

5-2006

Medical Malpractice Standard-Setting: Developing Malpractice "Safe Harbors" as a New Role for QIOs?

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VANDERBILT LAW REVIEW

VOLUME 59

MAY 2006

NUMBER 4

Medical Malpractice Standard-Setting: Developing Malpractice “Safe Harbors” as a New Role for QIOs?

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I. INTRODUCTION

Concern about medical malpractice issues has reemerged, again stemming from escalating costs in some geographic regions and sectors of medical practice. The Bush Administration has (so far unsuccessfully) supported¹ a cap² on noneconomic loss as a strategy for coping with the cost aspects of those medical malpractice concerns,³ the model being the California approach.⁴

1. Catherine M. Sharkey, *Unintended Consequences of Medical Malpractice Damages Caps*, 80 N.Y.U.L. REV. 391, 394 (2005) (reporting on the Bush Administration's support for a \$250,000 cap on noneconomic damages in medical malpractice cases).

2. By the end of the 1980s, most states had capped awards in some fashion. Randall R. Bovbjerg, *Legislation on Medical Malpractice: Further Developments and a Preliminary Report Card*, 22 U.C. DAVIS L. REV. 499, 525 (1989). Most caps apply to nonpecuniary, not other, components of damages. Randall R. Bovbjerg et al., *Valuing Life and Limb in Tort: Scheduling "Pain and Suffering,"* 83 NW. U. L. REV. 908, 957 (1987). *But see* Etheridge v. Medical Center Hosps., 376 S.E.2d 525 (Va. 1989) (upholding against constitutional challenge Virginia's total damage cap in medical malpractice actions of \$750,000); *Boyd v. Bulala*, 877 F.2d 1191 (4th Cir. 1989) (same). For criticism of flat caps, see Bovbjerg et al., *supra*, at 957–58 (proposing a system of a flexible range of floors and ceilings as an alternative to a flat cap). For a thoughtful recent proposal to address the problem of valuing noneconomic loss, see Ronen Avraham, *Putting a Price on Pain-and-Suffering Damages: A Critique of the Current Approaches and a Preliminary Proposal for Change*, 100 NW. U. L. REV. 87, 110 (2006).

3. For a critique of the legitimacy of damages for noneconomic loss, see, e.g., Joseph H. King, Jr., *Pain and Suffering, Noneconomic Damages, and the Goals of Tort Law*, 57 SMU L. REV. 163 (2004); Bovbjerg et al., *supra* note 2, at 931–32 (cataloguing arguments against awards for noneconomic loss). For a proposal to limit noneconomic loss recoveries through a system of incentives, see Jeffrey O'Connell et al., *An Economic Model Costing "Early Offers" Medical Malpractice Reform: Trading Noneconomic Damages for Prompt Payment of Economic Damages*, 35 N.M. L. REV. 259 (2005). For arguments maintaining the validity of damage awards for nonpecuniary loss, see James F. Blumstein, *Making the System Work Better: Improving the Process for Determination of Noneconomic Loss*, 35 N.M. L. REV. 401, 409–11 (2005) [hereinafter Blumstein, *Making the System Work Better*] (arguing in favor of controlling but not eliminating jury discretion in making nonpecuniary damage awards); Ronen Avraham, *Should Pain-And-Suffering Damages Be Abolished from Tort Law? More Experimental Evidence*, 55 U. TORONTO L.J. 941 (2005) (contending that sovereign consumers would demand pain-and-suffering insurance and concluding that pain-and-suffering damages advance the goals of tort law); Bovbjerg et al., *supra* note 2, at 932–36 (arguing that pain-and-suffering damages advance the insurance goal of tort law); Steven P. Croley & Jon D. Hanson, *The Nonpecuniary Costs of Accidents: Pain-and-Suffering Damages in Tort Law*, 108 HARV. L. REV. 1785 (1995) (arguing that pain-and-suffering damages are not against consumer interests); Mark Geistfeld, *Placing a Price on Pain and Suffering: A Method for Helping Juries Determine Tort Damages for Nonpecuniary Injuries*, 83 CAL. L. REV. 773 (1995) (providing a model for determining the amount of pain-and-suffering damages). For skepticism about the viability or legitimacy of the

Although the overall initiative for reform has considerable merit,⁵ the damage-cap has its opponents and its drawbacks.⁶ The damage-cap approach is remedy-centric, focusing on the scope of remedy as a vehicle for containing costs in the area of medical malpractice. By concentrating on remedies, the reform of damage caps assumes that a plaintiff can establish liability, as remedial issues traditionally follow in the wake of and as a consequence of a finding of liability.

In earlier work, colleagues and I have addressed the remedy issue, focusing on damages for noneconomic loss.⁷ The objective was to develop a way to improve the system for awarding damages for noneconomic loss.⁸

The approach to reform put forward in this Article looks at the medical-malpractice cost-containment issue in a different way. Like the work on noneconomic damages, it is designed to improve the functioning of the system; unlike that earlier work, however, its focus is not on the remedy—damages issues—but on the determination of liability. The systemic improvement is designed to allow for the appropriate consideration of trade-offs between quality and risk on the one hand and cost on the other.

That is, the approach developed in this Article is designed to deal with the systemic cost-escalation aspects of the medical

distinction between economic and noneconomic loss, see Heidi Li Feldman, *Loss*, 35 N.M. L. REV. 375 (2005) (arguing that both pecuniary and nonpecuniary losses are injuries to welfare); Ellen Smith Pryor, *The Tort Law Debate, Efficiency, and the Kingdom of the Ill: A Critique of the Insurance Theory of Compensation*, 79 VA. L. REV. 91, 91–106, 125–36 (1993) (advocating rejection of the insurance theory of compensation); Neil K. Komesar, *Injuries and Institutions: Tort Reform, Tort Theory, and Beyond*, 65 N.Y.U. L. REV. 23, 58 (1990) (arguing that prevention is another important goal of tort law).

4. In 1975, California adopted a statutory cap on nonpecuniary damages for medical malpractice actions in the amount of \$250,000. CAL. CIV. CODE § 3333.2 (2006). No provision for upward adjustment for inflation was included. *Id.* See *Fein v. Permanente Med. Group*, 695 P.2d 665, *appeal dismissed*, 474 U.S. 892 (1985) (upholding cap on nonpecuniary damages in medical malpractice actions against constitutional challenge). *Cf.* *Etheridge v. Medical Center Hosps.*, 376 S.E.2d 525 (Va. 1989) (upholding against constitutional challenge Virginia’s total damage cap in medical malpractice of \$750,000); *Boyd v. Bulala*, 877 F.2d 1191 (4th Cir. 1989) (same).

5. See Blumstein, *Making the System Work Better*, *supra* note 3, at 409–15 (noting that noneconomic awards are the most variable component of damages but also an appropriate component); Bovbjerg et al., *supra* note 2, at 936–65 (arguing for the validity of noneconomic damages and the need for structured decisionmaking).

6. See *supra* note 2.

7. See Bovbjerg et al., *supra* note 2 (suggesting three methods for calculating nonpecuniary damages); James F. Blumstein et al., *Beyond Tort Reform: Developing Better Tools for Assessing Damages for Personal Injury*, 8 YALE J. ON REG. 171 (1991) (offering two proposals for reforming damage calculations in specified circumstances).

8. *Cf.* Blumstein, *Making the System Work Better*, *supra* note 3, at 409–13 (developing scenario proposal for improved jury determination of noneconomic loss).

malpractice issue through modification of the process for determining standards of liability in targeted areas. This reflects a different, albeit complementary, approach to problems of medical-malpractice cost escalation—a departure from the remedy-focused policy issues that have traditionally dominated the medical malpractice reform debate for years. The unit of inquiry is not on the damages component of the medical negligence liability system but on the standards of conduct themselves under the liability regime.⁹ A particular reason for concern about liability standards for medical malpractice is the prevalence of third-party payment for medical care, which both creates incentives for increased utilization of services¹⁰ and provides the financial vehicle for implementing that increased level of utilization.

It is an objective of the torts system to deter certain risky conduct—conduct that is deemed inappropriately risky, all things considered. Providers are expected to respond to and conform their behavior to standards of conduct set through the tort-liability-determination process. The often-stated-but-hard-to-define problem of defensive medicine¹¹ is a claim by providers that over-deterrence is occurring in medical practice.¹² Providers, according to this account,

9. Cf. James F. Blumstein, *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?*, 11 ANNALS HEALTH L. 125, 130 (2002) [hereinafter Blumstein, *The Legal Liability Regime*] (focusing on the standard of liability in medical negligence cases); E. HAAVI MORREIM, HOLDING HEALTH CARE ACCOUNTABLE: LAW AND THE NEW MEDICAL MARKETPLACE (2001) (considering medical malpractice liability standards in the context of cost-containment objectives); James F. Blumstein, *Cost Containment and Medical Malpractice* [hereinafter Blumstein, *Cost Containment and Medical Malpractice*], in HEALTH CARE DELIVERY AND TORT: SYSTEMS ON A COLLISION COURSE? 89 (Elizabeth Rolph ed., 1993) [hereinafter Rolph] (discussing how to accommodate cost-containment objectives with medical malpractice liability standards).

10. James A. Henderson, Jr. & John A. Siliciano, *Universal Health Care and the Continued Reliance on Custom in Determining Medical Malpractice*, 79 CORNELL L. REV. 1382, 1393 (1994).

11. See TOM BAKER, THE MEDICAL MALPRACTICE MYTH 118-19 (2005) (noting the problem of defining “defensive medicine” and the need for “distinguishing between the good, injury-prevention effects of malpractice lawsuits and the bad, wasteful effects”). Defensive medicine comes in a “negative” and a “positive” form. “When physicians avoid high-risk patients or procedures to the detriment of patient health, they are practicing negative defensive medicine. When physicians engage in precautionary treatment with minimal expected medical benefit relative to the cost of the treatment, they are practicing positive defensive medicine.” Daniel P. Kessler & Mark B. McClellan, *The Effects of Malpractice Pressure and Liability Reforms on Physicians’ Perceptions of Medical Care*, LAW & CONTEMP. PROBS. Winter 1997, at 81, 82 n.11. For an early empirical study of defensive medicine, see Project, *The Medical Malpractice Threat: A Study of Defensive Medicine*, 1971 DUKE L. J. 939.

