The Legal Liability Regime: How Well Is It Doing in Assuring Quality, Accounting for Costs, and Coping with an Evolving Reality in the Health Care Marketplace?

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The Legal Liability Regime: How Well Is It Doing In Assuring Quality, Accounting For Costs, and Coping With an Evolving Reality In The Health Care Marketplace?

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I. INTRODUCTION

This brief Essay will focus, in somewhat truncated fashion, on the following broad set of questions: How well does the legal liability regime deal with selected current issues? The Essay will raise some issues regarding the current state of liability law and relate those issues to current health policy concerns such as quality assurance and cost containment. I will conclude that some premises of liability law have been called into question and are in need of rethinking.

II. DIFFERENT WAYS OF THINKING ABOUT MEDICAL CARE AND THEIR IMPLICATIONS

 Fundamental to an understanding of a discussion of the legal liability regime is an awareness of competing visions of medical care1 – the professional model and an economic model.2 These competing visions are broad categories, and elements of both must exist. The analytical issue typically is not whether to select either category or paradigm to the exclusion of the other. Rather, the critical question is to determine where along a con-

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tinuum between the competing visions public policy (such as tort law) should be located.

A. The Different Models

1. The Professional Model: Assumptions and Implications

The professional paradigm reflects an approach to perceived market failure – an asymmetry of information. It observes the lack of knowledge on the part of consumers of health care and the scientific expertise of physicians – the providers of health care. The professional model substitutes professional control of decision-making for that of consumers.

This vests authority to determine quality and volume of services (and ultimately costs) on professional providers. One assumption is that patients are uninformed and that the market cannot function properly in the face of such consumer ignorance. Another assumption is that medical care follows a scientific approach to diagnosis and treatment. That is, diagnosis and treatment decisions are based on scientific evidence – scientific certainty in the most unreconstructed version. Financial incentives do not (empirically) and should not (normatively) affect professional judgment, which is based on scientific criteria.

The professional paradigm allowed for the development of the existing third-party payment system in medical care. At least until the advent of managed care, the professional model and its assumption that the flow of dollars would not affect levels of utilization allowed for and justified minimal oversight of professional judgment and, basically, an expectation by providers and consumers that third-party payers would write a blank check to implement the professional judgment of physician-providers. Much of the impetus behind the federal patients' bill of rights legislation seems driven by its vision of medical care as comporting with this professional paradigm.

Under the professional model, patients are assumed to be unable to become adequately informed about their own medical care. This suggests that patients are somewhat passive recipi-

3. For a discussion of the significance of the asymmetry of information in the medical care marketplace between the expert physicians and the uninformed consumers, see Kenneth Arrow, Uncertainty and the Welfare Economics of Medical Care, 53 AM. ECON. REV. 941 (1963).
4. Id. For a critique of Arrow's analysis, see PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 226-27 (1982).
5. Blumstein, Economics-Free Zone, supra note 2.
ents of medical care, unable to play a "pivotal role." Because of their expertise, professional providers (physicians) exercise control over medical care decision-making, and, because of the scientific nature of the decision-making at stake and the professional nature of those providers making the decisions, those decisions are unaffected (and should be unaffected) by economic considerations.

Medical decisions are conceived of as technical judgments that rely on scientific knowledge. The only legitimate questions are scientific: Is the diagnosis or proposed course of treatment medically appropriate? Appropriateness in that context means asking whether the procedure or treatment is "safe and effective." If the answer is "yes," then the proper role of the third-party payer is "merely to write a check and not ask questions." In that environment, marketplace considerations such as cost-effectiveness or "cost-benefit trade-offs are not only seen as irrelevant, but as corruptive of medical judgments."

2. The Market Model: Assumptions and Implications

A number of the assumptions underlying the traditional professional model have been called into question. For example, incentives seem to have an effect on behavior in medical care decision-making, "both among providers and consumers." As the growth of medical information websites attests, patients have a desire to learn more about the issues that relate to their own medical care and appear capable of absorbing much relevant information. The recognized existence of clinical uncertainty, moreover, raises important questions about the assumption that science commands a single pathway of diagnosis or treatment. Further, many decisions often characterized as "medical" typically involve a variety of nonmedical personal preferences as well, a reality that suggests a greater role for consumers in the decision-making process. "In short, personal preferences and economic trade-offs matter, and incentives

6. Id.
7. Id.
8. Id.
9. Id.
10. See, e.g., Barbara J. McNeil, The Shattuck Lecture – Hidden Barriers to Improvement in the Quality of Care, 345 N. ENG. J. MED. 1612, 1612 (2001) (noting that "[u]ncertainty influences virtually all of medical decision making" and that "[m]any sources have documented" that clinical uncertainty).
influence conduct. . . . Medical care looks more like a market than many believed (or feared)." 11

The market-oriented response to consumer ignorance is consumer education, improving the flow of information to patients. This can occur directly from provider (e.g., physician or expanded-role nurse) to patient, 12 or indirectly through trusted information intermediaries upon whose judgment patients can rely. 13 The market model contemplates a greater role in decision-making for patients; in this vision, payers and consumers should have a substantial role regarding levels of quality and overall levels of service (quantity provided). 14 This economic model has been adapted into the world of medical care and is known as shared decision-making. 15 The goal is to recognize and make use of incentives to achieve balanced decisions that account for both medical and economic considerations, as is the case in a typical market transaction.

