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Liability and the Health Care Bill: An “Alternative” Perspective

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The recently passed health care bill¹ contains many provisions that deserve celebration. Improving access to care is an important first step. Enhancing patient safety and accountability is an important second step, one that proponents of medical malpractice reform often undermine with attempts to restrict the liability of health care providers through “litigation alternatives.” During the health care debate, these advocates frequently raised liability issues (couched in politicized rhetoric),² despite studies that show civil litigation is protecting patient safety in the health care system now and will continue to play a significant role in the future.³

Congress ultimately rejected proposals to create new federal tort law for medical malpractice cases as part of health care reform.⁴ Many of these

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1. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10607, 124 Stat. 119, 1009–14 (2010).

2. See, e.g., Linda Feldmann, *Healthcare Summit: Is Obama Ready to Tee Up Tort Reform?*, CHRISTIAN SCI. MONITOR, Feb. 24, 2010, available at <http://www.csmonitor.com/USA/Politics/2010/0224/Healthcare-summit-Is-Obama-ready-to-tee-up-tort-reform> (describing medical malpractice reform as a “holy grail” for Republicans in health care debates).

3. 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).

4. One point of contention concerned the cost-savings created by medical malpractice reform. At the request of Sen. Orrin Hatch (R-UT), the Congressional Budget Office (CBO) evaluated the potential impacts of: a federal \$250,000 cap on noneconomic damages; a cap on punitive damages of \$500,000 or two times the award for economic damages, whichever is

proposals suffered from severe legal, efficiency, and fairness concerns. They also would have amounted to serious intrusions into state power, thus raising constitutional concerns.⁵

Instead, in the Patient Protection and Affordable Care Act (PPACA), Congress authorized the Department of Health and Human Services (HHS) to award grants to state demonstration programs that would create alternatives to litigation.⁶ A few important conditions apply to these grants; for example, HHS shall only award them to programs that ensure “prompt and fair resolution of disputes,” enhance patient safety, and provide patients with the ability to opt-out.⁷ Further, the programs cannot conflict with existing state law or limit any existing legal rights.⁸ Even before Congress authorized this program, President Obama issued a Presidential Memorandum asking HHS to make available \$25 million in “demonstration grants to States, localities, and health systems for the development, implementation, and evaluation of alternatives to our current medical liability system.”⁹ The process for awarding these grants is underway.¹⁰

greater; repeal of the collateral source rule; a statute of limitations that is one year from date of discovery (three years for children); and repeal of joint and several liability. *See, e.g.*, Letter from Douglas W. Elmendorf, Director, Congressional Budget Office, to Sen. Orrin G. Hatch (Oct. 9, 2009), available at http://www.cbo.gov/ftpdocs/106xx/doc10641/10-09-Tort_Reform.pdf. The CBO determined the savings would amount to a mere 0.5% of health care costs. *Id.* Other Senators expressed concern that even these CBO figures overstated savings. *See, e.g.*, Letter from Sen. John D. Rockefeller IV (D-WV) to Douglas W. Elmendorf, Director, Congressional Budget Office (Oct. 21, 2009), available at <http://rockefeller.senate.gov/press/102109%20Ltr%20to%20CBO%20on%20Med%20Mal.pdf>.

5. These concerns include violations of the Commerce Clause, the Spending Clause, the Seventh Amendment, and separation of powers principles. *See* Amy Widman & Francine Hochsberg, *Federal Administrative Health Courts Are Unconstitutional: A Reply to Elliott, Narayan, and Nasmith*, 33 J. HEALTH POL., POL’Y & L. 799 (2008).

6. Patient Protection and Affordable Care Act § 10607.

7. *Id.* § 10607(c)(2); *see also id.* § 6801(2) (“States should be encouraged to develop and test alternatives to the existing civil litigation system as a way of improving patient safety, reducing medical errors, encouraging the efficient resolution of disputes, increasing the availability of prompt and fair resolution of disputes, and improving access to liability insurance, while preserving an individual’s right to seek redress in court . . .”).

8. *Id.* § 10607(l)–(m).

9. Memorandum from the White House to the Secretary of Health & Human Services, *Demonstration Grants for the Development, Implementation, and Evaluation of Alternatives to the Current Medical Liability System* (Sept. 17, 2009), available at http://www.whitehouse.gov/the_press_office/Presidential-Memorandum-Concerning-Medical-Liability-Reform; Press Briefing, Robert Gibbs and Kathleen Sebelius (Sept. 17, 2009), http://www.whitehouse.gov/the_press_office/Briefing-by-White-House-Pres-Secretary-Robert-Gibbs-and-Secretary-of-Health-and-Human-Services-Kathleen-Sebelius-9/17/09/ (“Grants are going to be available for the development, implementation, and evaluation of models that do four things: put patient safety first and work to reduce preventable injuries; foster better communication between doctors and their patients; ensure that patients are compensated in a fair and timely manner for medical injuries, while reducing the incidence of frivolous lawsuits; and finally, reduce liability premiums.”).