12. One study of defensive medicine defined it in relevant part as follows: “Defensive medicine occurs when doctors order tests, procedures, visits, or avoid high-risk patients or procedures, primarily (but not necessarily solely) to reduce their exposure to malpractice liability.” U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, DEFENSIVE MEDICINE AND MEDICAL MALPRACTICE, OTA-H-602, at 3 (1994). Under that definition, some defensive medicine

conform their behavior to the uncertain risk of being found negligent despite adhering to best, socially optimal practices.¹³ Responding to an uncertain (and in some practical sense unknowable-in-advance) norm or standard of practice can raise the cost of medical practice, both to the payer and to the provider, above an optimal level. In this sense, the medical malpractice system, which is linked to practice styles already influenced upward by the prevalence of third-party payment,¹⁴ may result in sub-optimal over-deterrence and higher costs unjustified by their correlative benefits.

A premise of this Article is that the desired cost-containment reformist goals underlying strategies such as caps on certain elements of damages (e.g., pain and suffering) may be advanced by an improved *process* of determining negligence and of determining standards of practice themselves.¹⁵

may be beneficial, since conforming behavior to a negligence-generated standard of conduct may result in optimal levels of quality. Only defensive medicine, so defined, that results in over-deterrence—in ordering tests “whose expected benefits are very low” because “physicians’ tolerance for uncertainty about medical outcomes” has been pushed to “very low levels” or to the “lowest possible level,” *id.*, and whose costs are unjustified by the putative benefits—is sub-optimal. For a good discussion of this issue, see Daniel Kessler & Mark McClellan, *Do Doctors Practice Defensive Medicine?*, 111 Q.J. ECON. 353, 356 (1996) (noting that inappropriate defensive medicine occurs when physicians take “excessive precaution . . . such that the marginal social benefit of precaution would be less than the marginal social cost”).

13. For expressions of skepticism of the defensive medicine account, see BAKER, *supra* note 11, at 134 (concluding that “the overall impact of . . . defensive medicine on health-care costs is not very large”); Michelle M. Mello & Troyen A. Brennan, *Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform*, 80 TEX. L. REV. 1595, 1606–07 (2002) (noting that overdeterrence “rhetoric has not been firmly grounded in fact”). For recent survey evidence of “widespread” defensive medicine practices among physicians in certain high-risk specialties, see David M. Studdert et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 JAMA 2609, 2612, 2615 (2005) (analyzing survey data). See also Daniel P. Kessler et al., *Effects of the Medical Liability System in Australia, the UK, and the USA*, 368 LANCET 240 (2006) (reviewing “findings of empirical studies that estimate the effects of tort law on medical care” and concluding that “[a]t least for the USA and UK, there is systematic evidence of defensive medicine”).

14. See Henderson & Siliciano, *supra* note 10, at 1392–93 (observing that widespread use of health care insurance causes the overutilization of medical resources).

15. See BAKER, *supra* note 11, at 135 (“If doctors had a clear, evidence-based standard for deciding when to order a test or a procedure, then they could . . . be more confident that they were doing the right thing. And they should be more confident that they would not be held liable for any unfortunate result”). It is undoubtedly true that “blaming the liability system as the sole cause of spending on unnecessary procedures and tests is problematic.” David A. Hyman & Charles Silver, *The Poor State of Health Care Quality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution?*, 90 CORNELL L. REV. 893, 938 (2005). That, of course, does not mean that the liability system is exonerated for its contributory role in encouraging (providing an incentive toward) defensive practices. It may be that defensive practices (over-deterrence of cost-containment activities) are more likely to occur on the part of physicians than on the part of managed care organizations. There is “some reason to believe that managed care organizations are better positioned to process liability signals than are individual clinicians,” since “managed care organizations are in the business of spreading risk, and, with time and

II. MEDICAL MALPRACTICE DOCTRINE: IN GENERAL

A. *Some Conceptual Background*

“Fundamental to an understanding of a discussion of the legal liability regime is an awareness of competing visions of medical care—the professional model and an economic model.”¹⁶ The professional model builds on what its adherents take to be a foundational insight—that doctors and patients face a market failure, an asymmetry of information.¹⁷ Patients lack information and knowledge; physicians possess scientific expertise. “The professional model substitutes professional control of decision-making for that of consumers,” with medical decisions being “conceived of as technical judgments that rely on scientific knowledge” and in which the “only legitimate questions are scientific.”¹⁸

The market model recognizes that a “number of the assumptions underlying the traditional professional model have been called into question,” observing that, contrary to the tenets of the professional/scientific paradigm,¹⁹ “incentives seem to have an effect on behavior in medical care decision-making.”²⁰ In this view, market failure from asymmetric information is addressed by improving the flow of information to patients, thereby empowering them.²¹ In addition, the existence of clinical uncertainty²² “raises important questions about the assumption that science commands a single

experience, should be more able to gauge their response to the increased risk of liability.” Gail B. Agrawal & Mark A. Hall, *What If You Could Sue Your HMO? Managed Care Liability Beyond the ERISA Shield*, 47 ST. LOUIS L.J. 235, 270–71 (2003).

16. Blumstein, *The Legal Liability Regime*, *supra* note 9, at 125. For a discussion of these competing visions of medical care, see James F. Blumstein, *Health Care Reform and Competing Visions of Medical Care: Antitrust and State Provider Cooperation Legislation*, 79 CORNELL L. REV. 1459, 1463–69 (1994) (discussing the professional and market paradigms).

17. See Kenneth Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941 (1963) (noting the significance of the asymmetry of information between expert physicians and uninformed patients/consumers).

18. Blumstein, *The Legal Liability Regime*, *supra* note 9, at 126–27.

19. *Id.* at 126 (noting that, under the professional model, “[f]inancial incentives do not (empirically) and should not (normatively) affect professional judgment, which is based on scientific criteria”). For a skeptical discussion of the effect of financial incentives in clinical decisionmaking, see David M. Frankford, *Managing Medical Clinicians’ Work Through the Use of Financial Incentives*, 29 WAKE FOREST L. REV. 71 (1994).

20. Blumstein, *The Legal Liability Regime*, *supra* note 9, at 127.

21. *Id.* at 128.

22. See, e.g., Barbara J. McNeil, *The Shattuck Lecture – Hidden Barriers to Improvement in the Quality of Care*, 245 N. ENG. J. MED. 1612, 1612 (2001) (noting the prevalence of clinical uncertainty).

pathway of diagnosis or treatment.”²³ Under the market model, “[t]he 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.”²⁴

The implications of the different paradigms—the “different ways of thinking about medical care”²⁵—for a legal liability regime are considerable: “If one believes that medical care decision-making does in fact and normatively should reflect an exclusive focus on science, use of economic criteria in such decision-making is anathema,” a “‘corruption’ of medical judgment,” since it diverts attention from the scientific ideal (“pursuit of a single right way of doing things”) to an approach that “advocates the virtues of pluralism in the marketplace and the desirability of choice based on individual preferences.”²⁶

B. The “Customary Practice” Standard of Care

Conventional medical malpractice doctrine is clearly located in the space of the professional paradigm and adheres to the assumptions of that paradigm. It is built on the professional/scientific model.

Medical malpractice doctrine relies on a professional standard and delegates standard-setting to the physician, as professional, through that professional standard.²⁷ The assumption—consistent with the scientific model—is that the profession (from its expertise) knows what works and that it has adopted and applied a scientifically-derived standard of practice. That is, a core assumption of conventional medical malpractice doctrine is that, as a scientific matter, a standard of practice exists and that, as an empirical matter, practitioners conform their conduct to that standard.

This vision is doctrinally embodied in the customary practice standard of medical liability. Medical malpractice doctrine relies on the “customary practices of the medical profession as the benchmark

23. Blumstein, *The Legal Liability Regime*, *supra* note 9, at 127.

24. *Id.* at 128.

25. *Id.* at 129.

26. *Id.* at 129–30.

27. For discussion of the use of private standards in lawmaking in a different context, see Lawrence A. Cunningham, *Private Standards in Public Law: Copyright, Lawmaking and the Case of Accounting*, 104 MICH. L. REV. 291 (2005) (discussing the government’s adoption of and use, in performing a regulatory function, of standards that have been developed, promulgated, and even copyrighted by nongovernmental organizations).

of acceptable behavior.”²⁸ The customary practice standard must be established by appropriate expert medical testimony.²⁹

Adherence to the customary practice approach is “essentially an empirical inquiry that focuses on the ways things are customarily done in the [relevant] medical community.”³⁰ That is “[i]n theory at least, the jury determines what the customary practice *is*. It does not decide what the custom *ought* to be.”³¹ This contrasts with the theory in ordinary tort cases in which “the defendant’s compliance with custom is admissible, but not binding on the jury,”³² and in which juries are charged with weighing risks and benefits to determine what behavior is deemed culpable as negligent.

In short, conventional medical malpractice doctrine is firmly rooted in the professional/scientific paradigm, “premised on the notion that there is a single correct [scientifically derived] way to provide medical care.”³³ Reliance on and 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.”³⁴ Thus, the professional standard governing medical liability is based on professional norms and on the “assumption that science has established a single or unitary standard of practice and that unitary standard is in fact uniformly implemented in the medical profession.”³⁵

The customary practice standard is operationalized in medical malpractice doctrine by requiring a plaintiff to establish: “(a) the appropriate standard of care, (b) breach of that standard of care, and

28. Henderson & Siliciano, *supra* note 10, at 1384.

29. Hood v. Phillips, 554 S.W.2d 160, 165–66 (Tex. 1977).

30. Blumstein, *Cost Containment and Medical Malpractice*, *supra* note 9, at 89.

31. Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 164 (2000) [hereinafter Peters, *The Quiet Demise of Deference to Custom*]. Professor Peters has also noted that, in a medical malpractice case, conventional doctrine contemplates that “the jury’s inquiry is positive, rather than normative.” Philip G. Peters, Jr., *The Role of the Jury in Modern Malpractice Law*, 87 IOWA L. REV. 909, 920 (2002); see also James F. Blumstein, *Rationing Medical Resources: A Constitutional, Legal, and Policy Analysis*, 59 TEX. L. REV. 1345, 1396 (1981) [hereinafter Blumstein, *Rationing Medical Resources*] (same).

