, criminal prosecution, and conducting research on patient safety under existing legal structures. Until systems thinking about preventing patient injury is widespread throughout both the legal and health care systems, it will be important to think of

(1995).

18. See NEIL K. KOMESAR, *IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY* 3 (1994) (elucidating the concept of "comparative institutional analysis," which refers to the way that decision making authority is allocated to and among complex institutional processes, such as the political process, the market process, and the adjudicative process, and analyzing the choice among these alternatives). For examples of applications of comparative institutional analysis to problems in law and medicine, see Larry I. Palmer, *Institutional Analysis and Physicians' Rights After Vacco v. Quill*, 7 CORNELL J.L. & PUB. POL'Y 415, 415, 418 (1998) (proposing that the arguments in *Vacco v. Quill*, in which the Court allowed the criminal prosecution of physicians for assisting patient suicides, can be read through the lens of comparative institutional analysis and, specifically, "an analysis of two basic social institutions: law and medicine"). For a more explicit positivist approach to institutional analysis in law, see Neil MacCormick, *Institutions and Laws Again*, 77 TEX. L. REV. 1429, 1429 (1999).

19. See, e.g., Bryan A. Liang, *Patient Injury Incentives in Law*, 17 YALE L. & POL'Y REV. 1, 5 (1998) (providing an "overview of the common law of tort and contract and the statutory regime that have together created incentives for MCOs [managed care organizations] to minimize care while exposing physicians to, on the one hand, patient injury liability and, on the other, unfettered termination power in the hands of the MCO"); E. Haavi Morreim, *Playing Doctor: Corporate Medical Practice and Medical Malpractice*, 32 U. MICH. J.L. REFORM (forthcoming 2000).

ways of reducing the legal risks to nurses and other health care professionals who are still “blamed” by legal actors for what scholars label “systems errors.”

To discover the appropriate role of law in the prevention of medical errors, this Article concludes that legal scholars must learn to pose empirical questions about how various institutions interact with the health care system. Some of these questions will involve issues related to the medical liability system, but the proposed interdisciplinary research will be informed by a public health law perspective and will necessitate new methodologies.

II. PATIENT SAFETY AND SYSTEMS THINKING

“Patient safety” and “systems thinking” are terms used by reformers to change health care delivery and the legal and regulatory structure surrounding health care. Reformers are motivated by visions that are often embedded in stories, rather than by the crisp categorical definitions of relatively stable legal or scientific constructs.²⁰ The following Martin Memorial Hospital case²¹ serves as a glimpse of such visions.

In December 1995, Ben Kolb’s parents took him to Martin Memorial Hospital for a routine surgical procedure.²² His heart stopped during the procedure, and he died twenty-four hours later.²³ Less than one month after his death, Ben’s family reached a monetary settlement with the hospital and its insurance

20. See, e.g., Lawrence M. O’Rourke & Tom Hamburger, “Government by Anecdote”: *In Managed-Care Debate*, MINN. STAR TRIB., July 2, 1999, at A12 (reporting that to push through their managed health care legislation in Congress, Democrats are “telling horror stories about ordinary people hurt by the decisions of their health insurance plans,” including a story about a woman who fell off a cliff, was knocked unconscious, and was taken by helicopter to a hospital emergency room where she was turned away because she had not called in advance to ensure that her HMO would pay the bill).

21. This story was widely reported in the media at the time. See, e.g., Lisa Belkin, *How Can We Save the Next Victim?*, N.Y. TIMES, June 15, 1997, § 6 (Magazine), at 28; Boodman, *supra* note 12, at 12. This story was also told by the hospital through its Director of Corporate Risk Management. See Doni Haas, *In Memory of Ben*, RISK MGMT. REP., Dec. 1998, at 1, 1.

22. See Haas, *supra* note 21, at 1 (noting that Ben needed some scar tissue removed from his ear); see also Belkin, *supra* note 21, at 28 (relating that this was Ben’s third surgery on his ear).

23. Moments after what was thought to be a local anesthetic had been injected inside and behind Ben’s ear, his heart rate and blood pressure increased alarmingly. See Belkin, *supra* note 21, at 28. He was stabilized, but shortly thereafter his heart rate and blood pressure dropped abruptly. See *id.* Doctors performed CPR on him for an hour and forty minutes. See *id.* Subsequently his heart began to beat again with the aid of a pacemaker. See Haas, *supra* note 21, at 2. Ben was in a coma for approximately 24 hours, after which time it was agreed that Ben was brain dead and the ventilator should be removed. See Belkin, *supra* note 21, at 28.

carrier.²⁴ What was unusual about this case was that the hospital's risk manager did not accept as the cause of death the coroner's preliminary assessment of idiosyncratic reaction to the anesthesia.²⁵ Rather, the risk manager conducted a thorough investigation, which revealed that Ben had been injected with the wrong drug after a mix-up of two different drugs in the operating room.²⁶ After those findings were confirmed by two independent laboratories,²⁷ the hospital's risk manager, accompanied by the anesthesiologist present at Ben's surgery, shared the results with the family and its lawyer.²⁸

Although the amount of the compensation paid to Ben's family is confidential,²⁹ the anesthesiologist, the hospital's lawyer, the insurance company's representative, the hospital's risk manager, and the family's lawyer have all publicly described their collaborative process as aimed at making Martin Memorial Hospital a safer place while dealing fairly with this tragic accident.³⁰ The candid and quick disclosure of the results of the error in this particular hospital's method of handling drugs led to a surprising outcome. The parents were able to question their son's caregivers and felt comfortable continuing to use Martin Memorial Hospital for health care services.³¹

24. See Belkin, *supra* note 21, at 28.

25. See Boodman, *supra* note 12, at 12 (noting that the coroner found this type of reaction to be "extremely rare").

26. Knowing that Ben's reaction occurred immediately after the injection of lidocaine with epinephrine, hospital staff secured the two syringes, a partially filled vial of the drug solution, and an empty vial of adrenaline. See Haas, *supra* note 21, at 3. The risk manager asserted that all syringes and vials were maintained and blood samples were kept in case additional testing was necessary. See *id.* She later held several meetings and the possibility of a mix-up of the two drugs was explored. See *id.* at 4. The risk manager was eventually able to reconstruct how the drugs left the pharmacy and were tracked through every step of the process. See *id.*

27. Tests were performed at the University of Georgia and at National Medical Services in Willow Grove, Pennsylvania, using different testing techniques. See Haas, *supra* note 21, at 3-5. Both labs found that the syringe contained a topical adrenaline instead of an anesthetic. See *id.*

28. See *id.* at 6.

29. See Boodman, *supra* note 12, at 12 (stating that the parties agreed to keep the amount of the settlement secret, but that the payment exceeded \$250,000, Florida's statutory maximum for noneconomic damages).

30. For example, in October 1996, a panel discussion of the Martin Memorial Hospital case was the centerpiece of the discussions at a conference addressing ways to reduce medical errors, which was organized by the American Medical Association, the Joint Commission on Accreditation of Healthcare Organizations, and others. See Doug Levy, *Helping Hospitals Learn from Tragic Mistakes*, USA TODAY, Nov. 5, 1996, at 6D. For a thorough recounting of her personal role as the chief investigator of this incident, see Haas, *supra* note 21.

31. See Belkin, *supra* note 21, at 28 (commenting that the risk manager was "grateful and amazed" at the parents' reaction).

More important, the hospital acknowledged not only to the family, but also to its professional peers, that it had changed its methods of handling drugs.³² Interestingly enough, no professional was disciplined or sued.³³ In the lingo of the current reform movement, the death of Ben Kolb was the result of a “latent system” failure in the way drugs were labeled, distributed, and handled in the hospital.³⁴ From this very inspiring story of professionals working together, it is apparent that for reformers, systems thinking means conceptualizing the “mistake” in terms of the interaction of all the human actors and the technology from the point at which both drugs were delivered to the hospital pharmacy to the fatal injection of the wrong drug.³⁵

Patient safety means developing processes, such as eliminating one of the steps in the drug delivery procedure, in order to decrease the likelihood that the same mistake will be made in the future.³⁵ Not mentioned by the reformers but implicit in the outcome is the willingness of a health care organization, namely Martin Memorial Hospital, to pay enough compensation to satisfy the family and pay their attorney’s fees so that no lawsuits were filed against any of the individual professionals arguably involved. The Martin Memorial Hospital case arrives at

32. See Haas, *supra* note 21, at 5 (revealing that the hospital was no longer using intermediate containers, which allowed the opportunity for the wrong drug to be drawn into an end-use container, but that the hospital now uses a filter straw, which allows for transfer of the drug directly from the vial to the end-use container); see also Boodman, *supra* note 12, at 12 (reporting other changes in drug-handling procedures, including that drugs are now transferred one at a time, two nurses must observe the transfer and verify the contents, topical adrenaline is never drawn into a syringe, and no vials can be discarded until surgery is over and the patient is stable).

33. See Boodman, *supra* note 12, at 12 (noting that the nurses involved in Ben’s death are still working at the hospital and that all had unblemished records).

34. In a statement made at the October 1996 conference on ways to reduce medical errors, the Kolb family’s lawyers indicated that they were exploring a products liability claim against the manufacturers despite the settlement with the hospital: “In representing this family, we try to make a difference. From a products liability standpoint, even though our investigation is in its infancy, we have developed some theories that we think together will make a change in the way the medications commonly used together, are packaged and sold.” Statement of the Law firm of Krupnick, Campbell, Malone, Roselli, Buser, Slama & Hancock (on file with the author and the *Houston Law Review*).

35. See, e.g., Leape, *Error in Medicine*, *supra* note 13, at 1854 (stating that “responsible individuals at each stage [must] think through the consequences of their decisions and . . . reason back from discovered deficiencies to redesign and reorganize the process”).

36. See *id.* (reasoning that to create a safe process requires attention to methods of error reduction at each stage of system development); see also Belkin, *supra* note 21, at 28 (discussing the flawed procedure in the Martin Memorial Hospital case and stating that “[t]he elimination of one step eliminates one opportunity for the human factor to get in the way”).

a kind of contractual no-fault³⁷ solution by which the family of an injured patient is adequately compensated, no individual health care professional is sued, and the health care organization takes systemic steps within its organization to prevent similar accidents and shares its “learning” with other health care providers. However, legal scholarship is not built upon visions, so systems thinking and patient safety could mean numerous things to lawyers, and this engenders the problem of definitions.

A. *Patient Safety, Medical Error, and Prevention of Injury*

Patient safety advocates and tort reform theorists have their respective notions of safety, as well as related notions of medical error and prevention of injury. Patient safety advocates’ definitions emphasize the processes of health care: patient safety is “the avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of healthcare.”³⁸ The adverse outcomes or injuries include “errors,” “deviations,” and “accidents.”³⁹

Modern tort theorists, on the other hand, have an explicit concern with the “safety” of the health system, but aim their analyses at the legal system’s response to actual adverse patient outcomes. Starting with the seminal works of law-and-economics scholars such as Guido Calabresi and Richard Posner, most modern tort theorists acknowledge that there is a connection between safety—prevention of future injuries—and other goals, such as the compensation of injured patients.⁴⁰ Within this tradition of legal reformist scholarship, patient safety is defined in terms of the costs and benefits of preventing the injury, presumably in some general or systemic sense.⁴¹ The liability system only deals with those medical errors that result in injury *and* are the subject of lawsuits or the threat of lawsuits. The hope of this modern analysis is that a

37. Refer to *supra* note 7 (discussing the no-fault system for compensating victims of medically caused injuries).

38. National Patient Safety Foundation at the American Medical Association, *Agenda for Research and Development in Patient Safety* (last modified May 24, 1999) <<http://www.ama-assn.org/med-sci.npsf/research/research.htm>>.

39. *See id.*

40. *See* KOMESAR, *supra* note 18, at 154 (discussing Judge Calabresi’s work, which has recognized that there is a “trade-off between the costs of unprevented harm and the costs of preventing that harm”). Judge Posner expanded upon Judge Calabresi’s ideas, arguing that “the logic of negligence law could be found in resource allocation efficiency and economic analysis.” *See id.* at 155.

41. *See, e.g., id.* at 155 (discussing safety in terms of the famous Judge Learned Hand formula, which defines negligence in terms of costs and benefits of prevention: if the burden of taking the safety step is greater than the probability of mishap multiplied by the loss if the mishap occurs ($B < p \times L$), then there is negligence).

“rational” response to patient injury will influence health care providers to develop “safer” practices.

The apparent conflict between the tort theorists’ and the advocates’ definitions of safety is resolved by one of the critics of the law-and-economics approach to tort reform. Neil Komesar notes that tort reformers focus solely on the process of adjudication—the liability model—and its many limitations.⁴² Discovery of a limitation in the liability model—for instance, that it does not adequately deter future injury—leads tort reformers to suggest modifications of judicial liability doctrines or legislative modification of liability systems, such as statutory limits on the amount of damages that can be recovered or even no-fault patient compensation.⁴³ Tort reformers fail to consider that legislative tinkering with the liability system will necessarily create another imperfect solution to the patient safety problem. For Komesar, the important issue is to try to determine which legal or nonlegal institutions achieve the socially optimal level of patient safety and health care.⁴⁴ He posits that resolving that issue requires a comparison of the strengths and weaknesses of imperfect institutional processes of enhancing safety in the health care system:

Safety is a goal choice; tort liability is a law or public policy choice. No goal choice standing on its own dictates law or public policy choices. The goal of safety is consistent with a wide variety of law and public policy choices. . . . Put in institutional terms, depending on the setting, optimal safety might be achieved by tort liability through the adjudicative process, by regulation through the political process, or by transactions through the market process. The link between goals and law and public policy results is institutional choice.⁴⁵

Komesar’s insight allows for acceptance of the social goal of patient safety as envisioned by the Martin Memorial Hospital case, while bearing in mind the problem of determining the appropriate institutional arrangement for optimizing safety within health care.

42. *See id.* at 154-56.

43. *See* PAUL C. WEILER, *MEDICAL MALPRACTICE ON TRIAL* 31-32, 70-92, 132-58 (1991) (exploring the prevention impact of malpractice litigation as well as discussing statutory limits on damages and detailing and endorsing no-fault patient compensation).

44. *See* KOMESAR, *supra* note 18, at 6, 153-55 (discussing the application of his general research question of whether “the market is better or worse than its available alternatives or the political process is better or worse” to safety issues).

45. *Id.* at 155.

