

PRIVATE REGULATION

RONEN AVRAHAM*

INTRODUCTION	546
I. THE VARIOUS COSTS OF THE HEALTHCARE SYSTEM.....	554
A. Costs Associated with Underuse	556
B. Costs Associated with Misuse	557
C. Costs Associated with Overuse.....	558
1. Defensive Medicine	558
2. Offensive Medicine.....	559
3. Cost-apathetic Medicine	561
4. Compassionate Medicine.....	561
D. Summary	562
II. IS CURRENT MEDICAL MALPRACTICE LAW THE ANSWER?	563
A. Can Tort Law Tackle the Healthcare System's Costs?.....	563
B. Can Current CPGs Tackle the Costs of the Healthcare System?	568
1. When the Government Writes Guidelines	568

* Thomas Shelton Maxey Professor of Law, University of Texas at Austin. I thank Jennifer Arlen, Bernie Black, Oren Bracha, Richard Epstein, John Golden, Clark Havighurst, Mark Hall, David Hyman, Timothy Jost, Ariel Porat, Osama Mikhail, Arnold Rosoff, Bill Sage, Catherine Sharkey, Charlie Silver, and the participants of the Interdisciplinary Center in Israel Faculty Colloquium (Mar. 2011), the American Society of Law, Medicine and Ethics Annual Meeting (June 2010), the American Association of Law and Economics Annual Meeting (May 2010), the University of Texas Innovation in Health Care Delivery Systems Symposium (Apr. 2010), the University of Texas School of Law Faculty Colloquium (Nov. 2009), the University of Texas Law and Economics colloquium (Oct. 2009), Bar-Ilan University Faculty of Law Faculty Colloquium (Oct. 2009), Hebrew University Faculty of Law Faculty Colloquium (Oct. 2009), and the International Conference on Medical Accidents and Patient Safety—Legal and Interdisciplinary Perspectives (May 2008). I also thank Jason Gott, Daniel Lenhoff, James Lindsey, Matt Kundinger, and Lindsey Peebles for great research assistance.

a.	Theory	568
b.	Evidence from States' Experience with Guidelines	571
c.	Evidence from Federal Experience with Guidelines	575
d.	Summary	578
2.	Guidelines Written by Hospitals and Hospital Organizations	579
3.	Guidelines Written by HMOs, Health Insurers, or Liability Insurers	580
4.	Guidelines Written by Professional Associations	581
C.	The Treatment of CPGs in Practice	584
1.	The Treatment of Guidelines Within the Medical Profession	584
2.	Courts' Treatment of Guidelines	586
D.	Summary	589
III.	THE DESIGN OF PRIVATE REGULATION REGIME.....	591
A.	The Legal Infrastructure	591
1.	Liability from the Ex Ante Perspective	591
2.	Contractually Standardized Care and Reimbursement Levels	594
3.	Private Regulatory-Compliance Defense	595
4.	Intellectual Property Protection for Guidelines	596
5.	Not Recognizing the State of the Art Defense	600
6.	Guaranteeing Private Regulators' Solvency	601
7.	The Value of Constrained Pluralism	601
B.	Implementation	602
IV.	EVALUATION IN LIGHT OF OBJECTIONS.....	606
A.	The PRR Compared to Alternative Regimes.....	606
1.	What is the Difference Between PRR and Liability for Gatekeepers?	606

2.	What is the Difference Between PRR and Self-Regulation?.....	607
3.	Why Not Strict Liability or No-Fault Regimes?	608
4.	Why Do We Need Legislation? Why Do We Not See It in the Market Already?.....	609
a.	MCOs as Cost Internalizers	610
b.	Liability Insurers as Cost Internalizers	612
c.	Government as Cost Internalizer	612
d.	Private Firms as Cost Internalizers	612
B.	Practical Medical Concerns.....	614
1.	Medical Ethics	614
2.	Good Medicine Requires Discretion	615
3.	Not Enough Reliable Scientific Information Exists To Make the Endeavor Worthwhile.....	619
4.	How Effective Will PRR Be in Reducing Costs?	620
a.	Misuse (Medical Errors)	621
b.	Underuse	623
c.	Overuse.....	623
C.	Legal and Political Concerns	628
1.	Are We Losing the Information Updating Benefit that Tort Law Provides?.....	628
2.	Would Private Regulation Lead to Pulling the Plug on Grandma?.....	629
3.	Could a Profit-Driven Regulatory Regime Ever Win Political Support?.....	633
V.	BEYOND MEDICAL MALPRACTICE	634
	CONCLUSION.....	635

"The more I have studied it, the more I believe that less discretion for doctors would improve patient safety."

Don Berwick¹

INTRODUCTION

Addressing the American Medical Association (AMA), President Obama described the healthcare system as a "ticking time-bomb for the federal budget."² He stressed the need "to improve the *quality of medical information* making its way to doctors and patients." He further noted that "it can take up to 17 years for this information to find its way to an exam room or operating table."³

Improving the quality of information channeled to doctors can further what legislators agree are healthcare reform's three main goals: increasing access for the uninsured, controlling rising costs, and improving patient safety by improving the quality of care. The main focus of the Patient Protection and

1. Don Berwick is Director of the Centers for Medicare and Medicaid Services, a federal agency that administers Medicare, Medicaid, and the Children's Health Insurance Program. He is formerly president and CEO of the Institute for Healthcare Improvement (IHI). The quotation is from Neil Swidey, *The Revolutionary*, BOS. GLOBE MAGAZINE, Jan. 4, 2004, at 10, 19, available at <http://www.hawaiiap.org/pdfs/DonaldBerwick.pdf>.

2. President Barack Obama, Address to American Medical Association House of Delegates (June 15, 2009), <http://www.ama-assn.org/ama/pub/about-ama/our-people/house-delegates/2009-annual-meeting/speeches/president-obama-speech.shtml>. Obama's statement is supported by a study of published research, which concluded that it takes seventeen years to implement the fourteen percent of original research that actually does reach the patient. The study also suggested that profit-maximizing factors, such as the public's interest in a disease, the pharmaceutical nature of discovery, and other commercial factors affect which studies get attention and which do not. See Paul H. Keckley, *Evidence-Based Medicine in Managed Care: A Survey of Current and Emerging Strategies*, MEDSCAPE GEN. MED., 2004 6(2), at 56, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1395794/> (citing E. Andrew Balas, *Information Technology and Physician Decision Support*, in PROGRAM AND ABSTRACTS OF ACCELERATING QUALITY IMPROVEMENT IN HEALTH CARE: STRATEGIES TO SPEED THE DIFFUSION OF EVIDENCE-BASED INNOVATIONS, NATIONAL COMMITTEE FOR QUALITY HEALTH CARE (Nat'l Comm. for Quality Health Care ed., 2003)). The Institute of Medicine (IOM) originally called attention to the health system's ineffectiveness in applying new scientific discoveries to the day-to-day practice of medicine. See INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 2-3 (2001).

3. Obama, *supra* note 2.

Affordable Care Act (ACA),⁴ a historic health care reform bill signed by President Obama on March 23, 2010, was the first of these goals—increasing access by providing insurance to thirty-two million uninsured Americans. This is important, but if quality does not improve and costs do not decrease, the United States will soon face another increase in the number of uninsured. ACA (as well as the American Recovery and Reinvestment Act of 2009) contains provisions that allocate grants to improve the quality of care.⁵ Specifically, these relatively small grants fund projects that increase patient-doctor communication, prevent mistakes, and deal with the aftermath of the mistakes that do happen.⁶ For access to healthcare to be sustainable in the long run, however, costs—estimated at \$940 billion over ten years for the ACA program⁷—must come down and the quality of care must improve sustainably and much more dramatically.

This Article proposes a novel reform which directly addresses the twin goals of improving care quality and lowering costs—and thus of making access to care for the uninsured sustainable—by improving the quality of the information available to physicians to facilitate implementation of cutting-edge procedures. I propose a private, market solution to a burning social problem. Specifically, I argue that the healthcare system is a suitable place for private regulation of medical procedures rather than the government or self-regulations that are prevalent today.

As explained, cost and quality are intimately intertwined. Too little care (underuse), incorrect care (misuse), and too much care (overuse) raise concerns about both the quality and the cost of care. Substantial research has established that all three problems are ubiquitous in the American healthcare system. Underuse is exemplified by the statistics that show half of

4. Patient Protection and Affordable Care Act of 2010 (ACA), Pub. L. No. 111-148, 124 Stat. 119 (2010).

5. *See, e.g.*, ACA § 3506(e), 124 Stat. at 529; American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, § 4101–4102, 123 Stat. 115 (2009).

6. ACA § 3506(e); *see also* Press Release, Agency for Healthcare Research & Quality, U.S. Dep't of Health & Human Servs., HHS Announces Patient Safety and Medical Liability Demonstration Projects (June 11, 2010), <http://www.hhs.gov/news/press/2010pres/06/20100611a.html>.

7. *See* Letter from Douglas Elmendorf, Dir., Cong. Budget Off., to Nancy Pelosi, Speaker, U.S. House of Representatives (Mar. 18, 2010), <http://www.cbo.gov/ftpdocs/113xx/doc11355/hr4872.pdf> (listing the “[g]ross cost” of ACA at \$940 billion).

Americans do not receive recommended preventive care, 30% do not receive recommended acute care, and 40% do not receive recommended chronic care.⁸ Likewise, misuse is exemplified by the estimated 300,000 annual injuries that result from preventable medical errors.⁹ Lastly, overuse is exemplified by the 30% of Americans who receive acute care and 20% who receive chronic care for clinically inappropriate reasons, regardless of their insurance plan.¹⁰

Underuse is insufficient care, which happens because of financial barriers such as lack of insurance, lack of coverage for preventive care, high deductibles and copayments, and so on. Underuse also occurs because some segments of the population distrust physicians and the health care system in general. These segments may decline to follow recommendations or may avoid the system altogether.¹¹ Underuse has been shown to lead to poorer health outcomes.¹²

Misuse, often referred to as medical errors, is caused by fatigue, poor judgment, over confidence, lack of facility resources, lack of adequate training, or lack of communication between medical team members. Medical errors can result in negative outcomes that range from unnecessary hospitalization and loss of income, to suffering and sometimes even death. The Institute of Medicine, a not-for-profit, nongovernmental organization under the U.S. National Academies, estimated that

8. Elise C. Becher & Mark R. Chassin, *Improving the Quality of Health Care: Who Will Lead?*, HEALTH AFF., Sept.–Oct. 2001, at 164, 166.

9. *Id.*

10. *Id.* Professor Wennberg concluded that in “supply-sensitive” areas of health care—“visits to physicians, diagnostic tests, and hospitalizations, mostly for patients with chronic illnesses”—“the most important problem is *overuse*” with the result that “patients are exposed to the burdens and risks of treatment that is unnecessary or counterproductive.” JOHN W. WENNBURG, VARIATION IN USE OF MEDICARE SERVICES AMONG REGIONS AND SELECTED ACADEMIC MEDICAL CENTERS: IS MORE BETTER? 1–2 (2005), available at <http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2005/Dec/Variation-in-Use-of-Medicare-Services-Among-Regions-and-Selected-Academic-Medical-Centers-Is-More-B.aspx>.

11. See, e.g., Lorna G. Canlas, *Issues of Health Care Mistrust in East Harlem*, 66 MT. SINAI J. MED. 257, 257–58 (1999).

12. See, e.g., Stephen F. Jencks et al., *Change in the Quality of Care Delivered to Medicare Beneficiaries, 1998–1999 to 2000–2001*, 289 JAMA 305, 305 (2003); Elizabeth A. McGlynn et al., *The Quality of Health Care Delivered to Adults in the United States*, 348 NEW ENG. J. MED. 2635, 2635 (2003).

up to 98,000 deaths every year are associated with medical error—about twice as many as from car accidents.¹³

Overuse, or overutilization, happens for four interrelated reasons. First, overuse can occur as a result of defensive medicine—that is, excessive care which a doctor provides to avoid liability. Second, overuse can arise from offensive medicine—that is, excessive care which doctors pursue to magnify their reimbursements. Third, overuse can result when doctors are unaware that a treatment's costs exceed its benefits, either because they have no relevant information or because they are not accustomed to considering care in those terms. I call this "cost-apatetic medicine" because providers are unaware of, or do not care about, costs when they deliver care. Fourth, overuse can occur because of compassionate medicine—that is, excessive care provided because doctors compassionately opt to do the most they possibly can for a patient—especially when the patient is dying.

Republicans focus on reducing the overuse associated with defensive medicine. They push for a medical liability reform that would decrease doctors' liability and reduce doctors' incentives to overtreat for fear of lawsuits. On the other hand, Democrats focus on reducing overuse associated with offensive medicine and misuse resulting in medical errors. They seek to change the way medical care and drugs are reimbursed, and they object to reforming medical liability. Both Republicans and Democrats, however, discuss reducing underuse through increased preventative medicine and improved access to insurance.

A better way than this political, piecemeal approach, however, would be to simultaneously address underuse, misuse, and all four types of overuse. How? As articulated in several reform proposals, doctors should be immune from medical

13. INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* 1 (Linda T. Kohn et al. eds., 2000), available at <http://books.nap.edu/openbook.php?isbn=0309068371>. Mr. Brennan and others explained that the estimates of the IOM study are severely problematic and likely led to an overestimation of deaths attributable to medical error. See Troyen A. Brennan et al., *Accidental Deaths, Saved Lives, and Improved Quality*, 353 *NEW ENG. J. MED.* 1405, 1406–07 (2005). In contrast, Professor Jennifer Arlen has stated that more than 150,000 people are killed every year from medical error. Jennifer Arlen, *Contracting Over Liability: Medical Malpractice and the Cost of Choice*, 158 *U. PA. L. REV.* 957, 959 (2010). This widely used number is probably an overestimation, but medical errors cause tens of thousands of deaths a year.

malpractice lawsuits if they comply with evidence-based medical guidelines. These reform proposals are reasonable because a central objective of medical malpractice liability is to encourage doctors to provide scientifically defined “optimal care.”¹⁴ Accordingly, immunity for those providers who act optimally by complying with evidence-based guidelines would further the same aims without imposing excessive costs on doctors. This proposal would thus address both misuse and overuse—especially the compassionate and cost-apatetic types and, to some extent, offensive medicine. Further, granting doctors immunity would address overuse of the defensive medicine type.

Unfortunately, this proposal ignores a critical issue: the actual development process and framework of existing clinical practice guidelines (CPGs). Currently, CPGs are produced by various entities, including professional medical organizations, hospitals, healthcare maintenance organizations (HMOs), liability insurers, and government agencies. These organizations should strive to provide guidelines focused towards a goal of optimizing patient care while minimizing unnecessary costs. Yet, these organizations often struggle to achieve this goal because they have neither the resources nor the financial incentives to invest constantly in updating the guidelines to reflect quickly evolving scientific research.¹⁵ Thus, they produce guidelines that lack adequate support from scientific evidence. Indeed, recent studies show that only a small percentage of CPGs are based on scientific evidence.¹⁶

The difficulties with CPGs are further compounded by two factors. First, the guidelines are often written by entities with conflicting goals. CPGs written by medical associations are usually designed to improve the care of patients. If all works well—and all seldom does—the guidelines are informed by clinical expertise and empirical research, and are driven by professional standards of care. In contrast, CPGs produced by third-party payers (such as HMOs) are often used for utiliza-

14. By “optimal,” I mean the socially optimal balance between safety, effectiveness, cost, and other relevant factors such as political or moral concerns.

15. See Dong Heun Lee & Ole Vielmeyer, *Analysis of Overall Level of Evidence Behind Infectious Diseases Society of America Practice Guidelines*, 171 ARCHIVES INTERNAL MED. 18, 21 (2011), available at <http://www.hcbl.nlm.nih.gov/pubmed/21220656>.

16. *Id.*; 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, 1464 (2001).

tion review and aimed at cost-containment and internalization of costs externalized onto patients, their doctors, and their doctors' liability insurers.¹⁷ Similarly, CPGs produced by malpractice insurers are usually primarily intended to lessen the risk of malpractice, and only secondarily to provide optimal care to patients, which externalizes costs onto patients and third-party payers.¹⁸ As Patricia Recupero pointed out, "If physicians try to follow every CPG, they may find themselves trying to serve potentially conflicting goals: to provide the best quality of care for their patients, to secure reimbursement for their services, and to avoid the risk of malpractice liability."¹⁹

The second complicating factor is that many professional organizations, and the clinical practice studies upon which they base their guidelines, have strong financial ties to drug companies and medical device producers. These two groups benefit greatly when guidelines recommend use of their products. Aggravating this problem, the organizations producing CPGs are not likely to face financial liability for their recommendations.²⁰ As a result, many doctors are suspicious of whether the guidelines reflect untainted, evidence-based advice.²¹ It is no wonder a recent study found that over 50% of doctors say they pay no attention to guidelines.²²

17. For example, HMOs may prefer fewer treatments to contain costs because they fully bear the costs of treatments, but do not fully bear the costs of malpractice.

18. For example, malpractice insurers would require doctors to perform mammograms every year to prevent breast cancer, even if they are not needed, because the malpractice insurers do not bear the costs of extra mammograms, but do bear the costs of lawsuits from late diagnosis of breast cancer.

19. Patricia R. Recupero, *Clinical Practice Guidelines as Learned Treatises: Understanding Their Use as Evidence in the Courtroom*, 36 J. AM. ACAD. PSYCHIATRY L. 290, 290–301 (2008) (emphasis added).

20. Though bases for CPG developers' liability have been postulated, such liability is almost never alleged or imposed for a variety of reasons. See Megan L. Sheetz, Note, *Toward Controlled Clinical Care Through Clinical Practice Guidelines: The Legal Liability for Developers and Issuers of Clinical Pathways*, 63 BROOKLYN L. REV. 1341, 1357–61 (1997).

21. Michael Cabana et al., *Why Don't Physicians Follow Clinical Practice Guidelines? Framework for Improvements*, 282 JAMA 1458 (1999).

22. Ronen Avraham, *Private Regulation of Medicine: A Win-Win-Win for Doctors, Patients, and Public*, HUFFINGTON POST (July 22, 2009, 2:36 PM), http://www.huffingtonpost.com/ronen-avraham/private-regulation-of-med_b_242937.html; Arthur Garson, Jr. & Carolyn L. Engelhard, *The Art of Science in Medicine: Health-Care Myth: Science Drives Most Medical Decisions*, GOVERNING (Aug. 10, 2009), <http://www.governing.com/topics/health-human-services/The-Art-of-Science.html>.

If CPGs are not produced under appropriate incentives and funding, then the guidelines produced are unlikely to be optimal. Consequently, the doctors following them are not behaving optimally, and immunity from medical malpractice for doctors who followed these sorts of guidelines is not justified.

Against this background, I propose a system where private regulators set the gold standard of patient care by developing guidelines and competing to sell or license them to providers—hospitals, doctors' groups, and so on. These firms will offer providers a safe harbor by bearing the costs of medical malpractice lawsuits so long as providers comply with the firms' prescribed guidelines. I demonstrate that under this Private Regulation Regime (PRR), guidelines will be developed by private firms that profit from cost-saving procedures and procedures which increase patient safety. Granting immunity from medical malpractice to doctors who follow those guidelines would be justified because the financial incentives behind the guidelines would be perfectly aligned with the social goals of minimizing unnecessary healthcare costs while maximizing patient safety. Such guidelines would inform providers about the appropriate care, thus reducing underuse and misuse. Informing providers about the appropriate care will also reduce overuse associated with cost-apatetic medicine, and will help combat compassionate medicine and offensive medicine by making them more risky for the provider. Granting immunity to those who follow such guidelines will also eliminate overuse resulting from defensive medicine.

The following transaction illustrates how the PRR would work. Hospital *A* will contract with Firm *P* to write evidence-based guidelines for its emergency room (ER). Firm *P*, an expert and a repeat player in this field, will use existing datasets and data sites and, if necessary, develop new information through observation, field studies, or root-cause analyses, to determine the optimal ER protocols for Hospital *A*. Firm *P* will compete against other similar firms to provide guidelines that take into account the hospital's current infrastructure, staff, and budget.²³ Hospital *A* will then contract with payers—HMOs,

23. The firm could also provide a five-year plan to continually improve the guidelines and keep them at an optimal level. This analysis assumes that the locality-rule, in which the standard of care is judged relative to a particular locality, applies. In contrast, if Hospital *A* operates in a state using the national standard rule, guide-

preferred payer organizations (PPOs), Medicare, and so on—to get reimbursements based on the quality and cost-effectiveness of the guidelines.

Once Hospital *A* decides to adopt the guidelines, the hospital would be immune from medical malpractice liability for accidents occurring in its ER provided it strictly followed the guidelines. I call this immunity the “private regulatory compliance defense.” Thus, unlike today, a patient’s only way to receive compensation from Hospital *A* (or its physicians) would be by showing that the hospital did not follow the guidelines. Alternatively, and this is where the novelty of my proposal is amplified, the patient could sue Firm *P* for writing suboptimal guidelines that exposed the patient, *ex ante*, to too much risk. Firm *P* would be held liable for the patient’s harm if a court determined that *P* wrote suboptimal guidelines that caused the patient’s harm. This model stands in stark contrast to the situation today, where guideline promulgators do not face tort liability despite the distorted incentives under which they operate.

The legal infrastructure for the PRR would require at most six (and probably far fewer) essential components, some of which may require some form of legislation. First, Firm *P* must face liability, judged from the *ex ante* perspective, for writing suboptimal regulations. Firm *P* should be found negligent if, and only if, it has written guidelines which are inefficient under an evidence-based cost-benefit or risk-risk analysis. The *ex ante* perspective will help eliminate various biases, and will allow for better accounting of benefits and costs. Second, when payers—HMOs, PPOs, and so on—contract with hospitals, they should have the power to structure a reimbursement scheme which takes into account the quality and cost-effectiveness of CPGs, thus diluting Firm *P*’s incentives to write guidelines which are too defensive and therefore expensive.²⁴

lines will have to conform to the national standard of care. In such cases, those hospitals lacking enough resources to properly comply with this standard may decide not to adopt the guidelines, thereby subjecting themselves to existing tort law. About twenty-nine states and the District of Columbia have adopted a national standard, while twenty-one states maintain some version of the locality rule. Michelle H. Lewis et al., *The Locality Rule and the Physician’s Dilemma: Local Medical Practices and the National Standard of Care*, 297 JAMA 2633 (2007).

24. Depending on how the market for private regulation develops, especially in its early stages, there may be a seventh requirement, which is that hospitals must adopt guidelines.

Third, courts will have to adopt a private regulatory-compliance defense, immunizing doctors who follow guidelines, thus eliminating incentives for defensive medicine.²⁵ Fourth, Firm *P* might need some degree of intellectual property protection for its guidelines to promote research and development of improved medical techniques.²⁶ Fifth, Firm *P* cannot be allowed to rely on the state of the art defense. Not recognizing that defense would incentivize Firm *P* to investigate ongoing research and update guidelines accordingly, while giving practitioners confidence in the guidelines. Sixth, Firm *P* might need to be licensed to guarantee its financial solvency in light of the financial risks it faces, requirements which would eliminate its incentives to write overly risky CPGs.

The proposed PRR will increase the evidence-based nature of medicine. Instead of performing medicine that is based on seventeen-year-old research (on average), care will be based on the most current medical research. The relationship between doctors and PRR firms will be like the relationship between architects and builders. Architects are primarily concerned with design, builders with execution. The PRR firms (architects) will synthesize tort law, regulatory requirements, and available medical research to design guidelines relevant to a hospital's practice areas. Doctors (builders) will execute the synthesized guidelines, assured that compliance will shield them from liability.

Structurally, this Article unfolds in five parts. Part I describes in more detail the costs in terms of the patient safety shortfalls that the current legal regime generates. Part II describes the problem with existing tort law, as well as the current experience with guidelines. Part III describes the theoretical framework for optimal private regulation, and Part IV responds to possible objections. Part V extends the theoretical framework beyond medical malpractice. The Article then concludes.

I. THE VARIOUS COSTS OF THE HEALTHCARE SYSTEM

The healthcare system is ailing badly. Doctors are accused of performing defensive medicine, performing offensive medicine (also known as "induced demand"), defrauding payers, aban-

25. For a detailed explanation of the private regulatory-compliance defense, see *infra* Part III.A.3.

26. See *infra* Part III.A.4.

doning the profession (in particularly risky specialties), neglecting rural areas, ignoring evidence-based medicine in favor of profits, committing too many errors, and even causing unnecessary deaths. Payers are accused of dictating suboptimal care to patients and of not fully reimbursing doctors for justified costs. Liability insurers are accused of inefficient (flat) pricing and of exploiting their power by charging doctors exorbitant premiums. Patients are blamed for having unrealistic expectations for complex medical procedures and for filing lawsuits whenever outcomes fall short of those expectations—even in cases where the harm results from patients' own failures to follow recovery instructions.

The legal system is blamed as well. Lawyers from both sides are accused of advancing or blocking policy reforms to further narrow self-interests. Courts are accused of not being able to distinguish between negligent and non-negligent injury and of focusing on compensating individual patients instead of increasing overall patient safety. Agency regulators (for example, the FDA) are accused of serving the interests of political actors at the expense of the common good. Finally, legislators are accused of catering too much to their particular constituents or, worse, their financial contributors. Plaintiffs accuse them of infringing upon patients' constitutional rights and of shielding defendants from liability. Defendants accuse them of unfairly taxing healthcare and liability insurance providers.

