

# Clinical Practice Guidelines: The Warped Incentives in the U.S. Healthcare System

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*The healthcare system is sick. The players are incentivized to maximize their own benefit and externalize their costs onto the other parties. This paper examines the warped incentives that underlie the system. The tort system, lacking expertise and slow to adapt, is unable to overcome cognitive biases to adequately solve the problems. Clinical practice guidelines could pose a solution, but not as they are currently developed. Guidelines promulgated by healthcare associations are infected by a web of conflicts of interest with every player in the industry. Government agencies, and their revolving doors, are underfunded and also subject to the industry's web of conflicts. Even if adequate guidelines could consistently be produced, state legislatures and courts have been unwilling and unable to substantially incorporate guidelines into the legal landscape. Lastly, this article proposes a private regulation regime that could be a solution which would align all of the players' incentives to society's interests.*

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## I. INTRODUCTION

Washington is boiling over healthcare reform. The landmark reform—called the Patient Protection and Affordable Care Act (ACA)—was signed into law on March 23, 2010, and was dubbed just ACA.<sup>1</sup> It seems every day brings a new headline discussing the Republicans' latest attempts to reverse ACA,<sup>2</sup> and the Democrats' promise to fight them.<sup>3</sup> Lost in the political spat, however, is what reforms would actually be effective. Everyone agrees that patients should be able to find cheap, safe, and efficient care. Not only is there disagreement as to how to achieve those goals, but, at least in Washington, there is very little discussion of the underlying principles behind the reform.

Any healthcare reform must deal with at least three categories of costs: medical errors, defensive medicine, and what I call offensive medicine.

Medical errors are caused by fatigue, poor judgment, over-confidence, lack of resources, lack of training, and lack of communication. The costs of medical errors include unnecessary hospitalization, injury, loss of income, and suffering. Patients, their insurers, and the hospital all bear the costs of these mistakes.

“Defensive medicine” is excessive care provided to avoid liability. For example, an overly cautious doctor may order a CT scan when only an X-ray is medically necessary, thus externalizing the extra cost to the patient and his health insurer.<sup>4</sup> A recent Wall Street Journal Op-Ed piece estimated that defensive medicine costs on average \$200 billion per year, although other estimates are significantly lower.<sup>5</sup>

“Offensive medicine” is excessive care which doctors provide in an attempt to maximize reimbursements. These costs usually include minor procedures, but can also include more lucrative treatments such as heart surgery.<sup>6</sup> These

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<sup>1</sup> Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (2010) (to be codified as amended in scattered sections of the Internal Revenue Code and 42 U.S.C.).

<sup>2</sup> The first attempt was scheduled for January 12, 2011. See Robert Lowes, *GOP Schedules House Vote to Repeal Healthcare Reform Law*, MEDSCAPE MED. NEWS (Jan. 4, 2011), <http://www.medscape.com/viewarticle/735209>.

<sup>3</sup> Michael D. Shear, *Democrats Plan Attack on Republican Repeal Effort*, N.Y. TIMES POL. & GOV'T BLOG (Jan. 6, 2011, 6:05 AM), <http://thecaucus.blogs.nytimes.com/2011/01/06/democrats-plan-attack-on-republican-repeal-effort/>.

<sup>4</sup> Another paradigmatic example of externalization is cesarean deliveries:

When the doctor chooses vaginal delivery and harm materializes, he is frequently sued, whereas in the event of a cesarean delivery, the patient rarely sues. Arguably this happens not because cesarean deliveries never end in harm, but because either the harm is too minor to justify a legal suit or there is a latent harm with long-term effects that can hardly be traced back years later to the operation. The result is that most of the harms caused by cesarean deliveries are externalized to the patient, while most of the harms caused by vaginal deliveries are internalized to the doctor.

Ariel Porat, *Offsetting Risks*, 106 MICH. L. REV. 243, 265 (2007).

<sup>5</sup> See Philip K. Howard, Op-Ed., *Why Medical Malpractice Is Off Limits*, WALL ST. J. (Oct. 15, 2009, 10:29 PM), <http://online.wsj.com/article/SB10001424052970204488304574432853190155972.html>; U.S. DEP'T OF HEALTH & HUMAN SERVS., ADDRESSING THE NEW HEALTH CARE CRISIS: REFORMING THE MEDICAL LITIGATION SYSTEM 11 (2003) (estimating that defensive medicine costs between \$70 and \$126 billion per year).

<sup>6</sup> See STEPHEN KLAIDMAN, CORONARY: A TRUE STORY OF MEDICINE GONE AWRY (2007) (detailing an FBI investigation which discovered that up to 50% of the 1,000 bypasses a year

costs grow because, among other reasons, patients are insured for their health costs. Doctors are essentially in an all-you-can-treat system, with the same incentives to save as in an all-you-can-eat restaurant. President Obama has described this as a system of “warped incentives.”<sup>7</sup> Similar to costs associated with defensive medicine, these costs are borne by both patients and their insurance carriers. Academics have long documented this problem—which economists call “induced demand”—yet no one has estimated its overall impact.<sup>8</sup> It is suspected, though, that the costs of offensive medicine are higher than the other two types of costs combined.

Some of the more promising proposals in Washington offer doctors immunity from medical malpractice in return for following evidence-based clinical practice guidelines.<sup>9</sup> These proposals make sense because a major role of medical malpractice liability is to create incentives for doctors to behave optimally.<sup>10</sup> It follows naturally to give immunity to those who behave optimally by delivering evidence-based medicine. Thus, medical errors would be addressed by incentivizing doctors to follow guidelines, and defensive medicine would be addressed by granting doctors immunity. However, these proposals miss perhaps the most important point: the intrinsic problem with the actual *production* of the evidence-based medical guidelines. If medical guidelines are not produced under appropriate incentives, then the guidelines produced are not optimal, the doctors following them are not behaving optimally, and immunity for doctors from medical malpractice is not justified.

In this paper I describe the costs of the current legal regime in terms of medical errors, defensive medicine, and offensive medicine. I also describe the problems with existing tort law and how it treats medical guidelines. I conclude by sketching a new alternative regime I call *private regulation* that may solve many of the intrinsic problems the current regime faces.

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at the Redding Medical Center in California were not medically justified). Atul Gawande recently documented how hospitals in McAllen, Texas perform offensive medicine to enrich themselves at the expense of the public. He pegged spending in McAllen at \$14,946 per Medicare enrollee per year, about twice as much as nearby and socio-demographically similar El Paso. Atul Gawande, *The Cost Conundrum: What a Texas Town Can Teach Us About Health Care*, NEW YORKER (June 1, 2009), at 36.

<sup>7</sup> Barack Obama, Pres., United States of America, Remarks by the President in Town Hall Meeting on Health Care (June 11, 2009) (transcript available at [http://www.whitehouse.gov/the\\_press\\_office/Remarks-by-the-President-in-Town-Hall-Meeting-on-Health-Care-in-Green-Bay-Wisconsin/](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.”).

<sup>8</sup> See Jonathan Gruber & Maria Owings, *Physician Financial Incentives and Cesarean Section Delivery*, 27 RAND J. ECON. 99, 120 (1996) (suggesting physicians substituted c-section delivery for normal delivery in order to make up for negative income shocks from decreased fertility rates); Jerry Cromwell & Janet B. Mitchell, *Physician-Induced Demand for Surgery*, 5 J. HEALTH ECON. 293, 311-13 (1986).

<sup>9</sup> Such a safe harbor is part of the Obama Administration’s drive to overhaul the medical malpractice system. 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-medical-malpractice-reforms-1014244.php>. For a recent summary of the proposals see Troven A. Brennan & Michelle M. Mello, Commentary, *Incremental Health Care Reform*, 301 JAMA 1814, 1815-16 (2009).

<sup>10</sup> By “optimal,” I mean the socially optimal balance between safety, effectiveness, cost, and other relevant factors such as political or moral concerns.

## II. REGULATING PROVIDERS' BEHAVIOR

### A. THE PROBLEM WITH TORT LAW

Currently healthcare is expensive—very expensive. In fact, ours is the most expensive healthcare system in the world, but it does not deliver measurably better outcomes.<sup>11</sup> There are many reasons why the healthcare system is so expensive, but in this paper, as mentioned above, I will focus on only three of the leading causes: medical errors, defensive medicine, and offensive medicine.

The law has tried to tackle these three problems separately. Offensive medicine is supposed to be controlled by various anti-kickbacks laws,<sup>12</sup> anti-self-referral laws (Stark laws),<sup>13</sup> utilization review, and by subjecting doctors to medical malpractice liability for negligent care. Defensive medicine is supposed to be controlled by utilization review and by enacting tort reform geared towards reducing doctors' liability. Medical errors are supposed to be controlled by subjecting doctors to tort law, specifically medical malpractice law, for committing negligent errors.

Using one policy tool, say tort law, to combat all these problems is problematic. Attempting to solve one problem immediately exacerbates another. For example, tort reform that reduces providers' liability does dilute incentives to perform defensive medicine, but at the same time has two adverse effects. First, it dilutes providers' incentives to take optimal care, thus potentially increasing costs from medical errors. Second, decreasing liability increases providers' incentives to perform offensive medicine. For example, providing an excessive bypass surgery is less risky when malpractice liability is capped.<sup>14</sup>

Indeed, tort law's primary mission is not to cure all three problems, but instead it focuses largely on medical errors. Tort law, in fact, is the primary way the legal system deals with medical errors by regulating providers' behavior. Unfortunately it does not do a satisfying job on that frontier. There are two necessary conditions for tort law to optimally regulate behavior under a regime of negligence. First, *all* negligence cases, not just the large ones, must be brought. If not all negligent cases are brought, then victims remain uncompensated for the harm they have incurred, and the signal from the legal system that is supposed to incentivize optimal behavior is distorted. Second, for cases that are brought, the court must find liability only when defendants

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<sup>11</sup> Uwe E. Reinhardt et al., *U.S. Health Care Spending in an International Context*, 23 HEALTH AFF. 10, 10-12 (2004).

<sup>12</sup> See 42 U.S.C. § 1320a-7b(b) (2006).

<sup>13</sup> See 42 U.S.C. § 1395nn (2006).

<sup>14</sup> In 2002, an FBI investigation of officials at the Redding Medical Center in California (also known as "little house of horrors") discovered that up to fifty percent 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 Paul Jacobs, *Heart Surgeries Lead Hospital Into Difficulties*, L.A. TIMES, July 31, 1980, B1 (reporting that doctors at Paramount General Hospital in California were "anxious to operate on almost anything"). See also KLADMAN, *supra* note 6, at 7-11 (reporting that officials from the Psychiatric Institutes of America in Texas bribed doctors for referrals; after an FBI investigation, some doctors were sent to jail and PIA paid \$379 million in fines and settlements with plaintiffs who had been wrongly admitted to the psychiatric institution).

were actually negligent (and caused harm thereby, to be technically correct).<sup>15</sup> Even unbiased, random judicial error will cause defendants to be too careful or to engage in too little activity.<sup>16</sup> If courts *are* biased—for example if false negatives (erroneously finding doctors not to be negligent) are more common than false positives (erroneously finding doctors negligent)—or if courts’ random errors are relatively large, the problem worsens.<sup>17</sup> The major reasons courts make biased decisions are the “identifiable other effect” and “hindsight bias.” The major reason courts can make relatively large random errors is that they lack expertise in dealing with complex medical issues. Lastly, the nature of the common law limits courts’ ability to incentivize (or at least not to impede) medical progress. What follows is a discussion of these barriers to the legal system, court biases, errors and limitations.