Distinguishing patient safety as a social goal from the choice of a legal or nonlegal strategy to achieve that goal clarifies the definitional issues in the term "medical error." Lucian Leape uses medical error to refer to a broad category of phenomena.⁴⁶ At one level, the term clearly encompasses those events that lead to patient injury, as in the Martin Memorial Hospital case.⁴⁷ But it also includes routine, nonconsequential errors: Leape and his colleagues use medical error to mean those mishaps or deviations from proper practice that do not result in substantial harm, let alone a lawsuit.⁴⁸ For example, a physician writes a prescription for a one-percent solution of a drug, but the pharmacist misreads the physician's handwriting and prepares a ten-percent solution. The nurse who is to administer the medication notices the unusually high concentration and brings her concern to the attention of the prescribing physician. The prescribing physician then corrects the dosage. Under prevailing practices in most health care organizations in this country, there is no formal reporting of this "near miss." However, to the safety prevention researcher this would be important data to collect in order to reduce or prevent the number of drug medication "errors" in hospitals and nursing homes.⁴⁹

Responding to the near miss might be thought of as an aspect of quality improvement,⁵⁰ but to confuse the safety problem in medicine with the current debate on improving quality in health care ignores the dynamic potential of the public safety advocates. To paraphrase Justice Stewart's famous observation about obscenity,⁵¹ we do not know what patient safety is because we do not yet have a method to translate information about reported patient injuries into meaningful strategies for detecting near misses and deviations from safe protocols that do not result in patient injury. The airline

46. See Leape, *Error in Medicine*, *supra* note 13, at 1853-57 (describing errors committed because of skill level, misperception, lack of knowledge, system design, poor maintenance, and inadequate management).

47. See *id.* at 1851-52.

48. See *id.* at 1851 (stating that "most errors do no harm" because the error is intercepted or the patient's natural defenses prevent injury).

49. See *id.* (advocating a national error-reporting system that would include near misses as a way to improve health care safety).

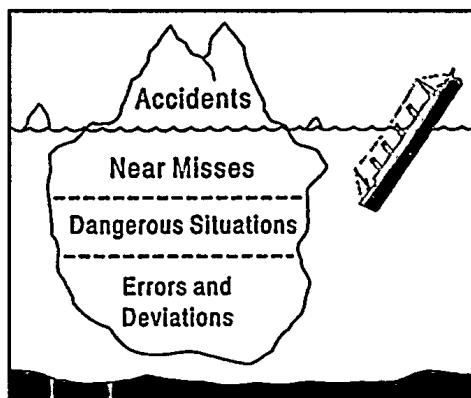
50. See PRESIDENT'S COMM'N REP., *supra* note 5, at 155-59 (calling for the establishment of an error-reporting system modeled in part on the Aviation Safety Reporting System). "A system of continuous quality improvement committed to preventing [medical] errors and correcting them when they do occur is a vital step in improving the quality of care in the United States." *Id.* at 156. Refer to note 16 *supra*.

51. "I know it when I see it." *Jacobellis v. Ohio*, 378 U.S. 184, 197 (1964) (Stewart, J., concurring).

metaphor for patient safety is merely a reminder that there may be systems of error reporting, regulation, adjudication, and implementation of technological innovations that can change the "safety record" of health care. At the moment, however, there is no evidence that the type of institutional arrangement in place to promote safety in aviation or other industries could, or more important should, be applied to health care.

To ensure that these important questions remain open, patient safety is defined as follows: the continuous efforts of actors within the institutions of medicine and law to reduce the level of iatrogenic patient injury⁵² through the systemic understanding of how errors are reduced. This definition of patient safety has two features that distinguish it from the definitions of safety proposed by both patient safety advocates and tort reformers. First, I join with Komesar in recognizing patient safety as a worthwhile social goal that could be pursued through a variety of legal and nonlegal institutions.⁵³ Second, the definition acknowledges the need for a new understanding of all the potential risks that never come to the attention of either medical or legal officials, but it does not explicitly embrace the patient safety advocates' position that aviation or any other industry provides the model for reduction of risks in health care.

The patient safety advocates' position can be contrasted with that of the tort reformists' by comparing their respective views of the world of errors.



Tort reformers, according to Komesar, analyze only the tip of the iceberg to make pronouncements about safety and law.⁵⁴

52. Paul Weiler defines medical or iatrogenic injury as "an unexpected or avoidable adverse event, as opposed to an inevitable or anticipated traumatic byproduct of necessary treatment." Paul C. Weiler, *The Case for No-Fault Medical Liability*, 52 MD. L. REV. 908, 912 n.22 (1993).

53. Refer to notes 44-45 *supra* and accompanying text.

54. See KOMESAR, *supra* note 18, at 154-56.

Under their view, the sinking of the *Titanic* provides an opportunity to discuss the positive or ill effects of imposing liability on ship owners as a means of preventing future mishaps with icebergs. Patient safety advocates argue that icebergs are always a risk of boating, so the first tool of prevention would be the development of a system of near misses of ships running into icebergs. The essential assumption behind this theory, which compels acknowledgement, is that near misses are very similar to actual accidents such as the *Titanic* hitting an iceberg. The patient safety advocates, however, do not have a theory of health care as delivered through complex organizations rather than by a mechanical system steered by the physician and his or her underlings.

B. Medical Liability as a System of Prevention

To be open to the lack of a role for traditional malpractice liability in the patient safety issue, one must also acknowledge the equal possibility that there is such a relationship. Even prior to the Harvard Medical Practice Study, leading law-and-economics scholars had noted a relationship between the possibility of tort liability and safety.⁵⁵ Other scholars may question this relationship,⁵⁶ but one need not resolve this longstanding debate. Both sides of the debate bring forth a prior ideological commitment that is often invisible and clearly not yet adopted as a matter of public policy. The more important point is to elucidate the social goals, matters of law, and public policy choices of medical liability.

The legal scholars associated with the Harvard Medical Practice Study have argued that the medical liability system's goals of redistributing the costs of accidents and providing incentives for accident prevention could be better achieved

55. See, e.g., GUIDO CALABRESI, *THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS* 17-20 (1970) (recognizing that liability under accident law is used to balance safety and economic cost); Richard A. Posner, *A Theory of Negligence*, 1 J. LEGAL STUD. 29, 73 (1972) (observing that "[t]he rules of liability seem to have been broadly designed to bring about the efficient . . . level of accidents and safety").

56. See, e.g., RICHARD A. EPSTEIN, *MORTAL PERIL: OUR INALIENABLE RIGHT TO HEALTH CARE?* 384-89 (1997) (questioning the tort liability system's capability to efficiently process claims, which negatively affects its capacity for deterrence). For a critique of Epstein's views on malpractice, see Gary T. Schwartz, *Medical Malpractice, Tort, Contract, and Managed Care*, 1998 U. ILL. L. REV. 885 (concluding that Epstein's contract recommendations in malpractice situations is innovative yet fails to consider the "dramatic" modern movement towards managed care).

through a system of “no fault.”⁵⁷ By positing two social goals—compensation and prevention—no-fault advocates can engage in a kind of “balancing” to form their policy recommendation of eliminating liability for medical injuries in the interest of promoting or optimizing patient safety.⁵⁸ This type of cost-benefit analysis is appealing because it is the kind of analysis judges often do when they manipulate tort doctrines, even in the medical malpractice context.⁵⁹

The no-fault analysis, however, is not useful to the patient safety debate for two reasons. First, the patient safety movement (if indeed it is a social movement) posits only one goal: prevention of injuries. When translated into a law or public policy position, this means that the issue of compensation is set aside without losing sight of the fact that compensation might be important to others, such as potential consumers of health care and the plaintiff's trial bar whose fees are usually paid from the recovery of damages.⁶⁰ In the actual political process, there might be some compromise between measures designed for prevention and those aimed at compensation, but from an analytical standpoint, safety is the only goal. How to achieve safety through political action or regulatory changes of health care is yet another question. The no-fault balancing reform confuses social goals with analyses of the processes of change—the political process.

Second, the evidence available from studies of limited no-fault systems for medical accidents indicates that the complete elimination of litigation of claims is nearly impossible.⁶¹ Virginia and Florida both enacted legislation in the late 1980s designed to

57. See, e.g., WEILER, *supra* note 43, at 134-50 (arguing that a no-fault system would provide wider and more generous compensation, result in significant savings in administrative costs, and retain adequate deterrence and preventative incentives).

58. See, e.g., *id.* at 149 (positing that the “prevention role” of a program will give health care organizations an incentive to learn about and correct injuries and their causes rather than simply blaming errant individuals through malpractice litigation).

59. See, e.g., *Areto v. Avedon*, 585 P.2d 598, 607 (Cal. 1993) (applying a cost-benefit analysis in an informed consent action and holding that a doctor was not required to inform a cancer patient of his statistical life expectancy); KOMESAR, *supra* note 18, at 155-56 (appropriating Judge Hand's classic cost-benefit formula to support his thesis of the “link [between] negligence liability, resource allocation efficiency, and safety”).

60. See *Bovbjerg & Sloan*, *supra* note 7, at 72-73 (noting that a no-fault system could reduce compensation by eliminating punitive damages, payment for nonpecuniary loss, and lump sum recoveries, which would ultimately result in lower attorney's fees).

61. See *id.* at 104 (observing that although a Florida no-fault system for specific birth-related injuries reduced tort claims, “a substantial number” of permanent injury and death tort claims were still filed).

remove severe neurological injuries to newborns from the tort system and place these cases in an administrative, no-fault system.⁶² Under both systems, parents of injured babies continued to bring lawsuits for a number of reasons: the allegedly insufficient compensation amounts,⁶³ the varied interpretations of courts allowing for suits to be filed,⁶⁴ and the general narrowness of the provisions.⁶⁵ This multiple-goals analysis of medical liability indicates that the political process must fine-tune any so-called reforms.⁶⁶

Once we focus on the social goal of prevention, it is apparent that other systems could be sources of prevention tactics. During the so-called malpractice crises of the 1970s and 1980s, certain specialties had considerable difficulty obtaining insurance, particularly obstetrics and anesthesiology.⁶⁷ Professionals in one of these specialties—*anesthesiology*—decided to take steps to reduce the cost of insurance by reducing the number of accidents.⁶⁸ In 1984, the formation of the Anesthesia Patient Safety Foundation (APSF) led to research and changes that reduced the number of anesthetic-related accidents, which tend to be extremely costly.⁶⁹

The APSF's improvement of anesthesia safety is a good example of Komesar's point that the "market" can have more

62. See *id.* at 82.

63. See *id.* at 90-93 (stating that the Virginia and Florida no-fault statutes lack explicit nonpecuniary loss provisions and compensate claimants with scheduled, rather than lump sum, payments).

64. See *id.* at 84-85, 89 (noting that although both the Florida and Virginia statutes state "that no-fault is to be an exclusive remedy," the statutes allow judicial review of administrative decisions and many claimants go directly to court to determine if no fault replaces the tort remedy).

65. See *id.* at 90 (describing the statutory eligibility criteria as "very specific and targeted" and "only a partial carve-out from tort").

66. See *id.* at 115 & n.294 (illustrating the recent amendments made to the Florida no-fault statute that attempt to bring many tort cases back under the statute).

67. See Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381, 409-11 (1994).

68. See John H. Eichhorn et al., *Standards for Patient Monitoring During Anesthesia at Harvard Medical School*, 256 JAMA 1017, 1017 (1986) (observing that upon concern expressed by Harvard Medical School's insurance carrier over rising claims related to anesthesia, Harvard appointed a risk management committee to improve safety).

69. See Walter Gellhorn, *Medical Malpractice Litigation (U.S.)—Medical Mishap Compensation (N.Z.)*, 73 CORNELL L. REV. 170, 186-87 & n.46 (1988) (noting the successful effect of the APSF's error-prevention campaigns). For more information on the APSF, see Anesthesia Patient Safety Foundation, *APSF Foundation Information* (visited Oct. 13, 1999) <<http://www.gasnet.org/societies/apsf/foundation/foundation.html>>.

effect on safety than the law.⁷⁰ It is not that law is irrelevant to safety, but in the APSF example, the market responded without any political change to incentives and disincentives to produce a more “safe” environment.⁷¹ In fact, there has been growth in knowledge about how to make the operating room safer by changing the configuration of technology, human resources, and methods of training anesthesiologists.⁷² Reaching the goal of patient safety requires a paradigm shift in the way we think about prevention of accidents in law. Rather than continue the debate about liability as instrumental or as an obstacle to increased safety in health care, we need to acknowledge that the single goal of preventing patient injuries requires a new and dynamic way of conceptualizing law so that knowledge about safety will continue to grow. In this new view, medical liability—the imposition of civil liability for damages on health care professionals and organizations—is acknowledged to be an imperfect system for enhancing patient safety. The goal is not to perfect or eliminate medical liability under the banner of efficiency or rationality. Rather, the goal of a new conceptualization of the role of law is to assess the capacity of the legal system to adopt new ways of viewing safety.

C. Public Health Law and the Use of New Knowledge

To infuse the entire health care system with systemic knowledge about reducing the risk of injuries to patients requires a new paradigm: public health. Public health law, broadly defined, is concerned with the well being of a given population.⁷³ Although preventing the spread of infectious disease has historically been the core function of public health, increasingly the social and behavioral aspects of a “healthy lifestyle”—opposing smoking, violence, and unprotected sexual intercourse and promoting designated drivers—are part of the public health agenda.⁷⁴ Some of the most dramatic safety increases in public health are in fact simple but systemic changes; for example, getting physicians to wash their hands after delivery has greatly

70. See KOMESAR, *supra* note 18, at 154.

71. See Gellhorn, *supra* note 69, at 186-87 & n.46 (noting a reduction in claims against anesthesiologists even in the years preceding the APSF's establishment).

72. These developments are described in Abraham & Weiler, *supra* note 67, at 412-13.

73. See, e.g., Lawrence O. Gostin et al., *The Law and the Public's Health: A Study of Infectious Disease Law in the United States*, 99 COLUM. L. REV. 59, 67 (1999).

74. See *id.* at 79-80.

decreased infection and death associated with childbirth,⁷⁵ and good sewage systems have reduced the spread of disease.⁷⁶ In addition, public health measures are based upon scientifically derived data about the risks to health.⁷⁷

Public health measures, by and large, become “law” through legislatively authorized regulatory schemes and are thus examples of how law reduces risks to overall health.⁷⁸ As tools of prevention, these regulatory measures are very different from the supposed prevention function of tort liability as applied to medicine. The tort liability system in medicine is best described as a means by which private individuals attempt to exercise control over medical professionals and health care organizations. Public health is a means by which public officials, in cooperation with citizens, seek to harness science and medicine to protect the

75. For an early illustration of systems thinking applied to medical care, see generally the work of Hungarian physician, Ignaz Semmelweis (1818-1865), who discovered the cause of puerperal (“childbed”) fever and introduced antisepsis into medical practice. See SHERWIN B. NULAND, *DOCTORS: THE BIOGRAPHY OF MEDICINE* 244-46 (1988). Semmelweis noted that poor women who gave birth in hospitals had a much higher incidence of mortality than well-to-do women who gave birth at home or even others who self-delivered in alleyways and streets. See *id.* at 245. Semmelweis followed the cause of the higher mortality rate back to the lack of hand washing on the part of medical students and physicians performing the deliveries. See *id.* at 246.

