# THE PATIENT INJURY EPIDEMIC: MEDICAL MALPRACTICE LITIGATION AS A CURATIVE TOOL

# Barry R. Furrow\*

#### TABLE OF CONTENTS

Int	Introduction				
I.	THES	STANDARD CRITIQUE OF TORT LIABILITY	51		
	А. В. С.	Compensation for Injury Is Inaccurate and Incomplete Underdeterrence Is the Norm Trust in Jury Verdicts Is Lacking	51 53 55		
II.	A. B.	CTIONS OF TORT LIABILITY Reinforces Good Medical Practice Articulates New Duties of Care Gives Voice to Mistreated Patients Exposes Obtuse Organizations	56 57 61 62 64		
III.		LITY AND TRANSPARENCY: UNCOVERING AND POLICING OVERSE EVENTS  The Obligation to Disclose Adverse Events  Refining the parameters of adverse events  Mandatory adverse event reporting  Sharpening the adverse event definition  Improving mandatory reporting  Bans on confidentiality agreements for adverse event claims	65 67 69 72 74 75		
	В.	<ul> <li>Malpractice Insurance as a Tool for Discovering and Policing Medical Errors</li> <li>Selective insurance marketing, complaint profiling, and office auditing</li> <li>Hospital complaint profiling</li> <li>Claims history auditing for risk factors</li> <li>Early discussions between insurers and plaintiffs</li> </ul>	78 80 82 83 84		
IV.		LITY AND THE RECONSTRUCTION OF MEDICAL PRACTICE: DUCING PRACTICE VARIATION	84		

<sup>\*</sup> B.A., Harvard College; J.D., Harvard Law School. Professor of Law and Director, Health Law Program, Earle Mack School of Law at Drexel University. I want to thank the *Brocher Foundation*, www.brocher.ch, for its generous support for this project, which I completed during the summer of 2011 while a Visiting Researcher at the foundation facilities in Geneva, Switzerland.

	A.	Practice Guidelines: Sharper Boundaries	86	
		Unnecessary Procedures: False Claims and Liability	89	
		"Never Events" Liability: Presumptions	91	
V.	LIABILITY AND THE RECONSTRUCTION OF LITIGATION:			
	IMPROVING CLAIMS ACCURACY			
	A.	Damage Award Reforms	92	
	В.	Mediation	94	
	C.	Provider-Based Early Offers of Payment + Apology +		
		Reform	96	
		1. The offer	96	
		2. The apology	97	
		3. Safety reforms	99	
	D.	Special Courts for Small Medical Injuries	99	
	E.	Enterprise Strict Liability	101	
VI.	THE A	AFFORDABLE CARE ACT REFORMS AND PATIENT SAFETY:		
		CAILWIND OF INNOVATION	102	
	A.	Physician Exposure	102	
		Institutional Liability	105	
Col	Conclusion			

#### INTRODUCTION

The debate over medical liability is noisy, discordant, and riddled with false claims. Reform proposals have typically aimed to reduce lawyers' incentives to sue<sup>1</sup> by capping noneconomic damages, reducing contingency fees, or making the case more expensive to try.<sup>2</sup> Physicians and the public have been fed a drumbeat of misinformation about "frivolous" litigation, which seems to mean any lawsuit against a doctor.<sup>3</sup> Patients, having progressively lost access to

<sup>1.</sup> Patricia W. Hatamyar, *The Effect of "Tort Reform" on Tort Case Filings*, 43 VAL. U. L. REV. 559, 592 (2009) ("By reducing plaintiffs' potential recoveries, and by enacting barriers to the filing and prosecution of tort claims, tort reforms make many potential cases uneconomical for plaintiffs' attorneys who normally operate on a contingency fee basis."); *see also* Kyle Graham, *Why Torts Die*, 35 Fla. St. U. L. Rev. 359, 431–32 (2008) ("Though the vast majority of tort reform measures do not single out a claim for elimination, by driving up the costs of a suit or reducing its potential returns, many of these laws make certain tort claims less profitable and thus less attractive to plaintiffs and their lawyers.").

<sup>2.</sup> See Allen Kachalia & Michelle M. Mello, New Directions in Medical Liability Reform, 364 New Eng. J. Med. 1564, 1566 (2011) (evaluating the success of various reform approaches).

<sup>3.</sup> See Sick of Lawsuits, http://sickoflawsuits.org (last visited Dec. 10, 2011) (for rants using flawed statistics about the flaws of litigation generally); Joe Messerli, Editorial: A New Frivolous Lawsuit Statute, Balanced Pol., http://www.balancedpolitics.org/editorial-frivolous\_lawsuits.htm (last visited Dec. 10, 2011) (for uninformed attacks on any form of litigation); Press Release, Am. Tort Reform Ass'n, Frivolous Lawsuits Undermine Healthcare System and Hurt Patients, According to New Survey (Apr. 1, 2004), available at http://www

lawyers and to full damage recovery, are forced to consider alternative dispute resolution mechanisms that offer significantly less money in forums that can often be controlled and gamed by repeat players—insurers, hospitals, or managed care organizations.<sup>4</sup> Insurers support any kind of reform, particularly damage caps that reduce their exposure to claims.<sup>5</sup> Politicians use the extreme outlier cases to propagandize and overstate the need for reforms,<sup>6</sup> then offer up reforms that reduce the power of the trial bar. Politicians then wave the banner of cost savings that are never convincingly established.<sup>7</sup> And practitioners of popular behavioral economics toy with the merits of patient waivers of their right to sue as an "efficient" approach to claims for medical injuries.<sup>8</sup> As Sage writes, "For both

.atra.org/show/7748 (claiming that "frivolous lawsuits [make] personal injury lawyers rich [while] harming healthcare for [the public as a whole]"). Most of the frivolous medicine attacks are based on opinion surveys of physicians, who proclaim that the majority of practice styles are based on defensive medicine concerns. *See* Am. Tort Reform Ass'n, *supra*.

- 4. See Marcus Nieto & Margaret Hosel, Arbitration in California Managed Health Care Systems 2 (Dec. 2009), http://www.library.ca.gov/crb/00/09/00-009.pdf (last visited Nov. 21, 2011) (noting that in California arbitration cases involving medical injuries, repeat players could select arbitrators that tended to favor their positions).
- 5. Richard S. Biondi & Arthur Gurevitch, *The Evidence Is in: Noneconomic Damage Caps Help Reduce Malpractice Insurance Premiums*, CONTINGENCIES 30 (2003), http://contingencies.org/novdec03/evidence.pdf (last visited Dec. 10, 2011) (one of authors works as an actuary for Milliman USA, a larger insurance firm). The problem with this insurance enthusiasm is that caps and early settlement reforms are unfavorable to plaintiffs in terms of the amount of money they recover. *See also* Andrew I. Friedson & Thomas J. Kniesner, *Losers and Losers: Some Demographics of Medical Malpractice Tort Reforms* (Aug. 12, 2011), http://aifrieds.mysite.syr.edu/Friedson%20Kniesner%20MedMal%208-12-11.pdf (summarizing a study of Texas claims, the authors concluded that plaintiffs "would have benefitted economically from a slower larger settlement typical of the prereform period").
- 6. See WILLIAM HALTON & MICHAEL MCCANN, DISTORTING THE LAW: POLITICS, MEDIA, AND THE LITIGATION CRISIS 149-50 (2004) (arguing that media reporting is biased in favor of outlier cases).
- 7. See Letter from Douglas W. Elmendorf, Dir., Cong. Budget Office, to Orrin G. Hatch, U.S. Senator (Oct. 9, 2009) 1, 3, 5, available at http://www.cbo.gov/ftpdocs/106xx/doc10641/10-09-TORT\_Reform.pdf. The letter represented the official response of the Congressional Budget Office ("CBO") to Senator Hatch's "request for an updated analysis of the effects of proposals to limit costs related to medical malpractice ('tort reform')." The CBO noted that tort reform might "reduce total national health care expenditures by about 0.2 percent." The CBO also noted, however, that tort reform cost reductions might increase overall patient mortality rates by limiting the rights of patients to sue.
- 8. See Tom Baker & Timothy D. Lytton, Allowing Patients to Waive the Right to Sue for Medical Malpractice: A Response to Thaler and Sunstein, 104 Nw. U. L. Rev. 233, 237–38 (2010) (responding to Thaler and Sunstein's chapter in Nudge); see also Richard H. Thaler & Cass R. Sunstein, Nudge: Improving Decisions About Health, Wealth, and Happiness 207–12 (2008).

Decisions to waive the right to sue for medical malpractice leave patients vulnerable to manipulation for all of these reasons. Waiver offers fee reductions now and defers financial risk until later; it involves complex issues of risk assessment; it is made in-

emotional and financial reasons, few issues rival tort reform in terms of aggressive partisanship, overheated rhetoric, and suspicion of new ideas."9

Like a bad rock concert, the reform noise has gone on for too long and at such a high volume that even thoughtful reformers have become tone deaf, too often succumbing to glib arguments to turn everything over to health courts, 10 provider-run alternative dispute resolution approaches, 11 or "nudges" that federal pay-forperformance payment reforms may create. Such approaches are likely to continue to undercompensate poor or elderly patients, 13 while shielding bad practices from public scrutiny. 14

The problem is that the medical liability system does need reform, but of a different sort. These reforms should force disclosure of adverse events, increase the number of claims filed, and promote swift settlements. Reformers have deliberately missed the point, driven by ideology and the self-interest of everyone except injured patients. 15 As Jeffrey O'Connell has written, "[A] 'solution' that merely

frequently and without any feedback (because if medical negligence occurs, patients are unlikely to learn of it in the absence of a law suit); and it is difficult to predict how the inability to sue for medical negligence will affect the patient's life in the future. The superior bargaining power of physicians over patients based on asymmetry of information, high demand for healthcare services, and the status of the physician as healer add to the risk of exploitation.

Baker & Lytton, supra, at 237-38.

- 9. See William M. Sage & Eleanor D. Kinney, Medicare-Led Malpractice Reform, in MEDICAL MALPRACTICE AND THE U.S. HEALTH CARE SYSTEM 318, 339 (William M. Sage & Rogan Kersh eds., 2006).
- 10. See generally Michelle M. Mello et al., "Health Courts" and Accountability for Patient Safety, 84 Milbank Q. 459 (2006) (developing the case for health courts as a solution that combines the best of prior reform ideas).
- 11. See Michelle M. Mello et al., The New Medical Malpractice Crisis, 348 NEW ENG. J. MED. 2281, 2284 (2003).
- 12. THALER & SUNSTEIN, supra note 8, at 5-6. Thaler and Sunstein argue that "nudges" are indirect, noncoercive ways to guide individual behavior toward socially productive ends. Id. In health care, they propose consumer waivers of the right to sue for medical malpractice as an approach that properly allows for rational choices by consumers. Id. at 207-12; see also Baker & Lytton, supra note 8, at 237-38.
- 13. Tort reforms in the medical malpractice area are associated with increases in death rates, and they harm women in particular by reducing tort judgments. Joanna Shepherd, Tort Reforms' Winners and Losers: The Competing Effects of Care and Activity Levels, 55 UCLA L. REV. 905, 905 (2008); see also Albert H. Yoon, Damage Caps and Civil Litigation: An Empirical Study of Medical Malpractice Litigation in the South, 3 AM. L. & ECON. REV. 199, 221-23 (2001) (noting that damage caps reduced the average recovery in medical malpractice litigation, while subsequent nullification increased the recovery).
  - 14. A lawsuit has a visibility that ADR or administrative solutions simply cannot match.
- 15. F. Patrick Hubbard, The Nature and Impact of the "Tort Reform" Movement, 35 HOFSTRA L. REV. 437, 538 (2007).

further limits the amount or availability of compensation to injured persons is a questionable solution indeed. The *least* appealing way to reform the tort system is to make it even harder for injured parties to be paid."<sup>16</sup>

Modern medicine is dangerous. A recent study concluded that patients suffer adverse events in one-third of all admissions.<sup>17</sup> The famous Institute of Medicine (IOM) report, *To Err Is Human*, extrapolated from earlier closed claim studies to predict almost 100,000 patient deaths annually due to medical errors.<sup>18</sup> This extrapolation may in fact have seriously underestimated the incidence of injuries. More recent studies have confirmed that adverse events occur at higher levels than previously thought.<sup>19</sup> While the Harvard data were based on hospital records, studies analyzing the actual incidence of negligent events in hospital wards found that many injuries were not reported in hospital records as required—especially when the main person responsible for the error was a senior physician.<sup>20</sup> Patients are killed or injured in hospitals because of system design shortcomings, failures of coordination, and plain old physi-

<sup>16.</sup> Jeffrey O'Connell, Balanced Proposals for Product Liability Reform, 48 OHIO St. L.J. 317, 318–19 (1987).

<sup>17.</sup> David C. Classen et al., 'Global Trigger Tool' Shows that Adverse Events in Hospitals May Be Ten Times Greater than Previously Measured, 30 HEALTH AFF. 581, 581 (2011).

<sup>18.</sup> This now famous extrapolation, predicting between 44,000 to 98,000 deaths per year, was made in INST. MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 26–27 (Linda T. Kohn et al. eds., 2000). It built on the Harvard Practice Study. HARVARD MEDICAL PRACTICE STUDY, PATIENTS, DOCTORS, AND LAWYERS: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION IN NEW YORK (1990). Follow-up articles discussing the incidence of adverse events include T.A. Brennan et al., Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study, 324 NEW ENG. J. MED. 370 (1991) and L. Leape et al., The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II, 324 NEW ENG J. MED. 377–84 (1991). The extrapolation of nearly 100,000 deaths per year, based on these findings, first showed up in INST. MED., supra.

<sup>19.</sup> U.S. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., ADVERSE EVENTS IN HOSPITALS: NATIONAL INCIDENCE AMONG MEDICARE BENEFICIARIES, at i–ii (2010), available at http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf (determining that approximately 13.5% of Medicare hospital admissions suffered an adverse event, with an equal percentage experiencing temporary harm).

<sup>20.</sup> Lori Andrews, Studying Medical Error in Situ: Implications for Malpractice Law and Policy, 54 DEPAUL L. REV. 357, 367 (2005). For another look at the Harvard study, see Tom Baker, Reconsidering the Harvard Medical Practice Study: Conclusions About the Validity of Medical Malpractice Claims, 33 J.L. MED. & ETHICS 501, 502 (2005) ("[T]he finding that most medical malpractice claims are not based on either iatrogenic injury or provider negligence stands on a small and precarious empirical base. Indeed, the HMPS data are as likely to support a very different finding, namely that most malpractice claims are reasonably related to medical management injuries and provider negligence.").

cian and nurse mistakes.<sup>21</sup> Health care institutions, and their doctors and nurses, injure and kill patients one at a time—unlike pilots in airplane crashes. This statistical phenomenon of scattered casualties over more than five thousand hospitals and thousands of outpatient clinics diffuses the visibility of harm and fogs our awareness of the volume of harms that occur.

Complexity in medicine—the combination of medical progress and industrialization—is producing more medical adverse events and errors than ever before. Mark Chassin and Jerod Loeb observe: "Hospitals house patients who are increasingly vulnerable to harm due to error, and the complexity of the care hospitals now provide increases the likelihood of those errors." A study of a large Chicago-area hospital concluded that the Harvard study, the bedrock for the data projections in *To Err Is Human*, underestimated the incidence of injuries by a significant percentage. Drugs continue to be a source of patient harm. Furthermore, studies of medical practice variation conclude that many physicians practice in ways that endanger patients, in spite of clear practice guidelines to the contrary. This complexity—the combination of medical progress and industrialization—is producing more medical adverse events and errors,

<sup>21.</sup> See, e.g., Eric Nalder & Cathleen F. Crowley, Patients Beware: Hospital Safety's a Wilderness of Data, HEARST NEWSPAPERS (Mar. 22, 2010), available at http://www.chron.com/news/article/Patients-beware-Hospital-safety-s-a-wilderness-1702575.php. This multi-part series on hospital errors, with many personal stories, uses public data to compare hospitals. Id. It surveys states' policies on adverse-event reporting and chronicles the chaotic federal picture of adverse event reporting generally. Id.

<sup>22.</sup> Mark R. Chassin & Jerod M. Loeb, *The Ongoing Quality Improvement Journey: Next Stop, High Reliability*, 30 HEALTH AFF. 559, 563 (2011).

<sup>23.</sup> While the Harvard data were based on hospital records, Andrews studied actual incidence of negligent events in hospital wards and discovered that many injuries were not reported in hospital records as required, especially when the main person responsible for the error was a senior physician. Lori B. Andrews et al., *An Alternative Strategy for Studying Adverse Events in Medical Care*, 349 LANCET 309, 313 (1997) (finding that proportion of patients with one or more events was 17.7%).

<sup>24.</sup> See, e.g., Thomas T. Tsai et al., Contraindicated Medication Use in Dialysis Patients Undergoing Percutaneous Coronary Intervention, 302 JAMA 2458, 2461 (2009). In a study of 22,778 hemodialysis patients undergoing percutaneous coronary interventions (PCI) such as angioplasty, the authors found that 22.3% were administered either enoxaparin, eptifibatide, or both medications. *Id.* The use of both is contraindicated in dialysis patients due to excessive bleeding risk. *Id.* 

<sup>25.</sup> See William B. Borden et al., Patterns and Intensity of Medical Therapy in Patients Undergoing Percutaneous Coronary Intervention, 305 JAMA 1882, 1886 (2011) ("[L]ess than half of patients undergoing PCI are taking optimal medical therapy (OMT) before their procedure, despite the guideline-based recommendations to maximize OMT and the clinical logic of doing so before PCI so that the need for additional symptom relief from revascularization can be appreciated.").

with new studies concluding that the frequency of patient injury continues to grow. In spite of this growing evidence of patient injury, in no other area of civil law has reform pushed so aggressively against the tool of litigation on behalf of injured plaintiffs, even with evidence of substantial underclaiming by patients who suffer adverse events.<sup>26</sup>

Medical litigation does not spring full grown from the heads of plaintiff lawyers. Rather, it is a product of the increasingly risky world of modern medicine.<sup>27</sup> Medical progress has been one of the driving forces of expanded tort liability by simultaneously increasing the risk of harm and the benefits of treatment.<sup>28</sup> Doctors can now diagnose and treat cancer, keep premature infants alive, and treat elderly patients who would not have survived surgery two decades ago.<sup>29</sup> At the same time, health care cost inflation has naturally increased the size of malpractice jury awards because medical damages have increased far more rapidly than wages.

Second, industrialization in the health care industry has expanded liability. Health care is delivered in hospitals, outpatient facilities, and group practices, a trend that will only accelerate under the Affordable Care Act (ACA) and its incentives. Hospital actions are now subject to increasingly intense scrutiny. Long-term care has become a growing target for malpractice litigation; even pharmacists are now exposed to substantial liability risks. Hospital malpractice crises historically have been driven by perceived litigation risks to physicians, all of the institutional players in today's health care system are now exposed to litigation risks.

<sup>26.</sup> Andrews et al., *supra* note 23 at 309 ("Although 17.7% of patients experienced serious events that led to longer hospital stays and increased costs to the patients, only 1.2% of the 1047 patients made claims for compensation.").

<sup>27.</sup> See generally Robert I. Field, The Malpractice Crisis Turns 175: What Lessons Does History Hold for Reform?, 4 DREXEL L. REV. 7 (2011) (providing a rich discussion of the history of malpractice and demands for its reform).

<sup>28.</sup> William M. Sage, Understanding the First Malpractice Crisis of the 21st Century, in HEALTH LAW HANDBOOK 1, 8 (Alice Gosfield ed., 2003).

<sup>29.</sup> See generally James C. Mohr, American Medical Malpractice Litigation in Historical Perspective, 283 JAMA 1731 (2000) (discussing notable progress in modern medicine and the attendant risks involved with such treatments).

<sup>30.</sup> Elisabeth Belmont et al., A New Quality Compass: Hospital Boards' Increased Role Under the Affordable Care Act, 30 HEALTH AFF. 1282, 1287 (2011) (discussing the ACA's system-based, clinically-integrated approach to health care reform and the need for hospital boards to take on a larger quality-supervision function).

<sup>31.</sup> See Barry R. Furrow, Enterprise Liability for Bad Outcomes from Drug Therapy: The Doctor, the Hospital, the Pharmacy, and the Drug Firm, 44 DRAKE L. REV. 377, 390 (1996).

Third, reimbursement of providers has a strong effect on the system. As the result of tightened reimbursement by both private and public payers in previous decades, physicians are no longer able to pass increased malpractice premiums on to their patients or insurers. At the same time, physicians have less time to talk to their patients, leaving an injured patient disgruntled and angry at the loss of a personal relationship. Angry and injured patients are more likely to sue in such a situation.<sup>32</sup> The current payment system has, until recently, paid for the medical costs of patients injured while in the hospital. The perverse byproduct of this system is that error costs have not been passed back to institutional providers, such as hospitals, and therefore, there are no strong financial incentives to improve. In addition, the fee-for-service payment system – still in place in many parts of the health care system—creates incentives for physicians to not only waste patient and government funds by giving unnecessary care, but to also harm patients.