On one side, plaintiffs' advocates point to the low ratio of lawsuits in relation to medical injuries to justify their complaints about a lack of legal recourse for malpractice victims. On the other side, defendants' advocates contend the opposite, pointing to a perceived high number of lawsuits to show the system provides too much leniency for frivolous plaintiffs.²⁷ Moreover, no agency, court, or legislature possesses the ability to respond to the rapid advances of science that push evidence-based medicine so quickly. Yesterday's gold standard of care can become unacceptable tomorrow. Courts and legislatures

27. However, other studies argue that the majority of patients who sustain a medical injury as a result of negligence do not sue. See, e.g., A. Russell Localio et al., *Relation Between Malpractice Claims and Adverse Events Due to Negligence: Results of the Harvard Medical Practice Study III*, 325 NEW. ENG. J. MED. 245, 245–51 (1991); David M. Studdert et al., *Negligent Care and Malpractice Claiming Behavior in Utah and Colorado*, 38 MED. CARE 250, 250–60 (2000).

fail to recognize that modern medical accidents involve systemic failures of multiparty coordination. These accidents are often far beyond an individual provider or doctor's control. Liability for malpractice as applied by courts thus misses its regulatory target because it fails to address the root cause of harm. With all these problems, it is no wonder that patient safety in the United States is so poor. Some numbers suggest that every year up to 98,000 deaths are associated with medical error, about twice as many as from car accidents, breast cancer, or AIDS.²⁸

It is commonly observed that our healthcare system is currently the most expensive in the world, though the system does not deliver measurably better results for patients.²⁹ Although there are a number of reasons why this is the case, I focus on three leading causes: underuse, misuse, and overuse (and its four types). Each of these problems also carries with it unnecessary and troublesome costs. Thus, understanding these three problems and how best to combat them is essential to achieving the dual goal of improving care and reducing costs.

A. *Costs Associated with Underuse*

Underuse occurs because of financial barriers such as lack of insurance, lack of coverage for preventive care, high deductibles and copayments, and so on. Capitation payments, which target overuse, might be a reason for underuse.³⁰ Yet studies have shown about equal levels of underuse exist for a variety of services in both fee-for-service and capitation arrangements.³¹ Another reason underuse occurs is because some segments of the population distrust physicians and the health care system in general. These segments may decline to follow rec-

28. See INST. OF MED., *supra* note 13, at 1.

29. See Uwe E. Reinhardt et al., *U.S. Health Care Spending in an International Context: Why is U.S. spending so high, and can we afford it?*, HEALTH AFF., May-June 2004, at 11-12.

30. Capitation payment, an alternative to fee for service, is a fixed amount of money per patient per unit of time paid in advance to the physician for the delivery of health care services.

31. See, e.g., Kenneth B. Wells et al., *Detection of Depressive Disorder for Patients Receiving Prepaid or Fee-for-Service Care: Results From the Medical Outcomes Study*, 262 JAMA 3298, 3298 (1989) (finding that fee arrangements do not influence depression detection rates for mental health specialists but do effect the odds that a regular clinician will detect depression).

ommendations or may avoid the system altogether.³² Thus, underuse goes well beyond the problem of the poor not having access to the healthcare system by encompassing lack of preventative care more generally.³³ Regardless of the reason, underuse has been shown to lead to poorer health outcomes.³⁴

B. *Costs Associated with Misuse*

There are two kinds of misuse, or of medical errors: errors of execution (when the correct action does not proceed as intended) and errors of planning (when the intended action is not correct).³⁵ These costs can be measured in terms such as hospitalization days because of repeated procedures and tests, increased insurance premiums based on these unnecessary tests, permanent disability, loss of income, pain and suffering, and lost trust between patient and doctor.³⁶ Loss of trust can itself result in less effective care prospectively. Some of these costs are born by patients, some are born by health insurers, and some are born by the hospital in which the error occurred or by the hospital's insurance provider. There are numerous sources of medical errors, including, among many others; long shifts which bring fatigue and inadequate judgment; cognitive biases such as over confidence, which affect a provider's judgment, insufficient resources; inadequate training; communication breakdowns between medical group members; and a lack of quality CPGs.³⁷ The Department of Health and Human Services Agency for Healthcare Research and Quality (AHRQ) estimates that 44,000 to 98,000 patients die every year in the United States

32. See, e.g., Canlas, *supra* note 11, at 257–58.

33. The U.S. healthcare system is notoriously known for not providing adequate preventative care. One reason for this are fragmented health insurance markets. See generally Ronen Avraham & K.A.D. Camara, *The Tragedy of The Human Commons*, 29 CARDOZO L. REV. 479 (2007) (identifying the problem of lack of preventative care, a problem of “human commons,” and proposing solutions).

34. See, e.g., *supra* note 12.

35. INST. OF MED., *supra* note 13, at 4.

36. *Id.* at 2.

37. Atul A. Gawande et al., *Analysis of errors reported by surgeons at three teaching hospitals*, 133 SURGERY 614 (2003) (finding that the most common factors contributing to medical errors were “inexperience/lack of competence in a surgical task (53% of incidents), communication breakdowns among personnel (43%), and fatigue or excessive workload (33%)”).

because of medical error.³⁸ An Institute of Medicine report stated that the “[t]otal national costs (lost income, lost household production, disability and health care costs) are estimated to be between \$37.6 billion and \$50 billion for adverse events and between \$17 billion and \$29 billion for preventable adverse events.”³⁹ In fact, more people die every year from prescription drug errors (7,000) than from workplace injuries (6,000).⁴⁰

C. Costs Associated with Overuse

Four overlapping types of costs are potentially associated with overuse.⁴¹

1. Defensive Medicine

Defensive medicine creates costs through the use of excessive care, which doctors often provide in an effort to shield themselves from liability. To protect themselves, doctors often externalize these costs to patients and their health insurers. Examples of these costs include excessive hospitalization and superfluous testing. Although these costs usually do not fall directly on patients, sometimes patients do bear costs indirectly. For example, patients may lose work days because of excessive care or complications, such as catching a disease from unneeded hospitalization. The costs associated with defensive medicine have been estimated by different studies at \$200 billion a year.⁴² Information from other

38. AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, U.S. DEP'T OF HEALTH & HUMAN SERVS., AHRQ PUB. NO. 00-PO58, REDUCING ERRORS IN HEALTH CARE: TRANSLATING RESEARCH INTO PRACTICE (2000), available at <http://www.ahrq.gov/qual/errors.htm> (citing INST. OF MED., *supra* note 13, at 1).

39. INST. OF MED., *supra* note 13, at 27.

40. *See id.* at 2.

41. *See, e.g.*, ELIZABETH A. MCGLYNN, RAND CORP., ASSESSING THE APPROPRIATENESS OF CARE: HOW MUCH IS TOO MUCH? (1998), available at www.rand.org/pubs/research_briefs/RB4522.

42. *See* Philip K. Howard, Opinion, *Why Medical Malpractice Is Off Limits*, WALL ST. J., Sept. 29, 2009, at A25 (suggesting the cost of defensive medicine is \$200 billion). The \$200 billion noted by Mr. Howard might be a figure rounded up from the \$178 billion recently cited by Rep. Michele Bachmann (R-Minn.). Michele Bachmann, *Defensive Medicine Driving Up Healthcare Costs*, THE HILL'S CONG. BLOG (Sept. 1, 2009, 11:46 AM), <http://thehill.com/blogs/congress-blog/>. Rep. Bachmann's statement reflected Rich Karlgaard's recent declaration in *Forbes* magazine that he believes the annual costs are between \$100 billion to \$178 billion. *See* Rich Karlgaard, *Our Health Care Crisis: Age, Obesity, Lawyers*, FORBES, Sept. 7, 2009, at 19. My guess is that the \$178 billion number is a typographical error, hopefully in good faith, of the high end

sources suggest, however, that \$45 billion a year is probably more accurate.⁴³

2. *Offensive Medicine*

Offensive medicine creates costs through excessive care, which physicians offer to maximize reimbursements. These costs ensue because providers are reimbursed on a fee-for-service method—that is, they are reimbursed for quantity, not quality.⁴⁴ Because patients are insured for their health costs, they are essentially in an all-you-can-treat system, with the same incentives to forebear as in an all-you-can-eat restaurant. President Obama has described this as a system of “warped

of a range cited in a study by the U.S. Department of Health and Human Services, which estimated defensive medicine’s costs to be between \$60 and \$108 billion. See OFFICE OF THE ASSISTANT SEC’Y FOR PLANNING & EVALUATION, U.S. DEP’T OF HEALTH & HUMAN SERVS., CONFRONTING THE NEW HEALTH CARE CRISIS: IMPROVING HEALTH CARE QUALITY AND LOWERING COSTS BY FIXING OUR MEDICAL LIABILITY SYSTEM 7 (2002). The numbers in this government study are extrapolations based on a 1996 study by Professors Kessler and McClellan, who found that tort reforms could save between 5% and 9% of healthcare costs for heart patients without adversely affecting mortality. See Daniel Kessler & Mark McClellan, *Do Doctors Practice Defensive Medicine?*, 111 Q.J. ECON. 353, 383 (1996) [hereinafter *Defensive Medicine*]. However, the authors of the government study were probably unaware of a 2002 study in which Kessler and McClellan repeated their 1996 study, this time controlling for costs containment achieved by managed care. The results were about 50% less than in the original study. See Daniel Kessler & Mark McClellan, *Malpractice Law and Health Care Reform: Optimal Liability Policy in an Era of Managed Care*, 82 J. PUB. ECON. 175, 189 (2002). Moreover, a 2004 study by the Congressional Budget Office that applied the methods used in the Kessler and McClellan study to a broader set of ailments could not replicate Kessler and McClellan’s results. See PERRY BEIDER & STUART HAGEN, CONG. BUDGET OFF., LIMITING TORT LIABILITY FOR MEDICAL MALPRACTICE 6 (2004), available at <http://www.cbo.gov/ftpdocs/49xx/doc4968/01-08-MedicalMalpractice.pdf>.

43. Michelle Mello et al., *National Costs Of The Medical Liability System*, HEALTH AFF., Sept.–Oct. 2010, at 1569 (Exhibit 1), available at <http://content.healthaffairs.org/content/29/9/1569.full.pdf+html>. While the quality of the evidence supporting Mello et al.’s estimate is low, their estimate is most likely not too far from the true number.

44. See, e.g., Sheldon Greenfield et al., *Variations in Resource Utilization Among Medical Specialties and Systems of Care*, 267 JAMA 1624, 1629 (1992). Yet almost no study has been able to show that the over utilization is useless because finding an appropriate outcome variable is tremendously hard. One exception is a study by Janet Currie and W. Bentley MacLeod, which found that for some childbirth procedures “caps on damages . . . increase[d] unnecessary procedure use. They also increase[d] complications of labor and delivery in some specifications.” Janet Currie & W. Bentley MacLeod, *First Do No Harm? Tort Reform and Birth Outcomes* 26 (Nat’l Bureau of Econ. Research, Working Paper No. 12478, 2006).

incentives.”⁴⁵ These costs can accrue in small amounts, including through superfluous, sometimes risky testing,⁴⁶ or from more lucrative treatments such as surgeries.⁴⁷ Similar to costs associated with defensive medicine, these costs are born by the patients and their health insurance carriers. Academics have long documented this problem—which they call “induced demand”—yet no one has ever estimated its overall impact.⁴⁸ The costs of offensive medicine, however, may be greater than the other two kinds of costs combined. Most recently, Atul Gawande documented how hospitals in McAllen, Texas perform offensive medicine to enrich themselves at the expense of the public. Dr. Gawande showed spending in McAllen at \$14,946 per Medicare enrollee per year, a number twice as much as the nearby and socio-demographically similar region of El Paso (\$7,504 per enrollee).⁴⁹

45. President Barack Obama, Remarks by the President in Town Hall Meeting on Health Care at Green Bay, Wisconsin (June 11, 2009), http://www.whitehouse.gov/the_press_office/Remarks-by-the-President-in-Town-Hall-Meeting-on-Health-Care-in-Green-Bay-Wisconsin (“[W]e should change the warped incentives that reward doctors and hospitals based on how many tests and procedures they do . . . even if those tests or procedures aren’t necessary or result from medical mistakes.”).

46. A recent Government Accountability Office report on medical imaging found an eight-fold variation between states on expenditures for in-office medical imaging. The report suggested that there may be significant overuse in parts of the country. See generally GOV’T ACCOUNTABILITY OFFICE, MEDICARE PART B IMAGING SERVICES: RAPID SPENDING GROWTH AND SHIFT TO PHYSICIAN OFFICES INDICATE NEED FOR CMS TO CONSIDER ADDITIONAL MANAGEMENT PRACTICES 21–22 (2008). Given that one CT coronary angiogram is as risky as 309 chest X-rays, and that one in every 270 forty-year-old women undergoing a CT coronary angiogram will eventually develop cancer from the procedure, the stakes of overuse are pretty high. Rebecca Smith-Bindman et al., *Radiation Dose Associated with Common Computed Tomography Examinations and the Associated Lifetime Attributable Risk of Cancer*, 169 ARCHIVES INTERNAL MED. 2078, 2080–81 (2009).

47. See, e.g., STEPHEN KLAIDMAN, CORONARY: A TRUE STORY OF MEDICINE GONE AWRY 119 (2007) (noting unnecessary use of surgical procedures).

48. See Jerry Cromwell & Janet B. Mitchell, *Physician-Induced Demand for Surgery*, 5 J. HEALTH ECON. 293, 293 (1986) (suggesting that number of surgeries performed in some areas exceeds expected surgical requirements); Jonathan Gruber & Maria Owings, *Physician financial incentives and cesarean section delivery*, 27 RAND J. ECON. 99, 99 (1996) (suggesting physicians substituted c-section delivery for normal delivery to make up for negative income shocks from decreased fertility rates).

49. Atul Gawande, *The Cost Conundrum: What a Texas Town Can Teach Us About Health Care*, THE NEW YORKER, June 1, 2009, at 36–37.

3. *Cost-apatetic Medicine*

Cost-apatetic medicine is overuse that happens in good faith. Doctors are trained (and the public expects them) to do everything they can to care for their patients, not to pay close attention to costs. New but expensive medical and surgical techniques developed over the last decades, combined with physicians' enthusiasm for being able to do good, have led to over usage of such care.⁵⁰ Once new technology penetrates the practice, it is hard to cut back on related over usage. Consider for example the mammogram uproar caused by a U.S. preventive services task force's recent recommendation increasing the age, at which routine screening mammograms should occur from forty to fifty years old.⁵¹ The same day that the task force released its recommendation, however, the Health and Human Services (HHS) Secretary, Kathleen Sebelius, stated she would be very surprised if the recommendation caused insurance companies to change their mammography coverage.⁵² The recommendation that mammograms should be reduced caused a furor, even though its sole basis was that mammograms' health risks outweighed their benefits. It is hard to imagine the outrage that would have resulted if the recommendation was based on their financial cost.

4. *Compassionate Medicine*

Compassionate medicine refers to medicine provided by doctors because they cannot bear the thought of doing nothing while their patients suffer. This is especially prevalent when suffering patients insist upon having excessive care. Compassionate medicine costs arise primarily during end-of-life care: care provided to people in the final year of their life. Nearly 30% of the

50. See Becher & Chassin, *supra* note 8, at 167; see also Richard A. Lange & L. David Hillis, Editorial, *Use and Overuse of Angiography and Revascularization for Acute Coronary Syndromes*, 338 NEW ENGL. J. MED. 1838, 1838-39 (1998); Pascal Nicod & Urs Scherrer, Letter to Editor, *Money, Fun, and Angioplasty*, 116 ANNALS INTERNAL MED. 779 (1992). See generally Mark R. Chassin, *Explaining Geographic Variations: The Enthusiasm Hypothesis*, 31 MED. CARE YS37 (1993).

51. U.S. Preventive Services Task Force, *Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement*, 151 ANNALS INTERNAL MED. 716, 716 (2009).

52. Press Release, Kathleen Sebelius, Sec'y, U.S. Dep't of Health & Human Servs, Secretary Sebelius Statement on New Breast Cancer Recommendations (Oct. 18, 2010), <http://www.hhs.gov/news/press/2009pres/11/20091118a.html>.

total Medicare budget goes to caring for patients during the final year of their lives; about 50% of this goes towards their final sixty days.⁵³ A recent study concluded that patients' rate of admission to intensive care units (ICU) for the last six months of life is seventy times higher for patient eighty-five years and older, compared with those eighteen to forty-four years, consuming a significant proportion of ICU resources.⁵⁴

Yet numerous studies have shown that the correlation between greater end-of-life spending and higher quality of care is nil or even negative.⁵⁵ A recent study found that, adjusted for various factors such as age, race, and sex, average end-of-life spending was \$16,059 for the lowest-spending quintile of hospitals and \$34,742 for hospitals in the highest-spending quintile.⁵⁶ Yet, the researcher found a statistically significant *negative* relationship between spending and overall quality.⁵⁷

D. Summary

As the previous sections showed, the health care system faces three main cost distortions: underuse, misuse, and overuse. Can the system fix itself? The answer is no. The reason is the lack of economic incentives for quality improvements. Solving overuse problems is not in the hospitals' financial interest because doing so would reduce their revenue and their physicians' income. Similarly, eliminating misuse problems by preventing medical errors is also not in the hospitals' or physicians' financial interest. Hospitals are reimbursed on a per diem basis; thus, they have no interest in shortening their patients'

53. See James D. Lubitz & Gerald F. Riley, *Trends in Medicare Payments in the Last Year of Life*, 328 NEW ENG. J. MED. 1092, 1093-94 (1993).

54. Edward G. Seferian & Bekele Afessa, *Adult Intensive Care Unit Use at the End of Life: A Population-Based Study*, 81 MAYO CLINIC PROC. 896, 898 (2006).

55. See, e.g., Katherine Baicker & Amitabh Chandra, *Medicare Spending, The Physician Workforce, and Beneficiaries' Quality of Care*, 23 HEALTH AFF. 184 (2004); Amitabh Chandra & Douglas O. Staiger, *Productivity Spillovers in Health Care: Evidence from the Treatment of Heart Attacks*, 115 J. POL. ECON. 103 (2007); Elliott S. Fisher et al., *The Implications of Regional Variations in Medicare Spending, Part 1: The Content, Quality, and Accessibility of Care*, 138 ANNALS INTERNAL MED. 273 (2003); Elliott S. Fisher et al., *The Implications of Regional Variations in Medicare Spending, Part 2: Health Outcomes and Satisfaction with Care*, 138 ANNALS INTERNAL MED. 288 (2003).

56. See, e.g., Laura Yasaitis et al., *Hospital Quality and Intensity of Spending: Is There an Association?*, 28 HEALTH AFF. 566 (2009).

57. *Id.* When the authors restricted their analysis to academic medical centers, they found there was no correlation between quality and spending.

lengths of stay. And physicians are always paid to treat complications, whether preventable or not. Doing away with underuse problems is also not financially beneficial for hospitals. First, it will require undertaking the costly activities of identifying individuals who are not appropriately treated, and then treating them. Second, these individuals are often uninsured and therefore cannot pay for the treatment. Otherwise, they may be insured by Medicaid, which has low reimbursements rates. Third, treating these individuals can decrease revenue because improving the outpatient treatment of chronic conditions can reduce hospital admissions for which the hospitals are more likely to be reimbursed.⁵⁸

II. IS CURRENT MEDICAL MALPRACTICE LAW THE ANSWER?

A. *Can Tort Law Tackle the Healthcare System's Costs?*

Tort law has tried to tackle some of the problems described above. The methods used by tort law, however, either address these problems separately or ignore them altogether. Underuse is outside of tort law's scope simply because the victims of underuse (primarily the uninsured poor) have no way to know of and realize their rights. Compassionate care and cost-apatetic care—both types of overuse—are also outside of tort law's radar because in most cases there are no victims. In theory, offensive medicine should be restrained by numerous anti kickback statutes,⁵⁹ laws against self-referrals (Stark laws),⁶⁰ utilization review, and the threat of medical malpractice liability for negligent care. Defensive medicine can be limited by utilization review and reforms in tort law designed to reduce malpractice litigation. Misuse, however, is arguably counteracted by the risk of medical malpractice lawsuits for performing negligent mistakes.

Yet reforming tort law to combat offensive medicine, defensive medicine, and medical errors simultaneously is not feasible. Addressing one problem directly exacerbates another. Tort reform, which lowers the risk of lawsuits for doctors, partly undermines providers' incentives to perform defensive medicine, but at the

58. See Becher & Chassin, *supra* note 8 at 168–70.

59. 42 U.S.C. § 1320a-7b(b) (2006).

60. 42 U.S.C. § 1395nn (2006).

same time it poses two significant problems. First, it might dilute providers' incentives to provide optimal care, thus potentially increasing costs from medical errors. Second, lowering liability boosts providers' incentives to engage in offensive medicine. For example, the legal risk of performing excessive bypass surgery is reduced with limits on malpractice liability.⁶¹

Granted, tort law's primary mission is not to cure all three problems, but only to decrease medical errors. Even in that role, scholars on both sides of the tort reform debate have argued that the link between court judgments and actual negligence is too remote to achieve such an end. First, not all negligence cases are brought—only the large ones. If not all negligence cases are pursued, then patients who do not sue are not made whole for the harm they have suffered, and the legal system's signal to doctors and hospitals, which is supposed to incentivize optimal behavior, is interrupted.⁶² Second, for the

61. In 2002 officials at the Redding Medical Center in California (also known as "little house of horrors") were subject to an FBI investigation which discovered that up to 40% of the 1,000 bypasses a year (three times the normal rate for a facility its size) were not medically justified. The hospital eventually settled for more than \$450 million with patients and the government. See KLAIDMAN, *supra* note 47, at 155. This is, of course, not the first time in the history of the United States that doctors have admitted patients for offensive medicine related reasons. See Paul Jacobs, *Heart Surgeries Lead Hospital Into Difficulties*, L.A. TIMES, July 31, 1980, at B1 (reporting that doctors at Paramount General Hospital in California were "anxious to operate on almost anything"); see also KLAIDMAN, *supra* note 47, at 7–11 (reporting that officials from the Psychiatric Institutes of America (PIA) in Texas bribed doctors to refer patients to PIA. A 1993 FBI investigation ended with some doctors jailed and \$379 million paid in fines, and settlements with plaintiffs who had been wrongly admitted to the psychiatric institution). For a more recent example, see Patricia Anstett, *A History of Suspect Diagnoses*, DETROIT FREE PRESS, June 15, 2010, at A2 (reporting that a physician in pediatric neurology increased his salary by falsely diagnosing hundreds of Detroit children with epilepsy, and that the false diagnoses brought business to the hospital, which paid the physician for the business).

62. Several important studies have analyzed the number of malpractice claims filed relative to actual cases of negligence. The most cited study is the Harvard Medical Practice Study (HMPS) which focused on hospitalizations in fifty-one hospitals in New York during 1984. David A. Hyman & Charles Silver, *Medical Malpractice Litigation and Tort Reform: It's the Incentives, Stupid*, 59 VAND. L. REV. 1085, 1090 (2006) (citing Troyen A. Brennan et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients*, 324 NEW ENG. J. MED. 370, 371 (1991)). The researchers matched cases of negligent injury with actual claim filings, and determined that only 2% of those who were negligently injured sued. A similar 1992 study, focusing on hospitalizations in Colorado and Utah, found similar numbers; only 2.5% of those who had been negligently injured filed a claim. See Studdert, *supra* note 27. Lastly, these findings were consistent with a late 1990s Florida study which found that, of 19,885 incidents of medical negligence self-reported by hospitals, only 3177 patients filed

cases that are brought, there exists much uncertainty regarding the appropriate standard of care, partly because of various tort doctrines unique to medical malpractice cases that increase uncertainty, such as the “respectable minority” rule and the “error in judgment” rule.⁶³ As a result of the uncertainty (both clinical and structural),⁶⁴ courts too often render incorrect judgments and award inaccurate damages.⁶⁵ Third, even under an unbiased negligence regime, random judicial error will motivate defendants to be too cautious or to engage in too little activity, both of which are forms of defensive medicine.⁶⁶ Further, if courts are biased—for example, if false negatives (incorrectly holding doctors not to be negligent) are more common than false positives (erroneously deeming physicians to be liable)—or if courts’ random errors are comparatively significant, the problem worsens.⁶⁷ Courts can be biased because they are not exposed to all the pertinent facts⁶⁸ or be-

claims. Press Release, Joan Claybrook, Pres., Public Citizen, Sham Crisis (in Florida) is Play by Insurance, Medical Lobbies to Strip Medical Victims’ Rights (Sept. 17, 2002), <http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=1213>.

63. Under the respected minority rule, doctors are not considered negligent even when they did not provide the best care, so long as they followed an established “school of practice.” Under the error in judgment rule, doctors are not considered negligent even when they did not provide the best care, so long as they chose a “legitimate” course of treatment. JOSEPH H. KING, *THE LAW OF MEDICAL MALPRACTICE IN A NUTSHELL* 66–69 (2d ed. 1986).

64. Clinical uncertainty is the uncertainty associated with the imprecise nature of medical standards of practice. This uncertainty is exacerbated by structural uncertainty—the ex post nature of the process for determining the applicable standard. See James F. Blumstein, *Medical Malpractice Standard-Setting: Developing Malpractice “Safe Harbors” As A New Role for QIOs?*, 59 *VAND. L. REV.* 1017, 1026–29 (2006).

65. David M. Studdert et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, 354 *NEW ENG. J. MED.* 2024, 2024–33 (2006) (showing that the legal system performs well roughly three quarters of the time, on the basis of those awarded compensation, deserving and undeserving, of medical malpractice claims, and that the size of the harm is the most important predictor of outcome).