32. Peters, *The Quiet Demise of Deference to Custom*, *supra* note 31, at 164.

33. Blumstein, *Cost Containment and Medical Malpractice*, *supra* note 9, at 89.

34. Blumstein, *The Legal Liability Regime*, *supra* note 9, at 132.

35. *Id.*; cf. Agrawal & Hall, *supra* note 15, at 285 (“‘Medical custom’ as a legal standard of care is based on a fallacy: that there exists one single correct medical response to every clinical problem and moreover that this single correct response is, and should be, determined without reference to cost.”).

(c) a causal relationship between the breach of the standard and the medical injury."³⁶

In tort generally, use of customary practice as a benchmark is often seen as a market-validated standard that appropriately (*i.e.*, optimally) balances costs and benefits, risks and rewards. In the medical liability context, however, that market-validation has been called into question as not reflecting a "socially optimal level of care."³⁷ 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."³⁸ Thus, the argument has been made that use of the "customary practice" standard may bias the standard in an inappropriate, sub-optimal upward direction since, among other things, "decisionmakers often lack the [financial] incentive or the ability to make appropriate choices among such solutions."³⁹

Other critics "rebel at the notion of delegating the standard of care to a profession."⁴⁰ For these commentators, the focus is not on the potential for ratcheting *up* levels of care inappropriately but on the ability of the medical profession "to retain sub-optimally low levels of care, essentially insulating itself from external scrutiny and accountability."⁴¹ 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."⁴² This is sometimes labeled the "accepted practice" standard,⁴³ and some courts have adopted that approach.⁴⁴ Indeed, Professor Peters has identified a movement away from the "customary practice" standard to a "reasonable physician" standard, driven by a judicial belief that the customary practice standard is insufficiently protective of patients' interest in quality.⁴⁵

36. Blumstein, *Cost Containment and Medical Malpractice*, *supra* note 9, at 89.

37. Henderson & Siliciano, *supra* note 10, at 1393.

38. *Id.*

39. *Id.* at 1394.

40. Blumstein, *The Legal Liability Regime*, *supra* note 9, at 131.

41. *Id.*

42. Blumstein, *Cost Containment and Medical Malpractice*, *supra* note 9, at 89.

43. See generally Joseph H. King Jr., *In Search of a Standard of Care for the Medical Profession: The "Accepted Practice" Formula*, 28 VAND. L. REV. 1213 (1975) (defining, analyzing, and advocating the "accepted practice" standard of care).

44. See, e.g., *Blair v. Ehlen*, 461 S.W.2d 370, 373 (Ky. 1970) (holding that a physician has "a duty to use that degree of care and skill which is expected of a reasonably competent practitioner in the same class to which [the physician] belongs, acting in the same or similar circumstances").

45. Peters, *The Quiet Demise of Deference to Custom*, *supra* note 31, at 170-72; see also Peters, *The Role of the Jury*, *supra* note 31, at 913-17 (same).

As a practical matter, if “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.”⁴⁶ As one court has stated, “when a particular mode of treatment is upheld 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.”⁴⁷ Rigid and mechanical application of customary practice standards in managed care, therefore, “could reduce [HMOs] ability to adopt innovative styles of practice,” which would allow for consideration of cost-containment objectives.⁴⁸

C. The Problem of Uncertainty

From the perspective of liability standards, the key strategic issue is how to develop standards for the regime of medical liability that are consistent with the twin objectives of promoting and maintaining high (optimum) levels of quality and accommodating the important objective of containing medical care costs.⁴⁹ What are the implications for system design and resource allocation when clinical and structural uncertainty exist?⁵⁰

1. Clinical Uncertainty: Its Embarrassing Implications

Recognition of the existence of clinical uncertainty stems from evidence of wide variation in practice patterns unexplained by outcomes data.⁵¹ The existence of clinical uncertainty is an embarrassment⁵² to adherents to the professional/scientific model

46. Blumstein, *Rationing Medical Resources*, *supra* note 31, at 1397.

47. *Jackson v. Burnham*, 39 P. 577, 580 (Colo. 1895).

48. Blumstein, *Rationing Medical Resources*, *supra* note 31, at 1399.

49. See generally MORREIM, *supra* note 9 (examining the problems associated with incorporating cost factors when imposing medical liability on physicians and health plans and proposing reshaped legal standards to address these issues); Rolph, *supra* note 37.

50. For a discussion of the impact that uncertainty might have on physician decisionmaking, see Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PENN. L. REV. 645, 647–48 (2001).

51. See, e.g., John W. Wennberg, *Variation in Use of Medicare Services Among Regions and Selected Academic Medical Centers: Is More Better?*, COMMONWEALTH FUND PUB. NO. 874, at 4 (Dec. 2005) [hereinafter Wennberg, *Variation in Use of Medicare Services*] (noting “striking regional variations in the proportion of early stage breast cancer patients who undergo lumpectomy” and identifying “idiosyncratic practice style” as the “major source of such widely varying discretionary surgery rates”).

52. While the existence of clinical uncertainty calls into question the underlying scientific basis of medicine, the resulting discretion gives physicians “considerable freedom and power,” encroachments on which have been resisted. Hyman & Silver, *supra* note 15, at 952–53.

because it challenges the underlying scientific foundation of that model. In a fundamental way and in many areas of practice, the widespread existence of clinical uncertainty calls into question a cornerstone of medical malpractice law—the assumption that there is a professionally determined and scientifically validated standard of care.

Health services research, pioneered by Dr. John E. Wennberg of Dartmouth Medical School, shows dramatic and scientifically unexplained variations in medical practice patterns across geographic regions—clinical uncertainty.⁵³ “These data call into question the hard scientific basis of much medical practice, and advocates of the strict scientific viewpoint have been critical of this variation.”⁵⁴ These variations in clinical practice “are unaccompanied by comprehensive data to answer the fundamental question of which practice style is most effective clinically.”⁵⁵ These findings have spurred intense efforts at outcomes research to improve knowledge in these areas of clinical uncertainty.⁵⁶

The long and the short of it is that “the existence of clinical uncertainty as reflected in variable practice data calls into question the infrastructure of medical malpractice law.”⁵⁷ The question at the heart of medical liability litigation—what is the “customary practice” on a national basis with regard to a certain field of practice—“is ... a question to which there cannot be, for many diagnosis and treatment decisions, a coherent answer.”⁵⁸

This suggests that, as an alternative to the “customary practice” approach, it may be appropriate to “unify[] medical malpractice doctrine with the rest of tort law under the reasonably

53. See, e.g., JOHN E. WENNBERG ET AL., *THE DARTMOUTH ATLAS OF HEALTH CARE IN THE UNITED STATES* (Megan McAndrew Cooper ed., 1996) (demonstrating substantial geographic variation in the provision of health care services). More recent work shows variation in practice patterns among hospitals rated as the best by U.S. News & World Report, some in the same community. See Wennberg, *Variation in Use of Medical Services*, *supra* note 51, at 12 (observing that even among hospitals “selected for their reputations for high-quality care,” there was a marked difference “in the way they managed severely ill Medicare patients . . . even among hospitals in the same state or city”).

54. Blumstein, *The Legal Liability Regime*, *supra* note 9, at 136 (citation omitted). See generally Lucian L. Leape, *Error in Medicine*, 272 *JAMA* 1851 (1994) (discussing the sources of medical errors and their impact on clinical treatment).

55. Blumstein, *The Legal Liability Regime*, *supra* note 9, at 136. See generally 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 various procedures).

56. See *infra* Part III.A (discussing the influence that the data on clinical uncertainty has had on the movement for development of practice guidelines).

57. Blumstein, *The Legal Liability Regime*, *supra* note 9, at 137.

58. *Id.*

prudent practitioner standard,”⁵⁹ which could allow for “consideration of such special factors as practice style (thereby accommodating HMOs and other managed care environments) and resource availability (thereby recognizing that medical insurance is not monolithic and that resource availability varies).”⁶⁰

2. Structural Uncertainty

Customary practice standards are not typically written down; they are traditionally established by expert testimony in a court in the context of a medical liability action. That is, they are not only imprecise but not definitively established until after a medical injury has occurred, a context in which a *risk* of injury (an *ex ante* perspective) has been transformed into an *ex post reality*. The context is that of an identified individual⁶¹ victimized by an adverse outcome.

Under current medical malpractice doctrine, therefore, controlling professional standards are set or at least operationalized *ex post* by selectively drawn expert witness testimony—not by a process in which a known organization systematically establishes in advance a standard of practice that governs the determination of liability. This after-the-fact process of professional standard-setting creates structural uncertainty—the uncertainty imposed by the liability system attributable to this *ex post* method of determining liability.

If structural uncertainty induces unwarranted and costly precautions—as the “defensive medicine” account teaches⁶²—then patients may face more cost and risk while not actually receiving

59. *Id.*

60. *Id.* at 138; see *Hood v. Phillips*, 554 S.W.2d 160, 165 (Tex. 1977) (adopting reasonable prudent physician standard); MORREIM, *supra* note 9, at 55–79 (exploring the legal liability issues associated with health plans’ control over physicians’ treatment decisions and advocating an approach that balances health plans’ and physicians’ relative expertise in allotting clinical control); Randall Bovbjerg, *The Medical Malpractice Standard of Care: HMOs and Customary Practice*, 1975 DUKE L.J. 1375, 1386 (suggesting an HMO-custom standard of care); Peters, *The Role of the Jury*, *supra* note 31, at 958–67 (advocating substitution of reasonable physician standard for professional customary practice standard).

61. For a discussion of the significance of context in medical care decisionmaking—*i.e.*, the impact of medical decisions on “clearly identifiable individuals”—, see James F. Blumstein, *Constitutional Perspectives on Governmental Decisions Affecting Human Life and Health*, LAW & CONTEMP. PROBS., Autumn 1976, at 231, 250–53.