12. For a discussion of the importance of improving the flow of information to patients, see James F. Blumstein & Frank A. Sloan, Redefining Government's Role in Health Care: Is a Dose of Competition What the Doctor Should Order?, 34 VAND. L. REV. 849, 902-08 (1981) (noting that "[s]ince patients are typically not medical experts, they must rely on their physicians for the information upon which to base their decisions") [hereinafter Blumstein & Sloan].
13. An information intermediary could be an organization such as Consumers Union, which through its Consumer Reports rates items according to specified criteria, or an entity such as a fiduciary, whose judgment a consumer would trust. For good discussions of the role of information intermediaries, see WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF TORT LAW 285 (1987); William M. Sage, Regulating Through Information: Disclosure Laws and American Healthcare, 99 COLUM. L. REV. 1701, 1737-41 (1999). A physician could be such an intermediary, providing information as required by the doctrine of informed consent. Blumstein & Sloan, supra note 12, at 902-08 (noting importance of physicians and providers as a source of information for patients under the doctrine of informed consent). For a general discussion of how a relatively small number of informed consumers can discipline a market, see REGINA HERZLINGER, MARKET DRIVEN HEALTH CARE: WHO WINS, WHO LOSES IN THE TRANSFORMATION OF AMERICA'S LARGEST SERVICE INDUSTRY (1997).
15. The degree of disclosure to patients regarding risks and benefits of different surgical procedures can affect procedure rates. Joseph F. Kasper, et al., Developing Shared Decision-Making Programs to Improve the Quality of Health Care, 18 QUALITY REV. BULL. 183, 184 (June 1992).
B. Implications

The different ways of thinking about medical care – the different paradigms – result in significantly different perceptions regarding the nature of medical care decision-making and the propriety of considering economic factors in that process.

If one believes that medical care decision-making does in fact and normatively should reflect an exclusive focus on science,\(^\text{16}\) use of economic criteria in such decision-making is anathema.\(^\text{17}\) Highly charged terms such as “rationing”\(^\text{18}\) and “corruption”\(^\text{19}\) of medical judgment have been applied to such uses of economic factors in the context of medical care decision-making. After all, under the professional paradigm, medical care deci-

\(^{16}\) This professional model is sometimes linked with a normative premise – an access-egalitarian view – that market-based economic factors should play no role in the allocation of medical resources. For example, some commentators have argued that medical need is the only acceptable basis for allocating scarce medical resources. See, e.g., Rand E. Rosenblatt, *Rationing “Normal” Health Care: The Hidden Legal Issues*, 59 Tex. L. Rev. 1401, 1403-04 (1981) [hereinafter Rosenblatt].

\(^{17}\) James F. Blumstein, *Regulatory Review by the Executive Office of the President: An Overview and Policy Analysis of Current Issues*, 51 Duke L.J. 851, 882 (2001) (stating that “[s]ome courts have reacted harshly, even punitively, to the market-oriented model. This is what one would expect from a clash of paradigms—when a decisionmaker with one model in mind confronts a set of decisions based upon a different paradigm”) [hereinafter Blumstein, Regulatory Review].

\(^{18}\) See, e.g., Blumstein, *Visions of Medical Care*, supra note 1, at 1467-68 (noting that use of the term rationing “reinforces the tenet of the professional paradigm that medical care service decisions are scientific and technical in character, without a substantial economic dimension”); James F. Blumstein, *Distinguishing Government’s Responsibility in Rationing Public and Private Medical Resources*, 60 Tex. L. Rev. 899, 906-11 (1982) (noting difference in government’s role in allocating or rationing public resources from its role in dictating the allocation or rationing of resources in the private sphere) [hereinafter Blumstein, *Distinguishing Government’s Responsibility*]; James F. Blumstein, *Rationing Medical Resources: A Constitutional, Legal, and Policy Analysis*, 59 Tex. L. Rev. 1345, 1347-48 (1981) (noting that in a market economy resources are allocated to their most efficient use - *i.e.*, rationed) [hereinafter Blumstein, *Rationing Medical Resources*]. For a more neutral use of the term rationing, see Pegram v. Herdrich, 530 U.S. 211, 221 (2000) (“[W]hatever the HMO, there must be rationing and inducement to ration”); Mark Hall, *Making Medical Spending Decisions: The Law, Ethics, and Economics of Rationing Mechanisms* (1997). If, as some commentators have argued, medical need is the only acceptable basis for allocating scarce medical resources, see, e.g., Rosenblatt, *supra* note 16, at 1403-04, then that forecloses the option of allowing economic criteria to apply to medical care decisionmaking and “obliterates the distinction between government’s need to ration public funds and its questionable role in rationing private funds.” Blumstein, *Distinguishing Government’s Responsibility*, supra at 906.