10. *Medical Liability Reform and Patient Safety: Demonstration Grants*, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, U.S. DEPT. HEALTH & HUMAN SERVICES (June 2010), <http://www.ahrq.gov/qual/liability/demogrants.htm>.

Expanding the number of people with health insurance—a main goal of health care reform—will likely reduce the number of people who use emergency rooms for primary care. This could have significant patient safety implications, since the hospital location with the highest proportion of negligent adverse events is the emergency department.¹¹ In contrast, a closer look at some previously proposed or enacted state litigation “alternatives” that may now be considered as part of federal health care reform reveals that most are not focused on patient safety. Furthermore, each “alternative” to litigation presents important new questions of fairness and constitutionality.

I

WHY LIMITING LITIGATION HINDERS PATIENT SAFETY

Some suggest that limiting litigation against health care providers would enhance patient safety by making it more likely that doctors would report errors.¹² The facts do not bear this out. For example, studies comparing the rate of error disclosure in the United States against countries with far less litigation and no jury trials show no difference in reporting.¹³ Further, according to some academics:

[I]t is naïve to think that error reporting and health care quality would improve automatically by removing the threat of liability. . . . No statistical study shows an inverse correlation between malpractice exposure and the frequency of error reporting, or indicates that malpractice liability discourages providers from reporting mistakes.¹⁴

These studies and others offer a number of explanations for physicians’ failure to report errors, which have nothing to do with litigation fears and would not change with alternative litigation systems.¹⁵

Moreover, widespread implementation of “litigation alternatives” could jeopardize the important relationship between patient safety and medical malpractice litigation. Contrary to the pervasive assumption that litigation needs limiting, what will help patients more is focusing on improving patient

11. INST. OF MED. OF THE NAT’L ACAD., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* 36 (Linda T. Kohn et al. eds., 2000).

12. See David A. Hyman & Charles Silver, *Medical Malpractice Litigation and Tort Reform: It’s the Incentives, Stupid*, 59 VAND. L. REV. 1085, 1113 (2006) (“Although one frequently hears that fear of litigation prevents providers from admitting mistakes, studies indicate that first-party disclosures are reasonably common, although far from universal.”) [hereinafter Hyman & Silver, *Medical Malpractice Litigation*]; see also Lauren Solberg, *Apology Laws: Protection for Disclosure of Adverse Medical Outcomes*, VAND. U. LAW SCH. HEALTH L. ENEWSLETTER (Nov. 2008), <http://vulsinbrief.com/health/nov08/heart.php>.

13. See e.g., Annas, *supra* note 3, at 2065–66 (reporting on studies in New Zealand).

14. David A. Hyman & Charles Silver, *The Poor State of Health Care Quality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution?*, 90 CORNELL L. REV. 893, 898–99, 914 (2005).

15. *Id.*; see also TOM BAKER, *THE MEDICAL MALPRACTICE MYTH* 97 (2005) (“[T]o prove that lawsuits drive medical mistakes underground, you first have to prove that mistakes would be out in the open if there were no medical malpractice lawsuits. That is clearly not the case.”).

safety.¹⁶ And litigation can actually play a role in improving patient safety.¹⁷

Furthermore, increased safety will, at the same time, decrease the need for litigation. A recently released study from the Rand Institute for Civil Justice empirically examined California malpractice claims and found 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.”¹⁸ The study concluded:

to the extent that improved safety performance can be shown to have a demonstrable impact on malpractice claims, that offers another focal point for policymakers in seeking to address the malpractice crisis [W]e would suggest that that focal point may be more immediately relevant than has previously been recognized.¹⁹

In other words, advancing patient safety would go a long way toward both improving patient care and reducing litigation.

II

WHY VARIOUS LITIGATION “ALTERNATIVES” ARE FLAWED

A collection of “alternatives” to tort litigation will receive federal grant support as part of health care reform, but prior experiences with such programs at the state level suggest they compromise patient safety and present constitutional and equity issues.

A. Health Courts

Industry groups like Common Good make a strong political case for piloting state health court programs as an alternative to medical malpractice litigation.²⁰ These programs consist of an alternative tribunal set up to hear

16. “[T]he reason why tort liability promotes patient safety is obvious. Providers are rational. When injuring patients becomes more expensive than not injuring them, providers will stop injuring patients In short, the notion that errors would decline if tort liability diminished is ridiculous.” MAXWELL J. MEHLMAN & DALE A. NANCE, *MEDICAL INJUSTICE: THE CASE AGAINST HEALTH COURTS* 47 (2007) (quoting Hyman & Silver, *Medical Malpractice Litigation*, *supra* note 12, at 1131). *See also* Lee Harris, *Tort Reform as a Carrot-and-Stick*, 46 *HARV. J. ON LEGIS.* 163, 178 (2009) (“Medical malpractice lawsuits with unlimited recovery are a way of policing misconduct and weeding out bad doctors, which neither insurance companies nor physician organizations track satisfactorily.”).