62. See Daniel P. Kessler & Mark B. McClellan, *How Liability Law Affects Medical Productivity*, 21 J. HEALTH ECON. 931, 946–48 (2002) (observing that “greater malpractice pressure leads to significant increases in [certain] hospital expenditures ... but not to important changes in health outcomes,” thereby suggesting that “greater malpractice pressure” promotes defensive medicine); Kessler & McClellan, *supra* note 12, at 388 (concluding that “treatment of elderly patients with heart disease does involve ‘defensive’ medical practices, and that limited reductions in liability can reduce these costly practices”).

additional (or at least warranted) protection against clinical uncertainty. This suggests that careful attention must be devoted to structural as well as clinical uncertainty. The shaky infrastructure of the "customary practice" standard for medical liability (derived from clinical uncertainty) is exacerbated by the *ad hoc* and *ex post* nature of its implementation (structural uncertainty).

3. Implications

The existence of clinical uncertainty "leaves the issue to factfinders to resolve on grounds other than observed empiricism or scientific evidence of outcomes in many circumstances."⁶³ 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."⁶⁴ The uncertainty of the standards places medical practitioners in the uncomfortable position of not knowing what is expected or what is required to avoid liability. The cost implications of such uncertainty and the costly steps necessary to overcome that uncertainty may be substantial, as the defensive medicine account of cost escalation asserts.

Clinical uncertainty (the uncertainty associated with the imprecise nature of medical malpractice standards of practice) is exacerbated by structural uncertainty (the *ex post* nature of the process for determining the applicable standard). At the time of diagnosis or treatment, the physician is unable to determine with precision what the appropriate standard of care is. The standard is only knowable *ex post*, after a medical injury has occurred, when a factfinder determines (based on competing versions of expert testimony) what the standard is.⁶⁵

Of course, this observation is generically applicable to tort standards, which are only knowable *ex post*. But an important distinction exists between conventional tort standards and medical

63. Blumstein, *The Legal Liability Regime*, *supra* note 9, at 137.

64. *Id.* See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589–92 (1993) (discussing the reliability and relevance requirements that must be satisfied for expert testimony to be admissible); see also *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151–52 (1999) (noting that *Daubert's* objective "is to ensure the reliability and relevancy of expert testimony . . . [and] to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field").

65. The existence of clinical uncertainty "essentially allows the jury to impose, based on its own independent judgment, the governing standard of care—the very result malpractice law attempts to avoid." Mark A. Hall, *The Defensive Effect of Medical Practice Policies in Malpractice Litigation*, LAW & CONTEMP. PROBS., Spring 1991, at 119, 129 [hereinafter Hall, *Defensive Effect*].

malpractice standards. A tort defendant under the typical reasonable prudent person standard may defend its conduct on the ground that the behavior is reasonable—that it reflects a prudent balance of risks, costs, and benefits. Custom is only evidence of the negligence standard.

In medical malpractice cases, that normative defense is unavailable. In the traditional model of medical malpractice liability, a physician is unable to defend his or her conduct on the basis that it reflects a reasonable accommodation of the various risks, costs, and benefits. The inquiry in medical malpractice cases is, at least in theory, an empirical one: what is the customary practice of physicians in the same or similar jurisdiction (or nationally in many circumstances)? Failure to conform to that customary practice standard means failure to conform to the law since the customary practice of peer physicians is not just evidence of the standard but the standard itself. To the extent that normative balancing enters into the calculation, that balancing is done by the profession in establishing the pattern of customary practice.⁶⁶

Accordingly, the stakes for physicians are, on theoretical grounds, much higher on this dimension alone. Deviation from customary practices is a deviation from the tort-imposed standard; a defense of reasonableness under the circumstances is unavailable. The consequence for the physician is that the uncertainty of *ex post* standard-setting is of considerably greater moment. Absent an ability to defend against a medical malpractice claim on the ground of reasonableness, the physician has a powerful incentive to conform to the obligatory customary practice standard. Its imprecision and its determination *ex post* may lead to rational conforming behavior—defensive medicine—that overshoots the mark of optimal precaution.

66. The “respectable minority” doctrine is a limited restraint on this in that it “give[s] flexibility to the exercise of clinical judgment” by allowing physicians to escape liability if they conform their conduct to that practiced by a “respectable minority” of the profession. Blumstein, *Rationing Medical Resources*, *supra* note 31, at 1396. The “respectable minority” doctrine holds that “a physician does not incur liability merely by electing to pursue one of several recognized courses of treatment.” *Downer v. Veilleux*, 322 A.2d 82, 87 (Me. 1974). This is a doctrinal recognition of variations in practice, acknowledging that conformity to a respectable school of thought in medical practice will suffice, even if not entirely in sync with overall customary practice standards. Typically, the respectable minority doctrine has both a qualitative component—the school of thought must gain professional acceptance—and a quantitative component—the school of thought must have a number of adherents, not just reflect the idiosyncratic judgment of an individual practitioner. See *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.”).

In the face of uncertainty—the ambiguous customary practice standard compounded by the *ex post* nature of the determination of that standard—physician conduct can be expected to reflect an adjustment for the risk of liability, resulting in excessively costly practice behavior. The prevalence of third-party payment for medical care makes this type of adaptive behavior on the part of providers easier to effectuate, thereby posing an especially significant resource allocation concern. The nature of medical malpractice doctrine—the professional customary practice standard—and the widespread presence of third-party payment, which facilitates (by paying for) defensive practices that may result from clinical and structural uncertainty, are not typically found linked together in other areas of tort law. This linkage makes for a particularly troubling potential for substantial impact on resource expenditures on defensive practices in medical care decisionmaking.

III. A RESPONSE TO UNCERTAINTY: *EX ANTE* STANDARDS AS SAFE HARBORS

The appropriate response to unproductive uncertainty—clinical and structural—is to reduce it. One way to do this is through properly designed and implemented *ex ante* standard-setting.⁶⁷ Such *ex ante* standards can reduce both clinical and structural uncertainty. Clinical uncertainty can be reduced because the standard-setting process evaluates clinical and other appropriate evidence and resolves uncertainty by adopting standards. Structural uncertainty is reduced because standards, if properly developed and implemented for this purpose, are set in advance and are thereby knowable.

67. To the extent that guidelines are vague or proliferate regarding specific conditions or treatment options, they may increase uncertainty and thereby exacerbate the defensive medicine problem. For discussions of these issues, see Mello, *supra* note 50, at 686–90; Arnold J. Rosoff, *The Role of Clinical Practice Guidelines in Health Care Reform*, 5 HEALTH MATRIX 369, 386 (1995) (“[A] pluralistic system allowing alternative, conflicting guidelines is inherently untidy and undoubtedly would complicate matters by inviting controversy over which guideline should be regarded as authoritative, or more authoritative Perhaps this would lead to better, more confident judicial decisionmaking; perhaps it just would lead to more confusion.”).

A. Standard-Setting: Some Background

The idea of *ex ante* standard-setting is far from new.⁶⁸ Standards of practice have previously been recommended on grounds of quality assurance and cost containment.⁶⁹ The federal government in 1989 specifically promoted the development of guidelines,⁷⁰ giving impetus to the guidelines movement.⁷¹ But the use of guidelines has been controversial.⁷² Even the proper nomenclature has been the subject of dispute.⁷³

Guidelines have been advanced as a tool for implementing evidence-based medicine,⁷⁴ responding to the findings of clinical uncertainty in observed medical practice.⁷⁵ While recognizing that such guidelines might have a salutary effect on the tort system of liability,⁷⁶ skeptical commentators have expressed concern that the "battle to capture the machinery for making practice guidelines may be little more than another skirmish in the long war between the medical profession and political institutions for control of the health care system's regulatory apparatus."⁷⁷

The Institute of Medicine has described guidelines in comprehensive terms—as "systematically developed statements to assist practitioner and patient decisions about appropriate health care

68. See Clark C. Havighurst, *Practice Guidelines as Legal Standards Governing Physician Liability*, LAW & CONTEMP. PROBS., Spring 1991, at 87, 87 [hereinafter Havighurst, *Practice Guidelines As Legal Standards*] (noting that, in the view of some advocates, practice guidelines "are widely viewed as a potential panacea for many of the health care industry's most pressing problems," such as being a possible means of "ameliorat[ing] the problems associated with the law governing medical malpractice").

69. David M. Eddy, *Clinical Decision-Making: From Theory to Practice. Practice Policies—What Are They?*, 263 JAMA 877, 877–78 (1990) (presenting various practice policies).

70. Omnibus Budget Reconciliation Act of 1989 § 6103, Pub. L. No. 101-239, 103 Stat. 2106, 2189-2209, 42 U.S.C. § 299b-1(b)(3) (2006).

71. See Havighurst, *Practice Guidelines As Legal Standards*, *supra* note 68, at 90 (discussing the budget reconciliation legislation's effect on the guidelines movement).

72. See Clark C. Havighurst, *Practice Guidelines for Medical Care: The Policy Rationale*, 34 ST. LOUIS U. L.J. 777, 779 (1990) [hereinafter Havighurst, *Practice Guidelines for Medical Care*] (outlining the basic issues in the debate over the guidelines that are further discussed in the article).

73. PHYSICIAN PAYMENT REVIEW COMM'N, 1989 ANNUAL REPORT TO CONGRESS 220 n.1, 226 n.14 (describing different terms, such as "practice parameters," "pathway guidelines," or "clinical standards" and emphasizing the difference between the type of practice guidelines that focus on a particular procedure and those that focus on a particular patient problem).

74. See Hyman & Silver, *The Poor State of Health Care Quality in the U.S.*, *supra* note 15, at 990 (recognizing the propriety of allowing compliance with evidence-based medicine standards as an absolute defense to a medical malpractice claim).

75. See Havighurst, *Practice Guidelines As Legal Standards*, *supra* note 68, at 88–90.

76. *Id.* at 96.

