Private Regulation- A New Approach To The US Healthcare Crisis

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

Don Berwick*

I. INTRODUCTION

Addressing the American Medical Association (AMA) in June 2009, President Obama described the healthcare system as a "ticking time bomb for the federal budget." He stressed the need to improve the quality of medical information making its way to doctors. Inferior information does contribute to the widespread use of expensive, ineffective, and sometimes dangerous treatments that could be effectively replaced by cheaper or more innovative alternatives. He further noted that "it can take up to 17 years for physicians to implement cutting-edge procedures.[1]

Indeed, any health care reform must focus on three primary goals: increasing access for the uninsured, controlling rising costs and improving quality of care. While trimming the number of uninsured Americans is a desirable goal, the most sensible way to achieve it is by targeting the other two goals; if quality of care is improved and cost of care is reduced, health insurance will automatically become more affordable and the number of uninsured will drop. In this essay I propose a reform which directly addresses

* President and CEO, Institute for Healthcare Improvement (IHI). The citation is from Neil Swidey, *The Revolutionary*, BOSTON GLOBE, Jan. 4, 2004, (magazine), at 10, *available at* http://www.hawaiiaap.org/pdfs/DonaldBerwick.pdf (last visited Oct. 2, 2009).

[1] *See* Full Text of Obama's Remarks to AMA, June 15th, 2009, Chicago Tribune Online, http://archives.chicagotribune.com/2009/jun/15/nation/chi-obama-ama-full-text-speech (last visited July 28, 2009). Obama's statement is supported by a study of the evolution of published research, which concluded that it takes 17 years to implement the 14% of original research that actually does reach the patient "bedside." These findings also suggested that profit-maximizing factors, such as the public's interest in a disease, the pharmaceutical nature of discovery, and other commercial factors affect which studies get attention and which do not. Paul H. Keckley, *Evidence Based Medicine in Managed Care: A Survey of Current and Emerging Strategies*, MEDSCAPE TODAY, April 01, 2004 (citing E. Andrew Balas, Information Technology and Physician Decision Support: Program and Abstracts Of Accelerating Quality Improvement in Health Care: Strategies to Speed the Diffusion of Evidence-Based Innovations, sponsored by National Committee for Quality Health Care (January 27-28, 2003; Washington, DC)) The Institute of Medicine (IOM) originally called attention to the health system's ineffectiveness in applying new scientific discoveries to the day-to-day practice of medicine. *See* THE INSTITUTE OF MEDICINE, CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY, (National Academy Press 2001).

the second two goals—controlling rising costs and improving the quality of medical care—in a manner not previously recognized.

As President Obama has observed, cost and quality are intimately intertwined. Too little care (underuse), incorrect care (misuse), and too much care (overuse) raise concerns about both quality of care as well as cost of care.[2] Substantial research has established that all three forms are ubiquitous in American healthcare system. Underuse is exemplified by the statistics that show half of Americans do not receive recommended preventive care, 30 percent do not receive recommended acute care, and 40 percent do not receive recommended chronic care, regardless of their age, insurance status, or geographical region. Likewise, misuse is exemplified by the 300,000 annual injuries (1/3 of which are deaths) due to negligent errors. Lastly overuse is exemplified by the 30 percent of Americans who receive acute care and 20 percent who receive chronic care for clinically inappropriate reasons, regardless of their insurance plan.[3]

Underuse is insufficient care which happens due to financial barriers such as lack of insurance, lack of coverage for preventive care, high deductibles and copayments, etc. Underuse has been shown to lead to poorer health outcomes.[4] Another reason underuse occurs is because some segments of the population distrust physicians and the health care system in general. These segments may decline to follow recommendations or may avoid the system altogether.[5]

Misuse, often referred to as medical errors, are caused by fatigue, poor judgment, over-confidence, lack of resources, lack of training, or lack of communication between medical team members. The costs of medical errors include unnecessary hospitalization, injury, loss of income, suffering and sometimes death. Patients, their insurers, and the

[2] Underuse is the failure to provide a service whose benefit is greater than its risk. Overuse is the failure to provide a service whose risks outweigh its benefits. Misuse is provision of the right service in a bad manner leading to avoidable complications and a reduction in the benefits service. Chassin M.R. (1997) Assessing Strategies for Quality Improvement. Health Affairs 16(3), 151-161.

[3] Becher E.C & Chassin M.R, Improving the Quality of Health Care: Who Will Lead? Health Affairs, vol 20(5), 2001 pp 164-179 at 166.

[4] See eg. Stephen F. Jencks, Edwin D. Huff, and Timothy Cuerdon, "Change in the Quality of Care Delivered to Medicare Beneficiaries, 1998–1999 to 2000–2001," *Journal of the American Medical Association*, vol. 289, no. 3 (January 15, 2003), pp. 305–312; and Elizabeth A. McGlynn and others, "The Quality of Health Care Delivered to Adults in the United States," *New England Journal of Medicine*, vol. 348, no. 26 (June 26, 2003), pp. 2635–2645..

[5] See for example L.G. Canlas, "Issues of Health Care Mistrust in East Harlem," *Mount Sinai Journal of Medicine* 66, no. 4 (1999): 257–258.

hospital all bear the costs of these mistakes. The Institute of Medicine estimated that up to 98,000 deaths every year are associated with medical error, about twice as many as from car accidents. This widely used number is probably an overestimation, but medical errors without a doubt cause tens of thousands of deaths a year.[6]

Overuse, or overutilization, is due to four interrelated reasons. First, overuse can occur through defensive medicine reasons, i.e excessive care which a doctor provides to avoid liability. In the process of attempting to protect themselves from future lawsuits, doctors externalize costs to patients and their health insurers by providing excessive care.[7] One example of defensive medicine would be ordering a CT scan when only an X-ray is medically necessary. Another example is when doctors choose a procedure that is not in the patient's best interests but poses less risk of legal liability.[8] A recent Wall Street Journal Op-Ed placed the cost of defensive medicine at $200 billion a year, though even a $60 to $108 billion range might be an overestimation.[9]

Second, overuse can arise from offensive medicine, i.e. excessive care which doctors provide in an attempt to maximize their reimbursements. These costs include everything from unnecessary minor procedures to excessive more lucrative treatments such as heart surgery.[10] Similar to costs associated with defensive medicine, these costs are borne by both patients and their insurance carriers. Academics have long documented

[6] TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM, 2 (Kohn, Linda et al. eds., Institute of Medicine, National Academy Press, 2000) available at *http://books.nap.edu/openbook.php?isbn=0309068371* . CITE WHY IT IS AN OVERESTIMATION.

[7] See for example Helling v. Carey, 519 P. 2d 981 (1974).

[8] *See* Ariel Porat, *Offsetting Risks*, 106 MICH L. REV. 243, 265 (2007) ("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."). *See also* the citations therein.

[9] *See infra*, note 25.

[10] *See* STEPHEN KLAIDMAN, CORONARY: A TRUE STORY OF MEDICINE GONE AWRY (Simon and Schuster, 2007) (detailing an FBI investigation which discovered that up to 50% of the 1000 bypasses a year 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).

this problem—which economists call "induced demand"—yet no one has estimated its overall impact.[11]

Third, overuse can occur because doctors are not aware of the fact that the costs of a treatment are higher than its benefit, either because they have no relevant information or because they are not accustomed to think about medicine in those terms. I call this cost-apathetic medicine because providers are unaware of, or do not care about, the importance of costs when they deliver care.

Fourth, overuse can occur due to compassionate medicine, i.e. excessive care provided because doctors derive satisfaction from doing the maximum they possibly can for the patient especially—when the patient is dying. About 30% of the total Medicare budget goes to caring for patients during the last year of their lives; about 50% of this goes towards their last 60 days. Yet, there is no measurable benefit to the overall health landscape.[12] In other words, the large amount of money spent on end-of-life care could be spent in other areas and derive, by any measure, a much larger benefit.

Republicans focus on reducing overuse associated with defensive medicine. This focus is the reason why they push for a medical liability reform that would decrease doctors' liability and reduce the doctors' incentives to over-treat for fear of lawsuits. Democrats, on the other hand, focus on reducing overuse associated with offensive medicine and misuse resulting in medical errors. This is a reason why they push for a healthcare reform that would change the way medical care and drugs are reimbursed and why they object to reforming medical liability. Both parties discuss reducing underuse through encouraging preventative medicine and the benefits of increased access to insurance. However, a better way than this political piecemeal approach would be to simultaneously address underuse, misuse and all four types of overuse. Indeed, over the last several months it has become increasingly clear that healthcare reform must be

[11] Jonathan Gruber & Maria Owings, *Physician Financial Incentives and Cesarean Section Delivery*, 27 RAND J. ECON. 99 (1996) (suggesting physicians substituted c-section delivery for normal delivery in order to make up for negative income shocks from decreased fertility rates); Cromwell, Jerry, and Janet B. Mitchell. 1986. Physician-Induced Demand for Surgery. *Journal of Health Economics* 5(4):293-313; Janet Currie & W. Bentley Macleod, *First Do No Harm? Tort Reform and Birth Outcomes* 3 (Nat'l Bureau of Econ. Research, Working Paper No. 12478, 2006) ("Many doctors perform unnecessary procedures not primarily because of fear of liability but because such procedures are more profitable . . . than the alternatives.").

[12] Lubtiz & Riley, Trends in Medicare Payments in the Last Year of Life, *New England Journal of Medicine* 328, no. 15 (1993): 1092-1096.

bundled with medical liability reform in order to strengthen political will and achieve optimal changes.[13] President Obama has endorsed this proposed pairing of healthcare reform with malpractice reform, a stance joined by the president of the AMA. A recent surge of related legislative proposals in Congress demonstrates that this idea is gaining momentum.[14]

Some of the more promising proposals offer doctors immunity from medical malpractice lawsuits in return for following evidence-based medical guidelines.[15] These proposals make sense because a major role of medical malpractice liability is to create incentives for doctors to behave optimally.[16] Therefore, giving immunity to those who behave optimally by following evidence-based medicine would achieve the same incentive goals without making doctors bear as much of the cost. These immunity proposals would address both misuse (medical errors) and overuse (especially the compassionate and cost-apathetic types but also to some extent offensive medicine) by forcing doctors to follow evidence-based guidelines. Overuse of the defensive medicine type would be addressed by granting doctors immunity. However, these proposals ignore a crucial point: there is an intrinsic problem with the actual *production* of existing clinical practice guidelines (CPGs).

Currently, CPGs are produced by various entities, including professional medical organizations, hospitals, HMOs, liability insurers, and government agencies. These organizations should strive to provide guidelines focused on optimizing patient care while minimizing costs. Unfortunately, these organizations often struggle to achieve this goal because they have neither the resources nor the financial incentives to constantly invest in updating the guidelines to reflect quickly evolving scientific research. This results in guidelines which lack adequate support from scientific evidence. Indeed, recent studies show that only a small percentage of CPGs are based on scientific evidence.[17]

[13] Michelle M. Mello and Troyen A. Brennan, *The Role of Medical Liability Reform in Federal Health Care Reform*, 361 NEJM 1, 1-3 (2009).
[14] *See e.g.*, Healthy Americans Act, S.391, 111th Cong. (2009).
[15] For a recent summary of the proposals see Mello and Brennan, *supra* note 2.
[16] By "optimal," I mean the socially optimal balance between safety, effectiveness, cost, and other relevant factors such as political or moral concerns.
[17] *See infra*, note 113.

The problem is compounded by two factors. First, guidelines are often written by entities with conflicting goals. CPGs written by medical associations are usually designed to improve the care of patients. If all works well – and all seldom does – the guidelines are informed by clinical expertise and empirical research and are driven by professional standards of care. In contrast, CPGs produced by third-party payers (such as HMOs) are often used for utilization review and aimed at cost-containment, externalizing costs onto liability insurers.[18] Similarly, CPGs produced by malpractice insurers are usually intended primarily to lessen the risk of malpractice and only secondarily to provide optimal care to patients, externalizing costs onto patients and third-party payers.[19] Thus, physicians are often faced with a choice between several conflicting guidelines which have goals in tension with each other: to provide the best care for patients, to secure reimbursement for the physicians, and to avoid the risk of malpractice liability.[20]

A further conflict arises because many professional organizations and the clinical practice studies upon which they base guidelines have strong financial ties to drug companies and medical device producers. These two groups can benefit greatly if guidelines recommend use of their products. The problem is amplified by the fact that the organizations producing CPGs are not subject to financial liability for their recommendations.[21] The result is that many doctors are suspicious of whether the guidelines reflect untainted, evidence-based advice. It is no wonder a recent study found that over 50% of doctors say they pay no attention to guidelines.[22]

If CPGs are not produced under appropriate incentives and funding, 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.

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

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

[20] Patricia R. Recupero, *Clinical Practice Guidelines as Learned Treatises: Understanding Their Use as Evidence in the Courtroom*,36 J. AM. ACAD. PSYCHIATRY L. 290, 290-301 (2008)

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

[22] *See infra*, page 27.

Against this background I propose a system where "private regulators" set the gold standard of patient care by developing guidelines and competing to sell them to providers (hospitals and doctors). These firms will offer providers a safe harbor by bearing the costs of medical malpractice lawsuits as long as providers comply with the firms' prescribed guidelines. I demonstrate that under this Private Regulation Regime (PRR), guidelines will be developed by private firms who profit from cost-saving procedures while also profiting from procedures which increase patient safety. Granting immunity from medical malpractice to doctors who follow such guidelines would be justified because the financial incentives behind the guidelines are perfectly aligned with the social goals of minimizing healthcare costs while maximizing patient safety. As I show in more detail below such guidelines will inform providers of the appropriate care, thus reducing underuse and misuse. Informing providers about the appropriate care will also reduce overuse associated with cost-apathetic medicine, and go a long way towards combating compassionate medicine and offensive medicine by making such types of medicine relatively more risky for the provider. Overuse due to defensive medicine will also be eliminated by granting immunity to those who follow such guidelines.