Fourth, as a result of the above factors, and others, the malpractice insurance market is not consistently profitable and is less stable than larger markets, such as auto insurance, given uncertainty about the actuarial risk of lawsuits.<sup>33</sup> The insurance cycle causes premium fluctuations and pricing shocks for physicians, contributing to a malpractice insurance premium crisis.<sup>34</sup>

The goal of most malpractice reforms is to reduce the total volume of litigation and the severity of the payouts, thereby driving lawyers

<sup>32.</sup> See Gerald B. Hickson et al., Patient Complaints and Malpractice Risk, 287 JAMA 2951, 2951 (2002) (discussing predictors of malpractice claims, the authors observe that "[r]isk seems not to be predicted by patient characteristics, illness complexity, or even physicians' technical skills. Instead, risk appears related to patients' dissatisfaction with their physicians' ability to establish rapport, provide access, administer care and treatment consistent with expectations, and communicate effectively"); see also Thomas H. Gallagher et al., Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors, 289 JAMA 1001, 1006 (2003) (finding that patients are troubled by the unwillingness of physicians to discuss the cause and future prevention of medical errors).

<sup>33.</sup> See U.S. Gov't Accountability Office, Medical Malpractice Insurance: Multiple Factors Have Contributed to Increased Premium Rates 28–32 (2003), http://www.gao.gov/new.items/d03702.pdf.

<sup>34.</sup> *Id.* at 5. The GAO report notes that multiple factors contribute to the movement of the medical malpractice insurance market through cycles of hard and soft markets-similar to those experienced by the property-casualty insurance market as a whole-during which premium rates fluctuate. Cycles in the medical malpractice market tend to be more extreme than in other insurance markets because of the longer period of time required to resolve medical malpractice claims, and factors such as changes in investment income and reduced competition can exacerbate the fluctuations.

Id. (internal citation omitted).

away from medical malpractice litigation as a well-compensated specialty of law practice.<sup>35</sup> Reforms, as practiced, are defendant and insurer friendly and deliberately ignore or obfuscate the costs to patient safety; most reforms reduce the level of litigation needed to police dangerous medicine.<sup>36</sup> A study of past tort reforms concludes that traditional tort reforms have focused on liability costs and not care related measures.<sup>37</sup> As such, tort reforms have been largely ineffective. Newer patient safety approaches, encouraging innovation in health care risk reduction, may foreshadow a liability system that, in Kachalia and Mello's words, "fosters, rather than obstructs, progress toward safe and high-quality healthcare."<sup>38</sup>

Profound underreporting of negligence means that patient safety improvements, contingent on reliable information about rates of adverse events, are made considerably more difficult. Hyman and Silver write that

[t]he main problem with the legal system is that it exerts too little pressure on health care providers to improve the quality of the services they deliver . . . . Safe health care is expensive, and the tort system forces providers to pay only pennies on the dollar for the injuries they inflict. <sup>39</sup>

Medical liability litigation is a critical component of a comprehensive patient safety solution to the high level of medical adverse events in the American health care system.<sup>40</sup> Litigation should be

<sup>35.</sup> For critical perspectives on the "crisis," see TOM BAKER, THE MEDICAL MALPRACTICE MYTH (2005); Kenneth J. Chesebro, Galileo's Retort: Peter Huber's Junk Scholarship, 42 Am. U. L. REV. 1637 (1993); Seth Oldmixon & Lara Causow, The Great Medical Malpractice Hoax: NPDB Data Continue to Show Medical Liability System Produces Rational Outcomes, PUBLIC CITIZEN (Jan. 2007), http://www.citizen.org/documents/NPDB%20Report\_Final.pdf; Michael J. Saks, In Search of the "Lawsuit Crisis," 14 L. MED. & HEALTH CARE 77 (1986) (looking at earlier-claimed crises)

<sup>36.</sup> See Maxwell J. Mehlman, Promoting Fairness in the Medical Malpractice System, in Medical Malpractice And the U.S. Healthcare System 137 (William M. Sage & Rogan Kersh eds., 2006); see also Marc Galanter, Reading the Landscape of Disputes: What We Know and Don't Know (and Think We Know) About Our Allegedly Contentious and Litigious Society, 31 UCLA L. Rev. 4, 69–71 (1983).

<sup>37.</sup> Kachalia & Mello, *supra* note 2 ("[T]raditional tort reforms have not proved to provide many improvements in these liability metrics[.]").

<sup>38.</sup> Id. at 1570.

<sup>39.</sup> David A. Hyman & Charles Silver, Medical Malpractice Litigation and Tort Reform: It's the Incentives, Stupid, 59 VAND. L. REV. 1085, 1130 (2006).

<sup>40.</sup> For a general critique of most malpractice reform proposals, including health courts, see Amy Widman, Liability and the Health Care Bill: An "Alternative" Perspective, 1 CALIF. L. REV. 57, 60–62 (2010) (arguing that limiting litigation serves to hinder patient safety); see also Hyman & Silver, supra note 39, at 1094; 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

viewed as a productive patient safety tool, one with sharp edges that help increase attention to medical errors that cause death or permanent harm to patients.<sup>41</sup> Litigation can be improved in terms of effective compensation to the plaintiff, and it can also be sharpened as a tool for both uncovering adverse events and creating incentives for their elimination from medical practice.<sup>42</sup>

This Article will consider the virtues of such litigation as a curative tool for the adverse event epidemic in U.S. health care, analyze the mistaken premises of the critics, and offer a series of improvements to the litigation system to make more and fairer litigation possible.<sup>43</sup> I propose a range of reforms that will increase the frequency of medical malpractice suits by improving the process of litigating, insuring, and awarding. Such reforms are intended to pull

CORNELL L. REV. 893, 979–80 (2005); David M. Studdert et al., Claims, Errors, and Compensation Payments in Medical Malpractice Litigation, 354 New Eng. J. Med. 2024, 2025 (2006).

41. Marc Galanter, *Real World Torts: An Antidote to Anecdote*, 55 MD. L. REV. 1093, 1160 (1996). Galanter discusses the United States tort system as follows:

[H]eavier reliance on the tort system signifies not only what the United States has more of, but also what it has less of. Compared to our industrialized counterparts, we do not have an administrative state with intensive governmental regulation of risks, nor do we have a comprehensive welfare state. . . . In short, our greater reliance on tort reflects not greater generosity to victims, but less reliance on administrative controls and social insurance.

Id. at 1141.

42. See Studdert et al., supra note 40, at 2031. The authors first concluded that "portraits of a malpractice system that is stricken with frivolous litigation are overblown. . . . [D]isputing and paying for errors account for the lion's share of malpractice costs." Id. Second, the authors concluded that "the malpractice system performs reasonably well in its function of separating claims without merit from those with merit and compensating the latter. In a sense, our findings lend support to this view: three quarters of the litigation outcomes were concordant with the merits of the claim." Id.

43. Another important project, beyond the scope of this Article, is the improvement of medical discipline in order to remove high-risk practitioners. Actions by state medical boards to discipline dangerous physicians are infrequent, leading to only a small number of doctors being held responsible for the majority of malpractice, and, subsequently, being removed from practice or otherwise sanctioned. See BLAIR HORNER ET AL., N.Y. PUB. INTEREST RESEARCH GRP. & CTR. FOR MED. CONSUMERS, SYSTEM FAILURE: A REVIEW OF NEW YORK STATE'S DOCTOR DISCIPLINE SYSTEM (2010), available at http://www.nypirg.org/pubs/health/2010.06 \_SystemFailure.pdf. Public Citizen, a nonprofit organization that reports annually on the rates of disciplinary actions across the states, used data from the National Practitioner Data Bank to conclude that only 45% of doctors against whom an adverse action relating to their staff privileges had been reported also had a report of a disciplinary action by the state medical board. See Letter from Sidney Wolfe, Dir. Health Res. Grp., Pub. Citizen, to Kathleen Sebelius, Sec'y, U.S. Dep't Health & Hum. Servs. (Mar. 15, 2011), http://www.citizen.org/documents /1937A.pdf. State medical boards fail to respond even in the face of reported hospital disciplinary actions against physicians. Alan Levine et al., State Medical Boards Fail to Discipline Doctors With Hospital Actions Against Them, Pub. CITIZEN (Mar. 2011), http://www.citizen.org /documents/1937.pdf.

in tandem with patient safety developments, with the ACA and federal money pouring into various reform initiatives providing a parallel stream of pressure for improving patient safety, particularly in hospitals.<sup>44</sup>

#### I. THE STANDARD CRITIQUE OF TORT LIABILITY

The standard critique of malpractice liability has at least three components: (1) compensation is incomplete, undercompensating or failing to compensate many injured patients while overcompensating others; (2) litigation as a deterrence mechanism is ineffective, causing providers either to ignore signals or to overreact and practice defensive medicine; and (3) the system is unfair to providers, given the ease with which a law suit can be filed (leading to frivolous suits) and the jury is an unreliable decision maker in complex medical cases.<sup>45</sup>

#### A. Compensation for Injury Is Inaccurate and Incomplete

Critics have claimed that there is only a small overlap between those injured by medical negligence and those filing a malpractice claim. This means that valid claims go uncompensated, some undeserving claims are compensated, and compensation is simply not correlated well to the nature and intensity of provider error. As a result, the administrative costs of adversarial litigation are too high given its inefficient compensation of the injured. The critics are certainly right that many potential claims go unfiled for a variety of reasons; however, they incorrectly argue that most claims that do proceed are invalid. Claims may end up unproven, but that is a function of the trial process, witness limitations, and uncertainties in fact finding.

<sup>44.</sup> Barry R. Furrow, *Regulating Patient Safety: The Patient Protection and Affordable Care Act*, 159 U. Pa. L. Rev. 1727, 1733 (2011) (discussing full range of patient safety provisions in the ACA and considering possible liability consequences of some of the reforms).

<sup>45.</sup> For a litany of flaws of medical liability litigation, see Ronen Avraham, *Clinical Practice Guidelines: The Warped Incentives in the U.S. Healthcare System*, 37 AM. J.L. & MED. 7, 16 (2011).

<sup>46.</sup> See generally Michelle Mello et al., The Leapfrog Standards: Ready to Jump from Marketplace to Courtroom?, 22 HEALTH AFF. 46, 55 (2003) (summarizing limitations of medical liability litigation). For criticism of claims for the existence of a medical malpractice crisis justifying the imposition of limitations on the medical liability regime and interference in the structure of the market for medical liability insurance and a review of the counter claims, see, for example, BAKER, supra note 35.

Critics correctly point out that patients who suffer harm from adverse events receive compensation too infrequently, but that is because they do not sue, not because the tort system is limited in any way. One study noted that, while a "high percentage of hospitalized surgical patients had errors in their care[,] . . . the vast majority of patients with errors (345 of 480) were not brought to the attention of the hospital as an institution, either by the health care providers or the patients. This impeded efforts to prevent future errors."47 Because providers are typically paid for the costs of correcting harm to patients who survive adverse events, often without patients knowing about the events, providers lack little incentives to correct the errors. "The slim possibility of having to pay compensation to a patient did not appear to provide a sufficient incentive to avoid errors, since only 1.24% of patients . . . made a claim and most people making claims did not receive compensation."48 People who receive medical malpractice payments do deserve the money, 49 but many people who also might deserve money cannot recover because they are not aware that they even have a claim.

What is an efficient compensation mechanism? The best candidate is first-party auto insurance, with millions of insured, little variation in claims compared to medical malpractice, and relatively easily proved damage causally linked to an accident. If we gave up on deterrence and just decided to create a pure compensation program for adverse medical events, what would it look like? We could insure against any adverse event we suffer in the hospital, so long as we can distinguish negative outcomes that are the inevitable results of a disease or our aging bodies. Adjusters can compare cars before and after a collision and measure the damage against a baseline. In health care, however, the baseline is more complicated, but it is still possible to adjust for age and condition. Granted, some harms are easier to define; so-called "never events" – wrong limb surgeries, kidnapped patients, etc. – are dramatic screw-ups that we all recognize as disasters. The problem remains that adverse medical events

<sup>47.</sup> Andrews, supra note 20, at 372.

<sup>48.</sup> Id.

<sup>49.</sup> See, e.g., Philip G. Peters Jr., What We Know About Medical Malpractice Settlements, 92 IOWA L. REV. 1783, 1786 (2007). The Harvard study, reporting a contrary finding, was poorly constructed to assess the accuracy of medical malpractice claiming and could easily be reinterpreted to support the consensus view. See generally Baker, supra note 20, at 504.

<sup>50. &</sup>quot;Never events" are now called "serious reportable events" by the National Quality Forum. NAT'L QUALITY FORUM, SERIOUS REPORTABLE EVENTS (SRES) TRANSPARENCY, ACCOUNT-ABILITY CRITICAL TO REDUCING MEDICAL ERRORS AND HARM (2008), available at http://www.qualityforum.org/Publications/2008/10/Serious\_Reportable\_Events\_Factsheet\_v3.aspx.

are hard to define if they must be attributed in each case to the negligence of providers, and defendants and insurers are unwilling to reveal likely causes to plaintiffs' lawyers. This uncertainty leads to substantial discovery before the causes of harm are properly understood. Many of these flaws are repairable.

An attempt to tie the definition of adverse events to a clear provider error is doomed to failure in many cases because of insufficient evidence as to causal links, which lead to the uncertainty and administrative costs that reformers complain about. Economists note that most of these problems are due to imperfect information on the part of patients, insurers, doctors, and the courts. Imperfect information leads to uncertain legal standards, creating incentives for physicians to overinvest in defensive practices and for both plaintiffs and defendants to invest in litigation, which lead to high overhead costs.<sup>51</sup> I will briefly discuss these flaws in the system.

#### B. Underdeterrence Is the Norm

The critics claim two problems with litigation as deterrence: (1) the small fraction of instances of negligent injury that result in claims, and (2) the lack of experience-rating for insurance premiums.<sup>52</sup> Too few claims and failures of insurers to experience-rate means that the level of incentives for improvement is too low. Both criticisms, though they have some merit, are overstated. The incentive effect of medical liability can be sharpened by several strategies to reduce uncertainty while expanding the obligations of providers to follow new and emerging best practices.

The 28 events in the list are largely preventable, grave errors and events that are of concern to the public and healthcare providers and that warrant careful investigation and should be targeted for mandatory public reporting. . . . [S]erious reportable events include[] both injuries caused by care management (rather than the underlying disease) and errors that occur from failure to follow standard care or institutional practices and policies.

Id.

<sup>51.</sup> See Patricia M. Danzon, Liability for Medical Malpractice, in HANDBOOK OF HEALTH ECON. 1339, 1341 (Anthony J. Culyer & Joseph P. Newhouse eds., 2000).

<sup>52.</sup> See generally Michelle Mello et al., supra note 46, at 55 (summarizing limitations of medical liability litigation). If a malpractice insurer does not employ experience rating to distinguish the litigation-prone providers from their colleagues, it is in effect causing an inaccurate signal to be sent, because all physicians in a practice area pay the same premiums regardless of their level of malpractice claims. The existence of insurance, therefore, dilutes or eliminates the financial incentives for physicians or other providers to change their behavior. But see Oldmixon & Causow, supra note 35 (contending that physicians experience financial incentives).

Lawsuits can be powerful tools of deterrence if they capture the maximum number of valid claims possible. They affect both provider behavior and patient choices. Lawsuits are neither random nor unfair, and liability tends to alter the behavior of health care providers. Physicians, too, learn from the experience of facing claims. Physicians respond to claims initiation more than claims resolution. One study concluded that most tort reforms would have little effect on physician behavior, with the exception of reforms aimed at reducing uncertainty about claims initiation—reforms such as the use of practice guidelines. The authors also found that claims affected consumer behavior, noting that "[t]he resolution of a malpractice claim provides public information that consumers can use when choosing a provider, and we provide some evidence that they do use this information—physician volume drops following the disposition of a large claim."

Insurers' failure to experience rate doctors' medical malpractice premiums may undermine the deterrence value of medical malpractice litigation. But, in fact, insurers have a variety of tools to alter behavior of their insureds.<sup>58</sup> Today, hospitals and other large health care provider organizations also commonly self-insure to a very substantial extent, with the result that they experience the full deterrent impact of settlements or judgments up to a level of five million dollars or more. Thus, the excess insurance that these organizations purchase to cover payments above this amount is experience rated.

As medical practices are acquired by hospitals, it is more likely that those doctors will obtain their medical malpractice insurance through their new employer.<sup>59</sup> This trend will only accelerate as the

<sup>53.</sup> Darren Grant & Melayne Morgan McInnes, Malpractice Experience and the Incidence of Cesarean Delivery: A Physician-Level Longitudinal Analysis, 41 INQUIRY 170, 171 (2004) ("[P]hysicians experiencing malpractice claims that lead to substantial indemnity payouts increase their risk-adjusted cesarean rates by about one percentage point.").

<sup>54.</sup> Id. at 185.

<sup>55.</sup> See id.

<sup>56.</sup> Id.

<sup>57.</sup> *Id.* 

<sup>58.</sup> See infra Part III.

<sup>59.</sup> See Michelle M. Mello, Robert Wood Johnson Found., Understanding Medical Malpractice Insurance: A Primer 1 (2006).

Physicians usually buy their insurance from a commercial company or a physicianowned mutual company, either individually or through a group practice. Hospitals and other health care facilities purchase their own insurance, and hospitals that directly employ physicians typically buy a policy that covers both the hospital and its medical staff. Physicians employed by the federal government don't buy insurance; if

provisions of the ACA come into effect, pushing coordination and integration of medical care. As a result, the fact that the medical malpractice insurance sold to individual doctors is not experience rated has less of an impact with each passing year.

Malpractice claims are also linked to hospital discipline, and multiple claims are useful evidence for discovering problematic physicians. Multiple malpractice claims are predictive of medical discipline, confirming the validity of such claims as predictors. One recent study of problems with state medical licensing boards concluded that "physicians with high numbers of medical malpractice reports in the NPDB [National Practitioner Data Bank] tend to have at least some adverse actions reports (e.g. hospital disciplinary report, medical board report) and Medicare/Medicaid exclusion reports and vice versa."60 Ten or more payouts predict adverse action reports, and almost 9% of those were excluded from the Medicare and Medicaid programs.<sup>61</sup> The NPBD data reveals that a few physicians account for most of the malpractice dollars paid: "Eleven percent . . . of physicians [in the NPDB] with at least one malpractice payment were responsible for half of all malpractice dollars paid from September 1, 1990 through December 31, 2006."62 Hospital data is harder to track because hospitals do not report liability claims and settlements to the database.

Deterrence, following the economic analysis, would be improved by making adverse events transparent to all parties, so that litigation would efficiently target all possible claims. This could be coupled with prompt early offer models and mediation to reduce costs while improving claiming. The solution here is to uncover adverse events, broadly defined, to promote effective remediation by providers, efficient recovery by patients, and experience rating by insurers.

#### C. Trust in Jury Verdicts Is Lacking

The criticism of juries is that medical malpractice cases are too complicated for them, that they are easily confused, and as a result,

they are sued, the suit is brought against the federal government, which insures itself. Some state-employed physicians receive coverage from the state.

Id.

<sup>60.</sup> Levine et al., supra note 43.

<sup>61.</sup> Id.

<sup>62.</sup> U.S. DEP'T OF HEALTH & HUMAN SERVS., NATIONAL PRACTITIONER DATA BANK 2006 ANNUAL REPORT 42 (2006), available at http://www.npdb-hipdb.hrsa.gov/resources/reports/2006NPDBAnnualReport.pdf.

are arbitrary in their awards.<sup>63</sup> Physicians, therefore, reject any claim that malpractice findings can be valid in revealing medical errors. The evidence is quite different. Scholars have concluded that juries are competent decision makers in complex medical cases, matching the performance of expert panels of physicians in most cases. Juries function well in medical liability cases when it comes to evaluating medical errors and harm. Neil Vidmar, after studying jury verdicts in medical malpractice cases, concluded that

widely held views of irresponsible and incompetent juries held by doctors and by the general public do not stand up to empirical evidence. This is not to say that every jury verdict is correct, but when verdicts for plaintiffs are compared against verdicts for doctors and against alternative criteria, such as ratings by medical professionals and decisions by legal professionals, juries come out reasonably well.<sup>64</sup>

Some adjustments to the rules of evidence and damages may also improve the fact-finding process, but the American jury process is unique in its ability to apply lay decision making to complex facts and reach an accurate decision.

#### II. FUNCTIONS OF TORT LIABILITY

The critiques of medical liability are overstated or just plain wrong. Lawsuits are powerful patient safety tools, if properly understood and improved. The functions of tort liability can be summarized in four important values. Tort liability (1) reinforces good medical practice; (2) articulates new duties of care; (3) gives voice to mistreated patients; and (4) exposes obtuse organizations.<sup>65</sup>

<sup>63.</sup> Kachalia and Mello claim that jury decisions are suboptimal, based on selected research that juries often do not faithfully perform their assigned task of applying the legal standard of care, frequently misunderstand instructions, permit a range of other factors to influence their decisions, and err in their negligence determinations relative to what experts would decide. *See* Kachalia & Mello, *supra* note 2.