### 1. Barriers to the Legal System

Although it is commonly perceived that Americans sue too often, evidence indicates that the opposite is true. 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.<sup>18</sup> The researchers matched cases of negligent injury with actual claim filings, and determined that only two percent of those who were negligently injured sued.<sup>19</sup> A similar 1992 study focusing on hospitalizations in Colorado and Utah found similar numbers; only 2.5% of those who were negligently injured filed a claim.<sup>20</sup> Lastly, these findings were consistent with a late 1990s Florida study that found that of 19,885 incidents of medical negligence self-reported by hospitals, only 3,177 patients filed claims.<sup>21</sup>

There are a number of barriers that prevent malpractice victims from pursuing claims, but I will discuss only two. First, many patients may not even realize that they have a valid claim. Even for those forms of negligence that cause great harm, patients may lack the ability to connect the dots.<sup>22</sup> For example, a wrongly-interpreted test result may cause the unnecessary progression of a harmful disease that does not begin debilitating the patient

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<sup>15</sup> The law also needs to award the correct amount of damages. In what follows, I assume that courts can determine damages well. I focus on better defining negligence.

<sup>16</sup> See Steve Shavell, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW 224-25 (2004).

<sup>17</sup> *Id.*

<sup>18</sup> See David Hyman & Charles Silver, *Medical Malpractice 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) (noting that the likelihood of a claim was substantially higher when the injury was more severe)).

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> See *id.* at 1090-91. See also FLORIDA AGENCY FOR HEALTH CARE ADMIN., DIV. OF HEALTH QUALITY ASSURANCE, REPORTED HMO MALPRACTICE CLAIMS BY DISTRICT COMPARED TO REPORTED ADVERSE INCIDENTS 2007, available at <http://www.fdhc.state.fl.us/SCHS/risk/documents/2007HMOMalp.pdf> (showing that in 2004 malpractice claims were only twenty-three percent of reported incidents). Since self-reported negligence numbers will almost certainly under-report the volume of negligence, the percentage of malpractice victims who filed a claim in the Florida study is probably much lower than these numbers suggest. See Hyman & Silver, *supra* note 18, at 1090-91.

<sup>22</sup> See Hyman & Silver, *supra* note 18, at 1113.

until the test itself is a distant memory. The problem may be amplified by the fact that the doctor who committed the error holds much of the information on whether an error occurred.<sup>23</sup>

Second, many aggrieved patients can be deterred from pursuing claims by the disproportionate cost, time, and stress of litigation in comparison to the amount of damages likely to be recovered.<sup>24</sup> The high cost to benefit ratio is often caused by high discovery costs, expensive expert witnesses, state-exacted tort reform which limits the recovery, and the typical defendant litigation strategy of fighting even meritorious claims.<sup>25</sup> Due to these high costs, most patients must find contingency fee attorneys. These lawyers have an incentive to take only the most lucrative cases, leaving many victims of malpractice without recourse. These “orphan” victims often come from states that enact tort reform, such as caps on damages.

## 2. The Identifiable Other Effect

There is some evidence suggesting that courts seem to compensate the injured when their harm is large, even in the absence of negligence.<sup>26</sup> Indeed, the urge to compensate victims is so strong that courts in the United States have developed various doctrines that appear at times to award plaintiffs as much compensation as possible. For example, the doctrine of lost chance (a doctrine which is primarily applied to medical malpractice) allows partial recovery even when the patient was already likely to die prior to her interaction with the doctor.<sup>27</sup> The reason for courts’ bias toward the compensation goals could well be rooted in the identifiable other effect. As first noted by Thomas Schelling, identifiable victims stimulate more powerful emotional reactions than do statistical victims.<sup>28</sup> For example, over \$700,000 was donated to rescue 18-month-old Jessica McClure (“Baby Jessica”) when she was trapped in a well in Texas. The same \$700,000 could have potentially saved many more lives if spent on preventative health care for children.<sup>29</sup> For various reasons, people seem to care more about identifiable victims than statistical victims.<sup>30</sup>

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<sup>23</sup> *Id.*

<sup>24</sup> *Id.* at 1132.

<sup>25</sup> *Id.* at 1123.

<sup>26</sup> See David M. Studdert et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, 354 NEW ENG. J. MED. 2024 (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).

<sup>27</sup> See Joseph King Jr., *Causation, Valuation and Chance in Personal Injury Torts Involving Preexisting Conditions and Future Consequences*, 90 YALE L.J. 1353, 1381-82 (1981). About half of the states have adopted some variation of the doctrine. See Torry Weigand, *Loss of Chance in Medical Malpractice: A Look at Recent Developments*, 70 DEF. COUNS. J. 301, 302-03 (2003).

<sup>28</sup> Thomas C. Schelling, *The Life You Save May Be Your Own*, in PROBLEMS IN PUBLIC EXPENDITURE ANALYSIS 127, 129 (Samuel B. Chase ed. 1968).

<sup>29</sup> See Deborah A. Small & George Loewenstein, *Helping a Victim or Helping the Victim: Altruism and Identifiability*, 26 J. RISK AND UNCERTAINTY 5, 5 (2003) (showing that “subjects were more willing to compensate others who lost money when the losers had already been determined” and people contributed more to a charity for a pre-selected family than when told that the family *would* be selected later).

<sup>30</sup> *Id.* at 5-6.

Recently, commentators have claimed that the identifiable victim effect is just an example of a more general tendency to react more strongly to identifiable others, whether they are victims or perpetrators.<sup>31</sup> If correct, the “identifiable other effect” suggests that courts react more strongly towards both the identified defendant-doctor and the identified plaintiff-victim, treating the identified doctor more harshly and the identified victim more sympathetically. This can lead to many more (presumably erroneous) findings of negligence compared to adjudication based on the efficiency of guidelines per se, a task that involves dealing with statistical victims and statistical doctors.<sup>32</sup>

### 3. The Hindsight Bias

Another well-known problem that courts suffer from is the hindsight bias, which emerges because courts engage in ex post analysis. Because of hindsight bias, “people consistently exaggerate what could have been anticipated in foresight.”<sup>33</sup> Thus, under the current medical malpractice negligence regime, doctors may be found liable when their patients are injured even though the doctors behaved reasonably. Anticipating courts’ hindsight bias and the impossibility of eliminating or even moderating it, doctors may be rational in practicing defensive medicine.<sup>34</sup> This problem has been noticed by courts, which use various techniques that potentially moderate the hindsight bias.<sup>35</sup> But the actual success of these techniques is an open question. Consider the way courts treat compliance with medical custom (but not with custom in other industries). In most jurisdictions such compliance is virtually a complete defense.<sup>36</sup> This should eliminate hindsight bias and reach the efficient outcome, but only if the custom evolved is indeed efficient. But there are reasons to doubt that an efficient custom will evolve in medicine, due to the heterogeneity of patients’ medical conditions, patients’ ignorance of the appropriate care they should receive, patients’ unequal financial conditions which ultimately determine the level of health care they receive, and the myriad agency problems between doctors, hospitals and payers.<sup>37</sup>

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<sup>31</sup> See Deborah A. Small & George Loewenstein, *The Devil You Know: The Effect of Identifiability on Punitiveness*, 18 J. BEHAV. DECISION MAKING 311, 311-18 (2005) (showing that “people are more punitive toward identified wrongdoers than toward equivalent, but unidentified, wrongdoers”).

<sup>32</sup> It is theoretically possible that the increased harshness and increased sympathy towards identifiable others is in fact the “accurate” level of harshness and sympathy. This would indicate that people’s judgment of the statistical victims and statistic perpetrators is actually what is distorted.

<sup>33</sup> Baruch Fischhoff, *Hindsight ≠ Foresight: The Effect of Outcome Knowledge on Judgment Under Uncertainty*, 1 J. EXP. PSYCH. 288 (1975).

<sup>34</sup> See Jeffrey J. Rachlinski, *A Positive Psychological Theory of Judging in Hindsight*, 65 U. CHI. L. REV. 571, 598 (1998) (explaining that defendants who take a higher level of care only have to pay for precautions, not additional damages).

<sup>35</sup> *Id.* at 610-20.

<sup>36</sup> See DAN B. DOBBS, *THE LAW OF TORTS* § 242 (2006). Over the last few decades, however, some courts have allowed risk-utility proof to override what they consider sub-optimal medical custom. See, e.g., *Helling v. Carey*, 519 P.2d 981 (Wash. 1974).

<sup>37</sup> See James A. Henderson Jr. & John A. Siliciano, *Universal Health Care and the Continued Reliance on Custom in Determining Medical Malpractice*, 79 CORNELL L. REV. 1384, 1389-1400 (1994).

#### 4. The Lack of Expertise

In addition to bias problems, courts suffer from a lack of expertise and information. Courts 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 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. But courts 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.

Moreover, even if the information on the relative value of various treatments exists, courts are unlikely to get it right. Many of the cases litigated deal with complex medical issues, and the likelihood that fact-finders (whether bench or jury) with little expertise will get things right is not promising. Expert witnesses do not solve the problem either, as these experts often are ex-doctors who make their living by providing expert testimony. These ex-doctors are usually no longer involved in active doctoring and potentially testify for the highest bidder. Judge Posner described expert witnesses as "paid liars."<sup>38</sup> Cross-examination of experts does not improve the jury's understanding of the problem, as cross-examination often deteriorates into haggling over credentials.<sup>39</sup>

A possible, yet only partial, solution to this problem would be to establish a health court system of administrative compensation for medical injuries, similar to the way injuries at work are handled. In February, 2011, the Obama administration announced its plan to do exactly that. Two of the potential advantages of such a system include the cultivation of a culture of transparency regarding medical errors and the creation of mechanisms for gathering and analyzing data on medical injuries. Indeed, several foreign countries—New Zealand, Sweden and Denmark—have already implemented such a system.<sup>40</sup> As attractive as this solution is, it is controversial and politically difficult. Moreover, health courts by themselves do not require a specific standard to judge doctors' behavior, and are susceptible to the other problems highlighted in this section.

#### 5. Common Law and Medical Progress

Another limitation of the common law is that it fails to encourage systematic knowledge-production as well as continuously updated behavior-regulation mechanisms. Unfortunately, the current system is inadequate with respect to both investigation and adoption of new medical procedures. The investigation of procedures such as surgical techniques is often left to the creativity and improvisation of any willing physician, which is of course

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<sup>38</sup> RICHARD POSNER, AN AFFAIR OF STATE: THE INVESTIGATION, IMPEACHMENT, AND TRIAL OF PRESIDENT CLINTON 147 (1999).

<sup>39</sup> See, e.g., Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 STAN. L. REV. 1, 37-39 (1993).

<sup>40</sup> Michelle M. Mello et al., "Health Courts" and Accountability for Patient Safety, 84 MILBANK Q. 459, 478-82 (2006).

problematic.<sup>41</sup> In most cases, a new procedure does not require the approval of any governmental agency. But still, physicians interested in developing new techniques face numerous informational barriers, as well as additional tort liability risk. Often an individual physician will see too few patients needing a particular procedure to confirm that an innovative procedure is a significant improvement. This is problematic since adopting new procedures can be costly (in terms of training, infrastructure, and the risk of being perceived as having adopted a poor procedure).