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

[23] The firm could also provide a 5-year plan to continually improve the guidelines and keep them at an optimal level. This analysis assumes that the locality-rule, in which the standard of care is judged relative to a particular locality, applies. In contrast, if Hospital A operates in a state using the national-standard rule then guidelines will have to conform to the national standard of care. In such cases, those hospitals lacking enough resources to properly comply with this standard may decide not to adopt the guidelines, thereby subjecting themselves to existing tort law. About 29 states and the District of Columbia have adopted a national standard, while 21 states maintain some version of the locality rule. Michelle Huckaby Lewis, John K. Gohagan, Daniel J. Merenstein, *The Locality Rule and the Physician's Dilemma*, 297 JAMA, 2633, 2633-37 (2007).

with payers (HMOs, PPOs, Medicare, etc) to get reimbursements based on the quality and cost-effectiveness of the guidelines.[24]

Once Hospital A decides to adopt the guidelines, the hospital would be immune from medical malpractice liability for accidents occurring in its emergency room provided it strictly followed the guidelines. This immunity is what I call a private regulatory compliance defense. A patient's only way to receive compensation from Hospital A (or its physicians) would be by showing that the hospital did not follow the guidelines. Alternatively, the patient could sue firm P for writing sub-optimal guidelines which exposed the patient, ex-ante, to too much risk. Firm P would be held liable for the patient's harm if a court determined that P wrote sub-optimal guidelines that caused the patient's harm.

The legal infrastructure for the PRR would require six essential components, most of which would require some form of government intervention.[25]. First, Firm P must get some degree of intellectual property protection for its guidelines in order to promote research and development of improved medical techniques.[26] Second, courts will have to adopt a private regulatory-compliance defense immunizing doctors who follow guidelines, thus eliminating incentives for defensive medicine.[27]

[24] There could be several levels of standard of care (platinum, gold and silver) based on the available resources and consumers' preferences. The reimbursements from payers will be adjusted to the quality and the cost effectiveness of the guidelines. See below supra note %%%

[25] The necessity of this government intervention could explain the current lack of a similar system.

[26] As will be explained below, current law roughly meets this requirement.

[27] In theory, parties could mimic such a legal regime via contractual arrangements. I elaborate below on the market failures that prevent the PR regime from contractually emerge.

defense would incentivize Firm P to investigate ongoing research and update guidelines accordingly, while giving practitioners confidence in the guidelines.[28] Sixth, when payers (HMOs, PPOs, etc) contract with hospitals they should have the power to structure a reimbursement scheme which takes into account the quality and cost effectiveness of CPGs, thus diluting Firm P's incentives to write guidelines which are too defensive and therefore expensive.

The proposed PRR will increase the evidence-based nature of medicine. Instead of performing medicine which is based on 17-year old research (on average), care delivered will be based on the most current medical research. The PRR is also better suited for individualized medicine, which is possibly the future of medicine.[29] The relationship between doctors and PR firms will be like the relationship between architects and builders. Architects are primarily concerned with design, builders with execution. The PR firms (the architects) will synthesize tort law, regulatory requirements, and available research to design guidelines relevant to the hospital's practice areas. Doctors (builders) will execute the synthesized guidelines, assured that compliance will shield them from liability.

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

Third, Firm P must be licensed to guarantee its financially solvent in light of the financial risk it faces, thus eliminating its incentive to write overly risky CPG. The financial liability Firm P faces is what guarantees it will not write guidelines that are too risky for patients only to save costs or generate revenue for hospitals. Fourth, Firm P must face liability, judged from the ex-ante perspective, for writing sub-optimal regulations. Firm P must be found negligent if and only if it has written guidelines which are inefficient under an evidence-based cost/benefit or risk/risk analysis. The ex-ante perspective will help eliminate various biases as well as allow for better accounting of benefits rather than just costs. Fifth, firm P cannot be allowed to rely on the state-of-the-art defense. Disallowing that

II. THE CURRENT REGIME AND (LACK OF) PATIENT SAFETY

The healthcare system is ailing badly. Doctors are accused of performing defensive medicine, performing offensive medicine (also known as "induced demand"), committing fraud on payers, abandoning the profession or particularly risky specialties, neglecting rural areas, ignoring evidence-based medicine in favor of profits, committing

[28] Depending on how the market for private regulation develops, especially in its early stages, there may be a sixth requirement which is that hospitals must adopt guidelines. *See infra*, note 133.
[29] See infra…

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

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

On one side, plaintiffs' advocates point to the low ratio of lawsuits in relation to medical injuries to justify their complaints about a lack of legal recourse for malpractice victims. On the other side, defendants' advocates contend the opposite, pointing to a perceived high number of lawsuits to show the system provides too much leniency for frivolous plaintiffs.[30] Moreover, neither agencies nor courts nor legislatures possess the ability to respond to the rapid advances of science that push evidence-based medicine so quickly, rendering yesterday's gold standard of care unacceptable tomorrow. Courts and legislatures fail to recognize that modern medical accidents involve systemic failures of multiparty coordination. These accidents are often far beyond an individual provider or doctor's control. Liability for malpractice as applied by courts thus misses its regulatory target because it fails to address the root cause of harm. With all these problems, it is no

[30] However, other studies argue that the majority of patients who sustain a medical injury as a result of negligence do not sue. *See* A. Russell Localio et al., *Relation between malpractice claims and adverse events due to negligence: results of the Harvard Medical Practice Study III*, 325 N. ENGL. J. MED. 245, 245-51 (1991); David M. Studdert et al., *Negligent Care and Malpractice Claiming Behavior in Utah and Colorado*, 38 MED. CARE250, 250- 60 (2000).

wonder that patient safety in the US is so poor; some numbers suggest that every year up to 98,000 deaths are associated with medical error, about twice as many as from car accidents, breast cancer or aids.[31] Any lawyer who cares must ask whether there is any way the law can be helpful.

This section first discusses the weaknesses of the current healthcare system, focusing on three of the primary problems: misuse (medical errors), underuse and overuse. Next, I describe what is wrong with how the current legal system regulates medical practice. I start by describing the defects with the current medical malpractice legal regime, an important component of our health care system. Then I show why tort law encourages these inefficiencies. First, structural barriers to the legal system prevent victims from getting their day in court. Then, for those patients who do pass through the courthouse door, fact-finders' lack of expertise and cognitive biases cause the court system to generate weak signals between real medical negligence and court-determined legal negligence. I next show why government agencies cannot serve as an adequate substitute. Lastly, , I briefly describe how lack of resources and adverse incentives thwart optimal regulation of medical practice by the government. I end the section by explaining why even the *combination* of agencies' regulation and tort law does not achieve optimal care.

a. Healthcare Problems

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.[32] There are many reasons why the healthcare system is so expensive, but I will focus on only three of the leading causes: misuse , overuse and undersue.

i. Costs Associated with Underuse.

Underuse occurs due to financial barriers such as lack of insurance, lack of coverage for preventive care, high deductibles and copayments, etc. Underuse has been shown to lead

[31] TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM, 2 (Kohn, Linda et al. eds., Institute of Medicine, National Academy Press, 2000) available at *http://books.nap.edu/openbook.php?isbn=0309068371* .
[32] Uwe E. Reinhardt et el., *U.S. Health Care Spending in an International Context*," 23 HEALTH AFFAIRS 10, 10–25 (2000), *available at* http://content.healthaffairs.org/cgi/content/abstract/23/3/10.

to poorer health outcomes.[33] Capitation payments, which targets overuse, might be a reason for underuse.[34] Yet, studies have shown about equal levels of underuse of a variety of services exist in both fee-for service and capitation arrangements.[35] Another reason underuse occurs is because some segments of the population distrust physicians and the health care system in general. These segments may decline to follow recommendations or may avoid the system altogether.[36]

ii. Costs Associated With Misuse.

There are two kinds of misuse, or of medical errors: errors of execution (when the correct action does not proceed as intended) and errors of planning (when the intended action is not correct).[37] These costs can be measured in terms such as hospitalization days due to repeated procedures and tests, increased insurance premiums based on these unnecessary tests, permanent disability, loss of income, pain and suffering, and lost trust between patient and doctor, which itself can result in less effective care prospectively.[38] Some of these costs are born by patients, some are born by health insurers, and some are born by the hospital in which the error occurred—or the hospital's insurance provider. There are numerous sources of medical errors, including, among many others, long shifts which bring fatigue and inadequate judgment, cognitive biases—such as over-confidence—which affect a provider's judgment, lack of resources, lack of training, communication breakdowns between medical group members, and a lack of quality clinical practice guidelines.[39]

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[33] see eg. Stephen F. Jencks, Edwin D. Huff, and Timothy Cuerdon, "Change in the Quality of Care Delivered to Medicare Beneficiaries, 1998–1999 to 2000–2001," *Journal of the American Medical Association*, vol. 289, no. 3 (January 15, 2003), pp. 305–312; and Elizabeth A. McGlynn and others, "The Quality of Health Care Delivered to Adults in the United States," *New England Journal of Medicine*, vol. 348, no. 26 (June 26, 2003), pp. 2635–2645..

[34] Capitation payment is an alternative to fee-for-service, under which a fixed amount of money per patient per unit of time paid in advance to the physician for the delivery of health care services

[35] See, for example, K.B. Wells et al., "Detection of Depressive Disorder for Patients Receiving Prepaid or Fee-for-Service Care," *Journal of the AmericanMedical Association* 262, no. 23 (1989): 3298–3302

[36] See for example L.G. Canlas, "Issues of Health Care Mistrust in East Harlem," *Mount Sinai Journal of Medicine* 66, no. 4 (1999): 257–258.

[37] *To Err Is Human* at 4.

[38] *To Err Is Human* at 2.

[39] *See e.g.*, Atul A. Gawande**,** *Analysis of Errors Reported by Surgeons at Three Teaching Hospitals*, 133 SURGERY 614, 614-21 (2003). As reported in the study which analyzed the factors contributing to medical errors, the most common factors were "inexperience/lack of competence in a surgical task (53% of

every year in the United States due to medical error.[40] The Institute of Medicine released a report in 1998 dealing with medical errors, finding that "medical errors cost the Nation approximately $37.6 billion each year; about $17 billion of those costs are associated with preventable errors."[41] In fact, more people die every year from prescription drug errors (7,000 deaths) than from workplace injuries (6,000).[42]

iii. Costs Associated With Overuse.

As was explained above there are four, non-mutually exclusive types of costs associated with overuse. [43]

1. Defensive Medicine.

Defensive medicine creates costs incurred through the use of excessive care which doctors often provide in an effort to shield themselves from liability. In the process of attempting to protect themselves, they often wind up externalizing these costs to patients' health insurers. Examples of these costs include excessive hospitalization and superfluous testing. Although these costs usually do not fall directly on patients, sometimes patients do bear costs indirectly. For example, patients may suffer income loss by losing work days due to excessive care or complications, such as catching a disease from unneeded hospitalization. The AHRQ estimates that 44,000 to 98,000 patients die defensive medicine alone were estimated to amount to up to $200 billion a year.[44]

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incidents), communication breakdowns among personnel (43%), and fatigue or excessive workload (33%)." *Id.*

[40] http://www.ahrq.gov/qual/errorsix.htm

[41] TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM, 1 (Kohn, Linda et al. eds., Institute of Medicine, National Academy Press, 2000) available at *http://books.nap.edu/openbook.php?isbn=0309068371* .

[42] *Id.* at 2.

[43] For overuse see eg. Elizabeth A. McGlynn, "Assessing the Appropriateness of Care: How Much Is Too Much?" RAND Research Brief (Santa Monica, Calif.: RAND, 1998), available at www.rand.org/pubs/research_briefs/RB4522.

[44] No one really knows what the costs of defensive medicine are. This did not prevent the Philip Howards, chairman of Common Good, from recently citing the number $200 billion. *See* Philip K. Howards *Why Medical Malpractice Is Off Limit,* Wall Street Journal, September 29, 2009 *available at* http://online.wsj.com/article/SB10001424052970204488304574432853190155972.html?mod=googlenews_wsj (defensive medicine costs $200 billion). This figure might be a rounded up from $178 billion which was recently cited by Rep. Michele Bachmann (R-Minn.) *See* Michele Bachmann, *Defensive Medicine*

2. **Offensive Medicine.**

Offensive medicine creates costs through excessive care which doctors provide in order to maximize reimbursements. These costs ensue from the fact that providers are reimbursed based on a fee-for-service method; that is, they are reimbursed for quantity, not quality.[45] President Obama has described this as a system of "warped incentives."[46] These costs can accrue in small amounts, including through superfluous testing or from more lucrative treatments such as surgeries.[47] Similar to costs associated with defensive medicine, these costs are born by the patient's health insurance carrier, although patients can indirectly bear some of these costs as well. Academics have long documented this problem—which they call "induced demand"—yet no one has ever estimated its overall

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Driving Up Healthcare Costs, THE HILL'S CONGRESS BLOG (Sept. 1, 2009) *available at* http://thehill.com/blogs/congress-blog/campaign/56957-defensive-medicine-driving-up-healthcare-costs-rep-michele-bachmann). Rep Bachmann's statement reflected Rich Karlgaard's recent declaration in Forbes Magazine that he believes the costs are $178 billion. *See* Rich Karlgaard, "Our Health Care Crisis: Age, Obesity, Lawyers," FORBES, August 20, 2009. My guess is that the $178 billion number is a typographical error, hopefully in good faith, of the high end of a range cited in a study by the U.S. Department of Health and Human Services which estimated the costs to be between $60 to $108 billion. *See* U.S. Department of Health and Human Services, *Confronting the New Health Care Crisis: Improving Health Care Quality and Lowering Costs By Fixing Our Medical Liability System* (July 25th, 2002) *available at* http://aspe.hhs.gov/daltcp/reports/litrefm.htm#note30. The numbers in this government study are extrapolations based on a 1996 study by Kessler and McClellan which found that tort reforms can save between 5%-9% of healthcare costs for heart patients without adversely affecting mortality. Daniel Kessler and Mark McClellan, *Do Doctors Practice Defensive Medicine?* 111 QUARTERLY J. ECON. 353 (1996). However, the authors of the government study were probably unaware of a 2002 study in which Kessler and McClellan repeated their 1996 study but this time controlling for costs containment achieved by managed care. The results were about 50% less than the in the original study. *See* Kessler, Daniel, and Mark McClellan. 2002. Malpractice Law and Health Care Reform: Optimal Liability Policy in an Era of Managed Care. *Journal of Public Economics* 84(2):175-97. Moreover, a 2004 study by the Congressional Budget Office which applied the methods used in the Kessler and McClellan study to a broader set of ailments could not replicate Kessler and McClellan's results. *See* Perry Beider and Stuart Hagen *Limiting Tort Liability for Medical Malpractice*, CONGRESSIONAL BUDGET OFFICE Jan. 8, 2004, *available at* http://www.cbo.gov/ftpdocs/49xx/doc4968/01-08-MedicalMalpractice.pdf

[45] See for example, S. Greenfiled at al, Variations in Resource Utilization Among Medical Specialties and Systems of Care, Journal of the American Medical Association267(12) (1992): 1624-1630. Yet, almost no study has been able to show that the over utilization is useless (and therefore offensive) because finding an appropriate outcome variable is tremendously hard. One exception is a study by Currie and McLeod which shows that caps on damages change doctors financial incentives such that ob/gyns overuse procedures in ways which increase rate of complications. See Currie and Mcleod supra note XXX

[46] "We should change the warped incentives that reward doctors and hospitals based on how many tests or procedures they prescribe, even if those tests or procedures aren't necessary or result from medical mistakes", *available at* http://articles.latimes.com/2009/jun/12/nation/na-obama-wisconsin12.