<sup>64.</sup> Neil Vidmar, Juries and Medical Malpractice Claims: Empirical Facts Versus Myths, in 467 CLINICAL ORTHOPAEDICS & RELATED RES. 367, 374 (2009). See also NEIL VIDMAR, MEDICAL MALPRACTICE AND THE AMERICAN JURY: CONFRONTING THE MYTHS ABOUT JURY INCOMPETENCE, DEEP POCKETS AND OUTRAGEOUS DAMAGE AWARDS 69–92 (1995).

<sup>65.</sup> I note that these four values create the acronym RAGE, which I dedicate to David Hyman and his excellent work on Texas malpractice claims, his love of acronymic poetry, and his general frustration with legal hyperbole without empirical foundation.

# A. Reinforces Good Medical Practice<sup>66</sup>

Medical adverse events trigger lawsuits. Patient safety activities reduce such lawsuits. A recent Rand study found strong correlations.<sup>67</sup> Their findings are worth comment. The authors concluded that there exists "a direct link between safety outcomes and the malpractice claims that spin out of them."<sup>68</sup> They drew several conclusions from their findings. First,

new safety interventions potentially can reduce the volume of malpractice litigation—a desirable result to seek out, even beyond the immediate impact of medical injuries avoided. Stated another way, improvements in safety performance have the potential to benefit both patients and providers and to align their interests while reducing litigation.<sup>69</sup>

Insurers should also be motivated to demand patient safety measures to reduce their own exposure. The inverse connection would also seem obvious—increases in the volume of litigation motivate safety interventions.

Second, the authors of the Rand study argued that "the relationship between safety and malpractice is complex and not fully described by the simple notion of deterring acts of negligence through civil liability." One can certainly concede the complexity of the

Our results showed a highly significant correlation between the frequency of adverse events and malpractice claims: On average, a county that shows a decrease of 10 adverse events in a given year would also see a decrease of 3.7 malpractice claims. Likewise, a county that shows an increase of 10 adverse events in a given year would also see, on average, an increase of 3.7 malpractice claims. According to the statistical analysis, nearly three-fourths of the within-county variation in annual malpractice claims could be accounted for by the changes in patient safety outcomes.

We also found that the correlation held true when we conducted similar analyses for medical specialties—specifically, surgeons, nonsurgical physicians, and obstetrician/gynecologists (OB-GYNs). Nearly two-thirds of the variation in malpractice claiming against surgeons and nonsurgeons can be explained by changes in safety. The association is weaker for OB-GYNs, but still significant.

<sup>66.</sup> MICHAEL D. GREENBERG ET AL., RAND CORP, IS BETTER PATIENT SAFETY ASSOCIATED WITH LESS MALPRACTICE ACTIVITY? EVIDENCE FROM CALIFORNIA 19 (2010). The authors described their findings as follows:

Id.

<sup>67.</sup> Id. at 17-18.

<sup>68.</sup> Id.

<sup>69.</sup> Id.

<sup>70.</sup> Id.

causal connections, but note that most well-designed studies find direct linkages, particularly in the high-risk specialties.

Third, the authors observe that

malpractice laws that place providers at risk for engaging in peer review risk-management activities, root-cause analysis, and the like, could have the perverse effect of detracting from broader patient safety efforts. In turn, that could increase the frequency of adverse events and preventable injuries and, indirectly, increase the volume of malpractice litigation itself.<sup>71</sup>

This speculation is contradicted by other studies—the evidence shows that without the threat of liability, providers are not more likely to embrace time-consuming patient safety initiatives.<sup>72</sup> Rather, properly calibrated litigation and increased costs will push providers to reduce adverse events in order to reduce liability.<sup>73</sup> Most peer review immunity statutes give thorough protection to physicians engaged in patient safety activities in hospitals, suggesting that the statutes' authors lack knowledge of the legal protections currently in place. If providers can be convinced that aggressive patient safety measures should be implemented to reduce their own tort risks, they might be more likely to respond.

Providers are sensitive to bright-line rules of practice and the costs of noncompliance.<sup>74</sup> So are malpractice insurers.<sup>75</sup> Malpractice suits, for all their inefficiencies, serve a range of functions in promoting medical accountability. Tort suits are not frivolous, and awards to plaintiffs are based on jury assessments of a defendant's error that are confirmed by studies using medical experts.<sup>76</sup> Tort litigation has

<sup>71.</sup> Id.

<sup>72.</sup> See Andrews, supra note 20, at 372.

<sup>73.</sup> See supra text accompanying note 66-71.

<sup>74.</sup> James F. Blumstein, Medical Malpractice Standard-Setting: Developing Malpractice "Safe Harbors" as a New Role for QIOs?, 59 VAND. L. REV. 1017, 1020–21 (2006).

<sup>75.</sup> Recent patient safety achievements in obstetrics began with concerns over liability exposure and costs associated with insurance audits of practice. Such concerns triggered major safety initiatives. See, e.g., Amos Grunebaum et al., Effect of a Comprehensive Obstetric Patient Safety Program on Compensation Payments and Sentinel Events, 204 AM. J. OBSTETRICS & GYNECOLOGY 97, 103 (2011); see also Steven L. Clark et al., Improved Outcomes, Fewer Cesarean Deliveries, and Reduced Litigation: Results of a New Paradigm in Patient Safety, 199 AM. J. OBSTETRICS & GYNECOLOGY 105e1, 105e4 (2008).

<sup>76.</sup> Baker, *supra* note 20, at 502. This article analyzes the empirical claims of the Harvard Medical Practice study, reviews the litigation studies to date, and concludes:

<sup>[</sup>T]he finding that most eligible people do not bring medical malpractice claims is well supported and confirmed by other studies using both similar and very different research methods. Second, the finding that most medical malpractice claims are not

changed medical practices for the better, without a doubt. Liability judgments—and the costs of settling such cases, the reputational effects, and the time lost—create incentives to change behavior. The specter of suit limits certain kinds of conduct and adds financial weight to other pressures that reinforce good medical practice.

Medical liability is more effective in altering provider behavior than the critics allow.<sup>77</sup> The strongest evidence comes from the long-term effort of the American Society of Anesthesiologists to systematically study and learn from malpractice claims,<sup>78</sup> but there are many practice areas, particularly obstetrics, where medical malpractice claims led to safer practices.<sup>79</sup> Medical liability has been a major force behind the patient safety movement of today. Its various manifestations in federal and state law promote digital patient safety records and other safe practices in hospitals today.<sup>80</sup> It may also cause unproductive responses by physicians in some specialties.<sup>81</sup>

based on either iatrogenic injury or provider negligence stands on a small and precarious empirical base. . . . [M]ost malpractice claims are reasonably related to medical management injuries and provider negligence. Finally, . . . the legal system filters out most of the weaker claims.

Id.

77. See, e.g., Danzon, supra note 51 (concluding that "[t]he limited empirical evidence of provider response to liability and the deterrent effect of claims suggests – but cannot prove – that the net benefits of the malpractice system may plausibly be positive"). See also Janet Currie & W. Bentley MacLeod, First Do No Harm? Tort Reform and Birth Outcomes, 123 Q.J. ECON. 795, 807 (2008) (finding a correlation between caps on damages and birth-related complications consistent with the hypothesis that liability serves a deterrence function). For a thorough review of the evidence for and against malpractice litigation as an effective deterrent to bad medical practices, see Michelle M. Mello & Troyen A. Brennan, Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform, 80 Tex. L. Rev. 1595, 1608–13 (2002) (using Harvard Study data to show evidence that a deterrent effect of malpractice suits is lacking). But see David A. Hyman, Medical Malpractice and the Tort System: What Do We Know and What (If Anything) Should We Do About It?, 80 Tex. L. Rev. 1639, 1643 n.13 (2002) (noting that other studies looking at single institutions have found more favorable deterrent effects).

78. Peter D. Jacobson, *Medical Liability and the Culture of Technology, in MEDICAL MALPRACTICE AND THE U.S. HEALTH CARE SYSTEM 115, 123 (William M. Sage & Rogan Kersh eds., 2006)* (discussing anesthesia monitoring and the development of new tools and guidelines to reduce anesthesia risk in the 1970s).

79. BAKER, supra note 35, at 98-105, 108-10.

80. See Tom Baker, Medical Malpractice Insurance Reform: 'Enterprise Insurance' and Some Alternatives, in Medical Malpractice and the U.S. Health Care System 278 (William M. Sage & Rogan Kersh eds., 2006).

81. Ity Shurtz, *The Impact of Malpractice Litigation on Physician Behavior: The Case of Childbirth*, (Nov. 2010), http://www.biu.ac.il/soc/ec/seminar/data/15\_12\_10/impact\_malpractice\_litigation.pdf. The author discusses the impact of adverse events on C-section rates as follows:

I find that immediately after an adverse event (defined as an obstetrical procedure that ultimately leads to a malpractice claim), C-section rates jump discontinuously by 4%. The increase in C-section rates persists even 4.5 years after the adverse event. . . .

Clear standards for practice would reduce provider uncertainty and sharpen incentive pressures. Such standards are more likely to be heeded by health care professionals in their practice where the rule is a relatively simple one.82 A technological innovation, for example, may reduce both the level of medical injury for a procedure and the risks of being sued. Consider the carbon dioxide monitor and the pulse oximeter, which monitors a patient's blood oxygen to indicate when his oxygen level drops due to breathing problems or overuse of anesthesia.83 This can give physicians three or four minutes to correct a problem before brain damage results.84 In 1984, no hospital operating room had such devices, but by 1990 all operating rooms did.85 Patients under anesthesia now suffer fewer injuries as a result. 86 Tort law is likely to influence medical practice by imposing financial burdens on providers and their malpractice insurers for medical errors where good practice was ignored or sloppy practice was tolerated. Providers, as consumers of lawyers and in-

[T]his study shows that following an adverse event physicians adopt more conservative and costly treatment strategies and that their response is likely to be related to fear of litigation and damage to reputation.

*Id.* at Abstract. The author finds that "the response to an adverse event is concentrated among successful claims, which, at the time of the adverse event, are more likely to be perceived as harmful to physicians' reputation than unsuccessful claims." *Id.* at 3. "The evidence in this paper suggest that, potential reputation loss following a malpractice claim, leads to a change in physician treatment patterns, possibly resulting in excessively conservative behavior." *Id.* at 22.

82. Daniel J. Givelber et al., Tarasoff, *Myth and Reality: An Empirical Study of Private Law in Action*, 1984 WIS. L. REV. 443, 485–86. After surveying 2875 psychotherapists nationwide, Givelber et al. concluded that therapists now warn third parties when a patient utters a threat. *Id.* at 485. The therapists feel bound by *Tarasoff*, even though the case is binding only on California therapists. *Id.* Therapists feel capable of assessing dangerousness and are comfortable with warning victims. *Id.* The authors argued that "if an appellate court desires to change behavior, it should use judicially established standards of behavior, not jury determined standards. The judicially determined rule of *Tarasoff I.*, protect through warning, appears to have affected therapist attitudes, knowledge and behavior to a far greater degree than *Tarasoff II." Id.* at 487.

83. See generally John W. Severinghaus, *Takuo Aoyagi: Discovery of Pulse Oximetry*, 105 AN-ESTHESIA & ANALGESIA, S1, S1-S4 (2007) (discussing the invention and implementation of the pulse oximeter).

84. Id. at S1.

85. See Washington v. Washington Hosp. Ctr., 579 A.2d 177 (D.C. 1990). These devices have so improved patient safety that malpractice insurers have lowered premiums for anesthesiologists. The Joint Commission now requires hospitals to develop protocols for anesthesia care that mandate pulse oximetry equipment for measuring oxygen saturation. See Revisions to Anesthesia Care Standards Comprehensive Accreditation Manual for Hospitals Effective January 1, 2001 (Standards and Intents for Sedation and Anesthesia Care), available at http://www.jointcommision.org.

86. *See* Severinghaus, *supra* note 83, at S4 ("Introduction of pulse oximetry coincided with a 90% reduction in anesthesia-related fatalities.").

surance, are at least somewhat sensitive to increases in price, which heightens their sensitivity to bright-line rules of practice.

The argument often made by providers—that tort suits promote defensive medicine—proves hard to establish.<sup>87</sup> Even if it could be proved, it would only affirm that the publicity and resulting reputational effects of the tort system magnify the relatively low risk—for any provider—of losing a malpractice claim.<sup>88</sup> We may not want to dull the tort signal to physicians, but rather fine-tune it to provide a better risk-taxing system. In some areas, like products liability, it is clear that the risk of suit has promoted product innovation in response to the judicial costs imposed. As liability shifts to group practices, accountable care organizations, and hospitals, it is equally likely that innovation will result, as the obstetric studies suggest.<sup>89</sup>

#### B. Articulates New Duties of Care

New tort doctrines have emerged over the past thirty years that impose obligations on physicians to protect patients from a range of risks. Such new duties include obligations to disclose a range of risks to third parties—infectious diseases, for example;<sup>90</sup> to refer a patient to a specialist when the doctor's own skill or experience is lacking;<sup>91</sup> to be honest about skill and experience when consulting with a patient about treatment;<sup>92</sup> and to put the patient's interests over the physician's in situations of conflict.<sup>93</sup> The tort doctrine of

<sup>87.</sup> Cong. Budget Office, Medical Malpractice Tort Limits and Health Care Spending 2, 9, 27 (Apr. 2006), available at http://www.cbo.gov/ftpdocs/71xx/doc7174/04-28-medicalmalpractice.pdf.

<sup>88.</sup> Laurence R. Tancredi & Jeremiah A. Barondess, *The Problem of Defensive Medicine*, 200 SCI. 879, 881–82 (1978).

<sup>89.</sup> See, e.g., Amos Grunebaum et al., supra note 75, at 103.

<sup>90.</sup> See generally Tracey A. Bateman, Annotation, Liability of Doctor or Other Health Practitioner to Third Party Contracting Contagious Disease from Doctor's Patient, 3 A.L.R. 5th 370 (1992) (discussing physicians' duty to disclose to third parties the risk of patients' infectious diseases). HIV-positivity and AIDS status have led to a variety of legislative and administrative approaches to confidentiality and disclosure of information. All states now require physicians to report both HIV and AIDS cases to the state health department. Several states have adopted statutes mandating strict confidentiality of AIDS-related information. See CAL. HEALTH & SAFETY CODE § 121022 (West 2010); FLA. STAT. ANN. § 381.004(3)(a) (West, Westlaw through ch. 236 (end) of 2011 1st Reg. Sess. of 22d Legis.); MASS. GEN. LAWS ANN. ch. 111, § 70F (West, Westlaw through ch. 175 of 2011 1st Ann. Sess.).

<sup>91.</sup> Johnson *ex rel*. Adler v. Kokemoor, 545 N.W.2d 495, 507–10 (Wis. 1996) (discussing surgeon's obligation to accurately disclose experience with surgical procedure to patient).

92. *Id.* 

<sup>93.</sup> Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 485 (Cal. 1990) ("[A] physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty

"loss of a chance" appears to create a new legal right as well as simply expanding damages for patients in cases of missed diagnoses where their chances of survival were less than 50%. 94

#### C. Gives Voice to Mistreated Patients

Patients are sometimes patronized, ignored, actively manipulated, lied to, cruelly treated, or bullied by physicians. Tort rules are moral beacons, giving voice to these patients, and providing remedies that alter provider behavior while satisfying the plaintiffs' needs to be heard and demand correction. The doctrine of the negligent infliction of emotional distress has allowed courts and juries to recognize unacceptable, cruel provider behavior toward vulnerable patients. What such cases have in common are vulnerable plaintiffs, either during the medical procedure or once they learn what has happened; an inattentive, rude, or disorganized medical staff; and general bad management by a hospital. The cases indicate judicial understanding of hospital failures to provide sensitive, well-trained health care and judicial willingness to extend tort doctrine to allow recovery in these highly charged situations.<sup>96</sup>

and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment.") (citation omitted).

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

Galanter, supra note 41, at 1160.

96. In malpractice cases that have allowed a mental distress claim without physical injury or expert testimony, the action of the defendant is evaluated by the lay trier of fact. For example, in *Campbell v. Delbridge*, 670 N.W.2d 108 (Iowa 2003), the plaintiff, a Jehovah's Witness, was tranfused with blood even though he had given explicit instructions, which were in his medical record, that he refused such transfusions. The court held that the heart of the plaintiff's claim was "that the care provided by defendants . . . fell below the standard of medical professionalism understood by laypersons and expected by them." *Id.* at 112. In *Oswald v. LeGrand*, 453 N.W.2d 634 (Iowa 1990), an earlier Iowa case on which *Campbell* relied, the plaintiff gave birth to an apparent stillborn child, which turned out in fact to be alive, and which lived briefly. *Oswald* involved an accumulation of uncaring acts by the health care providers, from the treating doctor to the nurses. *See Campbell*, 670 N.W.2d at 110–11 (discussing *Oswald*, 453 N.W.2d at 636–37). The court noted that a lay jury could easily decide whether the statements and actions by the providers were rude and uncaring. *Id.*; *see also* Wargelin v. Sisters of

an

<sup>94.</sup> One author has described the "loss of a chance" doctrine as one of the "ethereal" torts. See Nancy Levit, Ethereal Torts, 61 GEO. WASH. L. REV. 136, 140 (1992) ("The individual expectancy, dignity, and autonomy interests that ethereal torts protect are intrinsically valuable.") See also Joseph H. King Jr., Causation, Valuation, and Chance in Personal Injury Torts Involving Preexisting Conditions and Future Consequences, 90 YALE L.J. 1353 (1981).

<sup>95.</sup> As Marc Galanter has written,

Many liability doctrines shine a bright light on less than salutary health care practices. Informed consent doctrine has forced medical recognition of patients' informational needs;<sup>97</sup> the damage provisions of the Emergency Medical Treatment and Active Labor Act have forced stabilizing treatment by hospitals inclined to simply push patients out the door through civil damage remedies;<sup>98</sup> and tort duties to warn and other disclosure obligations have built on the physician's fiduciary duty toward patients.<sup>99</sup>

Judicial decisions have imposed new duties on providers. Physicians must treat patients with respect, more fully disclose possible risks of treatment, and generally place the patient's interests higher than their own. Judicial expression of tort duties is a "register of our moral concerns" that illuminates conduct by providers. Such duties draw attention to how providers, as failed moral agents, at times treat patients badly. 100

As a beacon, tort suits can shed light on poorly designed and poorly managed institutions. And in a broader sense, the deliberation process in medical liability cases generally gives juries a platform from which to speak out about the problems with technological, industrialized medicine.<sup>101</sup>

Mercy Health Corporation, 385 N.W.2d 732, 738 (Mich. Ct. App. 1986) ("[T]he cumulative effect of all the events surrounding the stillbirth of the child, if proven to be negligent at trial, are sufficient to cause a parent to suffer emotional and mental distress.").

<sup>97.</sup> See Barry R. Furrow et al., Health Law: Cases, Materials and Problems 230–83 (6th ed. 2008).

<sup>98. 42</sup> U.S.C. § 1395dd(d) (2006). EMTALA was enacted by Congress in response to evidence of patient dumping from hospitals due to lack of insurance. For a landmark study, see R.L. Schiff et al., *Transfers to a Public Hospital: A Prospective Study of 467 Patients*. 314 New Eng. J. Med. 552 (1986).

<sup>99.</sup> See Barry R. Furrow, Patient Safety and the Fiduciary Hospital: Sharpening Judicial Remedies, 1 DREXEL L. REV. 439, 444–50 (2009) (developing the fiduciary concept as it applies to health care providers).

<sup>100.</sup> Barry R. Furrow, Regulating Patient Safety: Toward a Federal Model of Medical Error Reduction, 12 WIDENER L. REV. 1, 10–11 (2005) (quoting Galanter, supra note 41, at 1160).

<sup>101.</sup> See Catharine Pierce Wells, Tort Law as Corrective Justice: A Pragmatic Justification for Jury Adjudication, 88 MICH. L. REV. 2348, 2411 (1990) (arguing "that tort law enforces community standards of financial responsibility and just compensation," counterbalancing the often subjective deliberation process by "allowing the jury to evaluate a wide range of issues" but "requiring that it operate in a decisional context that produces locally objective judgments"); see also Seana Valentine Shiffrin, Inducing Moral Deliberation: On the Occasional Virtues of Fog, 123 HARV. L. REV. 1214, 1214 (2010) (arguing that the "opaque features" of liability standards can have a "salutary impact . . . on citizens' moral deliberation and on robust democratic engagement . . . with law").