76. See Gostin et al., *supra* note 73, at 78-79 (describing the early sanitation reformers’ agenda that focused on sewer line improvement and stating that “purity of water supplies” is an important traditional public health practice). For a fictionalized account of a public health issue—contaminated public baths—and the professional and public reactions to remedying the problem, see Henrik Ibsen, *An Enemy of the People* (1883), reprinted in HENRIK IBSEN, *THE COMPLETE MAJOR PROSE PLAYS* 277-386 (Rolf Fjelde Trans., Farrar Straus Giroux, 1st ed. 1978).

77. In fact, when legislatures give public health officials the authority to impose sanctions against individuals, the Constitution requires that there be a *scientific basis* for legislative enactment of public health measures as exercises of the police power. See *Jacobson v. Massachusetts*, 197 U.S. 11, 24-25, 30-31 (1905) (holding that a state legislature is within its police power in establishing a public health vaccination statute based upon an “effective” scientific theory). In *Jacobson*, the Supreme Court upheld the constitutionality of a state law that authorized local towns to require vaccination when necessary for public health and safety and authorized a fine for adults who refused. See *id.* at 12-13, 39. An interesting aspect of *Jacobson* is that, at the time, some medical professionals did not believe the particular vaccination that the state used prevented the spread of small pox. See *id.* at 30. The Court stated that the legislature was entitled to choose among competing theories of preventing the spread of the disease. See *id.*

78. It is important to distinguish between health and health care to understand some of the issues, particularly the behavior issue, on the public health agenda. For instance, decreasing the amount of smoking among a given population raises the overall health status of that population without any increase in the amount of health care for lung cancer in that population. See, e.g., Lester Breslow & William G. Cumberland, *Progress and Objectives in Cancer Control*, 259 *JAMA* 1690, 1690, 1692 (1988).

health of the community.⁷⁹ Although coercion is used, public health relies heavily upon education and voluntary cooperation as the primary means of obtaining compliance.⁸⁰ Even though the system of public health law regarding its core function of preventing communicable disease is in disarray,⁸¹ a shift to a public health paradigm highlights the unique problems of public safety.

The risk to patient safety is not in some "disease" process that can be studied and objectified by medical and public health professionals. Rather, the subjects of study in patient safety are health care professionals and the tools they choose to do their work. Making health care the subject of intense scientific study is not likely to be achieved without the voluntary cooperation of professionals within the health care system.

III. COMPARATIVE INSTITUTIONAL ANALYSIS AND PROFESSIONAL KNOWLEDGE

At the present time, knowledge about patient safety is in an embryonic stage, but the larger universe of knowledge about risk reduction is more developed. Systemic thinking about prevention of patient injury requires the creation of new kinds of knowledge that are embedded within organizations rather than individuals. In health care organizations, the kind of knowledge that is valued is "professional knowledge," meaning that it is derived from some scientific body of knowledge.⁸² Yet there is another tradition of professionalism, less aligned with a positivist interpretation, that the patient safety movement evokes. This

79. See, e.g., Gostin et al., *supra* note 73, at 61 (extolling the use of both scientific inquiry and the law as methods by which norms of healthy behavior are established).

80. See *id.* at 120.

81. See *id.* at 88-101 (discussing three challenges to health law's goal of preventing communicable diseases: the decline in public health funding and increasing public apathy, the emergence of new treatment-intensive communicable diseases, and the advent of managed care).

82. In describing this dominant mode of thinking about the nature of professional knowledge as "technical rationality," Donald Schön provides a critique of positivism. He writes:

Technical Rationality is the heritage of Positivism, the powerful philosophical doctrine that grew up in the nineteenth century as an account of the rise of science and technology and as a social movement aimed at applying the achievements of science and technology to the well-being of mankind. Technical Rationality is the Positivist epistemology of practice.

SCHÖN, REFLECTIVE PRACTITIONER, *supra* note 17, at 31. See generally *id.* at 22-69 (discussing the nature and limitations of "Technical Rationality," or instrumental, science-based problem-solving, and proposing "Reflection-in-Action," an intuitive, action-based method, as an alternative).

other tradition of professionalism in health care is patient-centered and modernly places a great deal of emphasis on patient autonomy.⁸³ This avocational aspect of caring for patients is best epitomized in the notions of caring for the dying.⁸⁴ The patient safety movement seeks to invoke this sense of professionalism in encouraging health care professionals to question the adversarial assumptions of the liability model and to speak the “truth” about medical error.

Thus infused with the liability model, patient safety advocates tend to see issues in terms of liability without considering the variety of options available in law or public policy. The regulation of health care is complex, and it is not surprising that on close examination, the model of liability fails to point to the correct empirical questions or to place the patient safety movement into proper historical context. Most important, the liability model fails to consider that many of the present legal protections physicians and health care organizations enjoy may in fact inhibit efforts to improve patient safety.

As an example, consider the relationship of the process of accrediting health care facilities to the promotion of patient safety. At present, the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) determines on a regular basis if a hospital should be accredited, and it uses a nominally “voluntary” process that certifies that the hospital meets certain standards and is presumably “safe.”⁸⁵ But without JCAHO accreditation, a hospital cannot receive payment from government or private reimbursement programs, such as

83. See generally LARRY I. PALMER, *LAW, MEDICINE, AND SOCIAL JUSTICE* 34-38 (1989) (proposing an alternative to the informed consent model of physician-patient decision making, which emphasizes a collaborative, rather than a contractual, approach).

84. How this ethical objection is enforced within the legal system has created considerable conceptual difficulties. See, e.g., *Wright v. Johns Hopkins Health Sys. Corp.*, 728 A.2d 166, 167, 171 (Md. 1999) (holding that the estate could not recover damages from health care professionals for administering cardiopulmonary resuscitation contrary to the written advance directive of an AIDS patient). Some of the confusion is a function of trying to understand the nature of the “right” to refuse treatment. The plaintiffs in *Wright* tried to argue that the patient had either a common law, statutory, or constitutional right that the physician had ignored. See *id.* at 167-68 (referencing Maryland’s Life-Sustaining Procedures Act, which governs directives of health care). The court held in effect that this right was a function of statutory enactment, and the lack of certification by two physicians that his condition was “terminal,” as required by the statute, was fatal to any claim of negligence. See *id.* at 175.

85. See Joint Commission on Accreditation of Healthcare Organizations (JCAHO), *Joint Commission Mission and History* (visited Jan. 20, 2000) <http://www.jcaho.org/mandh_frm.html> (noting the voluntary nature of accreditation).

Medicare or indemnity health insurance programs.⁸⁶ The JCAHO in fact wields considerable power and is best thought of as a quasi-political body. Not surprisingly, as the media have given more attention to prevention of patient injury,⁸⁷ the JCAHO has modified its standards about reporting adverse incidents—what are called “sentinel events.”⁸⁸ One recent change was the implementation of a standard that encouraged healthcare organizations to voluntarily provide the JCAHO with a copy of the document analyzing the systemic cause or causes of the sentinel event, called a “root cause analysis,” along with corrective plans.⁸⁹

Some professional organizations with seats on the JCAHO board objected to this policy on the grounds that once disclosed, these reports might be discoverable in a future lawsuit by the injured party.⁹⁰ One might wonder why giving a patient an explanation of why he or she was injured along with the steps the hospital is taking to prevent future occurrences is perceived as a grave risk to the organization. One explanation is that health care organizations benefit from some legislative protection against the usual rules of discovery in most states—protection believed to be necessary for “peer review” and “quality assurance” programs.⁹¹ Health care organizations are not willing to risk their

86. See *id.* (noting that Congress passed the Social Security Amendments of 1965 with a provision that hospitals accredited by the JCAHO are able to participate in Medicare and Medicaid programs); see also WILLIAM J. CURRAN ET AL., *HEALTH CARE LAW AND ETHICS* 1192-93 (5th ed. 1998) (stating that Medicare and Medicaid certification are vital to an organization’s financial health).

87. See, e.g., Belkin, *supra* note 21, at 28 (discussing the need for systemic change to prevent patient injury in the context of several case studies of medical error); Atul Gawande, *When Doctors Make Mistakes*, *NEW YORKER*, Feb. 1, 1999, at 40, 48-49 (relating instances of doctor error and describing a weekly intrahospital conference held to address and correct them); J.M. Sharfstein, *Asleep on the Job*, *NEW REPUBLIC*, June 21, 1999, at 17, 17-18 (recommending a reduction in resident work hours to reduce patient injury); see also, e.g., Sandeep Jauhar, M.D., *First, Do No Harm: When Patients Suffer*, *N.Y. TIMES*, Aug. 10, 1999, at F8 (cataloguing incidences of inefficient or dangerous health care and suggesting that less aggressive treatment methods are safer).

88. See JCAHO, *Sentinel Events Policy and Procedures* (last modified June 15, 1999) <http://www.jcaho.org/sentinel/se_pp.html> (explaining that unexpected instances of patient injury are called “sentinel” because “they signal the need for immediate investigation and response”).

89. See *id.*

90. For instance, the American Hospital Association and the American Society for Healthcare Risk Management opposed the policy. See American Society for Healthcare Risk Management, *Position Statement and Recommendations: JCAHO Sentinel Event Reporting Program* (visited Jan. 20, 2000) <<http://www.ashrm.org/news/jcaho/blast3co.html>> [hereinafter ASHRM, *Position Statement*] (stating that the ASHRM believes that the JCAHO policy places complying organizations at risk of financial and reputational damage).

91. See, e.g., *Scripps Mem’l Hosp. v. Superior Court*, 44 Cal. Rptr. 2d 725, 725

legislative privileges in order to comply with a JCAHO request ostensibly aimed at preventing patient injury.⁹² The linkage between the rules for accreditation and legal discovery assumes that the adjudication of malpractice claims should predominate over other institutional perspectives.

The patient safety perspective would start with an analysis that sees the JCAHO as "law related" but primarily aligned with political or administrative institutions rather than with courts and the process of adjudication. Analyzing the JCAHO's recent actions as part of political institutional analysis, the change in policy is explained as an attempt to ward off regulatory or legislative responses to "medical error." By offering to use its influence to get more safety-related information, the JCAHO hopes to maintain its own position as mediator between health care organizations and political and administrative units of the state. Or, to put the matter in terms of public choice theory, the goal of the JCAHO is to maintain the political status of the accreditation function it now exercises.⁹³

In less cynical terms, the JCAHO's modification of its standards dealing with sentinel events is a signal that political institutions may be seeking a new equilibrium with health care. The legislative privileges obtained during previous periods of "malpractice crisis"⁹⁴ are no longer considered sacred.

(Cal. Ct. App. 1995) (holding that to allow the subpoena of hospital peer review records for the purpose of impeaching an expert witness in a criminal trial would subvert the legislature's intent to provide a broad privilege against such discovery).

92. See, e.g., ASHRM, *Position Statement*, *supra* note 90.

93. There also exists a wide variety of theories about how to analyze the political process in law. For a description of those theories, see WILLIAM N. ESKRIDGE, JR. & PHILIP P. FRICKEY, *CASES AND MATERIALS ON LEGISLATION: STATUTES AND THE CREATION OF PUBLIC POLICY* 43-66 (2d ed. 1995) (discussing the mechanics of several theories of the legislative process: proceduralist (how a bill becomes a law), interest group (the influence of political groups), and institutional (broad governmental structures)).

94. Nearly every state has some type of statute protecting records from internal hospital review proceedings of patient injuries from discovery or admission into evidence. See, e.g., ARIZ. REV. STAT. ANN. §§ 36-445, 36-445.01 (West 1993); CAL. EVID. CODE § 1157 (West 1995); N.Y. EDUC. LAW § 6527 (McKinney 1985) (relating a law prohibiting the disclosure of medical review records); TEX. HEALTH & SAFETY CODE ANN. § 161.032 (West 1992 & Supp. 1999) (making medical committee records confidential and not subject to subpoena); see also *Scripps Mem'l Hosp.*, 44 Cal. Rptr. 2d at 726-27 (discussing California's enactment of legislative privileges against discovery in 1968 and significant amendments made in the mid-1980s that limited the privileges' scope). Congress sought to encourage these professional review activities through the enactment of the Health Quality Improvement Act of 1986, Pub. L. 99-660, tit. IV, § 401, 101 Stat. 3784 (codified at 42 U.S.C. § 1101(5)) (proclaiming that "[t]here is an overriding national need to provide incentive and protection for physicians engaging in effective professional review"). The effectiveness of this federal and state legislation in promoting "quality assurance" in

Furthermore, judicial attitudes toward privileges may be changing because the costs of litigation over the scope of these privileges are viewed as excessive as arbitration and other means for settling disputes are developed.⁹⁵ More important, the JCAHO's new policy might become an incentive for health care organizations to free themselves from the medical liability paradigm.

Consider again the Martin Memorial Hospital case.⁹⁶ In that instance, the hospital gave the plaintiffs and their lawyers what was in effect a root cause analysis as described in JCAHO policy.⁹⁷ The hospital's purpose in waiving its legal right to keep the document confidential, and offering an apology for the accident, was to induce the plaintiffs to settle the case.⁹⁸ There was, of course, some risk that the plaintiffs would not agree on a settlement figure, but obviously the organization was willing to take that risk to achieve its organizational goal of quickly restoring public confidence in the safety of the hospital.⁹⁹ If an organization is willing to deal candidly with the injured patient in terms of future injury prevention, there is no legal risk to providing the accreditation organization with its root cause analysis. Apparently, the hospital and its insurer were more interested in reducing the amount of overall economic loss than in "winning" the lawsuit under the rules of adjudication.¹⁰⁰

Additionally, there is no empirical evidence to support the claim that the privileges obtained through legislative lobbying have in fact made hospitals safer for patients. The reason for this

health care has been criticized by one of Lucian Leape's co-investigators in the Harvard Medical Practice Study. See Troyen A. Brennan, *Hospital Peer Review and Clinical Privileges Actions: To Report or Not to Report*, 28 JAMA 381, 381 (1999).

95. See, e.g., *Goodwich v. Nolan*, 680 A.2d 1040, 1042-43 (Md. 1996) (considering the privilege issue in the context of the arbitration of a medical malpractice claim).

96. Refer to notes 21-35 *supra* and accompanying text.

97. See Haas, *supra* note 21, at 2-6 (documenting the hospital's efforts at finding the "root cause").

98. See *id.* at 6 (observing that the risk manager's candor in disclosing the hospital error "stunned" the victim's family and that a settlement was reached shortly thereafter); see also Jonathan R. Cohen, *Advising a Client to Apologize*, 72 S. CAL. L. REV. 1009, 1011-12 nn.7-8 (1999) (citing the effects of a lack of an apology on the propensity of patients to sue for malpractice).

99. Refer to notes 30-35 *supra* and accompanying text (describing the positive effects of public acknowledgement of the hospital's error).