77. *Id.* at 92.

for specific clinical circumstances."⁷⁸ In this sense, guidelines can be seen as "consensus statements developed by various bodies—public and private—about what constitutes appropriate treatment for a specific condition, set of symptoms, or preventive care goal."⁷⁹

While guidelines can be developed by diverse groups,⁸⁰ they have often been promoted by professional medical societies seeking to improve the quality of care.⁸¹ These guidelines (reflective of the Institute of Medicine's broad conceptual approach), however, "tend to be broad and flexible in nature, leaving substantial room for physicians to exercise clinical judgment."⁸² Such guidelines have been infrequently invoked.⁸³

The usefulness of guidelines from a defensive liability viewpoint becomes adulterated to the extent that the guidelines are ambitious (*i.e.*, comprehensive) and thereby imprecise. Guidelines that provide flexible floors or ceilings—professionally-preferred practice parameters—may furnish providers with useful boundaries of practice,⁸⁴ but they do not well perform the role of *ex ante* standards in the context of medical malpractice. To be effective from a defensive viewpoint, guidelines "must be both prescriptive and precise,"⁸⁵ and there must be a "single" guideline upon which a physician can rely.⁸⁶

That is, an effective⁸⁷ guideline must be modest in ambition, narrow in design and scope, and precise in its prescriptive approach.⁸⁸

78. COMMITTEE ON CLINICAL PRACTICE GUIDELINES, GUIDELINES FOR CLINICAL PRACTICE 2 (Marilyn J. Field & Kathleen N. Lohr eds., 1992) (internal quotes omitted). See Steven H. Woolf, *Practice Guidelines, a New Reality in Medicine: II. Method of Developing Guidelines*, 152 ARCHIVES INTERNAL MED. 946 (1992) (describing the process of developing guidelines).

79. Mello, *supra* note 50, at 647.

80. See Andrew L. Hyams et al., *Practice Guidelines and Malpractice Litigation: A Two-Way Street*, 122 ANNALS OF INTERNAL MEDICINE 450 (1995) (noting that the federal government has "committed substantial resources to guideline development," that numerous professional organizations have advocated the use of guidelines "to improve quality of care," and that "more than 1400 sets of guidelines" exist).

81. See Edward B. Hirshfeld, *From the Office of the General Counsel: Should Practice Parameters Be the Standard of Care in Malpractice Litigation?*, 266 JAMA 2886, 2887 (1991) (noting that "practice parameters" can reduce the amount of inappropriate care, reduce the incidence of "avoidable injuries," and reduce the amount of defensive medicine).

82. Mello, *supra* note 50, at 650.

83. *Id.* at 676; Hyams et al., *supra* note 80, at 650.

84. Some evidence exists that these guidelines are not adhered to in practice. See Elizabeth A. McGlynn et al., *The Quality of Health Care Delivered to Adults in the United States*, 348 NEW ENG. J. MED. 2635, 2635 (2003) (finding that patients included in the study received about half of the recommended care).

85. Hall, *Defensive Effect*, *supra* note 65, at 142.

86. Mello, *supra* note 50, at 686.

87. "Effective" in this context means effective in a medical-malpractice-defense context as providing a vehicle for reducing the impetus toward defensive medicine.

Comprehensiveness and indeterminacy are the enemies of the modest, targeted use of *ex ante* guidelines as legal standards. The effectiveness of the strategy of using guidelines, established *ex ante*, as legal standards to offset the impetus toward defensive medicine practices turns on targeting specific circumstances and practices in which high-cost defensive medicine practices may be addressed and offset.⁸⁹

In other words, to be useful in a defensive setting—as a defense against defensive medicine—less is more in the guideline-construction enterprise.

B. Ex Ante Guidelines/Standards as Medical Malpractice “Safe Harbors”

To be successful in the defensive-medicine setting, guidelines must be conceived of as narrowly targeted “safe harbors,”⁹⁰ not as flexible parametric guidelines generally reflective of and accommodative of broad ranges of clinical practice. Yet, it is that very type of precise, focused guideline that confronts professional

88. It may also be true that effectiveness from a quality-assurance perspective would be improved by adherence to such design characteristics. Evidence of non-compliance with guidelines suggests that better design may be important in improving the implementation of guideline recommendations. See McGlynn et al., *supra* note 84 (detailing the results of a study that concluded that patients participating in the survey received an average of half the recommended care). For a discussion of how clinical guidelines can be used effectively “to identify and eliminate inappropriate care,” see Gerald B. Hickson et al., *Development of an Early Identification and Response Model of Malpractice Prevention*, LAW & CONTEMP. PROBS. Winter 1997, at 7, 26. The salutary possibility exists, therefore, that guidelines designed with effective medical malpractice defense in mind might have the consequence of improving quality by increasing compliance (and providing an incentive for compliance).

89. See Studdert et al., *supra* note 13, at 2617 (noting the value of “developing and disseminating clinical guidelines that target common defensive practices” such as “ordering costly imaging studies”).

90. Cf. Mark V. Pauly, *Competition and New Technology*, 24 HEALTH AFFS. 1523, 1534 (2005) (advocating “some type of legal safe harbor” to allow health plans to limit the introduction of new technology on cost-effectiveness grounds).

opposition, often as "cookbook medicine,"⁹¹ at least when perceived as a comprehensive regulatory regime of medical practice.⁹²

The process of *ex ante* standard-setting provides an opportunity for the introduction of cost-benefit considerations into the standard-setting process. This is consistent with traditional negligence principles, which involve a weighing of costs and benefits. Under the professional customary practice standard, medical malpractice doctrine delegates authority to set standards of practice to the medical profession, "but it does so in the name of science not economics."⁹³ Some practitioners and theorists acknowledge that professional standards, at least implicitly, take economic criteria into account.⁹⁴ But the traditional professional/scientific paradigm does not, at least overtly, recognize the conventional balancing of costs and benefits that underlies normal tort doctrines. "Indeed, some courts view the introduction of economic trade-offs into medical care decision-making to be corrosive or corruptive of the medical care decision-making process."⁹⁵ *Ex ante* standard-setting that has the force of law could, therefore, serve as a constructive forum in which traditional economic considerations could be introduced, consistent with professional concerns about costly defensive medicine practices.⁹⁶

Reducing uncertainty—by clarifying standards of practice and formulating them *ex ante* as standards set in advance to guide medical decisionmaking—and introducing cost consciousness into that standard-setting process require a rethinking of the traditional *ex post*

91. Professors Hyman and Silver provide a good discussion of this issue. They note that clinical uncertainty gives physicians "considerable freedom and power" to exercise discretion in clinical judgment. That discretion and the resultant autonomy of professionals in medical decisionmaking are "likely . . . constrain[ed]" by "clinical practice guidelines," which are "deride[d] . . . as 'cookbook' medicine." Hyman & Silver, *The Poor State of Health Care Quality in the U.S.*, *supra* note 15, at 952. Accordingly, physicians have shown "[r]esistance to guidelines" and have slowed their development in ways that constrain physicians' practice autonomy. *Id.* at 955. Somewhat ironically, this resistance has impeded development of targeted safe-harbor guidelines that could achieve medical malpractice defense objectives.

92. See Arnold J. Rosoff, *Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POLITICS POL. & L. 327, 329 (2001) [hereinafter Rosoff, *Evidence-Based Medicine*] (discussing concerns with the potential result of comprehensive guidelines); Havighurst, *Practice Guidelines As Legal Standards*, *supra* note 68, at 88–90 (detailing the origin and development of the movement to create practice guidelines).

93. Blumstein, *The Legal Liability Regime*, *supra* note 9, at 141.

94. See DAVID EDDY, *CLINICAL DECISION MAKING: FROM THEORY TO PRACTICE 2* (1996).

95. Blumstein, *The Legal Liability Regime*, *supra* note 9, at 141–42.

96. See Studdert et al., *supra* note 13, at 2616 (noting that "the total cost of defensive medicine is substantial" and that "practice guidelines" could "empower physicians to withhold low-yield tests" whose costs outweigh their putative benefits). Cf. Hyman & Silver, *The Poor State of Health Care Quality in the U.S.*, *supra* note 15, at 990 (endorsing absolute defense for physicians' compliance with "consensus standards of quality").

case-by-case method of establishing the standard of care. In developing narrowly conceived and highly targeted *ex ante* standards as medical malpractice safe harbors, the standard-setting process would migrate in those specially selected and carefully circumscribed circumstances away from after-the-fact expert testimony about a unitary national standard presented in the context of litigation. This would shift not only the process of standard-setting but the timing as well; the evaluation of risks and benefits would occur in advance when the analysis would focus on the risk of injury—rather than in a context in which the risk had already materialized as a result of an adverse medical event.⁹⁷

One practical concern, from the defense viewpoint, about the reliance on guidelines in medical malpractice matters has been the possible “asymmetry” in their impact.⁹⁸ The fear is that failure of a physician to adhere to a practice guideline would be harmful to a defendant’s case before a jury,⁹⁹ but “[c]ompliance with a guideline would not be as likely to insulate a physician from liability.”¹⁰⁰ To be effective as a medical malpractice safe harbor, a guideline therefore must not only be narrowly conceived in design, scope and implementation, it must also have the force of law—not be evidence of the standard of care but *be* the standard of care. Not only is this important for defensive effectiveness, it is desirable from a balanced (*i.e.*, symmetrical) fairness perspective. If the *ex ante* standard becomes the controlling legal standard, then the troubling problem of asymmetric use of the guidelines disappears.¹⁰¹ The guideline, as a controlling legal standard, serves as an evenhanded metric—both as a

97. Facilitating contract-oriented approaches to medical liability might be desirable as a way of rationalizing behavior and introducing cost consciousness into medical decisionmaking. See CLARK C. HAVIGHURST, *HEALTH CARE CHOICES: PRIVATE CONTRACTS AS INSTRUMENTS OF HEALTH REFORM* (1995) (advocating contract approach). This may be possible if the appropriate basis for contractual obligations regarding medical liability can be established. See *Dukes v. U. S. Healthcare, Inc.*, 57 F.3d 350, 359 n.5 (3d Cir. 1995) (discussing the possibility that a health care plan can contractually create its own set of standards of care, preempting state medical malpractice law). *But see infra* note 105.