Even for those procedures already proven superior, significant barriers to adoption by physicians exist.<sup>42</sup> Because the new procedures are often taught in medical school, less impressionable doctors, long out of school, are unlikely to adopt them.<sup>43</sup> Underlying everything is the risk of tort liability. The common law proceeds in a decentralized, amorphous fashion as development is informed by uncoordinated and self-interested advocates. Therefore, notwithstanding theories of efficient evolution of the common law, there is no guarantee—in fact it is highly unlikely—that the long process of generalization and rationalization of disparate outcomes will yield efficient rules *quickly enough* to keep pace with advances in medicine. Second, as recently argued by Stein and Parchomovsky, since following current industry custom is still the best way to prevent potential medical malpractice liability, doctors are often reluctant to embrace medical innovations, and consequently there is substantially sub-optimal incentive to innovate.<sup>44</sup> Because innovation is cumulative, by impeding certain innovations from being produced in a timely fashion, the custom rules deprive society not only of those particular innovations but also of many subsequent innovations. Indeed, it takes an average of seventeen years for quality medical research to actually be endorsed by clinical practice guidelines.<sup>45</sup> Third, individual judges are too unaware of the process of which they are a part, a process that leaves little margin for correcting erroneous paths. To the extent that courts' determinations of the reasonableness of any medical procedure are taken into account by doctors in their future medical decision-making, society faces the risk of stagnation in the implementation of medical innovation. These problems are not inherent in the quality of litigators and judges. Instead, they are integral to common law adjudication itself.<sup>46</sup> Furthermore, courts, especially juries, lack accountability. While it is true that a trial judge can render a decision n.o.v., and that a court of appeals could find a jury verdict unsupported by facts, in general a jury answers to no one. And even if inexperienced judges sometimes check

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<sup>41</sup> See, e.g., Elena A. Gates, *New Surgical Procedures: Can Our Patients Benefit While We Learn?*, 176 AM. J. OBSTETRICS & GYNECOLOGY 1293, 1293-96 (1997).

<sup>42</sup> Michael D. Cabana et al., *Why Don't Physicians Follow Clinical Practice Guidelines?: A Framework for Improvement*, 282 JAMA 1458, 1461-62 (1999).

<sup>43</sup> See *id.*

<sup>44</sup> Gideon Parchomovsky & Alex Stein, *Torts and Innovation*, 107 MICH. L. REV. 285, 305-06 (2008).

<sup>45</sup> Paul H. Keckley, *Evidence Based Medicine in Managed Care: A Survey of Current and Emerging Strategies*, 6 MEDSCAPE GEN. MED. 56, 56 (footnote omitted). See also AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, CLOSING THE QUALITY GAP: A CRITICAL ANALYSIS OF QUALITY IMPROVEMENT STRATEGIES 1 (2004), available at <http://www.ahrq.gov/clinic/epc/qgapfact.pdf>.

<sup>46</sup> Peter H. Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, 13 ROGER WILLIAMS U. L. REV. 73, 97-98 (2008).

the jury, nothing short of legislation or voters checks the judges. From the perspective of optimal implementation of medical innovation, this is too little and too late.<sup>47</sup>

## 6. Summary of Problems with Tort Law

The result of these problems is a disconnect between negligence and liability. Scholars on both sides of the tort reform map have insisted that the signals between court outcome and real negligence are too weak. Doctors complain that court outcomes cannot be seriously taken into account when decisions are being made about patients' lives. As a result we risk defensive medicine and offensive medicine.

Moreover, uncertainty arising from the prospect of liability under varying negligence determinations can inhibit hospitals and doctors from investing in the development of socially valuable medical procedures, adversely affecting patient safety. Furthermore, since our system evaluates negligence relative to customary care, widely-practiced defensive medicine may create inefficient norms that further undermine any potential of tort law to encourage efficient medical practices.

More generally, current tort law misses something important—the encouragement of efficient doctoring. It creates large incentives for over-treatment by means of defensive and offensive medicine.

Clinical practice guidelines (CPGs) produced under the right incentives could avoid many of the current costs. Optimal CPGs would reduce costs associated with medical errors, because they would limit providers' discretion and encourage evidence-based medical practices. The presumption that doctors following the CPGs are not negligent would reduce costs associated with defensive medicine because providers would no longer feel compelled to shield themselves from liability by providing or ordering unnecessary services. CPGs may also reduce costs associated with offensive medicine. First, they would provide doctors with information on the most efficient care level. Second, doctors would have a relatively weak incentive to provide excessive care because doing so would cause them to lose the presumption of non-negligence. The next section explains why existing guidelines do not achieve these benefits.

## B. THE PROBLEM WITH GUIDELINES

### 1. A Brief History of CPGs in the United States

Medical guidelines have proliferated over the last fifty years, but starting in the 1990s, the number of guidelines being produced increased dramatically. This increase coincided with widely publicized studies that demonstrated a large variation in clinical practice across geographic areas and even within the same area.<sup>48</sup> During this time, guidelines were increasingly being produced by

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<sup>47</sup> This should not be read broadly as an indictment against the entire legal system, but more specifically to the inability of the courts to efficiently regulate procedures in quickly-evolving medical fields when the only checks against their decisions require considerable time.

<sup>48</sup> For example, a study published in the early 1980s described how in Maine, the likelihood of a woman having a hysterectomy by the time she reached age seventy varied from

a variety of different organizations, including professional societies, hospitals, health plans, and review boards. Notably, it was during this time that the Agency for Health Care Policy and Research spearheaded the development of about twenty guidelines across key clinical practice areas.<sup>49</sup>

Many of these guidelines eventually gave way to the push from Evidence-Based Practice Centers working with private organizations, but the degree to which new guidelines actually coincided with scientific evidence varied widely.<sup>50</sup> This lack of consistency was enhanced by variability in the quality and specificity of information used to create guidelines. Organizations often find it difficult to incorporate new research promulgated after the guideline creation process has been initiated, and physicians are understandably critical of guidelines of inconsistent evidentiary backing. To combat these problems, the Agency for Healthcare Research and Quality (AHRQ), in partnership with the American Medical Association (AMA), and American Association of Health Plans, has developed a National Guideline Clearinghouse. The Clearinghouse was designed to provide access to the overwhelming number of guidelines along with the strength of the evidence supporting the guidelines according to the guideline producer so that practitioners can judge the evidence for themselves.<sup>51</sup> Currently, the Cochrane Collaborations, the Trip database and the National Guideline Clearinghouse serve as links to literally thousands of medical treatment guidelines.<sup>52</sup> Although guidelines are problematic, they represent a significant advance in the effort to promote consistent clinical care standards that efficiently utilize evidence-based medicine.

Guideline optimality clearly depends on the specific nature of the applicable procedure. Given the fast progress of medical research, even guidelines that were initially optimal will not remain so for more than a few years unless updated.<sup>53</sup> More importantly, it is questionable whether guidelines are initially developed under the appropriate incentives and whether the practitioners have appropriate incentives to follow them. Despite wide promulgation, guidelines seem to have had limited effect on incentivizing physician behavior.<sup>54</sup> A recent study found that barriers primarily include lack of awareness, lack of familiarity, lack of agreement with the validity of guidelines, and external barriers such as time limitations and

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twenty to seventy percent in different hospital markets. In Iowa, the likelihood that a man who reached the age of eighty-five would have had a prostatectomy varied from fifteen to sixty percent in different areas. In Vermont, children who had undergone a tonsillectomy varied from eight to seventy percent depending on geographic area. John E. Wennberg, *Dealing with Medical Practice Variations: A Proposal for Action*, 3 HEALTH AFF. 6, 9 (1984).

<sup>49</sup> See Eleanor M. Perfetto & Lisa Stockwell Morris, *Agency for Health Care Policy and Research Clinical Practice Guidelines*, 30 ANNALS OF PHARMACOTHERAPY 1117, 1119 (1996).

<sup>50</sup> Kathleen N. Lohr et al., *Health Policy Issues and Applications for Evidence-Based Medicine and Clinical Practice Guidelines*, 46 HEALTH POL. 1, 7 (1998).

<sup>51</sup> See U.S. Dep't Health & Human Servs., Agency for Healthcare Research & Quality, *National Guideline Clearinghouse*, [www.guideline.gov](http://www.guideline.gov).

<sup>52</sup> THE COCHRANE COLLABORATION, <http://www.cochrane.org> (last visited Jan. 27, 2011); TRIP DATABASE, <http://www.tripdatabase.com> (last visited Jan. 27, 2011).

<sup>53</sup> The American College of Physicians considers guidelines "automatically withdrawn or invalid 5 years after publication." See Amir Qaseem et al., *Screening for Osteoporosis in Men: A Clinical Guideline from the American College of Physicians*, 148 ANNALS OF INTERNAL MED. 680, 683 (2008).

<sup>54</sup> See Michael D. Cabana et al., *supra* note 42, at 1458.

lack of resources.<sup>55</sup> In this study, 54.5% of doctors 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.<sup>56</sup> Indeed, there is evidence suggesting that most clinicians' practices are based upon tradition, their most recent experience, what they learned years ago in medical school, or what they have heard from friends.<sup>57</sup>

*i. The Use of Guidelines in the Courts*

Just as the success of guidelines depends upon their acceptance within the medical profession itself, the law's treatment of guidelines is critical to the nature of their acceptance.<sup>58</sup> Unfortunately, there is not a great deal of empirical knowledge of how courts and lawyers are using CPGs. The information we do have indicates their use is marked by incoherency and inconsistency.<sup>59</sup> The most comprehensive empirical study of the courts' use of CPGs was conducted by Hyams, Shapiro and Brennan in 1996.<sup>60</sup> Their research included surveys of medical malpractice attorneys and a review of all relevant case law from January 1, 1980 through May 31, 1994.<sup>61</sup> While they found only thirty-seven published cases involving CPGs, their surveys of medical malpractice attorneys indicated that the legal profession was aware of CPGs and that guidelines figured into both decisions to take certain cases and settlement negotiations.<sup>62</sup>

The search also yielded twenty-eight cases in which guidelines were used successfully: twenty-two used as swords (inculpatory), and six cases used as shields (exculpatory).<sup>63</sup> Additionally, the use of guidelines was unsuccessful in seven cases by plaintiffs and two by defendants.<sup>64</sup> The authors considered their findings to indicate a clear "two-way street," although plaintiffs were clearly using guidelines more often than defendants in litigation, "at least as reflected in reported decisions."<sup>65</sup> What's more, they thought the number of cases where guidelines had been unsuccessful in achieving their intended purpose was indicative of courts' willingness "to look at guidelines critically"

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<sup>55</sup> *Id.* at 1460.

<sup>56</sup> *Id.*

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

<sup>58</sup> See Arnold J. Rosoff, *Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POL., POL'Y & L. 327, 330 (2001). See also Arnold J. Rosoff, *On Being a Physician in the Electronic Age: Peering into the Mists at Point-&-Click Medicine*, 46 ST. LOUIS U. L.J. 111, 116 (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.").

<sup>59</sup> See Rosoff, *Evidence-Based Medicine and the Law*, *supra* note 58, at 332-33.

<sup>60</sup> Andrew L. Hyams et al., *Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective*, 21 J. HEALTH POL., POL'Y & L. 289 (1996).

<sup>61</sup> See *id.* at 295.

<sup>62</sup> See Rosoff, *Evidence-Based Medicine and the Law*, *supra* note 58, at 341.

<sup>63</sup> See Hyams et al., *supra* note 60, at 296.

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

and to “carefully assess the guideline to assure that it fits the facts of the case.”<sup>66</sup>

As the Hyams, Shapiro and Brennan study and subsequent articles indicate, courts historically have not made extensive use of CPGs in medical malpractice cases, and when they have, they have tended to use them conservatively.<sup>67</sup> A recent study included a similar review of cases published in the last ten years, and tells us that this behavior has not drastically changed.<sup>68</sup> The review does show that the relative use of guidelines for inculpatory purposes has tended to decrease while use for exculpatory purposes has tended to increase. In addition, the rate of success, especially for inculpatory use, tended to decrease.

When guidelines are used in medical malpractice cases, they almost exclusively go towards articulating the legal standard of care.<sup>69</sup> The Hyams, Shapiro and Brennan study notes courts’ increasing willingness to admit guidelines as evidence, generally under the learned treatise exception to the hearsay rule.<sup>70</sup> The trend towards the admissibility of guidelines has continued over the past decade, although the more recent research found no reported cases where guidelines were accepted, on their own, to prove the standard of care.<sup>71</sup> Rather, an expert witness is almost always the conduit for admitting guidelines into court.<sup>72</sup> That they usually come in through an expert is one reason why it is not always clear how dispositive guidelines are when they are used.<sup>73</sup>

When CPGs are accepted, courts generally have been unwilling to view them as strict requirements, but rather adopt the view that guidelines must be flexible and applied on a case-by-case basis. This approach weakens a common concern that CPGs are the harbinger of “cookbook medicine,” expecting doctors to convert from practitioners to automaton applicators of medical standards.<sup>74</sup> That courts generally consider the circumstances of an individual patient, rather than blankly accept any set of guidelines, should lessen the cookbook medicine concern. Ultimately, however, flexibility brings with it inconsistency, and confirms Mello’s observation that “judicial and

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<sup>66</sup> *Id.*

<sup>67</sup> *Id.* at 310. See also Rosoff, *Evidence-Based Medicine and the Law*, *supra* note 58, at 352; Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 665 (2001).