\(^{19}\) See, e.g., Muse v. Charter Hosp. of Winston-Salem, Inc., 452 S.E.2d 589, 595 (N.C. Ct. App. 1995) (sustaining an award of punitive damages and finding the medical decision in question, which was influenced by the defendant hospital’s economic considerations, to be wanton and willful because it interfered with a physician’s purely medical judgment), aff’d, 464 S.E.2d 44 (N.C. 1995).
sion-making is and should be based exclusively on scientific criteria. Such an approach would suggest pursuit of a single right way of doing things, based on science (and, from an access-egalitarian perspective, available to all patients on the basis of medical need). When that mind-set confronts the economic model, which advocates the virtues of pluralism in the marketplace and the desirability of choice based on individual preferences and stratified resource availability, the mix can be predictably combustible. "The confrontation between market and professional paradigms can generate considerable vitriol." 20

III. THE LEGAL LIABILITY REGIME: THE DOCTRINE AND ITS ASSUMPTIONS

A. The Doctrine: A Few Basics

In a medical malpractice action, "the plaintiff has the burden of establishing (a) the appropriate standard of care, (b) breach of that standard of care, and (c) a causal relationship between the breach of the standard and the medical injury." 21 The standard of care is typically based on professional norms; 22 a plaintiff must establish the standard of care by use of expert testimony. 23

"In ordinary tort cases, the defendant's compliance with custom is admissible, but not binding on the jury." 24 That is, custom is a factor to be considered and evaluated by a fact-finder in the determination of negligence, but it is not determinative of the inquiry. 25 In medical malpractice actions, on the other hand, conventional doctrine relies on the "customary practices of the medical profession as the benchmark of acceptable behavior." 26

22. W. PAGE KEETON, ET AL., PROSSER AND KEETON ON TORTS § 32, at 189 (5th ed. 1984) (traditional tort law "gives the medical profession... the privilege, which is usually emphatically denied to other groups, of setting their own legal standards of conduct, merely by adopting their own practices").
The "customary practice" rule has expanded its once-narrow geographic scope so that it is normally described as customary practice in the same or similar community.\footnote{27} The customary practice approach is "essentially an empirical inquiry that focuses on the ways things are customarily done in the medical community."\footnote{28} It has been criticized in some quarters because specific institutional arrangements in medical care financing would suggest that professional standards of customary practice may not result in a "socially optimal level of care."\footnote{29} The prevalence of third-party medical insurance allows patients and providers to "overutiliz[e] medical resources" because they are "partially free[d] . . . from cost constraints in choosing among treatments."\footnote{30} Hence, for those commentators, use of the "customary practice" standard may bias the standard of care in an inappropriate upward direction since, among other things, "decision-makers often lack the [financial] incentive or the ability to make appropriate choices among such solutions."\footnote{31}

Other critics rebel at the notion of delegating the standard of care to a profession. Rather than worrying, on cost-containment grounds, that the "customary practice" standard inappropriately ratchets levels of care up to unwarranted levels, these commentators express concern that the profession is in a position to retain sub-optimally low levels of care, essentially insulating itself from external scrutiny and accountability. Such commentators advocate "that the empirical inquiry embodied in the customary practice standard . . . be modified by a normative judgment about the propriety of the customary practice."\footnote{32} This is sometimes labeled the "acceptable practice" standard,\footnote{33} and some courts have adopted that approach.\footnote{34} While the case has been made that courts have shown less deference to customary practice in recent years - that the black letter rule that customary practice controls in medical malpractice actions is no longer re-


\footnote{28} Blumstein, \textit{Cost Containment and Medical Malpractice}, supra note 21, at 89; \textit{see also} Peters, \textit{supra} note 24, at 165 ("In theory at least, the jury determines what the customary practice is. It does not decide what the custom ought to be").

\footnote{29} Henderson & Siliciano, \textit{supra} note 26, at 1393.

\footnote{30} \textit{Id.}

\footnote{31} \textit{Id.} at 1394.

\footnote{32} Blumstein, \textit{Cost Containment and Medical Malpractice}, \textit{supra} note 21, at 89.

\footnote{33} Joseph King, \textit{In Search of a Standard of Care for the Medical Profession: The "Accepted Practice" Formula}, 28 \textit{VAND. L. REV.} 1213 (1975).

\footnote{34} \textit{See, e.g.}, Blair v. Eblen, 461 S.W.2d 370, 373 (Ky. 1970).
flective of an empirical reality, the customary practice rule is still perceived as the controlling understanding of the law of medical malpractice.

B. The Doctrine: Some of Its Premises and Assumptions

The reliance on a professional standard seems premised on an understanding of medical care that comports with the professional paradigm. That is, it "appears to be premised on the notion that there is a single correct way to provide medical care," which is scientifically driven. The deference to customary practice reflects a belief that science determines the propriety of a diagnosis or treatment decision, that professional decision-makers have the knowledge to determine what standards are dictated by the scientific evidence, and that economic trade-offs have virtually no role in the medical care decision-making process. If economic considerations, which inhere in traditional notions of the determination of negligence - weighing the costs and benefits of conduct in determining what levels of safety are required - are empirically or normatively inappropriate factors to consider in making medical care decisions, then it is unsurprising that the law of torts would reflect that traditional understanding. The customary practice standard is a manifestation of the traditional acceptance of the professional model.