66. See STEVEN SHAVELL, *FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW* 224–25 (2004).

67. *Id.*

68. Courts suffer from a biased information problem because they deal with the few who were injured by a given treatment rather than the many who benefited from that same treatment. This selective perspective is problematic because the volume of medical treatment is often probabilistic, not deterministic. The most appropriate course of action may involve a treatment that likely leads to a patient’s recovery but also involves a small chance of exacerbating the patient’s condition. Courts, however, often lack the relevant evidence on the comparative benefits of the treatment, especially with new treatments. This problem might cause courts to find negligence even when the practice under review was cost-beneficial.

cause of numerous cognitive biases such as the “identifiable-other effect”⁶⁹ and the “hindsight bias.”⁷⁰ Courts might make rather large random errors because they are not intimately familiar or experienced with intricate medical issues and because they largely ignore the ex ante perspective. Lastly, the nature of the common law essentially restrains courts’ ability to encourage (or at least not to block) medical advances.⁷¹

69. As first noted by Professor Thomas Schelling, identifiable victims stimulate more powerful emotional reactions than do statistical victims. T.C. Schelling, *The Life You Save May Be Your Own*, in PROBLEMS IN PUBLIC EXPENDITURE ANALYSIS (Samuel B. Chase ed., 1968). See also Deborah A. Small & George Loewenstein, *Helping a Victim or Helping the Victim: Altruism and Identifiability*, 26 J. RISK & UNCERTAINTY 5, 5–6 (2003). Thus, jurors are more likely to focus on compensating the “identifiable victim” than on weighing more abstract evidence concerning general deterrence. Recently, commentators have suggested that the identifiable victim effect is a special case of a more general tendency to react more strongly to identifiable others whether they are victims or perpetrators. Deborah A. Small & George Loewenstein, *The Devil You Know: The Effects of Identifiability on Punishment*, 18 J. BEHAVIORAL DECISION MAKING 311, 311–18 (2005) (showing that people are more punitive toward identified wrongdoers than toward equivalent but unidentified wrongdoers, even when identifying the wrongdoer conveys no meaningful information about her). If correct, the identifiable other effect also suggests that courts react more strongly towards the identified defendant-doctor, treating her more harshly. This can lead to many more (presumably erroneous) findings of negligence compared to adjudication based on the efficiency of guidelines per se, a task which involves dealing with statistical victims and statistical doctors. Indeed, there is some evidence suggesting that courts compensate the injured when their harm is large, even in the absence of negligence. See Studdert et al., *supra* note 65, at 2024 (“When claims not involving [medical] errors were compensated, payments were significantly lower on average than were payments for claims involving errors.”).

70. Hindsight bias is when “people consistently exaggerate what could have been anticipated in foresight.” Baruch Fischhoff, *Hindsight ≠ Foresight: The Effect of Outcome Knowledge on Judgment Under Uncertainty*, 1 J. EXPERIMENTAL PSYCHOLOGY 288, 297 (1975). Thus, doctors may be found liable under the current medical malpractice negligence regime when their patients are injured even though the doctors behaved reasonably. Anticipating hindsight bias and the impossibility of eliminating or even moderating it, doctors may be rational in practicing defensive medicine. See Jeffrey J. Rachlinski, *A Positive Psychological Theory of Judging in Hindsight*, 65 U. CHI. L. REV. 571 (1998). This problem has been noticed by courts, which use various techniques to potentially moderate the hindsight bias.

71. The common law fails to encourage systematic knowledge-production and continuously updated behavior-regulation mechanisms. The investigation of procedures such as surgical techniques is often left to the creativity and improvisation of any willing physician, which is of course problematic. Although developing a new procedure does not require the approval of any governmental agency, physicians interested in developing new techniques face numerous informational barriers. See, e.g., Elena A. Gates, *New surgical procedures: Can our patients benefit while we learn?*, 176 AM. J. OBSTETRICS & GYNECOLOGY 1293 (1997). As recently argued by Professors Alex Stein and Gideon Parchomovsky, because following current industry custom is still the best way to prevent potential medical malpractice liability, doctors are often

As a result, doctors protest that court judgments cannot seriously be taken into consideration when determinations about patients' health are made. In addition, the threat of liability under non uniform conceptions of negligence can deter hospitals and providers from pursuing the creation of collectively valuable medical practices, adversely affecting patient safety. Furthermore, because our system assesses medical negligence based on customary practices, generally accepted defensive medical procedures may promote inefficient standards that impede any potential of tort law to encourage efficient medical practices.

Fundamentally, then, current tort law fails to address a central issue—the need for more efficient doctoring. A Private Regulatory Regime (PRR), in contrast, should do better on all fronts. A PRR will act from the *ex ante* perspective—thus accounting for benefits but also for costs, eliminating hindsight bias—and consider statistical doctors and statistical patients, eliminating the identifiable-other effect. PRR firms would not be able to avail themselves of the state of the art defense, further encouraging the efficient implementation of medical innovations—under PRR the guidelines will be on trial, not the physician, encouraging optimal doctoring. Better guidelines will be developed and adopted. PRR firms would see a broader picture than would individual physicians, enabling them to better perceive the effectiveness of new procedures. The immunity offered by PRR firms could counter physicians' decreased willingness to adopt new procedures over the course of their careers.

Clinical practice guidelines promulgated under the right incentives could reduce many of the current costs. Optimal CPGs would lower expenses generated by both types of misuse (errors of execution and errors of planning) because they would curb providers' discretion and promote evidence-based medical practices. CPGs will cut back on underuse and overuse in the form of compassionate and cost-apatetic medicine because they will communicate the gold standard of care. The immu-

reluctant to embrace medical innovations and consequently there is substantially suboptimal incentive to innovate. Gideon Parchomovsky & Alex Stein, *Torts and Innovation*, 107 MICH. L. REV. 285 (2008). Indeed, it takes an average of seventeen years for quality medical research to actually be endorsed by clinical practice guidelines. Keckley, *supra* note 2.

nity granted for following the CPGs would also reduce defensive medicine because providers would no longer feel compelled to shield themselves from liability. Finally, CPGs under the PRR would also reduce offensive medicine. First, they would provide doctors with information on the optimal level of care. Second, doctors would be less inclined to offer unnecessary services because doing so would cause them to lose their immunity.

B. *Can Current CPGs Tackle the Costs of the Healthcare System?*

1. *When the Government Writes Guidelines*

a. *Theory*

Regarding medical malpractice, the regulations of two government agencies are relevant: the FDA, which regulates drugs and medical devices, and the AHRQ, which perceives itself as facilitating the creation of CPGs by other actors. Unlike other federal agencies which write and then enforce regulations, AHRQ has never enforced guidelines. The Agency has never filed a claim against a provider who delivered care which deviated from its guidelines, leaving to victims of medical malpractice the option, and responsibility, to file a lawsuit alleging deviation from such CPGs.⁷²

The interesting question, though, is whether the incentives for the government to write CPGs are such that the guidelines should be binding in courts. Generally, government agencies develop exceedingly flexible regulations, or simply under-enforce their regulations, for several reasons.⁷³ Foremost, agencies frequently lack the resources to issue regulations efficiently and to regularly update them.⁷⁴ Furthermore, agencies can be compromised by the parochial perspectives of the government and self-serving administrators, or be subject to interest group capture. A change in administration can lead to oscillation be-

72. Bradford H. Gray et al., *AHCPR and the changing politics of health services research*, HEALTH AFF., June 25, 2003, at W3-297, available at <http://content.healthaffairs.org/content/early/2003/06/25/hlthaff.w3.283.full.pdf>.

73. See Rachlinski, *supra* note 70, at 609.

74. *Id.*

tween standards.⁷⁵ Transferring between the public and private sectors, myopic administrators may improve their prospects in industry by advancing the interests of interest groups that desire loose policies. Most importantly, interest group capture can lead to under enforcement and, in the case of AHRQ, has led to the decision to abandon the promulgation of CPGs altogether.⁷⁶

On the other hand, federal agencies may also have incentives to develop excessively cautious guidelines. First, agencies intermittently overreact to crises, and years, if not decades, may pass before guidelines developed in the aftermath of crises are corrected. Second, government agencies are not liable for inefficient rules, undermining the financial accountability necessary to incentivize efficient rulemaking and thereby potentially promoting over-regulation. The over regulation can be exacerbated because the regulator is *politically* accountable, which may encourage a defensive or cautious approach. If the agency neglects to regulate, the agency may suffer administrative or political consequences, but the agency will seldom be punished politically for excessive restraint in guidelines.⁷⁷

Given these opposing motives, there is debate over whether agencies regulate in an overly strict or overly lax manner. This uncertainty, however, says nothing about efficiency. With the exception of the FDA, whose rigorous ex ante approval procedures and explicit policy to monitor risks for optimality indicate that its procedures aim for both safety and cost control,⁷⁸ most other agencies seem to only stipulate minimum standards of care (floors).⁷⁹ Standards that are only a floor are quite often

75. For example, during the second Bush administration the FDA changed policy regarding its ability to determine preemption. See Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. TORT. L. 17, 20 (2006).

76. See Gray et al., *supra* note 72 (describing how the AHRQ stopped promulgating guidelines because of interest group pressure).

77. See Epstein, *supra* note 75, at 22 (discussing the problem of agency overregulation).

78. Brief for United States as Amicus Curiae Supporting Appellees at 16–17, *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006) (No. 05-5500) (“FDA seeks to encourage the optimal level of use in light of reasonable safety concerns, by requiring scientific evidence that establishes an association between a drug and a particular hazard before warning of that association on a drug’s labeling.”).

79. Few cases exist where Congress decided to replace state tort law with a complete regulatory regime that was viewed as optimal regulation. Examples of this include workers’ compensation, automobile accidents, nuclear energy (Price-

suboptimal. Thus only one jurisdiction, Michigan, has implemented the regulatory compliance defense. Under the Michigan scheme, a defendant is not liable if he follows the government regulatory standards. Still, the regulatory compliance defense can only be invoked in the pharmaceutical context and only when the government agency is the FDA.⁸⁰

Fast-moving medical research exacerbates the general agency regulation problems in the health care industry. Medical research evolves very quickly, so it is likely that government CPGs would fail to keep up with current medical research. A 2001 report assessed the reliability of seventeen CPGs developed between 1990 and 1996 by the AHRQ and concluded that thirteen were out of date with then current research.⁸¹ According to the study, approximately \$4 million per guideline was needed to adequately revise them through the AHRQ's Evidence Based Practice Center Program.⁸² Unfortunately, medical research does not follow a set schedule, and agency guidelines can fall even further behind new developments in medicine. In sum, as with the tort system, the likelihood that regulation would be comprehensively and consistently efficient is minimal.

A PRR firm would be less susceptible to these problems. Unlike an agency, a PRR firm would be financially liable for rulemaking and would have financial incentives to engage in the correct level of regulation. Unlike an agency, which is subject only to administrative review of its rulemaking, the PRR firm will continuously be liable for damages caused by any inefficient prescription. Moreover, a PRR firm could expect to profit from refining standards, an incentive that reduces the

Anderson Nuclear Industries Indemnity Act), and child vaccines (The National Childhood Vaccine Injury Act of 1986).

80. Michigan alone provides for a complete regulatory compliance defense, subject only to a fraud-on-the agency exception; a handful of other states offer manufacturers various forms of more limited protection. MICH. COMP. LAWS ANN. § 600.2946(5) (West 2000). *See, e.g.*, COLO. REV. STAT. ANN. § 13-21-403(1)(b) (West 2007); IND. CODE ANN. § 34-20-5-1 (West 1999); KAN. CIV. PROC. CODE ANN. § 60-3304(a) (West 2008); N.J. STAT. ANN. § 2A:58C-4 (West 2000); TENN. CODE ANN. § 29-28-104 (2000); TEX. CIV. PRAC. & REM. CODE ANN. § 82.007 (a) (West 2005); UTAH CODE ANN. § 78B-6-703 (West 2008). By and large, neither the Restatement (Second) nor the (Third) allows for a complete defense.

81. Shekelle, *supra* note 16, at 1464.

82. *See id.* at 1462.

risk that its employees will underperform.⁸³ This helps solve the ossification and agency capture problems. In a PRR firm, an administrator's career success would be tied to the firm's profitability, diminishing the likelihood that decisionmakers in PRR firms would aggrandize themselves at the cost of efficiency. This helps solve aggrandizement and defensive regulation problems.

Lastly, a PRR regime fares better with respect to the compensation goal, because there is no preemption in the PRR. Victims of doctors who did not follow the guidelines would get their day in court, as would victims of suboptimal guidelines.

b. Evidence from States' Experience with Guidelines

i. Maine

In recent years, a number of states have engaged in projects that established CPGs as statutory standards of care for physicians to use as a defense in malpractice suits.⁸⁴ The most noteworthy initiative was the Maine Medical Liability Demonstration Project, which expired in 1999.⁸⁵ The Maine project established special advisory committees to formulate CPGs for four practice areas considered to be racked with malpractice lawsuits and potential defensive medicine.⁸⁶ The committees promulgated twenty practice guidelines in anesthesiology, emergency medicine, obstetrics-gynecology, and radiology.⁸⁷ The guidelines were then made available for use in malpractice litigation as a shield, and not a sword, because the purpose of the reform was to reduce liability. For doctors in those specialties, those who chose to comply with the guidelines could utilize them as an affirmative defense in any malpractice lawsuit.⁸⁸

83. See Report: *SEC Staffers Watched Porn as Economy Crashed*, CNN.COM (Apr. 23, 2010), http://articles.cnn.com/2010-04-23/politics/sec.porn_1_sec-employees-sec-spokesman-john-nester-inspector-general?_s=PM:POLITICS.

84. See Linda L. LeCraw, *Use of Clinical Practice Guidelines in Medical Malpractice Litigation*, 3 J. ONCOLOGY PRAC. 254, 254 (2007).

85. *Id.*

86. *Id.*; see GEN. ACCOUNTING OFFICE, *MEDICAL MALPRACTICE: MAINE'S USE OF PRACTICE GUIDELINES TO REDUCE COSTS 2-3* (1993), [hereinafter ME. PRACTICE GUIDELINES].

87. ME. PRACTICE GUIDELINES, *supra* note 86, at 3.

88. *Id.*

Plaintiffs, on the other hand, were not permitted to introduce the guidelines as evidence in a malpractice suit.⁸⁹

Unfortunately, the results of the Maine project were indeterminate.⁹⁰ The vast majority of doctors did not believe that the guidelines had any material impact, and in only one lawsuit was the affirmative defense even invoked.⁹¹ An official at the Maine Bureau of Insurance explained that “the medical demonstration project had no measurable effect on medical professional liability claims, claims settlement costs, or malpractice premiums.”⁹²

ii. Florida

In 1994, concern for the costs of defensive medicine prompted Florida to initiate its own CPG demonstration project, which was administered by the state’s Agency for Health Care Administration (AHCA).⁹³ Similar to the Maine project, Florida created an affirmative defense for participating physicians provided that they followed the CPGs (guidelines as a shield).⁹⁴ In contrast to Maine’s project, Florida’s initiative did not explicitly prevent plaintiffs from using guidelines to prove that physicians did not meet appropriate standards of care (guidelines as a sword).⁹⁵ Proving that physicians did not comply with guidelines, however, did not create a prima facie case of negligence, and physicians were given leeway to demonstrate that their decisions to deviate from the guidelines were prudent given the specific circumstances of their cases.⁹⁶

89. See ME. REV. STAT. ANN. tit. 24, §§ 2971–2979 (1993).

90. See LeCraw, *supra* note 84, at 254. By one estimate, the guidelines affect only about three to four percent of medical practice in Maine. See Gordon H. Smith, *A Case Study in Progress: Practice Guidelines and the Affirmative Defense in Maine*, 19 JOINT COMMISSION J. ON QUALITY IMPROVEMENT 355, 361 (1993).

91. Howard Zonana, *Commentary: When Is a Practice Guideline Only a Guideline?*, 36 J. AM. ACAD. PSYCHIATRY & L. 302, 303 (2008).

92. LeCraw, *supra* note 84, at 254 (citing ME. BUREAU OF INS. & BD. OF LICENSURE IN MED., MEDICAL LIABILITY DEMONSTRATION PROJECT 2, 5 (2000)).

93. See FLA. AGENCY FOR HEALTH CARE ADMIN., PRACTICE GUIDELINES AS AFFIRMATIVE DEFENSE: THE CESAREAN DEMONSTRATION PROJECT REPORT 1 (1998).

94. FLA. STAT. ANN. § 408.02(9)(e) (West 1996).

95. See William R. Trail & Brad A. Allen, *Government Created Medical Practice Guidelines: The Opening of Pandora’s Box*, 10 J.L. & HEALTH 231, 246 (1996).

96. *Id.*

Florida's project focused on guidelines for cesarean section deliveries,⁹⁷ which were to serve as a pilot program to determine the potential of CPGs for use in other procedures, but the project ultimately failed. Florida chose the cesarean section delivery as its test project because it was the most common surgical procedure performed in Florida hospitals at the time.⁹⁸ It was predicted that the cesarean rate would decline if physicians followed the CPGs.⁹⁹ However, the affirmative defense proved to be an inadequate incentive to convince physicians to participate in the project.¹⁰⁰ Only 20% of eligible physicians participated in the project, and the participants tended to be the physicians that were less likely to perform cesarean deliveries.¹⁰¹ In addition to the lack of participation, the project "was completely unable to obtain data on the cost of liability insurance or the frequency of malpractice cases."¹⁰²

Because of these problems, the project could not help determine whether following guidelines could decrease malpractice claims or reduce the incentive for physicians to practice defensive medicine. The failed project was terminated in 1998, at which point there was no known case of a doctor actually using guideline compliance as an affirmative defense in a malpractice case.¹⁰³ The agency, however, found that "the amount of defensive medicine, as measured by cesarean deliveries without a sufficiently documented reason, was at most eight percent."¹⁰⁴ Ultimately, despite the failure of the project, the agency concluded that, "It might be worthwhile to investigate the use of affirmative defense as an incentive for compliance with other guidelines where it is more likely to result in meaningful changes in medical practice patterns or the defensibility of liability claims."¹⁰⁵

97. FLA. STAT. ANN. § 408.02(9)(e).

98. J. Rosser Matthews, *Practice Guidelines and Tort Reform: The Legal System Confronts the Technocratic Wish*, 24 J. HEALTH POL. POL'Y & L. 275, 299 (1999).

99. *Id.*

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.*

104. FLA. AGENCY FOR HEALTH CARE ADMIN, *supra* note 93, at 19.

105. *Id.* at 20.

iii. Minnesota and Vermont

Minnesota and Vermont also made attempts to use CPGs as tools for health care reform. Vermont passed health care legislation that provided authority to the Vermont Health Care Authority (VHCA) to approve practice guidelines that could be used as the standard of care for health care.¹⁰⁶ Unlike the Maine and Florida guidelines, physician compliance with Vermont guidelines does not create an affirmative defense.¹⁰⁷ Instead, the guidelines function as expert testimony concerning the standard of care and can be introduced by either the plaintiff or the defendant.¹⁰⁸

Minnesota attempted to take the use of guidelines a step further by passing legislation which enabled the health care commissioner to approve and disseminate practice guidelines for physicians that could serve as an absolute defense against malpractice claims.¹⁰⁹ By allowing the defendant to use guidelines as an absolute defense and prohibiting plaintiffs from introducing the guidelines as evidence that physicians failed to meet the standard of care, Minnesota created a legal structure which was extremely similar to the Maine project.¹¹⁰ Unfortunately, the authorizing statute was repealed before the first guideline was generated.¹¹¹

The crucial missing aspect in these projects is that there is no justification for awarding doctors liability protection unless the guidelines are created under a system in which incentives prioritize progress towards creating safer, more cost effective procedures. Under the PRR, the threat of liability for inefficient guidelines and competition from other firms would encourage firms to create efficient guidelines.

106. See VT. STAT. ANN. tit. 18, § 9411 (2010).

107. See OFFICE OF TECH. ASSESSMENT, U.S. CONG., IMPACT OF LEGAL REFORMS ON MEDICAL MALPRACTICE COSTS 33 (1993), available at <http://www.fas.org/ota/reports/9329.pdf>.

108. Trail & Allen, *supra* note 95, at 248.

109. See MINN. ST. ANN. § 62J.34(3)(a) (West 2005) (repealed by 1995 Minn. Laws c. 234, art. 5, § 24).

110. See Trail & Allen, *supra* note 95, at 247–48.

111. See *id.* at 248 (noting that by March 1995, no guideline had been approved); see also 1995 Minn. Laws c. 234, art. 5, § 24 (repealing the law authorizing the promulgation of those guidelines).

c. *Evidence from Federal Experience with Guidelines*

As the debate about health care reform continues, the concept of allowing guideline compliance to provide doctors with immunity from liability has attracted attention. As part of the U.S. Senate Committee on Finance, Senator Baucus solicited talks on the idea of a malpractice shield for observant doctors.¹¹² In February 2009, Senator Wynden introduced a bill that would have provided a rebuttable presumption that care was not negligent if the physician followed official CPGs.¹¹³ Although thus far this legislation has lacked the requisite sponsors, the White House did recently reveal its potential receptiveness to backing the idea. In a May 2009 meeting, President Obama reportedly told Dr. J. James Rohack, the president of the AMA, that he would be amenable to granting some liability safeguards to physicians who complied with standard guidelines for unusual medical procedures.¹¹⁴ However, the ACA fell short of providing immunity for doctors. Rather, funds were assigned for various demonstration projects, among them projects exploring the role such immunity can play in the system.¹¹⁵ In February 2011 the Obama administration launched a drive to overhaul state medical malpractice laws which includes providing “safe harbor” to doctors who follow guidelines.¹¹⁶

Today’s developments built upon earlier attempts where the federal government had initially tried to use medical guideline reform as part of an effort to enhance broader health care improvements. The first link between care, costs, and a safe harbor for doctors was enacted in 1972 as part of the omnibus Social Security Act, against concerns about overutilization in

112. MAX BAUCUS, CALL TO ACTION: HEALTH REFORM 2009 (2009).

113. See Healthy Americans Act, S. 391, 111th Cong. § 712(5) (2009).

114. See Sheryl Gay Stolberg & Robert Pear, *Obama Open To Reining In Medical Suits*, N.Y. TIMES, June 15, 2009, at A1.

115. See Agency for Healthcare Research & Quality, U.S. Dep’t of Health & Human Servs., *Medical Liability Reform and Patient Safety: Planning Grants*, AHRG.GOV (June 2010), <http://www.ahrq.gov/qual/liability/planninggrants.htm> (stating that one project is scheduled to “develop and implement a method for setting priorities for developing evidence-based practice guidelines, craft a broadly supported safe harbor legislative proposal that will define the legal standard of care, and develop a plan to evaluate the effectiveness of the legislative proposal, if enacted”).

116. Ricardo Alonso-Zaldivar, *Obama Starts Drive for Medical Malpractice Reforms*, STAMFORD ADVOCATE (Feb. 15, 2011, 11:41 AM), <http://www.stamfordadvocate.com/news/article/Obama-starts-drive-for-medicalmalpractice-reforms-1014244.php>.

Medicare and Medicaid.¹¹⁷ The act created Professional Standard-Review Organizations (PSROs) that were responsible for monitoring physicians' decisions affecting the use of health care resources. Recognizing the link between utilization control and medical malpractice, the law provided that actions taken "in compliance with or in reliance upon professionally developed norms of care and treatment applied by" a statutorily designated Peer Review Organization (PRO) would be immune from challenge in a civil suit. The immunity was clearly meant to combat defensive medicine.¹¹⁸

This immunity provision was never applied, probably for two reasons. First, the section qualifies the immunity so that it applied only if the physician "exercised due care in all professional conduct" related to such actions, a requirement that basically voided the immunity.¹¹⁹ Second, and more importantly, for various reasons PROs (now called Quality Improvement Organizations or QIOs) have never implemented their authority to develop guidelines, thus rendering the provision inapplicable.¹²⁰ QIOs are not expected to exercise their guideline making powers in the future.¹²¹

During the last two decades, the steep rise in medical expenditures has forced Congress to find solutions to improve the quality of health care delivery and curtail the costs from malpractice litigation. To this end, President George H. W. Bush and Congress established the Agency for Health Care Policy and Research (AHCPR) in 1989 to "enhance the quality, appropriateness, and effectiveness of health care services" through, among other things, "the development and periodic review and updating of . . . clinically relevant guidelines."¹²² Several of AHCPR's CPGs were considered the definitive statements of

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

118. See Blumstein, *supra* note 64, at 1039.

119. 42 U.S.C. § 1320c(2).

120. See Blumstein, *supra* note 64, at 1039–40; see also Clark C. Havighurst, *Practice Guidelines as Legal Standards Governing Physician Liability*, 54 LAW & CONTEMP. PROBS. 87 (1991).

121. *But see* Blumstein, *supra* note 64, at 1043–44 (expressing cautious optimism that they might).

122. Michelle M. Mello, *Of Swords And Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 651 (2001) (citing Stephen M. Merz, *Clinical Practice Guidelines: Policy Issues and Legal Implications*, 19 JOINT COMMISSION J. ON QUALITY IMPROVEMENT 306, 308 (1993)).

excellence in their clinical areas.¹²³ The Clinton Administration attempted to advance this idea by proposing a pilot program under which doctors able to show that their clinical procedures or actions complied with AHCPR guidelines would not face medical malpractice liability.¹²⁴ Because of political opposition to President Clinton's healthcare reform and fierce interest group politics, President Clinton's experimental initiative stalled and the AHCPR was almost completely eliminated in 1995.