17. MEHLMAN & NANCE, *supra* note 16, at 47.

18. MICHAEL D. GREENBERG ET AL., *RAND INST. FOR CIVIL JUSTICE, IS BETTER PATIENT SAFETY ASSOCIATED WITH LESS MALPRACTICE ACTIVITY? EVIDENCE FROM CALIFORNIA* 12 (2010). Moreover, “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.” *Id.*

19. *Id.* at 19.

20. Common Good was founded by Philip K. Howard, Vice Chairman of the corporate law firm Covington & Burling, one of the principal architects of the so-called “tort reform” movement

malpractice claims.²¹ Common features of the proposed health courts include: (1) a new standard of liability, termed “avoidability,” which resides somewhere closer to negligence than strict liability; (2) no juries; and (3) some sort of schedule for benefits.

Health court proponents point to worker’s compensation and no-fault auto insurance as models for such a program.²² However, there is a significant constitutional difference between those programs and the proposed health courts: the standard of liability. Those alternatives share a strict liability theory, which sharply contrasts with the health court model’s avoidability theory.²³ This difference is vital to the constitutionality of such programs because the general maxim is that the legislature may not remove a right from the jury without offering a quid pro quo.²⁴ Strict liability is the quid, and without it, these pilot programs are vulnerable to constitutional attacks at both the state and federal levels.²⁵

Beyond the constitutional questions, health court proposals do not ameliorate the political and bureaucratic problems currently plaguing other alternative tribunal systems. The health court model does not address the possibility for bias and inefficiency—problems that afflict workers’ compensation and other alternative compensation programs.²⁶ Moreover, the inevitable slide toward a schedule of benefits—and, more likely, caps on damages—is another hidden restriction on access inside the health courts model that both states and academics have rejected as unfair.²⁷ As with other

as counsel for Big Tobacco. For more on this history, see CARL DEAL & JOANNE DOROSHOW, CENTER FOR JUSTICE & DEMOCRACY AND PUBLIC CITIZEN, THE CALA FILES: THE SECRET CAMPAIGN BY BIG TOBACCO AND OTHER MAJOR INDUSTRIES TO TAKE AWAY YOUR RIGHTS 1–3 (2008), available at <http://www.centerjd.org/archives/issues-facts/stories/cala.php>.

21. See, e.g., Fair and Reliable Medical Justice Act, S. 1337, 109th Cong. (2005).

22. Paul Barringer et al., *Administrative Compensation of Medical Injury: A Hardy Perennial Blooms Again*, 33 J. HEALTH POL., POL’Y & L. 725, 725–60 (2008).

23. David M. Studdert et al., *Can the United States Afford a ‘No-Fault’ System of Compensation for Medical Injury?* 60 LAW & CONTEMP. PROBS 1 (1997); see also Remarks at the Harvard School of Public Health & Common Good Symposium, *Administrative Approaches to Compensating for Medical Injuries: National and International Perspectives* (Oct. 31, 2005) (transcript available at http://commongood.org/assets/attachments/Transcript_-_October_31st_Event.pdf) (discussing how the avoidability standard has “some similarities to the negligence standard”).

24. N.Y. Cent. R.R. Co. v. White, 243 U.S. 188, 201 (1917); Crowell v. Benson, 285 U.S. 22, 41 (1932).

25. For more discussion of the state constitutional problems, see Amy Widman, *Why Health Courts are Unconstitutional* 27 PACE L. REV. 55 (2006). For more discussion of the federal constitutional implications, see Amy Widman & Francine Hochsberg, *Federal Administrative Health Courts Are Unconstitutional: A Reply to Elliott, Narayan, and Nasmith*, 33 J. HEALTH POL., POL’Y & L. 799 (2008).

26. Martha McClusky, *The Illusion of Efficiency in Workers’ Compensation ‘Reform’*, 50 RUTGERS L. REV. 657, 670–71 nn.34–35 (1998). See also Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD & DRUG L.J. 351 (2001).

27. See, e.g., *Medical Liability: New Ideas for Making the System Work Better for Patients, 2006: Hearing of the S. Comm. on Health, Education, Labor and Pensions*, 109th Cong. 78–80 (June 22, 2006) (statement of Neil Vidmar, Professor of Law, Duke Law School). See also Royal

administrative compensation schemes, schedules of benefits are subject to political changes and will likely be reduced over the years.²⁸

Finally, health courts will not improve patient safety. Proponents of the model assert that by removing the “negligence” standard of liability, more health care professionals will feel less stigma and be more forthcoming with errors.²⁹ However, empirical research suggests this is a false assumption.³⁰ Proponents also point to a proposed database compiled from all avoidable events that hospitals could use to assess quality and enhance patient safety.³¹ Notably, however, this database would not be accessible to disciplinary groups because opening it up might chill disclosure.³² The end result is a database that relies purely on a hospital’s desire to address error, without any public mechanism to ensure or encourage that result. The tort system, on the other hand, puts hospitals on notice of errors and creates a stronger incentive to address systemic failures. In fact, according to the *New England Journal of Medicine*, “more liability suits against hospitals may be necessary to motivate hospital boards to take patient safety more seriously.”³³