100. One of the implications of the approach suggested in this Article is that the entire process of settling cases of alleged malpractice should be studied from a "systems thinking" perspective. The prominent role of the risk manager in the Martin Memorial Hospital case points out the need to study the interaction of lawyers, risk managers, and insurance representatives in settling cases from a patient safety perspective. Refer to notes 25-28 *supra* and accompanying text.

assertion is that the "privilege," when asserted on behalf of a corporate entity such as a hospital, does not in fact protect organizational knowledge about the nature of errors within that particular facility.¹⁰¹ Rather, the privilege protects the knowledge that is skewed by the process of litigation, which possesses its own particular notion of "cause" and rules for presenting evidence to the jury. Although this external perspective on the cause of injury is an important constraint on health care professionals, consider the possibility that the organization *as an organization* knows very little about what causes injuries.

Most important, as pointed out by the Harvard Medical Practice Study, the amount of litigation over adverse patient outcomes is clearly not a complete picture of the amount of "malpractice," not to mention the number of near misses so often praised as the advantage of the aviation reporting systems.¹⁰² But the Harvard study's findings have larger theoretical implications in terms of comparative institutional analysis.

The litigation process is always based upon a skewed distribution of true rates of injury because there are barriers to entry into the adjudication process,¹⁰³ which like all institutional processes, is imperfect in its attempts at achieving safety. Thus, the real problem is which admittedly "imperfect institution" should be allowed to balance the costs and benefits of safety.¹⁰⁴ Choosing the least detrimental institution requires some empirical evidence and a willingness to set forth the value premises driving the institutional choice.¹⁰⁵ Because we already have some evidence that adjudication does not appropriately accommodate the number of "negligent" injuries that occur,¹⁰⁶

101. See, e.g., TEX. HEALTH & SAFETY CODE ANN. § 161.032 (West 1992 & Supp. 1999) (specifically exempting from the privilege records made in the regular course of business); see also, e.g., *Bush v. Dolan*, 540 N.Y.S.2d 21, 23 (N.Y. App. Div. 1989) (concluding that the privilege only applies to information obtained in the course of the hospital's review proceedings); *Barnes v. Whittington*, 751 S.W.2d 493, 495-96 (Tex. 1988) (holding that the privilege for hospital committee records extends only to documents generated by the committee in its investigation process).

102. See *Localio et al.*, *supra* note 8, at 245 (concluding that litigation rarely identifies substandard health care providers or compensates victims). Refer to notes 48-50 *supra* and accompanying text (stressing the importance of reporting "near misses," as the airline industry has done, in improving patient safety); see also *generally To Err Is Human*, *supra* note 16.

103. See, e.g., FED. R. CIV. P. 1-3 (listing the numerous rules dealing with a commencement of action, pleadings and motions, parties, and depositions and discovery, all of which carry substantial burdens).

104. See *KOMESAR*, *supra* note 18, at 156.

105. See, e.g., *id.* at 171-77 (using an economic analysis to evaluate institutional responses to product liability based upon the economic and social characteristics of those responses).

106. See *Localio et al.*, *supra* note 8, at 245 (finding that litigation "infrequently"

why should adjudication over medical injuries provide the model for prevention of injuries?

Furthermore, adjudication is, when viewed objectively, concerned with the post-injury state of the world. Prevention, on the other hand, seeks to affect the pre-injury world. Legal scholars arguably have little knowledge about the pre-injury world in health care organizations because the debate over the liability or adjudicatory process has so dominated our thinking. From the perspective of generating new knowledge, the handling of potential litigation (which is often years away) is analytically a distinct function from safety improvement. If actors within the health care organization are only concerned with adjudicative consequences, not only are safety solutions often ignored, but the actors also lack a framework for asking questions about systemic safety issues.

The generation of new knowledge begins with questions about systems processes, not about who is responsible for injury. Responsibility for injury is a socially defined process that may or may not make a given procedure safer. The attractiveness of the aviation-reporting model should not foster ignorance of the fact that when passengers are injured or killed, there is an independent liability system for compensating the victims or their family members.¹⁰⁷ That is, those who administer the reporting system for aviation do not have the authority to grant immunity to anyone when there has been an injury, death, or serious damage to an aircraft.¹⁰⁸ The investigation into the causes of airline accidents by other government agencies can be used in subsequent litigation and might encourage settlements rather than prolong litigation.¹⁰⁹ In some cases, such as the 1996 crash of the ValuJet plane into the Florida Everglades, criminal charges have been brought against certain corporate and individual actors.¹¹⁰

compensates medical malpractice victims).

107. See Charles E. Billings & William D. Reynard, *Human Factors in Aircraft Incidents: Results of a 7-Year Study*, 55 AVIATION, SPACE & ENVTL. MED. 960, 961 (1984) (noting that the potential liability associated with "every accident" may complicate investigation).

108. *But see id.* (commenting that the FAA offers a "limited waiver of sanctions" for the reporting of certain violations).

109. For example, after the Canadian investigation of the cause of a SwissAir crash in September 1998 discovered some evidence of faulty wiring in the plane, SwissAir and the manufacturer of the aircraft agreed, in an unusual move, to accept responsibility for the accident despite the fact that the exact cause of the accident had not yet been determined. See Anthony Ramirez, *SwissAir and Boeing to Split Payment of Damages in Crash*, N.Y. TIMES, Aug. 6, 1999, at B6 (reporting that SwissAir and Boeing hoped that the action would speed claims settlement and compensation to the victims' families).

110. See Rick Bragg, *Politics Hinted in ValuJet-Crash Charges*, N.Y. TIMES,

From the perspective of safety, it is not clear whether any of the reforms that health care professionals hail as necessary, such as damages limitations or the heavy reliance on custom evidence in malpractice actions, increases the market forces for safety.¹¹¹ Similarly, it is equally unclear whether the medical liability system increases the amount of safety or provides incentives for actions of prevention in the pre-injury world of health care delivery.¹¹² The issue is whether some institution—for instance, a legislature—is convinced that some new institution—such as a regulatory agency—would increase the margin of patient safety within an acceptable cost range.¹¹³ The answer to that question is not solely theoretical, but obtained by careful assessment of the relative strengths and weaknesses of the institutional alternatives, including allowing market forces to operate.

“Market forces” do not simply mean economic costs, but all forces driving actors in the health care system. These forces include the sense of professionalism of various actors and prospective patient demands and preferences as well as costs. As systems thinking about medical errors continues to be part of the media’s portrayal of health care,¹¹⁴ the general public’s image of medicine could be changing. The public perception that a single bad outcome, such as the wrong foot being amputated, means that the responsible health care facility is “unsafe” drives the action of managers.¹¹⁵ At a public relations level, health care organizations may have to demonstrate that they practice “safe medicine.” At a scholarly level, researchers from various disciplines must join in a multidisciplinary effort to generate new

July 15, 1999, at A12 (stating that third-degree murder and manslaughter charges were being pursued against an aircraft maintenance company); see also Matthew L. Wald, *Murder Charges Filed by Florida in ValuJet Crash*, N.Y. TIMES, July 14, 1999, at A1 (reporting on the company’s shocked response to the “criminaliz[ation] of a series of mistakes”); *When a Crash Can Be a Crime*, N.Y. TIMES, July 15, 1999, at A22 (editorializing against a widespread use of indictments against air industry personnel in plane crashes, absent criminal negligence).

111. See KOMESAR, *supra* note 18, at 182-85 (arguing that where prevention is obtainable, reforms that limit damages will too severely limit recovery and reduce the impetus towards preventative measures).

112. See WEILER, *supra* note 43, at 70-73 (finding that plausible arguments can be made on both sides of the medical liability debate).

113. See *id.* at 24-32 (recounting the various considerations of legislatures in response to the medical malpractice crisis of the 1970s).

114. See, e.g., Belkin, *supra* note 21, at 28 (calling for a change in hospital error analysis from a personal liability model to a systems model).

115. After a highly publicized case in which surgeons removed the wrong foot of a diabetic patient in Florida, hospital executives announced sweeping changes in their procedures. See Doug Stanley, *UCH Reduces Number of Surgeries*, TAMPA TRIB., Apr. 7, 1995, at 1, available in LEXIS, News Library, Major Newspapers File (stating that the hospital would reduce its volume of surgeries by one-fourth).

knowledge about patient safety so that policymakers, both public and private, can create the appropriate institutional arrangements to promote patient safety. That research must proceed during a period of uncertainty about the legal framework of health care.

IV. PUBLIC HEALTH, MEDICAL LIABILITY, AND PATIENT SAFETY

The move from the liability model to the public health model creates a great deal of legal uncertainty. The liability model focuses analytical resources on an institution with which lawyers are quite comfortable, and which health care professionals fear—courts.¹¹⁶ In the past, this perspective has meant that legislative reform should correct for the misdeeds of the adjudicatory process through damage limitations,¹¹⁷ arbitration panels,¹¹⁸ or some form of no fault.¹¹⁹ Research under this model operates beneath the metaphorical banner of a “blame-free system” that would enhance safety.¹²⁰

A public health model for patient safety begins with the assumption that developing scientific knowledge about the nature of medical errors is the most effective way to change the behavior of actors. As a result, the coercive instruments of law are to be used only as a last resort, and therefore public health pursues a more diffuse and pragmatic strategy to achieve the goal of enhancing patient safety.¹²¹ Sometimes, education—a market strategy—might be employed. At other times, seeking the creation of a new legislative authority to deal with patient safety might be chosen.¹²²

116. See, e.g., WEILER, *supra* note 43, at 6 (describing the lack of familiarity that doctors have with courtrooms and their fear of juries' tendencies to sympathize with injured patients).

117. See *id.* at 31 (detailing the motives of legislatures in limiting damages and the means by which they have limited damage awards).

118. See *id.* at 102 (explaining that more than 12 states have authorized pretreatment agreements “in which the patient agrees to accept binding arbitration in lieu of a jury trial”).

119. See, e.g., David M. Studdert et al., *Can the United States Afford a “No Fault” System of Compensation for Medical Injury?*, LAW & CONTEMP. PROBS., Spring 1997, at 1, 1-2 (introducing a comparison of patient compensation costs under a liability model and a no-fault model).

120. See, e.g., Edward A. Dauer & Leonard J. Marcus, *Adapting Mediation to Link Resolution of Medical Malpractice Disputes with Health Care Quality Improvement*, LAW & CONTEMP. PROBS., Winter 1997, at 185, 185-86 (hypothesizing, based upon empirical data, that iatrogenically injured claimants want to ensure that errors are not repeated and that mediation can produce quality improvements).

121. Refer to text accompanying notes 78-81 *supra* (comparing the cooperative means used by a public health model with the tort liability system's tactics of coercion).

122. See, e.g., Gostin et al., *supra* note 73, at 75 (describing the government's

The compensation of injured patients through the medical liability system might occur, but eliminating the threat of liability or imposing liability has never been high on the public health agenda. Focusing on the community's health and community resources for health improvement helps to diminish the search for an individual to "blame" for a particular disaster or tragedy.

Given that new knowledge is not yet available, the public rhetoric of systems thinking must confront the reality that existing instruments of law (such as liability suits for compensation, disciplinary procedures, and even criminal prosecutions) are sometimes employed when there is in fact a well-publicized instance of error that has led to injury. Confronting the legal risks of liability for health care organizations and professionals as well as disciplinary actions and criminal prosecutions against professionals is necessary because the kind of research that needs to be done requires the cooperation of health care professionals. Achieving this cooperation will require lawyers to increase their understanding of the complexity and diversity of health care organizations.

A. *Systems Thinking in Organizations and in Law*

With their various notions about the interrelationship of injury prevention and liability, tort reformers have proposed normative models of how the "system of law" and the health care system should relate. "Enterprise liability," initially applied to hospitals¹²³ and later to health plans and managed care organizations,¹²⁴ is one model widely discussed in the legal literature that might be offered as law's response to systems thinking about injury prevention within health care organizations.¹²⁵ These reforms are based upon certain assumptions as well as some empirical evidence about how the incentives of enterprise liability operate within health care organizations.

use of education, the marketing of alternative behaviors, and legislative measures taken to discourage activities that are public health threats).

123. See Abraham & Weiler, *supra* note 67, at 384-94 (chronicling the rise of hospital liability for medical injuries).

124. See *id.* at 393 n.45 (noting that HMOs are subject to vicarious liability for the negligent acts of their employee-doctors).

125. See *id.* at 401-04 (stating the reasons for the adoption of an enterprise medical liability model, which include protection against dramatic medical malpractice and insurance rate changes, an increase in the size of risk pools leading to more predictable claims for hospitals, and a greater guarantee to victims of actual payment on a judgment).

The systems thinking that Lucian Leape and others promote has been best described in the legal literature not by any tort theorist, but by a bankruptcy lawyer, Lynn LoPucki. As he noted in a recent publication, systems analysis is a “methodology developed in the fields of engineering, business information systems, and computer programming specifically to manage complexity.”¹²⁶ LoPucki has emphasized that the major contribution of systems analysis as applied to law is the “shift in perspective from law as a conceptual system to law as an element of concrete, empirically-verifiable ‘law-related’ systems.”¹²⁷

It is tempting to simply adopt the LoPucki model of a systems approach to law, with its emphasis on empirically verifiable elements. But to do so would ignore the fact that a systems approach to error in health care is itself a search for data, or as I prefer to call it, “knowledge.” The premise underlying the new emphasis on patient safety is that the extent of the patient error problem in medicine is unknown because the culture of medicine assumes that errors are simply a function of poor performance by individual professionals.¹²⁸ In plain terms, there is no data on error because, heretofore, only injuries, mortality, and perhaps lawsuits were relevant from the perspective of gaining knowledge about poor professional performance. The kind of systems thinking that Leape and his colleagues call for comes from engineering as well as numerous other disciplines, such as “human factors” research and organizational development.¹²⁹ It is the latter disciplines, which do not necessarily have the patina that LoPucki refers to as “scientific,” that are of particular relevance to the patient safety debate.¹³⁰

126. Lynn M. LoPucki, *The Systems Approach to Law*, 82 CORNELL L. REV. 479, 481 (1997).

127. *Id.* at 482, 488-91 (endorsing the benefits of confining the study of law to concrete systems, or systems composed of “real people and/or other physical objects,” which include objectivity and the ability to infer functioning of the system when direct investigation is not feasible).

128. *See* Belkin, *supra* note 21, at 28 (describing medicine as continuing to focus on who made the error although other disciplines try to determine why an error occurred); Leape, *Error in Medicine*, *supra* note 13, at 1852 (describing the medical culture as manipulating blame and the punishment of individuals in order to discourage error).

129. *See, e.g.*, Lucian L. Leape, *A Systems Analysis of Approaches to Medical Error*, 3 J. EVAL. CLIN. PRACT. 213, 213 (1997); Billings & Reynard, *supra* note 107, at 960 (studying aircraft incident data to better understand the phenomenon of human error, which contributes to at least half of all aviation mishaps).