The conflict that nearly eliminated the AHCPR emerged from a debate regarding spinal fusion surgery. Following many years of controversy over the merits of surgical procedures for low-back disorders, AHCPR funded a study that concluded that there was no evidence to support the use of spinal fusion surgery, that such surgery commonly had complications, and that more randomized controlled trials were needed to compare fusion surgery with non surgical treatment.¹²⁵ An association of back surgeons who disagreed with the conclusions launched an attack on the study and the agency itself.¹²⁶ The Center for Patient Advocacy, which was formed by a back surgeon to lobby on the issue, mobilized an effort in the House of Representatives to end the agency's funding. Only on the night of the vote was an amendment to reduce the agency's budget to zero withdrawn, leaving the agency instead with a 21% budget cut.¹²⁷

One of the consequences of this battle was that the agency dropped its CPG development program and initiated support for external evidence-based practice centers that organize data to help private-sector organizations develop CPGs. In 1999, Congress passed legislation that changed the agency's name to the Agency for Healthcare Research and Quality (AHRQ). AHRQ has since become a major force in the dissemination of

123. See Becher & Chassin, *supra* note 8, at 172.

124. ME. PRACTICE GUIDELINES, *supra* note 86, at 1-2.

125. Judith A. Turner et al., *Patient Outcomes after Lumbar Spinal Fusions*, 268 JAMA 907, 907 (1992).

126. Gray, *supra* note 72, at W3-297.

127. *Id.* at W3-295. The 1995 battle between the AHRQ and the back physicians was not the first time AHRQ faced attacks by physician groups. Earlier in 1993, an AHCPR study came under attack from various ophthalmology associations. *Id.* However, that attack never extended to attempts to defund AHCPR, and it came to an end when the ophthalmologists discovered they could use the data to discredit a GAO study alleging that inappropriate cataract surgery was widespread and to get insurers to pay for some surgery. *Id.*

medical guidelines, though the actual creation of CPGs was eliminated from its mission.¹²⁸

d. Summary

Tort law and government agency regulation are inappropriate mechanisms for developing optimal medical care. If the regulatory process were perfect—that is, if institutions could comprehensively, objectively, and adeptly analyze medical practices to maximize the net benefits for society—tort law would play a minimal role. As discussed, the chance of such a world is small. More likely, we can expect a system where government agencies regulate a minimum standard and tort law plays a supplemental role where it is theoretically pushing medicine towards optimality. In truth, this is how regulation of medical practice works in almost all states and for nearly all injury types. There are advantages to this system. For one, it provides some predictability because the violation of a regulation means that the defendant would most likely be found liable. This is perfectly sensible considering that a violation of a minimum standard would certainly be unreasonable.

Nevertheless, the existing system has several drawbacks. First, when regulation provides a floor, courts must still determine negligence when a defendant has complied with regulations. Because of this issue, there is much debate about the appropriate scope of the regulatory compliance defense, which has been rejected in all states but Michigan.¹²⁹ For this defense, compliance with regulation is important, and maybe even dispositive, for a determination of non negligence. Regulation compliance is, however, a poor indication of a standard of care where only a floor is involved. The issue of preemption has also become especially problematic in recent years. Courts and scholars struggle to make sense of this complicated area of law, and there is a great deal of uncertainty in determining whether tort law or government regulation should apply.¹³⁰

128. See *id.* at W3-303.

129. See MICH. COMP. LAWS ANN. § 600.2946(5) (West 2000). Even in Michigan, this applies only to pharmaceuticals.

130. See Epstein, *supra* note 75; Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. 727 (2008); Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L. 4, 3 (2006); Peter H. Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, 13 ROGER

If government-promulgated CPGs will not work, then perhaps existing institutions' CPGs will. The following three parts consider private-entity clinical practice guidelines, an alternative to the high-cost, inefficient role of regulation and litigation. These guidelines have been formulated by several entities, including hospitals, insurers, and doctors' association.

2. Guidelines Written by Hospitals and Hospital Organizations

Hospitals and hospital organizations, such as the Joint Commission on Accreditation of Hospitals, design guidelines to review staff performance, to enhance care, and to institute consistent practices in hospitals.¹³¹ Hospitals using root cause analysis (RCA) and other proactive approaches to guideline-promulgation can, and occasionally have, improved patient care in significant ways.¹³² For example, hip fractures represent the largest portion of injury-related hospitalizations in the United States, and procedures to repair hip fractures result in a high rate of deaths (state quality benchmarks set it around 5%). At the State Island University Hospital (SIUH), meeting state benchmarks was not considered enough. After performing an RCA on the case of a seventy-eight-year-old woman who had died during a hip fracture repair, the hospital realized that it failed to require special training or qualifications to operate on high-risk patients, resulting in patients being unnecessarily exposed to risk and error.¹³³ After promulgating its own evidence-based guidelines for the use of relevant treatments, the hospital saw an 80% drop in mortality rates from hip fracture repair in the following three years.¹³⁴ Given its successful use, it is perhaps unsurprising that RCA services have also been implemented by private organizations. TapRoot, a company offer-

WILLIAMS U. L. REV. 73 (2008); Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 103 NW. U. L. REV. 437 (2009).

131. See Katharine Van Tassel, *Hospital Peer Review Standards and Due Process: Moving from Tort Doctrine Toward Contract Principles Based on Clinical Practice Guidelines*, 36 SETON HALL L. REV. 1179, 1187-88 (2006).

132. Daniel R. Longo et al., *Hospital Patient Safety: Characteristics of Best-Performing Hospitals*, 52 J. HEALTHCARE MGMT. 188, 200 (2007).

133. Thomas McGinn et al., *Decreasing Mortality For Patients Undergoing Hip Fracture Repair Surgery*, 31 JOINT COMMISSION J. QUALITY PATIENT SAFETY 304 (2005).

134. *Id.*

ing risk assessment for various industries, recently entered the RCA market.¹³⁵

Despite the successful results, SIUH did not develop optimal guidelines. The reduction in hip fracture repair mortality from 4.9% to 1% only indicated the possibility of improved care, not necessarily the most favorable outcome. Unquestionably, one of the easiest criticisms levied against hospital guidelines is that they are designed to protect the organization from liability while maximizing reimbursements from insurers, HMOs, Medicare, and Medicaid. If this is true, then guidelines written by hospitals and hospital organizations can encompass defensive and offensive medicine, and so do little to prevent the associated waste of valuable and limited social resources.

3. *Guidelines Written by HMOs, Health Insurers, or Liability Insurers*

Health care insurers and managed care organizations are increasingly developing their own guidelines for medical care. Often, these guidelines will be used in physician profiling or in utilization reviews. Profiling is used to determine whether a physician's treatment plans are cost effective. Utilization reviews determine whether a patient's treatment will be reimbursed. To a physician, it is critical to comply with such guidelines even though they are not a shield against liability,¹³⁶ because the treatment will not be reimbursed unless the insurer's guidelines are followed. Compliance could even be a requirement—even if not explicit—for a physician's participation in an HMO.¹³⁷ These guidelines are not usually disclosed fully to the public, and are largely employed to minimize costs.

Liability insurance carriers, being interested mainly in enlarging profits by cutting liability costs, similarly advocate specific clinical standards. In obstetrics, the Utah Medical Insurance Association and a Colorado insurance group both require physicians to follow their respective guidelines if they

135. See *Success Stories*, TAPROOT, <http://www.taproot.com/about.php> (last visited Feb. 17, 2011).

136. See *Wickline v. California*, 239 Cal. Rptr. 810, 819 (Cal. Ct. App. 1986) (holding that a doctor must comply with professional standards of care even when insurer has declined to cover the medical services required to satisfy that standard).

137. See Arnold J. Rosoff, *The Role of Clinical Practice Guidelines in Health Care Reform*, 5 HEALTH MATRIX 369, 374 (1995).

wish to be offered malpractice coverage.¹³⁸ Furthermore, rates might be raised or lowered based on a practitioner's willingness to follow particular CPGs.¹³⁹

Of course, present here too are externality problems and self-interests distorting the incentive structure. Liability insurance carriers might require a follow-up examination for breast carcinoma within six weeks of the discovery of palpable dominant lesions, even if such a requirement is an unnecessary waste of resources. Liability carriers do not bear the costs of extra care, but do bear the costs of malpractice lawsuits arising from the late diagnosis of breast cancer.¹⁴⁰ This example demonstrates the distorting effect of defensive medicine, which is estimated by some at up to 9% of total healthcare costs for some ailments.¹⁴¹ Likewise, HMOs commonly prefer fewer procedures because they bear the costs of procedure and not the costs of malpractice, thereby externalizing their costs onto liability insurers.

4. Guidelines Written by Professional Associations

Medical professional associations' guidelines are often respected, as they incorporate recent work on a topic and tend to stress first-rate care for patients. The motivations for the development of these guidelines on the surface derive from genuine interests in improving quality care, educating physicians, reducing negative outcomes in care, and combatting defensive medicine. Moreover, guidelines written by the medical profession can be seen as a response to the third-party payers' guidelines, which are negatively viewed as being written with cost controls in mind and as a threat to physician autonomy.¹⁴²

For four main reasons, among other factors, even these guidelines may be of questionable validity. Professional organizations have been criticized for a bias towards establishing minimum—rather than optimal—standards of care. Also, the

138. Mello, *supra* note 122, at 653.

139. *Id.*

140. *See generally* Quigley v. Jobe, 851 P.2d 236, 238 (Colo. App. 1992) (holding that guidelines written by a liability insurance carrier did not meet the relevant test for scientific evidence, because they were created "by a private insurance company as part of an insurance contract and did not reflect a generally recognized standard of care within the medical profession").

141. Kessler & McClennan, *supra* note 42, at 383 (noting that after malpractice reform, hospital expenditures for ischemic heart disease fell 9% over five years).

142. Zonana, *supra* note 91, at 303.

organizations tend to establish guidelines that rapidly become obsolete, provide an insufficient supply of reliable evidence, and create conflicts of interest within the promulgations process.

Medical guidelines developed by professional specialty societies are prone to being “floors,” the meeting of which does not result in optimal care and below which care is considered inadequate. The reason for this tendency is that these societies see their job, among other things, as protecting their members’ autonomy. Promulgating exact standards of optimal care is perceived by the medical societies as “cook book” medicine.¹⁴³

Medical guidelines are especially vulnerable to becoming outmoded, and these associations usually create guidelines without the funding necessary to continually update them. Creating guidelines that are comprehensive and well-written takes time and a great deal of money. By the time they are released, the guidelines could easily be subsumed by newer research.¹⁴⁴ As a result, the high costs of investing in sound research may influence guideline writers to rely on insufficient evidence. One report that recently assessed the evidence used to develop the ACC/AHA practice guidelines for treating cardiovascular disease determined that 48% of the guidelines’ recommendations were based on the lowest tier of suitable research.¹⁴⁵

Finally, conflicts of interest are significant problems within the current guideline creation process. Writers of guidelines commonly have financial relationships with a particular industry (often pharmaceuticals), which directly impair those writers from objectively developing guidelines. A 2002 study found that 58% of the 192 guideline authors surveyed had received financial support to perform clinical research from an industry actor, and that 38% had served as employees or consultants for a pharmaceutical company.¹⁴⁶ Interestingly, 19% of respondents

143. Havighurst, *supra* note 120, at 92 n.19.

144. Richard Amerlinga et al., *Guideline Have Done More Harm Than Good*, 26 BLOOD PURIFICATION 73 (2008).

145. See Pierluigi Tricoci et al., *Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines*, 301 JAMA 831, 831 (2009) (categorizing its lowest level of acceptable evidence as level C, indicating little to no objective empirical evidence for the recommended action).

146. Niteesh K. Choudhry et al., *Relationships Between Authors of Clinical Practice Guidelines and the Pharmaceutical Industry*, 287 JAMA 612, 612 (2002).

believed their coauthors' recommendations were influenced by their relationships with companies.¹⁴⁷

Indeed, the New Code For Interactions With Companies, published in April 2010 by the Council of Medical Specialty Societies, highlights conflicts of interest.¹⁴⁸ The new code prohibits actors in the pharmaceutical and medical device industries from paying for the development of medical guidelines, but the industry may finance distribution, updating, and repurposing of the guidelines.¹⁴⁹ It is hard to believe medical societies would write guidelines without caring about whether they will later be distributed or updated. It is equally hard to believe the industry would distribute or pay for updating the guidelines without influencing the content.

One way for the industry to have such an impact is through the panel members. Alas, the new code requires that only a majority of the panelists developing the CPGs not have conflicts of interest relevant to the subject matter of the guidelines.¹⁵⁰ It is indeed disturbing to imagine an ethical code requiring that only the majority of the judges sitting in a case not have conflicts of interest. More than being cluttered with such loopholes, the new code reveals how defective things were before April 2010. For instance, industry money financed the initial promulgation of CPGs, and the majority of the panelists of the medical societies promulgating these guidelines could have had conflicts of interest—that is, they could have received money from an interested party.¹⁵¹

147. *Id.* Interestingly, even the authors of the study were not immune, as all of them had attended events sponsored by or received money from pharmaceutical companies. *See id.*

148. COUNCIL OF MED. SPECIALTY SOC'YS, CMSS CODE FOR INTERACTIONS WITH COMPANIES (2010), available at http://www.cmss.org/uploadedFiles/Site/CMSS_Policies/CMSS%20Code%20for%20Interactions%20with%20Companies%204-19-10.pdf. The council includes thirty-four medical societies with 650,000 members, which make up the vast majority of providers in the United States. *See About CMSS, CMSS.ORG*, <http://www.cmss.org/About/Default.aspx> (last visited Jan. 7, 2011).

149. COUNCIL OF MED. SPECIALTY SOC'YS, *supra* note 148, at 19.

150. *Id.* at 20.

151. Consider the following two examples, one from Connecticut and one from Texas. The Connecticut Attorney General recently challenged the 2000 and 2006 Lyme disease guidelines produced by the Infectious Diseases Society of America (IDSA). The International Lyme and Associated Diseases Society (ILADS), in tipping off the Attorney General, challenged the validity of the IDSA guidelines while simultaneously asserting its own guidelines as authoritative, even though they had also been developed using dubious methods. *See* Press Release, Conn. Att'y Gen.'s

In the PRR that I propose, private firms have the incentive to constantly update and improve guidelines, as well as the financial resources needed to invest in the necessary research, without having to subject themselves to a conflict of interest by relying on outside funding. Pharmaceutical companies' influence may not ever be entirely avoided, but it would substantially decrease under this PRR because potentially biased guidelines would be disciplined by market forces as well as legal liability.

C. *The Treatment of CPGs in Practice*

1. *The Treatment of Guidelines Within the Medical Profession*

Since the 1990s, the number of guidelines has risen dramatically. This proliferation is largely attributable to oft-repeated studies indicating that practices could vary widely across regions, or even between health care providers within the same area.¹⁵² The Agency for Health Care Policy and Research (now AHRQ) was amongst a number of professional societies, hospitals, and review boards producing guidelines, and was at the

Office, Attorney General's Investigation Reveals Flawed Lyme Disease Guideline Process, IDSA Agrees To Reassess Guidelines, Install Independent Arbiter (May 1, 2009), <http://www.ct.gov/ag/cwp/view.asp?A=2341&Q=414290>. The office suspected significant financial conflicts, suggested by the intentional exclusion of differing viewpoints during guideline development, which may have even constituted anti-trust violations. John D. Kraemer & Lawrence O. Gostin, *Science, Politics, and Values: The Politicization of Professional Practice Guidelines*, 301 JAMA 6 (2009). Interestingly, although IDSA agreed to settle without admitting guilt, the ILADS guidelines went unchallenged despite a failure to disclose conflicts of interest on the guidelines committee, which included the president of a company that manufactured an alternative Lyme disease diagnostic test, and multiple physicians listed with an associated patient referral service. Another, arguably more troublesome, example occurred recently when the Texas legislature nearly mandated insurance coverage of cardiovascular screening. Peter D. Jacobson, *Transforming Clinical Practice Guidelines Into Legislative Mandates: Proceed With Abundant Caution*, 299 JAMA 208, 208 (2008). The mandate was spearheaded by a prominent group of cardiologists proposing their highly suspect guidelines, which were not endorsed by a single major cardiology association (like the ACC or AHA), and which included the statement "Publication of this supplement was supported by Pfizer, Inc." *Id.*

152. See John E. Wennberg, *Dealing with medical practice variations: a proposal for action*, 3 HEALTH AFF. 6, 9 (1984) ("[O]bserv[ing] that in Maine, by the time women reach seventy years of age in one hospital market the likelihood they have undergone a hysterectomy is 20 percent while in another market is [sic] is 70 percent.").

forefront of the development of about twenty guidelines across key clinical practice areas during this time.¹⁵³

These guidelines have since yielded to Evidence-Based Practice Centers, which work with private organizations to develop guidelines. Unfortunately, the degree of actual scientific evidence used to produce these guidelines is widely inconsistent,¹⁵⁴ and the quality or specificity of the information used is at times dubious. Moreover, once the development of a new set of guidelines has begun, organizations find it difficult to constantly incorporate later research, and physicians are likewise skeptical of guidelines that are not buttressed by consistent evidence. The AHRQ attempted to address these deficiencies through the development of a National Guideline Clearinghouse, which evaluates guidelines for their basis in valid and current science, and generally operates as a point of access to the innumerable sets of guidelines.¹⁵⁵

One difficulty is that the optimality of guideline utilization depends on the specific procedure at issue, and because medical research is a constantly changing field, guidelines cannot stay up to date for long. Furthermore, the incentives behind guideline development may not be appropriate for goals such as improving physician care, decreasing care-related patient injuries, and simultaneously reducing medical costs. Despite their abundance, guidelines seem to have had limited effect on incentivizing physician behavior.¹⁵⁶ A recent study by Professor Michael Cabana and others attributes this subdued effect primarily to a lack of awareness, familiarity, and agreement with the validity of guidelines and external barriers.¹⁵⁷ The late John Eisenberg, a former Executive Director of the AHRQ, went so

153. Eleanor M. Perfetto & Lisa S. Morris, *Agency for Health Care Policy and Research Clinical Practice Guidelines*, 30 ANNALS PHARMACOTHERAPY 1117, 1119 (1996).

154. See Kathleen N. Lohr et al., *Health Policy Issues and Applications for Evidence-Based Medicine and Clinical Practice Guidelines*, 46 HEALTH POL'Y 1 (1998).

155. See generally INST. OF MED., *supra* note 2, at 151; COCHRANE COLLABORATIONS, <http://www.cochrane.org/> (last visited Feb. 17, 2011); TRIP DATABASE, <http://www.tripdatabase.com/SearchResults.htmlcategoryid=9&sort=t&criteria=guidelines+medicine> (last visited Feb. 17, 2011).

156. See Michael D. Cabana et al., *Why Don't Physicians Follow Clinical Practice Guidelines?: A Framework for Improvement*, 282 JAMA 1458 (1999).

157. *Id.* at 1460–61 (a study showed that 54.5% of physicians surveyed attributed their failure in adherence to medical guidelines to a lack of awareness that relevant guidelines even existed, and another 56.5% attributed their failure in adherence to a lack of familiarity).

far as to suggest that the wide variation in medical practice patterns documented in numerous studies is directly attributable to physicians' widespread reluctance to incorporate evidence-based guidelines into practice.¹⁵⁸ Indeed, other studies observe that much of a clinician's practice is based not on systemic evidence, but on personal experience and observation, traditions, and what she learned in medical school.¹⁵⁹

Under the PRR, these problems would not exist because doctors would have much stronger incentives to become both aware of and familiar with all relevant guidelines. First, as will be explained below, the guidelines would be a product of a much better developmental process, such that doctors would have stronger reasons to trust the guidelines. Second, unlike the legal regime today, the PRR would exempt doctors from liability for following guidelines.

2. Courts' Treatment of Guidelines

Although the functionality of guidelines in improving care, reducing costs, and facilitating sustainable access for the uninsured depends primarily on their acceptance by the medical profession, it also depends on their treatment by the law.¹⁶⁰ Unfortunately, there is not a great deal of empirical knowledge on how courts and lawyers use guidelines because it is difficult to garner complete information on the subject. The information available, however, suggests that the use of guidelines within medical malpractice law can be characterized as largely incoherent and inconsistent.¹⁶¹

In one of the most extensive analyses on the subject to date, Mr. Hyams, Dr. Shapiro, and Dr. Brennan (Hyams study) surveyed medical malpractice attorneys and conducted a case law

158. See Keckley, *supra* note 2 (citing John M. Eisenberg, *Quality Research for Quality Healthcare: The Data Connection*, 35 HEALTH SERVICES RES. 12 (2000)).

159. *Id.*

160. Arnold J. Rosoff, *Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POL. POL'Y & L. 327, 331 (2001), [hereinafter *Medicine and the Law*]; see also Arnold J. Rosoff, *On Being a Physician in the Electronic Age: Peering into the Mists at Point-&-Click Medicine*, 46 ST. LOUIS L.J. 111, 115 (2002) ("[P]hysicians may be wary of following CPGs for fear that the patient care actions they take to comply with CPGs may expose them to liability because of the way CPGs relate, or fail to relate, to traditional legal principles measuring the adequacy of physician performance by reference to standard professional practice.").

161. See, e.g., Rosoff, *Medicine and the Law*, *supra* note 160, at 333.

review between January 1, 1980 and May 31, 1994.¹⁶² One of their main conclusions was that despite finding only thirty-seven published cases referring to CPGs, guidelines anecdotally played a part in settlement negotiations and in decisions to pursue certain cases.¹⁶³ Therefore, although lawyers have certainly known about and appeared to rely on guidelines as a tool, their use of them openly and in court has not been widespread.

I recently continued the case review of guideline use in malpractice suits, covering cases from 2000 to 2010.¹⁶⁴ The Hyams study, taken together with my case review, reveals several important observations. Perhaps most significantly, the case reviews indicate that courts have tended to use guidelines conservatively when they are used at all.¹⁶⁵ This is arguably because of the lack of legislation befitting their expansive use, as will be discussed further below.¹⁶⁶

When guidelines are used in court, they are employed nearly exclusively as evidence of the legal standard of care.¹⁶⁷ Courts, however, virtually never indicate whether guidelines are the *per se* standard of care, as rules of evidence and the general prohibition against hearsay nearly always require an expert witness to be the vehicle for interpreting guidelines.¹⁶⁸ The Hyams study detailed courts' increasing receptivity to the use of guidelines as evidence as learned treatises.¹⁶⁹ It even observed that in some jurisdictions, a party could rely on guidelines more easily than articles from medical periodicals or treatises.¹⁷⁰

162. Andrew L. Hyams et al., *Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective*, 21 J. HEALTH POL. POL'Y & L. 289 (1996).

163. Rosoff, *Medicine and the Law*, *supra* note 160, at 341.

164. The observations are included in greater detail in my recent paper. See Ronen Avraham, *Clinical Practice Guidelines: The Warped Incentives in US Healthcare Systems*, 37 AM. J. LAW & MED. (forthcoming 2011).

165. See Hyams et al., *supra* note 162, at 310. For further discussion, see generally Mello, *supra* note 122.

166. See Rosoff, *Medicine and the Law*, *supra* note 160, at 353.

167. See *id.* at 331–32 (noting that even if a CPG had information relevant to other elements of medical malpractice like causation, damages, and prognosis, “it is hard to see how a court could make use of this information without the accompanying testimony of a medical expert witness”). Nevertheless, as discussed herein, courts and legislatures have made little progress in the use of CPGs for establishing the standard of care *without* the mouthpiece of expert witness testimony.

168. Mello, *supra* note 122, at 660.

169. See Hyams et al., *supra* note 162, at 293–95.

170. See *id.*

My case review and the Hyams study indicate a two-way street in that both plaintiffs and defendants seek to use guidelines. Although, in the Hyams study, plaintiffs using guidelines greatly outnumbered defendants, in my case review only a decade later, the two-way street had become more pronounced. Of the thirty-seven cases the Hyams study found, twenty-eight used guidelines successfully (twenty-two for inculpatory purposes, six exculpatory).¹⁷¹ The rate of success, according to my case review, has slightly decreased.¹⁷²

However, there are limits to these two studies. Namely, we can only evaluate published cases, and the figures do not necessarily reveal whether cases were decided based on the guidelines. Although guidelines can vary widely in quality and scientific basis, courts do not seem to be expending efforts to evaluate their attributes. As Professor Mello observed, “most commentators tend to lump all guidelines together rather than acknowledging the varying levels of empirical certainty that undergird them.”¹⁷³ For example, courts seldom even recognize the differences between evidence-based and consensus-review based CPGs—even when such a distinction might be relevant in deciding the weight to accord particular guidelines.¹⁷⁴

With no legislative directive to rely on guidelines as a standard of care, and with numerous and widely varying guidelines from which to choose, courts understandably struggle in applying guidelines. They face a difficult situation where com-

171. *Id.* at 296.

172. Specifically, I found that

Of the 28 cases found with parties using guidelines in some form, 16 involved use by plaintiffs (as a “sword”) and 12 use by defendants (as “shields”). Specifically, guidelines as swords were used 57% of the time compared to the 78% found by Hyam et al. Guidelines as shields were used 43% of the time compared to 22% found by Hyam et al. Interestingly, in 8 of the 12 cases where guidelines were used for exculpatory purposes, the defendant was successful. This is a 66% success rate compared with 75% Hyam et al. found. In 7 of the 16 cases where guidelines were used for inculpatory purposes, the plaintiff was successful. This is a 43% success rate compared with 75% found by Hyam et al.

Avraham, *supra* note 164, at 18–19.