B. Apology and Early Offer Laws

Apology laws, which already exist in many states, are another proposed alternative to malpractice litigation.³⁴ These laws typically allow physicians and other medical staff involved in medical errors to apologize to the family and not have their words used against them if an incident is ever brought to court.³⁵ Laws vary as to what types of statements they protect from future use in litigation. A few states, like Colorado, protect many types of statements, including statements of fault; most other states, like Texas, protect just the expressions of sympathy but not other comments made in the context of the apology.³⁶ Vermont protects oral statements, but not written statements.³⁷

Furgeson, *Civil Jury Trials R.I.P.? Can it Actually Happen in America?* 40 ST. MARY’S L.J. 795, 884 (2009); Harris, *supra* note 16, at 168; Patrick Salvi, *Why Medical Malpractice Caps Are Wrong*, 26 N. ILL. U. L. REV. 553 (2006).

28. Experience with workers’ compensation and vaccine injury compensation programs suggests schedules of benefits will be reduced over time. See AMY WIDMAN, CENTER FOR JUSTICE & DEMOCRACY, *WORKERS’ COMPENSATION: A CAUTIONARY TALE* 8–9, 19 (2006).

29. Michelle M. Mello et al., *Health Courts and Accountability for Patient Safety*, 84 MILBANK Q. 459, 475 (2006).

30. See *supra* text accompanying notes 13–15.

31. Mello et al., *supra* note 29, at 476.

32. *Id.*

33. Annas, *supra* note 3, at 2064.

34. At least thirty-six states have enacted some form of apology law to date. William M. McDonnell & Elisabeth Guenther, *Narrative Review: Do State Laws Make it Easier to Say I’m Sorry?*, 149 ANNALS INTERNAL MED. 811, 812 (2008). Certain hospitals and insurance companies have also enacted similar policies, and the Federal Government has a voluntary program for Federal Tort Claims Act cases against the Dept. of Health & Human Services. See *infra* note 40.

35. Solberg, *supra* note 12.

36. *Id.*; see also Edward A. Dauer, *Apology in the Aftermath of Injury: Colorado’s “I’m Sorry” Law*, 34 COLO. LAW. 47 (2005); TEX. CIV. PRAC. & REM. CODE § 18.061 (2009).

None of these laws provide for compensation.³⁸

Some advocates of apology laws also propose early offer statutes, or “disclosure and offer laws,” which take the apology program even further and provide for an offer of compensation, made alongside the apology.³⁹ Although no state has enacted an early offer law, a few hospitals and insurance companies have initiated pilot programs.⁴⁰ Academics and other groups advocating for medical malpractice lawsuit restrictions have also developed model early offer statutes.⁴¹

HHS recently awarded New York a \$3 million grant under the PPACA to institute an early disclosure and settlement program.⁴² Under the New York program model, disclosure of an adverse event triggers the hospital administration to conduct a “rapid investigation” that independently determines whether malpractice occurred.⁴³ If the hospital concludes there was malpractice, it preemptively offers compensation to the patient, in an amount chosen by the hospital. If the hospital concludes there was no malpractice, the administrators “explain this to families and indicate that the institution will vigorously defend the involved clinicians.”⁴⁴ If the patient does not accept the hospital’s assessment and offer, he or she may sue in certain courts, where specially trained judges (assisted by “Medical Advisors”) will handle all aspects of the case and strongly encourage settlement.⁴⁵ The grant proposal envisions a model whereby hospital administrators have a high degree of control over the investigatory process. Moreover, the medical community and specialty groups are responsible for training the “Medical Advisor” who is then

37. Solberg, *supra* note 12; see also VT. STAT. tit. 12, § 1912 (2006).

38. McDonnell & Guenther, *supra* note 34, at 811–15.

39. See, e.g., Hillary Rodham Clinton & Barack Obama, *Making Patient Safety the Centerpiece of Medical Liability Reform*, 354 NEW ENG. J. MED. 2205, 2205–08 (2006) (describing then-Senator Clinton’s (D-N.Y.) and then-Senator Obama’s (D-Ill.) legislation, the National Medical Error Disclosure and Compensation (MEDIc) bill, coauthored in 2006).

40. To date, the main models of early offer programs are a program run by a Colorado insurance group (COPIC), a program instituted at the Lexington, Kentucky Veterans Affairs Medical Center (and repeated in other Virginia hospitals and some insurance groups), and a pilot program within HHS. These programs are all voluntary. See Robert J. Walling & Shawna S. Ackerman, *Having to Say You’re Sorry: A More Efficient Medical Malpractice Insurance Model*, CONTINGENCIES, Nov./Dec. 2006, at 46, 46; COPIC, 3RS PROGRAM, <http://www.callcopic.com/home/what-we-offer/coverages/medical-professional-liability-insurance-co/physicians-medical-practices/special-programs/3rs-program/> (last updated April 5, 2009); see also Press Release, U.S. Dept. of Health & Human Services, Thompson Launches “Early Offers” Pilot Program to Speed Compensation to Injured Patients, Help Reduce Medical Costs (Sept. 21, 2004), <http://archive.hhs.gov/news/press/2004pres/20040921b.html>.