Under conventional medical malpractice doctrine, a plaintiff must establish the standard of care and prove that there has been a deviation from that standard. Thus, not only is the standard based on professional norms, it is based on the assumption that science has established a single or unitary standard of practice and that unitary standard is in fact implemented uniformly by the medical profession. In addition, the "single-standard-of-care philosophy is based on an . . . access-egalitarian philosophy that calls for equality of access to medical care for all, irrespective of preferences and irrespective of resource availability." A particularly rigid application of this approach is the requirement that a physician apply the prevailing customary standard without deviation: "[W]hen a particular mode of treatment is upheld

35. Peters, supra note 24, at 187-88 ("The era of uniform deference to physician norms clearly is over. Modern malpractice law is moving slowly away from a custom-based standard of care and toward a reasonable physician standard").
36. Id. at 204 (contending that reduced reliance on customary practice in medical malpractice doctrine "has gone largely unnoticed").
37. Blumstein, Cost Containment and Medical Malpractice, supra note 21, at 89.
38. Id. at 91.
by a consensus of opinion among the members of the profession, it should be followed by the ordinary practitioner; and if a physician sees fit to experiment with some other mode, he should do so at his peril.

For practitioners, the "respectable minority" rule provides some relief from the constraint of medical orthodoxy, and it is somewhat of an acknowledgment that even a scientifically-based professional norm may spawn scientifically-based disagreements and, therefore, a form of scientifically-validated pluralism. The "respectable minority" rule serves as an accommodation for the exercise of clinical judgment, holding that "a physician does not incur liability merely by electing to pursue one of several recognized courses of treatment." The term "respectable" encompasses both a normative or qualitative dimension – that a school of thought is recognized as "respectable" by practitioners in the field – and a quantitative dimension – that a school of thought is practiced by a considerable number of practitioners in the field so that it fairly represents an actual school of thought and not just an outlying idiosyncrasy.

While some recognition of pluralism is accommodated by the "respectable minority rule," the rule itself is based on scientific premises and criteria. It is a professional standard but acknowledges that professional disagreements can occur and that science allows for different schools of thought to coexist peacefully. The rule, in essence, provides something of a safe harbor for those professional/scientific disagreements. Whether, as a matter of doctrinal principle, the "respectable minority" rule can be adapted to an economic paradigm that allows for cost-benefit analysis is unclear. As a matter of pragmatism,

39. Jackson v. Burnham, 39 P. 577, 580 (Colo. 1895); see also Blumstein, Rationing Medical Resources, supra note 18, at 1397 ("Where private medical practitioners seek to engage in cost containment rationing on their own, they risk running afoul of either the customary or accepted practice rule").


41. See, e.g., Jones v. Chidester, 610 A.2d 964, 969 (Pa. 1992) ("Where competent medical authority is divided, a physician will not be held responsible if in the exercise of his judgment he followed a course of treatment advocated by a considerable number of recognized and respected professionals in his given area of expertise").

42. Cf. Blumstein, Rationing Medical Resources, supra note 18, at 1399 ("Mechanical application of customary practice standards to HMOs could reduce their ability to adopt innovative styles of practice. Perhaps the respectable minority principle can offset this risk for HMOs, or perhaps courts can be persuaded to adopt an 'HMO custom' approach to govern malpractice actions against HMOs"). See generally Randall Bovbjerg, The Medical Malpractice Standard of Care: HMOs and Customary Practice, 1975 Duke L.J. 1375, 1386 (noting that “[t]he malpractice standard of care

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however, once there is a shift in practice styles (even if driven by economic considerations under managed care), a new practice-style reality creates a school of practice that could qualify for protection, provided that it meets both the qualitative and the quantitative requirements of the "respectable minority" doctrine.\footnote{43} But the "respectable minority" doctrine "exposes innovators who depart from dominant medical practice to serious legal risks until such time as others follow their lead."\footnote{44}

The scientific aspirations of the unitary, professional standard of practice, linked to the access-egalitarian ideal, have sought validation and reinforcement through expansion of the geographic domain of the uniform standard principle. "At one time, the plaintiff had to show that the defendant had deviated from local custom. Most courts no longer make local custom the benchmark, opting instead to measure the defendant against the standards in similar localities or nationwide."\footnote{45}

The "locality rule," now in demise, allowed for a pluralistic standard of care based on geography. That is, under the locality rule, the "standard of care had a geographic frame of reference"\footnote{46} and "gave tacit recognition to the possible existence of multiple standards of care across geographical areas."\footnote{47} But, in the name of science and uniformity, many courts have abandoned the locality rule, for generalists\footnote{48} as well as specialists.\footnote{49}

\footnotesize{applied to HMO health care services is the same as that governing medical services generally" and suggesting an HMO custom approach).}

\footnote{43. For a discussion of this phenomenon, see Mark A. Hall, The Malpractice Standard Under Health Care Cost Containment, 17 LAW, MED. & HEALTH CARE 347, 348-49 (1989) [hereinafter Hall, Malpractice Standard].}

\footnote{44. Clark C. Havighurst, Prospective Self-Denial: Can Consumers Contract Today to Accept Health Care Rationing Tomorrow?, 140 U. PA. L. REV. 1755, 1779 (1992).}

\footnote{45. Peters, supra note 24, at 166 n.15.}

\footnote{46. Blumstein, Cost Containment and Medical Malpractice, supra note 21, at 90.}