173. Mello, *supra* note 122, at 680.

174. Rosoff, *Medicine and the Law*, *supra* note 160, at 329 (“[C]ourts, in deciding the weight to accord to CPGs, may find it useful, even necessary, to distinguish between those that are based on EBM and those that are not.”).

peting guidelines are proffered by experts on both sides.¹⁷⁵ Particularly when guidelines are used for inculpatory purposes, the defense will commonly attempt to argue that the guidelines were not applicable to the medical situation at issue. Plaintiffs countering defendants' exculpatory use with a similar argument is also possible. Either way, the common fear that guidelines herald the advent of cookbook medicine appears to be shared by courts.¹⁷⁶

Judges tend to take the position that guidelines are best applied on a case-by-case basis, considering the circumstances of the individual patient. This flexibility, though, produces great uncertainty in malpractice case law. Neither lawyers, physicians, nor patients can know quite where they stand when it comes to the use of guidelines in a case. Professor Mello's observation thus far remains true, that "judicial and academic statements of what CPGs are meant to represent are characterized by confusion and overgeneralization. There exists little agreement about whether CPGs represent a minimum baseline, a not-yet-attained ideal, or a customary practice that lies somewhere in between these two extremes."¹⁷⁷

D. Summary

A lack of appropriate incentives means that optimal guidelines are difficult to obtain. When the government writes guidelines, they suffer from various problems like conflicts of interest and difficulty keeping up with changes in medical research. Meanwhile, hospitals, HMOs, and health insurers are too preoccupied with cost containment to be adequately responsive to patient safety. On the other hand, liability insurers' main motivations are to prevent liability and lawsuits, so their guidelines are overly cautious and disregard cost-effectiveness. As for doctors, they are too vulnerable to contamination by conflicts of interest.¹⁷⁸ Indeed, disclaimers are commonly at-

175. See Mello, *supra* note 122, at 684; see also Mark A. Hall, *The Defensive Effect of Medical Practice Policies in Malpractice Litigation*, 54 L. & CONTEMP. PROBS. 119, 140 (1991).

176. Rosoff, *Medicine and the Law*, *supra* note 160, at 329.

177. Mello, *supra* note 122, at 680.

178. *Quigley v. Jobe*, 851 P.2d 236, 238 (Colo. App. 1992).

tached to guidelines written by all of these entities.¹⁷⁹ As a result, even the most authoritative guidelines cannot be a substitute for expert testimony. Courts do not have to apply guidelines or rely on them to establish a standard of care,¹⁸⁰ and can even refuse to admit guidelines from less authoritative or biased sources as hearsay.¹⁸¹ Given the state of guideline promulgation and their legal weight, it is perhaps preferable that doctors not be bound to comply with guidelines and that they do not extensively adhere to them.¹⁸² Otherwise, the current legal regime's distorted incentives toward defensive and offensive medicine would be exacerbated.

The problems would be resolved, however, if optimal guidelines were promulgated. Because the recent healthcare reform jumpstarted, at both the federal and state level, government encouragement of data collection and guidelines promulgation and implementation, there is hope that the proposed PRR would be met with legislative and judicial sympathy. The most difficult part of an optimal PRR, research and guidelines promulgation, is already happening, so the law need only provide incentives for optimal promulgation and implementation of guidelines. As will be shown in the next section, to achieve this goal, the law should impose liability on PRR firms based on the ex ante perspective only, recognize a private regulatory compliance defense, subject PRR firms to solvency requirements, and allow payers to condition reimbursement on level of care.

179. See Agency for Healthcare Research & Quality, U.S. Dep't of Health & Human Servs., *Web Site Disclaimers*, AHRQ.GOV (June 20, 2003), <http://www.ahrq.gov/news/disclaim.htm> (The American Medical Association calls its guidelines "parameters" to emphasize the discretion left with the doctors and further suggests that all guidelines contain disclaimers renouncing any implied intention to replace doctors' discretion.); see also AM. PSYCHIATRIC ASS'N, STATEMENT OF INTENT: PRACTICE GUIDELINE FOR THE TREATMENT OF PATIENTS WITH ALZHEIMER'S DISEASE AND OTHER DEMENTIAS 7 (2d ed. 2007) (explaining that "the APA Practice Guidelines are not intended to be construed or to serve as a standard of medical care"); Mark Chassin, *Standard of Care in Medicine*, 25 INQUIRY 436 (1988).

180. See *Quigley*, 851 P.2d at 238 (refusing to accept CPG written by liability insurers of the doctor because they were created "by a private insurance company as part of an insurance contract and did not reflect a generally recognized standard of care within the medical profession").

181. *Id.*

182. See Andrew L. Hyams et al., *Practice Guidelines and Malpractice Litigation: A Two-Way Street*, 122 ANNALS INTERNAL MED. 450, 451-52 (1995) (stating that guidelines are not only not determinative in lawsuits, but in fact are used in malpractice cases only infrequently).

III. THE DESIGN OF PRIVATE REGULATION REGIME

The PRR creates a separation of duties by delegating the role of designing guidelines to experts in private firms, and the role of implementing guidelines to medical providers. The private regulators (architects) would design guidelines by synthesizing available scientific evidence, regulatory requirements, and other legal norms, such as those embedded in tort law. Doctors (builders) would execute the synthesized guidelines based on assurances that the guidelines reflect the best practice and that compliance with the evidence-based protocols would shield them from malpractice liability. Just as architects need builders' feedback before they seal their plans, private regulators would communicate with doctors regarding the applicability and wisdom of their guidelines.

A. *The Legal Infrastructure*

The legal infrastructure for the PRR has the following requirements: the evaluation of guidelines from the ex ante perspective, development of contractually standardized care (and reimbursement) levels, recognition of a new legal doctrine called the private regulatory compliance defense that would grant immunity for compliant doctors, creation of some form of intellectual property protection for medical procedures, denial of the state of the art defense, and the imposition of solvency requirements for the private firms. This section takes these requirements into account to further detail the optimal design of the PRR.

1. *Liability from the Ex Ante Perspective*

Under the PRR, medical guidelines would be developed by experts in private firms operating under adequate and appropriate incentives. Providers could be subjected to liability, but only for deviating from the CPGs. This should help prevent errors of execution. More importantly, the firms promulgating these guidelines would be subject to liability only as determined from the ex ante perspective, for writing guidelines that are inefficiently risky.¹⁸³ This should help prevent errors of

183. Firms cannot be sued for writing guidelines that are safe, if for no other reason than that there is no immediate plaintiff. Incentives to write overly safe guidelines will be eliminated by market forces, as these guidelines are more expensive.

planning. The evaluation of the CPGs from the ex ante perspective would eliminate courts' ex post structural uncertainty and biases such as the hindsight bias and the identified-other effect. The ex ante perspective is also important, as Justice Scalia recently observed, because it takes into account all potential beneficiaries, and not just the injured parties before the court.¹⁸⁴ Knowing that they would be subject to review from the ex ante perspective, the private firms would likely develop more efficient, objective, and reliable CPGs.¹⁸⁵

To demonstrate the importance of the ex ante perspective in combating defensive medicine, consider a problem presented when a doctor diagnoses a possible head injury. Should a skull x-ray be ordered? Doctors know that they may be found negligent for failing to order an x-ray if the patient's condition gets worse and can be linked to inadequate diagnosis. As a result, doctors have an incentive to order an x-ray even when they believe it is unnecessary. This is defensive medicine: the ordering of procedures that are not medically indicated but rather are intended to prevent physician liability. Under the PRR, doctors would be immune from liability if they followed CPGs with respect to x-rays, and the PRR firm would not be found liable if an x-ray was not necessary as judged from the ex ante perspective.¹⁸⁶

184. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324–25 (2008) (The ex post nature of state tort laws that require a manufacturer's catheters to be safer—but hence less effective—than the ex ante model approved by the FDA, disrupting the federal scheme. Therefore, excluding common law duties from the scope of pre-emption would make little sense because “a jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.”).

185. See Sheetz, *supra* note 20, at 1360–61, 1377. Several theories of promulgators' liability have been proposed under the current system, and these are likely also to hold under the PRR. *Id.* Ms. Sheetz describes four general bases for the liability of guidelines developers: negligence in compiling or translating data, negligence in assembling the specific aspects of the research into recommendations, lack of good faith, and failure to update and maintain guidelines. *Id.* Though many lament this potential for liability as an impediment to the growth and development of CPGs, the benefit is apparent: promulgators will have the incentive to write guidelines based on appropriately comprehensive testing and analysis, which should lead to more credible and more effective guidelines. *Id.*; see also Blumstein, *supra* note 64, at 1036.

186. See Russell Bell & John Loop, *The Utility and Futility of Radiographic Skull Examination For Trauma*, 284 NEW ENGL. J. MED. 236, 236–39 (1971). In a seminal study analyzing 1500 skull x-rays in cases involving head trauma, Bell and Loop found that ordering routine x-rays in all head trauma cases was not efficient from the ex ante perspective. *Id.* By limiting x-rays to cases with at least one of several discrete clinical symptoms, 434 unnecessary x-rays—and their resulting costs—could have

More generally, consider medical procedure *A* which can treat terminal condition *B*. Further, assume that procedure *A* helps many patients, yet injures and even kills a few of them. In other words, the procedure has side effects, but is still efficient in that it is better than doing nothing, because there is no other procedure that better combats problem *B*. Patients with problem *B* must then consider whether they are willing to trade a significant risk of death from *B* in exchange for a probable improvement in their quality of life, and a much smaller risk of suffering injury or dying from *A*.

A current example of this analysis revolves around denosumab, an innovative new drug touted as potentially the most effective treatment for osteoporosis yet.¹⁸⁷ Although the drug is believed to treat a disease which is a major cause of death for the elderly, it has also been known to cause eczema and skin infection in some patients.¹⁸⁸ Despite these potential side effects, many patients would be better off taking the drug than letting the disease take its course. Guidelines incorporating denosumab would be attractive from the *ex ante* perspective, even in the total absence of any *ex post* tort remedy.¹⁸⁹

Where the use of procedure *A*, incorporating the denosumab drug in the example above, has the highest positive expected value to all class members, imposing *ex post* tort liability can decrease net welfare. The higher cost of running a tort liability system with its deadweight administrative costs and high rates of error might prevent procedure *A* from being implemented, in spite of its value to many patients. Applying tort liability from an *ex post* perspective can therefore not only increase the

been avoided. *Id.* Although not ordering the extra 434 x-rays makes sense *ex ante*—this approach would miss one valid skull fracture out of 434 which could not have been detected without an x-ray—doctors will continue to order unnecessary tests to safeguard against the 1/435 chance of liability. *Id.* Drs. Bell and Loop's seminal study has sparked worldwide interest regarding the place of skull x-rays in the management of patients with head injuries. *Id.*; see also P.A.M. Hofman et al., *Value of Radiological Diagnosis of Skull Fracture in the Management of Mild Head Injury: Meta-Analysis*, 68 J. NEUROLOGY, NEUROSURGERY, & PSYCHIATRY 416 (2000) (concluding that recent meta-analysis concluding X-rays are of little value).

187. Thomas H. Maugh II, *New Osteoporosis Drug Shown to Reduce Spinal Fractures*, L.A. TIMES, Aug. 12, 2009, <http://articles.latimes.com/print/2009/aug/12/science/sci-bone-drug12>.

188. Miranda Hitti, *New Osteoporosis Drug Coming*, WEBMD HEALTH NEWS (Aug. 11, 2009), <http://www.emedicinehealth.com/script/main/art.asp?articlekey=104603>.

189. *Id.*

costs of medicine, but can also make the relevant class members worse off as a whole.

Of course, more can always be said about the exact contours of the legal regime. For example, in lawsuits against providers for deviating from CPGs, it would be conceivable to shift the burden of proving non deviation from CPGs onto providers. The law has developed in a way to shift the burden of proof in various contexts. The doctrine of *res ipsa loquitur*, and some versions of market share liability, do exactly that. Additionally, in lawsuits against private CPG firms, it is possible to mimic structural aspects of class actions or public nuisance.

2. *Contractually Standardized Care and Reimbursement Levels*

The previous sections explained how liability from the *ex ante* perspective can dilute PRR firms' incentives to promulgate overly defensive CPGs. But this is not enough. Because payers (HMOs, PPOs, Medicare) thereby bear the extra costs of defensive, and therefore expensive, CPGs, there is a danger that hospitals and PRR firms will collude against payers and contract for guidelines which are too defensive, thereby externalizing costs onto payers. One possibility would be to allow payers to sue PRR firms for writing guidelines that are too expensive.¹⁹⁰ Our current tort law does not allow for such claims because, in most cases, when the defendant incurs wasteful social costs by acting too cautiously, there is no direct victim.

The best way to address this issue is through contract. Payers would reimburse hospitals for patient care based on the quality and cost-effectiveness of the CPGs. If the CPGs adopted by the hospital are too defensive, the reimbursement would decrease, reflecting the lack of necessity in such guidelines. For example, hospitals with CPGs advising them to administer CT scans every time a patient faints will get significantly lower reimbursements per scan than hospitals with CPGs advising them to scan only when several other clinical markers are present. If payers were relatively informed and were to possess some degree of market power, this contractual mechanism could make the PRR firms internalize not only error costs, but also the costs of excessive care.

190. Allowing non victims to bring suit (as suggested at the end of the previous section) will also enable suits for overly safe CPGs.

There are at least three reasons to be optimistic about such contractual arrangements. First, the opposite phenomenon, doctors adjusting their practice based on reimbursement payments, has been around for years,¹⁹¹ suggesting that data about the supply curve of medical procedures exist. Second, these contracts may be cheap and feasible because of the voluntary nature of such a system.¹⁹² Third, various insurance companies have already launched programs reimbursing doctors based on the quality of their procedures.¹⁹³

If payers were uninformed or did not possess enough market power to structure the reimbursement scheme based on the quality and cost effectiveness of the guidelines, though, then some form of government regulation would be necessary.

3. Private Regulatory-Compliance Defense

Litigation against doctors would probably become simpler and cheaper under a PRR system like this because doctors who comply with PRR guidelines would be immune under the private regulatory-compliance defense, and doctors who do not comply with the guidelines would be liable. I call it the private regulatory-compliance defense because, similar to the current doctrine of regulatory-compliance defense, compliance with guidelines would be a defense against the tort suit. However, in contrast with the doctrines of statutory or regulatory compliance, which provide that compliance with a statute or regulation is of evidentiary value to the question of negligence, but do not preclude a finding of negligence,¹⁹⁴ the private regulatory-compliance doctrine would make compliance an absolute defense. From a policymaking perspective, a private regulatory-compliance defense would enable doctors to stop per-

191. See, e.g., Editorial, *The Doctor Payment Follies*, N.Y. TIMES, June 5, 2010, at WK9, available at http://www.nytimes.com/2010/06/06/opinion/06sun1.html?_r=1&ref=global-home.

192. See Clark C. Havighurst, *Practice Guidelines for Medical Care: The Policy Rationale*, 34 ST. LOUIS U. L.J. 777, 798 (1990).

193. Prometheus System is one such example. See *infra* note 288 and accompanying text.

194. See RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 16 (2005); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 (1998). In several states, when a product manufacturer complies with a federal or state regulatory standard, it entitles the manufacturer to a rebuttable presumption against a finding of negligence or product defect. See *supra* notes 79–80.

forming defensive medicine by shielding them from liability if they followed a private regulator's guidelines. As was already mentioned, most states have not adopted the defense of government regulatory compliance—not unreasonably, given that current guidelines are not set at optimal levels, instead tending to operate as minimum floors.

The guidelines would not only serve doctors as a complete shield, but could also be wielded against them as a blunt sword: compliance with CPGs would totally insulate the physician from liability, but failure to comply with CPGs would not be determinative of negligence. A physician would still have the opportunity to convince the court that deviation from the CPG was clinically justified. Granted, given the respect CPGs may attain in court, the burden of persuasion may be heavy. Still, the blunt sword property of CPGs would benefit doctors by preserving their autonomy to deviate from the guidelines.

The private regulatory-compliance defense is similar to granting doctors immunity from malpractice. As mentioned above, the idea of immunity for doctors who followed guidelines garnered support from President Obama, the president of the American Medical Association, and numerous scholars, was part of various demonstration projects in the past, and is part of a current AHRQ-funded demonstration project that emerged from the 2010 ACA law.¹⁹⁵ Under the PRR, however, CPGs promulgated from the ex ante perspective would be optimal, not just floors. Therefore it would be justifiable to allow CPGs to serve both as a shield and as a blunt sword, rather than merely a shield, as has been suggested by the movements mentioned above.

4. *Intellectual Property Protection for Guidelines*

One may argue that PRR firms would lack adequate incentives to develop guidelines continually, fearing other PRR firms and providers may free ride on their efforts in the absence of intellectual property protections. Yet it is possible to imagine that PRR firms could rely on business models that would ren-

195. See *supra* Introduction. For examples of works supporting a safe harbor, see Blumstein, *supra* note 64; Havighurst, *supra* note 192, at 798; 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, 990 (2005). For works objecting to safe harbor, see Mello, *supra* note 122, at 686–90, 700–02.

der intellectual property protection unnecessary. For example, by bundling support services with licensing of CPGs, PRR firms might be able to deter free riders. However, assuming that intellectual property protection would be necessary, what form and shape would it take?

Current intellectual property laws may be insufficient to protect CPGs under the PRR. Copyright law protects only the expression of the work, not underlying ideas and facts.¹⁹⁶ But it is the factual information (that is, how to conduct a heart surgery on morbidly obese patients), and not the expression (the specific style in which the information is conveyed), that would require protection under the PRR. Trade secrecy may also be insufficient because a major component of the PRR would be litigation regarding the optimality of CPGs. CPGs would become public during litigation, and would no longer be protectable as trade secrets. On the other hand, litigation usually is not immediate, and even then CPGs could be submitted under seal.

On its surface, patent law shows potential. After all, medical procedures are occasionally patented. As recently as 1996, Congress considered prohibiting medical procedure patents. Instead, Congress “opted to deprive patent holders of remedies against health care practitioners,” while continuing to subject non clinicians to liability for use of a patented process for commercial purposes.¹⁹⁷ Nevertheless, there are several other impediments that prevent the PRR from fitting within current patent law. First, filing for a patent is an intricate process that would require transforming medical guidelines to “patent claims,” which would be difficult for a PRR firm. Second, obtaining a patent is a lengthy, time-consuming task, and prosecution of patents can take years. The whole point of the PRR is to become a dynamic alternative to the current regime. Under the current regime, it takes seventeen years to incorporate good research into practice. Under the PRR, guidelines would be updated much faster to ensure optimal healthcare. If it takes months or years to obtain patent protection, the time savings would be greatly diminished. Third, the main standards for patent review—novelty and nonobviousness—do not neatly fit

196. See 17 U.S.C. § 102(b) (2006) (codifying the holding in *Baker v. Selden*, 101 U.S. 99 (1879)).

197. Aaron S. Kesselheim & Michelle M. Mello, *Medical-Process Patents—Monopolizing the Delivery of Health Care*, 355 NEW ENGL. J. MED. 2036, 2037 (2006).

the requirements of the PRR.¹⁹⁸ Nonobviousness implies that new patents could not be granted for a variation or combination of previously known guidelines unless it was proven to be non-trivial. This again would run in the face of the dynamic nature of the PRR, in which CPGs are continuously updated based on previous guidelines and new research.

The best solution would be a *sui generis* regime legislatively customized for the PRR. *Sui generis* regimes are not unknown within intellectual property law. They exist for mask works,¹⁹⁹ ship hull designs,²⁰⁰ databases (in the European Union only),²⁰¹ designs (Chapter 16 to the Patent Act),²⁰² and plant varieties.²⁰³ While fully describing the *sui generis* regime goes beyond the scope of this paper, several points may be made here. First, such a regime should prohibit both copying (like copyright) and independent creation or development (like patents). Second, such a regime should provide shorter protection than current patent law. Plausibly, at the end of the protection period, the information would enter the public domain. Third, the regime should apply standards of review that are distinct from those applied under current patent law. Fourth, such a regime should borrow the notion from current patent law permitting remedies only against non practitioners.²⁰⁴ The provisions

198. U.S. Patent and Trademark Office, *General Information Concerning Patents*, USPTO.GOV, <http://www.uspto.gov/web/offices/pac/doc/general/#novelty> (last modified Jan. 2005).

199. 17 U.S.C. § 904 (2006).

200. 17 U.S.C. § 1301 (2006).

201. Council Directive 96/9, 1996 O.J. (L 077) 20 (EC) (database protection).

202. 35 U.S.C. § 171 (2006).

203. 35 U.S.C. § 161 (2006).

204. Although the private benefits for providers specifically receiving malpractice immunity will generally be large enough to justify paying for guidelines, there would still exist a temptation for providers to free ride on PRR firms' efforts. Thus, hospitals may choose not to pay for the guidelines but simply to adopt them. A *sui generis* protection of the guidelines should, in theory, be a strong enough shield against providers' incentive to free ride. Yet, because it may be so difficult to detect violations in practice, such a regime might not be a strong enough protection. To prevent this potential problem, hospitals could be required to purchase guidelines in a free market. Therefore, depending on how the market for private regulation evolves, there may be an additional requirement: Providers—that is, hospitals, doctors' groups, and so on—should be forbidden from operating without first acquiring guidelines. Another option would be to make guidelines inadmissible in court unless the hospital legally purchased them. Hopefully, losing the liability protections of the guidelines because they did not properly license them would outweigh the benefit from free-riding the guidelines.

should be tailored to achieve the dual goals of a dynamic regime allowing the fast implementation of state of the art research and the preservation of the initial incentives to synthesize that research into these CPGs.

A problem may arise if PRR firms receive *sui generis* protection and then hold out for an unreasonably high price to license those guidelines, thereby frustrating the efficient distribution of innovation. This problem would be bothersome in the medical context because much of the innovation is likely to be cumulative and built upon past innovations. Holdout problems may be mitigated by limiting the lifespan of the protection so that firms cannot hold on to CPGs for too long before having to pay a renewal fee.²⁰⁵ Although instituting more frequent renewal fees will not solve all holdout problems, the additional overhead may encourage firms to sell their licenses sooner in an effort to cover renewal costs.²⁰⁶

Another problem with providing protection to CPGs is the threat of complicating medical practice, increasing costs, restraining the dissemination of new information throughout the scientific community, and overly restricting patients' access to therapeutic and diagnostic procedures. Indeed, this is exactly why the American Medical Association objected to the expansion of patent law into "purely process" medical guidelines.²⁰⁷ First, even if intellectual property protection is required, providing short-term protection can mitigate this concern. Second, there are other creative solutions: The private regulatory-compliance defense discussed in the previous section could, for example, be structured to apply only to those care providers who have paid for the guidelines they followed. If smartly structured, such a solution may well prevent free riding without hampering innovation. Lastly, as mentioned above, it is not clear whether intellectual property protection is required at all. It could be that firms can design a business model that prevents free riding. Indeed, over the past decade a market for CPGs where multiple actors profit from distributing

205. See Ian Ayres & Gideon Parchomovsky, *Tradable Patent Rights*, 60 STAN. L. REV. 863, 865 (2007).

206. Another problem that could emerge in the context of clinical guidelines is patent thickets, which are multiple patents covering a single product or technology. For various solutions to this problem see *id.* at 876-77.

207. See Kesselheim & Mello, *supra* note 197, at 2036.

CPGs has emerged. This market is a proof that intellectual property protection is not mandatory for the existence of a PRR.

5. *Not Recognizing the State of the Art Defense*

It would also be important for the PRR that society not recognize the state of the art defense. Some states presently provide defendants with immunity from liability if they can show that their product was up-to-date when it was first introduced to the market. Traditionally, this defense was only relevant for product liability cases,²⁰⁸ but in recent years similar logic has also become part of medical malpractice case law.²⁰⁹ Not recognizing this defense would incentivize private regulators to update guidelines continually to reflect ongoing research, while giving practitioners reason to rely on the guidelines.²¹⁰

The benefit is clear when one considers the modern day overflow of unreliable information for individual doctors to screen and absorb. Professor Ian Ayres recently calculated that a cardiologist who wants to keep up with progress in the field would have to read more than ten articles every day, including weekends, spending two and a half hours a day reading solely about coronary diseases.²¹¹ The PRR, without the state of the art defense, solves this problem. Unlike the current tort regime, which unrealistically requires doctors to keep up with their fields while still seeing patients and sometimes generating their own studies, under the PRR, a group of experts in the field would continuously update the guidelines according to the most up-to-date research.

Furthermore, PRR firms would likely provide optimal regulations because of competition and informational advantages.

208. Indeed, it is reflected in the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §§ 1–2 (1998).

209. Bruno Deffains & Dominique Demougin, *Customary Versus Technological Advancement Tests*, 28 INT'L REV. L. & ECON. 106, 111 (2008).

210. For an interesting analysis on the pros and cons of eliminating the state of the art defense, see Omri Ben-Shahar, *Should Products Liability Be Based on Hindsight?*, 14 J.L. ECON. & ORG. 325 (1998). Professor Ben-Shahar argues that where it is “socially important and at the same time feasible to promote post-distribution safety efforts . . . and yet it is difficult to monitor such efforts directly because of lags in the public’s knowledge of the defects,” eliminating the defense would be superior to keeping it. *Id.* at 350–51.

211. IAN AYRES, *SUPER CRUNCHERS: WHY THINKING-BY-NUMBERS IS THE NEW WAY TO BE SMART* 92 (2007).

The existence of multiple PRR firms would encourage experimentation with various procedures and arguably only the fittest would survive—competition would drive the best procedures and regulatory regimes to the forefront of medical practice. A PRR firm would have superior capacity and motivation to learn from its environment and correct its policy mistakes in a timely fashion. Firms should be able to find context-specific data on medical procedures, which could be used to analyze cost-benefit and risk-risk tradeoffs, and then apply those findings in future guidelines. If the firms cannot rely on the defense that their guidelines were state of the art when they were issued, they will be all the more encouraged to incorporate all new medical research and techniques into their guidelines.