# *D. Exposes Obtuse Organizations*<sup>102</sup>

Hospitals are "obtuse" organizations dominated by high-status physicians and administrators who struggle to manage them. The problem is twofold: hospitals must discover errors and their causes and must develop leadership tools to fix mistakes systematically. Adverse events in hospitals are often due to interaction problems and systemic failures rather than to mistakes made by individual providers. And the severity of injury is much higher than the IOM report suggests. Many institutions and practices need a new patient safety culture. The problems are dominated by high-status physicians and their causes and their causes and their causes.

102. "Obtuse" is used by Amy Edmondson, a specialist in organizational behavior, to describe how hospitals often fail to learn from their mistakes. See Craig Lambert, Obtuse Organizations: Secret Errors Kill, HARV. MAG., Mar.-Apr. 2001, at 11, available at http://harvardmagazine.com/2001/03/secret-errors-kill.html (last visited Dec. 10, 2011). Edmondson, an assistant professor at the Harvard Business School, teamed up with two colleagues to study factors that encourage, or inhibit, surfacing errors in small work groups. Id. Leadership that encourages the surfacing of errors can reduce mistakes. As Edmondson found, "You don't find yourself repeating the same mistake—since you didn't know about it—that a colleague made last week. When errors aren't surfaced, an individual may be learning, but the group doesn't learn. Obtuse organizations can make the same mistake again and again." Id.

103. Anita L. Tucker & Amy C. Edmondson, Why Hospitals Don't Learn from Failures: Organizational and Psychological Dynamics That Inhibit System Change, 45 CAL. MGMT. REV. 55, 63–64 (2003) (discussing how the individual vigilance and staffing shortages that pervade the industry create barriers to organizational improvement); see also Linda H. Aiken & Patricia A. Patrician, Measuring Organizational Traits of Hospitals: The Revised Nursing Work Index, 49 NURSING RES. 146, 147 (2000) (empowerment of nurses is associated with high quality care and low nursing turnover).

104. Lambert, *supra* note 102. ("Leadership that encourages the surfacing of errors can actually reduce mistakes significantly in the long run. If errors surface and are publicly discussed, team members can help each other avoid the booby traps hidden in their work environment.").

105. See Andrews et al., supra note 23, at 312 ("Although the practice of medicine is often viewed as an individual effort between doctor and patient[,] . . . the proportion of errors with interactive or administrative causes (25.4%) underscores the influence of the inter-relationship among healthcare professionals and administrative actions on errors.").

106. Id. at 311-12. The authors note,

One or more causes were mentioned for just over half the adverse events; 37.8% were said to have been caused by an individual—for example, by poor technical performance, poor judgment, or failure to act on or to obtain information. 15.6% of adverse events had causes related to the interaction between individuals, or between individuals and hospital entities, or between hospital entities, such as the failure of a consultant team to communicate adequately with the requesting team. 9.8% of adverse events had causes related generally to administrative decisions and protocols—eg, defective or unavailable equipment or inadequate staffing.

Id. at 311.

107. See Timothy J. Vogus et al., Doing No Harm: Enabling, Enacting, and Elaborating a Culture of Safety in Health Care, ACAD. MGMT. PERSP., Nov. 2010, at 60, available at

The development of tort doctrines such as corporate negligence has been valuable in imposing expanded liability on enterprises such as hospitals. This direct liability provides powerful financial incentives to push institutional practice toward convergence on validated standards of care. Avoidance of litigation has led to the growth of offices of risk and quality management, Patient Safety Compliance Officers, and has promoted a new emphasis on problem-solving behavior in complex health care settings like hospitals. A renewed internal focus on adverse events driven by the filing of more tort claims, coupled with the ACA's patient safety initiatives and money, will increase pressure to remake obtuse institutions like hospitals.

The creation of a safety culture in complex institutions like hospitals requires a leadership focus that is hard to achieve. Pressure from multiple sources is building in hospitals, as hospitals bear the brunt of new reimbursement and adverse event disclosure rules. A move toward institutional liability will provide an additional boost toward an obsessive focus on patient safety as a new area of compliance.<sup>112</sup>

# III. LIABILITY AND TRANSPARENCY: UNCOVERING AND POLICING ADVERSE EVENTS

Patient safety has become a powerful new component of health care management, driven by both the threat of malpractice litigation and by federal regulatory movement toward pay for performance, among other factors. <sup>113</sup> The language of industrial improvement has

http://ssrn.com/abstract=1904620 (providing a comprehensive and integrated framework of patient safety).

<sup>108.</sup> See Barry R. Furrow et al., supra note 97, at 466–74.

<sup>109.</sup> See generally, Risk Management, Quality Improvement and Patient Safety, ECRI INST., http://www.ecri.org/Products/Pages/Healthcare-Risk-Control-System-Table-of-Contents .aspx#riskqual (last visited Dec. 10, 2011) (illustrating the vast array of avenues for risk control in every medical field).

<sup>110.</sup> THE HANDBOOK OF PATIENT SAFETY COMPLIANCE: A PRACTICAL GUIDE FOR HEALTH CARE ORGANIZATIONS 21 (Fay A. Rozovsky & James R. Woods, Jr. eds., 2005).

<sup>111.</sup> See, e.g., George J. Annas, The Patient's Right to Safety—Improving the Quality of Care Through Litigation Against Hospitals, 354 New Eng. J. Med. 2063, 2065 (2006), available at http://www.nejm.org/doi/full/10.1056/NEJMsb053756.

<sup>112.</sup> See Vogus et al., supra note 107, at 60.

<sup>113.</sup> The need to manage liability risk has led to new professional categories within hospitals and other health care organizations, from risk managers in hospitals to compliance officers. These professionals and their professional associations deal with liability and regulatory risks. They collect information about medical errors, reimbursement mistakes, and patient

moved into health care: continuous quality improvement, Six Sigma Quality, and so on.<sup>114</sup> This momentum pushes the ACA forward, focusing on existing and new models of delivery that promote system management of quality and adverse events.<sup>115</sup> New models of coordination and care integration are a central feature of the quality initiatives of the ACA.<sup>116</sup>

Medical liability reform is only a minor component of the ACA, with demonstration projects to be funded. Liability as a tool for quality improvement is not discussed anywhere in the ACA, and it would appear to have been relegated to a fading player in the drama of health care quality improvement. The ACA tries to pressure the health care market to improve quality, in Mark Pauly's words, through an "array of subsidies, demonstration projects, commissions, and study groups." <sup>117</sup>

This Article takes the position that medical liability lawsuits should be strengthened as a useful tool for patient safety, using existing tools and rules, and some new ideas, to sharpen incentives for providers to improve safety. Litigation has substantial benefits, providing a strong source of pressure toward institutional change, a data source for adverse events, and a continuing method of pinpointing medical failures and articulating new and necessary duties of care. Liability often operates at ethical frontiers of provider behavior, asking whether a new technology or management approach is necessary and whether provider conduct is ethical and, therefore, legal.

safety issues generally. See generally Margo Schlanger, Operationalizing Deterrence: Claims Management (in Hospitals, a Large Retailer, and Jails and Prisons), 2 J. TORT L. 1 (2008) (focusing on the operation of deterrence and the steps taken by organizations with respect to claims management). For an example of a rapidly growing association dedicated to training and certifying health care compliance officers, see HEALTH CARE COMPLIANCE ASS'N, http://www.hcca-info.org//AM/Template.cfm?Section=Home (last visited Dec. 10, 2011).

\_

<sup>114.</sup> For a summary of evolution of health care toward a model of high reliability organizations, see Chassin & Loeb, *supra* note 22, at 563.

<sup>115.</sup> Furrow, supra note 44, at 1737, 1743.

<sup>116.</sup> Id. at 1758-65.

<sup>117.</sup> Mark V. Pauly, The Trade-Off Among Quality, Quantity, and Cost: How to Make It – If We Must, 30 HEALTH AFF. 574, 579 (2011).

<sup>118.</sup> Eric Helland et al., Tort Liability and the Market for Prescription Drugs 2 (July 6, 2011) (unpublished manuscript), available at http://ssrn.com/abstract=1883691 ("[T]ighter liability standards [punitive damage caps in particular] lead to higher prices and higher utilization. We also find that tighter liability rules reduce adverse safety events associated with prescription drugs. This suggests that, on balance, liability improves consumer and social welfare.").

The perceived success of medical liability reforms should depend on (1) how well they succeed at exposing as many adverse medical events as possible that cause serious patient harm or death and (2) maintaining a steady background pressure on medical providers to constantly review patient safety practices. Other tort goals—compensation, loss spreading, efficiency—will be subordinated to this patient safety metric for the purposes of this Article. This simplifying assumption allows us to examine the strengths and weaknesses of liability as a patient safety tool.

#### A. The Obligation to Disclose Adverse Events

Health care providers are special, providing a service that we view as essential and life extending. We therefore give providers an exemplary status, coupled with a higher level of expectation. A health care provider is a "fiduciary," and thus has special obligations to patients. Courts in the United States, Australia, and Canada have expanded fiduciary concepts to the health care setting in light of the vulnerability of patients and the power of providers. It can be argued that this fiduciary duty includes a duty to reveal adverse events to patients, such as injuries to the patient requiring further treatment that could have been prevented. It might even demand the disclosure of outcome disparities among providers.

<sup>119.</sup> These goals, including an overall test of fairness in the tort system, are all important, but have been well discussed elsewhere. *See, e.g.,* Daniel P. Kessler & David J. Becker, *The Effects of the U.S. Malpractice System on the Cost and Quality of Care, in MEDICAL MALPRACTICE AND THE U.S. HEALTHCARE SYSTEM, supra 36, at 84; Mehlman, <i>supra* note 36.

<sup>120.</sup> See generally Furrow, supra note 99, at 444–50 (developing the fiduciary concept as it applies to health care providers).

<sup>121.</sup> For a discussion of Australian cases recognizing a fiduciary duty between doctors and patients, see Thomas A. Faunce & S. N. Bolsin, *Fiduciary Disclosure of Medical Mistakes: The Duty to Promptly Notify Patients of Adverse Health Care Events*, 12 J. LAW. & MED. 478, 479–81 (2005) (Austl.). For a discussion of the evolution of an identical fiduciary obligation in Canada, see Moe Litman, *Fiduciary Law in the Hospital Context: The Prescriptive Duty of Protective Intervention*, 15 HEALTH L.J. 295 (2007) (Can.), *available at* http://findarticles.com/p/articles/mi\_hb1361/is\_15/ai\_n28566478. For a discussion of the recognition of the same affirmative duty in the United States, see Furrow, *supra* note 99; Maxwell J. Mehlman, *Dishonest Medical Mistakes*, 59 VAND. L. REV. 1137, 1147–54 (2006).

<sup>122.</sup> See Andrews, supra note 20, at 373 ("One approach with a solid grounding in existing law would be to impose upon health care providers a duty to inform patients that errors have occurred in their care."); Joan Vogel & Richard Delgado, To Tell the Truth: Physicians' Duty to Disclose Medical Mistakes, 28 UCLA L. REV. 52, 67 (1980) (explaining that duty to disclose medical mistakes allows more patients to bring malpractice suits, increasing pressure to improve patient safety).

<sup>123.</sup> See Nadine Housri et al., Should Informed Consent for Cancer Treatment Include a Discussion About Hospital Outcome Disparities?, 5 PLoS Med. 1413, 1415 (2008), available at

Courts have shown little patience for physicians' concealment of their role in causing patient injury through malpractice-viewing such concealment as a form of lying – and have stripped away some powerful legal defenses that would otherwise be available to defendants. 124 Patients may suffer injuries that their physicians conceal until the statute of limitations runs on the patients' right to sue. 125 Tort doctrine has developed a doctrine of equitable estoppel, or fraudulent concealment in some states, to bar the provider from raising an affirmative defense of the running of the statute of limitations. As one court wrote, "During the continuance of the professional, fiduciary relationship between the physician and the patient, 'the degree of diligence required of a patient in ferreting out and learning of the negligent causes of his condition is diminished,""126 especially where a physician's actions are based on concealment, a lie perpetrated to protect the physician's interests at the expense of the patient's right to sue. While courts have typically applied fiduciary analysis to physicians, it is appropriately also applied to hospitals and other institutional providers who have every incentive to conceal information about adverse events experienced by patients.<sup>127</sup>

A hospital arguably is a co-fiduciary with its physicians and staff, taking on a higher duty to protect patient safety and health than is normally required by normal medical liability doctrines. McCullough has argued that such a duty is a strong ethical obligation. He writes, "Healthcare organizations that deliver or influence the delivery of healthcare are co-fiduciaries with healthcare professionals of the population patients for whom the organization is responsible, so that each receives an evidence-based standard of care." The language of fiduciary duty has entered judicial discussions about the doctor-patient relationship in the hospital setting. Courts have noted that patients rely on hospitals, just as they rely on

ŀ

http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0050214 (follow "Download: PDF") (proposing that physicians have an ethical obligation to inform patients about hospital outcome disparities for select cancers and discussing the logistical and practical hurdles they would face to do so).

<sup>124.</sup> See Furrow, supra note 99, at 451-52.

<sup>125.</sup> See, e.g., Hardi v. Mezzanotte, 818 A.2d 974, 977–81 (D.C. 2003) (holding patient could not sue after statute of limitations had run where patient was unaware of her claim against the defendant physician until after statute of limitations and because she could not have discovered that she had a valid claim earlier).

<sup>126.</sup> Peik v. Kawesch, No. D048562, 2007 WL 1821381, at \*5 (Cal. Ct. App. June 26, 2007) (quoting Sanchez v. S. Hoover Hosp., 553 P.2d 1129, 1135 (Cal. 1976)).

<sup>127.</sup> Furrow, supra note 99, at 452.

<sup>128.</sup> LAURENCE B. MCCULLOUGH, A PRIMER ON BIOETHICS 1, 4 (2d ed. 2006), available at http://net.acpe.org/interact/ethics/bioethicsprimer.pdf.

physicians, to treat their condition with loyalty and skill.<sup>129</sup> Patients in most cases rely on the reputation of the hospital, not any particular doctor, and for that reason select a particular hospital.<sup>130</sup>

## 1. Refining the parameters of adverse events

Adverse events are underreported in hospitals, 131 and therefore not enough suits are brought in light of the universe of potential claims. 132 Why would an injured patient not file a claim? Several reasons provide an explanation. First, if the injury is relatively minor, a lawyer lacks financial incentives to bring a suit, given his dependence on a contingency fee to recover his costs. Second, if the patient's health insurance covers the cost of rehabilitation or cure, there is little incentive to seek money from the defendant for smaller harms. Third, patients often have affection for their physician and are reluctant to sue the physician, even if negligence is clear. Fourth, the patient is often ignorant of the link between his injury and physician negligence. Fifth, a patient has to discover that he suffered a real preventable injury, not just an unavoidable risk that materialized. How does he discover this? Absent medical training, the average lay person is not familiar with outliers, with the exception of res ipsa loquitur kinds of situations captured by "never events" such as wrong-site surgery. 133 As injuries become less accessible to lay understanding, the patient has to discover the category into which the injury falls. Through disclosure, the provider arms the patient with

<sup>129.</sup> We start to see a focus on hospital boards by those who analyze and provide advice to hospitals. *See, e.g.*, ECRI INST., THE ROLES OF HEALTHCARE GOVERNING BOARDS (2009), *available at* http://www.ecri.org/documents/rm/hrc\_toc/lawreg8es.pdf.

<sup>130.</sup> See, e.g., White v. Methodist Hosp. S., 844 S.W.2d 642, 647 (Tenn. Ct. App. 1992).

<sup>131.</sup> Andrews, supra note 20, at 372.

<sup>132.</sup> The Agency for Healthcare Research and Quality (AHRQ) defines "adverse events" as "any injury caused by medical care." The AHRQ cites the following examples: pneumothorax from central venous catheter placement; anaphylaxis to penicillin; postoperative wound infection; and hospital-acquired delirium (or "sundowning") in elderly patients. It continues:

Identifying something as an adverse event does not imply 'error,' 'negligence,' or poor quality care. It simply indicates that an undesirable clinical outcome resulted from some aspect of diagnosis or therapy, not an underlying disease process. Thus, pneumothorax from central venous catheter placement counts as an adverse event regardless of insertion technique. Similarly, postoperative wound infections count as adverse events even if the operation proceeded with optimal adherence to sterile procedures, the patient received appropriate antibiotic prophylaxis in the perioperative setting, and so on.

Agency for Healthcare Research & Quality, Glossary, U.S. DEP'T HEALTH & HUM. SERVS. http://psnet.ahrq.gov/glossary.aspx (last visited Dec. 11, 2011).

<sup>133.</sup> NAT'L QUALITY FORUM, supra note 50.

information. This information helps the patient understand the provider's causal contribution to his experience of adverse events.

Absent a mandate to disclose, why should a provider voluntarily disclose, except out of altruistic motivations unlikely to be found in the majority of doctors? Voluntary reporting efforts are consistently unsuccessful in the states, as providers avoid reporting whenever possible. Florida, for example, tried to encourage voluntary reporting several years ago to provide concrete teaching examples for providers. After spending one million dollars on the project, the state found that 90% of state hospitals reported no adverse events.<sup>134</sup> Studies of other states confirm little effective reporting of adverse events under voluntary systems.<sup>135</sup>

Now suppose that the provider neither caused the adverse event nor knew of its occurrence. Assume instead a recurrent team failure, such as a particular surgical team in a hospital, which only a statistical analysis would reveal. If surgical teams A and B are compared, and one has a mortality or infection rate double or triple that of the other, is this a medical-error-induced injury for the patient who suffers? What if a toxic physician is not aware of his own toxicity? Or what if the members of a surgical team are not aware of their short-comings?<sup>136</sup> Here, discovery of the event requires data-mining strategies and other tools to ferret out the source of the problem.

Or assume an "obtuse organization"—a hospital that refuses to learn from its errors—that buries errors underground in a hostile environment where the staff is afraid or unwilling to discuss errors, bad outcomes short of death, or other adverse events.

Medical liability litigation is an outcome-driven patient safety mechanism, awaiting evidence of patient injury before crossing the threshold for a possible claim. It does not reveal "near misses" or cases of predictable side effects of drugs, therapies, or surgeries. The low level of claiming suggests that lawsuits underdeter rather than overdeter in most medical specialties, despite physicians' exaggerated complaints about defensive medical practices. Even when a suit is filed, there is evidence that recoveries for non-economic damages are too small on average (in states without statutory limits on such

<sup>134.</sup> Sally Kestin & Bob LaMendola, Little Or No Progress on Medical Mistakes in Florida, SUN-SENTINEL (July 29, 2011), http://articles.sun-sentinel.com/2011-07-29/health/fl-hk-medical-mistakes-overview-20110710\_1\_wrong-site-surgeries-medical-mistakes-wrong-body-part.

<sup>135.</sup> Nalder & Crowley, supra note 21, at A23.

<sup>136.</sup> See Barry R. Furrow, Data Mining and Substandard Medical Practice: The Difference Between Privacy, Secrets and Hidden Defects, 51 VILL. L. REV. 803, 820–23 (2006).

damages).<sup>137</sup> But a suit's performance can be improved as a detector of adverse events generally, with help from changes in legal rules and statutory authority.

If imperfect information is part of the criticism of the lack of deterrent effects of medical malpractice litigation, then improving that information as to adverse events is the first step; the second step is to simplify the legal handling of such information in a tort suit. <sup>138</sup> Fear of medical malpractice liability is the reason that we know what we know about medical malpractice. Most of the existing research on medical malpractice has been motivated by liability concerns. <sup>139</sup> It seems clear that more claims would tell us more about the universe of adverse events and how to cure them.

The collection and reporting of hospital adverse events is a mess. The hospital data currently available in some states is flawed by content gaps, inputting errors, failures by hospitals to conform to data-entry standards, and inadequate government oversight of the data collection process. Federal efforts to improve such data collection have been lackluster at best. Congress enacted the Patient Safety and Quality Improvement Act in 2005 to encourage voluntary reporting through the creation of a system of patient safety organizations (PSOs). Reports of medical errors are sent to these organizations and kept confidential so that they cannot be used against the reporter in malpractice litigation. The Act fails to provide any incentives for reporting, however, and without incentives for physicians to report, these PSOs are unlikely to uncover adverse events. Its

<sup>137.</sup> See, e.g., Randall R. Bovbjerg et al., Valuing Life and Limb in Tort: Scheduling "Pain and Suffering," 83 Nw. U. L. Rev. 908, 928–29 (1989).

<sup>138.</sup> See Danzon, supra note 51, at 1344.

Imperfect and asymmetric information can lead to legal standards of care that are systematically biased and have high variance. Legal standards that are unpredictable and open to influence can create incentives for physicians to practice defensive medicine and incentives for plaintiffs and defendants to invest in litigation to influence the outcome . . . .

Id.

<sup>139.</sup> Baker & Lytton, supra note 8, at 105, 121-22; Baker, supra note 80, at 278.

<sup>140.</sup> See Hyman & Silver, supra note 40, at 896 (summarizing research showing that medical providers do not disclose errors).

<sup>141.</sup> Nalder & Crowley, supra note 21, at A23.