41. See e.g., Jeffrey O’Connell, *Commentary: Binding Early Offers Versus Caps for Medical Malpractice Claims?*, 85 MILLBANK Q. 287, 288 (2007).

42. Noeleen G. Walder, *State Gets \$2.9 Million U.S. Grant To Reduce Malpractice Suit Costs*, N.Y. L.J., June 16, 2010, at 1 col. 5.

43. N.Y. Unified Court Sys., *New York State Medical Liability Reform and Patient Safety Model Grant Proposal* (2010), available at <http://www.nylj.com/nylawyer/adgifs/decisions/061610grant.pdf>.

44. *Id.*

45. *Id.*

tasked with researching the standard of care, assessing whether a breach of the standard occurred, and advising the judge.⁴⁶ This program calls into question longstanding accountability mechanisms, operates within a system riddled with bias against the patient, and creates a real possibility of deleterious effects on patient safety.

In other existing programs, the hospital, provider, or insurance company involved in the negligent or otherwise culpable adverse outcome makes an offer, based purely on economic damages, to the injured party.⁴⁷ The patient or patient's family who accepts this offer is usually precluded from suing the medical staff.⁴⁸ Because plaintiffs will receive early offers soon after the adverse event, while still working through the trauma of the injury or loss of a loved one, and before the extent of their future costs are known, plaintiffs will feel an inordinate amount of economic or emotional pressure to accept the offers made. This pressure is likely even when the offers do not cover all of a plaintiff's economic damages and contain virtually no noneconomic damages.⁴⁹

Some early offer proposals are extremely punitive toward patients who do not accept the settlement provided by the hospital. For example, some proposals advocate requiring that fee-shifting penalties attach to a patient who rejects an offer, or would allow the plaintiff to retain the right to sue but with a much higher burden of proof.⁵⁰

All of these programs would only cover economic damages.⁵¹ In the context of proposed laws that would preclude the injured party from suing, this essentially removes any ability for an injured patient to recover noneconomic damages. Such limits on damages disproportionately affect populations with lessened earning power, such as women, children, minorities and the elderly.⁵² An elderly person who is severely injured by medical malpractice and is eligible to have his or her injuries covered by Medicare/Medicaid, and who has no other economic damages from the injury, will generally receive nothing under an early offer scheme. These types of damage restrictions also disproportionately affect injured children, whose damages depend in part on future life expectancies and future medical technology.⁵³ Early offer proposals relying on a fixed schedule of compensation for economic damages would leave parents of injured children with less compensation than may well be

46. *Id.*

47. See, e.g., Richard C. Boothman et al., *A Better Approach to Medical Malpractice Claims? The University of Michigan Experience*, 2 J. HEALTH LIFE SCI. L. 125, 156–57 (2009).

48. See *id.* at 141–42.

49. Such emotional pressure is perhaps the highest for injured baby/child cases.

50. Bernard Black et al., *The Effects of 'Early Offers' in Medical Malpractice Cases: Evidence from Texas*, 6 J. EMP. LEGAL STUD. 723, 727 (2009).

51. See O'Connell, *supra* note 41, at 287–88.

52. Lucinda M. Finley, *The Hidden Victims of Tort Reform: Women, Children, and the Elderly*, 53 EMORY L.J. 1263, 1265 (2004). For more discussion of this issue, see Joanne Doroshov & Amy Widman, *The Racial Implications of Tort Reform*, 25 WASH. U. J.L. & POL'Y 161 (2007).

53. See Black et al., *supra* note 50, at 754–55.

needed.⁵⁴

C. Clinical Practice Guidelines

Underlying the health courts model, and lurking in most alternative-to-litigation programs, is a proposal that doctors who practice “evidence-based medicine” or, more specifically, follow “clinical practice guidelines” (that may or may not stem from “evidence-based medicine”), should be immune, or presumed to be immune, from lawsuits.⁵⁵ Under this proposal, doctors adhering to clinical practice guidelines would receive the benefit of immunity even though a patient may have been injured or killed.⁵⁶ Both sides in malpractice litigation currently make limited use of clinical practice guidelines to negotiate settlements, or even to help lawyers decide whether to file suits.⁵⁷ However, that is very different from allowing such guidelines to become the legal standard for deciding liability in a medical malpractice case and allowing the one-sided use of such guidelines by the defense to exculpate a physician.⁵⁸

The relevance of clinical guidelines depends largely on the impetus behind their use. When triggered by the desire to reduce unwarranted variation in practice and provide patients with benchmark quality care rooted in science, adherence to clinical guidelines can improve patient safety.⁵⁹ However, appropriating clinical practice guidelines for uses divorced from patient safety considerations creates unwarranted consequences.