\footnote{47. Id.}

\footnote{48. See, e.g., Hall v. Hilbun, 466 So. 2d 856, 867 (Miss. 1985); Shilkret v. Annapolis Emergency Hosp. Ass'n., 349 A.2d 245, 249 (Md. 1975). With respect to general practitioners, "there is something of a trend toward the abandonment of the locality rule," although the "similar-locality rule for nonspecialists still survives in some places." CLARK C. HAVIGHURST, ET AL., HEALTH CARE LAW AND POLICY: READINGS, NOTES, AND QUESTIONS 1062-63 (2d ed. 1998) [hereinafter HAVIGHURST, ET AL., HEALTH CARE LAW AND POLICY]. In some jurisdictions, limits on the qualifications of experts restore some geographical dimension to the standard of care. In Tennessee, for example, an expert witness must come from Tennessee or a contiguous state. Ralph v. Nagy, 749 F. Supp. 169, 174 (M.D. Tenn. 1990).}

\footnote{49. See, e.g., Jordan v. Bogner, 844 P.2d 664, 666 (Colo. 1993) (en banc) ("[A] physician who holds himself or herself out as a specialist in a particular field of medicine is measured against a standard commensurate with that of a reasonable physician practicing in that specialty"). The locality rule has largely been abandoned for}
The conventional justification for abandoning the locality rule—and it is a powerful one—has been quality improvement, a sense that medical backwaters cannot be allowed to persist to the detriment of patients in those areas. Thus, courts could “with reason and fairness” expect that a physician should “possess or have reasonable access to such medical knowledge as is commonly possessed [by] or reasonably available to minimally competent physicians in the same specialty or general field of practice throughout the United States.” At the same time, the demise of the principle that customary practice should include a geographic component seems in part driven by a view “that professional standards [are] national in scope.” That is, “the demise of the locality rule conformed to professional notions that there should be a single proper way of managing a patient in a specified circumstance” and reinforced acceptance of the professional/scientific account of medical care. “Courts seized on the improvements in communication, transportation, and educational opportunities to reject” the principle that geography should control liability, thereby providing an important legal bulwark for the professional paradigm.

IV. How Well Does the Doctrine Cope With Some Current Issues?

In this Part, I consider whether the existing medical malpractice doctrine makes a good match with certain current issues or realities in the healthcare field.

board-certified specialists “except where statutes have reintroduced a more localized standard.” HAVIGHURST, ET AL., HEALTH CARE LAW AND POLICY, supra note 48, at 1061.

50. Hall, 466 So.2d at 871.

51. Blumstein, Cost Containment and Medical Malpractice, supra note 21, at 90.

52. Id.

53. Id. The Mississippi Supreme Court has noted “that the locality rule ha[s] two components – professional expertise and resource availability. While modern communications, transportation, and the availability of continuing educational opportunities suggested that the professional expertise rationale for the locality rule no longer applied, the differences in resource availability between geographic areas suggested that the standard of care could not reasonably be identical in all circumstances across geographical areas.” Id.; see also Hall, 466 So. 2d at 872-73. For an assessment of the demise of the locality rule, tentatively raising some issues in its defense, see HAVIGHURST, ET AL., HEALTH CARE LAW AND POLICY, supra note 48, at 1065.

54. For a discussion of other legal-institutional bulwarks of the professional model, see Blumstein, Visions of Medical Care, supra note 1, at 1469-74.
A. The Challenge of Clinical Uncertainty

Dr. John Wennberg has pioneered research that shows dramatic and scientifically unexplained variations in medical practice across geographic regions.55 These data call into the question the hard scientific basis of much medical practice,56 and advocates of the strict scientific viewpoint have been critical of this variation.57 Strikingly, the variations are unaccompanied by comprehensive data to answer the fundamental question of which practice style is most effective clinically.58 This, of course, has been an embarrassment to the profession, and predictably the result has been a thrust for increased research expenditures on the “outcomes” and “effectiveness” of medical care; the goal is to “develop ‘evidence-based’ diagnostic and therapeutic recommendations for each medical condition.”59 That is, the response of the adherents of the professional/scientific paradigm has been to develop better science to restore the confidence in the scientific ideal.60


56. Other differences observed in the literature relate to resource intensity by different types of practitioners, Sheldon Greenfield, et al, Variations in Resource Utilization Among Medical Specialties and Systems of Care, 267 J. Am. Med. Ass’n 1624 (1992), and possibly hospitalization and lengths of stay, James R. Knickman & Anne-Marie Foltz, A Statistical Analysis of Reasons for East-West Differences in Hospital Use, 22 INQUIRY 45 (1985) (finding that West Coast residents spent 40% fewer days in the hospital than East Coast residents); but see Paul D. Cleary, et al., Variations in Length of Stay and Outcomes for Six Medical and Surgical Conditions in Massachusetts and California, 266 J. Am. Med. Ass’n 73 (1991) (finding no consistent East-West difference in length of stay but also finding statistically significant and important length-of-stay differences among hospitals).


58. See Mark Chassin, et al., Variations in the Use of Medical and Surgical Services by the Medicare Population, 314 N. ENG. J. MED. 285 (1986) (demonstrating significant variations in procedure rates and acknowledging that they did not know the “correct” use rate for the various procedures).