<sup>142.</sup> Patient Safety and Quality Improvement Act, Pub. L. No. 109-41, 119 Stat. 424 (2005).

<sup>143.</sup> See Hyman & Silver, supra note 40 at 988 (criticizing the plan because it is not adequately funded and because health care professionals have no significant incentive to make reports).

Current approaches to tracking adverse events include voluntary, sentinel event and "never event" reporting systems, often mandated either by state regulators or by the Joint Commission. These methods function poorly. A recent analysis of varied methods for adverse event tracking concluded that "these reporting systems fail to detect most adverse events. . . . Hospitals that use such methods alone to measure their overall performance on patient safety may be seriously misjudging actual performance."

Mandatory adverse event reporting (discussed below) is the ideal approach to full discovery of adverse events, but it is often limited by poor compliance as the direct result of weak enforcement sanctions. Other approaches to detection of adverse event patterns include the Institute for Healthcare Improvement's Global Trigger Tool<sup>145</sup> and the use of data mining software programs, such as Midas and other vendor programs, to mine hospital records.<sup>146</sup> Such tools are designed to detect outlier problems in care that may otherwise be invisible to medical staff and administrators.<sup>147</sup> They are unlikely, however, to pick up the range of adverse events that nurses and other providers would detect in their own patient care.

## 2. Mandatory adverse event reporting

Adverse event reporting is a central component of patient safety, identifying threats to patient safety and providing crucial information for fixes. <sup>148</sup> Mandatory reporting with sanctions for failures

<sup>144.</sup> Classen et al., *supra* note 17, at 585. The authors describe their findings as follows: Our findings indicate that two methods commonly used by most care delivery organizations and supported by policy makers to measure the safety of care—enhanced voluntary reporting systems and the use of the Agency for Healthcare Research and Quality's Patient Safety Indicators—fail to detect more than 90 percent of the adverse events that occur among hospitalized patients.

*ld.; see also* Daniel R. Levinson, Office of Inspector Gen., Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries 5 (Nov. 2010), *available at* http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf.

<sup>145.</sup> Introduction to Trigger Tools for Identifying Adverse Events, INST. FOR HEALTHCARE IMPROVEMENT, http://www.ihi.org/knowledge/Pages/Tools/IntrotoTriggerToolsforIdentifyingAEs.aspx (last visited Dec. 11, 2011).

<sup>146.</sup> See generally Jiawei Han et al., Data Mining: Concepts and Techniques (3d ed. 2012) (discussing different techniques for analyzing data). See also Furrow, supra note 136, at 820–23

<sup>147.</sup> Furrow, *supra* note 136, at 820–23.

<sup>148.</sup> Lucian L. Leape, *Patient Safety: Reporting of Adverse Events*, 347 New Eng. J. Med. 1633, 1633 (2002). Leape writes,

The primary purpose of reporting is to learn from experience. Many other methods are also used to identify threats to safety, but a good internal reporting system en-

to report, properly designed, would increase the level of reporting dramatically. Critics argue that such reporting would drive errors underground and deter physicians from reporting. The evidence for this assumption is weak at best, and there is evidence to the contrary indicating that full disclosure in a properly designed framework reduces litigation risk and settlement and payout costs. Baker and Lytton observe that "[t]he claim that medical malpractice liability discourages error reporting has never been documented by empirical research, and a recent, careful review has thoroughly discredited this conventional wisdom." Among other points, the review documents that physicians who are not exposed to liability are no more likely to report errors than physicians who are exposed to liability.

The best current model of adverse event reporting is that of the Veterans Administration (VA) system. It served as the model for Pennsylvania's legislation creating the Patient Safety Authority. As of 2005, the VA required disclosure of adverse events to patients and their representatives, including adverse events that have—or are expected to have—a clinical effect on the patient or necessitate a change in the patient's care.<sup>152</sup> The Joint Commission disclosure

sures that all responsible parties are aware of major hazards. Reporting is also important for monitoring progress in the prevention of errors. Thus, the reporting of close calls, as well as adverse events, is valuable. External reporting allows lessons to be shared so that others can avoid the same mishaps. State-run mandatory reporting systems have an additional purpose: to hold hospitals accountable for safe practices.

Id.

149. Bryan A. Liang, 2005 Institute Healthliners, INST. HEALTH L. STUD. (June 2, 2005), http://www.ihls.org/healthliners\_05.html.

150. Leape, supra note 148, at 1635.

The fear of litigation may also be overblown. No link between reporting and litigation has ever been demonstrated. In addition, hospitals have an ethical obligation to inform patients fully of the causes of their injuries, and such disclosure was recently made a requirement by the JCAHO. If patients know, then so could their lawyers. In fact, several reports indicate that full disclosure reduces the risk of litigation.

Id. See also Steve S. Kraman & Ginny Hamm, Risk Management: Extreme Honesty May Be the Best Policy, 131 ANNALS INTERNAL MED. 963, 966 (1999) (examining a full disclosure policy implemented by the VA Medical Center in Lexington, Kentucky and finding that it often diminished patients' propensity to litigate).

151. Baker & Lytton, *supra* note 8, at 244-45.

152. See VETERANS HEALTH ADMIN., DEP'T VETERANS AFF., DISCLOSURE OF ADVERSE EVENTS TO PATIENTS (2005), available at http://www.sorryworks.net/pdf/VA\_Link.pdf.

Adverse events that have had or are expected to have a clinical effect on the patient that is perceptible to either the patient or the health care team. For example, if a patient is mistakenly given a dose of furosemide (a diuretic that dramatically increases urine output), disclosure is required because a perceptible effect is expected to occur.

Id. at A-1.

standard also requires that "[p]atients and, when appropriate, their families, are informed about the outcomes of care, including unanticipated outcomes." <sup>153</sup>

Another example is Pennsylvania's Patient Safety Authority, which mandates that hospitals report all "serious event[s]" to the Authority. Fines may be levied for failures to report, and the statute provides for whistleblower protections, among other things. Pennsylvania also adopted a patient notification requirement. Despite some modest regulatory tools to penalize reporting-failures, Pennsylvania still has a low and erratic level of adverse event reporting.

The patient notification requirements of the Joint Commission and the VA are intended to force hospitals to gather data and share it with the public. This form of transparency regarding adverse events and error reporting represents an evolution in the kind of fiduciary duty the hospital owes to its patient population.

#### 3. Sharpening the adverse event definition

Adverse event reporting is limited not only by its voluntary nature, but also by limited definitions. The categories of adverse events are often too narrow to capture the range of events that endanger patients and should be corrected. Classen et al. use the term "harm" as a replacement for "adverse event" to describe an "unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment, or hospitalization, or that results in death." <sup>157</sup> The language, "resulting from or contributed to by medical care" is a causal test and is not conditioned on a test of preventability. <sup>158</sup> It adopts the modern view of patient safety that requires a relentless focus on safety, assuming that

<sup>153.</sup> JOINT COMM'N ON ACCREDITATION OF HEALTHCARE ORGS., REVISIONS TO JOINT COMMISSION STANDARDS IN SUPPORT OF PATIENT SAFETY AND MEDICAL/HEALTH CARE ERROR REDUCTION RI.1.2.2 (2001), available at http://www.dcha.org/JCAHORevision.htm. The intent statement provides, "The responsible licensed independent practitioner or his or her designee clearly explains the outcome of any treatments or procedures to the patient and, when appropriate, the family, whenever those outcomes differ significantly from the anticipated outcomes." *Id.* This practitioner is someone with clinical privileges, typically the patient's attending physician. *Id.* 

<sup>154. 40</sup> PA. CONS. STAT. ANN. § 1303.308(a) (West 2011).

<sup>155.</sup> Id. § 1303.308(c).

<sup>156.</sup> See id. § 1303.308(b).

<sup>157.</sup> Classen et al., supra note 17, at 583.

<sup>158.</sup> *Id.* 

virtually all adverse events can be eliminated. This definition also moves the definition in the direction recommended by the Government Accounting Office (GAO). It still leaves causal issues to be resolved in some cases but avoids the preventability criteria of other proposals. It requires a distinction between preexisting problems and a compensable adverse event but does not try to connect the event to negligence or preventable conduct as a condition of compensation.

#### 4. Improving mandatory reporting

One suggestion has been to create a new federal agency to collect data on medical care, publish it, set rules, and impose penalties, operating like the National Highway Transportation Administration or the Federal Aviation Administration.<sup>161</sup> Penalties would also be needed in this case. Such reporting assumes institutional collection of data whether by hospitals, clinics, or individual physician offices, which may have the capacity to collect such data as computer software becomes less expensive.

The sanctions currently imposed in some states and by the Joint Commission are mild and difficult to enforce. <sup>162</sup> The next step is to

Id.

<sup>159.</sup> See Veterans Health Admin., supra note 152, at 7.

<sup>160.</sup> LEVINSON, supra note 144, at 30-31 (2010). Levinson writes,

AHRQ and CMS should broaden patient safety efforts to include all types of adverse events. Efforts to improve patient safety often focus on a small subset of events that harm hospital patients. For example, NQF Serious Reportable Events or Medicare HACs represented only a fraction of the adverse events we identified in this report. Additionally, patient safety provisions in the ACA often refer specifically to reducing medical errors, rather than to the broader range of adverse events. AHRQ and CMS should avoid focusing patient safety efforts too narrowly on a small list of specific events, possibly failing to address the wider array of events that lead to most instances of patient harm. Rather, AHRQ and CMS should promote a definition of adverse events that more fully encompasses harm resulting from medical care.

<sup>161.</sup> Dr. Peter Pronovost has argued for a new regulatory agency with the ability to mandate changes in hospitals. *Id.* He suggests, for example, an agency modeled after the Securities and Exchange Commission that articulates rules governing mandated data production by hospitals, collects that data, and publishes it. *Id.* The agency would have the ability to impose penalties for hospital failures to submit accurate data. *Id.*; Nalder & Crowley, *supra* note 21, at

<sup>162.</sup> See Nalder & Crowley, supra note 21, at 1 (Washington's program also is among the worst in the nation for enforcing its reporting requirements. At least sixteen of twenty-seven states with mandatory error reporting programs investigate hospital compliance by comparing medical-error reporting rates with other data like patient complaints and medical malpractice settlements, according to the HHS inspector general report. Four states conduct onsite audits.)

use the threat of litigation to compound the penalty. An intentional failure to disclose a serious adverse event, if discovered, might impose a federal penalty of up to \$10,000 per day, coupled with a treble damages claim in a malpractice suit by any patient suffering adverse harm from the event. If there is an obligation to disclose adverse events, then failure to disclose a known or readily discoverable event is fraudulent concealment, which both tolls the statute of limitations and allows for punitive damages. If an adverse event leads to patient injury, proof of failure to report creates a presumption of negligence, thereby shifting the burden of proof to the defendant to rebut by excuse or justification. <sup>163</sup>

#### 5. Bans on confidentiality agreements for adverse event claims

Most civil litigation ends in settlement. Typically, defense counsel will then request a confidentiality agreement. These confidentiality agreements may be legitimate if protecting trade secrets of a defendant corporation, but beyond that, they have no public value. Such agreements, and their sibling judicial protective orders on behalf of defendants, raise a host of issues. First, confidentiality provisions block public awareness of a provider's adverse event problems and limit any incentive effects that public scrutiny of a hospital's conduct might create. 164 Second, they deny an additional source of data about errors and adverse events on a provider-specific basis, which would provide a cross-check to the Joint Commission and Centers for Medicare and Medicaid Services (CMS) on adverse event reporting in states that require it. Protective orders and other secrecy agreements have shielded many malpractice settlements from public scrutiny. Tort suits are a major influence on systemic corporate behaviors that endanger people. Reducing adverse events, however, requires that such litigation generates accurate signals to force avoidance of unnecessary injuries. As Givelber and Robbins

<sup>163.</sup> This is akin to the application of res ipsa loquitur to sponges left in patients, where an inference of negligence is created. The surgical sponge is one of the most common objects left in patients after surgery. Atul A. Gawande et al., *Risk Factors for Retained Instruments and Sponges After Surgery*, 348 NEW ENG. J. MED. 229, 234 (2003). The authors found that roughly 4000 sponges are accidentally left inside patients annually. *Id.* at 231. Of the many cases of retained foreign bodies in which counts were performed, 88% involved a final count that was erroneously thought to be correct, raising the possibility of record falsification. *Id.* at 232. The study found that of fifty-four patients who filed a claim, thirty-seven patients needed corrective surgery and one died. *Id.* 

<sup>164.</sup> Daniel J. Givelber & Anthony Robbins, *Public Health Versus Court-Sponsored Secrecy*, 68 L. & CONTEMP. PROBS. 131, 135–36 (2006).

argue, "[S]ecrecy agreements are designed, among other things, to avoid enforcement by suppressing information that would otherwise affect the behavior of other injured parties and those at risk of injury." <sup>165</sup>

Suppressing information about the dangers inherent in corporate behavior, whether in health care delivery or the manufacture of consumer goods or drugs, deprives regulators, litigants, and consumers of knowledge relating to safety. Regulators can act more quickly and effectively with full information on the number of lawsuits, the settlements, and information revealed in pretrial discovery. Other potential litigants can sue earlier and in greater numbers with awareness that their injuries were not unique. These suits, in turn, alter a provider's calculus of liability and system risks.

The free flow of information might advance public health in a more straightforward fashion. Consumers who are aware of a higher level of risk at a particular hospital might choose to avoid that hospital in favor of another. Some current Department of Health and Human Services websites created to help consumers compare health care providers are relatively undeveloped. The use of adverse event data as part of such website information would give consumers far more useful information about institutional providers in particular, facilitating choices by consumers and providers that will have powerful impacts on hospitals in particular.

<sup>165.</sup> Id. at 135.

<sup>166.</sup> See, e.g., Hospital Compare, U.S. DEPT. HEALTH & HUMAN SERVS., http://www.hospitalcompare.hhs.gov (last visited Dec. 11, 2011); Physician Compare, MEDICARE.GOV, http://medicare.gov/find-a-doctor/provider-search.aspx (last visited Dec. 11, 2011).

# B. Malpractice Insurance as a Tool for Discovering and Policing Medical Errors<sup>167</sup>

Health care providers buy medical malpractice insurance to protect themselves from medical malpractice claims. Under the insurance contract, the insurance company agrees to accept financial responsibility for payment of any claims up to a specific level of coverage during a fixed period in return for a fee. The insurer investigates the claim and defends the health care provider. This insurance is sold by commercial insurance companies, health care-provider-owned companies, and joint underwriting associations. Some large hospitals also self-insure for medical malpractice losses rather than purchasing insurance, and a few physicians practice without insurance. Joint underwriting associations are nonprofit pooling arrangements created by state legislatures to provide medical malpractice insurance to health care providers in the states in which they are established.

Malpractice crises come and go in the United States; they are driven by an apparent insurance cycle of competitive entry in the market and followed by rapid premium increases as the insurers' returns drop. 168 Any serious analysis of liability reform must consider the role of the insurance industry. 169 The most visible manifestations of a malpractice crisis have been the rapid increases in premiums for malpractice insurance purchased by health care professionals and institutions. In past crises, some insurance carriers have gone bankrupt or dropped out of the malpractice market, while others raised their malpractice premiums precipitously to compensate for invest-

<sup>167.</sup> See, e.g., William M. Sage, The Forgotten Third: Liability Insurance and the Medical Malpractice Crisis, 23 HEALTH AFF. 10, 20 (2004). As Sage proposes,

A second, even more promising option is for the federal government to propose a comprehensive restructuring of malpractice claims involving Medicare and Medicaid patients, which could then set the standard for the rest of the health care system. The surest way for malpractice to be placed on the national health policy agenda is for Medicare to take ownership of it. Medicare-led reform, which could take advantage of Medicare's established systems of administrative adjudication, would link the process of identifying and compensating avoidable injuries to Medicare's other quality improvement initiatives and would incorporate liability insurance into Medicare payment formulas.

Id.

<sup>168.</sup> See generally Sage & Kinney, supra note 9, at 339–40 (giving an overview of the existing problem).

<sup>169.</sup> See, for example, BAKER, *supra* note 35, and Mello et al., *supra* note 11, at 2284, for reviews of claims that an existing medical malpractice crisis justifies the imposition of limitations on the medical liability regime and a review of the counterclaims.

ment losses.<sup>170</sup> Each crisis has brought a new round of legislative reform efforts spearheaded by angry physician groups. Some physicians face increases in their insurance premiums and pockets of unavailability in some areas for certain specialties. Physicians' strong reactions are justified to an extent, as there is evidence that physicians bear the brunt of premium costs. This is the result of tort law and the focus on physician liability rather than institutional liability.<sup>171</sup>

Medical liability would not exist without liability insurance. Liability insurance defines the limits of coverage and provides the process by which payments are made to claimants. Therefore, medical insurer practices may at times help to reduce provider risks through underwriting and other controls on physician insurance availability and price. Insurers try to police moral hazard, which describes the effect of insurance on loss prevention behavior by health care providers. Providers with insurance coverage are less inclined to worry about risk prevention because they have funds that will pay for any risk-created costs, including litigation costs. Ambiguity and uncertainty haunt the liability insurance underwriting process. Much of tort reform is a response to insurers' demands that the legal rules reduce or eliminate this uncertainty as much as possible, without

<sup>170.</sup> See, e.g., Mo. Dep't of Ins., Medical Malpractice Insurance in Missouri: The Current Difficulties in Perspective 10–31 (2003).

<sup>171.</sup> Sage, supra note 28, at 15.

<sup>172.</sup> Tom Baker, Liability Insurance as Tort Regulation: Six Ways that Liability Insurance Shapes Tort Law in Action, 12 CONN. INS. L.J. 1, 3–4 (2005).

First, for claims against all but the wealthiest individuals and organizations, liability insurance is a de facto element of tort liability. Second, liability insurance limits are a de facto cap on tort damages. Third, tort claims are shaped to match the available liability insurance, with the result that liability insurance policy exclusions become de facto limits on tort liability. Fourth, liability insurance makes lawsuits against ordinary individuals and small organizations into "repeat player" lawsuits on the defense side, making tort law in action less focused on the fault of individual defendants and more focused on managing aggregate costs. Fifth, liability insurance personnel transform complex tort rules into simple "rules of thumb," also with the result that tort law in action is less concerned with the fault of individual defendants than tort law on the books. Sixth, negotiations over the boundaries of liability insurance coverage . . . drive tort law in action.

Id.

<sup>173.</sup> Tom Baker & Peter Siegelman, *The Law and Economics of Liability Insurance: A Theoretical and Empirical Review, in* HANDBOOK ON THE ECONOMICS OF TORTS (Jennifer Arlen ed.) (forthcoming 2011) (Research Paper No. 11-09, Institute for Law and Economics, University of Pennsylvania Law School), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract\_id =1783793.

regard to fairness to plaintiffs or other tests of the proper functioning of the tort system.<sup>174</sup>

Insurers adopt at least six different strategies of control in insurance generally. 175 First, underwriting controls select applicants and locate them in risk categories based on their likely loss prevention behavior. This reduces both ex-ante and ex-post moral hazard. Second, experience rating and nonrenewal adjusts premiums or refuses renewal for those with bad claims experience. 176 Third, coverage can be designed to reduce moral hazard by exclusions and coverage limitations, bundling defense coverage with indemnity coverage and allowing the insurer to control both, and cost sharing and partial coverage, designed to keep insureds at risk and aware of it. Fourth, insurers can impose loss control services, mandating certain behavior or giving advice. Fifth, insurers may use after-the-fact auditing tools to enforce the insured's representations at the time the policy was written. Sixth, insurers may rely on external control measures - such as professional norms, legal rules, or regulatory rules – on the assumption that such measures limit their risk by deterring providers from risky behavior.

We can see several of these control techniques in medical liability insurance, at least with regard to some insurers.

# 1. Selective insurance marketing, complaint profiling, and office auditing

Some insurers have become more careful in trying to manage their risks in the malpractice area. The Healthcare Providers Insurance Exchange (HPIX), formed in 2003, promises an intensive commitment to risk management:

<sup>174.</sup> Mark A. Geistfeld, Legal Ambiguity, Liability Insurance, and Tort Reform, 60 DEPAUL L. REV. 539, 539-40 (2011).

<sup>175.</sup> Baker, supra note 172, at 3.

<sup>176.</sup> See Gary M. Fournier & Melayne M. McInnes, The Case for Experience Rating in Medical Malpractice Insurance: An Empirical Evaluation, 68 J. RISK & INS. 255, 274 (2001) ("Proponents of experience rating argue that the tort system is designed to provide incentives for care by allocating costs of negligence to the physician, and that current insurance blunts these incentives because all physicians share the costs.").

<sup>177.</sup> See, e.g., DOCTORS COMPANY, http://www.thedoctors.com (last visited Nov. 21, 2011). The Doctors Company insurance website discusses patient safety, links to recent studies and articles, and promises to help providers reduce their risk. The website claims, about itself, that "[w]e were the first medical malpractice insurer to establish a patient safety department, and we set the industry standard with innovation products and services that improve patient care and help you avoid claims." *Id.* The website provides patient safety risk managers, around the clock consultations, and educational tools for evaluating practice risks.