98. Blumstein, *Making the System Work Better*, *supra* note 3, at 414.

99. Guidelines, under this scenario, would be admitted into evidence in connection with expert testimony as suggesting the appropriate customary standard—somewhat akin to the status of a learned treatise. For a discussion of these evidentiary matters, see Mello, *supra* note 50, at 662–67 (explaining the evidentiary implications of CPGs).

100. Havighurst, *Practice Guidelines As Legal Standards*, *supra* note 68, at 105–06. See Hyams et al., *supra* note 80, at 454 (guidelines were used more than twice as often for inculpatory as for exculpatory purposes).

101. For an expression of concern with the asymmetric use of guidelines in the medical malpractice setting, see Mello, *supra* note 50, at 695–704. The asymmetric use of guidelines “arguably frustrates the rational use of guidelines in malpractice litigation.” Hyams et al., *supra* note 80, at 454.

sword and a shield. Failure to comply with the standard constitutes a breach of the duty of care; compliance with the standard (and non-negligent implementation of the standard) satisfies the physician's duty of care.

Normally, the way that a standard becomes an *ex ante* legal standard is through legislation.¹⁰² That certainly would be an option for the type of standards advocated herein. But the legislative track record does not suggest success.¹⁰³ In some circumstances, a standard could be adopted through contract,¹⁰⁴ but uncertainty of enforceability has resulted in little success in the contract realm.¹⁰⁵ This raises the question whether a different vehicle exists through which narrowly focused medical malpractice safe harbors can be promulgated with the force of law. In the next Part, the potential role of Quality Improvement Organizations ("QIOs")¹⁰⁶ in the standard-setting process will be developed.

102. See Rosoff, *Evidence-Based Medicine*, *supra* note 92, at 339 (indicating that use of a guideline as the "applicable legal standard . . . would, presumably, require legislative action").

103. See Mello, *supra* note 50, at 674–77 (discussing the experience of states that have adopted guidelines and provided an affirmative defense to physicians who comply with the guidelines). The nature of the standard-setting process may not be the kind of initiative at which legislatures excel; the expertise involved reflects the kind of decisionmaking that legislatures often delegate to administrative agencies or nongovernmental standard-setting entities. See generally Lisa Schultz Bressman, Schecter Poultry at the Millennium: A Delegation Doctrine for the Administrative State, 109 YALE L.J. 1399, 1402 (2000) (advocating agency standard-setting).

104. See, e.g., Havighurst, *Practice Guidelines as Legal Standards*, *supra* note 68, at 108, 113–16 (asserting that an alternative to guidelines could be found in the contract between a patient and his or her physician).

105. The Third Circuit decision in *Dukes v. U.S. Healthcare, Inc.*, 57 F.3d 350, 359 n.5 (3d Cir. 1995), suggested that the preemption provisions of the federal Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. § 1144(a) (2006), could authorize the use of employer-sponsored health plans as a vehicle for superseding certain state tort doctrines through employer-based contracting. Contractual adoption of "tort" standards through an employer's health plan, under that theory, could serve as the standard of care in litigation involving participants and beneficiaries of that plan, state medical malpractice law to the contrary notwithstanding. Uncertainty about the enforceability of such provisions has left the idea advanced tentatively in *Dukes* undeveloped.

106. Federal law refers to a "utilization and quality control peer review organization" ("PRO") as an entity with which the federal government contracts to provide designated services, including the setting of "standards of health care." 42 U.S.C. § 1320c-3(a) (2006). The term Quality Improvement Organization ("QIO") has been substituted for the term PRO in federal regulatory parlance, e.g., the PROs with which the federal government now contracts to perform PRO functions are called QIOs. See INSTITUTE OF MEDICINE, MEDICARE'S QUALITY IMPROVEMENT ORGANIZATION PROGRAM: MAXIMIZING POTENTIAL 29–32 (2006) [hereinafter IOM QIO REPORT] (describing and providing historical overview of QIO program). This change occurred when the term QIO was substituted for the term PRO in the scope of work covering the contract period 1999–2002. *Id.* at 37 (noting change in terminology). Section 109(d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, 117 Stat. 2173 (2003), called for a study by the Institute of Medicine of the role of QIOs, which resulted in a report

IV. QIOS AND MEDICAL MALPRACTICE STANDARD-SETTING

A provision in federal law since 1972—part of the original Professional Standards Review Organization (“PSRO”) legislation—provides the vehicle for implementing the proposal put forward in this Article.¹⁰⁷

A. *The PSRO Legislation: Some Background*

PSROs were established in 1972 as part of omnibus Social Security Act amendments as “self-regulatory organizations of physicians . . . charged with monitoring individual physicians’ decisions affecting the use of health care resources under federal health programs.”¹⁰⁸ The PSRO legislation arose in the Senate Finance Committee “against a background of intense concern . . . about cost overruns in the Medicare and Medicaid programs.”¹⁰⁹ Hospital utilization review was viewed as “ineffective as a curb to unnecessary use of institutionalized care and services.”¹¹⁰ PSROs institutionalized peer review, but placed authority for such review (including utilization review) outside the control of individual hospitals.

In recognition of the relationship between utilization control and medical malpractice exposure, the PSRO legislation specifically addressed the medical malpractice risk to providers that stems from restraints on utilization in furtherance of cost-containment objectives.¹¹¹

B. *Standard-Setting and Immunity-Conferring Authority of QIOs*

“The federal PSRO legislation contains a provision that immunizes from malpractice liability a physician who practices in conformity with the standard set forth by the PSRO. The clear intent of that provision was to remove the ‘defensive medicine’ excuse from practitioners who claim that fear of malpractice liability causes them

published in March 2006. IOM QIO REPORT, *supra*. Accordingly, the more recent (and current) term QIO will be used in this Article to refer to authority statutorily conferred on PROs.

107. 42 U.S.C. § 1320c-6(c) (2006).

108. Clark C. Havighurst & James F. Blumstein, *Coping with Quality/Cost Trade-offs in Medical Care: The Role of PSROs*, 70 NW. U. L. REV. 6, 8 (1975).

109. *Id.* at 38.

110. S. REP. NO. 92-1230, at 255 (1972) [hereinafter S. REP. NO. 1230].

111. Blumstein, *Rationing Medical Resources*, *supra* note 31, at 1397.

to order more costly testing than ordinarily called for in their clinical judgment."¹¹² The Senate Report is quite explicit about this point.¹¹³

When doctors and institutional providers act "in compliance with or reliance upon professionally developed norms of care and treatment applied by" PSROs¹¹⁴ (now QIOs),¹¹⁵ 42 U.S.C. §1320c-6(c) provides immunity¹¹⁶ for such doctors and institutional providers. That is, if QIOs develop and apply standards of care for medical practice, those standards become the standards for medical liability, and "compliance with or reliance upon" those standards on the part of providers cannot result in liability, provided that the provider exercised "due care" in the implementation of those standards.¹¹⁷

In addressing the PSROs' standard-setting and immunity-conferring authority, the Senate Report directly draws the relationship between the statutory immunity provision and the costly practice of defensive medicine. The Report notes that providers are "exempt from civil liability arising from adherence to" the standards set by the PSRO, "provided they exercise due care in the performance of their functions."¹¹⁸ It then proceeds unambiguously to link this immunity-conferring provision to the concern about defensive medicine: "The intention of this provision . . . is to remove any inhibition to . . . the following by practitioners and providers, of standards . . . recommended by the review organization."¹¹⁹ Thus, "a physician following practices which fall within the scope of those recommended by a PSRO would not be liable, in the absence of negligence in other respects for having done so."¹²⁰

The specific example used in the Report involves a typical defensive medicine issue—length of stay. The Report addresses the situation where the "usual length of stay for a given illness might be 6 days, but an individual practitioner might only hospitalize his patient

112. *Id.*

113. S. REP. NO. 1230, *supra* note 110, at 267.

114. The PSRO program became the PRO program in 1982. Timothy Stoltzfus Jost, *Administrative Law Issues Involving the Medicare Utilization and Quality Control Peer Review Organization (PRO) Program: Analysis and Recommendations*, 50 OHIO ST. L.J. 1, 5 (1989).

115. Sec IOM QIO REPORT, *supra* note 106, at 3.

116. See Hall, *Defensive Effect*, *supra* note 65, at 136–40 (describing the statutory goal of malpractice immunity from compliance with peer-review-established norms in PSROs); Note, *Federally Imposed Self-Regulation of Medical Practice: A Critique of the Professional Standards Review Organization*, 42 GEO. WASH. L. REV. 822, 838–42 (1974) (same); Kenneth W. Kleinman, Comment, *PSRO: Malpractice Liability and the Impact of the Civil Immunity Clause*, 62 GEO. L. J. 1499 (1974) (same).

117. 42 U.S.C. § 1320c-6(c)(2) (2006).

118. S. REP. NO. 1230, *supra* note 110, at 267.

119. *Id.*

120. *Id.*

for 4 days.”¹²¹ In such a circumstance, “to assure himself of exemption from liability”—*i.e.*, because of defensive medicine—“the doctor might be motivated to keep his patient in the hospital for an extra 2 days.”¹²² Adherence to a PSRO-developed standard that authorized a four-day stay in such a situation would provide the practitioner with immunity from medical malpractice as long as the practitioner does not “misappl[y] the professional standards promulgated by a review organization.”¹²³

Thus, since 1972 QIOs have been specifically authorized by statute¹²⁴ to develop and implement standards of care as a tool for dealing with the practice of defensive medicine. But this role has not been part of their scope of work,¹²⁵ and QIOs have not pursued this mission (even though they are and have been so authorized).¹²⁶

Within the framework of medical malpractice doctrine, therefore, the first element—establishing a standard of care—can be performed by a QIO if it were to establish and apply “professionally developed norms of care and treatment.”¹²⁷ When physicians or institutional providers act “in compliance with or reliance on” QIO-adopted “norms of care and treatment” and have exercised “due care” in applying such “norms of care and treatment,” they cannot be held “civilly liable to any person under any law of the United States or of any State (or political subdivision thereof) on account of any [such] action.”¹²⁸

Since QIOs have not, as a general matter, implemented their authority to set standards of care, it is uncertain just how far the immunity-conferring authority extends. One could argue that because the QIO authority developed in the context of concerns about cost escalation in Medicare and Medicaid, QIO authority to set standards of care that confer immunity for compliance only extends to care provided under Medicare, Medicaid, or other federal programs. But the statutory language itself contains no such limiting provision. It seems to confer immunity on all providers that comply with or act in reliance “upon professionally developed norms of care and treatment applied by” QIOs.¹²⁹ The statute itself, therefore, does not confine the

121. *Id.*

122. *Id.*

123. *Id.*

124. 42 U.S.C. §§ 1320c-2(c)(7), 3(a)(6) & (8) (2006).