130. LoPucki is probably a positivist. He concludes his article:

The systems approach provides a way for legal scholars to get in touch with reality, to discover how law-related systems work through empiricism, and

For patient safety advocates, systems thinking requires an exploration of how individuals interact not only with technology, but also with other human beings. For instance, organizational theorists have developed the concept of “high reliability organizations”¹³¹ in determining how organizations reduce risk. An oft-cited example is that of Navy aircraft carriers—organizations that manage numerous takeoffs and landings with few accidents leading to injury, death, or loss of property.¹³² The low accident rate is impressive when one considers the speed at which jet planes are moving when they touch the small surface of the deck, and that those most responsible for “hooking” the planes are young seamen.¹³³ These organizational theorists emphasize the notions of “team work” and shared responsibility for “safety” on aircraft carriers, and among flight crews in general, that are antithetical to the hierarchical stereotype of the chain of command in military organizations.¹³⁴ Despite a rigid bureaucratic structure, the military in fact operates on a different set of rules when it comes to “safety,” not only with regard to the pilots and crew working on the deck, but also to protecting the millions of dollars invested in each military aircraft and the aircraft carrier itself.¹³⁵

Advocates for patient safety have offered solutions from the airline industry without noting how different health care is from the airline industry in terms of both organization and surrounding legal structure. Without demeaning the impressive ways in which many industries have reduced risk, I suggest that we need a way of thinking about individuals within systems before we undertake the empirical search for error data.

It is important to outline, rather than to resolve, the contours of the debate about the meaning of systems thinking. First, systems thinking for the health care industry is greatly

to discover how they can be improved through modeling. The method is analogous to the kind of systems analysis used to manage complexity in the creation of business information systems and other complex computer programs.

LoPucki, *supra* note 126, at 521.

131. See, e.g., Martha Grabowski & Karlene Roberts, *Risk Mitigation in Large-Scale Systems: Lessons from High Reliability Organizations*, 39 CAL. MGMT. REV. 152, 152-53 (1997) (studying the characteristics of high-reliability organizations and finding that their characteristics include “simultaneous autonomy and interdependence, intended and unintended consequences, long [problem] incubation periods . . . and risk mitigation”).

132. See Karl E. Weick & Karlene H. Roberts, *Collective Mind in Organizations: Heedful Interrelating on Flight Decks*, 38 ADMIN. SCI. Q. 357, 357-58 (1993).

133. See *id.* at 357-63.

134. See *id.* at 364.

135. See *id.* at 371-72.

informed by the aviation narrative of safety, but ignores, at least in its public rhetoric, the gradual reorganization of health care's method of delivery and financial structures over the past twenty years.¹³⁶ This reorganization—call it “managed care”—has occurred, by and large, without governmental mandate or direct intervention.¹³⁷ Although there is a growing body of legal scholarship aimed at changing this market-driven reorganization,¹³⁸ there is also a large body of literature about systems thinking that is applied to organizations.¹³⁹ For the patient safety debate, the question becomes: are there social and economic forces that might lead health care organizations to embrace “patient safety”?

The systems thinking that deals with organizational development in businesses is in fact grounded in general social theory.¹⁴⁰ One social fact about health care organizations is that a great many of the actors are licensed professionals—nurses, respiratory therapists, pharmacists, social workers, physicians, et cetera.¹⁴¹ Each of these professional groups has its own licensure board and method of disciplining professionals.¹⁴² Although physicians are assumed to be at the apex of the social system, systems thinking about the issues of patient safety would make us question whether *physician* behavior is the key variable in making the organization a “safer” environment, just as the Navy discards its traditional hierarchies on aircraft carriers.¹⁴³

136. See Liang, *supra* note 19, at 4.

137. See *id.* at 2-3.

138. See, e.g., *id.* at 92-93 (proposing a shift in incentive structures from a focus on cost limits to one on patient care).

139. See, e.g., ROBERT L. FLOOD & NORMA R.A. ROMM, *DIVERSITY MANAGEMENT: TRIPLE LOOP LEARNING* xi-xii (1996) (describing the focus of their study on diversity management, or the management of various models and methodologies, and “triple loop learning,” a deeper and more reflexive learning process); PETER M. SENGE, *THE FIFTH DISCIPLINE: THE ART AND PRACTICE OF THE LEARNING ORGANIZATION* 1-7 (1990) (introducing the concept of “learning organizations,” which incorporate a systems thinking approach, to management and business).

140. See FLOOD & ROMM, *supra* note 139, at 36-52 (stating that systems thinking, based upon metatheory, has incorporated societal theory into its goal of unifying science).

141. See CURRAN ET AL., *supra* note 86, at 927-31 (discussing various aspects of medical professionals' licensure and their impact on the availability of providers, benefits to consumers, and the effectiveness of licensing board disciplinary actions).

142. See *id.* at 930 (describing the history of disciplinary boards and recent changes that have effected improvements in the collection of data on disciplinary actions).

143. See SENGE, *supra* note 139, at 27-54 (providing examples from a systems perspective in which problem solving focuses beyond individual mistakes to the underlying structures that shape events).

This wider view of the actors makes us aware of the social construction of knowledge within health care organizations—following “doctors’ orders”—that may in fact create risks to patient well being in some situations. When, for instance, a physician makes a mistake in the decimal point of the dosage of a drug, the failure of the nurse or pharmacist to question the dosage can lead to tragic consequences.¹⁴⁴ We know that some entity or person in the health care system is legally liable after the fact for the injury or death, but from a social theory perspective, the patient is the client of the physician as well as the pharmacist, various nurses, and the hospital.¹⁴⁵ The underlying premise of systems thinking, when applied to social organizations, is that “[w]hen placed in the same system, people, however different, tend to produce similar results.”¹⁴⁶ The “system” in this sense is not simply the organizational structure, but the interrelationships of individuals, the technology employed in the organization, and the various organizational goals such as patient care, cost effectiveness, and being a “good employer.”¹⁴⁷

The most important difference between the organizational structures of health care and aviation, as systems, is that the former is significantly more “diverse” than the latter in terms of goals. “Diverse” in this context means that there is more tension among the goals of various actors within the system of health care than in aviation.¹⁴⁸ For instance, nurses, who are employees of the hospital, might define their role as “caring” for the patient, whereas surgeons, who are independent contractors, might define their role as “curing” or “ameliorating” the patient’s disease. The hospital administrator must manage this type of diversity in establishing staffing levels consistent with the amount of expected reimbursement from private and governmental insurance programs.¹⁴⁹

144. Refer to Part IV.C.1 *infra* (discussing accidental deaths resulting from the misreading of a chemotherapy dose).

145. See, e.g., *Settlement Reached in Overdose Lawsuit*, N.Y. TIMES, Aug. 25, 1995, at A20 [hereinafter *Settlement Reached*] (noting that the error leading to a patient’s chemotherapy overdose was overlooked by “[a]t least a dozen doctors, nurses, and pharmacists”).

146. SENGE, *supra* note 139, at 42-43 (advocating a perspective that looks beyond individual mistakes to the system that shaped the erroneous actions).

147. See Leape, *Error in Medicine*, *supra* note 13, at 1851 (labeling the nature of medical practice as “complex” and involving a “multitude of interventions that each patient receives” with an unsurprisingly high error rate); SENGE, *supra* note 139, at 44 (explaining “systemic structure” as a term that is concerned with the interrelationships between people and among key variables that influence behavior over time).

148. See Leape, *Error in Medicine*, *supra* note 13, at 1855.

149. Cf. FLOOD & ROMM, *supra* note 139, at 11 (defining “systemic” in terms of

Although the military officers overseeing the departure and landing of aircraft on an aircraft carrier have to manage diversity, the military has the advantage that everyone on the carrier is “in the Navy.” As a result, everyone is a government employee ultimately subject to the coercion of government sanctions. The loss of an aircraft can, for instance, mean that the officer in charge of the carrier is reassigned to a desk job even if someone else lower in the chain of command was “responsible” or “to blame” for the loss of the aircraft. At the same time, the individual “responsible” is sanctioned, but in a public organization such as the military, it is arguably difficult to hide errors or accidents unless there is a “cover up.” In effect, within public systems, in contrast to essentially private systems such as health care, the problem of diversity is more “manageable” because the conflicts among social goals are less intense.¹⁵⁰

Two other points about organizational systems thinking as applied to health care must be noted. First, some aspects of systems thinking are grounded in what one writer has called “cybernetics”—a belief that society is organized around scientific and technological knowledge.¹⁵¹ Such a belief, when applied to health care, would posit solutions in technocratic terms such as moving to computerized systems for writing and dispensing drug prescriptions within hospitals.¹⁵² Given that modern medicine is

being able to manage this type of diversity). For an example of a court trying to sort out the systems issues involved when a patient's insurance expires, see *Muse v. Charter Hospital, Inc.*, 452 S.E.2d 589, 596 (N.C. Ct. App. 1995), *aff'd per curiam*, 464 S.E.2d 44 (1996) (stating that the hospital could be held liable for a physician's discharge of a patient who later committed suicide because its policy of discharging patients when their insurance expired interfered with the physician's professional judgment).

150. The veterans' health system is government owned, but the professionals in the system view themselves primarily as autonomous and quite often, at the hospital level, they mirror those actors in a private system. From a legal perspective, the rules of liability are different from those in the private sector. All health care personnel working for the Department of Veteran's Affairs are immune from suits regarding alleged malpractice committed in the exercise of their duties to the VA under the Tort Claims Act. See 28 U.S.C. § 2679(b)(1) (1994); 38 C.F.R. § 14.605(a) (1998). A patient with such a claim would have no recourse except to sue the United States. See 39 C.F.R. § 14.605(b). The Department of Justice may defend VA employees in suits brought against them for such claims, see *id.* § 14.514(b), and the VA may indemnify those employees for judgments against them, see *id.* § 14.514(c). For an example of how one VA hospital has handled medical mistakes, see S.S. Karman & G. Hamm, *Risk Management: Extreme Honesty Makes the Best Policy*, 131 ANNALS OF INTERNAL MED. 963, 963-67 (1999).

151. See FLOOD & ROMM, *supra* note 139, at 37.

152. See David W. Bates et al., *Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors*, 280 JAMA 1311, 1315 (1998) (commenting that a physician computer order system prevented “more than half of the serious medical errors” when used at a large tertiary care hospital).

closely aligned with science, one should expect that the systems approach to health care issues will place a heavy emphasis upon "data" as objective depictions of the real world.¹⁵³

Second, this analytical/empirical view of systems thinking as applied to social organizations has a close relationship to the recent debates over the dominance of positivism in the social sciences.¹⁵⁴ This debate has had its influence on legal theorists, as challengers to the dominance of legal positivism have offered other methods of interpreting law.¹⁵⁵ Given this wide-ranging debate, a variety of approaches to law is possible. At the same time, there are a variety of ways in which law interacts with the health care system. Finding the appropriate point of leverage in the legal structure requires an openness to the possibility that law—at least the system of imposing liability after a medical injury—may in fact have little effect upon safety in the health care system.

B. The Blurry Line Between Public Health and Medical Liability

To illustrate how this paradigm shift affects our thinking, consider two cases from the borderline among public health, medical liability, and the delivery of health care services. First is the problem of HIV-infected blood in the early days of the AIDS epidemic. In *Doe v. American National Red Cross*,¹⁵⁶ the court held that the supplier of blood products had provided a professional service and could be found liable to a person transfused with blood that had not been screened for the HIV virus in 1983.¹⁵⁷ The Food and Drug Administration (FDA) did not approve the antibody test for blood until March 1985.¹⁵⁸

153. See generally LARRY I. PALMER, ENDINGS AND BEGINNINGS: LAW, MEDICINE AND SOCIETY IN ASSISTED LIFE AND DEATH (forthcoming).

154. See FLOOD & ROMM, *supra* note 139, at 22-23 (outlining the debate between those societal scientists who espouse a "positivist, value-free" methodology taken from the natural sciences and those who believe that the societal sciences ought to develop their own methodology that would acknowledge "the influences of values on theoretical interpretation").

155. For an interesting critique of the dominance of "scientism" in legal scholarship, see MARTHA C. NUSSBAUM, POETIC JUSTICE: THE LITERARY IMAGINATION AND PUBLIC LIFE 83-86 (1995) (rejecting fixed, scientific approaches to lawmaking and praising the common law process for its congruence with an Aristotelian norm of practical reasoning that accommodates changes in circumstances and values over time).

156. 848 F. Supp. 1228 (S.D. W. Va. 1994).

157. See *id.* at 1229, 1234-35.

158. See Robert Pear, *AIDS Blood Test to Be Available in 2 to 6 Weeks*, N.Y. TIMES, Mar. 3, 1985, at 23.

Shortly thereafter, the entire industry started to use the test to screen the blood supply.¹⁵⁹

Once there was an understanding of how HIV was transmitted, it seemed logical that screening the blood supply would be a source of prevention. From a patient safety perspective, the use of blood screening devices is crucial to prevent the spread of the HIV virus through medical treatment. In hindsight, most of this makes sense, but it is apparent that the threat of liability for negligence also played a role in the speed with which the industry adopted screening for HIV. In *Doe*, the Red Cross argued unsuccessfully that the standard of due care should be whether it had followed industry practices in screening blood prior to the FDA's 1985 edict.¹⁶⁰ At the time of the transfusion, blood banks were not screening blood for the HIV virus. The court rejected this analysis and allowed the jury to decide, under a common law standard of negligence, if the industry's practice (and thus that of the Red Cross) was "reasonable."¹⁶¹ By rejecting the Red Cross's request for summary judgment, the court allowed the plaintiffs to proceed to trial.¹⁶²

It is tempting to read *Doe* as representing the need for public health perspectives to prevent the spread of infectious diseases and ignore the larger systemic issues of patient safety. How does a society assure itself that the products and devices used in health care delivery minimize the risk of further injury to patients? Although these issues were eventually resolved by FDA regulation,¹⁶³ one must remember that FDA regulation is, like any other institutional response, of limited effectiveness. FDA approval of a device does not and should not eliminate the possibility of "product liability" for the manufacturer of a heart

159. See *id.* (describing FDA plans to distribute the test to 2300 blood banks, plasma centers, and laboratories).

160. See *American Nat'l Red Cross*, 848 F. Supp. at 1231, 1235.

161. See *id.* at 1233 (stating that the defendant would face liability if "its practices fell below the standards promulgated and practiced by the blood-banking industry, or that the industry standards were themselves unacceptably deficient given the [available] reliable data and knowledge"). Cases of this type were often settled because the facts were usually quite egregious. For instance, in *Doe*, the Red Cross had known for several years prior to the filing of the lawsuit that the blood transfused into the young child in 1983 was contaminated because the donor had died of AIDS. See *id.* at 1230. By 1990, when the child was diagnosed with HIV, the hospital's transfusion service had destroyed the records indicating who had received the contaminated blood that the Red Cross had shipped. See *id.*

162. See *id.* at 1235-36.

163. See, e.g., *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-77 (1996) (discussing the history and development from the early part of this century of the FDA's mandate to approve drugs and, later, medical devices).

pacemaker, for example.¹⁶⁴ What is important to learn from *Doe* is that there is interplay among the growth of knowledge (recall that the test for routine screening of blood for the HIV virus had not yet been developed when the *Doe* patient was infected), the possibility of liability for failing to operate in accordance with that knowledge, and the development of regulatory schemes.