The Exchange's approach fosters an environment of patient safety, quality of care and trust . . . . We talk with physicians and draw upon their clinical knowledge in formulating our policies. We require early reporting of adverse patient outcomes and joint defense where feasible and ethically permissible to reduce the risk of large claim payouts. 178

The company promises stable premiums through strong risk management practices; on their website, they state that "[c]ontrolling risk doesn't have *something* to do with maintaining a fair premium, it has *everything* to do with it, which is why—along with a sound organizational structure—we are taking an aggressive stance as risk management leaders."<sup>179</sup> The company wants to make the control of claims a daily task for covered physicians, under the theory that a malpractice carrier must manage risks, as well as underwrite them, in order to control exposure.<sup>180</sup>

Insurers have a range of institutional advantages over hospitals and health care providers, generally because they are able to force information into the open and change provider behavior. First, insurers have an overview of claiming frequency across providers and specialties and more experience with a range of claims than any particular provider can have. Second, they have what Baker terms a "behavioral" advantage—they don't care what the status quo health care provider behavior is because they have no ego investment in it; they simply want to reduce their exposure to claims and uncertainty about when and how claims occur. Third, insurers have skin in the game—their money is only at risk if adverse events occur at higher levels than predicted. Fourth, hospitals in particular are in a weak position vís-a-vís high status professionals, like physicians, making it hard to change safety cultures quickly. It is easier for a

<sup>178.</sup> Insurance Products & Services, HEALTHCARE PROVIDERS INS. EXCH., http://www.hpix-ins.com/insurance-products-services/insurance-products-services.html (last visited Dec. 11, 2011).

<sup>179.</sup> Risk Management Services, HEALTHCARE PROVIDERS INS. EXCH., http://www.hpix-ins.com/insurance-products-services/insurance-products-services.html (last visited Dec. 11, 2011).

<sup>180.</sup> Id.

<sup>181.</sup> See Baker, supra note 80, at 284-85.

<sup>182.</sup> Id. at 284.

<sup>183.</sup> Id.

<sup>184.</sup> Id. at 284-85.

<sup>185.</sup> Id. at 285.

hospital administrator to blame insurers for required safety precautions, shifting responsibility away from the administration.

The problem is that many medical malpractice insurers do not pursue safety enforcement aggressively, with some exceptions noted above. There would be more aggressive safety policing if more claims were filed, upping the ante for safety audits and pressure. If barriers to claiming were lowered so more claims were filed (small claims, enterprise liability, or broader definitions of adverse events), and damage awards were increased, insurers would face increased frequency of claims and higher volumes of payouts. I will make some suggestions to improve the process of plaintiff claiming to push in this direction. 187

### 2. Hospital complaint profiling

Larger hospitals often self-insure, reserving funds to cover liability costs. Hospitals are adopting complaint profiling to spot litigation-prone staff physicians and intervene to retrain them to avoid risks. The Hickson study took six years' worth of hospital patient advocacy files and concluded that unsolicited patient complaints about physicians are a highly reliable predictor of litigation-prone physicians. The study found that 9% of the physicians produced 50% of the complaints. Moreover, "physicians' complaint generation was positively associated with risk management outcomes, ranging from file openings to multiple lawsuits. Relationships between overall complaint generation and risk management activity remained even when clinical activity was controlled, suggesting that patient complaints may serve as an important indicator for a risk management monitoring system." The various explanations given for higher physician loss ratios, such as serving a litigation-prone

<sup>186.</sup> See id.

<sup>187.</sup> *Id.* at 285–86 (noting that injury prevention pushes against prevailing pressures of tort reform). Baker offers two other suggestions: (1) injury prevention awards or tax credits, whereby regulators could tie return on investment to injury prevention goals, and (2) enterprise insurance, whereby the liability remains on doctors while the enterprise carries insurance. The problem with insurance regulation is that state regulators often lack power to regulate in this way, given bias toward letting the market largely govern insurance practices. The enterprise insurance proposal already occurs in some hospital-physician relationships but fails to look closely at the complicated liability rules that create a hybrid liability model. Baker's concern is that reforms leave physicians with moral authority, helping them retain autonomy. *Id.* at 285–87.

<sup>188.</sup> See Hickson et al., supra note 32, at 2955.

<sup>189.</sup> Id. at 2953.

<sup>190.</sup> Id. at 2955.

population, treating higher-risk patients, and technical incompetence, were not statistically significant. Only "connecting" to patients was significant. <sup>191</sup> If hospitals face a larger volume of claims for adverse events, including smaller claims, they are far more likely to improve their patient safety monitoring, which now is second to financial compliance monitoring in most health systems. <sup>192</sup>

### 3. Claims history auditing for risk factors

Tort claims or incident reports retained by insurers can provide a useful database of medical harms that can be mined for patient safety information.<sup>193</sup> As Marcheve writes,

In spite of the many problems associated with malpractice litigation, the system is potentially a very rich source of error data which could be used to improve the quality and safety of health care. With all avenues to information being restricted, consumers and injured patients are likely to become increasingly dissatisfied with this trend and may become more assertive in demanding the disclosure of medical error data. <sup>194</sup>

The goal of transparency in insurance regulation is for a sound regulatory strategy. As a result of health care reform over the next decade, state insurance regulators must adjust to a larger role in regulating insurance.<sup>195</sup>

<sup>191.</sup> See id. at 2955–57; see also Nalini Ambady et al., Surgeons' Tone of Voice: A Clue to Malpractice History, 132 SURGERY 5, 8–9 (2002) (discussing a study that showed poor physician-patient communication is a significant indicator of malpractice claims).

<sup>192.</sup> I am on the board of a large hospital system, and it seems that the time spent by the board on compliance with Medicare reimbursement rules is far higher than the time spent scrutinizing patient safety efforts.

<sup>193.</sup> See, e.g., Gawande et al., supra note 163, at 233–34. Gawande and his colleagues found that "[t]he risk of retention of a foreign body after surgery significantly increases in emergencies, with unplanned changes in procedure, and with higher body-mass index. Case-control analysis of medical-malpractice claims may identify and quantify risk factors for specific types of errors." *Id.* at 229.

<sup>194.</sup> MIMI MARCHEV, NAT'L ACAD. FOR STATE HEALTH POL'Y, MEDICAL MALPRACTICE AND MEDICAL ERROR DISCLOSURE: BALANCING FACTS AND FEARS 11 (2003).

<sup>195.</sup> *Id.* ("The current direction of tort reform—which effectively restricts access to the courts—coupled with the trend to protect medical error data have raised concerns that consumer access to information is being blocked.").

### 4. Early discussions between insurers and plaintiffs

Too many claims end up being dropped by plaintiffs after they learn more about the underlying causes of a patient's injury. Early information could reduce the level of such filings or induce early settlement, saving provider and plaintiff lawyer resources. One recent study, after examining insurer practices and plaintiff lawyer claiming, argued that

[t]he challenge is to induce insurers and plaintiff lawyers to exchange information and discuss the merits of cases candidly and efficiently. A few changes could move the process in that direction. To be willing to disclose information voluntarily and make realistic offers to resolve cases, each side must trust the other to reciprocate. <sup>196</sup>

If insurers and hospitals should adopt new procedures to get lawyers for both sides to exchange information quickly and efficiently and discuss the merits of the cases, cases would be resolved far more rapidly. Golan writes, "Such reforms would greatly reduce both the frequency and the duration of cases that are dropped, and thus the cost of malpractice litigation." <sup>197</sup>

Model programs exist where judges intervene early in the litigation to push for settlements or resolution of the cases aggressively. <sup>198</sup> The success of such programs suggests that they should be scaled up in the states to improve the speed of case resolution.

# IV. LIABILITY AND THE RECONSTRUCTION OF MEDICAL PRACTICE: REDUCING PRACTICE VARIATION

Malpractice litigation focuses on an error by a provider, which must be established by reference to an acceptable standard of care. Customary practice is the normal benchmark for evaluating devia-

<sup>196.</sup> Dwight Golann, *Dropped Medical Malpractice Claims: Their Surprising Frequency, Apparent Causes, and Potential Remedies,* 30 HEALTH AFF. 1343, 1348 (2010). Golann concludes that [i]nsurers and plaintiff attorneys should reform their methods of resolving malpractice claims as outlined above. By doing so, they could reduce the number of dropped claims and settle cases more quickly, sparing both health care providers and patients the experience of being involved in litigation that ultimately benefits no one. *Id.* at 1349.

<sup>197.</sup> Id. at 1343.

<sup>198.</sup> William Glaberson, *To Curb Malpractice Costs, Judges Jump in Early*, N.Y. TIMES, June 12, 2011, at A1, *available at* http://www.nytimes.com/2011/06/13/nyregion/to-curb-malpractice-costs-judges-jump-in-early.html.

tion and, therefore, negligence. Medical practice, however, often lacks clear standards, with several approaches often viewed as acceptable, and with many practices lacking scientific validity. Reconstructing medical practice requires motivation and a systematic approach, incorporating guidelines, proven systems, and staff education. A comprehensive safety program offers systematic safety changes in some areas of practice such as obstetrics, often spurred by insurance audits of high-risk practices. Driven by the goal of reducing liability exposure, as well as lowering insurance premiums, physicians have achieved dramatic drops in patient injury (and resulting liability exposure), producing up to a ten-fold drop in payouts for patient injury.<sup>199</sup>

One such program made major changes on a labor and delivery unit. 200 Changes included implementing a standardized oxytocin protocol, electronic charting, team training, and the use of a central communication system to improve provider situational awareness. 201 The authors argued that such changes "should be considered by all obstetric services. . . . [T]hese changes can increase patient safety, decrease sentinel events, and, as a consequence, reduce compensation payments." 202 Obstetrics is a high-liability risk area of practice, and these changes reduced patient harm, and therefore compensation payments, from almost \$28 million per year for an earlier four-year period, to \$2.5 million per year after the changes were implemented. 203 What was good for patients turned out to be good for liability costs as well.

<sup>199.</sup> Grunebaum et al., *supra* note 75, at 97. The authors report on a series of patient safety changes in an obstetrical practice. They found that

<sup>[</sup>b]eginning with the fourth year of the program, compensation payments began to drop significantly. Yearly payments for the most recent 3 years (2007–2009) averaged \$2,550,136 as compared with average yearly payments of \$27,591,610 for the preceding 4 years (2003–2006). The \$25,041,474 yearly savings in compensation payments for the last 3 years alone dwarf the incremental cost of the patient safety program and are well above those reported by Simpson et al. In our opinion the documented success of our patient safety improvement program in decreasing compensation payments for the past years understates the true long-term impact of the program on patient safety, as we expect significant savings to continue into the future.

Id. at 103; see also Clark et al., supra note 75, at e1-105.e7.

<sup>200.</sup> See Grunebaum et al., supra note 75, at 104.

<sup>201.</sup> Id.

<sup>202.</sup> Id.

<sup>203.</sup> Id. at 97.

### A. Practice Guidelines: Sharper Boundaries

The pressure to produce suitable guidelines that will set predictable standards of practice for both physicians and hospitals is growing.<sup>204</sup> Practice guidelines are needed in current medical practice. Current guidelines are often not grounded in good science; instead, they serve primarily as self-protective shields created by insurers and medical societies.<sup>205</sup> Guidelines have been attacked as biased and generally flawed,<sup>206</sup> and even well-accepted guidelines are ignored by doctors who may be unaware of them.<sup>207</sup>

Clinical guidelines, easily accessible to lawyers through internet research, are beginning to provide bright-line rules formerly lacking in malpractice cases.<sup>208</sup> This availability adds to the institutional

204. Ronen Avraham, Clinical Practice Guidelines: The Warped Incentives in the U.S. Healthcare System, 37 AM. J.L. & MED. 7, 16 (2011) (advocating for a new method of practice guidelines development as the best approach to efficient doctoring: "Clinical practice guidelines (CPGs) produced under the right incentives could avoid many of the current costs. Optimal CPGs would reduce costs associated with medical errors, because they would limit providers' discretion and encourage evidence-based medical practices.").

205. See, e.g., Michelle M. Mello, Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation, 149 U. PA. L. REV. 645, 653 (2001) (noting the varying quality of such guidelines, which are often drafted to meet the goals of the drafting organization).

206. Lars Noah, Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community, 44 ARIZ. L. REV. 373, 420–26 (2002). See also Niteesh K. Choudhry et al., Relationships Between Authors of Clinical Practice Guidelines and the Pharmaceutical Industry, 287 JAMA 612, 612 (2002) (survey results illustrate "considerable interaction" between pharmaceutical companies and the authors of clinical practice guidelines); Jodi M. Finder, The Future of Practice Guidelines: Should They Constitute Conclusive Evidence of the Standard of Care?, 10 HEALTH MATRIX 67, 111–13 (2000) (discussing the influence of insurers on practice guidelines); Paul G. Shekelle et al., Validity of the Agency for Healthcare Research and Quality Clinical Practice Guidelines: How Quickly Do Guidelines Become Outdated?, 286 JAMA 1461, 1466 (2001); Steven H. Woolf et al., Clinical Guidelines: Potential Benefits, Limitations, and Harms of Clinical Guidelines, 318 BRIT. MED. J. 527, 529 (1999) ("Guideline development groups often lack the time, resources, and skills to gather and scrutinize every last piece of evidence.").

207. See Borden et al., supra note 25, at 1882 (noting that less than half of patients undergoing percutaneous coronary intervention (PCI) were found to be receiving optimal medical therapy (OMT) before their procedure, "despite the guideline-based recommendations to maximize OMT and the clinical logic of doing so before PCI so that the need for additional symptom relief from revascularization could be appreciated"); see also Andrew L. Hyams et al., Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective, 21 J. HEALTH POL. POL'Y & L. 289 (1996); Arnold J. Rosoff, Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines, 26 J. HEALTH POL. POL'Y & L. 327, 337 (2001).

208. Rosoff, in a seminal article, described such clinical practice guidelines as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" and as "standardized specifications for care, either for using a procedure or for managing a particular clinical problem." Arnold J. Rosoff, The Role of Clinical Practice Guidelines in Health Care Reform, 5 HEALTH MATRIX 369, 370 (1995) (quoting INSTITUTE OF MEDICINE, CLINICAL PRACTICE GUIDELINES: DIRECTIONS FOR A NEW PROGRAM 8 (Marilyn J. Field & Kathleen N. Lohr eds., 1990); Troyen A. Brennan, Practice

pressure toward convergence on validated standards of practice. Lawyers can introduce evidence of clinical practice guidelines as a way of arguing for a standard of care that the defendant failed to satisfy.<sup>209</sup> Proof of malpractice thus slowly moves from elastic expert opinion toward more empirically validated clinical practices.<sup>210</sup> This means that the defense has less wiggle room in the average malpractice case, and as a result, the law indirectly forces physicians toward heightened awareness of standards and insurers toward a more nuanced approach to defense.

Many of the ACA's proposed reforms will have to confront this larger issue of physician resistance to change. The ACA operates as a top-down model of regulation, but the general use of research dollars and financial payment incentives seeks to alter provider behavior from the bottom up. The ACA, along with the stimulus bill entitled the American Recovery and Reinvestment Act of 2009,<sup>211</sup> represents a major federal initiative to standardize medical practice—a systematic and well-funded national effort to improve American medicine, pouring millions of dollars into government-funded research on effectiveness, best practices, and practice guidelines.<sup>212</sup> This research is backed by new centers and initiatives to disseminate findings and motivate providers to incorporate new findings into practice.

The federal government focused on practice guidelines even before the ACA was passed. The Office of the Inspector General, in a recent report on adverse events in hospitals, observed,

Guidelines and Malpractice Litigation: Collision or Cohesion?, 16 J. HEALTH POL. POL'Y & L. 67, 67 (1991).

<sup>209.</sup> See, e.g., Travers v. District of Columbia, 672 A.2d 566, 569 (D.C. 1996) (requiring that an expert needs "published medical standards, manuals, or protocols" to support the expert opinion, rather than just the expert's own opinion or casual conversation with a few colleagues).

<sup>210.</sup> See Frakes v. Cardiology Consultants, P.C., No. 01-A-9702-CV-00069, 1997 WL 536949, at \*6 (Tenn. Ct. App. Aug. 29, 1997) (Koch, Jr., J., concurring) (noting that clinical practice guidelines have emerged as a response by the medical profession to "perceived shortcomings in medical practice" and that such guidelines can materially assist jurors when properly authenticated, though they "should not necessarily be viewed as conclusive evidence of the standard of care").

<sup>211.</sup> American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115, 115 (2009).

<sup>212.</sup> See id. at 176–78 (allocating hundreds of millions of dollars to the AHRQ). Dissemination has been happening for more than a decade. The ARHQ sponsors the National Guideline Clearinghouse, which reviews all guidelines for the quality of the evidence supporting them. See U.S. DEP'T OF HEALTH & HUMAN SERVS., NAT'L GUIDELINE CLEARINGHOUSE, http://www.guideline.gov (last visited Nov. 21, 2011) (describing the website as a "public resource for evidence-based clinical practice guidelines").

CMS should look for opportunities to hold hospitals accountable for adoption of evidence-based practice guidelines. The conditions of participation for Medicare and Medicaid require that hospitals have programs to demonstrate quality improvement where evidence shows practices can improve outcomes. CMS should further influence hospitals to reduce adverse events through enforcement of the conditions of participation. This could include more closely examining patient safety issues through the survey and certification process, as recommended in our prior report. This could also include encouraging hospitals to adopt evidence-based practices shown to prevent adverse events.<sup>213</sup>

Guidelines can surmount the cookbook medicine objection of inflexibility by being individualized, using medical record information and computer processing speed.<sup>214</sup>

The section of the ACA that creates the *Patient-Centered Outcomes Research Institute* specifies that its findings must be rapidly disseminated to clinicians, presumably so that they can adopt them.<sup>215</sup> Judges and academics have written about the diffusion of new medical technologies and standards of practice through social and cultural forces aided by medical specialty societies—a slow evolutionary process. One effect of the cumulative ACA requirements—with money for research on practice guidelines, best practices, and out-

Our results indicate that individualized guidelines can potentially improve quality and reduce costs compared with current population-based guidelines. This conclusion is already well-known to persons who design guidelines, as indicated by the trend toward greater realism and inclusion of risk calculators. The relative simplicity of current guidelines has been caused by lack of sufficiently powerful and accurate risk calculators and of ways to incorporate these guidelines efficiently into the workflow of clinical practice, which left few options except to keep guidelines simple.

These limitations are changing rapidly with increased availability of personspecific data, improvements in mathematical modeling, and increased implementation of clinical information systems. These changes enable us to begin moving to a new generation of guidelines that are more clinically realistic and that may deliver higher quality at lower cost than has been possible in the past.

<sup>213.</sup> LEVINSON, supra note 144, at 32.

<sup>214.</sup> David M. Eddy et al., *Individualized Guidelines: The Potential for Increasing Quality and Reducing Costs*, 154 ANNALS INTERNAL MED. 627, 633 (2011). As Eddy concludes,

*Id.* For a discussion of the use of empirical evidence to set medical standards of care, *see* Mark A. Hall & Michael D. Green, *Symposium: Empirical Approaches to Proving the Standard of Care in Medical Malpractice Cases: Introduction*, 37 WAKE FOREST L. REV. 663, 663 (2002).

<sup>215.</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6301(a), 124 Stat. 119, 734 (2010) (specifying that such research findings shall "not be construed as mandates for practice guidelines, coverage recommendations, payment, or policy recommendations").

come measures—will be to accelerate the diffusion of these new standards for best practice.

First, millions of dollars in federal funding are pouring into the world of research to analyze and determine the practice-outcome linkages and best practices. Over time, practice guidelines generated by research will supplant and replace specialty guidelines.

Second, the ACA mandates dissemination in a variety of ways, including websites, pay-for-performance reforms, and models of integrated practice. New payment reforms will tie physician performance to these measures, particularly in ACOs, medical homes, and other new integrated modes of practice. Best practices, grounded in research and made accessible and transparent to providers, patients, and payers, will start to squeeze out medical practice variations in clinical practice. The effect of such narrowing of practice is clear: defenses under liability rules (e.g., respectable minority defenses, variations in practice, proximate causation) will rapidly narrow as practice choices also narrow. The physician who fails to keep up with new research will not only suffer income loss, she will also suffer a higher risk of liability for failing to conform to what becomes the future standard of care.<sup>216</sup>

## B. Unnecessary Procedures: False Claims and Liability

The field of medicine includes many examples of unjustified medical practices, driven by payment incentives, uncertainty about practices, and often just inertia. The most recent example involves implantable cardioverter-defibrillators to prevent sudden cardiac death. Hospitals were found to use such devices in 20–40% of patients for whom use was not justified by practice guidelines. An-

<sup>216.</sup> The Third Circuit has held that specific provisions in the federal nursing home standards create a private right of action under § 1983 for residents in government-owned nursing homes. See Grammer v. John J. Kane Reg'l Ctrs.–Glen Hazel, 570 F.3d 520 (3d Cir. 2009), cert. denied, 130 S. Ct. 1524 (2010). In this case, the plaintiff claimed that her mother's death was caused by malnutrition, decubitus ulcers, and resulting sepsis, and that the failure to provide quality care violated her mother's rights under OBRA. Id. at 522. Citing several of the provisions in this problem, the court of appeals found that the statute was "replete with rightscreating language," that the resident was the intended beneficiary of the statute, and that Congress intended to create a private right of action. Id. at 529. The case extends only to government-owned facilities. Id. at 523.