[47] *See supra* note 5.

impact.[48] However, it is suspected that the costs of offensive medicine are larger than the other two types of costs combined. Most recently, Atul Gawande documented how hospitals in McAllen Texas perform offensive medicine to enrich themselves at the expense of the public. Gawande showed spending in McAllen at $14,946 per Medicare enrollee per year, a number which is twice as much as the nearby and socio-demographically similar region of El-Paso which is marked at $7,504 per enrollee.[49]

3. **Cost-apathetic Medicine.**

Cost-apathetic medicine is overuse which happens in good faith. Doctors are not trained to account for costs but rather to do everything they can to care for their patients. New medical and surgical techniques developed over the last decades, combined with physicians' enthusiasm from being able to do good, have led to over usage of new and expensive care which lacks good evidence regarding its efficacy.[50] Once new technology penetrates the practice it is hard to cut back on overusage related to that technology. Consider for example the mammogram uproar caused by a US preventive services task force's recent recommendation that increasing the age, from 40 to 50 years old, at which routine screening mammograms should.[51] Yet, the same day that the task force released its recommendation the Health and Human Services Secretary stated she would be very surprised if insurance companies changed their mammography coverage as a result.[52] The suggestion that mammograms should be reduced caused a furor even when the

[48] Jonathan Gruber and Maria Owings, *Physician Financial Incentives and Cesarean Section Delivery*, 27 RAND J. ECON. 99 (1996) (suggesting physicians substituted c-section delivery for normal delivery in order to make up for negative income shocks from decreased fertility rates); Cromwell, Jerry and Janet B. Mitchell, *Physician-Induced Demand for Surgery*, 5 J. OF HEALTH ECON. 293, 293-313; Janet Currie and W. Bentley Macleod, *First Do No Harm? Tort Reform and Birth Outcomes* 3(Nat'l Bureau of Econ. Research, Working Paper No. 12478, 2006) ("Many doctors perform unnecessary procedures not primarily because of fear of liability but because such procedures are more profitable . . . than the alternatives.").
[49] Atul Gawande, *The Cost Conundrum: What a Texas Town Can Teach Us About Health Care*, THE NEW YORKER, June 1, 2009.
[50] Becher and Chassin infra note 88 at 166. P. Nicod and U. Scherrer, "Money, Fun, and Angioplasty," *Annals of Internal Medicine* 116, no. 9 (1992): 779; and R.A. Lange and L.D. Hillis, "Use and Overuse of Angiography and Revascularization for Acute Coronary Syndromes," *New England Journal of Medicine* 338, no. 25 (1998): 1838–1839; and M.R. Chassin, "Explaining Geographic Variations: The Enthusiasm Hypothesis," *Medical Care* 31, no. 5 Supplement (1993): YS37–44.
[51] Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement, *annals of Internal Medicine*, vol 151(10), (2009) pp 716-726, available at: http://www.annals.org/content/151/10/716.full
[52] Available at http://www.hhs.gov/news/press/2009pres/11/20091118a.html

recommendation was based solely on the fact that their health risks outweigh their benefits. It is hard to imagine the outrage that would have resulted if the recommendation was based on their financial cost.

4. **Compassionate Medicine.**

Compassionate medicine refers to medicine provided because doctors have hard time seeing their patients suffering and do nothing especially when their patients insist upon having the excessive care.Compassionate medicine costs arise primarily during end-of-life care, that is, care provided to people in the last year of their life. About 30% of the total Medicare budget goes to caring for patients during the last year of their lives; about 50% of this goes towards their last 60 days.[53] A recent study concluded that patients' rate of admission to ICU is 70 times higher for patient 85 years and older compared to those of 18 to 44 years, consuming a significant proportion of ICU resources.[54]

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

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[53] Lubtiz & Riley, Trends in Medicare Payments in the Last Year of Life, *New England Journal of Medicine* 328, no. 15 (1993): 1092-1096.
[54] Seferian & Afessa, Adult Intensive Care Unit Use at the End of Life: A Population Based Study, Mayo Clin Proc. 2006;81(7):896-901.
[55] E.S. Fisher et al., "The Implications of Regional Variations in Medicare Spending, Part 1: The Content, Quality, and Accessibility of Care," *Annals of Internal Medicine* 138, no. 4 (2003): 273–287; E.S. Fisher et al., "The Implications of Regional Variations in Medicare Spending, Part 2: Health Outcomes and Satisfaction with Care," *Annals of Internal Medicine* 138, no. 4 (2003): 288–298; K. Baicker and A. Chandra, "Medicare Spending, the Physician Workforce, and Beneficiaries' Quality of Care," *Health Affairs* 23 (2004): w184–; and A. Chandra and D.O. Staiger, "Productivity Spillovers in Healthcare: Evidence from the Treatment of Heart Attacks," *Journal of Political Economy* 115 (2007): 103–140.
[56] Yasaitis, Fisher, Skinner & Chandra, Hospital Quality and Intensity of Spending: Is There an Association? *Health Affairs* 28, no. 4 (2009): w566–w572. When the authors restricted their analysis to academic medical centers, they found there was no correlation between quality and spending.

iv. Summary.

As the previous sections showed, the health care system faces three main cost distortions: underuse, misuse, and overuse. Can the system fix itself? The answer is no. The reason is the lack of economic incentives for quality improvements. Solving overuse problems is not in the hospitals' financial interest because doing so would reduce their revenue and their physicians' income. Similarly, eliminating misuse problems by preventing medical errors is also not in the hospitals' or physicians' financial interest. Hospitals are reimbursed on a per diem basis, thus they have no interest in shortening their patients' lengths of stay, and physicians are always paid to treat complications, whether preventable or not. Doing away with underuse problems is also not financially beneficial for hospitals. First, because it will require undertaking the costly activities of identifying individuals who are not appropriately treated, and then treating them. Second, these people are often uninsured and therefore cannot pay for the treatment. Otherwise, they may be insured by Medicaid, which has low reimbursements rates. Third, treating these patients can decrease revenue because improving the outpatient treatment of chronic conditions can reduce hospital admissions for which they are more likely to be reimbursed.[57]

The next section discusses whether tort law can solve these three problems.

b. The Problems With Tort Law.

[57] See Becher & Chassin, supra note 3 at 168-9.

Tort law has tried to tackle some of these problems. However, the methods used by tort law either address the problems separately or ignore them altogether. Underuse is outside of tort law's radar simply because the victims of underuse (primarily the uninsured poor) have no way to know and realize their rights. Compassionate care and cost-apathetic care—both types of overuse—are also outside of tort law's radar because in most cases there are no victims. Offensive medicine is supposed to be controlled by various anti-kickbacks laws,[58] anti-self-referrals laws (Stark laws)[59], 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. Misuse—medical errors—are supposed to be controlled by subjecting doctors to medical malpractice for committing negligent errors.

Yet, using tort law to combat offensive medicine, defensive medicine and medical errors is problematic. Attempting to solve one problem immediately exacerbates another. Tort reform, which reduces providers' liability, does dilute providers' incentives to perform defensive medicine, but at the same time has two adverse effects. First, it also 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. [60]

However, tort law's primary mission is not to cure all three problems, but instead to decrease medical errors. Tort law, in fact, is the primary way the legal system deals with medical errors. Yet even in that role scholars on both sides of the tort-reform map have insisted that the signals between court outcome and real negligence are too weak.

[58] 2 U.S.C. § 1320a-7b(b)
[59] 42 U.S.C.S. §1395nn
[60] In 2002 officials at the Redding Medical Center in California (also known as "little house of horrors") were subject to an FBI investigation which discovered that up to 50% of the 1000 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* STEPHEN KLAIDMAN, CORONARY: A TRUE STORY OF MEDICINE GONE AWRY (Simon and Schuster, 2007). This is of course not the first time in the history of the U.S that doctors admit patients for offensive medicine-related reasons. *See* Paul Jacobs, *Heart Surgeries Lead Hospital Into Difficulties*, LOS ANGELES TIMES, JULY 31, 1980, B1 (reporting that doctors at Paramount General Hospital in California were "anxious to operate on almost anything"); *see also* Klaidman *id.* at 7-11 (reporting how officials from the Psychiatric Institutes of America in Texas bribed doctors to refer patients to PIA. A 1993 FBI investigation ended with some doctors sent to jail and $379 million paid in fines and settlements with plaintiffs who had been wrongly admitted to the psychiatric institution).

First, not *all* negligent cases, but just the large ones, are brought. If all negligent cases are not brought then victims remain uncompensated for the harm they have incurred and the signal from the legal system which is supposed incentivize optimal behavior is distorted.[61] Second, for cases that are brought, courts fail to find liability only when defendants are actually negligent.[62] Under a negligence regime even unbiased, random judicial error will cause defendants to be too careful or to engage in too little activity, both of which are forms of defensive medicine.[63] 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.[64] The major reasons courts make biased decisions are that they do not face all the relevant evidence,[65] and they are subject to various biases such as the "identifiable-other effect" [66], and the "hindsight bias."[67] The major reasons

[61] Several important studies have analyzed the number of malpractice claims filed relative to actual cases of negligence. The most cited study is the Harvard Medical Practice Study (HMPS) which focused on hospitalizations in fifty-one hospitals in New York during 1984.David Hyman and Charles Silver, *Medical Malpractice and Tort Reform: It's the Incentives, Stupid*, 59 VAND. L. REV., 1085 (2006) (citing Troyen A. Brennan et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients*, 324 NEW ENG. J. MED. 370, 371 (1991). The researchers matched cases of negligent injury with actual claim filings, and determined that only 2 percent of those who were negligently injured sued. *Id*. 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. *Id*. Lastly, these findings were consistent with a late 1990's Florida study which found that, of 19,885 incidents of medical negligence self-reported by hospitals, only 3,177 patients filed claims. Id at 1085.

[62] The law needs also to award the correct amount of damages. In what follows I assume that court can determine damages well. I focus on better defining negligence.

[63] *See* STEVE SHAVELL, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW, 224-25 (Harvard, 2004).

[64] *Id.*

[65] Courts suffer from a biased information problem because they deal with the few who were injured by a given treatment rather than the many who benefited from that same treatment. This selective perspective is problematic because 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.

[66] As first noted by Thomas Schelling, identifiable victims stimulate more powerful emotional reactions than do statistical victims. Thomas C. Schelling, , THE LIFE YOU SAVE MAY BE YOUR OWN, in SAMUEL B. CHASE (ED.), PROBLEMS IN PUBLIC EXPENDITURE ANALYSIS (The Brookings Institute 1968). Thus, jurors are more likely to focus on compensating the "identifiable victim" than on weighing more abstract evidence concerning general deterrence. Deborah. A. Small and George Loewenstein, *Helping* a *Victim or Helping* the *Victim: Altruism and Identifiabilty*, 26 J. OF RISK AND UNCERTAINTY 5, 5-16 (2003) at 5-6. Recently, commentators have claimed that that the identifiable victim effect is a special case of a more general tendency to react more strongly to identifiable others whether they are victims or perpetrators Deborah. A. Small and George Loewenstein, *The Devil You Know: The Effect of Identifiability on Punitiveness.* 18 J. OF BEHAVIORAL DECISION MAKING 311, 311-18 (2005) (showing that people are more punitive toward identified wrongdoers than toward equivalent, but unidentified, wrongdoers, even when identifying the

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 to not impede) medical progress.[68]

As a result doctors complain court outcomes cannot be seriously taken into account when decisions are being made about patients' lives. 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 medical practices 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. A PR regime, in contrast, should do better on all fronts. A PR regime will act from the ex-ante perspective (eliminating hindsight bias) where statistical

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wrongdoer conveys no meaningful information about him or her.) If correct, the "identifiable other effect" also suggests that courts react more strongly also towards the identified defendant-doctor treating her more harshly. This can lead to many more (presumably erroneous) findings of negligence compared to adjudication based on the efficiency of guidelines per se, a task which involves dealing with statistical victims and statistical doctors. Indeed, there is some evidence which suggests that courts seem to compensate the injured when their harm is large, even in the absence of negligence. David M. Studdert et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, 354 NEW ENG. J. MED. 2024, 2024-33 (2006). (showing that the legal system performs well roughly three quarters of the time, on the basis of those awarded compensation (deserving and undeserving) of medical malpractice claims, and that the size of the harm is the most important predictor of outcome).

[67] Hindsight bias is when "people consistently exaggerate what could have been anticipated in foresight."Baruch Fischhoff, *Hindsight (Not Equal To) Foresight: The Effect of Outcome Knowledge on Judgment Under Uncertainty*, 1 J. EXP. PSYCH. 288 (1975). [67] Thus, doctors may be found liable under the current medical malpractice negligence regime when their patients are injured even though the doctors behaved reasonably. Anticipating hindsight bias and the impossibility of eliminating or even moderating it, doctors may be rational in practicing defensive medicine. *See* Jeffrey J. Rachlinski, *A Positive Psychological Theory of Judging in Hindsight*, 65 U. OF CHI. L. REV. 571 (1998). This problem has been noticed by courts, which use various techniques that potentially moderate the hindsight bias. *Id.*

[68] The common law is that it fails to encourage systematic knowledge-production as well as continuously updated behavior-regulation mechanisms. The investigation of procedures such as surgical techniques is often left to the creativity and improvisation of any willing physician, which is of course problematic. *See e.g.*, Elena A. Gates, *New Surgical Procedures: Can Our Patients Benefit While We Learn?*, 176 AMER. J. OBSTETRICS & GYNECOLOGY 1293 (1997). While developing a new procedure does not require the approval of any governmental agency, physicians interested in developing new techniques face numerous informational barriers. As recently argued by Stein and Porchamovski, 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. Gideon Parchomovsky and Alex Stein, *Torts and Innovation* ,107 MICH. L. REV. 285 2008). Indeed, it takes an average of 17 years for quality medical research to actually be endorsed by clinical practice guidelines.

doctors and statistical patients are considered, (eliminating the identifiable other effect). Under the PR regime there will be no state of the art defense, further encouraging the efficient implementation of medical innovations. Under PRR, the guidelines will be on trial, not the physician (encouraging optimal, even if risky doctoring). Under the PRR better guidelines will be developed and adopted. PR firms would see a broader picture than would individual physicians, enabling them to better perceive the effectiveness of new procedures. The immunity offered by PR firms could counter physicians' decreased willingness over their careers to adopt new procedures.