6. *Guaranteeing Private Regulators' Solvency*

Finally, regulation of the solvency of the PRR firms would guarantee that they would refrain from developing guidelines that are excessively risky. Without this guarantee, PRR firms might be tempted to offer precarious guidelines, knowing that if worse came to worst, they could seek bankruptcy protection, essentially passing costs on to the patients, shareholders, and creditors. Requiring firms to have minimum assets or liability insurance can force them to bear directly the costs of their risky behaviors, causing them to take an efficient level of risk.²¹² Unfortunately, minimum asset requirements may impede some potential PRR firms with minimal capital from engaging in private regulation. Liability insurance requirements tend to improve parties' incentives to reduce risk only if insurers can observe levels of care, and also dilute incentives to reduce risk when insurers cannot observe levels of care. Therefore, when insurers cannot observe the level of care, minimum asset requirements should be enforced.²¹³

7. *The Value of Constrained Pluralism*

In addition to the benefits of PRR already mentioned—increasing quality of care while reducing costs, thereby facili-

212. Steven Shavell, *Minimum Asset Requirements and Compulsory Liability Insurance as Solutions to the Judgment Proof Problem*, 36 RAND J. ECON. 63, 64 (2005) [hereinafter *Minimum Asset Requirements*]; Steven Shavell, *The Judgment Proof Problem*, 6 INT'L REV. L. & ECON. 45 (1986).

213. Shavell, *Minimum Asset Requirements*, *supra* note 212, at 63.

tating sustainable access—private regulation of CPGs will also facilitate something which is missing from the healthcare system: constrained pluralism. As was described above, there are many CPGs written by different entities. The large number of CPGs leads doctors to ignore them and courts to struggle with them.²¹⁴ There are very few CPGs—those written by doctors' associations—which gain relatively high respect. Even that respect is only from doctors, not courts, and remains only temporarily, until the guidelines become outdated. Such CPGs, as argued above, are also not necessarily optimal because they are written behind closed doors and under the wrong incentive structures.

Under the PRR, in contrast, several CPGs would be developed. I call it constrained pluralism because market forces would support more than one set of guidelines, but not many more. Thus, pluralism and decentralization would be encouraged by the promulgation of competing CPGs. The nature of medicine is such that reasonable minds can disagree about the appropriate care, and there is no reason to limit care to the official guidelines of the government, the medical specialty societies, or insurance companies.²¹⁵

B. Implementation

As discussed above, for the PRR to thrive, no more than six elements (but potentially fewer) need to be incorporated into the legal infrastructure: (1) evaluating guidelines *ex ante*, (2) empowering payers to dictate reimbursement based on the quality and cost-effectiveness of the guidelines, (3) acknowledging the private regulatory-compliance defense, (4) providing intellectual property protection for medical process, (5) not recognizing the state of the art defense, and (6) imposing solvency requirements on PRR firms.

One way to implement all of these elements is by *sui generis* legislation. However there is a real question as to whether legislation is required at all. After all, a market for CPGs already exists in many ways, even if not in the way envisioned here. It is quite conceivable that courts can carry a lot of the weight needed to implement the PRR in full. Common law courts

214. As mentioned above, courts have developed the respectable minority rule to deal with the problem of conflicting practices. See KING, *supra* note 63, at 66–69.

215. Havighurst, *supra* note 192, at 801.

clearly have the authority not to recognize the state of the art defense; indeed, most of them do not. Courts can acknowledge the private regulatory-compliance defense by applying the same rationales used in the normal doctrine of regulatory compliance defense or in the preemption doctrine. Another potential means of implementation is for courts to invoke the 1972 federal law which provides immunity to doctors following PSROs' promulgated guidelines.²¹⁶ Market forces, through smart business planning and sophisticated contracting, could carry some of the weight required to implement intellectual property protection and an optimal reimbursement structure. Thus, the question really is whether courts can impose liability on PRR firms. And the answer is probably yes.

Courts have been willing to impose liability on standard setters, certifiers, and accreditors, which are fairly analogous to PRR firms.²¹⁷ A variety of causes of action generally classifiable as negligence claims have resulted in findings of liability against these players.²¹⁸ The most basic is an allegation of neg-

216. For a discussion about PSROs, see *supra* Part II.B.1.c. Professor Blumstein argued recently that private firms can seek to contract with QIOs, enabling doctors who followed their guidelines to enjoy their statutory immunity, even outside of Medicare and Medicaid programs. See Blumstein, *supra* note 64, at 1038–44. A problem with this approach is that the federal law which exempted providers from following guidelines may also exempt QIOs. See 42 U.S.C. § 1320c-6(a), (b) (2006). However, if PRR firms were considered to be furnishing “professional services,” rather than providing information, then PRR firms would be subject to negligence. See *id.*

217. For liability on standard setters, see, for example, *King v. National Spa & Pool Institute Inc.*, 570 So. 2d 612, 616 (Ala. 1990) (holding that NSPI’s voluntary undertaking to promulgate minimum safety design standards for pools “made it foreseeable that harm might result to the consumer if it did not exercise due care”). For liability on certifiers, see, for example, *Hanberry v. Hearst Corp.*, 81 Cal. Rptr. 519, 523 (Cal. Ct. App. 1969) (finding Good Housekeeping magazine liable for negligent misrepresentation because the magazine represented that the shoes plaintiff bought were “safe”). For liability on accreditors, see *Peterson v. Multnomah County School District. No.1*, 668 P.2d 385 (Or. Ct. App. 1983). It should be noted that liability for accreditors is less common. See, e.g., *Louisiana v. Joint Comm’n on Accreditation of Hosps., Inc.*, 470 So. 2d 169, 175–77 (La. Ct. App. 1985) (refusing to impose liability on the Joint Commission on Accreditation of Hospitals (JCAH) for failing to discover that a renal unit water purification system had violated JCAH’s own standards, resulting in injuries to patients).

218. Other theories of liability, including strict product liability and breach of warranty, have been unsuccessful when levied against such actors. Holly Piehler Rockwell, Annotation, *Products Liability of Endorser, Trade Association, Certifier, or Similar Party Who Expresses Approval of Product*, 1 A.L.R. 5th 431 (1992).

ligence in the performance of the applicable service.²¹⁹ For example, in *State of Louisiana v. Joint Commission on Accreditation of Hospitals, Inc.*, the Commission (JCAH) failed to discover a standards violation in the renal unit water purification system.²²⁰ There, the negligence claim failed because the court ruled that any duty to the patients was only incidental.²²¹ At least one commentator, however, finds that position “wholly unconvincing as a general legal principle.”²²² As Professor Schuck argued, the purpose of the JCAH accreditations was patient protection, the goal was to induce reliance on those accreditations, and increased risk of harm to patients relying on those services was easily foreseeable.²²³ These general principles of increased risk and detrimental reliance could be, and have been, applied to any of the three classes of service providers at issue.²²⁴

Another form of basic negligence claim possibly giving rise to liability is negligent misrepresentation.²²⁵ The legal theory supporting such a claim is essentially the same as that for a negligent performance claim.²²⁶ A standard setter, certifier, or accreditor who misrepresents the quality of some product could be held liable if that misrepresentation is made negligently with respect to its falsity, an allegation which would ultimately hinge in all likelihood on the quality of performance. Significantly, other allegations of negligence—such as negligent failure to warn and negligent promulgation of standards—have relied on similar arguments.²²⁷

Courts have also relied on Section 324A of the Restatement (Second) of Torts—recently coded as Section 43 in the Restatement (Third) of Torts—to find that a duty of care, and often

219. RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 42 (Proposed Final Draft No. 1, 2005); Rockwell, *supra* note 218, § 2(a).

220. 470 So. 2d at 177.

221. *Id.* at 178.

222. Peter H. Schuck, *Tort Liability to Those Injured by Negligent Accreditation Decisions*, 57 LAW & CONTEMP. PROBS. 185, 189 (1994).

223. *Id.*

224. The principles have in fact been applied to standard setters, see *Wissel v. Ohio High School Athletic Association*, 605 N.E.2d 458 (Ohio Ct. App. 1992), and to inspectors, which may also be analogized to private regulators, see *Canipe v. National Loss Control Service Corp.*, 736 F.2d 1055 (5th Cir. 1984).

225. Rockwell, *supra* note 218, § 2(a).

226. *See id.*

227. *See id.*

liability, exists in the accreditation, certification, or standard setting field.²²⁸ This is true especially when standard setters seemed to have some control over the manufacturer's implementation of the standards.²²⁹ Section 324A imposes a duty of care on a defendant when a defendant undertakes to render services to another which the defendant should recognize are necessary for the protection of a third party, the plaintiff.²³⁰ The increased risk and detrimental reliance principles described above are directly evident in Section 324A.²³¹

To this point, the development of liability for these service providers has been entirely court driven.²³² Given the current trends in these areas, it is reasonable to assume that courts would be willing to impose liability on private regulators under PRR, as their task is very similar to those of standard setters, certifiers, or accreditors, and because the influence of CPGs on the practice of medicine is significant, particularly in PRR.²³³

But would courts apply liability from the *ex ante* perspective? Courts routinely apply something similar to the *ex ante* perspective when they employ the risk-utility test in product liability, as reflected in Section 2(b) of the Restatement (Third) and the cases it cites.²³⁴ However, the risk-utility test has also

228. *Id.*

229. See *Snyder v. Am. Ass'n of Blood Banks*, 676 A.2d 1036 (N.J. 1996) (finding that because the American Association of Blood Banks (AABB), which sets the standards for every blood bank in the U.S., had tremendous influence over the blood banking industry, it could be held liable to a third party who received a blood transfusion contaminated with HIV).

230. See *King v. Nat'l Spa & Pool Inst. Inc.*, 570 So. 2d 612, 616 (Ala. 1990) (holding that NSPI's voluntary undertaking to promulgate minimum safety design standards for pools made it foreseeable that harm might result to the consumer).

231. RESTATEMENT (SECOND) OF TORTS § 324A(a), (c) (1965).

232. Legislatures have not shown particular interest in extending tort liability to this area. Further, some legislatures have expressly restricted products liability to parties in the chain of manufacture and sale, precluding such liability against standard setters, certifiers, or accreditors. See *e.g.*, S.D. CODIFIED LAWS § 20-9-9 (2004).

233. Cf. Kimberly J. Todd, Note, *Snyder v. American Association of Blood Banks: Expansion of Trade Association Liability—Does It Reach Medical Societies?*, 29 U. TOL. L. REV. 149 (1997) (arguing that trade association liability could be expanded to medical societies).

234. Section 2(b) says that a product "is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller . . . and the omission of the alternative design renders the product not reasonably safe." RESTATEMENT (THIRD) TORTS: PRODUCT LIABILITY (1998). See also *id.* cmt.d.

been harshly criticized for being difficult to implement.²³⁵ Moreover, courts do not always apply an *ex ante* perspective when analyzing whether standard setters or manufacturers were negligent, essentially creating a situation where individual juries applying varying laws in different jurisdictions impose conflicting requirements on manufacturers.²³⁶ Therefore, it is not at all clear that, even if courts were to impose liability on PRR firms, they would do it correctly, from the *ex ante* perspective.²³⁷

A possible alternative to legislating a full-blown PRR reform addressing the six components discussed above could be simply to legislate a new tort called negligent promulgation of guidelines, explicitly defined from the *ex ante* perspective. This step would be an improvement over the current regime because it would distance courts from an identified patient and an identified doctor and make them face statistical patients and statistical doctors. Hopefully, courts would get it right within a reasonable time. Otherwise, health courts or other types of panels of experts would be necessary.

IV. EVALUATION IN LIGHT OF OBJECTIONS

This Part evaluates the PRR in response to various concerns raised with earlier drafts. The concerns are divided into four groups: concerns with PRR as compared to alternative regimes, practical medical concerns, legal concerns, and political concerns.

A. *The PRR Compared to Alternative Regimes*

1. *What is the Difference Between PRR and Liability for Gatekeepers?*

One may wonder how the PRR is different from the liability faced by accountants, tax lawyers, credit rating agencies, and other gatekeepers. There are several differences. First, in most

235. See *e.g.*, *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008); James A. Henderson, Jr., *Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication*, 73 COLUM. L. REV. 1531, 1534 (1973); W. Kip Viscusi, *Jurors, Judges, and the Mistreatment of Risk by the Courts*, 30 J. LEGAL STUD. 107, 116 (2001).

236. See, *e.g.*, *Dawson v. Chrysler Corp.*, 630 F.2d 950, 962 (3d Cir. 1980).

237. See *Gardner v. Chrysler Corp.*, 89 F.3d 729, 736–37 (10th Cir. 1996) (expressing concern that a jury will ignore extent to which plaintiff's proposed design decreases overall safety, even though it avoids injury to plaintiff).

cases, gatekeepers provide merely a stamp of approval indicating that an industry player meets minimum standards of care. Such is the case for accountants who certify financial reports, law firms that approve business practice, etc. PRR, in contrast, is not about meeting minimum standards, but about meeting optimal standards. Second, although gatekeepers are either not held liable or are held jointly liable with the main tortfeasor, under PRR the gatekeeper-like private regulator would be held liable, but the main tortfeasor would be immune from liability, provided that she complied with the regulation.²³⁸ Third, under the PRR the private regulator would be held liable for inefficient guidelines viewed from the ex ante perspective, whereas gatekeepers are normally held liable, if at all, based on the ex post perspective.

2. *What is the Difference Between PRR and Self-Regulation?*

The PRR is also different from self-regulation. Industry self-regulation is the “voluntary association of firms to control their collective behavior” through self-policing arrangements.²³⁹ In recent years, a number of different industries have created self-policing programs in an attempt to forestall costly government regulation.²⁴⁰ In some cases, these self-policing programs even mature into full-fledged self-regulatory organizations (SROs) with formal rules and dedicated resources.²⁴¹ In addition, thousands of standard-setting organizations promulgate tens of

238. I could find only one case of a negligence claim brought against Underwriters Laboratories Inc., which they easily won. See *Dekens v. Underwriters Laboratory Inc.*, 132 Cal. Rptr. 2d 699 (Cal. Ct. App. 2003). Despite the economic meltdown, Congress is still grappling with imposing liability on credit rating agencies. See Rachelle Younglai, *SEC, Congress Eyes Increasing Liability of Credit Rating Agencies*, INSURANCE JOURNAL (July 16, 2009), <http://www.insurancejournal.com/news/national/2009/07/16/102271.htm>. Even the Sarbanes-Oxley Act, Pub. L. No. 107-204, 116 Stat. 745 (2002), which was enacted after the Enron crisis, instructed the Securities and Exchange Commission to further regulate accountants, lawyers, and investment banks, but fell short of imposing liability. See generally Assaf Hamdani, *Gatekeeper Liability*, 77 S. CAL. L. REV. 53 (2003).

239. Michael J. Lenox, *The Role of Private Decentralized Institutions in Sustaining Industry Self-Regulation*, 17 ORGANIZATION SCI. 677, 677 (2006)

240. *Id.*

241. See *id.*

thousands of standards based on principles developed by the American National Standards Institute.²⁴²

Private regulation is both similar to and different from industry self-regulation and standard setting. Similar to these SROs and standard-setters, the PRR firms would utilize private information from industry participants to inform the guideline creation process with little government agency interference. Additionally, the private regulation regime would have built-in compliance monitoring. However, unlike participation in self-regulation, where disclosure of crucial regulatory information is completely voluntary, physicians in a PRR scheme would be forced to disclose information to be eligible for the liability shield. As a result, in contrast to self-regulation, which relies on internal auditing and self-reporting to detect guideline deviation, industry compliance with guidelines in the PRR would be virtually ensured through the offer of liability protection. Lastly, and most importantly, whereas SROs and standard setters usually set minimum standards to be met by the industry players, guidelines under the PRR would be set at the optimal level because private regulators would face tort liability for promulgating suboptimal guidelines, and face competition preventing them from promulgating guidelines that are too expensive.²⁴³

3. *Why Not Strict Liability or No-Fault Regimes?*

Instead of gatekeeper liability or self-regulation, others may wonder why we should not adopt a traditional strict liability regime or a no-fault regime instead of the PRR. After all, under both these regimes, hospitals would internalize all the accident costs associated with their care level and activity level deci-

242. See *ANSI Standards Activities: Domestic Programs Overview*, ANSI.ORG, http://www.ansi.org/standards_activities/domestic_programs/overview.aspx?menuid=3 (last visited Feb. 19, 2011).

243. Some courts impose liability on standard setters by applying the Restatement (Second) of Torts § 324A, especially when it seems the setter has some control over the manufacturer's implementation of the standards. That section imposes a duty of care on a defendant toward a plaintiff when a defendant undertakes to render services to another which the defendant should recognize are necessary for the protection of a third party, the plaintiff. See, e.g., *King v. Nat'l Spa & Pool Inst. Inc.*, 570 So. 2d 612, 616 (Ala. 1990) (holding that a standard setter's voluntary undertaking to promulgate minimum safety design standards for pools made it foreseeable that harm might result to the consumer).

sions. Moreover, under both regimes, patients would be compensated more often than under PRR.

There are several reasons why the PRR is superior to strict liability and no-fault. First, although strict liability would cause hospitals to internalize the cost of medical errors, it would not force them to internalize the cost of healthcare. Thus, hospitals would have incentives to overuse resources, whether on defensive or offensive medicine grounds. Second, the major advantage of the PRR is that it provides the legal infrastructure necessary to enable market-regulated guidelines to evolve optimally. It is true that a web of contracts between payers, providers, insurers, and patients could potentially duplicate the benefits of the PRR. However, as described below, this sort of system is unlikely to emerge.

Third, PRR is likely to compensate victims more efficiently. Although both strict liability and no-fault would incur lower administrative costs per claim, both would encourage more claims, meaning that overall savings are not guaranteed. Additional claims filed under strict liability or no-fault could still be a good thing if these additional claims were meritorious. Compared to a properly functioning PRR, though, the additional claims are unlikely to be meritorious, making hospitals insurers of non-negligence accidents. For such a system to be efficient, one would need to show that the hospital is a better insurer than the private insurers that patients can find in the market. Lastly, under the PRR, victims of doctors who did not follow guidelines would be compensated more frequently than ever before and in a faster process. Because the guidelines would likely be efficient, compensating these victims would surely be the correct outcome. In that sense, the proposed regime is a huge improvement even on compensation grounds.

4. *Why Do We Need Legislation? Why Do We Not See It in the Market Already?*

One may wonder why parties do not contract for a PRR arrangement themselves. If the PRR is so superior, why has it not already been developed privately?

There are four ways PRR imitations could emerge through contracting. First, managed care organizations (MCOs) could be held liable for any suboptimal care they direct. Second, liability insurers could be required to pay for the cost of medical services they provide. Third, the government could assume

both the cost of care and cost of liability. Fourth, a totally new entity, a private regulator, could be formed voluntarily and bear both the cost of care and the cost of liability.

What is common to all four solutions is the internalization of externalities. As was explained above, one of the major problems with current guidelines is that they are written by entities that only bear one type of cost. For instance, HMOs bear only the cost of providing care, liability insurers bear only the cost of liability, and doctors' associations bear no costs at all. As a result, every entity has an incentive to pass some costs onto other parties. Like the entities in the four hypothetical situations described above, PRR firms would bear both the cost of providing care and the cost of liability. After discussion of each of these four options in more detail below, however, the implausibility of the four situations will be apparent.

a. MCOs as Cost Internalizers

During the 1990s, MCOs came to dominate America's health insurance industry.²⁴⁴ Often, an MCO, not the actual care provider, controls the care a patient receives.²⁴⁵ It therefore makes sense to hold MCOs liable for suboptimal care caused by their increased control. There are several reasons why this has not happened.

First, MCO liability cannot emerge spontaneously because several structural problems prevent patients from effectively contracting for optimal care. For example, most HMOs that grew in the 1990s were network models for which contractual liability would not work easily. Other structural problems include patients' inability to specify treatment choice at the time of contracting, patients' inability to determine *ex ante* the level of physician expertise, and the distressed position patients are often in when they contract for medical care.²⁴⁶ In other words, too much medical care relies on "non-contract-amenable actions taken post-contract."²⁴⁷ Moreover, even informed and sophisti-

244. Jennifer Arlen & W. Bentley MacLeod, *Malpractice Liability for Physicians and Managed Care Organizations*, 78 N.Y.U. L. REV. 1929, 1940 (2003) [hereinafter *Malpractice Liability*]; Jennifer Arlen & W. Bentley Macleod, *Torts, expertise and authority: Liability of physicians and managed care organizations*, 36 RAND J. ECON. 494, 498 (2005).

245. Arlen & MacLeod, *Malpractice Liability*, *supra* note 244, at 1934–35.

246. *Id.* at 1962, 1966, 2005.

247. *Id.* at 2005.

cated patients do not have optimal incentives to impose liability individually on MCOs because they are unable to appropriate any of the positive externalities received by other patients. The reason is that the key benefits of MCO liability would be structural reforms that help patients collectively, both now and in the future, in the form of investments in safety.²⁴⁸

Second, the Supreme Court recently interpreted the Employee Retirement Income Security Act of 1974 (ERISA) in a manner finding ERISA's remedial procedures broad enough to preempt any state tort action against an MCO for denial of benefits resulting in suboptimal care.²⁴⁹ In the wake of *Aetna Health Inc. v. Davila*, patients' recovery is limited to the cost of benefits purportedly denied them, instead of much higher compensatory damages for injuries they suffer. This ruling, which affects about 70% of insured Americans, constitutes a strong enough shield for MCOs that they have had little incentive to assume liability. After *Davila*, only Congress can impose liability on MCOs for their role in providing suboptimal care. Although that step would solve many of the problems the PRR solves, there is almost no chance that the healthcare industry would accept liability for suboptimal care lightly.

Third, doctors may choose to protect their independence from MCOs. If the hospital pays for liability insurance, then the hospital can, and will need to, exercise greater control over how doctors practice. Doctors hate malpractice lawsuits and love autonomy. The latter might often trump the former even when cold financial calculation suggests otherwise.

Interestingly, there are some examples where MCOs assume liability. These examples demonstrate the feasibility of such a regime. The main example is Kaiser Permanente, a large health plan that covers its doctors' liability. Why do we not see more Kaisers? Kaiser's battle to keep its binding arbitration was hard fought, and perhaps other MCOs are uncertain they could constitutionally prevail in other states.²⁵⁰ Without that assurance,

248. *See id.* at 2002–04. Patients would not have optimal incentives to contract more collectively with MCOs over liability because MCOs contracting over liability introduces adverse selection; the patients who most value the deterrence benefits that liability provides will disproportionately include sick people. *See id.*

249. *Aetna Health Inc. v. Davila*, 542 U.S. 200, 204 (2004).

250. *See, e.g.,* Lisa Perrochet, *Impact is Uncertain, Mandatory Arbitration Dealt a Blow, but Not a Fatal One*, 14 MED. MALPRACTICE L. & STRATEGY 1 (1997).

the prospect of internalizing liability may simply be too daunting for MCOs.

b. Liability Insurers as Cost Internalizers

The idea here is making liability insurers bear the cost of treatment. In this model, liability insurers would bear both the cost of care and of liability. Liability insurers emerged exclusively to shield doctors from liability, and they have a minimal understanding of delivery of care. Kaiser Permanente could be seen as an example here as well, because a health plan that covers its doctors is like a liability insurer that provides health care. The rest of the discussion above follows.

c. Government as Cost Internalizer

The government bearing both the cost of care and the cost of liability is not as bizarre an idea as one might think. Indeed, this is the situation in the Veteran Affairs system as well as in some countries such as the U.K., Spain, and Israel. However, one of the clearest lessons from the legislative process that led to the ACA is how politically infeasible the idea of a single payer is in the United States. Therefore, it is impossible to envision the approval of the more extreme approach in which the government is not only a single payer but also a central liability insurer. Moreover, even if such a regime were politically possible in the United States, it would probably be inferior to a PRR because the government would dominate the provision of public health and doctors' insurance instead of harnessing competition and market forces for that purpose.

d. Private Firms as Cost Internalizers

We are left with the question of why a PRR has not spontaneously emerged. Why do we not see private firms promulgating guidelines? Why do we not see existing promulgators assuming liability for misuse?

With respect to the first question, the answer is simple. We do see private firms promulgating guidelines. We even see them compete. UptoDate, FirstConsult, DynaMed, Isabel, and eMedicine, to name several, are all private firms that transformed EBM guidelines written by various entities from a technical document into an accessible one. There are differences between the firms, but also a lot of overlap. UpToDate is directed towards internal medicine, especially doctors in sub-

specialties, and FirstConsult is directed towards primary care physicians.²⁵¹ DynaMed competes with UpToDate on the basis of its evidence and competes with FirstConsult by appealing directly to primary care physicians.²⁵² DynaMed and Isabel offer products like databases and hard infrastructure that are used to bring evidence-based solutions more directly into the examination room. Such products involve summaries of advances discussed in medical journals, computerized analysis of clinical observations for determining diagnoses and treatment, and electronic data-sharing. eMedicine is similar to UpToDate, FirstConsult, and DynaMed, except that it incorporates user feedback from medical professionals, much like Clinicalmedicine.com.

In reality, the difference between these services is largely in their marketing. Other than the divide between primary care and specialties, these services all gather information from the same source—PubMed’s compilation of journals—using widely known background materials like *Harrison’s Guide to Internal Medicine* or other authoritative texts, and develop clinical guidelines based on them. All these private regulators are currently careful to disclaim liability for decisions physicians make based on their guidelines. Therefore, a physician must devote time to determining the validity of an EBM guideline, knowing full well that following the guideline will not insulate her from liability.