<sup>217.</sup> See JOHN E. WENNBERG, TRACKING MEDICINE: A RESEARCHER'S QUEST TO UNDERSTAND HEALTH CARE 4 (2010) ("Unwarranted variation in health care delivery — variation that cannot be explained on the basis of illness, medical evidence, or patient preference — is ubiquitous.").

<sup>218.</sup> Sana M. Al Khatib et al., *Non-Evidence-Based ICD Implantations in the United States*, 305 JAMA 43, 43 (2011). The authors divided the use of ICDs in hospital patients into two catego-

other recent study examined the link between malpractice reform and levels of practice of questionable value. A study of obstetric practice (a high-risk specialty for liability) by Currie and MacLeod looked at the effect of caps and changes in joint and several liability (ISL) on induction and stimulation of labor (i.e., C-sections, and complications of labor and delivery). They conclude that reforms of JSL reduced those behaviors, while caps on non-economic damages increased them.<sup>219</sup> They found that "reducing the threat of malpractice can increase the use of procedures . . . and may reduce the effort made by doctors in realistic scenarios."220 Reform of JSL reduces the level of C-sections performed by physicians studied, as well as the complications of labor and delivery.<sup>221</sup> This strongly supports the idea that strengthening the liability signal causes physicians to increase their care and avoid potentially harmful procedures that are discretionary and arguably unnecessary. Hospitals likewise respond strongly to avoid additional liability. Caps, by contrast, "increase unnecessary procedure use. They also increase complications of labor and delivery in some specifications."222

Unnecessary procedures may represent a false claim in Medicare reimbursement.<sup>223</sup> These procedures also expose patients to unnecessary risks because the practice guidelines conclude there is no benefit in such cases. A liability theory can be built on a foundation of unnecessary risk since such care that causes harm unnecessarily is not counterbalanced by any expectation of benefit. Unnecessary care that lacks therapeutic benefit is presumptively poor quality care, and it arguably represents malpractice if harm occurs to the patient. Donabedian has argued that such care should be judged as poor in

-

ries: uses supported by practice guidelines (evidence-based ICDs) and uses that were not supported by practice guidelines (non-evidence-based ICDs). They found that the "risk of inhospital death was significantly higher in patients who received a non-evidence-based device than in patients who received an evidence-based device." *Id.* at 46. Despite the evident risk posed by the non-evidence-based ICDs, over 20% of patients in the study received such devices, with some hospitals using them more than 40% of the time. *Id.* at 43, 48.

<sup>219.</sup> Currie & MacLeod, *supra* note 77, at 812 ("Consistent with the standard economic theory of tort law, the theory we outline here predicts that with less liability physicians will exert less care.") (citation omitted).

<sup>220.</sup> Id. at 825.

<sup>221.</sup> Id.

<sup>222.</sup> Id. at 826.

<sup>223.</sup> False Claims Act, 31 U.S.C. §§ 3729–3733 (2009) (stating those who knowingly submit, or cause another person or entity to submit false claims for payment of government funds are liable for three times the government's damages plus civil penalties between \$5500 and \$11,000 per false claim).

quality.<sup>224</sup> This type of care is not expected to yield benefits: the use of redundant care, even when it is harmless, indicates carelessness, poor judgment, or ignorance on the part of the practitioner who is responsible for care.<sup>225</sup>

Courts have generally deferred to doctors' medical judgment as to the benefit of a particular treatment. However, if the diagnostic or treatment modality is found to have no value, the physician may be negligent if a bad outcome results. In *Riser v. American Medical International, Inc.*, the doctor performed a femoral arteriogram on the patient, who then suffered a stroke and died.<sup>226</sup> The court found that the physician had breached the standard of care by subjecting the patient to a technology which he should reasonably have known would be of "no practical benefit to the patient."<sup>227</sup>

As definitions of "necessary" and "ineffective" expand with medical research, the prospect of no reimbursement through Medicare or private insurance for such procedures (and even false claims actions against providers in the more extreme cases) should be coupled with presumptive liability for any harms that result from such unnecessary treatments. Such an accumulation of incentives will push providers to better monitor their levels of care.

# C. "Never Events" Liability: Presumptions

The phrase "never events" was coined to capture a range of hospital-acquired injuries that should never happen—those that are "largely preventable but also very serious." An ordinary person can look at the result of wrong-site surgery and say, "That is not acceptable." The concept bears a strong resemblance to the tort doc-

<sup>224.</sup> AVEDIS DONABEDIAN, THE DEFINITION OF QUALITY AND APPROACHES TO ITS ASSESSMENT 6-7 (1980).

<sup>225.</sup> Id.

<sup>226.</sup> Riser v. Am. Med. Int'l, Inc., 620 So. 2d 372, 374 (La. Ct. App. 1993).

<sup>227.</sup> Id. at 378.

<sup>228. &</sup>quot;Never events" are now called "serious reportable events" by the National Quality Forum. They are defined as

injuries caused by care management (rather than the underlying disease) and errors that occur from failure to follow standard care or institutional practices and policies. The events are largely preventable, but also very serious. The errors are of concern to the public and healthcare providers and warrant careful investigation that should be targeted for mandatory public reporting.

NAT'L QUALITY FORUM, SERIOUS REPORTABLE EVENTS TRANSPARENCY & ACCOUNTABILITY ARE CRITICAL TO REDUCING MEDICAL ERRORS (2007), http://www.qualityforum.org/Projects/s-z/SRE\_Maintenance\_2006/Fact\_Sheet\_-\_Serious\_Reportable\_Events\_in\_Healthcare\_2005-2006\_Update.aspx.

trine of res ipsa loquitur, which describes events that ordinarily do not occur in the absence of negligence—like the falling of an elevator. In 2006, the CMS began a new reimbursement program wherein Medicare will not reimburse, at the normal rate, the costs of treating these events in the hospital.<sup>229</sup> The limit on reimbursement is justified because these events are presumptively preventable.<sup>230</sup> More so, the CMS continually adds new hospital-acquired conditions to the list.<sup>231</sup>

The next step is to develop a claim, akin to a res ipsa loquitur argument, that patient harms are presumptively caused by the hospital or provider, relieving the patient of the burden of proving harm and its causes, other than its occurrence in a hospital. The only issue remaining would be the calculation of damages for added costs of hospitalization, loss of wages, and other injuries suffered. This would be a type of corporate negligence aimed at the hospital rather than individual physicians, giving patients additional claims for damages at all levels.

# V. LIABILITY AND THE RECONSTRUCTION OF LITIGATION: IMPROVING CLAIMS ACCURACY

## A. Damage Award Reforms

Starting in the 1970s, states enacted tort reform legislation. Tort reform measures were intended by their proponents to reduce either the frequency of malpractice litigation or the size of the settlement or judgment. The goal was not to improve the injured patients' situation, but rather to satisfy both the medical profession and the insurance industry.<sup>232</sup> These measures were designed to restrict the operation of the tort system in four ways: (1) by affecting the filing of malpractice claims; (2) by limiting the award recoverable by the plaintiff; (3) by altering the plaintiff's burden of proof through changes in evidence rules and legal doctrine; and (4) by changing the role of the courts by substituting an alternative forum. These are characterized by Eleanor Kinney as "first-generation" reforms.<sup>233</sup>

<sup>229.</sup> Andrew Miller, *Hospital Reporting and "Never Events,"* 4 MEDICARE PATIENT MGMT. 20, 20 (2009), *available at* http://www.medicarepatientmanagement.com/issues/04-03/mpmMJ09-NeverEvents.pdf.

<sup>230.</sup> Id.

<sup>231.</sup> Id.

<sup>232.</sup> See Currie & MacLeod, supra note 77, at 796.

<sup>233.</sup> See generally Eleanor D. Kinney, Learning from Experience, Malpractice Reforms in the 1990s: Past Disappointments, Future Success?, 20 J. HEALTH POL. POL'Y & L. 99 (1995). "Second-

The most powerful reform in actually reducing the size of malpractice awards (and therefore the most unfair to plaintiffs) has been a dollar limit, or cap, on awards. Caps may take the form of a limit on the amount of recovery of general damages, typically pain and suffering, or a maximum recoverable per case including all damages. Such caps may create predictability for insurers calculating their risk exposure, but they clearly are cruel, denying recovery for real harms and failing to keep up with inflation in health care generally. They may also be counterproductive, reducing provider liability risk and leading to unnecessary and harmful procedures. <sup>235</sup>

One reform proposal has been to create guideposts for jury decision making, attempting to "schedule" pain and suffering awards, rather than cap them, in order to narrow the range of variability in jury awards.<sup>236</sup> This is a useful idea; it allows for "full" recovery without penalizing plaintiffs, as long as the schedules are fair in the ranges of awards they allow. The potential value of these guideposts is particularly worth considering in light of the fact that the legal system has rejected nearly all other forms of advice to the jury in medical liability and other tort litigation. The rules of tort litigation require only general jury instructions on damages, rejecting more specific instructions, with the exception of life expectancy. Juries are often given no real guidance on how to calculate awards for pain and suffering. One goal of the tort system should be horizontal equity (i.e., treating like cases alike). Open-ended instructions do not promote this goal, and scholars have offered a range of useful proposals to guide jury decisions and reduce variation. 237 These include

generation" reform proposals aim to eliminate or reduce some of these perceived flaws of the current system, without impairing consumer access to compensation. Such proposals can be categorized in light of several central attributes. These proposals involve combining different reforms by choosing variables from a series of categories into a single package. The categories that are available include: (1) the compensable event; (2) the measure of compensation; (3) the payment mechanism; (4) the forum used to resolve disputes; and (5) the method of implementing the new rights and responsibilities. *Id.* at 102–10.

234. Pub. CITIZEN'S CONG. WATCH, THE FACTS ABOUT MEDICAL MALPRACTICE IN PA 5-6 (2004), available at http://www.citizen.org/documents/PA\_MedMal\_Exec.pdf.

235. See Currie & MacLeod, supra note 77, at 812.

[T]he theory we outline here predicts that with less liability, physicians will exert less care . . . . Reducing liability through the imposition of damage caps will then increase procedure use. Increasing liability through JSL reform will reduce procedure use. The model also suggests that physician responses to tort reform provide some evidence about whether there is an excessive use of procedures initially.

Id.

236. See Bovbjerg et al., supra note 137, at 908.

237. See, e.g., Ronen Shamir, 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 (2006).

standardized awards based on age and severity of injury,<sup>238</sup> a distribution of the amounts awarded in comparable cases,<sup>239</sup> and scenarios of prototypical injuries and their corresponding awards.<sup>240</sup> One recent proposal uses grading of health states to evaluate non-economic losses.<sup>241</sup>

None of these approaches are easy to apply. They all require judgments about cases, their categories, how to compare them, and how to attach damage amounts. Undoubtedly, because of the aforementioned complexities, none of these approaches have been adopted. However, tort demonstration projects under the ACA might well test some out.

#### B. Mediation

Alternative Dispute Resolution (ADR) is often proposed as a way to avoid the claimed flaws of medical malpractice litigation. He diation has been one of the most popular forms of ADR proposed. Several private models exist, such as the Drexel University Hospital

Caps preserve some inequities and worsen others, and if they ameliorate inequities at all, they do so accidentally.

This article presents an alternative to flat caps. Methodologies used to grade health states, developed over decades to aid health program evaluations and difficult resource-allocation decisions, could be gainfully trained on the problem of how to evaluate noneconomic losses. Using a health-utilities index as the basis of a schedule of noneconomic damages for medical-malpractice injuries is an attractive idea.

Id.

242. See Thomas Metzloff, Alternative Dispute Resolution Strategies in Medical Malpractice, 9 ALASKA L. REV. 429, 435 (1992); David B. Simpson, Compulsory Arbitration: An Instrument of Medical Malpractice Reform and a Step Towards Reduced Health Care Costs?, 17 Seton Hall Legis. J. 457, 463 (1993); U.S. Cong., Office of Tech. Assessment, OTA-BP-H-119, Impact of Legal Reforms on Medical Malpractice Costs 23 (1993).

243. See Carol B. Liebman, Medical Malpractice Mediation: Benefits Gained, Opportunities Lost, 74 L. & CONTEMP. PROBS. 135, 135–37 (2011); Carol B. Liebman & Chris Stern Hyman, A Mediation Skills Model to Manage Disclosure of Errors and Adverse Events to Patients, 23 HEALTH AFF. 22, 30 (2004). See generally Edward A. Dauer et al., Prometheus and the Litigators: A Mediation Odyssey, 21 J. LEGAL MED. 159 (2000) (discussing the role of mediation in medical malpractice reform).

<sup>238.</sup> See, e.g., Bovbjerg et al., supra note 137, at 941.

<sup>239.</sup> See, e.g., Michael J. Saks et al., Reducing Variability in Civil Jury Awards, 21 LAW & HUM. BEHAV. 243, 255 (1997).

<sup>240.</sup> Bovbjerg et al., supra note 137, at 953-56.

<sup>241.</sup> See David M. Studdert et al., Rationalizing Noneconomic Damages: A Health-Utilities Approach, 74 L. & CONTEMP. PROBS. 57, 100 (Summer 2011). The authors note the usual critique of caps and offer their health utility methodology as a possible solution:

elective mediation program<sup>244</sup> and a similar program at the University of Pittsburgh Medical Center.<sup>245</sup> Mediation, like arbitration, promises diminished complexity in fact finding, lower costs, fairer results, greater access for plaintiffs with smaller claims, and a reduced burden on the courts.<sup>246</sup> Mediation provides a useful model so long as it is optional—the plaintiff can elect to litigate if dissatisfied with the results of the mediation.

Arbitration, by contrast, is mandatory, displacing litigation. It has severe disadvantages from a consumer perspective. Lawyers can drive up the costs and length of arbitration to match litigation. Evidence is also emerging that the "repeat player" phenomenon means a much higher victory rate for employers and other institutional players who regularly engage in arbitration, in contrast to one-shot players such as employees or consumers. In employment arbitration cases, one study found that the odds are five-to-one against the employee in a repeat-player case. Much of this imbalance may be due to the ability and incentive of repeat players to track the predisposition of arbitrators and bias the selection process in their favor. Awards are also typically confidential, and unlike litigation, the arbitrator's reasoning is unknown.

Newer risk-management approaches by some hospitals follow a transparency model where hospitals disclose adverse events to pa-

<sup>244.</sup> See, e.g., Susan M. Rapp, Mediation Successfully Used for Malpractice Claims, ORTHOPE-DICS TODAY (May 2004), available at http://www.orthosupersite.com/view.aspx?rid=1796 (describing the increased usage of mediation by hospital systems such as Rush University Medical Center in Chicago and Drexel University Hospital in Philadelphia); Deborah R. Lorber & Carl Oxholm III, ADR Can Play Important Role in Success of Tort Reform, 1 ASHRM RISK FINANCING & CLAIMS ADMIN. INT. NETWORK INSIGHTS 1, 3 (2005). Lorber and Oxholm write,

When significant adverse event[s] occur to Drexel University patients, the organization encourages doctors to get back to the patient and the family as soon as possible and to keep the lines of communication open. They are encouraged to explain what they think happened and what they are going to do to further investigate the occurrence. The risk management staff gets involved with patients and helps them contact their physicians to continue get the information they need.

Id.

<sup>245.</sup> See Joyce Gannon, Mediation Helps Hospitals Steer Clear of Courtrooms, PITTSBURGH POST-GAZETTE, Mar. 7, 2007, http://www.post-gazette.com/pg/07066/767315-28.stm.

<sup>246.</sup> See, e.g., AM. ARBITRATION ASS'N, ARBITRATION: ALTERNATIVE TO MALPRACTICE SUITS 5 (1975); Irving Ladimer et al., Experience in Medical Malpractice Arbitration, 2 J. LEGAL MED. 433, 437 (1981).

<sup>247.</sup> See generally Amanda Perwin, Ctr. For Justice & Democracy, Mandatory Binding Arbitration: Civil Injustice by Corporate America (2005), available at http://www.centerjd.org/archives/issues-facts/ArbitrationWhitePaper.pdf (critiquing the use of arbitration in dispute resolution of all kinds).

<sup>248.</sup> See Richard C. Reuben, The Lawyer Turns Peacemaker, 82 A.B.A. J. 54, 61 (1996).

<sup>249.</sup> See id.

tients. Hospitals hold discussions with patients and their lawyers in a manner that resembles mediation, removing some of the hard-edged litigation negotiating that is more typical of medical malpractice cases. The University of Michigan Health System adopted such a risk-management model, expanding their risk management offices and training staff in mediation techniques to better handle adverse patient events.<sup>250</sup> The model, however, is based on a negligence standard of review: "unreasonable medical mistakes."<sup>251</sup>

### C. Provider-Based Early Offers of Payment + Apology + Reform

These approaches are based on avoidable injuries, which are coupled with damage limitations to sweeten the deal. The proposals have been around for a long time and have been amended over time. The Michigan approach, above, uses elements of these ideas. The idea is to induce settlements more quickly by co-opting plaintiff lawyers with the promise of much quicker, less adversarial settlements that bring the injured plaintiffs into the conversation earlier.

## 1. The offer

Under this approach, providers would voluntarily agree to identify and promptly compensate patients for avoidable injuries. Damages would be limited under most proposals.<sup>252</sup> Under the approach,

250. Richard C. Boothman et al., *A Better Approach to Medical Malpractice Claims? The University of Michigan Experience*, 2 J. HEALTH & LIFE SCI. L. 125, 135 (2009). Boothman et al. summarize the approach as follows:

After an unanticipated outcome occurs:

- Patients/families are approached, acknowledged, and engaged in the acute phase.
- · Patient care needs are prioritized.
- Patients/families receive answers (to the extent they are known).
- Expectations for follow-up are established, the patient and family understand the situation is being addressed, and the patient and family are doing their parts.
- Patients and families receive acknowledgement of, and an apology for, true mistakes. They receive a thorough explanation regardless.
- The patient's experience is studied for improvements that later are shared with the patient and family.
- Future clinical care is monitored via metrics established and measured to evaluate efficacy and durability of improvements.

Id.

251. Id. at 132.

252. This approach was first proposed by Clark Havighurst and Laurence Tancredi. See Clark C. Havighurst & Laurence R. Tancredi, "Medical Adversity Insurance" – A No-Fault Approach to Medical Malpractice and Quality Assurance, 51 MILBANK MEMORIAL FUND Q. HEALTH 125, 128 (1973); Clark C. Havighurst, "Medical Adversity Insurance"—Has Its Time Come?, 1975 DUKE L.J. 1233, 1241 (1975); Laurence R. Tancredi, Designing a No-Fault Alternative, 49 L. &

the patient or provider would file the claim with the insurer when the adverse outcome first occurred. The insurer would then decide whether the injury was covered. If so, it would make a prompt payment. Disputes would be resolved through the courts or mediation. The proposed plan would include rate-insurance premiums paid by providers to incentivize providers to improve the quality of care by reducing their exposure to the listed adverse outcomes. The plan would also use provider experience to strengthen peer review within hospitals.<sup>253</sup>

### 2. The apology

A primary goal of many tort plaintiffs is to hold defendants accountable for their wrongful behavior and the harm they have caused.<sup>254</sup> The significant personal and social value of apology in

CONTEMP. PROBS. 277, 277-83 (1986). It has been recommended as a system demonstration with federal support in Inst. of Med., Fostering Rapid Advances in Health Care: Learn-ING FROM SYSTEM DEMONSTRATIONS 82 (Janet M. Corrigan et al. eds., 2002). A variation on the Tancredi proposals is provided by Professor Jeffrey O'Connell, who has proposed a variety of elective no-fault options using a list of covered injuries and contract agreements between providers and patients. See Jeffrey O'Connell, No-Fault Insurance for Injuries Arising from Medical Treatment: A Proposal for Elective Coverage, 24 EMORY L.J. 21, 32-42 (1975); see also Randall R. Bovbjerg & Laurence R. Tancredi, Liability Reform Should Make Patients Safer: "Avoidable Classes of Events" Are a Key Improvement, 33 J.L. MED. & ETHICS 478, 485 (2005) ("A very promising alternative that facilitates discovery and prompt resolution of cases is to establish avoidable classes of events, or ACEs, in advance."); id. at 489 ("Medical providers should disclose injuries and routinely compensate patients injured with an ACE"); Laurence R. Tancredi & Randall R. Bovbjerg, Rethinking Responsibility for Patient Injury: Accelerated Compensation Events, A Malpractice and Quality Reform Ripe for a Test, 54 L. & CONTEMP. PROBS. 147, 149 (1991) ("ACES do not cover all injuries, just classes of adverse outcomes that are usually, although not invariably, avoidable through good care."); Laurence R. Tancredi & Randall R. Bovjberg, Creating Outcomes-Based Systems for Quality and Malpractice Reform: Methodology of Accelerated-Compensation Events (ACEs), 70 MILBANK MEMORIAL FUND Q. HEALTH 183, 185, 191-92 (1992) ("Essentially, in reviewing information to develop lists, the experts ask themselves, based on their clinical expertise and knowledge of the medical literature, 'In what percentage of a large number of similar cases could this outcome be avoided, given good care?""); Laurence R. Tancredi & Randall R. Bovbjerg, Advancing the Epidemiology of Injury and Methods of Quality Control: ACEs as an Outcomes-Based System for Quality Improvement, 18 QUALITY REV. BULL. 201, 203 (June 1992) ("ACEs cover only those classes of adverse outcomes that are normally avoidable through good medicine"); Randall R. Bovbjerg, Medical Malpractice: Folklore, Facts, and the Future, 117 ANNALS INTERNAL MED. 788, 790 (1992) (discussing that such an approach would create "predefined lists of bad medical outcomes that should not normally happen when patients receive good care").