The second example of the interplay among potential medical liability, public health, and health care delivery is dramatically illustrated by *Bradshaw v. Daniel*.¹⁶⁵ In *Bradshaw*, the court held that a physician may be held liable for failing to warn a wife of her risk of having Rocky Mountain Spotted Fever after her husband died from the disease.¹⁶⁶ The physician treated the husband for Rocky Mountain Spotted Fever, but allegedly never communicated to the wife the findings of the autopsy that her husband's death, which occurred four days after admission to the hospital's emergency room, was caused by the disease.¹⁶⁷ The court's refusal to grant the defendant-physician summary judgment¹⁶⁸ is significant for two reasons. First, there was no physician-patient relationship between the wife and her husband's treating physician.¹⁶⁹ In point of fact, a week after her husband's death, she was admitted and treated for Rocky Mountain Spotted Fever at a different hospital by a different physician.¹⁷⁰ She died shortly thereafter.¹⁷¹ There was in fact a limited time window to communicate to anyone the exact cause of the husband's death because the Centers for Disease Control did not confirm the physician's initial diagnosis of Rocky Mountain Spotted Fever until nearly two months after the man's death.¹⁷² Second, under most circumstances, a physician is potentially liable under several theories if he or she wrongfully discloses the medical records of a patient.¹⁷³

164. See *id.* at 474, 507 (holding that FDA approval of a pacemaker did not preempt the plaintiff's common-law claims).

165. 854 S.W.2d 865 (Tenn. 1993).

166. See *id.* at 872-73.

167. See *id.* at 866-67.

168. See *id.* at 873.

169. See *id.* at 867.

170. See *id.*

171. See *id.*

172. See *id.* (relating, however, that an autopsy was initially performed by the hospital shortly after his death).

173. See, e.g., *Warner v. Lerner*, 705 A.2d 1169, 1173 (Md. 1998) (finding a physician liable to a patient for the disclosure of his medical records without the patient's or hospital's permission). Cf. *Estate of Berthiaume v. Pratt*, 365 A.2d 792 (Me. 1976) (holding a physician liable for invasion of privacy for taking photographs of a patient without permission).

The court's finding of an affirmative duty to warn identifiable third parties of the risk of Rocky Mountain Spotted Fever is justified, however, if one considers the case as one about the distribution of professional knowledge. Rocky Mountain Spotted Fever is not contagious,¹⁷⁴ but the plaintiff's experts testified that the ticks that cause the disease "cluster."¹⁷⁵ As a result, anyone in close proximity to a person infected with the disease is likely to have been exposed to the ticks at the same time as the infected person.¹⁷⁶ As between a layperson and a physician with access to knowledge about the etiology of the disease in a public health sense, the court held that physicians have a legal duty to warn persons they can identify as potentially exposed.¹⁷⁷ This goes beyond the medical model of attempting to treat the disease with the appropriate drugs and imposes a duty to know about the public health consequences of the causative agents—the bite from the ticks. Put in plain terms, every camper should know of the risk of Rocky Mountain Spotted Fever, but the court's ruling implies that a reasonable physician has a duty to know about the phenomenon of clustering and the risks to others closely associated with the patient who sought treatment. In effect, the court ruled that the delivery of health care could not be separated from the larger context of scientific knowledge about the origins and spread of disease, including the public health implications of professional practice.

C. "Blaming" Nurses

Nurses, rather than physicians, have been subject to discipline or criminal prosecution for medical errors in some recent, highly publicized cases. A focus on nurses will help to delineate the systemic issues because nurses are most often "employees" of health care organizations.¹⁷⁸ Many physicians and surgeons are, conversely, "independent contractors" working within health care organizations, be they hospitals or networks of managed care organizations.¹⁷⁹ Both incidents discussed in this section involve the (mis)administration of drugs, the most common source of medical error.¹⁸⁰

174. See *Bradshaw*, 854 S.W.2d at 869.

175. See *id.* at 867, 872.

176. See *id.*

177. See *id.* at 872-73 (emphasizing a duty to warn "identifiable third persons in the patient's immediate family against foreseeable risks emanating from a patient's illness").

178. See *Abraham & Weiler*, *supra* note 67, at 387.

179. See *id.*

180. Less well documented is the effect of "culture" on work in health care

1. *The Wrong Dosage of Chemotherapy.* In 1994, Betsy Lehman, a 39-year-old health care columnist for the *Boston Globe*, and Maureen Bateman, a 53-year-old school teacher, were patients at the Dana-Farber Cancer Institute in Boston.¹⁸¹ Both women had breast cancer.¹⁸² An oncology resident ordered that both women be given the same form of chemotherapy that was approved for use at Dana-Farber under a special research grant from the National Institutes of Health.¹⁸³ The protocol for this treatment required that each patient receive the intravenous drip over a four-day period.¹⁸⁴ Instead, the entire amount of the drug was given to each woman during each twenty-four hour period for four days.¹⁸⁵ Betsy Lehman died shortly after the treatment overdose.¹⁸⁶ Maureen Bateman suffered cardiac damage and died three years later.¹⁸⁷ Several months after Betsy Lehman's death in March 1995, a clerk at Dana-Farber discovered that Ms. Lehman had been given an overdose.¹⁸⁸

Defining the "error" that led to injury and death during the course of an experimental treatment depends upon the perspective taken. From a systems thinking perspective, the injuries and deaths were caused by the process with which drug

organizations. See, e.g., David M. Gaba, M.D., *Physician Work Hours: The "Sore Thumb" of Organizational Safety in Tertiary Health Care*, Presented at the Enhancing Patient Safety and Reducing Errors in Health Care Conference, Nov. 8-10, 1998, at 302 (proceedings on file with the author and the *Houston Law Review*).

181. See Lawrence K. Altman, *2 Chemotherapy Overdoses Lead to Review of Nurses*, N.Y. TIMES, Jan. 6, 1999, at A14.

182. See *id.*

183. See Richard A. Knox, *Dana-Farber Tests Signaled an Overdose, Records Show*, BOSTON GLOBE, May 2, 1995, at 1, available in LEXIS, News Library, Bglobe File.

184. See Richard A. Knox & Daniel Golden, *Drug Overdose Was Questioned: Dana-Farber Pharmacist Sent Order Back to Doctor in Breast Cancer Case*, BOSTON GLOBE, June 19, 1995, at 1, available in LEXIS, News Library, Bglobe File.

185. See Richard A. Knox, *Doctor's Orders Killed Cancer Patient; Dana-Farber Admits Drug Overdose Caused Death of Globe Columnist, Damage to Second Woman*, BOSTON GLOBE, Mar. 23, 1995, at 1, available in LEXIS, News Library, Bglobe File.

186. See Altman, *supra* note 181, at A14.

187. See *id.*

188. See Robin Romano, *Fatal Error Becomes Catalyst for Reform*, BOSTON GLOBE, Mar. 15, 1999, at A11. The chemotherapy overdose at Dana-Farber has become a "case study" at the Harvard Business School. See Richard Bohmer & Ann Winslow, *The Dana-Farber Cancer Institute*, Harv. Bus. Sch. Case #9-699-025 (1999) (relating the history of Dana-Farber, its development and organization, and the overdose and death of Betsy Lehman). The tutorial supplement to the case study introduces "human factors" in health care. See Richard Bohmer, *Complexity and Error in Medicine*, Harv. Bus. Sch. Case #9-699-024, at 4-8 (1998) (analyzing various types of human error as they stem from either an "automatic" or "problem-solving" mode of cognition). Human factors is one of the disciplines used by aviation experts to enhance safety.

prescriptions are written, filled, and delivered to patients.¹⁸⁹ Most obvious in these cases was the fact that the handwritten prescription for the drug used as chemotherapy for the two patients' form of breast cancer was not clearly legible.¹⁹⁰ Another possible source of the error is the ethos that nurses (and pharmacists) do not question doctors' orders, especially on an experimental treatment protocol that has no "routine procedure."¹⁹¹

From a health care delivery perspective, Dana-Farber's small hospital for inpatients did not have a cardiologist on the scene that might have provided expert care when the two patients suffered cardiac problems. A further organizational issue was the fact that Dana-Farber was historically led by biomedical researchers rather than health care professionals emphasizing patient care.¹⁹² Finally, from the perspective of medical liability, Dana-Farber was liable for both the injuries and the deaths even if the physician who wrote the unclear order might also be individually liable.¹⁹³

189. See Leape et al., *The Nature of Adverse Events*, *supra* note 6, at 383-84 (noting the role of the "medical-industrial system" in supplying drugs and equipment); cf. Bohmer, *supra* note 188, at 7-8, 13-14 (revealing that adverse drug events resulted from systems failures).

190. See Bohmer & Winslow, *supra* note 188, at 7. The physician who wrote the prescription admitted in a consent proceeding with the Massachusetts physician licensing board that he had been guilty of malpractice. See Bruce Mohl, *Doctor Penalized for Error in Dosage*, BOSTON GLOBE, Nov. 10, 1998, at B3, available in LEXIS, News Library, Bglobe File (discussing James M. Foran's consent agreement with the Board of Registration and the Board's reasoning in asserting only mild disciplinary action against him). The Board suspended his license for three years. See *id.* (noting, however, that the license suspension was retroactive to a date three years earlier, meaning Foran could immediately reapply for his license). At the time the sanction was announced, he left the country for a research position at a London, England hospital. See *id.*

191. Refer to notes 143-45 *supra* and accompanying text. The nurse's ethical and clinical dilemma in "innovative" treatment is powerfully portrayed in a fictionalized account of the Tuskegee Syphilis Study in David Feldshuh's play focusing on an African-American public health nurse. See generally MISS EVERS' BOYS (David Feldshuh 1995). The play was later developed into a prizewinning made-for-television movie by Home Box Office and was a force in President Clinton's apology to survivors for the United States Public Health-sponsored study. See Larry I. Palmer, *Paying for Suffering: The Problem of Human Experimentation*, 56 MD. L. REV. 604, 604-05 (1997).

192. See Bohmer & Winslow, *supra* note 188, at 3 (citing many of Dana-Farber's medical breakthroughs to demonstrate that research has always been at the core of Dana-Farber's mission); Richard A. Knox, *Dana-Farber Puts Focus on Mistakes in Overdoses*, BOSTON GLOBE, Oct. 31, 1995, at 1, available in LEXIS, News Library, Bglobe File (commenting that Dana-Farber's investigators found that the institute lacked patient-care expertise).

193. See Abraham & Weiler, *supra* note 67, at 387-88 (relating that hospitals are often found liable for their independent contractor physicians under a theory of "apparent authority").

Dana-Farber quickly offered settlements in both cases.¹⁹⁴ Relying upon the growing knowledge about systems errors, Dana-Farber made changes in the way drugs were dispensed by adopting the computer-order-entry system advocated by Lucian Leape and his colleagues.¹⁹⁵ The organization went even further and installed a new chief executive with patient care experience.¹⁹⁶ The organization also transferred the operation of its hospital to a Partners Hospital, a recent merger of several hospitals affiliated with the Harvard Medical School.¹⁹⁷ In effect, Dana-Farber recognized that it did not have the infrastructure to run a "safe" inpatient hospital service and chose to focus on outpatient care and research.¹⁹⁸ Of course, the JCAHO investigated this highly publicized event, as did the Massachusetts Department of Health.¹⁹⁹ Both agencies praised the corrective efforts that Dana-Farber took to prevent future occurrences.²⁰⁰

However, nearly five years after the event, the Massachusetts Board of Registration in Nursing charged eighteen nurses with failing to meet the standards of nursing practice.²⁰¹ These charges of unprofessional conduct were based upon the theory that one of the nurses hung the infusion bags for the drugs and connected them to the patients, and the other nurses, on subsequent shifts during the twenty-four hour period, monitored the flow of the drugs.²⁰² The Board argued that the nurses should have "verified" the dosage.²⁰³ The executive director

194. See *Settlement Reached*, *supra* note 145, at A20. In newspaper reports of the settlement with Betsy Lehman's husband, a Dana-Farber employee, the husband indicated that a portion of the settlement was donated to Dana-Farber for research on finding a cure for cancer. See, e.g., *id.* The settlement with the other patient, Maureen Bates, is described in a story of how she overcame the effects of the overdose. See Richard A. Knox, *Survivor's Spirit Beats a Chemotherapy Error*, BOSTON GLOBE, Dec. 17, 1995, at 1, available in LEXIS, News Library, Bglobe File.

195. See Robin Romano, *supra* note 188, at A11. Refer to note 152 *supra* and accompanying text (describing the advantages of a computerized drug dispensing system).

196. See Richard Knox, *Top Dana-Farber Doctor Steps Down*, BOSTON GLOBE, May 11, 1995, at 1, available in LEXIS, News Library, Bglobe File.

197. See Richard A. Knox, *Three Hospitals Form Cancer Partnership; Dana-Farber, Brigham, MGH Will Consolidate Treatment*, BOSTON GLOBE, Jan. 17, 1996, at 1, available in LEXIS, News Library, Bglobe File.

198. See *id.*

199. See Lucian L. Leape, *Faulty Systems, Not Faulty People*, BOSTON GLOBE, Jan. 12, 1999, at A15, available in LEXIS, News Library, Bglobe File [hereinafter Leape, *Faulty Systems*].

200. See *id.*

201. See Altman, *supra* note 181, at A14.

202. See *id.*

203. See *id.*

of the Board made it clear that the "system" she thought appropriate was an individual professional system of "double checking."²⁰⁴ Of the Dana-Farber practice, she said: "Apparently the system in place at the time did not require the nurses to double check."²⁰⁵

The nurse-as-a-check on physician prescription error seeks to elevate the status of nurses as the ultimate caretakers of patients and protectors of patient safety. The statute granting the Board of Registration authority to investigate complaints against nurses, however, gives the Board the discretion to develop its own standards of professionalism based upon individual conduct.²⁰⁶ The real issue for the patient safety debate is whether the Board would use its discretion to sanction a nurse who failed to participate in the new computerized medication system at Dana-Farber in instances in which no patient was injured or killed. It is highly probable that disciplinary boards are not yet ready to embrace "systems changes" as part of individual professional responsibility. Therefore, those engaged in systems changes after a tragic accident must take on the burden of protecting individual professionals.²⁰⁷ This is what Dana-Farber has in fact done by publicly defending the nurses.²⁰⁸ Yet two of the nurses quickly settled with the Board and agreed to a year's probation and retraining.²⁰⁹

2. *Giving the Right Drug in the Wrong Fashion.* Miguel Angel Sanchez died one day after he was born at a Colorado hospital in October 1996.²¹⁰ Three nurses who gave him a large dosage of an oil-based penicillin intravenously rather than intramuscularly were charged with criminally negligent homicide.²¹¹ The nurses not only gave the baby the drug in an improper fashion, they gave him more than ten times the amount

204. See Leslie Miller, *Nurses Face Sanctions for Following Orders that Led to Overdoses*, HOUS. CHRON., Jan. 6, 1999, at 9A (squarely blaming the tragedy on the nurses' failure to question the dose).