Clinical practice guidelines produced under the right incentives could reduce many of the current costs. Optimal CPGs would reduce costs associated with both types of misuse, or medical errors (errors of execution and errors of planning), because they would limit provider's discretion and encourage evidence based medical practices. CPGs will eliminate underuse because they will communicate the gold standard of care. CPGs will also reduce overuse. For the same reason compassionate and cost-apathetic medicine should be significantly constrained. The resulting immunity for following the CPGs would also reduce costs associated with defensive medicine because providers would no longer feel compelled to shield themselves from liability. CPGs under the PR regime would also reduce costs associated with offensive medicine. First, they would provide doctors with information on the most efficient care level. Second, doctors would have relatively weak incentive to provide excessive care because doing so would cause them to lose their immunity shield. The next section explains why existing guidelines do not achieve these benefits.

c. The Problem with Guidelines.

i. A Brief History of CPGs in the US.

A number of medical guidelines have been proliferated over the last 50 years, but starting in the 1990s, the number of guidelines being produced increased dramatically. This increase was primarily due to widely publicized studies which demonstrated a large

variation in clinical practice across geographic areas and even within the same area.[69] During this time, guidelines were increasingly being produced by a variety of different organizations including professional societies, hospitals, health plans, and review boards. Most notably, it was during this time that the Agency for Health Care Policy and Research spearheaded the development of about 20 guidelines across key clinical practice areas.[70]

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.[71] 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 AHRQ in partnership with the AMA, and American Association of Health Plans, has developed a National Guideline Clearinghouse designed to provide access to the overwhelming number of guidelines and evaluate guidelines adherence to sound evidence.[72] Currently, the Cochrane Collaborations, the Trip database and the National Guideline Clearinghouse serve as a link to literally thousands of medical treatment guidelines.[73] Although they have the problems with guidelines, 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 which were

[69] For example, a study published in the early 1980s described how in Maine, the likelihood of a woman's having a hysterectomy by the time she reached age 70 varied from 20 to 70 percent in different hospital markets. In Iowa, the likelihood that a man who reached the age of 85 would have had a prostatectomy varied from 15 to 60 percent in different areas. In Vermont, children who had undergone a tonsillectomy varied from 8 to 70 percent depending on geographic area. John E. Wennberg, *Dealing with medical practice variations: a proposal for action.* 3 HEALTH AFFAIRS 6, 6 –32 (1984).
[70] Eleanor M. Perfetto and Lisa Stockwell Morris, *Agency for Health Care Policy and Research Clinical Practice Guidelines*, 30 ANNALS OF PHARMACOTHERAPY 1117 (1996).
[71] Kathleen N. Lohr, , Kristen Eleazer, and Josephine Mauskopf, *Health Policy Issues and Applications for Evidence-Based Medicine and Clinical Practice Guidelines*, 46 HEALTH POLICY 1 (1998).
[72] THE INSTITUTE OF MEDICINE, *supra* note 1, at 151.
[73] See in order: http://www.cochrane.org/, http://www.tripdatabase.com/SearchResults.html?categoryid=9&sort=t&criteria=guidelines+medicine, http://www.guideline.gov/.

initially optimal will not remain so for long. More importantly, there is question whether guidelines are developed under 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.[74] 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.[75] 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.[76] The late John Eisenberg, former Executive Director of the Agency for Healthcare Research and Quality, even suggested that the root cause for widespread variation in medical practice patterns is the physicians' conscious reluctance to incorporate evidence-based guidelines in their practices.[77] 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.[78]

Under the PR regime, these problems would not exist because doctors would have much stronger incentives to become both aware and familiar with all guidelines. First, as will be explained below, the guidelines will be a product of a much better developmental process, driven by efficiency concerns only so that doctors will have stronger reasons to trust the guidelines. Second, unlike the legal regime today which does not exempt doctors from liability if they follow the guidelines, under the PR regime, following the guidelines will exempt doctors from liability.

The next sections explain specific problems with the various types of existing guidelines.

ii. When The Government Writes Guidelines.

[74] Michael D. Cabana; Cynthia S. Rand; Neil R. Powe, *Why Don't Physicians Follow Clinical Practice Guidelines?: A Framework for Improvement,* 282 JAMA 1458 (1999). .
[75] *Id.*
[76] *Id.*
[77] *See* Keckley, *supra* note 1 (citing John M. Eisenberg, *Quality Research for Quality Healthcare: The Data Connection*, 35 HEALTH SERVS. RES. 12 (2000)).
[78] *Id.*

1. **Theory.**

In the context of medical malpractice, two main federal agencies create regulations: the FDA, which regulates drugs and medical devices, and the Department of Health and Human Services Agency for Healthcare Research and Quality (AHRQ), which is responsible to collect and help promulgate CPGs. As far as questions of legal liability go, government guidelines, like other clinical guidelines, are not binding. Therefore, unlike other federal agencies which write and then enforce regulations, the AHRQ has never enforced its guidelines. That is, it has never filed a claim against a provider who delivered care which deviated from the Agency's guidelines. Instead, the AHRQ perceives itself as facilitating the creation of CPGs, by other actors only, leaving to victims of medical malpractice the option, and responsibility, to file a lawsuit claiming such deviation from such CPGs, (which courts were free to reject).

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, in general, government agencies may create overly lax regulations (or under-enforce regulations).[79] First, agencies will often lack the resources to set the regulations efficiently and then periodically update them.[80] Second, agencies are vulnerable to perverse political preferences by the government and self-aggrandizing administrators as well as to interest-group capture. A change in the government can lead to ossification between standards.[81] Self-aggrandizing administrators, operating in a revolving door environment, may advance their post-agency careers by catering to interest groups that favor lax standards. Most importantly, Interest-group capture can lead to under-enforcement, and, in the case of AHRQ has led to the decision to *abandon* the promulgation of CPGs altogether.[82]

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[79] *See* Catherine Sharkey *Products Liability Preemption: An Institutional Approach*, 76 Geo. Wash. L. Rev. 449, 495 (2008).
[80] Rachlinski, *supra* note 54, at 609.
[81] For example the FDA changed 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. iss. 2 art.5, at 20 (2006) *available at* http://www.bepress.com/jtl/vol1/iss1/art5/ (last visited Sept. 1, 2009).
[82] See supra around footnote 100 (describing how the AHRQ had to stop promulgating guidelines due to interest group pressure).

regulate in response to crises. It might take years, if not decades, to fix regulation enacted immediately after scandals. Second, agencies lack the financial accountability necessary to incentivize efficient rule-making. Government agencies cannot be sued for making poor guidelines.[83] Due to this, an agency rule-maker will not become aware of the financial consequences of his rule-making and may over-regulate. The over-regulation can be enhanced because the regulator is *politically* accountable, which can lead to a defensive policy. If the agency errs by failing to regulate, their political accountability assures they will be punished, but the agency will seldom be punished politically for overly stringent regulation.[84]

Due to these countervailing considerations, there is some uncertainty whether agencies regulate in an overly strict or overly lax manner. This uncertainty however says nothing about efficiency. Indeed, other than the FDA, whose stringent ex-ante approval procedures and explicit claims to regulate hazards for optimality indicate their standards strive for both safety and cost efficiency,[85] most other agencies seem to only regulate minimum standards of care (or "floors").[86] Standards which are only a floor are quite often suboptimal. This possibility of suboptimal standards explains why only one state, Michigan, has accepted the regulatory compliance defense. Under the Michigan scheme, the defendant is off the hook if he complies with the government regulatory standards. Even in Michigan, though, the regulatory compliance defense only applies in the pharmaceutical context and when the government agency is the FDA. [87]

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[83] In the US one cannot sue the FDA or any other agency for a wrong decision within their discretion.

[84] *See* Epstein, *supra* note 78, at 22 (arguing agencies have incentives to regulate in an overly risk-adverse fashion because of self interest).

[85] *See e.g.*, Brief of Amicus Curiae The United States of America, 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 sufficient evidence to establish an association between a drug and a particular hazard before warning of that association on a drug's labeling.").

[86] On the contrary, there are several reasons why some federal agencies may make overly defensive regulations. First, occasionally agencies

[87] 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).

[87] 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. § 13-21-403(1)(b) (2007); IND. CODE § 34-20-5-1(2) (1999) (same); 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) (Vernon 2005); UTAH CODE ANN. § 78-15-6(3) (2005). By and large, neither the Restatement Second nor the Third allow for a complete defense.

Furthermore fast-moving medical research exacerbates the general agency regulation problems in relation to the health care industry. Because medical research evolves very quickly, it is likely that government CPGs would fail to keep up with current medical research. In 2001, a study examined the validity of 17 CPGs developed from 1990 to 1996 by the AHRQ (U.S. Agency for Health care Policy and Research) and found that 13 were out of date with current research.[88] The study also found that it was estimated to cost $4 million per guideline to properly update them using AHRQ's Evidence Based Practice Center Program.[89] 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.

A PR firm would be less susceptible to these problems. Unlike an agency, a PR firm would be financially liable for rule making and would have financial incentives to engage in the correct level of regulation. Unlike an agency which is subject only to administrative review of its rulemaking, the PR firm will continuously be held liable for damages caused by its inefficient prescription. And a PR firm could expect to profit from refining standards. This helps solve the ossification and agency capture problems. In a PR firm, an administrator's career success would be tied to the PR's profitability, diminishing the likelihood that decision-makers in PR firms would aggrandize themselves at the cost of efficiency. This helps solve aggrandizement and defensive regulation problems. PR performs better also with respect to the compensation goal, because there is no preemption in the PR regime. Victims of doctors who did not follow the guidelines will get their day in court, as would victims of overly lax guidelines.

2. **Some Evidence From the Maine Pilot Project.**

In recent years a number of states have begun projects that established clinical practice guidelines as statutory standards of care used as baselines for physicians to use as

[88] Paul G. Shekelle, et al., *Validity of the Agency for Healthcare Research and Quality Clinical Practice Guidelines: How Quickly Do Guidelines Become Outdated?*, 286 JAMA 1461, 1464 (2001).
[89] *Id.* at 1462.

a defense in malpractice suits.[90] The most famous project was the Maine Medical Liability Demonstration Project, which expired in 1999.[91] The Maine project instituted special advisory committees in charge of developing clinical practice guidelines for four practice areas classified as hotbeds for malpractice litigation and suspected defensive medicine.[92] The State adopted twenty practice guidelines in anesthesiology, emergency medicine, obstetrics/ gynecology, and radiology. For physicians in these areas, those who elected to participate could introduce the guidelines into evidence as an affirmative defense to any malpractice claim[93]. Plaintiffs bringing such claims, however, could not introduce the guidelines into evidence to argue that failure to comply with a guideline was malpractice.[94] The guidelines were used as only a shield and not a sword because the purpose of the reform was to reduce liability. Unfortunately, the Maine project had little practical effect.[95] Few doctors believed that these regulations had any discernable effect, and in only one case was the affirmative defense even raised.[96] The superintendent of the Maine Bureau of Insurance explained that "the medical demonstration project had no measurable effect on medical professional liability claims, claims settlement costs, or malpractice premiums."[97] Similar projects were attempted in Florida, Vermont, Kentucky, Maryland, and Minnesota.[98] However, for a variety of reasons, none of the projects managed to garner enough physician support to reach full implementation or realize any quantifiable benefits.

The crucial missing aspect of these projects was that there is no justification for awarding doctors liability protection, unless the guidelines are created under a system which incentives progress towards creating safer, more cost effective procedures. Under

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[90] Linda L. LeCraw, *Use of Clinical Practice Guidelines in Medical Malpractice Litigation*, 3 J. ONCOL. PRAC. 254 (2007).
[91] *Id.*
[92] Report to the Honorable William S. Cohen and the Honorable George S. Mitchell, *Medical Malpractice: Maine's Use of Practice Guidelines to Reduce Costs* (Oct. 1993).
[93] *Id*.
[94] ME. REV. STAT. ANN. Tit. 24, §§ 2971-79 (1993).
[95] LeCraw, *supra* note 86**.** By one estimate, the guidelines affect only about three to four percent of medical practice in Maine. *See* Gordon H. Smith, *A Case Study in Progress: Practice Guideline5 and the Affirmative Defense in Maine,* 19Joint Commission J.. ON QUALITY IMPROVEMENT 355, 361 (1993)
[96] Howard Zonana, *Commentary: When Is a Practice Guideline Only a Guideline?,*36 J. AM. ACAD. PSYCHIATRY L, 302, 303 (2008)..
[97] LeCraw, *supra* note 86 (citing ME. BUREAU OF INS. AND BD. OF LIC. IN MED., MEDICAL LIABILITY DEMONSTRATION PROJECT 2AND 5 (2000)).
[98] *Id.*

the PR regime, the threat of liability for inefficient guidelines and competition from other firms would encourage firms to create efficient guidelines.

3. The Past and Present of Federal Bills Dealing With Guidelines

In the midst of the current push for health care reform, it appears the idea of providing liability protection to doctors for adherence to medical guidelines is once again receiving consideration. Recently, in the U.S. Committee on Finance, Senator Baucus has been facilitating discussions regarding the notion of a malpractice liability safe harbor for doctors who follow guidelines.[99] Earlier this year, Senator Ron Wyden had even proposed specific legislation which would have created a rebuttable presumption that care was not negligent if the physician followed accepted CPGs.[100] While thus far this legislation has failed to gain the necessary support, President Obama did recently indicate his potential willingness to endorse this concept. In a May 2009 meeting, the President reportedly told Dr. J. James Rohack, the president of the AMA, that he would be open to offering some liability protection to doctors who follow standard guidelines for medical practice.[101]

This recent activity is by no means the first federal attempt to use medical guideline reform to spur broader health care improvements. Over the last 20 years, the escalation of health care costs has forced Congress to search for ways to improve the quality of health care delivery and decrease malpractice liability costs. For this purpose, in 1989 President Bush and 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 ... clinically relevant guidelines."[102] AHCPR's CPGs were considered the

[99] Max Baucus, Call to Action: Health Reform 2009. (United States Senate Committee on Finance 2009) *available at* http://finance.senate.gov/healthreform2009/finalwhitepaper.pdf *(*last visited Sept. 1, 2009).
[100] Healthy Americans Act, S.391.
[101] Sheryl Gay Stolberg and Robert Pear, *Obama Open to Reining in Medical Suits*, THE NEW YORK TIMES, June 15, 2009.
[102] Michelle Mello, OF SWORDS AND SHIELDS: THE ROLE OF CLINICAL PRACTICE GUIDELINES IN MEDICAL MALPRACTICE LITIGATION, 149 U. PA. L. REV. 645, 651 (2001).

definite statements of excellence in their clinical areas.[103] Indeed, several years later, the Clinton administration attempted to take this initiative a step further by proposing a pilot program under which physicians able to demonstrate that their professional conduct or treatment complied with AHCPR practice guidelines would not be liable for medical malpractice.[104] Yet, due to a lack of support to Clinton's healthcare reform, not only has the Clinton's pilot program failed to materialize, but due to fierce interest group politics the AHCPR was almost totally eliminated in 1995.