60. Those seeking to restore the scientific ideal would tend to favor formulation and adoption of clinical practice guidelines as a regulatory technique for establishing uniformity in clinical practice as conceptualized under the professional/scientific ideal. Advocates of a pluralistic approach, which would be sensitive to concerns of cost-
In the meantime, however, the existence of clinical uncertainty as reflected in variable practice data calls into question the infrastructure of medical malpractice law. The law is premised on acceptance of the unitary and uniform standard promised by the professional/scientific paradigm. But that ideal is not reflective of the actual reality in how much of medicine is practiced. To ask an expert witness to state what the professional standard of care is – what the "customary practice" is on a national basis – is to ask a question to which there cannot be, for many diagnosis and treatment decisions, a coherent answer. The purely empirical question regarding "customary practice" is a question that can have widely divergent answers depending on – yes – geography, the criterion that has been so widely scorned as antithetical to the scientific ideal. As a purely empirical matter, the "customary practice" question, for so many areas of practice, has no unitary response. Experts can look at certain geographic areas, perhaps, to answer the question, or the expert can introduce a normative element in responding to the question, but experts cannot really answer the national "standard of care" question empirically for many areas of practice. The absence of good outcomes data on these issues makes the problem even more troubling. This leaves the issue to fact-finders to resolve on grounds other than observed empiricism or scientific evidence of outcomes in many circumstances. And that, in turn, raises the question whether experts in those contested areas can even be asked to testify reliably under the current standards governing the admissibility of expert testimony.61

If the professional standard, as reflected by the "customary practice" rule, is subject to criticism and reevaluation, it may be appropriate to consider alternatives, such as unifying medical malpractice doctrine with the rest of tort law under the reasonably prudent practitioner standard.62 Such a step would require dealing with the unitary standard of care issue, since a tradi

consciousness and to consumer/payer preferences as reflected in private contracting would view the role of such guidelines differently – as grounds for specifying different levels or styles of service through private choice. Clark C. Havighurst, Practice Guidelines as Legal Standards Governing Physician Liability, LAW & CONTEMP. PROBS., Spring 1991, at 87.


62. There is some evidence that the courts have been moving in this direction, at least tacitly. See Peters, supra note 24, at 201-05.
tional tort standard could allow for pluralism or stratification. Provided that such a traditional tort standard allowed for consideration of such special factors as practice style (thereby accommodating HMOs and other managed care environments)\(^{63}\) and resource availability (thereby recognizing that medical insurance is not monolithic and that resource availability varies),\(^{64}\) multiple standards might emerge in recognition of pluralistic patterns of medical care, of different resource constraints, and of patient/payer preferences (as reflected in private contracts).

**B. The Threat to Quality from Systemic Errors**

In 1999, the prestigious Institute of Medicine (IOM), a division of the National Academy of Sciences, issued a report\(^{65}\) whose “central message” was that “errors are caused by faulty systems not by faulty people.”\(^{66}\) The remedy proposed by the IOM for this systems shortcoming was systems re-design. This thesis had been presented in the literature,\(^{67}\) but “[f]ew publications in recent memory have had the impact” of that IOM report.\(^{68}\)

Probably the most attention-getting finding of the IOM report was that between 44,000 and 98,000 patients die each year because of “adverse events” in medical care, with over a million people being injured by medical treatment each year.\(^{69}\) While “[t]here is considerable dispute over the accuracy of these numbers,”\(^{70}\) there can be no dispute that concern about medical errors has become commonplace.\(^{71}\)

\(^{63}\) See Blumstein, *Cost Containment and Medical Malpractice*, supra note 21, at 95; Blumstein, *Rationing Medical Resources*, supra note 18, at 1399; Bovbjerg, *supra* note 42, at 1408-14.

\(^{64}\) See Hall v. Hilbun, 466 So.2d at 872-73.

\(^{65}\) *COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, INSTITUTE OF MEDICINE, TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Krohn, et al. eds., 2000) [hereinafter To ERR Is HUMAN].


\(^{68}\) Leape, *Foreword, supra* note 66, at 145.

\(^{69}\) Id. at 146.


By emphasizing a systems approach to the problem of medical error and patient safety, the IOM report seeks to shift the focus of quality assurance away from an approach characterized by a "blaming frame of reference," which has traditionally emphasized "an intensely personal responsibility: insuring safe care." In its place, the IOM report advocates an emphasis on "systems theory," whose premise is that "human errors are caused by systems failures."

The systems-oriented thrust of the IOM report is in considerable tension with many traditional assumptions and premises of medical malpractice doctrine. Some of the IOM recommendations pose direct challenges to traditional medical malpractice norms and understandings. For example, a systems approach focuses on quality assurance through improved systemic management techniques and processes. It relies on improved communication, which in turn depends on securing a flow of timely and accurate information. A systems strategy encourages development of error-reporting systems and data-collection systems, and to achieve these goals the strategy would provide incentives for participants in the process to report accurately and candidly (or at least minimize disincentives for such reporting).

It is clear that achievement of these goals can be impeded by traditional principles of medical malpractice, which deal with quality issues by deterring poor quality of care through liability of individuals and institutions that negligently commit errors that cause harm to patients. Many of the strategies advocated in the IOM systems approach, such as protections from discovery for error-reporting and the elimination of identifying characteristics from data collected, would make imposition of legal liability more difficult or impossible. Indeed, the systems approach advocated by the IOM, in essence, views traditional medical malpractice doctrine, itself justified as a form of quality assurance as well as a mechanism for victim compensation, as something of an impediment to achieving patient safety.