125. IOM QIO REPORT, *supra* note 106, at 34–41.

126. See Hall, *Defensive Effect*, *supra* note 65, at 136–38 & n.77.

127. 42 U.S.C. § 1320c-6(e) (2006).

128. *Id.*

129. *Id.*

context of QIO standard-setting authority to federal programs; this suggests that the QIOs' immunity-conferring authority (and therefore their medical malpractice standard-setting authority) extends to all medical care, irrespective of payer.¹³⁰

The QIOs' standard-setting process, if implemented, will not eliminate the potential of litigation focusing on the "due care" implementation issue. Negligence in carrying out the standard of care would still result in liability if it causes injury. But the QIO standard-setting process would allow for the development of *ex ante* standards that could guide medical decisionmaking, thereby reducing some of the clinical and structural uncertainty associated with such decisionmaking. In short, QIOs possess the statutory authority to develop standards that would serve as controlling legal standards in medical malpractice litigation.

To be effective in performing its defensive role in cost containment, such standard-setting must be precise and targeted, in the nature of particularized safe harbors. Elimination of the standard-setting component of putative liability litigation in carefully targeted circumstances could reduce the scope of issues for potential liability and contribute to cost-reduction from the development of practice styles that comport with the standards developed and promulgated by QIOs. Compliance with a previously developed and articulated standard would allow practice styles to accommodate to those standards, with the attendant cost reduction, even if in some cases lack of due care in the implementation of the standards causes injury and results in liability.

If QIOs took on this standard-setting assignment, their task would be to identify and target areas in which *ex ante* standard-setting can provide substantial cost-containment relief with little but warranted (*i.e.*, optimal) impact on quality. This could occur where costly defensive medicine is currently being practiced and where reduced uncertainty regarding liability could result in a more optimal balance of costs and benefits. As suggested by the recent work of Studdert et al.,¹³¹ defensive diagnostic tests such as imaging (especially in emergency settings) hold promise for utilization reduction through *ex ante* standard setting. Similar savings might accrue in the area of low-benefit yet expensive technology innovation.¹³²

130. For the suggestion that medical malpractice reform requires restructuring medical liability insurance, and that payers such as Medicare should lead the way, see William M. Sage, *Medical Malpractice Insurance and the Emperor's Clothes*, 54 DEPAUL L. REV. 463, 464 & n.6, 484 & n.84 (2005).

131. Studdert et al., *supra* note 13, at 2616.

132. Pauly, *supra* note 90, at 1524–28, 1533–35.

One way to get this ball rolling would be for the federal government to commission a pilot study that would identify and develop standards in areas in which optimization of existing practice could benefit from the development and promulgation of *ex ante* standards. Picking off the low-hanging fruit through a pilot study could develop the approach, methodology, and analysis for pursuing other carefully targeted “safe harbor” opportunities.

C. Can QIOs Perform the Standard-Setting Role?

While QIOs have—and have had for over thirty years—the authority to engage in medical malpractice standard-setting, they have not acted on this role. The existing federal scope of work, which describes the contractual obligations of a QIO, does not contemplate medical malpractice standard-setting as a contractual role for QIOs.¹³³

Historically, the tension between QIOs’ role in cost containment and quality assurance has been an underlying reality.¹³⁴ From the very outset of the PSRO program, organized medicine has resisted a significant QIO role in cost containment. Thus, in 1974, the director of the American Medical Association’s Center for Health Services Research and Development quite explicitly sought to redirect the mission thrust of PSROs away from cost containment to quality assurance:

It seems apparent after examining the [PSRO] legislation that the primary, if not total intent of the program is to contain the cost of medical care. Despite the legislative intent of the program, however, the concern of health care providers and insurers should be to reassign priorities of the PSRO program to assure that maintenance of high quality care is the primary focus of PSROs.¹³⁵

Over the years, the Medicare program itself has evolved as the payment method shifted to a modified prospective payment system based on diagnosis-related groups (“DRGs”).¹³⁶ “This system ended the prior cost-related reimbursement system, under which Medicare had reimbursed hospitals the costs they incurred in caring for Medicare patients, and substituted for it a program that paid hospitals primarily on a lump sum per hospitalization basis.”¹³⁷ At least in the hospital context, financial incentives shifted under prospective

133. See IOM QIO REPORT, *supra* note 106, at 40 (noting QIOs’ focus on quality improvement in scope of work governing the period 2005-2008).

134. See Havighurst & Blumstein, *supra* note 108, at 36–68 (explaining the competing goals of quality assurance and cost containment).

135. *Id.* at 42 n.123.

136. Social Security Amendments of 1983, Pub. L. No. 98-21, 97 Stat. 65 (codified as amended in scattered sections of 42 U.S.C.).

137. Jost, *supra* note 114, at 5.

payment, so that hospitals had an incentive to under-serve rather than to over-serve, as they did under cost-based reimbursement. The shift in incentives raised the specter of lower quality hospital services under Medicare and solidified the conception of QIOs as quality-assurance institutions.¹³⁸

In this process of mission evolution, the QIOs' role in standard-setting has remained in desuetude. It is not now part of the scope of work of QIO contracts with the federal government. And a recently released report on the role of QIOs by the prestigious Institute of Medicine envisions the role of QIOs exclusively in the context of quality-promotion¹³⁹ with barely a bow to the statutory cost-containment mission of QIOs' PSRO forebears.¹⁴⁰ The single-minded orientation of this recent report is reminiscent of the very early attempts to blunt any cost-containment role for QIOs and, in that respect, has a certain "Back to the Future" ambience. So, given the history and the recent Institute of Medicine report that deemphasizes any role for QIOs other than "the provision of technical assistance for performance measurement and quality improvement,"¹⁴¹ one can reasonably wonder whether QIOs can be tasked with the standard-setting mission envisioned for them in this Article.

Despite this history and the Institute of Medicine report, there are several reasons for cautious optimism. First, the QIOs' legal authority for standard-setting has survived intact even as the mission for QIOs themselves has evolved. And the standard-setting function has remained in the authorizing statute. Thus, the legal capacity of QIOs to perform the standard-setting function persists. It just needs administrative resuscitation (or perhaps birthing would be a more appropriate term).

Second, QIOs are not entirely dependent on their contract with the federal government. They are authorized to contract with public and private payers to perform review functions;¹⁴² there does not seem to be any express limitation on QIOs' ability to receive non-federal funding to support their standard-setting function. Again, this has been a largely unknown authority of QIOs, and, properly informed and

138. *See id.* at 5-6 (discussing the changed incentives and the resulting risk of decreased quality of care).

139. *See* IOM QIO REPORT, *supra* note 106, at 10 (QIOs should "concentrate their resources on quality improvement efforts with providers").

140. *Id.* at 33.

141. *Id.* at 9.

142. 42 U.S.C. § 1320c-3(a)(11) (2006). *See* Jost, *supra* note 114, at 3 (reporting on private contracting by PROs).

energized, private entities might well seek to contract with QIOs to support QIOs' standard-setting role.

Third, Congress in Section 109(d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003¹⁴³ commissioned an overview by the Institute of Medicine of the QIO program. While QIOs' standard-setting role was not on the radar screen of the Institute of Medicine's review process and found no consideration in its report, the recent release of the IOM's report will trigger discussion within the Department of Health and Human Services and in Congress about the appropriate role of and scope of work for QIOs in the future. Consideration of QIOs' role in standard-setting is therefore timely.

The vision for QIOs contained in the Institute of Medicine report—institutions devoted to quality assurance—is not incompatible with the *ex ante* standard-setting role for QIOs still contemplated in the QIOs' underlying statute and advocated herein. Standard-setting can well fit within an overall quality-enhancement agenda,¹⁴⁴ so long as quality is a broad enough notion that can accommodate the introduction of cost-effectiveness considerations. Given the Bush Administration's commitment to tort reform as a means of reducing costs, it seems reasonable that the Administration would be drawn to implement a strategy of dealing with the problem of defensive medicine through a liability-based (and not only a remedy-centric) approach. That liability-based strategy of reform can effectively be addressed by invigorating QIOs' longstanding authority to set controlling legal standards for medical malpractice.

D. Are There Liability Risks Associated With the Standard-Setting Process Itself?

Participants in the putative QIO standard-setting process would be empowered to develop appropriate standards of practice that have teeth. This would allow those participants to have an impact on the quality of care and on reducing unwarranted costs associated with the excessive deterrence that may arise from complying with ambiguous standards determined after-the-fact in a judicial proceeding based on *ad hoc* testimony of experts with 20-20 hindsight. This should provide a vehicle for physicians and other providers to make a real contribution to rationalizing and optimizing the process of

143. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 42 U.S.C.).

144. See McGlynn, *supra* note 84, at 2644 (discussing ways to improve the deficits in receipt of recommended medical care).

care-delivery; this should be viewed as an act of physician empowerment not alienation.

Would participants in this putative standard-setting process be at-risk for liability for their role in a QIO's standard-setting process? If so, this could be a significant practical impediment to implementing this proposal for an expanded QIO standard-setting role.

The QIO statute contains two separate immunity provisions that would seem to provide considerable immunity to QIOs, their employees, and any person "who furnishes professional services to" a QIO.¹⁴⁵

In general, persons who "provid[e] information" to QIOs cannot be held liable "by reason of having provided such information."¹⁴⁶ That is, those who provide information to QIOs are afforded immunity from civil and criminal liability unless the information is "unrelated to" a QIO's contractual function¹⁴⁷ or "is false and the person providing it knew, or had reason to believe, that such information was false."¹⁴⁸ This seems to be a broad immunity provision that protects against good faith official conduct.