Following many years of controversy over the merits of surgical procedures for low-back disorders, AHCPR funded a study which concluded that there was no evidence to support the use of spinal fusion surgery, that such surgery commonly had complications and that more randomized controlled trials were needed to compare fusion surgery and non surgical treatment.[105] An association of back surgeons who disagreed with the conclusions launched an attack on the study and also on the agency itself.[106] The Center for Patient Advocacy, which was formed by a back surgeon to lobby on the issue, mobilized an effort in the House to end the agency's funding. Only on the night of the vote was the amendment to reduce the agency's budget to zero withdrawn; though the agency did suffer a 21% budget cut.[107]

[103] Elise C. Becher and Mark R. Chassin, Improving The Quality Of Health Care: Who Will Lead? Health Affairs. Sept/Oct 2001, pp 164-179 at 172.
[104] Report to the Honorable William S. Cohen and the Honorable George S. Mitchell, *supra* note 88.
[105] J. Turner et al., "Patient Outcomes after Lumbar Spinal Fusions," *Journal of the American Medical Association* (19 August 1992): 907–911.
[106] This was not the first time AHRQ faced attacks by physician groups. In 1993 an AHCPR study came under attack from various ophthalmology associations. However, that attack never extended to attempts to defund AHCPR, and it came to an end when the ophthalmologists discovered they could use the data in discrediting a GAO study alleging that inappropriate cataract surgery was widespread and in getting insurers to pay for some surgery. Id.

[107] Bradford H. Gray, Michael K. Gusmano, and Sara R. Collins, AHCPR And The Changing Politics Of Health Services Research, Health Affairs (web exclusive) 2003, W3-283, at 301.

force in the dissemination of medical guidelines, yet the actual creation of CPGs was eliminated from its mission.[108]

Unfortunately, as was discussed above, the existing guidelines have failed to create a sustainable improvement in both the quality of medical procedures and the costs of care.

4. **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 that it provides predictability in the sense that 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. However, the existing system has several disadvantages. First, it does not help resolve the issue of determining negligence for the large number of cases where 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 which has been rejected by all but one jurisdiction (Michigan)[109]. Under the doctrine, compliance with regulation should be important if not determinative to finding the defendant *not* negligent. But if the standards

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

[108] Id.

[109] And even in Michigan it is just for pharmaceuticals. *See* MICH. COMP. LAWS ANN. § 600.2946(5), *supra* note 83.

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. Unfortunately, courts and scholars are still struggling to make sense of this jurisprudence.[110]

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 clinical practice guidelines. These guidelines are promulgated by various groups such as doctors' association, hospitals and insurers.

iii. When Hospitals and Hospitals Organizations Write Guidelines.

As was mentioned above, hospitals and hospital organizations such as the Joint Commission also write guidelines for various purposes such as peer review of staff performance, a better way to improve care, and consistency between hospitals.[111]

Occasionally hospitals utilizing proactive guideline-promulgating approaches such as root cause analysis ("RCA") have significantly improved patient healthcare outcomes.[112] 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

[110] *See* Catherine Sharkey, *What* Riegel *Portends for FDA Preemption of State Law Products Liability Claims*, 103 NW. U. L. REV. 437 (2009); Peter Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, available at http://ssrn.com/abstract=1078013; Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L. iss. art. 4, 3 (2006) *available at* http://www.bepress.com/jtl/vol1/iss1/art4/ (last visited Sept. 1, 2009); Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. 727 (2008); Epstein, *supra* note 78.
[111] 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 (2006).
[112] *See* Daniel R. Longo et al., *Hospital Patient Safety: Characteristics of Best-Performing Hospitals*, J. HEALTHCARE MGMT., May, 2007, at188.

on the case history of a 78 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.[113] 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.[114]

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[115].

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, the major criticism against 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.

iv. 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 appropriate care. These guidelines are often used for utilization review and physician profiling. Utilization review is used to determine whether a physician's treatment plan will be

[113] Thomas McGinn et al., *Decreasing Mortality For Patients Undergoing Hip Fracture Repair Surgery*, 31 JT. COMM. J. QUAL. PATIENT SAF. 304 (2005).
[114] *Id.*
[115] *See* http://www.taproot.com/about.php.

reimbursed. Profiling is used to see whether the physician's care is cost effective. For Physicians, compliance with the guidelines is very important because even though it might not shield the doctor from malpractice liability[116], 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.[117] 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.[118]

However, here too, problems of self-interest and externality 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.[119] This demonstrates the problem of defensive medicine which many believe comprises up to 9% of total healthcare costs.[120] 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.

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[116] See Wickline v. California, 239 Cal.Rptr.810 (Ct. App. 1986) (court held that a doctor must comply with professional standards of care even when insurer has declined to cover medical services required to satisfy that standard).

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

[118] Mello *supra* note @@, at 653.

[119] Indeed a Colorado appellate court held that guidelines written by a liability insurance carrier did not meet the relevance test for scientific evidence, because they were created "by a private insurance company as part of an insurance contract and did not reflect a generally recognized standard of care within the medical profession." Quigley v. Jobe, 851 P.2d 236, 238 (Colo. Ct. App. 1992).

[120] Daniel Kessler and Mark McClellan, *Do Doctor's Practice Defensive Medicine?* 111 QTRLY. J. ECON. 353, 371-72 (1996).

v. When Professional Associations Write Guidelines.

Guidelines written by doctors' professional association tend to be highly regarded since they reflect physicians' reviews of the current literature and emphasize quality care for patients. The impetus for their development seems to come from an interest in improving the quality of care and education, reducing negative outcomes and injuries, and decreasing the need for defensive medical practices. They also are a response to guidelines developed by third-party payers, which are perceived as being motivated by cost control and as threatening to physician autonomy.[121]

Unfortunately, the validity of these guidelines may be questionable for a variety of reasons, but three of the most frequently discussed reasons include the tendency for guidelines to become quickly obsolete, 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 is expensive and time-consuming the guidelines produced may already be obsolete by the time they are released or quickly thereafter.[122] This leads to the second problem, that the high costs of investing in proper research has resulted in guidelines which 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 48% of the recommendations derived from the lowest level of acceptable evidence.[123]

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

[121] Zonana, *supra* note 92, at 303.
[122] Richard Amerlinga, James F. Winchestera, Claudio Roncob, *Guideline Have Done More Harm Than Good*,26 BLOOD PURIFICATION 73 (2008).
[123] Tricoci, Pierluigi et al., *Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines*, 301 JAMA 831 (2009).. The study categorized its lowest level of acceptable evidence as ,level C, indicating little to no objective empirical evidence for the recommended action.

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.[124] More generally, one 2002 cross study involving 192 guideline authors found that 58% of the authors surveyed had received financial support to perform clinical research and 38% had served as employees or consultants for a pharmaceutical company.[125] Indeed, 19% of respondents believed that their coauthors' recommendations were influenced by their relationships with these companies.[126]

In the PR regime, private firms will have both the incentive to improve guidelines continuously and the financial resources needed to invest in research without relying on groups who represent a conflict of interest. Although the influence of pharmaceutical companies may be hard to escape completely, it would likely be substantially decreased under the PR regime. This is because potentially biased guidelines in the PR regime would be disciplined by market forces as well as by legal liability.

d. **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

[124]Connecticut Attorney General's Office, *Press Release: Attorney General's Investigation Reveals Flawed Lyme Disease Guideline Process, IDSA Agrees To Reassess Guidelines, Install Independent Arbiter*, May 1, 2008, available at http://www.ct.gov/ag/cwp/view.asp?A=2341&Q=414290 (*last visited*Sept. 1, 2009).
[125] Relationships Between Authors of Clinical Practice Guidelines and the Pharmaceutical Industry
[126] Niteesh K. Choudhry, Henry Thomas Stelfox, and Allan S. Detsky, *Relationships Between Authors of Clinical Practice Guidelines and the Pharmaceutical Industry*, 287 JAMA 612 (2002). Interestingly, even the authors of the study had attended events sponsored by or received money from pharmaceutical companies.

by doctors are often contaminated by conflicts of interest.[127] Indeed, disclaimers are commonly attached to guidelines written by all of these entities.[128] 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,[129] and they often refuse to admit as hearsay guidelines for less authoritative or biased sources.[130]

Also, because of the problems, it is perhaps a good thing that under the current regime, guidelines are not binding on doctors, are not determinative in medical malpractice lawsuits, and are not extensively followed.[131] Otherwise, the current legal regime's distorted incentives toward defensive and offensive medicine would be even worse.

The problems will be resolved if optimal guidelines are promulgated. Since the federal and some state governments seek to encourage data collection, guidelines and RCA promulgation and implementation, [132]

[127] Quigley v. Jobe, 851 P..2d 236 (Colo. Ct. App. 1992).
[128] *See* http://www.ahrq.gov/news/disclaim.htm. The American Medical Association calls its guidelines "parameters" to emphasize the discretion left with the doctors and further suggests that all guidelines contain disclaimers renouncing any implied intention to replace doctors' discretion. Mark Chassin, *Standard of Care in Medicine*, 25 INQUIRY 436 (1988). *See* also AMERICAN PSYCHIATRIC ASSOCIATION, STATEMENT OF INTENT: PRACTICE GUIDELINE FOR THE TREATMENT OF PATIENTS WITH ALZHEIMER'S DISEASE AND OTHER DEMENTIAS 7 (2d ed. 2007). (explaining that "the APA Practice Guidelines are not intended to be construed or to serve as a standard of medical care")
[129] For example in Quigley v. Jobe, 851 P.2d 236 (Colo. Ct. App. 1992) a Colorado appellate court refuse to accept CPG written by liability insurers of the doctor because they were created "by a private insurance company as part of an insurance contract and did not reflect a generally recognized standard of care within the medical profession." 851 P.2d at 238. *See also* Parchomovsky and Stein, *supra* note 63.
[130] *Id*. For example in Quigley v. Jobe, a Colorado appellate court refuse to accept CPG written by liability insurers of the doctor because they were created "by a private insurance company as part of an insurance contract and did not reflect a generally recognized standard of care within the medical profession." 851 P.2d 236, 238.
[131] In fact, guidelines are not only not determinative in lawsuits but in fact are used in malpractice cases only infrequently. *See* Andrew L. Hyams et al., *Practice Guidelines and Malpractice Litigation: A Two-Way Street*, 122 ANNALS INTERNAL MED. 450, 451-52 (1995)
[132] *See* J. Duncan Moore, Jr., *JCAHO Urges 'Do Tell,' in Sentinel Event Fight: Aviation's Lessson: Learn From Experience*, 28 MOD. HEALTHC. 60 (discussing federal policy); *see also* Ansley Boyd Barton, *Recent Remedies for Health Care Ills*, 21 GA. ST. U. L. REV. 831 (2005) (discussing some state policies).

the law should impose liability based on the ex-ante perspective only, should recognize a private regulatory compliance defense (subject to PR firm solvency requirements), and should not allow the state-of-the-art defense.

III. THE DESIGN OF PRIVATE REGULATION REGIME

a. Introduction

The Private Regulation Regime creates a separation of duties by delegating the role of designing guidelines to experts in private firms and the role of implementing guidelines to medical providers. Just as architects need builders' feedback before they seal their plans, private regulators will communicate with doctors about the wisdom of their guidelines. The private regulators (the architects) will design guidelines by synthesizing available scientific evidence, regulatory requirements, and tort law. Doctors (builders) will execute the synthesized guidelines as they will be proposed. If compliance with the evidence-based guidelines will shield doctors from malpractice liability, part of an optimal PR regime (research and guidelines promulgation) already happens, all that is required is for the law to provide incentives for *optimal* promulgation and implementation of guidelines. As will be shown in the next section, to achieve that goal,

b. The Legal Infrastructure

The legal infrastructure for the PRR has the following requirements: the evaluation of guidelines from the ex ante perspective, recognition of a new legal doctrine called the private regulatory-compliance-defense, patent protection for medical procedures, the elimination of the state-of-the-art defense, and the imposition of solvency requirements for the private firms. This section takes these requirements into account to further detail the optimal design of the Private Regulation Regime.

i. Liability from the Ex-ante Perspective.

Under the Private Regulation Regime, medical guidelines will be developed by experts in private firms operating under adequate incentives. Providers can be subject to liability for deviating from the CPGs. This should help prevent errors of execution. More importantly however, the firms will be subject to liability (judged from the ex-ante

perspective) for writing guidelines which are inefficiently risky, not for writing guidelines which do not provide the highest standard of care. This should help preventing errors of planning. The evaluation of the CPGs will be done from the ex-ante perspective, thereby eliminating courts' ex-post biases such as the hindsight bias and the identified-other effect. The ex-ante perspective is important also because it takes into account all potential beneficiaries, not just those injured who are before the court. Knowing that they will be subject to review from the ex-ante perspective the private firms will develop CPGs which are efficient, impartial and reliable.[133]

For example, consider a problem presented when a doctor diagnoses a possible head injury. Should a skull X-ray be ordered? Doctors know that they may be found negligent for failing to order an X-ray if the patient's condition gets worse and can be linked to inadequate diagnosis. As a result, doctors have an incentive to order an X-ray even when they believe it is unnecessary. This is defensive medicine – the ordering of procedures that are not medically indicated but rather are intended to prevent physician liability. Under the PR regime, doctors will be immune from liability if they followed CPGs with respect to X-rays, and the PR firm will not be found liable if an X-ray was not necessary as judged from the ex-ante perspective.[134]

To better see this point, assume there is a medical procedure A used to treat a fatal problem Z. Further, assume that procedure A helps many patients, yet injures and even

[133]Several theories of promulgators' liability have been proposed under the current system, and these are likely also to hold under the PRR. One commentator describes four general bases for the liability of guidelines developers: negligence in compiling or translating data, negligence in assembling the specific aspects of the research into recommendations, lack of good faith, and failure to update and maintain guidelines. Sheetz, *supra* note 21, at 1360-61. Though many lament this potential for liability as an impediment to the growth and development of CPGs, the benefit is apparent: promulgators will have the incentive to write guidelines based on appropriately comprehensive testing and analysis, which should lead to more credible and more effective guidelines. *Id.* at 1377.