The IOM systems approach, and its deemphasis on individual responsibility or accountability through legal liability, has its critics. For example, Professor Stephen Latham has cautioned against a rush toward adoption of the IOM systems approach, at least at the total expense of the traditional medical malpractice

72. Leape, Foreword, supra note 66, at 147.
73. Id. (emphasis in original).
74. To Err Is Human, supra note 65, at 109-31 (Chapter 6).
He is concerned that the systems approach is overly antiseptic, cleansing the commission of error from human responsibility or accountability. In the IOM systems world, he writes, individuals do not err, "they are merely the instrumentalities of error" since the "[e]rror happens through them." Individuals are acted upon by a system and, in effect, are passive players in a system's design.

Latham contrasts the IOM vision with the legal notion of accountability and responsibility, in which an injury "result[s] from wrongdoing (including failure to meet a required standard of care)." Medical malpractice law seeks to "locate a specific wrongdoing causal agent, whether personal or institutional, from whom compensation can be demanded." For Latham, the IOM approach is "an attempt to claim the phenomenon of medical error for medicine and to wrest it from law's grasp." This is the "medicalization of medical error," and Latham interestingly places the debate in jurisdictional terms – whether quality assurance remains within the ken of the legal system or whether it becomes transferred to the medical sphere – a "jurisdictional incursion" by medicine into law.

At the end of the day, Latham concludes that the IOM systems approach makes sense for patient safety: "If you want patient safety – and you do – the IOM's prescriptions seem to be the correct ones." But even if patient safety is much improved, there will be cases of avoidable injury, a need for compensation, and perhaps some role for traditional notions of liability in the cause of deterrence and quality assurance. The true believers in the systems approach reject even this residual role for tort, but one is left to wonder whether the systems approach can do away entirely with individualized notions of responsibility and accountability. The entire substitution of management for liability requires a leap of faith that many will be unwilling to make.

Thus, the issue for hard thought is how to accommodate the insights of the IOM systems approach to medical error with a

75. Latham, supra note 70, at 164-65.
76. Id. at 166.
77. Id. at 175.
78. Id.
79. Id.
80. Id.
81. Id. at 177.
82. Id. at 179.
83. Leape, Foreword, supra note 66, at 147.
residual role for medical malpractice. The evidence of clinical uncertainty suggests that a total reliance on science is risky. The special problems associated with management of professionals and the particular difficulties associated with the management of healthcare institutions leave the analyst reluctant to cede total jurisdiction to the medicalization of medical error. Yet, it is also clear that the IOM insights regarding a systems approach require some hard rethinking of the existing regime of medical malpractice liability doctrine. Current doctrine may well stand in the way of (instead of advancing) improvements in quality of care, precisely the opposite of the objective of the traditional tort system. Constructive dialogue and flexibility rather than true-believing adherence to either the traditional tort system or IOM's systems approach will be needed to reach the doctrinal hybrid that will be needed.

C. Accounting for Cost Considerations

Traditional negligence principles involve a weighing of costs and benefits. The professional practice standard in medical malpractice delegates the authority to set standards of practice to the medical profession, but it does so in the name of science not economics. On the basis of scientific expertise and the asymmetry of information between physicians and patients/laypersons, the professional/scientific paradigm justifies recognition of professional standards under the "customary practice" standard.

In the world of science, the focus is on the course of diagnosis or treatment that leads to the best outcome for an individual patient. The traditional balancing of costs and benefits is not acknowledged in the professional/scientific paradigm, even if some theorists recognize that professional standards at least implicitly take economic criteria into account. Indeed, some courts view the introduction of economic trade-offs into medical

84. The special problems of managing healthcare institutions stem in part from the separation and autonomy of the medical staff of a hospital from its management. This autonomous medical staff is required by the accreditation standards of the Joint Commission on Accreditation of Health Care Organizations. Blumstein, Competing Visions of Medical Care, supra note 1, at 1470-71. Hospital managers have considerably less authority over the conduct of their medical staff than managers in other spheres. In the hospital setting "coax and cajole" rather than "command and control" are the watchwords of management-medical staff interaction. For insights on management issues in the hospital setting, see Stephen M. Shortell, Effective Hospital-Physician Relationships (1991).

85. See, e.g., Eddy, Clinical Decision Making, supra note 59, at 2.
care decision-making to be corrosive or corruptive of the medical care decision-making process.\textsuperscript{86}

The unitary standard stands as a bulwark against the introduction of economic considerations into medical care decision-making.\textsuperscript{87} The scientific ideal of uniformity is in tension with the economic perspective that a marketplace contemplates pluralism, based on consumer/payer preferences and resource availability.\textsuperscript{88} That is, "the unitary standard principle is premised on a professional aspiration: that medical protocols are scientifically based and that therefore there is a single appropriate mode of treatment under a given set of circumstances."\textsuperscript{89} It is also built on a "certain view of access-egalitarianism: that modes of treatment should not vary among patients because of differential levels of resource availability or private preferences regarding priorities."\textsuperscript{90} But the unitary standard concept does not fit well with the goal of cost-containment programs. In order to accommodate cost-containment initiatives, "a critical threshold issue is whether the law will countenance multiple standards of care or whether it will continue to impose, at least in theory, a unitary standard of customary practice as the yardstick by which to measure malpractice liability."\textsuperscript{91}