Pressure from managed care and health plans to lower costs has been at the root of some clinical guideline development, and guidelines developed for the sole purpose of streamlining coverage decisions are not relevant to patient safety.⁶⁰ In fact, guidelines created for that purpose are not always developed through the typical, science-based professional consensus process.⁶¹ Adopting

54. See Finley, *supra* note 52, at 1292–95.

55. See Andrew L. Hyams et al., *Practice Guidelines and Malpractice Litigation: A Two-Way Street*, 122 ANNALS INTERNAL MED. 450, 450–55 (1995); see also Arnold J. Rosoff, *Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POL., POL'Y & L. 327 (2001).

56. See *id.* at 337.

57. Hyams et al., *supra* note 55, at 454.

58. Current proposals do not allow “inculpatory” use by patients when presenting their cases. Center for Justice & Democracy, *Clinical Practice Guidelines as Legal Standards: The Wrong Cure for Health Care*, <http://www.centerjd.org/archives/issues-facts/PracticeGuidelinesFactSheetF2.pdf> (last visited Aug. 26, 2010).

59. In 1985, for example, anesthesiologists, motivated by increasing malpractice premiums and studies showing that human error was the most frequent cause of patient harm, undertook a thorough examination of their practices. Annas, *supra* note 3, at 2065. After reviewing claims from different insurers, the specialty of anesthesiology developed practice guidelines specifically aimed at reducing preventable harm to patients. See *id.* As a result, “the risk of death from anesthesia dropped from 1 in 5000 to about 1 in 250,000.” *Id.*

60. Rosoff, *supra* note 55, at 339.

61. *Id.* at 329. (“EBM [evidence-based medicine] can show up in forms other than CPG [clinical practice guidelines]—for example, in journal articles, unpublished studies, and expert testimony. Conversely, CPGs are not necessarily based upon EBM—although the vast majority of

such guidelines as a legal standard “would be a substantial departure from existing law.”⁶²

There is a general recognition that conflicts of interest and specialty bias are ongoing problems in the development of clinical practice guidelines.⁶³ Allowing medical and specialty societies to participate in writing guidelines they know will be exculpatory for their members will exacerbate the problems stemming from conflicts of interest and bias.⁶⁴ It would be fundamentally unjust for patients to have their cases judged by liability standards chosen by specialty medical societies for the purpose of exculpating fellow specialists.

Moreover, since the guidelines cannot encompass the huge variation in how patients present their conditions, there may be good reason for caregivers to depart from a guideline’s recommendation for a patient. Even experts firmly committed to evidence-based medical practice recognize that it might be beneficial to avoid a one-size-fits-all approach.⁶⁵ Because of past questions about the guidelines’ specificity, the American Medical Association has opposed the use of guidelines as a legal standard even for exculpatory purposes, urging instead “that they be used only as evidence of the customarily observed professional standard of practice and that their degree of authority be dependent upon the degree of their acceptance among medical practitioners.”⁶⁶

Only a few states have attempted to develop and use clinical practice guidelines as legal standards.⁶⁷ These limited state experiments, which began

the CPGs being generated nowadays are, or at least purport to be. Cynthia Mulrow and Kathleen Lohr’s essay recognizes that guidelines generated primarily through a professional consensus process—the traditional approach—may differ from those based more directly on hard, empirical evidence—the EBM approach.”).

62. *Id.* at 339.

63. INST. OF MED. OF THE NAT’L ACAD., KNOWING WHAT WORKS IN HEALTH CARE: A ROADMAP FOR THE NATION 121–52 (Jill Eden et al. eds., 2008).

64. *Id.* For example, specialty societies, like the American College of Obstetricians and Gynecologists, have been aggressive leaders in the medical lobbies’ push for liability limits in the last few years and remain committed to that goal. *See, e.g.*, Press Release, Am. Coll. of Obstetricians and Gynecologists, Help Your Patients Push for Medical Liability Reform (Mar. 25, 2005), available at http://www.acog.org/departments/dept_notice.cfm?recno=11&bulletin=3933. A new and well-funded coalition of specialty societies, Doctors for Medical Liability Reform, is focused on raising the public profile of tort reform. Peggy Peck, *Coalition Includes ACOG: Specialty Societies Push Tort Reform*, 29 OB/GYN NEWS, no. 5, Mar. 1, 2004, at 1, 1–4. One-million-dollar donors include the Society of Thoracic Surgeons, the American Association of Neurological Surgeons/Congress of Neurological Surgeons, the American College of Emergency Physicians, the American College of Surgeons, and the American Academy of Orthopedic Surgeons. *Id.* The American College of Cardiology has pledged \$500,000, the North American Spine Society has pledged \$100,000, and the American College of Obstetricians and Gynecologists and the American Academy of Dermatology have joined and agreed to donate undisclosed amounts. *Id.*

65. *See, e.g.*, Terrence M. Shaneyfelt & Robert M. Centor, *Reassessment of Clinical Practice Guidelines: Go Gently Into That Good Night*, 301 J. AM. MED. ASSOC. 868, 868–69 (2009).