[134] In a seminal study analyzing 1500 skull X-rays in cases involving head trauma, Bell and Loop found that ordering routine X-rays in all head trauma cases was not efficient from the ex-ante perspective. By limiting X-rays to cases with at least one of several discrete clinical symptoms, 434 unnecessary X-rays—and their resulting costs—could be avoided. Although not ordering the extra 434 X-rays makes sense ex-ante— this approach would miss one valid skull fracture out of 434 which could not have been detected without an X-ray—doctors will continue to order unnecessary tests to safeguard against the 1/435 chance of liability. R. Bell and J. Loop, *The Utility and Futility of Radiographic Skull Examination For Trauma*,284 N. Engl. J. Med. 236, 236-39 (1971). Bell and Loop's seminal study has sparked worldwide interest regarding the place of skull X-rays in the management of patients with head injuries. For a recent metaanalysis concluding X-rays are of little value see P. A. M. Hofman et al., *Value of Radiological Diagnosis of Skull Fracture in the Management of Mild Head Injury: Meta-Analysis*, 68 *J. Neurol. Neurosurg. Psych. 416*, 416-22 (2000).

kills a few of them. In other words, the procedure has side effects, yet the procedure is still efficient in the sense that it is better than doing nothing and there is no other procedure which better combats problem Z. For people with problem Z, they must decide whether they are willing to trade a large risk of dying by Z in exchange for a probable improvement in their quality of life and a much smaller risk of suffering injury or dying by A.

A current example of this analysis revolves around denosumab, an innovative new drug touted as potentially the most effective treatment for osteoporosis yet invented.[135] While the drug is believed to treat a disease which is a major cause of death for the elderly, it has also been known to cause eczema and skin infection in some patients.[136] Despite these potential side effects, many patients would be better off taking the drug than they would be letting the disease take its course.[137] That deal seems to be attractive from the ex ante perspective—even in the total absence of any ex-post tort remedy.[138]

Where the use of procedure A, the drug denosumab in the example above, has the highest positive expected value to all class members, imposing tort liability can sometimes only muddy the waters. The higher cost of running a tort liability system, with its deadweight administrative costs and high rates of error, might eliminate procedure A, even though it is valuable to many, from being implemented. Tort liability can therefore not only increase the costs of medicine, but also make the relevant class members worse off as a whole.[139]

Of course, more can always be said about the exact contours of the legal regime. For example, in lawsuits against the providers for deviating from CPGs, it would be conceivable to shift the burden of proving non-deviation from CPGs onto providers. The law has developed in a way to shift the burden of proof in various contexts. The doctrine of res-ipsa-loquitor and some versions of market share liability do exactly that. In

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[135] Thomas H. Maugh, *New Osteoporosis Drug Shown to Reduce Spinal Fractures*, CHICAGO TRIBUNE, Aug. 12, 2009.
[136] Miranda Hitti, *New Osteoporosis Drug Coming*, WEBMD HEALTH, Aug. 11, 2009 *available at* http://www.emedicinehealth.com/script/main/art.asp?articlekey=104603 (last visited Sept. 1, 2009).
[137] *Id.*
[138] *Id.*; Epstein, *supra* note 78.
[139] For example, scientists believe that despite the substantial number of lawsuits against anti-inflammatory drugs like Vioxx these drugs may still be the best option for patients. *Vioxx like' drugs may still be best option for arthritis write scientists*, IMPERIAL COLLEGE OF LONDON, Jan. 18, 2006, *available at* http://www.imperial.ac.uk/college.asp?P=7352. (last visited Sept. 1, 2009).

lawsuits against the private firms it is conceivable to think in terms of class actions or even lawsuits brought by non-victims, similar to public nuisance suits. I leave the discussion of these details for another day.

ii. Battling Defensive Guidelines with Contractually Standardized Care Levels.

The previous sections explained how liability from the ex-ante perspective can cause PR firms to internalize costs of too risky CPGs. But what about liability for writing CPGs which are too safe, or defensive, and therefore too expensive? One possibility would be to allow payers (HMOs, PPOs, Medicare) to sue PR firms for writing guidelines which are too expensive. However, a more likely, and better, solution exists. Our current tort law does not allow for such claims because, in most cases, when the defendant acts too cautiously there is no direct victim. In the health care world, though, payers bear the extra costs of defensive and therefore expensive CPGs. The problem in other words is that hospitals and PR firms will collude against payers and contract for guidelines which are too defensive, thus externalizing costs onto payers. The best way to deal with this problem is through contracts. That is, payers will reimburse hospitals for care given to their patients based on the quality and cost effectiveness of the CPGs. If the CPGs adopted by the hospital are too defensive, the reimbursement should decrease reflecting the lack of necessity in such guidelines. Thus, for example, hospitals which have CPGs advising them to administer CT scans every time a patient faints will get significantly lower reimbursements per scan than hospitals with CPGs advising them to do it only when several other clinical markers are present. If payers are relatively informed, and posses some degree of market power, this contractual mechanism can make the PR firms internalize not only error costs, but also the costs of care. If, in contrast, payers are uninformed, or do not posses enough market power to structure the reimbursement scheme based on the quality and cost effectiveness of the guidelines, then some form of government regulation will be needed.

iii. Private-Regulatory-Compliance defense

Aside from contesting the PR guidelines, litigation against doctors would become simpler and cheaper. Either a doctor complied with PR guidelines, in which case she is immune under the private regulatory compliance defense, or she did not comply with the guidelines and is liable. I call it the private-regulatory compliance defense because similar to the current doctrine of regulatory compliance defense, complying with guidelines is a defense against the tort suit.[140] However, unlike the doctrines of statutory or regulatory compliance, which provide that compliance with a statute or regulation is of evidentiary value to the question of negligence but do not preclude a finding of negligence in a tort case, the private-regulatory compliance doctrine will make compliance a complete defense. [141] This should help doctors out of the current catch-22 where, as Epstein put it, they are damned if they do, and they are damned if they don't. From a policy-making perspective, a private regulatory compliance defense would enable doctors to stop performing defensive medicine, shielding them from liability provided that they followed a private regulator's guidelines. Currently only one state (Michigan) has adopted the doctrine of government regulatory compliance defense and even this is limited to the context of pharmaceuticals and the FDA. However, as already mentioned, the limitation is probably a good idea given that guidelines are usually floors.

As was mentioned before, some private companies, such as DynaMed and Isabel, offer products, such as databases and hard infrastructure, which are used for bringing evidence-based solutions more directly into the examination room. Such products involve summaries of advances discussed in medical journals, computerized analysis of clinical observations for determining diagnoses and treatment, and electronic data-sharing. However, since courts do not simply treat adherence to EBM guidelines as exculpatory for malpractice, and since EBM services do not assume liability for a

[140] As mentioned *supra* note 20 something like the private regulatory compliance defense could be established through contractual indemnification.

[141] *See* RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 16 (2005); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 (1998). In several states, when a product manufacturer complies with a federal or state regulatory standard, it entitles the manufacturer to a "rebuttable presumption" against a finding of negligence or product defect. *See supra* note 83.

physician's treatment decisions, a physician must devote time to determining the validity of an EBM guideline, and following the guideline does not ensure avoidance of liability.

Therese organizations are currently careful to disclaim liability for decisions physicians make based on their guidelines. However, under the PR regime, physicians could rely on PR guideline to shield them for liability, thus enabling physicians to devote more time where it is most valuable—treating patients rather than evaluating the validity of myriad studies (or, more likely, ignoring most of the studies). The competitive pressure to provide something better than current EBM services combined with the threat of liability would encourage a PR firm to correctly balance the values of comprehensiveness and ease-of-use when creating guidelines.

A problem might arise if hospitals choose not to pay for the guidelines but secretly adopt guideline standards. Such free-riding conduct might frustrate the private regulator's effort in promulgating guidelines and would deter firms from spending resources on research and development. While the next section explains how intellectual property law could prevent free-riding, it should be noted here that the private-regulatory compliance defense could be structured as to only apply to those care providers who pay for guidelines.

iv. Intellectual Property Protection for Guidelines.

One may argue that PR firms would have to get some form of intellectual property protection for their guidelines. Otherwise, they will lack adequate incentives to continually develop guidelines, fearing other PR firms and providers will free-ride on their efforts. Yet, it is possible to imagine that PR firms could rely on business models which would make intellectual property protection unnecessary. For example, by bundling support services with the licensing of the CPGs, the PR firms might be able to deter free riders. However, assuming that intellectual property protection will be required, what form and shape would it have?

Current intellectual property laws do not seem to match the protection required under the PR regime. Copyright law protects only the expression of the work, not ideas and facts. But it is the factual information, (eg. how to conduct a heart surgery on

morbidly obese patients), and not the utilitarian and functional procedures (the specific way the information is conveyed)) which would require protection under the PR regime.[142] Trade secrecy will not be a viable option either because a major component of the PR regime is litigation regarding the optimality of CPGs. CPGs would become public during litigation, and once the CPGs are no longer a secret they would also become non-protectable as trade secrets. On the other hand, litigation is usually not immediate, and even then CPGs could be under seal.

Patents may look more promising superficially. After all, medical procedures are occasionally patented. However, as recently as 1996, Congress considered prohibiting these types of patents. Instead, Congress opted to deprive patent holders of remedies against health care practitioners, while continuing to leave non-clinicians subject to liability for using a patented process for commercial purposes.[143] Nonetheless, there are several other impediments that prevent the PR regime from fitting within current patent law. First, filing for a patent is a complicated process which would require transforming medical guidelines to "patent claims," not a trivial task for a PR firm.[144] Second, obtaining a patent is a lengthy process which can take many months and prosecution of patents can take years. Yet, the whole point of the PR regime is to become a dynamic alternative to the current regime. Under that current regime it takes good research 17 years to be incorporated into practice. Under the PR regime guidelines should be updated much faster. [145] If it takes months to obtain patent protection, this need for speed could be defeated. Third, the main standards for patent review, novelty and non-obviousness do not neatly fit the requirements of the PR regime.[146] Non-obviousness would imply that the new patents could not be granted for a variation or combination of previously known guidelines unless it is proved to be non-trivial. This again would run in the face of the dynamic nature of the PR regime where CPGs are continuously updated based on previous guidelines and new research.

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[142] See section 102(b) to the Copy Right Act which codified the holding in ***Baker v. Selden***, 101 U.S. 99 (1879)

[143] Aaron S. Kesselheim and Michelle M. Mello, *Medical-Process Patents — Monopolizing the Delivery of Health Care*, 355 N. ENGL. J. MED. 2036 (2006) at 2037.

[144] CITE.

[145] CITE.

[146] CITE.

Therefore the best solution seems to be a sui-generis regime legislatively tailored to the PR regime. Sui generis regimes are not strangers to intellectual property law. They exist for mask works, ship hull designs, databases (in the EU only), designs (Chapter 16 to the Patent Act) and plant varieties.[147] While fully describing the sui generis regime goes beyond the scope of this paper, several things can be said here. First, such a regime should provide protection against both copying (like copyright) and independent creation or development (like patents). Second, such a regime should provide shorter protection than current patent law. Plausibly, at the end of the protection period,the information would fall to the public domain. Third, the regime should apply different standards of review than the current patent law does. Fourth, such a regime should also borrow the notion, from current patent law, that remedies will be allowed only against non-practitioners.[148] The provisions should be tailored to achieving the dual goals of a dynamic regime which allows for state of the art research to be implemented fast, and preserving the initial incentives to synthesize the research into these CPGs.

A possible problem may arise if PR firms receive sui-generis protection and then hold out for an unreasonably high price to license those guidelines, thereby frustrating the efficient distribution of innovation. This problem is bothersome for medical procedures because much of the innovation is likely to be cumulative, i.e. builds upon past innovations. Hold out problems may be mitigated by limiting the lifespan of the protection, so that firms cannot hold on to CPGs for too long before having to pay a renewal fee.[149]

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[147] CITE

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

[149] Ian Ayres and Gideon Porchamovksy, *Tradable Patent Rights*, 60 STAN. L. REV. *863 (2007).*

out problems, the additional overhead may encourage firms to sell their licensees sooner in an effort to cover renewal costs. [150]

Another problem is that providing protection to CPGs threatens to complicate medical practice, increase costs, restrain the decimation of new information throughout the scientific community, and overly restricts patient's access to therapeutic and diagnostic procedures. Indeed, this is exactly why the American Medical Association objected to the expansion of patent law into "purely process" medical guidelines. [151] Again, while more research is required to determine whether intellectual property protection is required at all, if it is then providing a short-time protection can mitigate this concern as well.

v. Eliminating the State of the Art defense.

Another important legal component for the PR regime requires society to bar the state-of-the-art defense. Many states currently allow defendants to escape liability if they can show their product was state-of-the-art when it was first introduced to the market. Traditionally this defense was only relevant for product liability law[152], but it has also penetrated medical malpractice. Eliminating this defense would incentivize private regulators to continually update guidelines to reflect ongoing research, while giving practitioners reason to rely on the guidelines.[153]

The benefit is clear when one considers the modern day overflow of unreliable information for individual doctors to screen and absorb. Ian Ayres has recently calculated that a cardiologist who wants to keep up with the progress in her field would have to read more than ten articles every day, including weekends, spending two and a half hours a

[150] Another problem which could emerge in the context of clinical guidelines is patent thickets, which are multiple patents covering a single product or technology. For various old and new solutions to this problem *See Id*.
[151] Aaron S. Kesselheim and Michelle M. Mello, *Medical-Process Patents — Monopolizing the Delivery of Health Care,* 355 N. ENGL. J. MED. 2036 (2006).
[152] Indeed it is reflected in the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §§ 1-2 (1998).
[153] For an interesting analysis on the pros and cons of eliminating the state-of-the-art defense *See* Omri Ben-Shahar, *Should Products Liability Be Based on Hindsight?,* 14 JLEO 325 (1998). Ben-Shahar argues that where it is "socially important and at the same time feasible to promote post distribution safety efforts…. and yet it is difficult to monitor such efforts directly due to lags in the public's knowledge of the defects", eliminating the defense would be superior to keeping it. *Id.* at 350.

day reading about just coronary diseases. (And it would be a waste of her time because most of the articles are not good.[154]) That is exactly what the PR regime, without the state-of-the-art defense, solves. Rather than the current tort regime, which unrealistically requires doctors to keep up with their fields while still seeing patients (and sometimes generating their own studies), under the PR regime, a group of experts in the field will continuously update the guidelines according to the most up to date research.