Under a pluralistic system of practice, which would include different levels of resource availability and varied private cost-containment efforts, one might anticipate the evolution of multiple standards of care and styles of practice. "This would mirror the typical pattern in other economic sectors of the economy, and it would reflect existing practice," but "recognition of pluralistic patterns of medical care conflicts with traditional norms."\textsuperscript{92}

\textsuperscript{86} See, e.g., Muse v. Charter Hosp. of Winston-Salem, Inc., 452 S.E.2d at 595.
\textsuperscript{87} Blumstein, Competing Visions of Medical Care, supra note 1, at 1468-69.
\textsuperscript{88} Id. As one commentator has put it colorfully, "variability in patients, illnesses, and possible therapeutic responses often will make the notion of an established custom a quaint fairy tale." Peters, supra note 24, at 187.
\textsuperscript{89} Blumstein, Cost Containment and Medical Malpractice, supra note 21, at 94.
\textsuperscript{90} Id.
\textsuperscript{92} Blumstein, Cost Containment and Medical Malpractice, supra note 21, at 94. It may be that the customary practice standard is up to the task of accommodating cost-sensitive decisionmaking. For example, Professor Mark Hall has argued that customary practice standards will adapt to cost-containment initiatives over time. The "respectable minority" principle could help once a new reality is established. See Mark
There is some evidence that, in practice, the law of medical malpractice as actually implemented varies from the nominal traditional professional paradigm. Having canvassed cases decided in numerous jurisdictions, Professor Philip Peters contends that state courts have tended to bring medical malpractice doctrine into closer accord with typical negligence doctrine in other areas. That is, Peters contends that "[j]udicial deference to physicians' customs is quietly eroding," with a significant number of courts "phras[ing] the duty owed by physicians in terms of reasonability." According to Professor Peters, "[m]odern malpractice law is moving slowly away from a custom-based standard of care and toward a reasonable physician standard."

Movement to a "reasonable physician" standard, when linked to the "respectable minority" doctrine, does potentially hold some promise for accommodating cost-containment objectives into liability law. Professor Peters suggests, as one possible implication of the shift in doctrine he identifies, that the "reasonable physician standard of care provides the flexibility needed to evaluate customs imposed on patients by managed care organizations." However, he also acknowledges that courts have not "defended their abandonment of customary practice standards as a way of freeing cost-conscious, socially responsible physicians from the profligate overtreatment encouraged by fee-for-service reimbursement." Quite the contrary is reflected in the cases Professor Peters discusses – cases that find that the customary practice standard is insufficiently protective of patient interests in quality. Unless medical malpractice doctrine can, in the process of moving toward a "reasonable physician" approach, accept some level of pluralism and recognize that resource availability and practice style are factors that should be encompassed in the reasonableness inquiry, liability law will not


94. *Id.*
95. *Id.*
96. *Id.* at 187-88.
97. *Id.* at 203.
98. *Id.* at 192.
99. *Id.* at 170-72.
be fully successful in coping with the necessity for cost contain-
ment in the modern health care context.  

V. Conclusion

The traditional professional/scientific paradigm has controlled
thinking about medical care, and the traditional regime of legal
liability is premised on that paradigm. It is also premised on
certain normative access-egalitarian assumptions that have been
called into question. The modern healthcare context reflects a
marketplace reality and approach. In the economic market-
place, economic issues are salient. The professional model must
bend a bit to accommodate the market reality, especially as evi-
dence of clinical uncertainty and other factors increasingly call
into question the underlying premises and assumptions of the
purely professional/scientific approach.

To effectuate this accommodation, modern legal liability law
must be receptive to pluralistic patterns of practice and to the
reality that costs matter in the medical decision-making calculus.
The apparent move to a “reasonable physician” standard holds
some promise if the “customary practice” standard is not seen as
a straitjacket to innovative and reasonable strategies of evi-
dence-based practice. Such a standard could create a risk of an
even more rigid system than currently in existence, but if it ac-
cepts resource availability and style of practice as appropriate
factors to weigh in the balance, it may hold some promise for a
realistic resolution of the problems.

On the front of patient safety, malpractice doctrine faces an-
other challenge—the challenge not of over-deterrence but of
counter-productivity. If the IOM report’s emphasis on manage-
ment and systems as vehicles for improving patient safety are
correct, malpractice doctrine may be standing in the way of
measures aimed at assuring quality, the very rationale for retain-
ing a tort-based liability system rather than moving to a less ex-

cpensive system that focuses exclusively on compensating

100. Ways in which malpractice doctrine could accommodate pluralism might in-
clude (1) allowing for the modest reintroduction of locality factors for resource (but
not skill) aspects of a malpractice case; (2) allowing private contracting for specific
types of standards of care; (3) perhaps allowing for contracting for choice-of-law rules
that would apply the standards of a particular jurisdiction with expert witnesses drawn
from that jurisdiction as governing legal liability in a contractual relationship (see
Dukes v. U.S. Healthcare, Inc., 57 F.3d 350, 359 n.5 (3d Cir. 1995)); or (4) allowing for
a “reasonable HMO” standard, which accommodates resource availability and prac-
tice style.

http://lawcommons.luc.edu/annals/vol11/iss1/8
victims. This, indeed, is the prescription that supporters of the IOM approach advocate. Proposals for no-fault proposals are not new. But the IOM report provides an occasion to revive consideration of those proposals, perhaps with an eye toward accommodating some of the concerns raised by critics of the hard version of the IOM approach.