<sup>68</sup> See Ronen Avraham & William M. Sage, *Legal Models for Assuring the Quality of CPGs* 49-59 (July 2010) (unpublished manuscript) (on file with author).

<sup>69</sup> Rosoff notes 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.” Rosoff, *Evidence-Based Medicine and the Law*, *supra* note 58, at 332. 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. See *supra* Parts B.1.i-ii.

<sup>70</sup> Hyams et al., *supra* note 60, at 293. Of course, state courts vary significantly in their rules for admissibility. See, e.g., *Hinlicky v. Dreyfuss*, 848 N.E.2d 1285, 1290 (N.Y. 2006) (allowing guidelines into evidence over hearsay objection but only to show the steps the physician had in fact taken, not for proof of the matter asserted).

<sup>71</sup> Avraham & Sage, *supra* note 68.

<sup>72</sup> See Mello, *supra* note 67, at 660.

<sup>73</sup> Hyams et al., *supra* note 60, at 295.

<sup>74</sup> Rosoff, *Evidence-Based Medicine and the Law*, *supra* note 58, at 329.

academic statements of what CPGs are meant to represent are characterized by confusion and overgeneralization. There exists little agreement as to whether CPGs represent a minimum baseline, a not-yet-attained ideal, or a customary practice that lies somewhere in between these two extremes.<sup>75</sup>

Courts do not appear to devote significant time to analyze the attributes of a persuasive set of guidelines.<sup>76</sup> As Mello observed, “most commentators tend to lump all guidelines together rather than acknowledge the varying levels of empirical certainty that undergird them.”<sup>77</sup> For example, courts seldom even acknowledge the distinction between evidence-based and consensus-based CPGs, even though, as Rosoff observes, such a distinction could be useful in deciding the weight to accord to the guidelines.<sup>78</sup> Not a single case was found from the last ten years that discussed the basis for guidelines in any real depth, regardless of whether they were relied upon or not. This failure to consider the basis of utilized guidelines, however, is consistent with the tendency of courts to accept guidelines only through expert witness testimony.

All in all, comparing the cases of the past decade with the Hyams, Shapiro and Brennan study does not indicate that courts have been using CPGs in particularly novel ways. The hesitation is surely due, at least partially, to the lack of legislation befitting their expansive use.<sup>79</sup>

#### *ii. Guidelines and State Statutes*

Over the past three decades, states have had some experience with CPGs. For example, a recent Oregon law was passed authorizing the Oregon Health Policy Board to, among other things, develop “evidence-based clinical standards and practice guidelines that may be used by providers.”<sup>80</sup> Guidelines promulgated by the Board, even though not expressly given the force of law, could nevertheless come to represent the standard of care in disciplinary proceedings and malpractice suits.

Some states have gone even further and passed legislation that created demonstration projects establishing clinical practice guidelines as statutory standards of care to be used as baselines for physicians as a defense in malpractice suits.<sup>81</sup> The most famous project, the Maine Medical Liability Demonstration Project, expired in 1999.<sup>82</sup>

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<sup>75</sup> Mello, *supra* note 67, at 680.

<sup>76</sup> There are two possible exceptions to this general rule that courts do not examine the bases for guidelines. First, some cases distinguish between *medical* guidelines and the guidelines applied by insurance companies in utilization reviews. See Rosoff, *Evidence-Based Medicine and the Law*, *supra* note 58, at 338, for a short discussion of the difference between medical practice guidelines and utilization review guidelines made by some academics. Second, the Hyams et al. study did find that guidelines written by the American College of Obstetrics and Gynecology (ACOG) were relied upon in a plurality of successful cases. Hyams et al., *supra* note 60, at 296.

<sup>77</sup> Mello, *supra* note 67, at 680.

<sup>78</sup> Rosoff, *Evidence-Based Medicine and the Law*, *supra* note 58, at 329 (“[I]n deciding what weight to accord to CPGs, [courts] may find it useful, even necessary, to distinguish between those that are based on EBM and those that are not.”).

<sup>79</sup> *Id.* at 353.

<sup>80</sup> OR. REV. STAT. ANN. § 413.011(1)(e) (West Supp. 2010).

<sup>81</sup> Linda L. LeCraw, *Use of Clinical Practice Guidelines in Medical Malpractice Litigation*, 3 J. ONCOLOGY PRAC. 254, 254 (2007).

<sup>82</sup> *Id.*

The Maine project established special advisory committees in charge of developing clinical practice guidelines for practice areas classified as hotbeds for malpractice litigation and suspected defensive medicine.<sup>83</sup> The four areas selected for this project included emergency medicine, radiology, anesthesiology, and obstetrics/gynecology. Physicians in these areas who elected to participate could introduce the guidelines into evidence as an affirmative defense to any malpractice claim.<sup>84</sup> Plaintiffs bringing such claims, however, could not introduce the guidelines into evidence to argue that failure to comply with a guideline was malpractice.<sup>85</sup> The guidelines were used only as a shield and not a sword because the purpose of the reform was to reduce liability. Unfortunately, the Maine project had little practical effect.<sup>86</sup> Few doctors believed the regulations had any discernable effect, and in only one case was the affirmative defense even raised.<sup>87</sup> The superintendent of the Maine Bureau of Insurance concluded that “the medical demonstration project had no measurable effect on medical professional liability claims, claims settlement costs, or malpractice premiums.”<sup>88</sup>

Minnesota established a project very similar to Maine’s.<sup>89</sup> The project, created through 1992 malpractice reform, provided an affirmative defense for doctors who followed the guidelines.<sup>90</sup> Also like in Maine, plaintiffs were expressly prohibited from using the guidelines offensively.<sup>91</sup> Florida also established a similar project.<sup>92</sup> A 1992 Florida healthcare reform law required, among other things, that the state Agency for Health Care Administration develop practice guidelines, either on its own or with other organizations.<sup>93</sup> Like the Maine and Minnesota projects, physicians in Florida who participated in the project and followed the guidelines had an affirmative defense to malpractice allegations.<sup>94</sup> One difference between the Florida and the Maine and Minnesota laws, however, is that the Florida statute contained no express prohibition of a plaintiff’s use of the guidelines as evidence that a physician provided substandard care.<sup>95</sup>

Vermont also incorporated guidelines into its malpractice law. As part of its healthcare reform in 1992, Vermont passed a law allowing guidelines to be

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<sup>83</sup> U.S. GOV’T ACCOUNTABILITY OFFICE, *MEDICAL MALPRACTICE: MAINE’S USE OF PRACTICE GUIDELINES TO REDUCE COSTS* 3 (1993) [hereinafter GAO REPORT].

<sup>84</sup> *Id.*

<sup>85</sup> ME. REV. STAT. ANN. tit. 24, §§ 2971-2979 (1989) (repealed in 1999).

<sup>86</sup> LeCraw, *supra* note 81.

<sup>87</sup> Howard Zonana, Commentary, *When Is a Practice Guideline Only a Guideline?*, 36 J. AM. ACAD. PSYCHIATRY L. 302, 303 (2008).

<sup>88</sup> LeCraw, *supra* note 81 (citing GAO REPORT, *supra* note 83, at 2, 5).

<sup>89</sup> See William R. Trail & Brad A. Allen, *Government Created Medical Practice Guidelines: The Opening Of Pandora’s Box*, 10 J.L. & HEALTH 231, 247-48 (1995).

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

<sup>92</sup> *Id.* at 245-46.

<sup>93</sup> See Bruce D. Platt, *A Summary of the Health Care and Insurance Reform Act of 1993: Florida Blazes the Trail*, 21 FLA. ST. U. L. REV. 483, 494 (citing 1993 Fla. Laws 657, 696).

<sup>94</sup> FLORENCE KAVALER & ALLEN D. SPIEGEL, *RISK MANAGEMENT IN HEALTH CARE INSTITUTIONS* 251 (2d ed. 2003).

<sup>95</sup> Eleanor D. Kinney, *Medical Malpractice Reform in the 1990s: Past Disappointments, Future Success?*, 20 J. HEALTH POL., POL’Y & L. 99, 111 (1995) (citing FLA. STAT. ANN. § 408.02 (West 1993)).

admitted as evidence of the standard of care.<sup>96</sup> Unlike in Maine, Minnesota and Florida, compliance with guidelines under the Vermont project is not considered the standard of care, instead they merely act as evidence introduced to help establish the standard of care—the same as expert testimony would.<sup>97</sup>

Kentucky and Maryland also have initiated projects to incorporate guidelines into their malpractice legal landscape.<sup>98</sup> For a variety of reasons, none of the projects managed to garner enough physician support to reach full implementation or realize any quantifiable benefits.<sup>99</sup>

Other states have attempted to direct the practice of medicine using other methods. Texas recently passed the Texas Heart Attack Prevention Bill (HB 1290), which requires health insurers to reimburse patients who receive screenings for asymptomatic atherosclerosis.<sup>100</sup> In the *Journal of the American Medical Association*, Peter Jacobson argues that such “legislative mandates” of specific technology or treatments are a very bad idea, noting that well-designed guidelines should be flexible instruments “based on the best available scientific and clinical information, represent professional consensus (including support from medical professional societies), and allow physicians to exercise individual judgment in treating patients.”<sup>101</sup> Jacobson noted that the Texas proposal was not an isolated event, and worried that we could see more CPGs being turned into ossified mandates.<sup>102</sup> In at least ten states, legislatures have recognized that health insurance companies “have become increasingly involved in health care treatment decisions, including, but not limited to, the use of financial incentives to providers and practice guidelines, in an effort to reduce health care costs.”<sup>103</sup> These ten states, at the least, created tort actions against health care insurance carriers. All ten laws are still on the books despite being hamstrung by the monumental 2004 case of *Aetna Health, Inc. v. Davila*.<sup>104</sup> In *Davila*, the Supreme Court held that state laws allowing tort actions against employer-funded health insurance carriers for injury due to a denial of insurance coverage were preempted by ERISA. As a

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<sup>96</sup> *Id.* at 110.

<sup>97</sup> *Id.* (citing 1992 Vt. Acts & Resolves 160).

<sup>98</sup> LeCraw, *supra* note 81 (citing KY. REV. STAT. ANN. §§ 216B.145, 342.035 (Michie 1995); MD. CODE ANN., Health-Gen. §§ 19-1601–19-1606 (West 1993)).

<sup>99</sup> The crucial missing aspect of these projects was that there is no justification for awarding doctors liability protection, unless, as is discussed more fully below, the guidelines are created under a system in which incentives progress towards creating safer, more cost effective procedures. *See* discussion *infra* Parts II.B & III.

<sup>100</sup> H.R. 1290, 81st Leg. Sess. (Tx. 2009).

<sup>101</sup> Peter D. Jacobson, Commentary, *Transforming Clinical Practice Guidelines Into Legislative Mandates: Proceed with Abundant Caution*, 299 JAMA 208, 209 (2009).

<sup>102</sup> *Id.* at 209-10. *See, e.g.*, MASS. GEN. LAWS ch. 176G, § 40 (2002) (requiring insurance plans to provide benefits for hormone replacement therapy for peri- and post-menopausal women, as well as outpatient contraceptive services).