Furthermore, PR firms are likely to provide optimal regulations because of competition and informational advantages. Multiple PR firms will encourage experimentation with various procedures and arguably the survival of the fittest will apply -- the competition will drive the best procedures and regulatory regimes to survive. A PR firm would have superior capacity and motivation to learn from its environment and correct its policy mistakes in a timely fashion. Firms should be able to find context-specific data on medical-procedures, which can be used to analyze cost-benefit and risk-risk tradeoffs. and then apply those findings in future guidelines. If the firms cannot rely on the defense that their guidelines were state-of-the-art when they were issued, they will be all the more encouraged to incorporate all new medical research and techniques into their guidelines.

vi. Guaranteeing Private Regulator's solvency.

Finally, regulation of the solvency of the PR firms would guarantee that the PR firms would refrain from promulgating guidelines that are overly risky. Without this guarantee, the PR firms might be tempted to promulgate guidelines which are overly risky knowing that if worse comes to worst; they will declare bankruptcy, essentially externalizing costs to the patients and the firm's equity and debt holders. The regulation of the solvency of PR firms does not have to be left to the government. Rather, as Shavell noted, requiring firms, which have the potential for being judgment-proof, to have minimum assets or liability insurance can force them to internalize the costs of their risky

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

activities, essentially getting them to scale back on the levels of these activities.[155] Between the two options, the choice can be made depending on the circumstances. Minimum assets requirements may undesirably prevent some potential PR firms with low assets from engaging in private regulation. Liability insurance requirements, on the other hand, tend to improve parties' incentives to reduce risk only if insurers can observe levels of care, but dilute incentives to reduce risk when insurers cannot observe levels of care. Therefore, in the latter case, compulsory liability insurance may be inferior to minimum asset requirements.[156]

c. Summary

I have argued that for the PR regime to thrive, the six aspects of the legal infrastructure would have to change: the evaluation of guidelines from the ex-ante perspective, empowering payers to dictate a reimbursement structure which is based on the quality and cost-effectiveness of the guidelines, acknowledging the private regulatory compliance defense, providing patent protection for medical process, the elimination of the state-of-the-art defense, and the imposition of solvency requirements for the private firms.

IV. EVALUATION IN LIGHT OF OBJECTIONS

In this section I evaluate the PR regime in response to various concerns raised with earlier drafts. The concerns are divided into four groups: PRR compared to alternative regimes, practical medical concerns, legal concerns, and political concerns.

a. The PRR Compared to Alternative Regimes

i. What is the difference between PR and liability for gatekeepers?

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

One may wonder how the PR regime is different from liability of accountants, tax lawyers, credit rating agencies and other gatekeepers. There are several differences. First, in most cases, gatekeepers provide merely a stamp of approval that some industry players meet minimum standards of care, safety, etc. Such is the case for accountants—who certify financial reports, credit rating agencies such as Standard and Poor—and also for Underwriters Laboratories and Good Housekeeping—which certify various appliances and other products and goods. PR, in contrast, is not about meeting minimum standards but about meeting *optimal* standards. Second, whereas gatekeepers are either not held liable or held jointly liable with the main tortfeasor, under PR the gate-keeping-like private regulator is held liable but the main "tortfeasor" is immune from liability, provided she complied with the regulation.[157] Third, under the PRR the private regulator is held liable for inefficient guidelines viewed from the ex-ante perspective, whereas gatekeepers are normally held liable, if at all, based on the ex-post perspective.

ii. What is the difference between PR and Self-Regulation?

The PRR is also different than self-regulation. Industry self-regulation is the "voluntary association of firms to control their collective behavior" through self-policing arrangements.[158] In recent years, a number of different industries have created self-policing programs in an attempt to forestall costly government regulation.[159] In some cases, these self-policing programs even mature into full-fledged self-regulatory organizations (SROs), with formal rules, and dedicated resources.[160]

Private Regulation is both similar and different from industry self-regulation. Similar to these self regulating organizations (SROs), the PR firms would utilize private

[157] I could find only one case of a negligence claim against Underwriters Laboratories Inc, which they easily won. Dekens v. Underwirters Laboratory Inc. 107 Cal.App.4th 1177, 132 Cal.Rptr.2d 699. Desipte the economic meltdown Congress is still grappling with imposing liability on credit rating agencies. See Rachellee Younglai, SEC, Congress Eye Increasing Liability of Credit Rating Agencies. Insurance Journal (July 16, 2009) available at: http://www.insurancejournal.com/news/national/2009/07/16/102271.htm. Even the Sarbanes-Oxley act (Sarbanes-Oxley Act of 2002, Pub. L. No. 107-204, 116 Stat. 745 (2002)), which was enacted after the Enron crisis, only instructed the Securities and Exchange Commission to further regulate accountants, lawyers and investment banks, but fell short of imposing liability. See more generally Assaf Hamdani, *Gatekeepers' Liability*, 77 S. Cal. L. Rev. 53 (2003-4).

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

[159] *Id*.

[160] *Id*.

information from industry participants to inform the guideline creation process with little government agency interference. Also similar to self regulation, the private regulation regime would have built-in compliance monitoring. However, unlike participation in self regulation where disclosure of crucial regulatory information is completely voluntary, physicians in a private regulatory scheme would be forced to disclose information to be eligible for the liability shield. As a result, in contrast to SROs, which rely on internal auditing and self-reporting to detect guideline deviation, industry compliance with guidelines in the PR regime would be virtually ensured through the offer of liability protection. Lastly, and most importantly, whereas SROs usually set minimum standards to be met by the industry players, guidelines will set at the *optimal* level because Private Regulators would be subject to tort liability for promulgating sub-optimal guidelines on the one hand, and face competition on the other.

iii. Why Not Strict Liability or No-Fault Regimes?

Instead of gatekeeper liability or self-regulation, others may wonder why we should not adopt a traditional strict liability regime or a no-fault regime instead of the PRR. After all, under both these regimes the hospitals will internalize all the accident costs associated with their care level and activity level decisions. Moreover, under both regimes patients will be compensated more often than under PR. There are several reasons the PRR is superior to strict liability and no-fault.

First, while strict liability will cause hospitals to internalize the cost of medical errors, it will not force them to internalize the cost of care. Thus, hospitals will have incentives to overuse resources, whether on defensive or offensive medicine grounds. Second, the major advantage of the PR regime is that it provides the necessary legal infrastructure to enable free market regulated guidelines to evolve optimally. It is true that a web of contracts between payers, providers, insurers, and patients could potentially duplicate the benefits of the PR regime. However, for various reasons described above, this is unlikely to happen. Third, both strict liability and no-fault are larger deviations from the current regime, and therefore politically less feasible. Fourth, while both strict liability and no-fault incur lower administrative costs per claim, both will encourage filings of claims so the overall saving is not guaranteed. Additional claims filed under

strict liability or no-fault will still be a good thing if these additional claims were meritorious. Compared to a properly functioning PR regime, the additional claims are unlikely to be meritorious, making hospitals insurers of non-negligent related accidents. For that to be efficient, one would need to show that the hospital is a better insurer than private party insurance the patients can find in the market. Lastly, victims of doctors who did not follow guidelines will be more frequently compensated than ever before, and in a faster process. Since the guidelines are likely to be efficient, compensating these victims is sure to be the right outcome. In that sense that proposed regime is a huge improvement even on compensation grounds.

iv. Why Do We Need Legislation? Why Don't We See It In The Market Already?

One may wonder why parties do not contract for a PR arrangement themselves. If the PRR is so superior, why has it not already been developed privately? There are four ways the PRR could be contractually mimicked. First, if managed care organizations (MCOs) were held liable for care they control. Second, if liability insurers could be held financially responsible for the cost of care provided. Third, if the government paid for both cost of care and cost of liability. Fourth, if a totally new entity, a private regulator, would bear both the cost of care and the cost of liability. What is common to all four solutions is the internalization of externalities. As was explained above, one of the major problems with current guidelines is that they are written by entities that only bear one type of cost. For instance, HMOs bear only the cost of care, liability insurers bear only the cost of liability, and doctors' associations bear no costs at all. As a result, every entity has an incentive to external some costs on other players. In contrast to all of the four cases described above, PR firms would bear both the cost of care and the cost of liability. I discuss each of these four options in more detail below.

1. MCOs as cost internalizers.

By the 1990s, MCOs came to dominate America's health insurance industry.[161] Many times an MCO, not the actual care provider, will control the care a patient receives.[162] It therefore makes sense to hold MCOs liable for sub-optimal care caused by their increased control. There are several reasons why this has not happened.

First, physician liability insurance markets were stable through the 1990s, with many insurers moving into new states and cutting prices, making it less likely that physicians would want to change their coverage.

Second, MCO liability cannot emerge spontaneously because several structural problems prevent patients from effectively contracting for optimal care. For example, most HMOs that grew in the 1990s were network models for which contractually liability wouldn't work easily. Other structural problems include patients' inability to specify treatment choice at the time of contracting, patients' inability to determine ex-ante the level of physician expertise, and the distressed position patients are often in when they contract for medical care.[163] In other words, too much medical care relies on "non-contractable actions taken post-contract."[164] Moreover, even informed and sophisticated patients do not have optimal incentives to impose liability individually on MCOs because doing so imposes positive externalities. The reason is that the key benefits of MCO liability would be structural reforms that benefit patients collectively in the form of investments in safety that benefit many patients collectively both now and in the future.[165]

Third, in a recent case interpreting the Employee Retirement Income Security Act of 1974 (ERISA), *Aetna Health Inc v. Davila*, the Supreme Court found ERISA's remedial procedures broad enough to preempt any state tort action against an MCO for

[161] 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).
[162] *Id.* at 1934
[163] Arlen and MacLeod, *supra* note 145, at 1962, 1966, 2005.
[164] *Id.* at 2005
[165] See Jennifer Arlen, Contracting Over Malpractice Liability (2009) available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1105368. Arlen shows that patients would not have optimal incentives to contract more collectively with MCOs over liability because MCO contracting over liability introduces adverse selection, because the patients who most value the deterrence benefits that liability provide will disproportionately include sick people. Id.

denial of benefits resulting in sub-optimal care.[166] *Davila* limits patients' recovery to the cost of benefits purportedly denied them instead of much higher compensatory damages for injuries they suffer. This ruling (which affects about 70% of insured Americans) constitutes a strong enough shield for MCOs that they have had little incentive to assume liability. After *Davila*, only Congress can impose liability on MCOs for their role in providing sub-optimal care. While doing so would be in the spirit of the private regulation regime, the almost no chance that the healthcare industry would agree to be subject to liability for suboptimal care.

Fourth, doctors may prefer to preserve their autonomy vis-à-vis MCOs. If the hospital pays for your liability insurance, then the hospital can, and will need to, exercise greater control over how you practice. Doctors hate malpractice lawsuits and love autonomy. The latter might often trump the former.

However, and interestingly, there are some scattered examples where MCOs assume liability. These examples demonstrate the feasibility of such a regime. The main example is Kaiser Permanente, a large health plan, which covers its doctors' liability.[167] Kaiser's battle to keep its binding arbitration was hard fought and perhaps other MCOs are uncertain they could constitutionally prevail in other states.[168] Without that assurance, the prospect of internalizing liability may simply be too daunting for MCOs.

2. Liability Insurers as cost internalizers.

The idea here is the opposite of the one above—i.e. make liability insurers bear the cost of treatment. In this way, liability insurers will bear both the cost of care and of liability. Again, as a matter of fact, liability insurers developed solely to protect doctors against liability and know very little about delivery of care. Kaiser Permanente and could be seen as an example here as well, because a health plan that covers its doctors is like a liability insurer that provides health care.

3. Government as cost internalizer.

[166] Aetna Health Inc. v. Davila, 542 U.S. 200, 204 (2004).
[167] Kaiser Permanente Website, Frequently Asked Questions About Our Medical Care, https://members.kaiserpermanente.org/kpweb/faqmedcare/entrypage.do.
[168] CITE.

The government to bearing both the cost of care and the cost of liability is not as bizarre an idea as one might think. Indeed, this is the situation in the veteran affairs system as well as in some countries such as the UK, Spain and Israel.[169] However, given how politically infeasible the idea of a single payer is in the US, it is impossible to imagine the acceptance of a more radical view where the government is not only a single payer but also a single liability insurer. Moreover, even if such a regime were politically feasible in the US, it will most probably be inferior to a PR regime because it gives the government a monopoly in providing public health and insuring doctors instead of harnessing competition and market forces for that purpose.

4. Private Firms as cost internalizers.

We are left with the question of why a PRR did not spontaneously emerge? Why don't we see guidelines promulgators assuming liability for misuse? Indeed, assuming liability for sub-optimal promulgation of CPGs is the linchpin in the PR regime. Without it incentives cannot be aligned. Possible reasons could be that it is too complicated to draft multi-party contractual arrangement that would mimic the PR regime, including requirements such as liability from the ex-ante perspective, etc. Add to this that the PR firms will also have to bear not only the cost of liability, but also the cost of care, and the contractual solutions seem even harder to achieve. The main reason, however, why this has not happened, and also another reason why MCOs do not assume liability, seems to be that creating such a regime will eliminate an externality which harms the patients but benefits all other parties. Specifically, because plaintiff lawyers tend to only go after doctors' liability insurance coverage and not after their personal assets (some of which are protected under bankruptcy laws or otherwise hidden), doctors' liability is effectively capped at their policy limit. As a result, the *joint* liability of doctors and MCOs under the current regime is smaller than under an alternative regime of MCO liability or PRR

[169] CITE.

where the joint liability is not capped.[170] The less liability that doctors and MCOs (or PR firms) face, the more harm that is externalized onto patients.

Of course, this externality is a major reason to create a new regime so that parties will internalize costs now being externalized on patients.

b. Practical Medical Concerns

i. Medical Ethics

Other critiques, instead of revolving around alternative proposals, dealt with practical and ethical concerns regarding the PRR raises. First is the worry that doctors would not have access to the best guideline for their patients and therefore could not deliver the best care. Medical ethics calls for doctors to take actions which serve the best interests of their patients.[171]

[170] Hyman et al, showed that doctors' liability is effectively capped under the current regime because plaintiff do not recover more than the policy limit, (which in itself is strategically set by the insurance companies). See David Hyman, Bernard Black, Kathryn Zeiler, Charles Silver & William Sage, *Do Defendants Pay What Juries Award?: Post-Verdict Haircuts in Texas Medical Malpractice Cases, 1988-2003*, 4 **Journal of Empirical Legal Studies** 3-68 (2007) (http://ssrn.com/abstract=914415). See also Tom Baker.

[171] *See* e.g., AMA Code of Medical Ethics, Preamble, section III, *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/principles-medical-ethics.shtml, ("A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.").

the patient's best interest because most times the prescribed guidelines would be in tune with the patient's best interests already. Moreover, doctor is free to deviate at the price of losing the guidelines shield.

ii. Good Medicine Requires Discretion.