Having established that the market for such firms exists, we are still left asking why we do not see private firms assuming

251. FirstConsult focuses on the most common medical conditions and diseases, whereas UpToDate covers a greater number of diseases and conditions. FirstConsult is designed to facilitate quick reference at the point of care. UpToDate has more in-depth coverage of the topics covered. There are also differences in presentation of the material: the material in FirstConsult is divided into separate sections (differential diagnosis, medical conditions, etc.) whereas topic reviews in UpToDate are presented in a narrative format that is linked to supplementary material via a table of contents sidebar for quick access to specific aspects of the disease or condition. See Mary V. Taylor et al., *Electronic Resources Reviews: FIRSTConsult*, J. MED. LIBR. ASS’N 285, 285–87 (2004), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC385322/>.

252. For a sense of the competition between the companies see the Frequently Asked Questions on Dynamed’s website. One of the answers there states that: “According to findings published in *Annals of Family Medicine* (Nov./Dec. 2005), the Level of Evidence for answers in *DynaMed* met or exceeded what could be found in a combination of commonly used point-of-care references 87% of the time. None of the other resources did as well.” *About Dynamed*, DYNAMED, <http://www.ebscohost.com/dynamed/faq.php> (last visited Feb. 18, 2011).

liability for their CPGs. Indeed, liability for suboptimal promulgation of CPGs is the linchpin in the PRR. Without the liability component, incentives cannot be aligned.

Possible reasons could be that it is too complicated to draft multi party contractual arrangements that would mimic the PRR, including requirements such as liability from the ex ante perspective, and so on. Add to this the notion that the PRR firms will have to bear not only the cost of liability, but also the cost of care, and contractual solutions seem even harder to achieve. The main reason why private assumption of liability has not occurred, though, is identical to yet another reason why MCOs do not assume liability: creating such a regime would eliminate an externality which harms the patient but benefits all other parties. Specifically, because plaintiffs' lawyers tend to go after doctors' liability insurance coverage and not after their personal assets (some of which are protected under bankruptcy laws or otherwise hidden), doctors' liability is effectively capped at their policy limit.²⁵³ As a result, the joint liability of doctors and MCOs under the current regime is smaller than under an alternative regime of MCO liability or PRR where the joint liability is not capped. The less liability that doctors and MCOs (or PRR firms) face, the greater the harm that will be externalized onto patients. Of course, this externality is itself a major reason to create a new regime where parties would internalize costs now being externally borne by patients.

B. Practical Medical Concerns

1. Medical Ethics

Other critiques deal with practical and ethical concerns regarding the PRR, instead of comparing alternative proposals. First is the worry that doctors would not have access to the best guidelines for their patients and therefore could not deliver the best care. Medical ethics calls for doctors to take actions that

253. Doctors' liability is effectively capped under the current regime because plaintiffs do not recover more than the policy limit, which is itself strategically set by the insurance companies. See David A. Hyman et al., *Do Defendants Pay What Juries Award? Post-Verdict Haircuts in Texas Medical Malpractice Cases, 1988–2003*, 4 J. EMPIRICAL LEGAL STUD. 3, 53 (2007).

serve the best interests of their patients.²⁵⁴ Although this ethical commitment is already threatened by the cost-based compensation models emerging in the medical insurance industry, the PRR may further complicate this dilemma. This may happen when a doctor disagrees with his firm's guideline or the guideline is not optimal in comparison with competing guidelines not licensed or purchased by the provider. However, ethical concerns regarding the costs of limiting patient access to optimal guidelines would likely be less of a problem than it may seem. When a company issues a new guideline that is particularly efficient, this guideline could then be licensed to competing companies. Because producing suboptimal guidelines would expose companies to potential liability for injuries, the incentives to produce or obtain optimal guidelines would be closely aligned with the welfare of the patients and the health-care system as a whole. Therefore, doctors would rarely be confronted with an ethical dilemma when deciding whether following the prescribed guideline is in the patient's best interest, because, in general, the prescribed guideline would already be in tune with the patient's best interests.

Moreover, recall that the guidelines serve as merely a blunt sword. Although deviating from the guidelines would cost a doctor her liability shield, such deviation would not impose per se liability on her. Instead, much like the malpractice regime she faces today, she could avoid liability by showing that she was not negligent.

2. *Good Medicine Requires Discretion*

Another ethical and practical concern is more general: Good medicine requires discretion. Some argue that guidelines constrain doctors' discretion, and because physician discretion is necessary for optimal care, the guidelines therefore yield inefficiencies and encourage poor patient care. The premise is that doctoring in general (not just in rare cases) is an art and cannot be reduced to a set of guidelines. It is said that by intruding on

254. See, e.g., AM. MED. ASS'N, CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS, at xvii (2010–11 ed. 2010), available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/principles-medical-ethics.shtml> ("A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.").

the art of medicine, mandatory adherence to guidelines will “erode clinical abilities, diminish clinical judgment, and reduce medical practice to ‘cookbook medicine.’”²⁵⁵ Although these criticisms have some truth to them, they are overstated.

First, doctoring is far from pure art, and the implications of mandating compliance with guidelines are nowhere near as dire as critics suggest. Some doctoring, perhaps most doctoring, can be reduced to guidelines. As was mentioned above, clinical practice guidelines are pervasive, directing physicians in areas as disparate as treating ulcers, heart failure, and smoking addiction.²⁵⁶ CPGs are written by various players such as government agencies, medical specialty societies, healthcare organizations, and health plans.

Second, research shows that physicians tend to find reasons to believe that the patients they are seeing are unique, and therefore that the CPGs should not apply to them, even when the evidence suggests otherwise.²⁵⁷ Encouraging doctors to follow guidelines by providing them with a liability shield can help solve this problem.

Third, the PRR would not apply to the entire world of medicine. Rather, as explained above, the guidelines would be written for those cases, such as the administration of anesthesia, where medicine can optimally be reduced to a set of rules that reduce costs and increase patient safety.²⁵⁸ For example, an emergency room doctor could invoke well-accepted guidelines to explain her decision to refrain from ordering a skull x-ray for a patient with a possible head injury, when one of the well-known clinical indicators of skull injury was not present. As another example, ophthalmologists can use well-accepted national guidelines to justify refraining from performing a tonometry test on a patient under the age of forty, because the test has a high rate of false positives and only one in 25,000 persons

255. Brian Hurwitz, *Legal and Political Considerations of Clinical Practice Guidelines*, 318 BRIT. MED. J. 661, 663 (1999) (citing P. M. Ellwood, *Outcomes Management, a Technology of Patient Experience*, 318 NEW ENG. J. MED. 1549, 1549–56 (1988)).

256. Agency for Healthcare Research & Quality, U.S. Dep’t of Health & Human Servs., *Clinical Practices Guidelines Archive*, AHRQ.GOV, <http://www.ahrq.gov/CLINIC/cpgarchv.htm> (last visited Jan. 28, 2011).

257. Rosoff, *Medicine and the Law*, *supra* note 160, at 347.

258. See Mello, *supra* note 122, at 653 (providing references that the administration of anesthesia is amenable to governance by a rigid algorithm).

under the age of forty is found to have glaucoma.²⁵⁹ Because the odds of the test detecting critical information result in a higher overall cost than benefit, the test is not worth applying in those circumstances.²⁶⁰

Moreover, depending on the nature of the procedure, it might make sense that certain guidelines will allow for more or less discretion within the boundaries of their requirements. One procedure may be best reduced to strict adherence down to detailed measurements, while another procedure may be better suited to a range of possible measures depending on the required discretionary factors.²⁶¹ Regardless, PRR firms would outperform the current system of vague standards generated by the tort system²⁶² and the varying standards generated by medical practice.²⁶³ PRR firms would at least identify floors and ceilings of appropriate care, thereby defining a range of accept-

259. *Helling v. Carey*, 519 P. 2d 981, 982–83 (1974). Although the Washington Supreme Court agreed that the doctors had followed both the local and national standard of care, the court found the doctors liable based on a cost analysis of tonometry, concluding it was efficient for a doctor to have administered a tonometry test in the plaintiff's circumstances. *Id.*

260. Research conducted after the Supreme Court's ruling has demonstrated that ophthalmologists' change of practice patterns in response to *Helling* resulted in an increase in the cost of care without a reduction in morbidity. D. Clay Kelly & Gina Manguno-Mire, *Commentary: Helling v. Carey, Caveat Medicus*, 36 J. AM. ACAD. PSYCHIATRY & L. 306, 307 (2008).

261. The question of optimal specificity of rules has received a great deal of attention. See Francesco Parisi, *Rules versus Standards* in THE ENCYCLOPEDIA OF PUBLIC CHOICE 510–16 (Charles K. Rowley & Fredrich Schneider eds., 2004). By and large, the more the promulgator lacks information about future circumstances, the more discretion needs to be left to the doctors—that is, the more the rules need to be general. Specific rules, however, are easier to comply with and adjudicate than general rules. Overall, specific rules are more expensive to promulgate ex ante, and general rules are more expensive to litigate ex post. This might lead one to wonder whether PRR firms will write general guidelines, leaving more discretion to the doctors, thus removing risks for themselves. This is highly unlikely in a competitive market where PRR firms will have to compete for hospitals' business. Doctors would not buy guidelines that are too general to provide immunity, nor would private firms write guidelines that are more than optimally specific, because doing so would expose them to more liability.

262. See Havighurst, *supra* note 120, at 96 (“There is little doubt, however, that [CPGs] will eventually be more explicit and more helpful than the vague standards that the tort system currently enforces.”).

263. As has been well documented by the *Dartmouth Atlas of Healthcare Project*, medical practice varies inexplicably between geographic areas, and even within the same community. See DARTMOUTH ATLAS OF HEALTHCARE, TRACKING THE CARE OF PATIENTS WITH SEVERE CHRONIC ILLNESS (2008), available at <http://www.dartmouthatlas.org/>.

able practice from which providers could select according to their judgment. Although PRR would constrain doctors' discretion more than the current tort regime, it would do so in a way that is more beneficial to patients, doctors, and society, because it would prevent errors stemming from lack of physician expertise or experience. Although some patients might be worse off for lack of physician discretion, the majority would receive better, more efficient care.

Lastly, recall that guidelines would serve as a complete shield, but only as a blunt sword. This means that doctors would retain their professional discretion regarding whether to comply with or deviate from guidelines. If they did deviate, they would risk liability under regular tort law, but on average they would not be worse off than under the current system. On the one hand, given the respect that CPGs will receive from both providers and courts, deviating from guidelines will require the doctor to work harder to convince the court she was not negligent. On the other hand, because doctors would generally follow guidelines, they would face liability far less frequently because the PRR firms would be liable for suboptimal guidelines.

As an example, consider a recent medical malpractice case, *Vede v. Delta Regional Medical Center*.²⁶⁴ In *Vede*, the plaintiff sued a hospital for failing to conform to both national and its own guidelines, which recommended that patients be turned once every two hours to prevent the development of bed sores.²⁶⁵ The hospital admitted to deviating from the guidelines, but argued that it did so for good reason: Turning the patient would have resulted in an airway obstruction, impairing his oxygen saturation level and threatening his survival.²⁶⁶ The Mississippi Court of Appeals ruled for the hospital, agreeing that keeping the patient on his back was medically required.²⁶⁷

Vede is useful in comparing the current system with the PRR. First, in *Vede*, multiple CPGs were applicable—both hospital and national guidelines. Though this issue did not arise in the case, such guidelines often conflict and courts must solve this

264. *Vede v. Delta Reg'l Med. Ctr.*, 933 So. 2d 310 (Miss. Ct. App. 2006).

265. *Id.* at 312.

266. *Id.*

267. *Id.* at 313.

so-called “battle of the guidelines.”²⁶⁸ Under the PRR, there would be one controlling set of guidelines per case: the guidelines the provider licensed or purchased. Second, in *Vede*, the hospital chose to depart from the guidelines’ recommendation, thereby increasing its liability risk in case of a lawsuit, because it believed it was the right thing to do for that specific patient. Under the PRR, the hospital could have handled the situation in the same way and faced the same chance of liability. Third, and most importantly, in *Vede* presumably neither of the guidelines anticipated patients who would not be able to breathe if turned over. Otherwise, the hospital would not have violated the guidelines at all. This omission suggests that for this particular medical issue, both the national and the hospital guidelines might have been suboptimal. Under the PRR, if the hospital in *Vede* had followed the guidelines, and the plaintiff died from lack of oxygen, his family and estate could have sued the PRR firm for writing suboptimal guidelines.²⁶⁹

3. *Not Enough Reliable Scientific Information Exists To Make the Endeavor Worthwhile*

A related critique often raised generally against evidence-based medicine is that there are simply not enough high quality studies to provide guidance for the myriad medical problems that arise in day-to-day clinical decisionmaking. Thus, goes the argument, even if one accepts the wisdom in transforming medicine from art to science, the argument goes, there is not enough information to do it for the vast majority of medical procedures. However, as discussed in the section above, the optimal specificity of guidelines will depend on the type of medical procedure. For procedures with little evidence-based research, guidelines would probably not be optimal and therefore would not be generated, at least not by the PRR. Indeed, some areas of medicine should not have any guidelines.

268. See Mello, *supra* note 122, at 685. In such cases courts often apply the “two schools of thought” doctrine. See, e.g., *Levine v. Rosen*, 616 A.2d 623 (Pa. 1992).

269. Other examples exist. Consider a drug which has 100% effectiveness but must be taken four times per day. Very few doctors will prescribe this drug when a once-a-day alternative, with less effectiveness, is available, unless the patient is extremely compliant. It might be malpractice to prescribe a drug assuming patients will take the medication every day, four times a day, when other alternatives are available. Simply put, theoretical, evidence-based effectiveness does not always translate into real-world effectiveness.

But, many areas of medicine are conducive to evidence-based improvement, and therefore could be a fruitful ground for guidelines. Under the PRR, guidelines will be most beneficial for medical procedures that are complex and carry with them high risk of failure with significant adverse consequences. For example, improved guidelines for obstetrics, surgery, missed diagnosis, and medication could have a tremendous impact, as these key clinical areas account for approximately 80% of all medical malpractice claims in the United States, and an even larger proportion of total indemnity costs.²⁷⁰ Additionally, unlike now, the lack of information will be less of an issue under the PRR because private firms will have the financial incentive to find and, if needed, fund the high-quality research necessary to make EBM guidelines possible.

4. *How Effective Will PRR Be in Reducing Costs?*

As mentioned above, there are three sources of excessive costs: underuse, misuse, and overuse. As examined above, a significant portion of medical practice can be, and is in fact, reduced to guidelines. Once it is, a major advantage of a PRR is that it can combat all three cost drivers simultaneously, thus avoiding problems that other tort and healthcare reforms face, in which attempting to solve one driver immediately exacerbates another.²⁷¹

One may wonder how CPGs can reduce costs at all. After all, as I showed above, CPGs are not a critical factor in very many malpractice cases because most cases involve factual questions, causation, or damages issues.²⁷² The answer is that in light of the threat of malpractice lawsuits, immunity given to doctors who follow CPGs should incentivize them to follow these guidelines. It is the adoption of the CPGs by the medical profession that is important for the improvement of quality of care, reduction of costs, and sustainable access for the uninsured to the healthcare system.²⁷³ Courts are only instrumental.

270. Hardeep Singh et al., *Medical Errors Involving Trainees: A Study of Closed Malpractice Claims From 5 Insurers*, 167 ARCHIVE INTERNAL MED. 2030, 2032 (2007).

271. A similar argument was made by Professor Havighurst more than twenty years ago. See Havighurst, *supra* note 192, at 798–99.

272. Havighurst, *supra* note 120, at 95.

273. *Id.*

But how effective would the PRR be in reducing these costs if adopted by the medical profession? The following subsections address the three cost drivers separately.

a. Misuse (Medical Errors)

The pervasive scope of errors is clear. The Institute of Medicine has determined that 1.68 to 1.96 percent of individuals entering a medical facility will suffer an adverse event that could have been completely prevented.²⁷⁴ 27.6 percent of those mistakes will result from negligence.²⁷⁵

Misdiagnosis and misprognosis, both of which arise from inadequate planning, are an instructive starting point. For many decades, studies have consistently demonstrated the benefits of statistical diagnosis over clinical diagnosis. Statistical methods of combining data yield better decisions than do less systematic approaches like relying on unaided human judgment. This has been shown in studies of medical decisionmaking ranging from diagnosis of thyroid disorder and heart diseases to surgery recommendations and surgery outcomes. In nonmedical research, this trend has been shown in areas like probation success and job performance.²⁷⁶ The reasons for this inferiority range from doctors' fatigue, to their reliance on knowledge derived from treating a limited number of previous patients with similar diseases, to various cognitive biases and heuristics that prevent them from reaching the correct judgment.²⁷⁷ However, despite overwhelming empirical support, treatment decisions based on statistical prediction nonetheless remain scarce because doctors clearly prefer to use their heads rather than formulas. CPGs can easily help with misdiagnosis and misprognosis. Rather than having doctors ask patients questions about medical history and symptoms, which forces doctors to rely on their memories and recall their own experiences, imagine doctors using a handheld device incorporating a deci-

274. INST. OF MED., *supra* note 13, at 26.

275. *Id.* at 30.

276. For a recent metaanalysis, see William M. Grove et al., *Clinical Versus Mechanical Prediction: A Meta-Analysis*, 12 PSYCHOL. ASSESSMENT 19, 22 (2000).

277. These include cognitive biases such as ignoring base rates, and heuristics such as the representativeness heuristic (which leads to belief in the law of small numbers) or the availability heuristic (which leads to overweighting vivid data). See JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES 25, 154, 176–77, (Daniel Kahneman et al. eds., 1982).

sion tree based on best available research, which guides them through the diagnostics.

But evidence exists that CPGs can do more than just improve diagnostics and survival predictions. One of the success stories demonstrating that CPGs can prevent errors is in the specialty of anesthesia, where deaths have gone from 1 of every 5,000 uses of general anesthesia to 1 of every 200,000 to 300,000 uses.²⁷⁸ The gains in anesthesia safety were accomplished through a variety of mechanisms, including the development and widespread adoption of practice guidelines.²⁷⁹ The PRR would help to extend those gains beyond the specialty of anesthesia to other practices by creating incentives for the development of equivalent comprehensive CPGs.

Moreover, the Institute of Medicine stated that “[d]rug complications were the most common type of adverse event (19 percent), followed by wound infections (14 percent), and technical complications (13 percent).”²⁸⁰ The PRR should be very effective in combating these medical errors because it would institute safer, evidence-based practices to address all three of these problems. Preventable drug complications would be limited by instituting evidence-based protocols for the questioning of patients, cross-referencing drugs for possible interactions, and initiating better-funded studies to discover side effects and dangers of using a particular drug. Preventable wound infections, known as nosocomial infections when they are acquired during hospitals stays, would be limited by mandated protocols that physicians would follow under the PRR. Both drug complications and wound infections are areas where standardized practices, based on solid evidence, would fit nicely within the physician’s role because the prescription of drugs in a way that limits complications and prevents wound infections is a process that is relatively free of subjective influence.

Lastly, the Institute of Medicine concluded that the more technologically dependent a given practice area becomes, the more likely it is that errors will occur in it.²⁸¹ Thus, as medicine

278. INST. OF MED., *supra* note 13, at 32.

279. *Id.*

280. *Id.* at 30.

281. *Id.* at 36 (citing Lucian Leape et al., *Preventing Medical Injury*, 19 QUAL. REV. BULL. 144, 144–49 (1993)) (“The contributions of complexity and technology to such error rates is highlighted by the higher rates of events that occur in the highly tech-

transforms from an art into a science, and as doctors become physician-scientists by applying new technologies and breakthroughs to help their patients, the need becomes even greater for a PRR in order to ensure that the power of new procedures and tools is tempered by research into the best way to implement them safely. CPGs, created by private firms, would be a clear way to move towards fewer errors. Thus, the PRR would mold doctors into even more significant stakeholders in the safety of their patients.

b. Underuse

One of the main problems with health care in the United States is insufficient preventive care. Mandatory adherence to CPGs can help providers administer preventive care. Furthermore, correcting incentives within the health care industry will improve efficiencies in every component of the system. These greater efficiencies will likely lead to cost savings in the public and private sectors. As discussed above, the savings will come primarily from a reduction in misuse and overuse. Savings in the private sector will likely be absorbed by all parties, including health care insurance providers. Competition in the market means that these savings will eventually be passed on to consumers, making health insurance more affordable and thereby increasing access for current uninsured and underinsured patients. The savings in the public sector can be reallocated to further expand access to insurance and other programs that are likely to reduce underuse. Thus, although the effect is indirect and seemingly small, the efficiency gains created by the PRR will ultimately result in a reduction of underuse. Even ignoring this indirect benefit, it is at least clear that the PRR will not exacerbate the problem.

c. Overuse

There are several methods for limiting overuse. First, the patient can refuse, or refuse to pay for, the procedure. Taking a CT scan carries some risks, and if the patient feels that the doctor is recommending it only because she has recently bought a

nical surgical specialties of vascular surgery, cardiac surgery, and neurosurgery. In hospitals, high error rates with serious consequences are most likely in intensive care units, operating rooms and emergency departments.”).

scanner and needs to recoup the investment (offensive medicine), or because the doctor does not really know what she is doing (cost-apatetic medicine), then the patient might refuse to take the scan.²⁸² However, most patients do not have the time, resources, information, or motivation to monitor or second-guess their doctor's treatment recommendations. Second, the insurer, especially an HMO, can refuse to pay for the procedure.²⁸³ But an HMO might still have a hard time combating providers' incentives and biases. The PRR will combat overuse stemming from defensive, compassionate, cost-apatetic, and offensive medicine.

i. Defensive Medicine

Perhaps the easiest savings to explain are costs associated with defensive medicine. The PRR will lower these costs by significantly reducing a doctor's motivation to perform defensive medicine as a result of the immunity from liability granted for complying with the guidelines.

ii. Compassionate Medicine

Almost 30% of Medicare spending is on end-of-life care, of which 50% is spent on the final sixty days of life.²⁸⁴ Relying on the liability shield provided by relevant CPGs, doctors might be more able to resist compassionate impulses and provide only care which they know is scientifically supported. The impact that CPGs will have on compassionate care is not easily estimable, but it is potentially large.

iii. Cost-Apatetic Care

Under the PRR, hard science will combat physician ignorance, significantly reducing cost-apatetic care. Because of the

282. See Shankar Vedantam, *Doctors Reap Benefits By Doing Own Tests*, WASH. POST, July 31, 2009, at A1, available at <http://www.washingtonpost.com/wp-dyn/content/article/2009/07/30/AR2009073004285.html>.

283. The law itself can ban the procedure, or a hospital can refuse to allow a procedure to be performed. Usually this refusal by the law or a hospital is based not on the cost of a procedure, but on its experimental nature. See Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 393 (2006) (outlining FDA agency oversight).

284. Lubitz & Riley, *supra* note 53, at 1093–94.

strong incentives doctors will have to follow CPGs, it will be almost impossible for them to provide cost-aphathetic care in any procedure for which CPGs exist. The CPGs will synthesize all current medical knowledge for a given procedure and present it in a way that is easy for the doctor to follow. Just like a builder following an architect's designs, the doctor will adhere to the CPGs and provide the patient with the optimal level of care based on the latest medical knowledge.

iv. Offensive Medicine

A great deal of skyrocketing healthcare costs may be rooted in offensive medicine, or induced demand. Under the predominant current payment system, a doctor is paid not for having a healthy patient, but for having performed a set number of tests, procedures, or examinations. Recently, some have proposed shifting from a compensation regime based on discrete procedures and tests to a system that pays doctors based on the health of individual patients.²⁸⁵ The idea is to allocate a patient with a given condition (such as congestive heart failure) a certain amount of money, paid by the insurance company. This money will be allocated to the doctor. If the doctor is able to keep the patient healthy for less than the insurance company expected, the physician would be able to keep a portion of the remaining funds.²⁸⁶ Problems with this solution abound, including uncertainty regarding who will decide if the patient is sufficiently healthy and whether insurance companies will lower allocations when doctors prove their ability to cut costs. Of course, a fear of allocations being cut may cause doctors to overreport the costs of care, thus returning us once again to the agency issue at which we started.

285. Julie Weed, *If All Doctors Had More Time to Listen*, N.Y. TIMES, June 7, 2009, at BU1, available at <http://www.nytimes.com/2009/06/07/health/07health.html> (describing an alternative system where a doctor treats fewer patients for much longer visits, including house calls, thus lowering costs by treating many problems preventatively and reducing the need to refer patients to specialists).

286. Kate Pickert, *Cutting Health-care Costs by Putting Doctors on a Budget*, TIME (July 6, 2009), <http://www.time.com/time/nation/article/0,8599,1908477,00.html> (describing a system where a doctor, if given \$25,000 on the assumption that the typical patient requires \$20,000 to be kept healthy, and able to reduce costs and keep the patient healthy for \$15,000, would double her reward from that particular patient).

This type of capitation system, where physicians are paid based on the health outcomes of a patient with a given disorder, has been implemented in several areas. The largest trial has been in Medicare and Medicaid, both of which mandated the capitation system in 2005.²⁸⁷ One problem with capitation is that disorders can overlap, making a given patient more expensive to treat than the average patient on which the payment rate is based.