205. *Id.*

206. See MASS. GEN. LAWS ANN. ch. 112, §§ 74, 80 (West 1996).

207. Cf. Leape, *Faulty Systems*, *supra* note 199, at A15 (urging that the Board of Registration in Nursing's bringing the 18 nurses involved in the Dana-Farber overdose to disciplinary hearings was inappropriate).

208. See Altman, *supra* note 181, at A14 (quoting Dana-Farber's president as saying that the nurses "did their job" as they should have).

209. See Leslie Miller, *supra* note 204, at 9A (commenting that the other 16 nurses still faced disciplinary charges).

210. See Ann Schrader & Marilyn Robinson, *Baby's Nurses Face Homicide Charges*, DENVER POST, Apr. 29, 1997, at A-01, available in 1997 WL 6071695 [hereinafter Schrader & Robinson, *Baby's Nurses*].

211. See *id.*

of the penicillin that the doctor had intended and in fact ordered.²¹² By calling a noted systems thinker on medication errors as an expert witness, the defense presented enough evidence about how the initial error made by the pharmacists in misreading the prescription led to the tragic death to raise a reasonable doubt about whether the nurses operated in a manner that deviated "grossly from the standard of care."²¹³ The two nurses who went to trial were acquitted, and the third nurse entered a plea of *nolo contendere* and did not receive a jail term or fine.²¹⁴

Not surprisingly, the grand jury indictment of the three nurses created a great deal of alarm among health care professionals involved in the patient safety movement.²¹⁵ Little attention has been given to determining whether there are means of providing some protection for nurses from criminal prosecution, but not immunity, within existing doctrines surrounding medicine. Once again, the fear of litigation (meaning malpractice) has obscured the need for careful analysis of the distinction between the way civil and criminal law operates, particularly how criminal law ought to operate vis-à-vis health care professionals. Even after looking at the facts in a light most

212. See *id.*; see also Michael R. Cohen, RPH. MS, FASHP, *Error, Negligence, Crime: The Denver Nurses Trial*, presented at the Enhancing Patient Safety and Reducing Errors in Health Care Conference 71 (Nov. 8-10, 1998) [hereinafter Cohen, *Error, Negligence, Crime*] (proceedings on file with the author and the *Houston Law Review*).

213. See *id.* "A person acts with criminal negligence when, through a gross deviation from the standard of care that a reasonable person would exercise, he fails to perceive a substantial and unjustifiable risk that a result will occur or that a circumstance exists." COLO. REV. STAT. § 18-1-501(3) (1999). "Any person who causes the death of another person by conduct amounting to criminal negligence commits criminally negligent homicide which is a class 5 felony." *Id.* § 18-3-105.

214. See Cohen, *Error, Negligence, Crime*, *supra* note 212, at 71. The *nolo contendere* plea is in substance a plea of guilty. See JOSEPH GOLDSTEIN ET AL., *CRIMINAL LAW: THEORY AND PROCESS* 6 (1974). A great deal of the criminal process is through nonadjudicative processes that often mask important questions of law, ethics, and public policy. See Larry I. Palmer, *Life, Death and Public Policy*, 81 CORNELL L. REV. 161, 161 (1995) (reviewing NEIL K. KOMESAR, *ALTERNATIVES: CHOOSING IN LAW, ECONOMICS AND PUBLIC POLICY* (1994) and presenting a provocative representation of the problems of analyzing issues of law and medicine in the context of a *nolo contendere* plea by a health care professional). Guilty pleas and acquittals present lawyers with a particular problem of analysis because our common law training is developed from adjudicated cases, particularly appellate cases. See *id.*

215. William Sage of Columbia Law School stated that the accountability issues involved in the Denver Nurses Trial encouraged the conference participants to consider safety in their own systems. See Plenary Session: Responses from Multiple Perspectives, Presented at the Enhancing Patient Safety and Reducing Errors in Health Care Conference 115 (Nov. 8-18, 1998) (Nancy W. Dickey, moderator) (proceedings on file with the author and the *Houston Law Review*).

favorable to the District Attorney who brought the charges, there are grounds to argue that the indictments should have been dismissed.

The Sanchez baby was “healthy.”²¹⁶ The problem was that the mother’s doctor was concerned about the effects of her history of syphilis on the newborn.²¹⁷ Although the mother tested positive for syphilis, she indicated that she had been treated for syphilis in Los Angeles.²¹⁸ Unwilling to take the mother’s word, someone in the hospital checked with the Los Angeles Department of Health about the mother’s treatment.²¹⁹ The Health Department was unable to confirm the mother’s treatment.²²⁰

It is, however, clear that the laboratory test conducted on the date of the baby’s death indicated the baby did *not* have congenital syphilis.²²¹ Without waiting for the results of these tests, a neonatologist, who had taken over the care of the baby from the family practitioner, wrote the prescription for a single dosage of the penicillin.²²² In hindsight, it is obvious that the prescription was written on the “hunch” that the thirty-two-year-old mother of then four children had untreated syphilis.

It is also clear that the form of penicillin prescribed, “Benzathine penicillin G,” was not a standard form of penicillin because it was described as a “non-formulary drug.”²²³ The pharmacist filling the prescription was unfamiliar with the drug and with the treatment for congenital syphilis and consulted

216. See Schrader & Robinson, *Baby’s Nurses*, *supra* note 210, at A-01.

217. See Keith Coffman, *Lawyer: Nurse Was Not at Fault; Woman on Trial in Baby’s Death*, DENVER POST, Jan. 29, 1998, at B-03, available in LEXIS, News Library, Dpost File (noting that the mother had been infected with syphilis 15 years before).

218. See Error, Negligence, Crime—The Denver Nurses Trial; Part One: The Anatomy of an Event, Presented at the Enhancing Patient Safety and Reducing Errors in Health Care Conference 68 (Nov. 8-18, 1998) (Philip Schneider, moderator) [hereinafter Schneider, *Anatomy of an Event*] (proceedings on file with the author and the *Houston Law Review*).

219. See *id.*

220. See *id.* at 67. There may have been some language barriers because it is apparent from newspaper reports, but not the hospital’s own description of the case, that the father spoke only Spanish. See, e.g., Michael Romano, *Day-Old Boy Dies After Injection; Hospital Acknowledges Error*, ROCKY MOUNTAIN NEWS, Oct. 24, 1996, at 1A, available in 1996 WL 12352690.

221. See Schneider, *Anatomy of an Event*, *supra* note 218, at 68 (listing five diagnostic tests performed on the infant, all of which were negative for syphilis).

222. See *id.*

223. See Error, Negligence, Crime—The Denver Nurses Trial; Part Two: Theory and Remedy, Presented at the Enhancing Patient Safety and Reducing Errors in Health Care Conference 71 (Nov. 8-18, 1998) (John W. Senders, moderator) (proceedings on file with the author and the *Houston Law Review*).

several texts to determine the dosage.²²⁴ In doing so, the pharmacist misread the dosages described in both texts and prepared a ten-fold increased dosage.²²⁵ She placed the dosages in two syringes and labeled the plastic bag containing the syringes to indicate that the drug was to be given intramuscularly.²²⁶

The nurses assumed that each syringe could be used in an intramuscular injection for only a limited amount of the mistakenly written dosage.²²⁷ They believed that giving the amount in hand intramuscularly would require five injections, and consulted a text in the neonatal nursery to determine if the drug could be given intravenously, allegedly to prevent the pain of giving multiple intramuscular injections to the infant.²²⁸ Unfortunately, the text they consulted did not mention Benzathine penicillin G, but did mention that another form of penicillin could be given intravenously for the treatment of congenital syphilis.²²⁹ In giving the drug intravenously, the nurses violated both the doctor's and the pharmacist's orders.²³⁰

Bearing in mind that the baby in fact did not have congenital syphilis as well as the other demographics of the case, one can imagine how an elected district attorney might easily see this as a case of gross carelessness in overmedication. On the other hand, in our adversary system, a lawyer for the nurses should have tried to test the legitimacy of the prosecutor's instincts by attempting to dismiss the indictment. Dismissing an indictment is very difficult in American criminal jurisprudence because prosecutors are given such wide discretion in charging crimes. There is, however, some precedent in the medical area developed for physicians that should be used for nurses.

3. *The "End-of-Life" (Mis)Diagnosis.* In *Barber v. Superior Court of Los Angeles*,²³¹ two doctors, who were charged with murder for allegedly "pulling the plug" too quickly on a patient in a persistent vegetative state, filed a writ of prohibition.²³² There

224. *See id.*

225. *See* Schrader & Robinson, *Baby's Nurses*, *supra* note 210, at A-01.

226. *See id.*

227. *See* Schneider, *Anatomy of an Event*, *supra* note 218, at 68-69.

228. *See* Ann Schrader & Marilyn Robinson, *Healthy Baby's Tragic Death at Hospital Being Probed*, DENVER POST, Oct. 25, 1996, at B-07, available in 1996 WL 12634805.

229. *See* Schneider, *Anatomy of an Event*, *supra* note 218, at 69.

230. *See* Schrader & Robinson, *Baby's Nurses*, *supra* note 210, at A-01 (revealing that the pharmacist affixed a label to the prescription order which stated that it was to be injected intramuscularly).

231. 195 Cal. Rptr. 484 (Cal. Ct. App. 1983).

232. *See id.* at 486.

was some doubt as to whether the diagnosis of a *persistent vegetative state* could have been made as quickly as the physicians did prior to seeking permission from the patient's family to terminate all life support.²³³ As a matter of fact, the evidence at the preliminary hearing indicated that the family members thought the patient was "brain dead" when they were asked to sign a consent and a release of liability.²³⁴ There is a legal distinction between being "brain dead"—which in nearly every state constitutes a definition of death—and being in a "persistent vegetative state" that may allow, but not require, the removal of all life support including nutrition and fluids. Nonetheless, the California court dismissed the indictment on a broad jurisprudential ground about how the conduct of health care professionals should be analyzed in the criminal law.²³⁵

The court ruled that the "act" of removing life support must be viewed in the context of the "physician's duty" to a patient.²³⁶ Thus, to support a criminal charge at the indictment stage, the prosecution must prove to a court (not a jury) that a physician had a duty to continue treatment.²³⁷ In effect, the court's duty analysis ironically views the physician's *acts* for the purposes of criminal law as if they were "omissions"—a failure to do something to prevent harm to the dead person.²³⁸ The rationale for such a ruling is that the role of physician carries with it risks to human life and health that must be accounted for before criminal liability is considered.²³⁹ This explains why so few prosecutions are in fact brought regarding "end-of-life care," why grand juries often refuse to indict, and why juries in fact are reluctant to convict physicians charged with crimes for their end-of-life actions.²⁴⁰ A prosecutor must overcome all the barriers in our common law system against convicting individuals for "omissions."

233. See *id.* at 486, 491.

234. See PALMER, LAW, MEDICINE, AND SOCIAL JUSTICE, *supra* note 83, at 100 (recounting evidence from the magistrate's findings).

235. See *Barber*, 195 Cal. Rptr. at 493 (concluding that there was no legal duty to continue medical treatment and, therefore, no reason for the court to ascertain whether the physicians' conduct was the proximate cause of death).

236. See *id.* at 490 (analyzing the physicians' conduct as an "omission rather than [an] affirmative action").

237. See *id.*

238. See Glanville Williams, *Euthanasia*, 41 MED. LEGAL J. 14, 21 (1973).

239. See *Barber*, 195 Cal. Rptr. at 488-89 (recognizing that this intersection of advanced medical technology and limited legislative guidance requires the evaluation of several social and philosophical issues).

240. See PALMER, ENDINGS AND BEGINNINGS, *supra* note 153, at 8-9, 13-14 (discussing the technical arguments made before juries by Jack Kevorkian's lawyers in his early trials for assisted suicide).

4. *Summary.* The application of this principle to the nurses in the *Sanchez* case requires the resolution of two issues. First, whether the duty analysis announced in the California murder case discussed above should apply to criminally negligent homicide, the crime with which the nurses were charged.²⁴¹ Murder and criminally negligent homicide or manslaughter represent two distinct theories about how human death is caused and concomitant widely different ranges of punishments.²⁴² Without attempting to resolve an issue that criminal law scholars have debated for years, it can be stated by asking whether the court in *Barber* would have dismissed the indictment if the prosecution had charged the physicians with criminally negligent homicide, rather than murder, under the California statutes.²⁴³

The second issue is whether nurses are entitled to the benefits of *Barber*. The argument against application of the *Barber* duty analysis to nurses is the notion that nurses are simply to follow doctors' (and pharmacists') orders and therefore should not and do not engage directly in the risky life and death actions of physicians. However, the argument for applying this barrier from criminal prosecution to nurses stems, perhaps ironically, from systems thinking about health care. Had the nurses questioned the pharmacists, and even the neonatologist, they might have prevented an "error." Had they gone further and asked for a confirmation of the supposed underlying diagnosis of congenital syphilis, they might have completely reversed the course of the "treatment" plan.

But the point of raising the theory to dismiss the indictment is not to prove that it would work, but to demonstrate the need for an understanding of the complexity of the legal system as health care organizations embark on efforts to reduce errors in health care. As the new scientific discipline of patient safety emerges, individuals will be subject to professional disciplinary proceedings and criminal charges.²⁴⁴ In practical terms, until the new knowledge is created, health care organizations concerned

241. See Schneider, *Anatomy of an Event*, *supra* note 218, at 69-70.

242. See MODEL PENAL CODE §§ 210.2, 210.4, available in WESTLAW (current through the May 1998 meeting of the American Law Institute) (suggesting that criminally negligent homicide is a third degree felony and murder is a first degree felony).

243. See PALMER, LAW, MEDICINE, AND SOCIAL JUSTICE, *supra* note 83, at 105.

244. See Leape, *Faulty Systems*, *supra* note 199, at 1 (condemning the disciplinary sanctions against the Dana-Farber nurses). Refer to note 110 *supra* and accompanying text (relating the criminal charges that air industry personnel faced after a crash).

with systemic approaches to safety must understand and account for the legal risks of proceeding.

D. *The Risks of Research on Patient Safety*

At present, the patient safety movement is a national movement, but the criminal and civil liability systems remain state based. The key actors in the movement, namely scholars, the American Medical Association (AMA), national pharmaceutical associations, and federal regulatory agencies such as the FDA, seek national solutions.²⁴⁵ In addition, some of these leaders, such as the National Patient Safety Foundation at the AMA, have spurred the development of state initiatives.²⁴⁶ There are legal risks both to individuals and organizations in attempting to create new knowledge about patient safety. The issue is not how to eliminate those risks, but how to minimize the legal risks while focusing on the overall goal of reducing physical risks to patients. More generally, there is legal instability because of the social, economic, and demographic changes affecting health care delivery in this country. To bring those forces into focus, we must consider a state in which the forces of managed care and liability reform over the past quarter of century are evident.