66. Rosoff, *supra* note 55, at 340–41.

67. *See, e.g.*, FLA. STAT. § 408.02(9)(e) (1999); 24 ME. REV. STAT. tit. 24, § 2975 (repealed in 1999 with expiration of program).

and ended in the 1990s, provide little support for adopting guidelines as national policy or expanding the use of guidelines in state pilot programs.⁶⁸ Regardless, HHS awarded Oregon a grant under the PPACA to institute legal safe harbors based on clinical practice guidelines.⁶⁹

D. Certificates of Merit and Screening Panels

Certificate of merit requirements and screening panels are not pilot programs. But tort reform advocates often propose them, sometimes as a component of a pilot program, to restrict the filing of lawsuits in medical malpractice cases.⁷⁰ Some states already have these laws on their books.⁷¹ These laws require that when an injured patient files a medical malpractice lawsuit, he or she must also file a certificate or affidavit stating that the case is legitimate, or alternatively present the case before a screening panel which evaluates the merits of the case before proceeding to trial.⁷²

Several states have repealed screening panel laws, either legislatively or judicially.⁷³ Some state courts have struck down certificates of merit for unconstitutionally interfering with access to the courts and equal protection guarantees, or violating separation of powers.⁷⁴ In addition to the constitutional

68. In the 1990s, Maine established a program that allowed doctors in four specialties— anesthesiology, emergency medicine, obstetrics and gynecology, and radiology—to participate in a program allowing the use of guidelines as exculpatory evidence in lawsuits (other specialties were encouraged to take advantage of this program but did not). Linda L. LeCraw, *Use of Clinical Practice Guidelines in Medical Malpractice Litigation*, 3 J. ONCOLOGY PRAC. 254, 254 (2007). The program expired, and the Maine Bureau of Insurance concluded, “the medical demonstration project had no measurable effect on medical professional liability claims, claims settlement costs, or malpractice premiums.” *Id.* In 1996, Florida also began a demonstration project for cesarean deliveries, but reportedly “garnered relatively little support among physicians—only 20% of physicians eligible to participate chose to do so. The project ended in 1998. Three other states (Kentucky, Maryland, and Minnesota) adopted test projects in the 1990s, though none of the projects is fully operational today (the Maryland and Minnesota projects have fully expired).” *Id.*

69. See *Medical Liability Reform and Patient Safety: Demonstration Grants*, *supra* note 10.

70. For example, screening panels were featured in legislation introduced by Sen. Tom Coburn (R-OK), Patient’s Choice Act, S. 1099, 111th Cong. § 601 (2009).

71. See, e.g., MD. CODE ANN. CTS. & JUD. PROC. § 3-2A-04 (2010); VA. CODE § 8.01-20.1 (2010); TEX. CIV. PRAC. & REM. CODE § 150.002 (2009).

72. See Catherine T. Struve, *Improving the Medical Malpractice Litigation Process*, 23 HEALTH AFFAIRS 33, 35–36 (2004).

73. See, e.g., Catherine T. Struve, *Doctors, the Adversary System, and Procedural Reform in Medical Liability Litigation*, 72 FORDHAM L. REV. 943, 990 (2004). See also *Bernier v. Burris*, 497 N.E.2d 763 (Ill. 1986); *Mattos v. Thompson*, 421 A.2d 190, 196 (Pa. 1980); *Aldana v. Holub*, 381 So. 2d 231, 237 (Fla. 1979); *Wright v. Cent. Du Page Hosp. Ass’n*, 347 N.E.2d 736, 739–41 (Ill. 1976).

74. See, e.g., *Putnam v. Wenatchee Valley Med. Ctr.*, 216 P.3d 375, 376 (Wash. 2009) (finding that a Washington law requiring a certificate of merit from a medical expert in malpractice suits “unduly burdens the right of access to courts and violates the separation of powers”); *Zeier v. Zimmer, Inc.*, 152 P.3d 861, 863 (Okla. 2006) (finding that an Oklahoma law requiring medical malpractice claimants to produce affidavits of merit is an unconstitutional special law and “creates an unconstitutional monetary barrier to court access”); *State ex. rel. Ohio Acad. of Trial Lawyers v. Sheward*, 715 N.E.2d 1067, 1087 (Ohio 1999) (finding the Ohio legislature’s enactment of a certificate of merit requirement to be “fundamentally contrary to the

questions, such restrictions also present other fairness concerns.