253. Randall R. Bovbjerg & Frank A. Sloan, No-Fault for Medical Injury: Theory and Evidence, 67 U. CIN. L. REV. 53, 100 (1998).

254. See, e.g., Timothy D. Lytton, Holding Bishops Accountable: How Lawsuits Helped the Catholic Church Confront Church Clergy Sexual Abuse 182–87 (2008)

health care is well established.<sup>255</sup> It appears that plaintiffs will settle for lower amounts if they also receive an apology. Potential release from liability also offers doctors a powerful incentive to take responsibility for their mistakes and to share information about the nature of what went wrong.<sup>256</sup> In addition to vindicating individual plaintiffs' claims, physician admissions of liability supply potential patients with information about the quality of care the physicians provided. Admissions of liability are also a potentially valuable source of aggregate information about medical error. Apology laws that make physicians' apologies inadmissible in a legal proceeding also have other effects:

In the short run, the law increases the number of resolved cases, while decreasing the average settlement payment for cases with more significant and permanent injuries. While having an insignificant impact on the settlement payments for cases involving minor injuries, the apology laws do reduce the total number of such cases. . . . Our findings suggest that apology laws reduce the amount of time it takes to reach a settlement in what would normally be protracted lawsuits, leading to more resolved cases in the short run. In the long run, the evidence suggests there could be fewer cases overall.257

Apology strategies have a real downside. From a defendant's perspective, such proposals offer a strategic tool to buy off plaintiffs by showing them how sorry the provider is, and to rush settlement by getting plaintiff lawyers to buy into early settlement. The provider controls the screening for potential claims as a filtering mechanism to reduce payouts, which is the wrong direction for tort reform.<sup>258</sup>

<sup>(</sup>discussing plaintiffs' desire for public accountability and apology in clergy sexual abuse litigation).

<sup>255.</sup> Benjamin Ho & Elaine Liu, Does Sorry Work? The Impact of Apology Laws on Medical Malpractice 2 (Johnson Sch. Research Paper Series, Working Paper No. 04 2011), available at http://ssrn.com/abstract=1744225 (citing anger as one of the main motivations of malpractice suits); Michal Alberstein & Nadav Davidovitch, Apologies in the Healthcare System: From Clinical Medicine to Public Health, 74 L. & CONTEMP. PROBS. 151, 175 (noting that "the purpose of apology should be as much the promotion of solidarity and harmony as saving money or avoiding litigation").

<sup>256.</sup> See Jennifer K. Robbennolt, Attorneys, Apologies, and Settlement Negotiations, 13 HARV. NEGOT. L. REV. 349, 359-60 (2008) (providing the most recent review of the literature); see also Lee Taft, Apology Subverted: The Commodification of Apology, 109 YALE L.J. 1135, 1150-54 (2000). 257. Ho & Liu, supra note 255, at 24-25.

<sup>258.</sup> See, e.g., Erin Ann O'Hara & Douglas Yarn, On Apology and Consilience, 77 WASH. L. REV. 1121, 1186 (2002); Erin Ann O'Hara, Apology and Thick Trust: What Spouse Abusers and

Strategic apologies may improve claims resolution, but at the cost of lower payments because conciliation has discounted the level of compensation that a plaintiff may really need. As O'Hara and Yarn write, "[T]he apology scholars have focused on the role of apology evidence in establishing liability, but they have neglected the fact that apology evidence very often has the practical effect of reducing damages."<sup>259</sup>

# 3. Safety reforms

Several private programs, such as the Johns Hopkins compensation program and the University of Michigan Health System approach, either include a patient safety reform offer as part of the offer and settlement mediation—promising patients that the cause of their injuries will be eliminated—or study and implement such changes as needed.<sup>260</sup> Particularly where a patient or family member died or suffered severe injury, the family often wants not just compensation, but also repair of the system's flaws to protect other patients.<sup>261</sup> Patients generally want to see hospital-wide changes and improvements in safety practices to prevent injuries for future patients.<sup>262</sup>

# D. Special Courts for Small Medical Injuries

Reformers have proposed health courts as a way to combine the reforms discussed above into one administrative model.<sup>263</sup> Such

Negligent Doctors Might Have in Common, 79 CHI.-KENT L. REV. 1055, 1076–77 (2004); Catherine T. Struve, Expertise in Medical Malpractice Litigation: Special Courts, Screening Panels, and Other Options, Pew Project on Medical Liability, 1, 63–64 (2003) available at http://www.pewtrusts.org/uploadedFiles/www.pewtrustsorg/Reports/Medical\_liability/medical\_malpractice\_101603.pdf.

- 259. O'Hara & Yarn, supra note 258, at 1129.
- 260. See generally Sorrel King, Josie's Story: A Mother's Inspiring Crusade to Make Medical Care Safe (2009).
- 261. *Id.* at 116–24 (describing how the family of Josie King decided to use their settlement money to start a patient safety foundation, working with Dr. Pronovost at Hopkins).
  - 262. Gallagher et al., supra note 32, at 1004, 1006.
  - 263. See Mello et al., supra note 10, at 460-61. The authors write,

A *health court* is a system of administrative compensation for medical injuries. It has five core features. First, injury compensation decisions are made outside the regular court system by specially trained judges. Second, compensation decisions are based on a standard of care that is broader than the negligence standard (but does not approach strict liability). "Avoidability" or "preventability" of the injury is the touchstone. To obtain compensation, claimants must show that the injury would not have occurred if best practices had been followed or an optimal system of care had been in

courts are claimed to balance the need for compensation of patients for their medical injuries with the need to improve the accountability and efficiency of the current liability system. Such health courts will use specially trained judges and an avoidability standard, compensation will be based on expert interpretations of the scientific literature, fast-track decision aids based on precedent will speed up the process, and compensation awards will be based on ex-ante guidelines.<sup>264</sup>

In the health court model, providers inform patients at the time of disclosure of an injury that patients can file a compensation claim with the provider or its insurer. A panel of experts, aided by decision guidelines, determines whether the injury was avoidable; that is, would the injury ordinarily have occurred if the best specialist—or an optimal health care system—had been provided? For avoidable injuries, the institution offers full compensation for economic losses plus a scheduled amount for pain and suffering based on injury severity. A voluntary model would allow a patient to reject the compensation offer and file a lawsuit, unless the patient had waived this right as a condition of receiving care.

The health court is a hybrid model based on earlier "early-settlement" models around since the 1970s. One example of such a model has been pioneered by the self-insured University of Michigan Health System, which limits compensation to cases in which the institution determines that the care was inappropriate. The offer may include compensation for all elements of loss that are compensable in tort cases, including medical expenses, lost income, other economic losses, and compensation for pain and suffering. A patient can only accept the tendered money after agreeing that it is a

place, but they need not show that care fell below the standard expected of a reasonable practitioner. Third, compensation criteria are based on evidence; that is, they are grounded in experts' interpretations of the leading scientific literature. To the maximum extent feasible, compensation decisions are guided by *ex ante* determinations about the preventability of common medical adverse events. Fourth, this knowledge, coupled with precedent, is converted to decision aids that allow fast-track compensation decisions for certain types of injury. Fifth and finally, *ex ante* guidelines also inform decisions about how much for economic and noneconomic damages should be paid.

Id.

264. Id.

265. See Michelle M. Mello & Thomas H. Gallagher, Malpractice Reform – Opportunities for Leadership by Health Care Institutions and Liability Insurers, 362 NEW ENG. J. MED. 1353, 1354 (2010).

266. Id.

final settlement, foreclosing a lawsuit.<sup>267</sup> The health courts model has a host of new problems, primarily based on the use of a new bureaucracy of decision making to replace trials. The health courts model decision-making process assumes that the current system is flawed.<sup>268</sup>

A better proposal to foster the handling of more small adverse events would be to create health care small claims courts to allow compensation for claims that otherwise are never filed because of discovery and other litigation costs. As Mehlman and Nance observe, "[I]f there is the political will to create a new bureaucracy to handle small claims, then there is nothing to stop the creation of an administrative system, voluntary for patients, alongside the traditional tort system."269 In 2005, for instance, the British government introduced a bill in Parliament to establish an administrative compensation system for smaller malpractice claims (i.e., less than £20,000). $^{270}$  The program is intended to be an alternative, rather than an exclusive, remedy, with injured patients free to pursue their claims in the traditional tort system. 271 Such a system could proceed on affidavits with a lower threshold of proof of the "adverse event" to allow for swift compensation for smaller injuries that otherwise never receive compensation under the current system. The British alternative program is a proposal worth further exploration.

### E. Enterprise Strict Liability

Enterprise liability proposals have existed in the legal literature since the 1970s. The development of a corporate negligence doctrine represents a first step toward holding hospitals liable for system mistakes and poor supervision. Some res ipsa loquitur cases, such as *Ybarra v. Spangard*,<sup>272</sup> represent a version of strict liability once the

<sup>267.</sup> See id.

<sup>268.</sup> Maxwell J. Mehlman & Dale A. Nance, *The Case Against "Health Courts"* 65 (Am. Ass'n for Justice, Working Paper 2007), available at http://ssrn.com/abstract=1785383.

<sup>269.</sup> Id. at 100.

<sup>270.</sup> U.K. DEP'T OF HEALTH, NHS REDRESS: STATEMENT OF POLICY 4 (2005), available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation /DH\_4123281 ("The NHS Redress Scheme will provide a mechanism for the swift resolution of low monetary value claims in tort arising out of hospital services provided as part of the NHS in England (wherever those services are provided), without the need to go to court. The scheme will only apply to claims in tort in respect of personal injury or loss arising out of a breach of a duty of care and arising as a consequence of any act or omission of a health care professional.").

<sup>271.</sup> Id. at 2.

<sup>272. 154</sup> P.2d 687 (Cal. 1944).

threshold is crossed. "Never events" are another regulatory move that captures events that speak for themselves—things that should never happen—that lead to required disclosures and to denials of Medicare reimbursement.

The best way to reduce uncertainty in risk evaluation for both insurers and providers is to impose some version of enterprise liability for an adverse medical event without requiring satisfaction of "unavoidability" or "unreasonable" criteria and without leaving the provider totally in control of whether to make an offer. If an adverse event occurs, it must be disclosed to the patient. Then, a provider may tender an early offer, perhaps coupled with mediation, to move the claims process forward rapidly with the plaintiff and the plaintiff's lawyer. If it is discovered that a reportable adverse event is not revealed, then the plaintiff is entitled to treble damages as an element of the damage claim. Procedural advantages, such as an extension of the statute of limitations, might also be considered.

# VI. THE AFFORDABLE CARE ACT REFORMS AND PATIENT SAFETY: A TAILWIND OF INNOVATION

The Affordable Care Act (ACA) does not explicitly propose liability reform, but it does offer up a range of patient safety initiatives that will streamline medical practice, reduce medical practice variation, and increase pressures on providers to discover and disclose adverse events. Both physician and institutional liability will be impacted by the ACA reforms.

#### A. Physician Exposure

The ACA is an access-improving reform bill, but it has dozens of patient safety provisions as well. These provisions include creating new centers, demonstration projects, and funding awards for a wide range of quality improvement initiatives. The bill mandates continuous, data-driven testing of the performance of health care professionals and facilities; launches "demonstration projects" through which the federal government funds particular forms of health care or health care delivery systems with a requirement that their performance be studied; funds research and orders the dissemination of findings to providers about what works; promotes transparency through performance based websites; and proposes the expansion of

existing payment strategies to better promote best practices and outcomes.<sup>273</sup>

The ACA creates four streams of pressure that converge toward measurable and specific standards of care in practice. First, outcome measures will be researched, developed, and disseminated.<sup>274</sup> Second, under Subtitle F, the ACA mandates the AHRQ director—in collaboration with other federal agencies—to develop "innovative methodologies and strategies" for improving patient safety and health care outcomes.<sup>275</sup> The AHRQ's Center for Quality Improvement and Patient Safety will disseminate best practices<sup>276</sup> and develop mechanisms for delivering health care reliably, safely, and efficiently; translate evidence into widely applicable practice recommendations; and identify and mitigate hazards by analyzing and responding to patient safety data.<sup>277</sup> This is quite a list, and it is likely to force hospitals' patient-safety and compliance officers into overtime as the hospitals struggle to absorb new findings. The use of "practice recommendations" approximates standard setting for physicians and will put a heavier burden of justification on physicians when they deviate from what lawyers will argue is a standard of care.

Third, research on outcome measures and best practices will be used to create clinical practice guidelines.<sup>278</sup> Fourth, outcomes, best practices, and guidelines will be rapidly disseminated to practice settings. Physician performance information will be available to consumers through websites,<sup>279</sup> just as comparative data on hospitals and nursing homes are currently available. Such information will include measures collected under the Physician Quality Reporting Initiative and also assessments of such factors as efficiency, safety, and effectiveness.<sup>280</sup> The Center for Quality Improvement and Patient Safety will push for adoption of best practices to improve the quality, safety, and efficiency of health care delivery services. Find-

<sup>273.</sup> See Furrow, supra note 31.

<sup>274.</sup> Patient Protection and Affordable Care Act, 42 U.S.C.A. § 299b-31(f) (West Supp. 2011); see also supra Section I.B. (discussing PPACA's provisions related to outcome measures in greater depth).

<sup>275.</sup> Id. § 299b-33(a).

<sup>276.</sup> Id. § 299(b)-(d).

<sup>277.</sup> Id. § 299b-33(c)(1)-(2).

<sup>278.</sup> See id. (requiring the HHS Secretary to identify existing and new clinical practice guidelines); see also id. §§ 10303(c), 304(b)(4).

<sup>279.</sup> See id. § 1395w-5.

<sup>280.</sup> Id.

ings will be disseminated through multiple media—linked with the Office of the National Coordinator of Health Information Technology—and used to "inform the activities of the health information technology extension program." A Patient-Centered Outcomes Research Institute will provide information to patients, providers, purchasers, and policymakers regarding disease management and recent research findings.

While the ACA specifies that such research findings do not include "practice guidelines, coverage recommendations, payment, or policy recommendations," this is hardly sufficient to keep such findings out of litigation over medical errors. Plaintiffs' lawyers will use the findings as at least some evidence of a standard of care, and potentially powerful evidence at that. This is one of the costs of improving medical practice by narrowing practice variation and medical uncertainty. As such, as American physicians move more and more into integrated systems and hospitals and away from small private practices, physicians' liability is likely to be shared with the health care systems.

The ACA does not generally federalize medical liability or reform litigation or malpractice insurance generally. Rather, it offers funds for demonstration projects to test various reform ideas. The primary liability reform provision in the ACA is section 10607. The HHS Secretary may award states demonstration grants for up to five years to explore alternatives to tort litigation for resolving claims filed against health care providers or organizations. The ACA specifies that the programs should resolve disputes over patient injuries and promote a reduction in medical errors "by encouraging the collection and analysis of patient safety data related to disputes resolved under subparagraph (A) by organizations that engage in efforts to improve patient safety and the quality of health care." The liability implications of the ACA are substantial, in spite of its silence on the subject.

<sup>281.</sup> Id. § 299b-33(d)(2).

<sup>282.</sup> Id. § 1320e(d)(8)(A)(iv).

<sup>283.</sup> One exception is the mandate of decision aids for certain categories of treatments. This exception replaces common law informed consent rules with mandated "decision aids" certified by an approved body. *See id.* § 299b-36.

<sup>284.</sup> ACA, Pub. L. No. 111-148, § 10607, 124 Stat. 119, 804 (codified at 42 U.S.C. § 280g-15 (2010)).

<sup>285. 42</sup> U.S.C. § 280g-15(a)-(b) (2010).

<sup>286.</sup> Id. § 280g-15(c)(1)(A)-(B).

### B. Institutional Liability

The ACA contains no provisions directly addressing agency relationships or corporate negligence, nor does it explicitly alter the existing common law rules relating to vicarious liability and independent contractors. Instead, it offers substantial financial incentives for providers to integrate and coordinate their care. <sup>287</sup> The ACA creates strong pressures for providers to integrate and coordinate their delivery of health care for Medicare recipients through centers, demonstration projects, and Medicare reimbursement incentives.

Assume that within a few years ACOs are successfully formed, comprehensive patient bundling is implemented in many hospitals, and salary-based payment systems proliferate. These reforms do several things at once: they move more physicians from solo or small group practice into salaried positions in a group model or a hospital; they move power toward enterprises that can buy and coordinate the technologies—from EHRs to case management strategies—to meet the demands of the federal government; and they therefore turn more providers into agents of institutional providers rather than independent contractors. Although the health reform measures in the ACA based on payment reform begin with Medicare providers and beneficiaries, it is predictable that institutional providers will create a system for all patients, private-pay and Medicare, for obvious efficiency reasons.

The liability result is clear if these various reforms, incentives, and forces converge. First, institutional providers will become liable for patient injury, as well as physicians directly causing patient injury, since agency law will carry liability upstream from agent to principal. Physicians will be more integrated in the system, whether they are salaried, and any argument of independent contractor status will evaporate.

Second, even if ACOs and other entities operate without a hospital as a part of the organization, they are now health care providers, subject to liability just as a hospital or managed-care organization is, under both vicarious liability and direct negligence principles.

Third, corporate negligence principles will likely apply to integrated organizations that manage care, whether a patient home, an ACO, or some other delivery form the ACA creates. Courts are willing to look beyond the hospital form in deciding whether a health care entity might be liable for corporate negligence, considering the

types of systems and activities suggest the management and coordination of patient care. <sup>288</sup>

Today most physician groups or office-based practices would not be said to possess such responsibility. But the entities fostered by the ACA and its millions of dollars in demonstration grants and Medicare mandates are far more likely to coordinate care, taking on new responsibilities that will make them appropriate defendants in tort litigation.

#### **CONCLUSION**

Health care settings are complicated, with dozens of personnel often interacting with a single patient who needs demanding care. The result is too often a high level of poorly managed and often unsafe care, harming thousands of patients. Changing a safety culture is a slow and difficult proposition. It is clear that we have just begun to design better systems and move providers into productive teamwork settings where harms are manageable. It is also clear that medical liability is a powerful tool, distorted in its image by relentless lobbying by parties interested in reducing tort to little more than a minor irritant. I would like to see litigation as a very large storm cloud instead of an irritant, looming large enough to drive medical practice to nearly zero adverse events. In the end, it might mean a reduction in malpractice suits and the need for insurance against such suits, but that would be a small price to pay for safer health care—and it would ultimately leave physicians happier knowing they did not have to fear being sued.

This Article offers a few modest proposals to improve the claiming process, incentivizing institutional providers to pay attention to safety in order to avoid suit and pay outs of millions of dollars in claims. These proposals are a varied group, recognizing the players in the system and the possibility that small tweaks may often make

<sup>288.</sup> In *Gianquitti v. Atwood Medical Associates*, 973 A.2d 580, 593 (R.I. 2009), the court held that a professional medical-group practice providing on-call medical care to its patients if they are hospitalized can be liable for corporate negligence if it lacks a formal backup system. In another case, *Davis v. Gish*, 2 Pa. D. & C.5th 154, 157 (2007), the court noted the kinds of activities that would turn a professional group or a physicians' practice group into an entity subject to corporate negligence. The entity would, much like an HMO, "involve [itself] daily in decisions affecting [its] subscriber's medical care. These decisions may, among others, limit the length of hospital stays, restrict the use of specialists, prohibit or limit post-hospital care, restrict access to therapy, or prevent rendering of emergency room care." *Id.* at 158. The entity must have general responsibility "for arranging and coordinating the total health care of its patients." *Id.* at 159. It must take "an active role in patients' care." *Id.* 

significant differences. Ultimately, however, change must come from within the health care system. Lawyers cannot reengineer hospitals to be safer places; they can simply spur the change.