California, a state that adopted some of the 1970s reforms of the malpractice system and that is dominated by managed care,²⁴⁷ has statutory provisions protecting certain kinds of “studies” from legal discovery or from being admitted into evidence at trial. The California Evidence Code, for instance, prohibits the records of in-hospital studies aimed at reducing “morbidity or mortality” from being admitted into evidence in a civil proceeding, although they are subject to discovery.²⁴⁸ Another provision of the Evidence Code protects the records of “peer review” committees aimed at “improvement of the quality of care” from discovery in a civil action.²⁴⁹ Finally, a provision of

245. See, e.g., National Patient Safety Foundation, *News Brief* (visited Jan. 20, 2000) <http://www.ama-assn.org/med-sci/npsf/news/06_14_99.htm> (noting, for example, the NPSF collaboration with the FDA, medical and pharmaceutical industries, and public interest groups to form cooperative improvements in pharmaceutical safety).

246. For information about the various regional forums held since 1997 in Washington, Minnesota, Louisiana, Texas, Massachusetts, and Florida see <<http://www.ama-assn.org/med-sci/npsf/forums.htm>> (visited Jan. 20, 2000).

247. See Elizabeth Rolph et al., *Arbitration Agreements in Health Care: Myths and Reality*, LAW & CONTEMP. PROBS., Winter 1997, at 153, 167 (noting that California adopted statutory medical malpractice tort reforms in 1975).

248. See CAL. EVID. CODE § 1156 (West 1995).

249. See *id.* § 1157(a).

the Health and Safety Code requires health plans to have continuous review of "quality of care, performance of medical personnel, utilization of services and facilities and costs."²⁵⁰ If these quality assurance activities are performed by a "peer review committee," these records are also protected from discovery.

Within existing legislation there are some exemptions from the usual rules favoring broad discovery in civil litigation for health care organizations.²⁵¹ These exemptions are justified on the assumption that patient risk is reduced if the data is not allowed to become part of the litigation or regulatory process.²⁵² Without verifying that assumption, these types of exemptions provide the umbrella under which health care organizations can undertake research on patient safety.²⁵³

But relying solely upon the professionals within health care organizations themselves to create the new knowledge about patient safety seems inappropriate for a number of reasons unrelated to possible conflicts of interest. First and foremost, the kind of knowledge necessary for patient safety—systems knowledge about organizational processes—is not particularly the province of clinicians. Second, perhaps out of their sense of responsibility for their patients, clinicians overestimate legal risks and should not be expected to make strategic decisions about those legal risks. Third, lawyers who work within health care organizations generally see risks only in terms of litigation because of health care professionals' fear of malpractice litigation. This is perhaps another way of saying that health care clinicians and their lawyers are "conservative" and therefore unlikely to see the context for change.

But in California and elsewhere, the seeds of change in the legal environment are evident. California is one of the few states that allows mandatory arbitration of malpractice claims as a way of avoiding the excessive costs of litigation over medical injury.²⁵⁴ Recently, however, the California Supreme Court, in *Engalla v.*

250. CAL. HEALTH & SAFETY CODE § 1370 (West Supp. 1999).

251. Refer to notes 248-50 *supra* and accompanying text (citing California statutes that protect health care organizations from discovery in civil actions).

252. See Laurent B. Frantz, Annotation, *Discovery of Hospital's Internal Records or Communications as to Qualifications or Evaluations of Individual Physician*, 81 A.L.R.3d 944, 946 (1977) (establishing that many states adopted these statutes out of fear that the committees would not function effectively if their proceedings were subject to discovery).

253. See *id.*

254. See CAL. CIV. PROC. CODE §§ 1281.2, 1290.2 (West 1982) (allowing a court to compel arbitration pursuant to a contract between the patient and a health care provider).

Permanente Medical Group, Inc.,²⁵⁵ ruled that Permanente's method of implementing arbitration was potentially "fraudulent."²⁵⁶ One of the reasons for this finding was the empirical evidence that arbitration took as long as litigation.²⁵⁷ Permanente settled the case and sought to "reform" its arbitration process by providing some independent oversight of the process.²⁵⁸ The invitation to outsiders to ensure the "quality" of its arbitration process is a model for how health care organizations must pursue research on patient safety.²⁵⁹ The organizations must form partnerships with scholars to achieve their goals. These partnerships between health care professionals and researchers are more typical in the public health model than in the liability model that dominates most of the tort reform literature.²⁶⁰

California also has imposed a statutory limit on the amount of nonpecuniary damages awardable in malpractice cases. Its \$250,000 limit on the recovery of nonpecuniary loss was established in 1975 and has not been raised since.²⁶¹ Lawyers have an incentive to get around this limitation through a number of devices, including filing products liability actions to which the limitation does not apply.²⁶² If some of the proposed reforms, such as imposing liability on managed care organizations, are implemented in California, the incentive to sue the managed care organization would grow because there would be no limit on the amount of recovery for "wrongful denial" of treatment. In effect,

255. 938 P.2d 903 (Cal. 1997).

256. *See id.* at 908 (concluding that there was sufficient evidence to support the trial court's initial findings of Permanente's fraudulent conduct, but that questions of fact remained to decide if there was "actual" fraud).

257. *See id.* at 912 (observing that on average, it takes almost two and a half years to actually reach an arbitration hearing with Kaiser).

258. *See* Mark A. Kadzielski et al., *Managed Care Contracting: Pitfalls and Promises*, 20 WHITTIER L. REV. 385, 403 (explaining that Kaiser convened an independent panel that recommended the creation of an advisory group to implement an independent administrator arbitration system, the opportunity to settle cases early through mediation, and the freedom for patients to choose a single arbitrator to settle the dispute).

259. *See* David R. Olmos, *Kaiser Agrees to Alter Process of Arbitration*, L.A. TIMES, Jan. 6, 1998, at 1D. *See generally* DAVYDD J. GREENWOOD & MORTEN LEVIN, INTRODUCTION TO ACTION RESEARCH: SOCIAL RESEARCH FOR SOCIAL CHANGE 4 (1998) (defining the concept of action research in part as cooperation between people outside and inside the organization).

260. *But see, e.g.*, Bovbjerg & Sloan, *supra* note 7, at 55 (promoting a no-fault liability system for medical malpractice).

261. *See* CAL. CIV. PROC. CODE § 3333.2(b) (West 1997) (effective Sept. 24, 1975).

262. Refer to note 34 *supra* (noting that in the Martin Memorial Hospital case, the plaintiffs employed a medical products liability lawyer).

there are many threats to the “stable cost structure” surrounding patient injury and safety in California and other states.

V. CONCLUSION

Lawyers and regulators cannot mandate the new system that is needed for error reduction in health care. The system for error reduction must be created through the reiterative process that has already created the public health system in this country and throughout most of the world. At some point, law or the regulatory process might put its imprimatur upon the system of error reduction. What that legal structure *should be*—the methods by which society holds organizations and individuals accountable for the safety of the health care system—is open to question. To create that system of accountability requires new knowledge. Creating that system also requires abandoning the liability model as the paradigm for ensuring safety or inhibiting its enhancement. One of the most important roles for lawyers in these multidisciplinary efforts is to begin asking questions about the relationship of the legal environment to error reduction.

Examples of the kinds of questions lawyers might pose for researchers from a variety of disciplines are as follows: Are the “error rates” different in systems in which physicians’ risk of legal liability for malpractice has been assumed by a health care organization? And, are the “error rates” different in fee-for-service settings as opposed to managed care settings?

The seminal study on errors in medicine and malpractice—the Harvard Medical Practice Study—was done in New York State on hospital data collected in the 1980s when New York was clearly in the “fee-for-service” mode of health care delivery.²⁶³ Thus, the error rates in medicine quoted in the literature and by the National Commission are likely based upon that study. Further studies in states more in the “managed care” mode need to be conducted.

California and Massachusetts are the two states with the largest concentration of managed care enrollees in the country.²⁶⁴ In addition, some of the largest hospitals in Boston, most of them associated with the Harvard Medical School, have moved to a

263. See Brennan et al., *supra* note 6, at 370 (presenting the methodology of the Harvard study and highlighting the fact that more than 31,000 hospital records were reviewed).

264. See Steven J. Balla, *Markets, Governments, and HMO Development in the 1990s*, 24 J. HEALTH POL., POL'Y & L. 215, 215-16 (1999) (noting that “well over 35 percent” of the populations of California and Massachusetts were enrolled in managed care).

system of contractually assuming the liability of the physicians practicing in their hospitals.²⁶⁵ The theory behind this notion of “enterprise liability” is that the hospital is more careful in selecting the doctors it allows to practice in its hospital and is likely to monitor their work more closely if it pays for the malpractice claims of its physicians.²⁶⁶ The reduction of errors and injuries in anesthesiology, and the accompanying reduction in malpractice claims since the 1980s,²⁶⁷ were the results of the synergistic efforts in these hospitals.

The combination of law-and-economics thinking that has led to both the dominance of managed care and “enterprise liability” in some aspects of the Massachusetts health care delivery scene suggests that researchers might find a different error rate from that found in New York in the 1980s. This is not to suggest that the error rate is higher or lower, but that researchers should be careful to explore whether there is evidence that the legal environment is a crucial factor in reducing error rates.

For slightly different reasons, a comparison between the error rates for a similar type of high-risk health care procedure in New York and California might provide some provocative discussion of the role of law in enhancing or inhibiting patient safety. There is also a significant difference in New York and California “malpractice law”—California has a more “liberal” standard for proving malpractice in court than does New York.²⁶⁸ Yet California has one of the most restrictive limitations on the amount of damages an injured person can recover for “pain and suffering” in this country (\$250,000),²⁶⁹ while New York has no restriction.²⁷⁰ The issue that I encourage researchers to focus on

265. See Paul C. Weiler, *Fixing the Tail: The Place of Malpractice in Health Care Reform*, 47 RUTGERS L. REV. 1157, 1185 (1995).

266. See Abraham & Weiler, *supra* note 67, at 393-94.

267. See Francis H. Miller, *Medical Discipline in the Twenty-First Century: Are Purchasers the Answer?*, LAW & CONTEMP. PROBS., Winter 1997, at 31, 44 (recounting how Harvard’s shift to self-insurance prompted development of quality standards for administering anesthesia, resulting in a remarkable decrease in error rates and malpractice claims).

268. Compare *Riley v. Wieman*, 528 N.Y.S.2d 925, 928-29 (N.Y. App. Div. 1988) (summarizing a two-tiered standard in medical malpractice cases that requires doctors to conform “to accepted community standards of practice” and use their “best judgment and whatever superior knowledge, skill and intelligence” they have), *with* *Barris v. Los Angeles*, 972 P.2d 966, 971 n.1 (Cal. 1999) (restating the California standard of care as requiring physicians to “exercise that degree of skill, knowledge and care ordinarily possessed and exercised by members of their profession under similar circumstances”).

269. Refer to note 261 *supra* and accompanying text (discussing the California statute limiting noneconomic loss).

270. See, e.g., *Tort Law in New York Today*, N.Y. ST. B.J., Apr. 1999, at 8, 12 (explaining that “there are literally no limits on awards for such highly subjective

is which aspect of law—the threat of adjudication of “blame” or “fault” in court, or the threat of loss of money through a monetary award to a patient—has the greater impact on patient safety. The search for new systems of accountability is, however, also a search for appropriate methodologies for these interdisciplinary efforts. We should not assume that empirical methods of economics are the only methods to employ. There may be more sophisticated mathematical models available, such as those developed in systems engineering.²⁷¹

Systems engineering is an alternative method of generating empirical methods that will free us from some of the limitations of the law-and-economics approach of tort reformers. The mathematical models used in systems engineering were designed to study complex organizations.²⁷² In contrast, economics started with a bias towards individual behavior and contractual notions, even when discussing notions such as the “firm.”²⁷³ Systems engineering will appeal to the positivist tendency of science-trained health care professionals and to legal scholars inclined towards positivist theories of law.

At the same time, lawyers who join with health care researchers working within health organizations may have to learn some different qualitative methods. This Article suggests exploring the applicability of “action research” with its explicit critique of the positivist notion of social science.²⁷⁴ Action research, on the other hand, is a way of studying organizations and their problems that assumes that the outside researchers and those within the organization share the same goal of enhancing patient safety.²⁷⁵ Action research’s commitment to democratic research—allowing those in the organization to

injuries as emotional trauma, loss of companionship, and pain and suffering”).

271. A method of modeling used in systems engineering that might be helpful in analyzing data in large, complex health care organizations is called Data Envelopment Analysis (DEA). See Jon A. Chilingirian, *Exploring Why Some Physicians’ Hospital Practices Are More Efficient: Taking DEA Inside the Hospital*, in DATA ENVELOPMENT ANALYSIS: THEORY, METHODOLOGY, AND APPLICATION 167, 168-69 (Abraham Charnes et al. eds., 1994) (reporting on a pilot study employing data envelopment to measure physician efficiency).

272. See Boaz Golany & Yaakov Roll, *Incorporating Standards Via DEA*, in DATA ENVELOPMENT ANALYSIS, *supra* note 271, at 313-14.

273. See, e.g., Jonathan R. Macey, *Fiduciary Duties as Residual Claims: Obligations to Nonshareholder Constituencies from a Theory of the Firm Perspective*, 84 CORNELL L. REV. 1266, 1266 (1999) (addressing the “nexus of contracts” paradigm of corporate law in contrast to the law-and-economics-influenced exclusive shareholder beneficiary of fiduciary duty paradigm).

274. For a description of the field of action research, see generally GREENWOOD & LEVIN, *supra* note 259, at 4.

275. See *id.*

participate in the definition of problems and the design of research—will help to deal with the problem of obtaining cooperation from those who must undertake the risks of change—the health care professionals themselves.

The positivist tradition sees the professionals as the objects of study, whereas the action researcher proposes to engage the professionals as co-investigators in improving safety. The action researcher does not claim a detached, positivist “indifference” or “neutrality” on the issue of patient safety. Furthermore, the action researcher is more open to the “politics” of change. In other words, the messy process of public health law can be invoked to promote change within organizations while generating new knowledge for the public policy processes.

The following hypothesis is therefore proposed: the medical liability system and other regulatory processes for health care will lose their centrality as optimizers of patient safety when health care providers develop systems of detecting, reporting, and preventing medical errors that the general public views as reliable. In collaborating with the public in a dialogue over patient safety, lawyers might learn more about the public health law model that is based upon the continuous generation of new knowledge to protect the health of the community, which includes all present and future patients. If there is to be real improvement in reducing the risk of iatrogenic injury to patients, we must find those improvements in the less than ideal world of constrained professionals and constrained legal institutions. Freeing ourselves from the liability model allows us to develop methods for incorporating the growth of new knowledge for the benefit of the “system of health” through political negotiation, new methods of education for professionals, and perhaps reformulation of some doctrine or agency practices.

We simply do not know enough about the safety within health care organizations to know what aspects of law are most in need of reform. A public health perspective, as a heuristic device, considers the possibility that the least amount of legal intervention helps to maintain a dynamic equilibrium between health care delivery and patient safety.