Some ambiguity arises with respect to the statutory immunity provision regarding the performance of services by a QIO employee, a person "who has a fiduciary relationship with" a QIO, or any person who "furnishes professional services" to a QIO.¹⁴⁹ That immunity seems weaker than the immunity granted for the provision of information and only applies if "due care" is exercised in the performance of "professional services."¹⁵⁰

While the statutory immunity provision seems to provide a form of qualified rather than absolute immunity, the sparse case law seems to support absolute immunity, at least in some contexts. In *Kwoun v. Southeast Missouri Professional Standards Review Organization*,¹⁵¹ the district court had granted qualified immunity to the QIO-related defendants and to certain state defendants in the context of a disciplinary proceeding; on appeal, the Eighth Circuit awarded absolute immunity to those defendants (as well as to the federal defendants).¹⁵² The dissent contended that the QIO-related

145. 42 U.S.C. §§ 1320c-6(a) & (b) (2006).

146. *Id.* § 1320c-6(a).

147. *Id.* § 1320c-6(a)(1).

148. *Id.* § 1320c-6(a)(2).

149. *Id.* § 1320c-6(b).

150. *Id.*

151. 811 F.2d 401 (8th Cir. 1987).

152. *Id.* at 404, 406-10; *accord* Wood v. Freedman, No. 89-3685, 1991 U.S. App. LEXIS 26317, at *2-3 (7th Cir. Oct. 25, 1991). These cases arose in the context of a PRO engaged in

defendants and state defendants were only eligible for qualified immunity under the QIO statute.

Under *Kwoun*, special attention must be given to determining how best to structure the tasking of QIOs by the Department of Health and Human Services. That structure and relationship could be important in determining whether the immunity that attaches is qualified or absolute. More generally, the risk of liability for participation in the standard-setting process seems manageable and unlikely to deter participation in the QIOs' putative standard-setting mission.

V. CONCLUSION

The costs of medical malpractice and medical malpractice litigation come in many flavors. To some extent, the existence of medical malpractice itself through medical error contributes to lower quality of care and to medical injury.¹⁵³ There has been much criticism of the system of fault-determination and compensation as excessively costly.¹⁵⁴ Because of variability, awards for noneconomic loss have been the subject of criticism¹⁵⁵ and pose concerns regarding horizontal and vertical equity.¹⁵⁶ Much of the recent tort and medical malpractice reform has been directed at damages for noneconomic loss, with questions being raised about their legitimacy and with responses to those critiques.¹⁵⁷ This remedy-centric approach to reform has led to the imposition of caps on damages for noneconomic

sanctioning conduct and applied absolute immunity on the model for prosecutorial and/or adjudicative functions, both of which receive absolute immunity. Whether the same type of immunity would be applied to the standard-setting, regulatory function of QIOs is uncertain. *But cf.* *Howard v. Suskie*, 26 F.3d 84, 85, 87 (8th Cir. 1994) (distinguishing *Kwoun* and granting qualified, not absolute, immunity for the performance of executive rather than adjudicative function). At the same time, it is far from clear what party would be in a position to bring an action against a QIO employee or agent for a QIO's standard-setting function.

153. See Hyman & Silver, *supra* note 15, at 900–09 (describing the magnitude of the problem of medical error).

154. See O'Connell et al., *supra* note 3, at 277 (noting litigation-induced costs of medical liability process).

155. Neil Vidmar, *Pap and Circumstance: What Jury Verdict Statistics Can Tell Us About Jury Behavior and the Tort System*, 28 SUFFOLK U. L. REV. 1205, 1224 (1994) ("The 'pain and suffering' component of jury awards represents one of the most criticized aspects of jury behavior.").

156. See Blumstein, *Making the System Work Better*, *supra* note 3, at 403–04 (expressing concern about systemic fairness in determination of noneconomic loss, while acknowledging the legitimacy of providing recovery for noneconomic loss).

157. See *supra* note 3 (providing sources that critique the legitimacy of damages for noneconomic loss).

loss,¹⁵⁸ to resistance to those caps,¹⁵⁹ and to proposals for improving the way that noneconomic loss is determined.¹⁶⁰

This Article has addressed the problem of cost not from a remedy-centric perspective but from the perspective of the impact of the liability-determination process on levels of utilization and therefore cost.¹⁶¹ This is the defensive medicine perspective.

The system of establishing medical liability relies on the professional customary practice standard and is premised on the assumption that science determines a standard of care that controls medical decisionmaking in individual circumstances. However, evidence of unexplained practice variation calls this scientific premise into question in a large number of situations. This clinical uncertainty makes compliance with a standard of care difficult, even mythical, in many clinical circumstances, yet that is the legal standard upon which liability is determined. Further, because the medical profession sets the standard, consideration of cost-benefit issues in individual cases is not part of the liability-determination process in medical malpractice cases. In this sense, medical liability is unlike conventional tort cases, in which factfinders are expected to weigh costs and benefits in deciding whether culpable conduct has occurred in a specific context.

The uncertainty associated with clinical variation (clinical uncertainty) and the inability of medical practitioners to defend their conduct in individual cases on conventional tort cost-benefit grounds are exacerbated by the after-the-fact method in which the professional standard of care is established (structural uncertainty). Experts who testify to the standard of care are assumed to be testifying about scientifically-validated customary practices. But, given the existence of clinical uncertainty, such after-the-fact testimony can be akin to picking out a particular friend in a crowd, a selection influenced by the reality that an injury has occurred and a potential risk has

158. See Sharkey, *supra* note 1, at 396 (noting that a majority of states "have imposed some kind of cap or limitation on the amount of damages that plaintiffs can recover in a lawsuit").

159. See *supra* note 3 (providing sources that critique the legitimacy of damages for noneconomic loss).

160. See, e.g., Avraham, *supra* note 2, at 110 (advocating "a system of nonbinding age-adjusted multipliers . . . associated with the medical costs of an injury"); Blumstein, *Making the System Work Better*, *supra* note 3, at 411-13 (advocating use of scenarios to assist juries by providing context for decisionmaking); Bovbjerg et al., *supra* note 2, at 939 (suggesting the use of award matrices).

161. Cf. Blumstein, *Making the System Work Better*, *supra* note 3, at 415 ("If we can generate real savings in the practice of medicine by the adoption of clear and definitive protocols of practice, then that might well alleviate some pressure from—and be a safety valve for—some of the other cost-based criticisms of the award of nonpecuniary damages.").

materialized with a concomitant adverse outcome. Such *ex post* standard-setting using the professional customary practice standard is understandable in a medical-practice world characterized by scientific evidence. But the evidence on clinical uncertainty undermines that claim. This creates structural uncertainty, which makes compliance with the after-the-fact “standards of care” difficult—pursuit of a moving target.

The result of clinical and structural uncertainty is an incentive for risk-averse medical decisionmaking—doing more than might be medically optimal to avoid liability. One of the purposes of tort liability in medical negligence cases is to achieve optimal deterrence, but the existence of clinical and structural uncertainty suggests that over-deterrence may occur in a significant number of cases with the resultant escalation of unwarranted costs. Such type of defensive medical decisionmaking is facilitated by the prevalence of third-party payment, which facilitates and funds this type of risk-averse decisionmaking by physicians. At the same time, the incentive for increased utilization from fee-for-service payment by third-party payers calls into question the very customary practice standard that undergirds the medical negligence system; customary practice does not exist in a vacuum. It is not solely scientifically driven, and to the extent that there is an economic dimension, it conduces toward greater utilization. That reduces the reliability that custom might otherwise reflect in balancing cost and benefit in a less subsidized market.

This Article has proposed the use of *ex ante* standard-setting as a tool for reducing uncertainty faced by medical providers. This would also allow for the appropriate balancing of costs and benefits in the formulation of such protocols. The use of such standards or protocols has “always failed” because “they can serve as just another tripwire for liability for providers.”¹⁶² To be palatable, such standards must be symmetrical—the controlling legal standard that serves both as a sword and a shield. Deviation from the standard establishes breach of the standard of care; compliance with the standard establishes conformity to the standard of care. From a quality-assurance perspective, this sword-and-shield dimension of symmetrical *ex ante* standard setting creates a powerful incentive for such compliance.

“So, in order to make the *ex ante* standard-setting approach work, there must be a process by which the standard that is set *ex ante* becomes the controlling standard.”¹⁶³ The federal QIO legislation

162. *Id.* at 414.

163. *Id.*

provides such a vehicle, allowing QIOs to establish practice standards that become the standards of care. Such QIO-developed standards trump state-created standards by conferring immunity for conduct in compliance with the QIO standards.

To be effective as a defense against defensive medicine, such QIO-developed standards must be modest in conception, narrow in design, and targeted in their implementation. Comprehensiveness and flexibility may be desirable objectives in practice guidelines aimed to assist practitioners in improving the quality of their medical decisionmaking practices, helping to shape the exercise of clinical judgment. They are not desirable in the context of defending against defensive medicine. In fact, such comprehensiveness and flexibility would defeat the goals espoused herein.

Instead, the practice guidelines contemplated in this Article must be targeted like a laser beam at narrow and specific circumstances, providing specific guidance to practitioners in carefully circumscribed situations. They should be conceived of as "safe harbors," not as broad parameters of practice. These safe harbors should be aimed at practices such as diagnostic imaging (especially in emergency settings) and the introduction of new technology—areas in which defensive practices are sub-optimal and areas in which quality can be maintained while reducing cost. That substantial savings from this type of intervention can be attained is strongly suggested by the most recent work of Dr. Wennberg, who concludes that in "supply-sensitive" areas of health care—"visits to physicians, diagnostic tests, and hospitalizations, mostly for patients with chronic illnesses"—the "most important problem is *overuse*" with the result that "patients are exposed to the burdens and risks of treatment that is unnecessary or counterproductive."¹⁶⁴

164. Wennberg, *supra* note 51, at 1–2.