A more advanced version of the same solution is proposed by the Prometheus System, a nonprofit consortium that has created an Evidence-Based Case Rate (ECR).²⁸⁸ These ECRs differ from capitation systems in that the ECRs use CPGs to inform medical care, as well as many different demographic variables to fine-tune the payments according to more correlative indicators of patient costs than capitation alone.²⁸⁹ Although both capitation and the Prometheus System are solid

287. Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5301, 120 Stat. 4, 48–51 (codified as amended at 42 U.S.C § 1395 (2006)); Pauline W. Chen, *Getting Off the Patient Treadmill*, N.Y. TIMES, Feb. 20, 2009, <http://www.nytimes.com/2009/02/20/health/19chen.html> (“[I]n the Deficit Reduction Act of 2005, Congress mandated that the Center for Medicare and Medicaid Services adopt a pay-for-performance plan into Medicare.”). These changes from a pay for service system to a capitation system for Medicare began in the early 1980s and defied the predictions of the Congressional Budget Office. The CBO had expected an increase in hospital admission rates once payments were tied to discrete patients rather than procedures, yet after the early reforms hospital admission rates actually declined. See Jon R. Gabel, Op-Ed, *Congress’s Health Care Numbers Don’t Add Up*, N.Y. TIMES, Aug. 26, 2009, at A23, available at <http://www.nytimes.com/2009/08/26/opinion/26gabel.html> (“In the early 1980s, Congress changed the way Medicare paid hospitals so that payments would no longer be based on costs incurred. Instead, hospitals would receive a predetermined amount per admission, based on the patient’s primary medical problem. This encouraged shorter stays, led to fewer diagnostic services and reduced administrative costs. The Congressional Budget Office predicted that, from 1983 to 1986, this change would slow Medicare hospital spending (which had been rising much faster than the rate of inflation) by \$10 billion, and that by 1986 total spending would be \$60 billion. Actual spending in 1986 was \$49 billion. The savings in 1986 alone were as much as three years of estimated savings.”).

288. *ECR Tool*, HEALTH CARE INCENTIVES IMPROVEMENT INST., <http://www.prometheuspayout.org/tools/user/ecr/form> (last visited Feb. 24, 2011).

289. *Frequently Asked Questions: Design of the Model*, HCI3.ORG, <http://www.hci3.org/?q=node/74#66> (last visited Feb. 24, 2011) (“In capitation, providers take the risk that they may have a sicker patient panel than average or that their condition or disease mix can be more unfavorable in terms of resource use per patient than the average. The PROMETHEUS Payment® model avoids this problem by (1) constructing the payment rates in a way that reflects the cost of what is clinically relevant to the patient’s condition, appropriate differentials in resource use by the condition, disease or procedure and (2) adjusting those ECRs® to account for the relative severity of the patients cared for under this system.”).

alternatives, there is a danger that either system might deter useful procedures if a physician feels that they could cut costs by ordering fewer clinically indicated procedures.

A somewhat similar approach has been taken recently by the Medica Health Plans insurance company—the second-largest insurer in Minnesota—which has teamed up with a group of Minnesota clinics to work towards holistic patient health, rather than crisis-based problemsolving, by using EBM guidelines.²⁹⁰ By shifting the focus towards patient health, physicians are incentivized financially, rather than professionally or ethically, to ensure good results from their contact with patients.²⁹¹ Together, both sides, insurer and clinic, are working to increase patient enrollment and decrease the numbers of individuals and companies that are dropping out of the health insurance system entirely.²⁹² Most recently, Medical Mutual of Ohio, a health insurance company, and Cleveland Clinic Community Physician, a physician group, have established a partnership to develop CPGs to manage chronic diseases and give doctors financial incentives to follow these guidelines.²⁹³

By encouraging evidence-based CPGs, the Prometheus System, Medica, and the Ohio partnership have laid the foundation for a regime of private regulation and, in a way, reflect its feasibility. However, although efficient in combating offensive medicine, the lack of immunity to providers and the lack of liability for suboptimal CPGs make these measures ineffective in combating defensive medicine and medical errors, respectively.

There is yet another tool being used by some organizations to fight rising health care costs: compensating doctors with salary rather than reimbursing them based on the number of patients seen and procedures performed. Such a salary system is an important step away from the current regime which reimburses for quantity, not quality. Indeed, most university hospitals and the entire VA system provide their doctors salaries.

290. David Welna, *Minnesota Experiment Puts Patient Health First*, NPR (Sept. 3, 2009), <http://www.npr.org/templates/story/story.php?storyId=112488466>; see also *Medica Fact Sheet*, MEDICA, <http://www.medica.com/C2/Factsheet/default.aspx> (last visited Nov. 10, 2010).

291. Welna, *supra* note 290.

292. *Id.*

293. Ellen Kleinerman, *Pay Incentives Would Encourage Wellness Care*, CLEVELAND.COM (Nov. 25, 2010), http://www.cleveland.com/healthfit/index.ssf/2010/11/pay_incentives_would_encourage.html.

Examples exist in the private market as well. Kaiser Permanente, as a large health plan, sets up payments for individual “medical groups” so that the physicians in the groups are paid salaries.²⁹⁴ Both the Cleveland Clinic and Mayo Clinic—considered among the best in the United States—compensate their doctors with salaries, rather than adjusting their pay according to the total number of patients served or services provided.²⁹⁵

As before, these solutions combat offensive medicine, but do little to limit defensive medicine and medical errors. In contrast, the PRR could combat all three cost drivers. However, when it comes to offensive medicine, the PRR is more limited. For high-risk offensive medicine procedures, such as unnecessary cardiac bypass, PRR firms have a clear incentive to lower the number of risky procedures, thus also lowering costs. In contrast, the PRR is less useful in combating the problem of excessive low-risk instances of induced demand, such as an MRI when an x-ray is sufficient. To address these problems, salaries for physicians and capitation may be useful adjuvant therapies for these healthcare woes. Additionally, as mentioned in the previous section, if MCOs buy into the PRR, they could incorporate innovative programs like these to better control offensive medicine, thus further lowering costs for themselves and for society.

C. *Legal and Political Concerns*

1. *Are We Losing the Information Updating Benefit that Tort Law Provides?*

Legal and political criticisms also confront the PRR. To start, one may wonder whether the information-updating benefit of tort law would be lost on account of the fundamental change to medical malpractice brought on by the required legislation. Professors Robert Rabin and Richard Nagareda discussed

294. *Frequently Asked Questions About Our Medical Care*, KAISER PERMANENTE, <https://members.kaiserpermanente.org/kpweb/faqmedcare/entrypage.do> (last visited Nov. 10, 2010).

295. See Kevin Sack, *For Two Health Care Systems, a Priceless Presidential Testimonial*, N.Y. TIMES PRESCRIPTIONS BLOG (Sept. 10, 2009, 7:26 PM), <http://prescriptions.blogs.nytimes.com/2009/09/10/for-two-health-care-systems-a-priceless-presidential-testimonial/>; *Careers at Cleveland Clinic*, CLEVELAND CLINIC, <http://my.clevelandclinic.org/careers/compensation.aspx> (last visited Nov. 10, 2010).

separately the information-updating effect of tort law.²⁹⁶ No doubt there are examples of tort litigation “eliciting information about risk and aberrant conduct,” as Professor Rabin puts it. Tobacco litigation, he notes, is probably the best example of plaintiffs’ lawyers unearthing vital information.²⁹⁷

The relevant analysis, however, is one of comparative institutional advantage. The current experience is not encouraging. It currently takes about seventeen years for new, credible knowledge generated by randomized, controlled trials to be incorporated into practice, and even then application is highly uneven.²⁹⁸ In contrast, recall that under the PRR a PRR firm does not have the state of the art defense, and therefore is required to constantly update its guidelines. Moreover, tort law will remain important under the PRR, but it will mostly target PRR firms rather than doctors. These factors should take care of the information updating concern in a much quicker, and more consistent, rational, systematic, and scientifically reliable way.

2. *Would Private Regulation Lead to Pulling the Plug on Grandma?*

To achieve the legal changes necessary, the PRR must be politically palatable. The first issue, also present in the wider debate about healthcare reform, has to do with rationing. Will guidelines ration care and keep sick people from being treated? It is true that guidelines incorporate rationing, but healthcare is already being rationed, only less visibly and based on a prospective patient’s ability to pay.²⁹⁹ Indeed, rationing healthcare in some way is simply inevitable.³⁰⁰ It is economically impossible and unethical to provide unlimited

296. Schuck, *supra* note 130, at 17.

297. *Id.* (quoting Robert L. Rabin, *Keynote Paper: Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2068 (2000)).

298. INST. OF MED., *supra* note 2, at 13.

299. See Peter Singer, *Why We Must Ration Health Care*, N.Y. TIMES MAGAZINE, July 15, 2009, at 38.

300. See, e.g., Einer Elhauge, *Allocating Health Care Morally*, 82 CALIF. L. REV. 1449, 1459–61 (1994); H. Tristram Engelhardt, Jr., *Toward Multiple Standards of Health Care Delivery: Taking Moral and Economic Diversity Seriously*, in ETHICAL ISSUES IN HEALTH CARE ON THE FRONTIERS OF THE TWENTY-FIRST CENTURY 25, 25–29 (Stephen Wear et al. eds., 2000); Ronald Dworkin, *Will Clinton’s Plan Be Fair?*, N.Y. REV. BOOKS, Jan. 13, 1994, at 5.

care to everyone. If a drug for cancer costs \$50,000, but only prolongs one's life by a few months, then there must be a rational way to determine whether this drug is worth providing. If resources were unlimited, then it would be worth doing almost anything that can save or prolong lives. However, rising costs have put Medicare on the brink of insolvency,³⁰¹ and President Obama has stated that "ever-escalating healthcare costs" are "the most significant driver by far of our long-term debt and our long-term deficits."³⁰²

Once we acknowledge the impending budget constraints and the rationing that these constraints will require, we must only decide on the best use of our healthcare dollars. Should priority go to the sickest patients, or should it go to the patients who would derive the most benefit from treatment? Should the wealth, number of dependents, moral character, age, gender, or race of the patient matter? If we decide that the \$50,000 cancer drug will not be covered, then those who suffer from that particular cancer may die. But, other people will die as a consequence of the decision to cover the drug. If the drug is paid for, the result would be higher health insurance premiums, which some currently insured individuals will no longer be able to afford. If people cannot afford health insurance, and therefore cannot afford healthcare to treat their diseases, they are more likely to die from those diseases.³⁰³ This is rationing too, just with a criterion of ability to pay.

301. See STAFF OF S. FINANCE COMM., 111TH CONG., DESCRIPTION OF POLICY OPTIONS, FINANCING COMPREHENSIVE HEALTH CARE REFORM: PROPOSED HEALTH SYSTEM SAVINGS AND REVENUE OPTIONS 1 (Comm. Print 2009).

302. See Jesse Lee, *Health Care Reform: 'Urgency and Determination,'* THE WHITE HOUSE BLOG (May 13, 2009, 1:12 P.M.), <http://www.whitehouse.gov/blog/Health-Reform-Urgency-and-Determination>.

303. *Id.* In a study conducted by the Urban Institute using data from the U.S. Census Bureau, researchers found that as many as 165,000 people likely died because of lack of insurance in the time period between 2000 and 2006. Sara Lubbes, *Thousands of U.S. Deaths Attributed to Lack of Health Insurance*, THE COMMONWEALTH FUND (Jan. 11, 2008), <http://www.commonwealthfund.org/Content/Newsletters/Washington-Health-Policy-in-Review/2008/Jan/Washington-Health-Policy-Week-in-Review---January-14-2008/Thousands-of-U-S--Deaths-Attributed-to-Lack-of-Health-Insurance.aspx>. As stated by the study lead, Senior Researcher Stan Dorn, "This is all a question of common sense. Nowadays we know that medicine can save your life and if you have to choose between food and medicine, for instance, you're playing Russian Roulette with your health." *Id.*

So, again, the question is how best to spend and ration society's healthcare dollars.³⁰⁴ The answer does not necessarily lead to pulling the plug on grandma, as some might put it, but must be determined based on how society wants to distribute a finite resource.³⁰⁵ Guidelines will simply incorporate society's moral and political preferences—optimal guidelines will reflect what society considers proper.³⁰⁶ The PRR does not, in and of itself, require grandma to be harmed. It is society's preferences incorporated into the guidelines which might decide that resources are better spent elsewhere.

Moreover, the PRR can also adapt to people's preferences between money spent now on insurance premiums and money spent later on health care. Under the PRR, there could be several levels of guidelines, say platinum, gold, silver, and bronze, which reflect larger benefits for higher premiums. If person *A* wants to receive a CT scan every time he has a headache, even if no other clinical markers are present, then person *A* should contract with a health insurance that contracts with providers who use platinum guidelines. Obviously, these are more expensive guidelines. But, if person *B* buys into gold standards—and those standards dictate a CT scan only when other markers exist—then person *B* has no claim against the doctor for not delivering a CT scan (when those markers do not exist), and has no claim against the PRR if such guidelines are optimal, given the level of coverage purchased.

Accounting for price complicates the analysis, although not by much. To facilitate effective competition between PRR firms, those standards (platinum, gold, and so on) would

304. This question is not unique to the healthcare context. Government agencies considering various safety measures must put a price on human life to evaluate whether or not the safety measure is worth the cost. The Department of Transportation uses \$3 million (in 2002 dollars), the EPA uses \$7.2 million (in 2005 dollars) and the FDA uses \$5 million per life saved (no dollar year reported). See Lisa A. Robinson, *How US Government Agencies Value Mortality Risk Reductions*, 1 REV. ENVTL. ECON. & POLICY 283, 295 (2007).

305. Critics of President Obama's healthcare reform argue that his plan rations healthcare and might lead to pulling the plug on grandma. See Laura Conaway, *Obama Says His Health Plan Won't 'Pull The Plug On Grandma'*, PLANET MONEY, (Aug. 11, 2009, 1:24 P.M.), http://www.npr.org/blogs/money/2009/08/obama_defends_health_insurance.htm.

306. See *supra* note 14.

need to be consistent across the industry. One way to regulate those standards would be by a legislature determining the amount of money each level has to spend per quality-adjusted-life-year (QALY).³⁰⁷ Suppose that gold means that the CPGs are committed to spending at least \$50,000 per QALY, whereas silver spends only \$40,000. If a person pays the gold premiums, she will go to a hospital which provides a gold standard of care and receive the drug for her cancer. If the person instead pays for the silver standard, then she will not have a complaint when her insurance refuses to pay for the drug.

The proposed multilevel guidelines for the PRR are actually very similar to recent health reform in Massachusetts that utilizes standardized health plans for unsubsidized insurance, in an attempt to improve consumer access to adequate insurance benefits. These plans, called Commonwealth Choice plans, were designed based on benefits “tiers” that include insurance coverage options with equivalent actuarial values (the value of health benefits).³⁰⁸ Similar to the PRR, the three categories of standardized coverage are Gold, Sil-

307. QALY is a metric that allows policymakers to compare the effectiveness of different treatments. If a treatment provides an additional year of life at full quality, it produces one QALY. If a treatment provides an additional year of life at one-half quality, it produces one-half of a QALY. David C. Hadorn, *The Oregon Priority-Setting Exercise: Quality of Life and Public Policy*, 21 HASTING CENTER REP. 11, 13–14 (1991). QALYs are used around the world. For example, in the U.K., the National Institute for Health and Clinical Excellence (NICE) decides whether drugs and other therapies are cost effective enough to justify coverage by the U.K.’s universal health care system. Steven D. Pearson & Michael D. Rawlins, *Quality, Innovation, and Value for Money: NICE and the British National Health Service*, 294 JAMA 2618, 2618–19 (2005). NICE makes recommendations of coverage based on treatments’ cost per QALY. *Id.*

308. CHRISTINE BARBER & MICHAEL MILLER, REVISITING MASSACHUSETTS HEALTH REFORM: 18 MONTHS LATER, COMMUNITY CATALYST 4–5 (Dec. 2007), available at http://www.communitycatalyst.org/doc_store/publications/revisiting_MA_health_reform_dec07.pdf. Similar to QALY measures:

Actuarial value . . . measures how much a particular health insurance plan is expected to cover of a typical population’s costs for covered medical services. It usually is expressed as a percentage of those costs, although it also can be converted into a dollar value. For example, a plan with an actuarial value of seventy-five percent would be expected to pay seventy-five percent of the medical expenses for covered health services for a typical population.

SARAH LUECK, WHAT LEVEL OF COVERAGE WILL HEALTH REFORM LIKELY PROVIDE? THE BASICS OF ACTUARIAL VALUE 2 (2009), available at <http://www.cbpp.org/files/10-13-09health2.pdf>.

ver, and Bronze.³⁰⁹ Gold plans have high premiums, the most comprehensive networks, no deductibles, and limited co-pays. Silver plans have medium premiums, with fairly comprehensive networks, some deductibles, and moderate co-pays. Bronze plans have low premiums, limited networks, high deductibles, and more substantial co-pays.³¹⁰ Benefits and pricing information for these standardized plans are provided at a centralized website so consumers can make informed choices about the level of care for which they are willing to pay.³¹¹

Similar to the Massachusetts model, the PRR guidelines would provide differing levels of care depending on the consumer's determination of their efficient combination of premium price and personal risk preference. The difference is that the Massachusetts model requires consumers to choose plans that will primarily affect their selection of hospitals and the costs of medical care, while the PRR guideline levels will more directly affect the quality of the health care consumers receive. This difference may not be that substantial, however, because by choosing a bronze insurance plan with a limited network and coverage, bronze consumers may inadvertently be choosing lower levels of care—lower costs of care could be what enable certain hospitals to participate in the bronze plan. If this is true, hospitals willing to participate in bronze insurance plans may also provide evidence helpful for determining efficient care levels for bronze guidelines.

3. *Could a Profit-Driven Regulatory Regime Ever Win Political Support?*

The last criticism is whether the PRR, relying on private, profit-driven companies to regulate healthcare, could be politically acceptable. Could these private companies ever achieve the kind of credibility that would make legislators comfortable in enacting such a regime? Those who share this concern may argue that it is better to work with already recognized bodies, like the AHRQ and IOM committees, but

309. BARBER & MILLER, *supra* note 308.

310. *Id.*

311. HEALTH CONNECTOR: HEALTH INSURANCE FOR MASSACHUSETTS RESIDENTS, <https://www.mahealthconnector.org/portal/site/connector> (last visited Dec. 4, 2010).

make sure they are better funded to keep guidelines up-to-date and free from corporate influence.

Given the bad reputation current guidelines have, it may actually be easier to get political support for a fresh start, rather than for doing more of the same.³¹² Even if enough funding could be provided—and there is no reason to believe the government could systematically provide better funding than the market—the mix of corporate finance and medical innovation is inevitable. So long as this mix exists—and for good reasons, it always exists—surmounting parties' financial self-interest in the healthcare industry will be unachievable. The PRR has a tremendous comparative advantage over the current regime in that it acknowledges this reality and attempts to align the private financial interest with the social ones.

V. BEYOND MEDICAL MALPRACTICE

I have developed a general theoretical framework of optimal private regulation and applied it to the healthcare system. Yet the framework applies even more broadly. Indeed, there is a well-known debate about the comparative advantages of using *ex ante* agency regulation versus *ex post* tort liability in response to market failures in various industries. Those who favor agency regulation emphasize the informational and coordination advantages, expertise, thorough analyses, and political accountability of regulatory agencies. Advocates of agency regulation also point to the interest that potential defendants have in uniform industry conduct and legal certainty. They argue that agency-developed *ex ante* perspectives are superior to the hindsight-biased, *ex post* perspectives of judges and juries.

In contrast, those who favor private tort liability emphasize supposed informational advantages of courts, the social laboratory advantages of federalism, and the socially beneficial information-discovery function of tort law. They argue that courts are more impartial because courts are less likely to suffer from agency capture or principal-agent problems. Finally, they appeal to the importance of the compensation

312. See *supra* Part II.B.

goal that tort law more directly achieves. Surprisingly, it seems that none have suggested regulating by way of the ex ante private regulation that would occur when the PRR contracts with an industry or a particular industry player to write detailed guidelines regulating some conduct.

The PRR combines most of the advantages of public regulation and private law, while discarding most of the drawbacks. Specifically, the PRR engages unbiased experts as repeat players in determining optimal conduct from the ex ante perspective. Public agencies are held accountable, at best, to the government or the media, and they normally cannot be sued for damages for their regulations.³¹³ Private regulators, in contrast, would be held financially accountable. Unlike courts that perform an ex post analysis which is subject to hindsight and other biases, a PRR would operate from the ex ante perspective, taking into account not only the costs of conduct, which courts usually do observe, but also the benefits to others, which courts, operating from the ex post perspective, usually do not. Unlike public regulation regimes, a PRR is not as susceptible to interest group politics. Also, a PRR allows for competition and experimentation with various guidelines in a way that ex ante single-agency public regulation could never allow.

CONCLUSION

The diagnosis for American healthcare is poor. Along with extreme underuse and overuse, the medical system is riddled with mistakes. Although the primary cause of overuse—defensive medicine or offensive medicine—are debatable, no one questions the existence of the problem. After his inauguration, President Obama stated that innovative approaches to these issues are needed and that he would be receptive to providing doctors with immunity from medical malpractice claims. Moreover, he promoted endorsing the standardization of medical treatments to control healthcare costs. Critically, current guidelines are not generally effec-

313. Spurred by an executive order issued from President Clinton in 1999, there has been a recent national push to increase federal agency accountability to state government interests. See Catherine M. Sharkey, *Federalism Accountability: "Agency Forcing" Measures*, 58 DUKE L.J. 2125, 2155 (2009).

tive because they are formulated with conflicting objectives and financial incentives. Without appropriate incentives, reductions in medical expenditures will not be realized, and insulating doctors from medical malpractice claims cannot be defended.

I have offered a potential answer, which combines these goals into one legislative bill. The solution is not, as many have feared, a government that closely regulates the health-care system, but a system of many private regulators which set standards for patient care. As I have demonstrated, a system of private regulators competing to provide EBM guidelines that offer liability protection to complying doctors could materially curtail the massive expense of malpractice litigation and, more significantly, improve patient safety while cutting aggregate healthcare costs.

To draw customers who desire lower prices, private regulators would have to promulgate guidelines that competitively address cost and simplicity. With this goal in mind, private regulators would be pressured to eliminate unjustifiably costly and unproductive procedures. Simultaneously, the threat of lawsuits would spur firms to push medical standards higher, in an effort to prevent unnecessary injuries to patients and unwieldy liability for the firm. In contrast with the current goals of clinical guideline providers, private firms' incentives would be in concert with patient safety, and these companies would be financially motivated to develop advancements constantly. Payers and liability insurers would prudently capitalize upon their expertise in the field to support and even pursue the private regulation of physician practices—all with the added benefit of improving patient safety. Reduced malpractice liability would allow doctors to devote more attention to patient care and to worry less about litigation. Although the transition will be difficult, the positive effects of privatizing medical guidelines will likely exceed the negative consequences, and will represent a material advance over the status quo and other alternatives.

My work develops, expands, and further theorizes on some ideas recently raised by others. Professors Silver and Hyman briefly discussed the possibility of recognizing evidence-based medicine as an absolute defense against liabil-

ity.³¹⁴ Professor Havighurst argued decades ago that promulgation of guidelines should be decentralized rather than being done behind closed doors.³¹⁵ Professor Blumstein has argued that to clarify the uncertain standard of care, guidelines should be promulgated *ex ante* and serve as a safe harbor for doctors.³¹⁶ All these scholars, however, fell short of advocating for private regulation of guidelines.³¹⁷ I, along with Professors Hyman and Silver have also suggested using a cap on damage awards as a carrot to doctors who comply with EBM norms.³¹⁸

Admittedly, this analysis does not fully address some important questions. Private regulation does not solve the problem of compensating the injured when they receive optimal care, yet some remote risk materializes. Some may argue that it is acceptable when people who receive a treatment with a small risk of an adverse outcome that actually materializes do not receive compensation. Others may believe this is a problem. There is much to be said about this. Here, however, it is sufficient to say that existing regulation and tort law do not fare any better than the proposed PRR on this issue. Regulations usually ignore the victim, and tort law is often preempted, explicitly or not, by regulations, leaving the victims without any recourse.³¹⁹ Even when tort law is

314. Hyman & Silver, *supra* note 195, at 990.

315. See Havighurst, *supra* note 120, at 801.

316. See Blumstein, *supra* note 64, at 1017, 1019, 1021.

317. *Id.*

318. In the context of internet regulation, Professor Philip Weiser has even suggested that self-regulatory organizations overseen by government agencies could utilize the expertise of industry players to induce optimal standards, while still maintaining the appropriate level of legal accountability. Philip J. Weiser, *The Future of Internet Regulation* 46–47 (Col. Legal Studies Research Paper Series, Working Paper No. 09-02, 2009). As Professor Weiser explains, the government lacks the ability and expertise to regulate optimally without the help of private regulatory organizations composed of representatives within the field which they are regulating. *Id.* Similar to the PRR, his proposal necessitates government intervention to enable the creation of private regulatory organizations whose expertise will facilitate an efficient regulatory market. *Id.*

319. As noted by Professor Catherine Sharkey, the trend towards increasing federal preemption of state tort claims has created a “troublesome asymmetry with respect to agency decision making: courts appear to grant agencies expansive discretion to interpret or declare the preemptive scope of the regulations that they promulgate, whereas agencies are not given corresponding latitude to infer private rights of action under those same regulations.” See Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227,

not preempted, it does not compensate victims of nonnegligent care.

Nevertheless, policymakers have a new and exciting alternative that goes well beyond capping damages or throwing more money at professional groups to write regulations. Private regulation deserves to be seriously considered by Congress as it attempts to reform the healthcare and liability systems. With the ACA in place and funds for various demonstration projects available, now is the perfect time to facilitate a regime of private regulation.

258–59 (2007). This issue is demonstrated by recent court decisions holding that, despite agency intent, no private action against agency regulations can either be created or taken away unless Congress has provided clear guidance. *Id.* at 248–50. Additionally, even where Congress has expressly provided a right for private action against agency regulations, the boundaries for those rights will primarily be interpreted *ex post* by the courts, not by the agencies themselves. *Id.* Professor Sharkey promotes a more cooperative *ex ante* approach, which would require agencies and courts to work together to define the boundaries of preemption issues before the full enactment of agency regulations. *Id.* at 258–59.