<sup>103</sup> N.J. STAT. ANN. § 2A:53A-30 et seq. (West 2001). *See* Brief of Texas et al. as Amici Curiae Supporting Respondents, *Aetna Health, Inc. v. Davila*, 542 U.S. 200 (2004) (No. 02-1845). *See also* ARIZ. REV. STAT. § 20-3153 (LexisNexis 2011); CAL. CIV. CODE § 3428 (West 2011); GA. CODE ANN. § 51-1-48 (2000); LA. REV. STAT. ANN. § 22:2085 (2011); ME. REV. STAT. tit. 24-A, § 4313 (1999); OKLA. STAT. tit. 36, § 6593 (2000); TEX. CIV. PRAC. & REM. CODE ANN. § 88.002 (West 2005); WASH. REV. CODE § 48.43.545 (2000); W. VA. CODE § 33-25C-7 (2010).

<sup>104</sup> *Aetna Health, Inc. v. Davila*, 542 U.S. 200, 223 (2004).

result of *Davila*, the state laws can only support a cause of action against non-employer-funded insurance providers, or for contract reimbursement.<sup>105</sup>

### *iii. Summary*

The preceding overview of the current use of guidelines in courts and statutes is intended to demonstrate two main points. First, guidelines certainly are used in court cases but to an inadequate, unpredictable, and inconsistent degree. Instead of offering courts and health providers alike a predictable standard of care with which to measure the treatment at issue, guidelines form just a portion of a montage of evidence used in establishing a legal standard of care. The usefulness or even characteristics of well-written guidelines is obfuscated by the muddle of medical negligence law in general. Second, the conservatism with which courts are exploring guidelines indicates that legislation is likely necessary to permit and encourage courts to fully utilize guidelines as a method of standard-setting. We know little more about what courts will do with guidelines than we did fifteen years ago from the Hyams, Shapiro, and Brennan study, and nine years ago from Rosoff's observations in *Evidence-Based Medicine and the Law*. A fact that has been confirmed, however, is Rosoff's observation that courts are "inherently conservative and backward-looking"<sup>106</sup> and are quite understandably waiting for legislatures to act. Meanwhile legislatures have not extensively pursued the use of guidelines to establish standards within the tort regime. When legislatures have attempted to incorporate guidelines into their regimes, the programs have not been successful. The next section turns to specific problems with existing guidelines as they are written by a variety of entities.

## 2. When the Government Writes Guidelines

### *i. Theory*

In the context of medical malpractice, two main federal agencies are involved in the creation of regulations: the Food and Drug Administration (FDA), which regulates drugs and medical devices, and AHRQ, which is responsible for collecting CPGs and promoting their use. As far as medical practice goes, governments' guidelines, like other clinical guidelines, are not binding. The interesting question is whether the incentives for the government to write CPGs are such that the guidelines *should be* binding. On the one hand, various dynamics suggest that government agencies may create overly lax regulations (or under-enforce regulations).<sup>107</sup> First, agencies will often lack the resources to set the regulations efficiently and then periodically update them.<sup>108</sup> Second, agencies are vulnerable to interest-group capture, perverse political preferences by the government, and self-aggrandizing

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<sup>105</sup> See, e.g., TEX. CIV. PRAC. & REM. CODE ANN. § 88.0015 (West 2005) (limiting applicability of statute to insurance plans not regulated under ERISA). See also David M. Humiston & James A. Toto, Department, *Practice Tips: The Prognosis for the Managed Care Liability Act after Davila*, 28 L.A. LAWYER 12, 12 (2005).

<sup>106</sup> Rosoff, *Evidence-Based Medicine and the Law*, *supra* note 58, at 352.

<sup>107</sup> See Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 495 (2008).

<sup>108</sup> Rachlinski, *supra* note 34, at 609.

administrators. Interest-group capture can lead to under-enforcement, and a change in the government can lead to ossification between already inefficient standards.<sup>109</sup> On top of that, self-aggrandizing administrators, operating in a revolving door environment, may advance their post-agency careers by catering to interest groups that favor lax standards. On the other hand, there are several reasons why agencies may make overly defensive regulations. First, agencies occasionally regulate in response to crises. It might take years, if not decades, to fix regulation improvidently created in the wake of scandals. Second, agencies lack the financial accountability necessary to incentivize efficient rulemaking. Government agencies cannot be sued for making poor guidelines and might over-regulate.<sup>110</sup> But because the regulator is *politically* accountable, this can lead to defensive policy: if agencies err by failing to regulate, their political accountability assures they will be punished, but the agency will seldom be punished politically for overly stringent regulation.<sup>111</sup>

Due to these countervailing considerations, there is some uncertainty whether agencies regulate in an overly strict or overly lax manner. This uncertainty, however, does not prove the resulting regulation is on average efficient. Indeed, other than the FDA, which has stringent ex-ante approval procedures and explicit claims to regulate hazards for optimality that indicate its standards strive for both safety and cost efficiency,<sup>112</sup> it is likely that most other agencies only regulate minimum standards of care (or “floors”).<sup>113</sup> For standards that are only a floor, it is very possible that the standards are suboptimal. This possibility of suboptimal standards explains why only one state, Michigan, has accepted the regulatory compliance defense in the pharmaceutical context. Under the Michigan scheme, the defendant is off the hook if he complies with the government regulatory standards. But even in Michigan, it is only when the government agency is the FDA.<sup>114</sup>

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<sup>109</sup> For example, the FDA changed its policy during the second Bush administration 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. 5 (2006).

<sup>110</sup> In the U.S., one cannot sue the FDA or any other agency for a wrong decision within its discretion. See Epstein, *supra* note 109, at 3, nn.6-7.

<sup>111</sup> *Id.* at 22 (arguing agencies have incentives to regulate in an overly risk-adverse fashion because of self-interest).

<sup>112</sup> See, e.g., Brief for the United States of America as Amicus Curiae Supporting Respondent at 16, *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006) (No. 05-CV-05500-MMB) (“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.”).

<sup>113</sup> 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 occurring include workers’ compensation, automobile accidents, nuclear energy (Price-Anderson Nuclear Industries Indemnity Act), and child vaccines (The National Childhood Vaccine Injury Act of 1986). See Price-Anderson Act of 1957, 42 U.S.C. § 2210 (2006); National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1–300aa-34 (2006).

<sup>114</sup> 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 2010); IND. CODE § 34-20-5-1(2) (1999); KAN. STAT. ANN. § 60-3304(a) (2005); 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. § 78-15-6(3) (West 2005). By and large, neither the Restatement Second nor the

Another problem with agency regulation is that it fails to keep up with quickly-evolving medical research. In 2001, a study examined the validity of seventeen CPGs developed in 1990 through 1996 by the AHRQ and found that thirteen were out of date with the then current research.<sup>115</sup> The study also found that it was estimated to cost four million dollars per guideline to properly update them using AHRQ's Evidence Based Practice Center Program.<sup>116</sup> Unfortunately, medical research does not evolve on a rigid timetable, and agency guidelines can lag significantly behind cutting-edge medical advances.

In sum, as in the case of tort liability, the result is that the chance that regulation would be systematically and continuously efficient is small.

*ii. The Past and Present of Federal Bills Dealing with Guidelines*

A year after the enactment of ACA, it appears the idea of providing liability protection to doctors for adherence to medical guidelines is once again receiving consideration. As of February 2011, the Obama administration has launched a drive to overhaul state medical malpractice laws which includes providing "safe harbor" to doctors who follow guidelines.<sup>117</sup> Indeed, even before the enactment of ACA, President Obama has indicated his potential willingness to endorse this concept. In a May 2009 meeting, President Obama told Dr. J. James Rohack, the incoming president of the AMA, that he would be open to offering some liability protection to doctors who follow standard guidelines for medical practice.<sup>118</sup> In the Senate Finance Committee, Senator Baucus had been facilitating discussions regarding such safe harbors.<sup>119</sup> In 2009, Senator Ron Wyden had even proposed specific legislation that would have created a rebuttable presumption that care was not negligent if the physician followed accepted CPGs.<sup>120</sup>

This recent activity is by no means the first federal attempt at using medical guidelines reform to spur broader healthcare improvement. Over the last twenty years, the escalation of healthcare costs has forced Congress to search for ways to improve the quality of healthcare delivery and decrease malpractice liability costs. For this purpose, in 1989 Congress created the Agency for Health Care Policy and Research (AHCPR) to "enhance the quality, appropriateness, and effectiveness of health care services" through, among other things, "the development and periodic review and updating of . .

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Third allow for a complete defense. See RESTATEMENT (SECOND) OF TORTS § 288C (1965); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 (1998).

<sup>115</sup> 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, 1464-65 (2001).

<sup>116</sup> *Id.* at 1462.

<sup>117</sup> See Alonso-Zaldivar, *supra* note 9 (listing malpractice reforms that could be funded under President Obama's grant proposal).

<sup>118</sup> Sheryl Gay Stolberg & Robert Pear, *Obama Open to Reining in Medical Malpractice Suits*, N.Y. TIMES, June 15, 2009, at A14.

<sup>119</sup> MAX BAUCUS, U.S. SENATE COMMITTEE ON FINANCE, CALL TO ACTION: HEALTH REFORM 2009 75 (2008), available at <http://finance.senate.gov/healthreform2009/finalwhitepaper.pdf>.

<sup>120</sup> Healthy Americans Act, S. 391, 111th Cong. (2009).

. clinically relevant guidelines.”<sup>121</sup> Several years later, the Clinton administration attempted to take this initiative a step further by proposing a medical liability pilot program based on the practice guidelines developed by the AHCPR. Under the pilot program, physicians able to demonstrate that their professional conduct or treatment complied with appropriate practice guidelines would not be liable for medical malpractice.<sup>122</sup> Due to a lack of support, Clinton’s pilot program failed to materialize. But over the years, the AHCPR, now renamed the Agency for Healthcare Research and Quality (AHRQ), has become a major force in the creation and dissemination of medical guidelines.<sup>123</sup> Unfortunately, as discussed above, these guidelines have failed to create a sustainable improvement in both the quality of medical procedures and the control of healthcare costs.

### *iii. Summary*

We have seen how tort law and government agency regulation are not well-suited to systematically develop optimal medical procedures. Can the *combination* of agency regulation and tort law provide adequate incentives for optimal medical practice? Of course, this question assumes regulation is indeed a floor, rather than optimal. If regulation were optimal, i.e., if agencies could perform a professional, non-biased, well-funded analysis of medical practice aiming at maximizing social welfare, tort law would have a small role, if any. As explained above, generally the likelihood of this is small. It is much more reasonable to expect that government agencies could regulate minimum standards, and that tort law could supplement it, thus pushing medical practice towards optimal standards. This is, in fact, the case in almost all states and across almost all types of injuries. Such a system has the advantage of providing predictability in the sense that a violation of regulation will most likely result in finding the defendant liable. And it makes sense, because violation of minimum standards is definitely unreasonable and therefore justifies finding for the plaintiff.

The existing system, however, has several disadvantages. First, it does not help resolve the issue of determining negligence for the large number of cases in which the defendant actually complied with the regulation. Second, as a result of the first issue, it raises questions about the appropriate scope of the doctrine of regulatory compliance defense, a doctrine that has been rejected by all but one jurisdiction (Michigan).<sup>124</sup> Under the doctrine, compliance with regulation should be important, if not determinative, to finding the defendant *not* negligent. But if the standards are just a floor, compliance with the standards is a poor barometer for determining whether negligence exists. The third issue, which has become especially problematic in recent years, pertains to solving the complicated jurisprudence of the doctrine of preemption, a doctrine which determines whether tort law or government regulation applies.

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<sup>121</sup> Mello, *supra* note 67, at 651 (quoting Stephen M. Merz, *Clinical Practice Guidelines: Policy Issues and Legal Implications*, 19 JOINT COMM’N J. ON QUALITY IMPROVEMENT 306, 307 (1993)).

<sup>122</sup> GAO REPORT, *supra* note 83.