These programs can make it prohibitively difficult and expensive for plaintiffs to find expert witnesses. Even without screening programs, the cultural and professional pressure against an expert testifying for a patient, certifying publicly to physician error, and making him or herself available for depositions complicates the process of finding experts to certify or testify to the merits of a case.⁷⁵ Such pressure reduces the size of the pool of available experts. Certificate of merit requirements further drive up the cost of experts, possibly foreclosing some cases due to a plaintiff's inability to afford the expert certification.⁷⁶ Requirements to disclose the identity of an expert in filing a case or to place an expert on a screening panel make it less likely that the same expert can testify at trial (as the defense might claim that the expert had predetermined the outcome or is otherwise biased). This increases the burden on plaintiff attorneys, both in terms of cost and time involved in finding additional experts for trial.⁷⁷

Moreover, as with other alternatives, reports of delay and other bureaucratic inefficiencies have plagued existing medical screening panels.⁷⁸ Worse yet, in the end, these programs do nothing to enhance patient safety. In fact, such restrictions may actually reduce patient safety by keeping legitimate cases from going forward due to the extra costs they impose on those who have been injured.

CONCLUSION

Given recent empirical work confirming that improving patient safety will reduce litigation costs, it is clear that enhancing patient safety should be the primary route toward addressing all aspects of liability in the medical system.⁷⁹

principle of separation of powers”).

75. See, e.g., Philip G. Peters, Jr., *Doctors & Juries*, 105 MICH. L. REV. 1453, 1494 (2007) (“[T]he public setting in which these experts will render their opinions could place considerable pressure on them to demonstrate their loyalty to the profession. As a consequence, these ‘neutral’ experts may show the same reluctance to label another physician’s care as negligent that physicians have exhibited in other settings [R]esearchers have found that physicians are so unwilling to label another physician’s care as negligent that they refuse to do so even when the treatment given to the patient was ‘clearly erroneous.’”).

76. *Westmoreland v. Vaidya*, 664 S.E.2d 90, 99 (W.Va. 2008) (Starcher, J., concurring).

77. For example, in *Westmoreland*, the plaintiff challenged a certificate of merit where the expert fee was \$40,000. 664 S.E.2d at 99. The West Virginia Supreme Court remanded the case without prejudice, while one Justice opined that such a cost “impose[d] upon [the plaintiff] a filing fee substantially different from that in every other type of lawsuit.” *Id.* Given that West Virginia is one of the states where an expert is not even identified, the cost of an expert who will have to testify and potentially mar his professional reputation (because of the culture within the medical community) will be higher and potentially high enough to foreclose the ability to sue for many of those injured.

78. Amy Lynn Sorrel, *Litigation Screening Panels on Trial: Are They Working?*, AMERICAN MED. NEWS (Aug. 3, 2009), <http://www.ama-assn.org/amednews/2009/08/03/prsa0803.htm>.

79. See Greenberg, *supra* note 18.

According to the Institute of Medicine, as many as 98,000 people may die from medical errors annually.⁸⁰ Any and all state demonstration programs must begin by addressing specific patient safety metrics such as reducing errors and expanding transparency system-wide.

Beyond safety improvements, policymakers should pay more attention to the legal and fairness concerns implicated by any new liability scheme. As described above, many of the proposed “alternatives” implicate these concerns, and, in some cases, state courts or state lawmakers have already repealed the programs for these reasons.⁸¹ At the same time, however, studies show the current system works in that legitimate claims are being paid—“portraits of a malpractice system that is stricken with frivolous litigation are overblown.”⁸² Litigation triggers investigations and information-sharing that may increase patient safety by illuminating how errors occurred.⁸³

None of the litigation alternatives currently proposed enhance patient safety while ensuring that injured patients are compensated.⁸⁴ Limiting patients’ access to courts and compensation for their injuries does nothing to increase patient safety. Reducing financial accountability on hospitals when errors occur will likely negatively impact patient safety. And allowing hospitals to control the fact-finding process surrounding medical errors also reduces transparency and, ultimately, accountability. While there is much to praise in the health care reform bill, awarding grants to reinstitute litigation “alternatives” that have been already been tried and rejected by both courts and patients makes little sense.

80. INST. OF MED. OF THE NAT’L ACAD., *supra* note 11, at 1.

81. *See supra* notes 67–68, 73–74.

82. David M. Studdert et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, 354 NEW ENG. J. MED. 2024, 2031 (2006).

83. *Id.* at 2030–31.

84. Some examples of reforms that would enhance patient safety are: (1) ensuring that safety practices are universally implemented; (2) requiring mandatory reporting of errors; and (3) strengthening laws requiring reporting when a doctor is disciplined as well as adequate peer review of physicians. *See* PUBLIC CITIZEN, BACK TO BASICS: TEN STEPS TO SAVE 85,000 LIVES AND \$35 BILLION A YEAR IN HEALTH CARE DELIVERY (2009). Another necessary reform is to adequately discipline the small number of doctors responsible for the majority of malpractice. *See* BLAIR HORNER ET AL., N.Y. PUB. RESEARCH INTEREST GRP., SYSTEM FAILURE: A REVIEW OF NEW YORK STATE’S DOCTOR DISCIPLINE SYSTEM (2010), available at <http://www.nypirg.org/HEALTH/SystemFailure.pdf>.