<sup>123</sup> Mello, *supra* note 67, at 651.

<sup>124</sup> Even in Michigan the doctrine is just for pharmaceuticals. *See* MICH. COMP. LAWS ANN. § 600.2946(5) (West 2010).

Unfortunately, courts and scholars are still struggling to make sense of this jurisprudence.<sup>125</sup>

Given the high costs of both agency regulation and litigation, there must be a better way than allowing both to play an active, yet inefficient, role. The next three sections discuss private-entity CPGs. These guidelines are promulgated by various groups, such as doctors' associations, hospitals and insurers.

### 3. When Hospitals and Hospital Organizations Write Guidelines

Hospitals and hospital organizations such as the Joint Commission also write guidelines for various purposes, such as peer review of staff performance, better ways to improve care, and consistency between hospitals.<sup>126</sup>

Occasionally hospitals use proactive guideline-promulgating approaches, such as root cause analysis (RCA), and have significantly improved patient healthcare outcomes.<sup>127</sup> Consider, for example, hip fracture mortality. Hip fractures cause the largest portion of injury-related hospitalizations in the nation, and hip fracture repair procedures have a high rate of mortality—state quality-benchmarks are set around five percent. Staten Island University Hospital (SIUH) had met state benchmarks, but was convinced something further could be done. To illuminate problem areas, SIUH preformed a RCA on the case history of a seventy-eight year-old woman who had died during a hip fracture repair procedure. The RCA showed that neither special training nor privilege based on qualifications had been required to work with high-risk patients, so patients were exposed to inadequate preoperative assessment and resulting treatment errors.<sup>128</sup> The hospital promulgated evidence-based guidelines for the use of relevant treatments, specifically addressing the “management of hypertension, use of beta blockers, [and treatment of] deep vein thrombosis prophylaxis,” which had been problematic. Indeed, in each of the following three years SIUH saw an eighty percent drop in mortality from hip fracture repair procedures.<sup>129</sup>

The promise of RCA services has not gone unnoticed by the private sector. For example, TapRooT, a company offering data services for risk assessment in various industries, has entered the market for RCA services.<sup>130</sup> Yet, one might still question whether SIUH arrived at optimal guidelines. After all, SIUH's demonstration that hip fracture repair mortality can be reduced from 4.9% to 1% over several years illustrates possibility, not optimality. Indeed, a

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<sup>125</sup> See Epstein, *supra* note 109; Schuck, *supra* note 46; Catherine Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 103 NW. U. L. REV. 437 (2009).

<sup>126</sup> 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, 1189-90 (2006).

<sup>127</sup> See Daniel R. Longo et al., *Hospital Patient Safety: Characteristics of Best-Performing Hospitals*, J. HEALTHCARE MGMT., May 2007, at 195-200.

<sup>128</sup> Thomas McGinn et al., *Decreasing Mortality for Patients Undergoing Hip Fracture Repair Surgery*, 31 JOINT COMM'N J. ON QUALITY & PATIENT SAFETY 304, 305 (2005).

<sup>129</sup> *Id.* at 306.

<sup>130</sup> See *About TapRooT*, TAPROOT, <http://www.taproot.com/about.php> (last visited Jan. 27, 2011).

major criticism of hospitals' guidelines is that the guidelines are designed to defend against hospital liability while maximizing reimbursements from Medicare or Medicaid, HMOs, and other health insurers. If the criticism is true, the guidelines would waste resources through both defensive and offensive medicine, all at the expense of the social pie.

#### 4. When HMOs, Health Insurers or Medical Liability Insurers Write Guidelines

In recent years it has also become increasingly common for managed care organizations and health care insurers to develop their own guidelines for utilization review and physician profiling. Utilization review is used to determine whether a physician's treatment plan will be reimbursed. Profiling is used to see whether the physician's care is cost effective. For physicians, compliance with the guidelines is very important because a treatment plan will not be covered unless it is consistent with the guidelines. Additionally, compliance may be a required condition, explicit or implicit, for a physician's eligibility to participate in the HMO. These guidelines are generally not made fully public and are primarily used for cost containment.

Along the same lines, liability insurance carriers, interested in increasing profits by reducing liability costs, have become strong advocates of the promulgation and enforcement of specific clinical standards. For example, in the field of obstetrics, the Utah Medical Insurance Association and a Colorado insurance company both require compliance with their guidelines as a condition for malpractice coverage. It is also common for insurance companies to raise or lower rates depending on the practitioner's willingness to comply with CPGs.<sup>131</sup>

However, here too, problems of self-interest and externalities exist. For example, liability insurance carriers would require doctors to perform yearly mammograms to prevent breast cancer, even if such a requirement unnecessarily wastes medical resources, because the liability carriers do not bear the costs of extra mammograms but do bear the costs of malpractice lawsuits arising from the late diagnosis of breast cancer. This demonstrates the problem of defensive medicine, which many believe comprises up to nine percent of total healthcare costs.<sup>132</sup> Similarly, guidelines written by HMOs often externalize costs on liability insurers. To contain costs, HMOs may prefer fewer procedures because they fully bear the costs of treatment but do not fully bear the costs of malpractice.

#### 5. When Professional Associations Write Guidelines

Guidelines written by doctors' professional associations tend to be highly regarded since they reflect physicians' reviews of the current literature, emphasize quality care for patients, and demonstrate an interest in decreasing the need for defensive medicine. Guidelines written by doctors are often created in response to those developed by third-party payers, which are

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<sup>131</sup> Zonana, *supra* note 87, at 303.

<sup>132</sup> Daniel Kessler & Mark McClellan, *Do Doctor's Practice Defensive Medicine?*, 111 Q. J. ECON. 353, 371-72 (1996).

perceived as both motivated by cost control and as a threat to physician autonomy.<sup>133</sup>

Unfortunately, the validity of these guidelines may be questionable for a variety of reasons. Three of the most frequently discussed reasons include the tendency for guidelines to become obsolete quickly, the deficiency of reliable evidence used to create guidelines, and the conflict of interest involved in the guideline-making process. Medical guidelines are especially vulnerable to becoming obsolete because these guidelines are currently created by organizations without the funding necessary to make continuous improvements as new research is released. Because the resources required to create comprehensive guidelines are expensive and time-consuming, the guidelines produced may already be obsolete by the time they are released or quickly thereafter.<sup>134</sup> This leads to the second problem: the high costs of investing in proper research have resulted in guidelines that are largely based on insufficient evidence. A recent study analyzing the evidence used to produce the ACC/AHA practice guidelines for managing cardiovascular disease found that forty-eight percent of the recommendations were derived from the lowest level of acceptable evidence.<sup>135</sup>

Lastly, there is a significant conflict of interest within the current guideline creation process. Guideline authors frequently have financial relationships with industries, usually pharmaceutical, whose interests are directly impacted by the guideline recommendations. It seems that much of the current clinical research is either directly or indirectly supported by pharmaceutical companies. For example, the Connecticut Attorney General recently challenged the 2000 and 2006 Lyme disease guidelines due to suspected financial conflicts of interest among panel members that may have led to antitrust violations in connection with the guideline development.<sup>136</sup> It is only from April 2010, when a New Code For Interactions With Companies, was published by the Council of Medicaid Specialty Societies, actors in the pharmaceutical and medical device industries were no longer allowed to pay for the *development* of medical guidelines, although the industry may still finance *distribution, updating, and repurposing* of the guidelines.<sup>137</sup> It is

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<sup>133</sup> Zonana, *supra* note 87, at 303.

<sup>134</sup> See Richard Amerling et al., *Guidelines Have Done More Harm Than Good*, 26 BLOOD PURIFICATION 73 (2008).

<sup>135</sup> Pierluigi Tricoci et al., *Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines*, 301 JAMA 831, 833 (2009). The study categorized its lowest level of acceptable evidence as indicating little to no objective empirical evidence for the recommended action.

<sup>136</sup> See Press Release, Connecticut Attorney General's Office, Attorney General's Investigation Reveals Flawed Lyme Disease Guideline Process, IDSA Agrees to Reassess Guidelines, Install Independent Arbiter (May 1, 2008), <http://www.ct.gov/ag/cwp/view.asp?a=2795&q=414284>.

<sup>137</sup> COUNCIL OF MED. SPECIALTY SOC'YS, NEW CODE FOR INTERACTIONS WITH COS. (2010), *available at* [http://www.cmss.org/uploadedFiles/Site/CMSS\\_Policies/CMSS%20Code%20for%20Interactions%20with%20Companies%204-19-10.pdf](http://www.cmss.org/uploadedFiles/Site/CMSS_Policies/CMSS%20Code%20for%20Interactions%20with%20Companies%204-19-10.pdf) (last visited Jan. 6, 2011). 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, <http://www.cmss.org/About/Default.aspx> (last visited Jan. 7, 2011) at 19.

More generally, one 2002 cross study involving 192 guideline authors found that fifty-eight percent of the authors surveyed had received financial support to perform clinical research, and thirty-eight percent had served as employees or consultants for a pharmaceutical

therefore not surprising that nineteen percent of respondents believed that their coauthors' recommendations were influenced by their relationships with these companies.<sup>138</sup>

## 6. Summary

It is unlikely that a given medical guideline is optimal because few guidelines are promulgated under the appropriate incentives. CPGs written by the government are often too outdated to retain authority. Guidelines written by hospitals, HMOs, or health insurers are primarily concerned with cost containment and therefore lack sufficient sensitivity to patient safety. CPGs written by liability insurers are intended to protect against lawsuits, and therefore are overly cautious and not cost effective. CPGs written by doctors are often contaminated by conflicts of interest.<sup>139</sup> Indeed, disclaimers are commonly attached to guidelines written by all of these entities.<sup>140</sup> The problems mean even the most authoritative guidelines cannot usually be introduced as a substitute for expert testimony. Courts are not obligated to apply these guidelines in establishing the standard of care, and they occasionally refuse to admit, as hearsay, guidelines for less authoritative or biased sources.<sup>141</sup>

Because of these problems, it is probably a good thing that current guidelines are not binding on doctors, are not determinative in medical malpractice lawsuits, and are not extensively followed. Otherwise, the current legal regime's distorted incentives toward defensive and offensive medicine would be even worse.

## III. PRIVATE REGULATION: A POTENTIAL SOLUTION

Despite the many current problems with CPGs, they could potentially serve as the foundation of a solution to the distorted incentives inherent in the current medical malpractice regime. The solution would combine the objectives of patient safety, cost-saving, and doctor immunity into a single legislative package. Although a full account of this solution, called the Private

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company. See Niteesh K. Choudhry et al., *Relationships Between Authors of Clinical Practice Guidelines and the Pharmaceutical Industry*, 287 JAMA 612, 614 (2002).

<sup>138</sup> *Id.* at 612. Interestingly, even the authors of the study had attended events sponsored by or received money from pharmaceutical companies. *Id.*

<sup>139</sup> *Quigley v. Jobe*, 851 P.2d 236, 238 (Colo. Ct. App. 1992).

<sup>140</sup> See Agency for Healthcare Research and Quality, *Web Site Disclaimers* (June 20, 2003), <http://www.ahrq.gov/news/disclaim.htm>. The AMA 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. Mark R. Chassin, *Standard of Care in Medicine*, 25 INQUIRY 437 (1988). See also AM. PSYCH. ASS'N, 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").

<sup>141</sup> For example, in *Quigley v. Jobe*, a Colorado court of appeals refused to accept a CPG written by liability insurers of the doctor because it was 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." *Quigley*, 851 P.2d, at 238. See also Parchomovsky & Stein, *supra* note 44.

Regulation Regime (PRR), is outside the scope of this paper, a summary is appropriate.<sup>142</sup>

The PRR would work by aligning the incentives of all parties with the interests of society. In the most general terms, the PRR would consist of private firms competing to provide evidence-based medical guidelines that offer liability protection to complying doctors. Such a regime could dramatically decrease the exorbitant administrative costs of malpractice lawsuits and, more importantly, increase patient safety while reducing overall healthcare costs.

The private firms would be forced to keep patient safety high and costs low by the dual forces of free market competition and legal liability. In order to attract customers seeking to minimize costs, the private regulators would have to offer guidelines that compete in the market on price and ease of use. To achieve this, private regulators would be forced to discard unduly expensive (and ineffective) procedures. At the same time, patients on whom the guidelines were used would be given a cause of action against the firms if a firm promulgated substandard guidelines that caused injury to a patient. The fear of legal liability would cause firms to push medical standards higher, in an effort to prevent unnecessary injuries to patients (and unwieldy liability for the private firm).

Unlike an agency or any other guideline promulgator, private firms would be financially liable for their guidelines and would have financial incentives to engage in the correct level of regulation. Unlike an agency that is subject only to administrative review of its rulemaking (or any other guideline promulgator which is not subject to any review), the private firms would continuously be held liable for damages caused by its inefficient prescription. Lastly, unlike an agency or any other guideline promulgator, a private firm could expect to legitimately profit from making standards safer and more efficient. In sum, unlike current medical guideline providers, a private firm's profit margin would be closely aligned with patient safety, so these firms would have the financial incentive needed to invest in continuous improvement without relying on groups who have a conflict of interest. Because potentially biased guidelines in the PRR would be disciplined by market forces or legal liability, the influence of other interested actors—namely drug and device manufacturers—would substantially decrease.

Healthcare providers would be incentivized to use the guidelines for two primary reasons. First, if a doctor or hospital purchased or licensed the guidelines and followed them when treating patients, that provider would be immune from malpractice liability. Second, the reduction in bias would lead to better guidelines and allow doctors to trust their recommendations. Thus, the providers' financial interests and professional responsibilities would be aligned, making it highly likely that they would utilize the evidence-based medical techniques prescribed by the guidelines. Part A describes the legal infrastructure required to establish the private regulation regime. Part B responds to some counter arguments.

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<sup>142</sup> The contours of the proposal are laid out in full in Ronen Avraham, *Private Regulation*, 34 HARV. J.L. & PUB. POL'Y (forthcoming).

### A. THE LEGAL INFRASTRUCTURE

Since the most difficult part of an optimal private regulation regime (research and guideline promulgation) already happens in one form or another, all that is required for this sort of regime to come into existence is for the law to provide incentives for *optimal* promulgation and implementation of guidelines. To provide these optimal incentives, the legal infrastructure would have to change in no more than six ways: evaluate guidelines from the ex ante perspective, recognize contractually standardized care (and reimbursement), recognize a new legal doctrine called the private regulatory compliance defense, provide intellectual property protection for medical procedures, not recognize the state-of-the-art defense—at least as it would apply to guidelines or medical practice, and impose solvency requirements on the private firms that would be producing the guidelines. Each of these requirements is detailed below.

#### 1. Ex Ante Liability for Guidelines

In order to properly incentivize the private firms promulgating guidelines, those firms must be exposed to legal liability for promulgating suboptimal guidelines. Such liability will prevent the firms from lowering their costs by promulgating excessively risky guidelines or otherwise inadequate guidelines. To create the *optimal* incentives, however, this liability must be judged from the ex ante perspective; otherwise guidelines will be too defensive. Deciding liability from the ex ante perspective would solve the hindsight and identified other biases discussed above. The ex ante perspective would also take into account all potential beneficiaries, not just the specific plaintiff in front of the court. Because the firms will know that they will be subject to review from the ex ante perspective, and thus from all potential angles, they will develop guidelines that are efficient, impartial, and reliable.

For example, assume there is a medical procedure X that is used to treat a fatal problem Z. Assume that X is very beneficial to most patients, but seriously harms a small number of patients. This is an extreme example of the common procedure that helps, but has side effects. In many cases, regardless of the side effects, procedure X could still be beneficial overall, something that is good for society, that does more good than bad. For people with Z, they must decide whether to trade a large risk of dying without treatment for a small risk of side effects with treatment. Assume now that someone who had Z and was treated with X suffered from the side effects and sued the doctor, or the guideline promulgator in the PRR. If liability were judged ex post, a court affected by the identifiable other effect and the hindsight bias might decide that the harm to the patient was not worth the good that treatment X did overall. Thus the provider—or promulgator—would be found liable. Judged from the ex ante perspective, however, the case would clearly be one where treatment did more good than bad, and thus the provider—or promulgator—would be found not liable.

#### 2. Contractual Standard of Care (and Reimbursement)

Ex ante liability will incentivize firms not to promulgate overly defensive guidelines. Without further intervention, however, there still might be an

incentive for overly safe guidelines. If the firms publish guidelines that are too safe, the only result is that they would be more expensive than optimal guidelines would be. Providers, however, can simply pass the cost onto the payers—generally HMOs and health insurers—as they do now with both offensive and defensive medicine.

One way to deal with this problem would be to allow payers to sue the firms when they promulgate overly safe guidelines. This would add administrative costs, however, and the incentives for payers to take legal action may not be high enough when they can simply pass the cost onto the insured (the patient). A simpler way to deal with the problem is by using contract law. Contracts between payers and providers could link reimbursements to the optimal level of safety and cost-effectiveness. If a provider uses guidelines that are too cautious, the provider would receive a smaller reimbursement for its services. For example, a provider that ordered too many X-rays because its guidelines were overly safe would receive a smaller reimbursement for each X-ray. If reimbursements were thus linked to guidelines, providers would demand optimal guidelines when they purchase them from private firms. In this way, the private firms would be incentivized through liability to produce safe guidelines, and through their customers to provide efficient guidelines.

### 3. Private Regulatory Compliance Defense

In order to incentivize providers to purchase and follow guidelines, a private regulatory compliance defense would have to be added to the legal landscape. This defense would be available to any doctor or hospital that purchased or licensed guidelines and followed them. Regardless of the consequences of a procedure, if the doctor follows her guidelines she will not face malpractice liability. The defense would not apply, however, to doctors who do not purchase or license guidelines or who deviate from their instructions. Unlike the doctrines of statutory or regulatory compliance, which attach evidentiary weight to the fact that a statute or regulation is followed, the private-regulatory compliance defense would have to be a complete defense.<sup>143</sup> The defense would allow doctors to stop performing defensive medicine because regardless of the results, they could not be held liable.

### 4. Intellectual Property Protection for Guidelines

It may be necessary to provide some sort of intellectual property protection for guidelines. The concern is that without protection, no private firm would have the proper incentives to develop guidelines because they would fear that as soon as the guidelines were promulgated, other PRR firms would free-ride. It is possible to imagine, however, business models that would make intellectual property protection unnecessary. For example, requiring a provider to actually purchase guidelines in order to benefit from

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<sup>143</sup> 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.

the private regulatory-compliance defense detailed above would help avoid free-riding. Alternatively, private firms could bundle the licensing of their guidelines with support services. Indeed, the existence of several private firms promulgating guidelines proves the economic feasibility of such a market.

If intellectual property protection were to be provided, the question becomes what the ideal form should be. Copyright law only protects the expression of work, not ideas and facts, so it would not be effective in the PRR context.<sup>144</sup> Trade secrecy would not work either because the necessity under the PRR to litigate the optimality of the guidelines, which would cause the guidelines to become public during the litigation, would cause them to lose their protection as trade secrets.

Patents look superficially more promising, but they are not ideal. Filing for and obtaining a patent is a complicated and lengthy process. Yet, one of the benefits of the PRR over the current system is its dynamism and adaptability. Additionally, the main patent review standards, novelty and non-obviousness, do not fit neatly within the PRR. The best solution, therefore, would be a sui-generis regime legislatively tailored to the PRR. Such a regime should provide protection against copying and independent creation or development, provide short-term protection,<sup>145</sup> apply different standards than patent law does, and allow remedies only against non-practitioners.<sup>146</sup>

##### 5. Not Recognizing the State-of-the-Art Defense

Some states currently allow defendants to escape liability if their product or, in medical cases, procedure was, at the time of the injury incurred by the plaintiff, the state-of-the-art.<sup>147</sup> Traditionally, this defense only applied to product liability cases, but it has penetrated medical malpractice. Under the PRR, this defense, to the extent it exists at all in this context, must not be recognized, in order to incentivize the private firms to research better medical procedures and incorporate them into their guidelines. One of the benefits of the PRR is that the firms promulgating the guidelines would have a competitive and a legal reason to continually develop new, better ways to treat patients. If the state-of-the-art defense is recognized, the firms would have no

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<sup>144</sup> See Copyright Act of 1976, 17 U.S.C. § 102 (2006) (codifying the holding in *Baker v. Selden*, 101 U.S. 99 (1879)).

<sup>145</sup> One problem with providing IP protection to guidelines is that firms that develop truly innovative and important procedures could hold out for exorbitant licensing prices. This would be especially bothersome because so much medical development is cumulative, building on previous work. The short time frame of protection discussed above would be one mitigation technique. Another could be frequent and expensive renewal fees.

<sup>146</sup> In 1996 Congress added this last element into the patent law landscape by expressly depriving patent holders of any remedy against healthcare practitioners who violate a patent. Remedy is still available in actions against non-clinicians. Aaron S. Kesselheim & Michelle M. Mello, *Medical-Process Patents: Monopolizing the Delivery of Health Care*, 355 N. ENGL. J. MED. 2036, 2037 (2006). Not enforcing IP protection against practitioners could provide an incentive for them to free-ride. Thus, hospitals may choose not to pay for the guidelines but simply to adopt them. This problem could be mitigated by granting immunity to providers who purchase guidelines and tailoring the sui-generis approach to prevent it. Yet, because it may be so hard to detect violations in practice, such a regime might not be a strong enough protection. If this became an issue, the additional step of requiring providers to purchase guidelines in the free market could be adopted.

<sup>147</sup> See, e.g., *Lewis v. Am. Cyanamid Co.*, 715 A.2d 967 (N.J. 1998).

legal reason to spend money on costly research. Once they issued guidelines, as long as they were state-of-the-art at the time of issuance, they would be safe from liability. With the elimination of the defense, however, the firms would have a legal incentive to incorporate any new research. Otherwise, they would face liability from patients injured by their outdated guidelines.

#### 6. Guaranteeing Solvency

Lastly, the solvency of the private firms promulgating guidelines would have to be ensured. Otherwise, the firms would have an incentive to promulgate overly risky guidelines because they would know that the worst thing that could happen is to declare bankruptcy. Declaring bankruptcy would externalize any cost above a firm's value onto the patient who the overly risky guideline harmed.

The solvency guarantee could be obtained, as Shavell noted, by requiring firms which have the potential for being judgment proof to have minimum assets or liability insurance.<sup>148</sup> This requirement would force the firms to internalize the costs of their risky activities, i.e., being at risk for insolvency.<sup>149</sup> Minimum asset requirements would undesirably prevent some low asset firms from entering the market. On the other hand, liability insurance is only beneficial if the insurer can observe the levels of care. Thus, the best solution would depend on the situation. If insurers can measure the proper level of care, then liability insurance would be sufficient. If not, then minimum asset guarantees would be necessary.

### B. COUNTER-ARGUMENTS

#### 1. Leave the PRR to the Market

One may wonder why, if the PRR would be superior to the current system, it has not already developed in the market. Indeed, there are four ways the PRR could be mimicked contractually: Managed Care Organizations (MCOs) facing liability for care they control, liability insurers being held financially responsible for the cost of care provided, the government paying for both cost of care and liability, and fourth, a contractual PRR.

Within the past two decades, MCOs have become a primary player in the health insurance industry.<sup>150</sup> Many times it is an MCO, not a patient's doctor, that decides what care the patient receives.<sup>151</sup> For this reason, it makes sense to hold MCOs liable for suboptimal care, thus making them internalize both the cost of care and the cost of liability. This has not happened, though, for several reasons. First, doctors may prefer to retain their autonomy vis-à-vis MCOs. Second, throughout the 1990s, when MCOs rose to prominence,

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<sup>148</sup> Steven Shavell, *The Judgment Proof Problem*, 6 INT'L REV. L. & ECON. 45, 55 (1986).

<sup>149</sup> Steven Shavell, *Minimum Asset Requirements and Compulsory Liability Insurance as Solutions to the Judgment-Proof Problem*, 36 RAND J. ECON. 63, 65 (2005).

<sup>150</sup> See Jennifer Arlen & W. Bentley MacLeod, *Malpractice Liability for Physicians and Managed Care Organizations*, 78 N.Y.U. L. REV. 1929, 1940 (2003); Jennifer Arlen & W. Bentley MacLeod, *Torts, Expertise and Authority: Liability of Physicians and Managed Care Organizations*, 36 RAND J. ECON. 494 (2005).

<sup>151</sup> Arlen & MacLeod, *Malpractice Liability*, *supra* note 150, at 1934.

liability insurance markets for providers were stable and prices were under control. Doctors had no reason to seek alternatives to the existing liability insurance system. Third, various structural problems and problems of positive externalities prevent patients from contracting for optimal care.<sup>152</sup> Lastly, in *Davila*, the U.S. Supreme Court found that most state tort actions against an MCO for denial of benefits resulting in suboptimal care are preempted by ERISA.<sup>153</sup>

The second contractual method is the opposite of the one above: liability insurers would take over the cost of care. The hurdles here are similar to those for MCOs assuming the cost of liability. Furthermore, liability insurers emerged solely to protect doctors against liability and know very little about the delivery of care.

The third option—the government as the internalizer—presents a political problem. Given that the idea of the government being the single payer seems highly unlikely in the current political climate, it is hard to imagine the acceptance of the even more radical idea where the government is not only the single payer, but also the single liability insurer. Even if it were feasible, it would give the government a monopoly in providing healthcare, making it probably less desirable than the PRR which utilizes market forces to achieve optimal care.

Lastly, there is the question of why the PRR has not developed on its own contractually. One possible reason is that it would be very difficult to multi-party contract to encompass all of the requirements of the PRR. More importantly, perhaps, is a problem that encompasses all four of these options. Their common thread is the internalization of externalities. As discussed above, the warped incentives present in the current system arise from the fact that the players only internalize one type of cost. HMOs bear only the cost of care, and liability insurers the cost of liability. In the current system, all of the other players are able to externalize costs onto patients. Doctors' liability is essentially capped at their liability insurance policy limit through bankruptcy laws and asset hiding.<sup>154</sup> Thus, the *joint* liability of doctors, their liability insurers, and MCOs under the current regime is less than the harm done to patients. Thus, all players (besides the patients) have no incentive to adopt the extra liability, no longer internalized onto patients, that any alternative regime would create.

## 2. Good Medicine Requires Discretion

An ethical and practical concern with the PRR, and guidelines in general, is that good medicine requires discretion, that doctors must be able to choose the best course of action upon examination of each and every patient. Thus, optimal care could not be achieved if doctors are forced, or strongly

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<sup>152</sup> *See id.* at 1962, 1966, 2005.

<sup>153</sup> *Davila*, 542 U.S. at 204.

<sup>154</sup> David Hyman et al., *Do Defendants Pay What Juries Award?: Post-Verdict Haircuts in Texas Medical Malpractice Cases, 1988-2003*, 4 J. EMPIRICAL LEGAL STUDIES 3 (2007) (showing that doctors' liability is effectively capped under the current regime because plaintiffs do not recover more than the policy limit, which in itself is strategically set by the insurance companies).

incentivized, to follow pre-written instructions. While these claims have some truth, they overstate the actual situation.

First, doctoring is far closer to science than art than these claims suggest. Some, possibly most, doctoring can be reduced to guidelines. As has already been discussed, guidelines are already prevalent. Guidelines written by the government, medical societies, and healthcare organizations guide doctors in areas from ulcer treatment to heart failure to nicotine addiction.<sup>155</sup> Second, there is research that suggests doctors have a cognitive bias towards seeing each patient as unique when the evidence points otherwise.<sup>156</sup> Third, no one suggests that guidelines will invade every aspect of medicine. Instead, the PRR would focus only on the areas of medicine that can be optimally reduced to a set of rules that reduce cost and increase patient safety. Additionally, each set of guidelines would allow for a different amount of discretion in its application. The PRR, with all incentives properly aligned, would be better able to determine floors and ceilings for guideline procedures than current medical practice or guideline promulgators. Finally, doctors would be able to deviate from the guidelines if they have to. They would do so with the knowledge that they would no longer be protected by the private regulatory compliance defense, but they would be no less protected than they are currently.

### 3. Would the PRR Actually Reduce Costs?

Another possible argument against the PRR is that it would not actually reduce costs. As discussed above, there are three primary sources of excess spending in the healthcare sector: medical errors, offensive medicine, and defensive medicine. The reason the PRR is superior to the current system is that it combats all three sources simultaneously, instead of treating one of them while exacerbating another.

Medical errors are prevalent. The Institute of Medicine reports that 1.4 or 2.2% of people entering the hospital will suffer an adverse event that was fully preventable.<sup>157</sup> Half of those errors are the result of negligence.<sup>158</sup> Errors can take several forms. Misdiagnosis and misprognosis often arise from doctors' biases towards clinical diagnosis over statistical diagnosis, which guidelines could address. Additionally, the PRR could install guidelines in some of the most error-prone areas of medicine. The Institute of Medicine reports that nineteen percent of adverse events come from drug complications, fourteen percent from wound infections, and thirteen percent from technical complications.<sup>159</sup> The PRR would be very effective at making each of these areas safer.

A large part of the ever-increasing cost of healthcare comes from offensive medicine. For this reason, recent proposals have been made for moving from a

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<sup>155</sup> U.S. Dep't Health & Human Servs., Agency for Healthcare Research & Quality, *Clinical Practice Guidelines Archive*, <http://www.ahrq.gov/CLINIC/cpgarchv.htm> (last visited Jan. 26, 2011).

<sup>156</sup> Rosoff, *Evidence-Based Medicine and the Law*, *supra* note 58, at 350.

<sup>157</sup> INSTITUTE OF MEDICINE, COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, *TO ERR IS HUMAN* 26 (Linda T. Kohn et al. eds., 2000).

<sup>158</sup> *Id.* at 30.

<sup>159</sup> *Id.*

compensation system based on services provided to a results-based system.<sup>160</sup> Another approach proposed, and used by some of the most reputable clinics, is paying doctors a salary instead of compensation for patients seen and procedures completed. Most universities and the entire VA system pay their doctors a salary. In the private sector, both the Cleveland Clinic and Mayo Clinic pay their doctors a salary,<sup>161</sup> and Kaiser Permanente sets up payments for individual medical groups so that the physicians comprising the groups receive salaries.<sup>162</sup> While the solutions being proposed appear to be effective at combating offensive medicine, the problem remains that they do little to combat the other cost-drivers. In contrast, the PRR can fair better. For example, for high-risk offensive medicine procedures, such as unnecessary cardiac by-pass, PRR firms have a clear incentive to lower the number of risky procedures, thus also lowering costs.

Defensive medicine is perhaps the most widely publicized medical cost-driver. As already discussed, defensive medicine happens when doctors provide overly cautious care because they are worried about malpractice liability if something goes wrong. The most widely publicized solution for defensive medicine is tort reform. However, as with the other solutions discussed, tort reform only attacks a part of the problem. The PRR, on the other hand, aligns all of the players' incentives with the public's interests. Thus, while different methods can individually attack a given cost-driver, each solution is likely to exacerbate another problem because it attempts to attack costs individually. The PRR attacks all cost-drivers at once.

#### 4. Would the PRR be Impossible Politically?

With the current uproar over healthcare reform, it must be asked whether the PRR could ever win political support. Based on the current political debate, one of the biggest questions with the PRR might be whether it imposes rationing. The short answer is yes. But healthcare must be and is currently already being rationed. The PRR would simply ration it more efficiently and sensibly.

Healthcare must be rationed. Assume a drug is developed that can extend your life by a few weeks. How much should society be willing to pay for that drug? If it can extend a person's life for one month and it costs \$100,000, is it worth it? In a world with unlimited resources, the answer is easily yes. But, as we know, resources are finite. Is it better for society to spend \$100,000 to extend a single person's life by a month, or should society instead spend that money on some other research or treatment that might do more good. In the real world, insurance companies make these decisions. If they decide to cover

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<sup>160</sup> Julie Weed, *If All Doctors Had More Time to Listen*, N.Y. TIMES, June 7, 2009, at B1 (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).

<sup>161</sup> 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/>.

<sup>162</sup> Kaiser Permanente, *Frequently Asked Questions About Our Medical Care*, <https://members.kaiserpermanente.org/kpweb/faqmedcare/entrypage.do> (last visited Jan. 26, 2011).

the \$100,000 drug, then their premiums will be higher and fewer people will be able to afford insurance. If they do not cover the drug, more people will be able to afford insurance, but only people who can pay \$100,000 out of pocket will be able to afford the drug to extend their life by a month. In both cases, this is rationing.

Thus, the question is not whether to ration, but how best to ration. We currently do it strictly on a person's ability to pay. Optimal guidelines will incorporate society's moral and political preferences into determinations of what to pay for; optimal guidelines will reflect what society considers proper. Furthermore, by incorporating contractual levels of care, guidelines can align individuals' preferences in how money is best spent. Care providers can segment care levels, having gold care and silver care. Silver care would be cheaper, but gold care would include more treatment options. If an individual wants to pay more, they can get a higher level of care.

The other political question revolving around the PRR is if a profit-driven regulatory system could ever win political support. People putting forth this argument may say it is better to use existing public agencies to promulgate guidelines rather than profit-driven private firms. In response, one first must remember the bad reputation that the guidelines currently promulgated have.<sup>163</sup> For this reason, it may be easier to win political support for a fresh start than it would be to better fund the current agencies. Even if this complication were overcome, there would still be the toxic mix of interests which infiltrate current guidelines. As long as corporate finance is so intertwined with medical innovation, it seems impossible to overcome the parties' financial self-interest to the level necessary to create unbiased guidelines. The PRR takes this fact as a given and works around it by creating a separate, profit-driven regime.

## 5. Summary

Thus, payers and liability insurers would be wise to use their expertise in the field to pursue the private regulation of physician conduct—all with the agreeable side effect of increasing patient safety. For doctors, the shelter from malpractice liability would enable them to focus more time on healing their patients and less time preparing for their day in court. Despite the initial administrative complexities, the benefits of privatizing medical guidelines are likely to far outweigh any additional costs as it would be a substantial improvement over the status quo, and is most likely superior to other alternatives.

## IV. CONCLUSION

The United States healthcare system is sick. It suffers from too many medical errors and from too much overtreatment. While there is debate between Republicans and Democrats over whether overtreatment is due to defensive medicine or offensive medicine, almost no one doubts there is overtreatment.

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<sup>163</sup> See *supra* notes 54-57 and accompanying text.

Since taking over, President Obama has indicated a commitment to seeking creative solutions to these problems by entertaining the idea of offering doctors insulation from medical malpractice claims, and endorsing the standardization of medical treatments to control healthcare costs. The problem, which is quite significant, is that current guidelines by-and-large do not work because they are not produced under the appropriate incentives. Without appropriate incentives, cost savings will not be achieved, and immunity for doctors from medical malpractice cannot be justified. Solutions to the healthcare problem must address these disincentives and inefficiency within the current healthcare system. Legislation providing for a private regulation scheme based on CPGs would go far in addressing these current problems. At a minimum, liability (measured from the ex-ante perspective) should be imposed on existing actors who profit from distributing guidelines, before doctors receive any safe harbor.