Another ethical and practical concern is that good medicine requires discretion. The argument goes that guidelines constrain doctors' discretion, doctors' discretion is necessary for optimal care, and thereby the guidelines yield inefficiencies and encourage poor patient care. The premise for the argument is that doctoring is an art and cannot be reduced to a set of guidelines. It is said that by intruding on the art of medicine, mandatory adherence to guidelines will erode clinical abilities, diminish clinical judgment, and reduce medical practice to "cookbook medicine."[172] Although this ethical commitment is already threatened by the cost-based compensation models involved in medical insurance, the PR regime may further complicate this dilemma. This may happen when a doctor disagrees with his firm's guideline or the guideline is not optimal in comparison to competing guidelines. However, ethical concerns regarding the costs of limiting patient access to optimum guidelines would likely be less of a problem than it may seem. This is because when a company patents a new guideline which is particularly efficient, then this guideline could be licensed to competing companies. Because producing sub-optimal guidelines would expose companies to potential liability for injuries, the incentives to produce or obtain optimum guidelines would be closely aligned with the welfare of the patients and the healthcare system as a whole. Therefore, doctors would not be frequently confronted with an ethical dilemma when deciding whether following the prescribed guideline is in

While these claims have some truth to them, they are overstated.

First, doctoring is far from 100% art, and the implications of requiring the use of guidelines are nowhere near as dire as critics claim. Some doctoring, perhaps most doctoring, can be reduced to guidelines. Indeed it is often reduced. As was mentioned above, clinical practice guidelines are pervasive, directing physicians in areas as disparate as ulcer treatment, heart failure, and helping patients to stop smoking.[173] CPGs are written by various players such as government agencies, medical special society, healthcare organizations, or health plans.

Second, there is research about doctors' biases showing that doctors tend to find reasons to believe the patients they are seeing is unique and therefore the CPGs should not apply to her, even when the evidence suggests otherwise.[174]

Third, it is not suggested that PR will apply to the entire world of medicine. That is perhaps unrealistic. Rather as explained above, the guidelines will be written in those

[172] Brian Hurwitz, *Legal and political considerations of clinical practice guidelines*, 318 BMJ 661 (1999) (citing Ellwood, *Outcomes Management, a Technology of Patient Experience*, 318 N ENGL J MED. 1549 (1988).
[173] http://www.ahrq.gov/CLINIC/cpgarchv.htm
[174] Arnold J. Rosoff, Evidence-Based Medicine and The Law: The Courts Confront Clinical Practice guidelines, Journal of Health Politics, Policy and Law 2001 26(2):327-368

cases, such as the administration of anesthesia, where medicine can be optimally reduced to a set of rules that reduce costs and increase patient safety.[175] For example, an emergency room doctor could invoke well-accepted guidelines to explain her decision to refrain from ordering a skull x-ray for a patient with a possible head injury when one of the well known clinical indicators of skull injury was not present. As another example, ophthalmologists can use well accepted national guidelines to justify refraining from performing a tonometry test on a patient under the age of 40, because the test has a high rate of false positive and only one in 25,000 persons under the age of 40 is found to have glaucoma.[176] Since the odds of the test detecting critical information result in a higher overall cost than benefit, the test is not worth applying in those circumstances.[177]

Moreover, depending on the nature of the procedure, it might make sense that certain guidelines will allow for more or less discretion within the boundaries of their requirements. One procedure may be best reduced to strict adherence down to detailed measurements, while another procedure may be better suited to a range of possible measures depending on the required discretionary factors.[178]

[175] See Mello, supra not @@ at 653 (providing references that the administration of anesthesia is amenable to governance by a rigid algorithm)

[176] Helling v. Carey, 519 P. 2d 981 (1974). Although the Washington Supreme Court agreed that the doctors had followed both the local and national standard of care, the court found the doctors liable based on a cost analysis of tonometry which concluded that it was efficient for doctors to administer tonometry tests in the plaintiff's circumstances.

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

[178] The question of optimal specificity of rules, of rules vs. standards, has received a great deal of attention. *See* FRANCESCO PARISI, RULES VERSUS STANDARDS IN THE ENCYCLOPEDIA OF PUBLIC CHOICE 510-16 (Rowley and Schneider editors 2003). By-and-large, the more the promulgator lacks information about future circumstances, the more discretion needs to be left to the doctors, i.e. the more the rules need to be general. Specific rules, however, are easier to comply with and adjudicate than general rules. Overall, specific rules are more expensive to promulgate ex-ante, while general rules are more expensive to litigate ex-post. This might lead one to wonder whether PR firms will write general guidelines leaving more discretion to the doctors, thus removing risks for themselves. This is highly unlikely in a competitive market where PR firms will have to compete for hospitals' business. Doctors would not buy guidelines that are too general to provide immunity, nor would private firms write guidelines that are more than optimally specific because doing so would expose them to more liability.

doctors, and society because it prevents errors stemming from lack of doctors' expertise or experience. While some patients might be worse off for lack of discretion, the majority will receive better, more efficient care.

Lastly, doctors will still have the ability to deviate from guidelines if necessary. If they do so they will risk liability under regular tort law, but it will be no different than the current system.[179] Consider a recent medical malpractice case, *Vede v. Delta Regional Medical Center*, as an example.[180] In *Vede* the plaintiff sued the hospital for failing to conform to national (and hospital) guidelines recommending that patients be turned once every two hours to prevent the development of bed sores. The hospital admitted to deviating from the guidelines but argued that it did so for good reason because turning the patient results in an airway obstruction that impairs his oxygen saturation level, thereby threatens his survival. The Mississippi Court of Appeals ruled for the hospital, agreeing that keeping the patient on his back was medically required.

Vede is useful in comparing the current system with the PRR. First, in *Vede*, multiple CPGs were applicable in this case as there were both hospital and national guidelines. Though it was not an issue in *Vede*, often such guidelines conflict and courts need to solve, the so called "battle of the guidelines".[181] Under the PRR there would be one clearly controlling set of guidelines. Second, in *Vede*, the hospital chose to depart from the guidelines' recommendation, thereby increasing its liability risk in case of a lawsuit, because it believed it was the right thing to do for that specific patient. Under the PRR, the hospital could have handled in the same and faced the same chance of liability. Third, and most importantly, in *Vede*, neither of the guidelines presumably anticipated patients who would not be able to breathe if turned over. (Otherwise, the hospital would not have violated the guidelines at all). This suggests that for this particular medical issue, both the national and the hospital guidelines might have been sub-optimal. Under the PRR, if the hospital in *Vede* had followed the guidelines, the plaintiff could have sued the PR firm for writing suboptimal guidelines.[182]

PR firms would do better than the current system because they will clearly identify "floors" and "ceilings" of appropriate care, thereby defining a range of acceptable practice from which providers can select according to their judgment. While PR will constrain doctors' discretion more than the current tort regime, it would do so in a way that is more beneficial to patients,

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[179] Because doctors would generally follow guidelines, they would face liability far less frequently.

[180] Vede v. Delta Regional Medical Center, 933 So.2d 310 (Miss. Ct. App. 2006).

[181] See Mello supra note @@@ at 685. In such cases court often apply the "two schools of thought" doctrine. *See e.g.*, Levine v. Rosen, 616 A.2d 623 (Pa. 1992).

[182] Although whether he would have won is a separate issue. *See supra* note 171. Other examples exist. Consider a drug which has 100% effectiveness but must be taken four times per day. Very few doctors will

iii. How Effective is the PRR in Reducing Costs?

As was mentioned above, there are three sources of excessive costs: misuse, underuse, and overuse. I argued above that a significant portion of medical practice can be, and is in fact, reduced to guidelines. I also argued that a major advantage of PRR is that it can combat all three cost drivers simultaneously, thus avoiding problems that other tort and healthcare reforms face where attempting to solve one problem immediately exacerbates another.[183]

But how effective would the PRR be in reducing these costs? I will analyze it for the three cost drivers separately.

1. Misuse (Medical Errors).

The pervasive nature of errors is clear. The Institute of Medicine reported that 1.4 or 2.2 percent of individuals entering the hospital will experience an adverse event that was fully preventable.[184] Half of those errors were the result of negligence.[185]

Let's start with misdiagnosis and misprognosis, both of which are errors of planning. For many decades studies have consistently demonstrated the benefits of statistical over clinical diagnosis. Statistical methods of combining data yield more valid decisions than do less systematic approaches, such as relying on unaided human judgment. This has been shown in studies of medical decision-making ranging from diagnosis of thyroid disorder and heart diseases to surgery recommendations and surgery outcomes. In non-medical research it has been shown in areas probation success and job performance.[186] The reasons for this inferiority range from doctors' fatigue, to their

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prescribe this drug when a once-a-day alternative, with less effectiveness, is available unless the patient is extremely compliant. It might be malpractice to prescribe a drug assuming patients will take a medication every day, four times a day when other alternatives are available. Simply put, theoretical, evidence-based effectiveness does not always translate into real-world effectiveness.

[183] See supra page 15.

[184] *To Err is Human* at 26.

[185] *To Err is Human* at 30.

[186] For a recent meta-analysis see Grove, W.M., Zald, D.H., Hallberg, A.M., Lebow, B., Snitz, E., & Nelson, C. (2000). Clinical versus mechanical prediction: A meta-analysis. *Psychological Assessment, 12*, 19–30.

reliance on a limited number of previous patients with similar diseases, to various cognitive biases and heuristics that prevent them from reaching the correct judgment.[187] However, despite overwhelming empirical support, treatment decisions based on statistical prediction nonetheless remain scarce as doctors clearly prefer to use their heads rather than formulas. CPGs can easily help with misdiagnosis and misprognosis. Rather than having the doctors ask patients questions about medical history, symptoms, etc., relying on their memory and own experience, imagine the doctors using a handheld device with a decision tree based on best available research guiding the doctors through the diagnostics.

But evidence exists that CPGs can do more than just improving diagnostics and survival predictions. One of the success stories demonstrating that CPGs can prevent errors is in the specialty of anesthesia, where deaths from anesthesia have gone from 2 of every 10,000 uses of general anesthesia to 1 of every 200,000 to 300,000 uses.[188] The gains in anesthesia were accomplished through a variety of mechanisms including the development and widespread adoption of practice guidelines.[189] The PRR regime would help to extend these gains beyond the specialty of anesthesia to other practices by creating incentives for the development of solid CPGs.

Moreover, the Institute of Medicine reported that Drug complications were the most common type of adverse event (19 percent), followed by wound infections (14 percent) and technical complications (13 percent).[190]

[187] These include cognitive biases such as ignoring base rates, and heuristics such as the representativeness heuristic (which leads to belief in the law of small numbers) or the availability heuristic (which leads to over-weighting vivid data). See Kahneman D., Slovic P., and Tversky, A. (Eds.) (1982) *Judgment Under Uncertainty: Heuristics and Biases*. New York: Cambridge University Press.

[188] TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM, 32 (Kohn, Linda et al. eds., Institute of Medicine, National Academy Press, 2000) available at http://books.nap.edu/openbook.php?isbn=0309068371 .

[189] *Id.*

[190] Id.

when they are acquired during hospitals stays, would be limited by mandated protocols that physicians would follow under the PRR. Both drug complications and wound infections are areas where standardized practices, based on solid evidence, would fit nicely within the physician's role because the prescribing of drugs in a way that limits complications, and the prevention of wound infections, are relatively free of subjective influence.

Lastly, the Institute of Medicine concluded that the more technologically-dependent a given practice area becomes, the more likely for errors to occur.[191] Thus, as medicine transforms from an art into a science, and as doctors become physician-scientists applying new technologies and breakthroughs to help their patients, the need becomes even greater for a PRR in order to ensure that the power of new procedures and tools is tempered by research into the best way to implement them safely. CPGs, created by private firms, would be a clear way to move forward towards fewer errors. The PRR would also make doctors into even more significant stakeholders in the safety of their patients.

2. Underuse

One of the main problems with health care in the United States is insufficient preventive care. Mandatory adherence to CPGs can help providers administer preventive care. Furthermore, correcting incentives within the health care industry will make every part of it more efficient. This greater efficiency will likely lead to cost savings in the public and private sectors. As discussed above, the savings will come primarily from a reduction in overuse. Savings in the private sector will likely be absorbed by all parties, including health care insurance providers. Competition in the market means that these savings will eventually be passed on to consumers, making health insurance more affordable, thus

The PRR should be very effective in combating medical errors because it would institute safer, evidence-based practices in all three of these. Preventable drug complications would be limited by the institution of evidence-based protocols for questioning of patients, cross-referencing of drugs for possible interactions, and better-funded studies to discover side effects and dangers of using a particular drug. Preventable wound infections, known as "nosocomial infections"

[191] "The contributions of complexity and technology to such error rates is highlighted by the higher rates of events that occur in the highly technical surgical specialties of vascular surgery, cardiac surgery, and neurosurgery. In hospitals, high error rates with serious consequences are most likely in intensive care units, operating rooms and emergency departments" Id. at 36 (citing Leape, Lucian; Lawthers, Ann G.; Brennan, Troyen A., et al. Preventing Medical Injury. Qual Rev Bull. 19(5):144–149, 1993).

increasing access to current uninsured and underinsured patients. The savings in the public sector can be reallocated to further expand access to insurance and to other programs likely to reduce underuse. Thus, while the PRR will have a small direct effect on underuse, the efficiency gains will indirectly result in a reduction of underuse. Even ignoring this indirect benefit, it is clear that the PRR will not exacerbate the problem.

3. Overuse

There are several methods for limiting overuse. First, the patient can refuse (or refuse to pay for) the procedure. Taking a CT scan carries some risks and if the patient feels the doctors is only doing it because she has recently bought a scanner and need to recoup the investment (offensive medicine), or because she feels the doctors does not really knows what she is doing (cost-apathetic medicine) she might refuse to take the scan.[192] However, most patients do not have the time, resources, information or motivation to monitor or second-guess their doctors' treatment recommendations. Second, the insurer, especially if the insurer is an HMO, can refuse to pay for the procedure.[193] But an HMO might still have hard time combating providers' incentives and biases. Is there a way to change combat overuse?

a. Defensive Medicine.

Perhaps the easiest savings to explain are costs associated with defensive medicine. It is obvious that the PR regime lowers these costs because it significantly dilutes doctors' incentive to perform defensive medicine as they receive a safe harbor from liability by following the guidelines.

b. Compassionate medicine

[192] *See* Shankar Vedantam, *Doctors Reap Benefits By Doing Own Tests*, WASH. POST July 31st, 2009, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2009/07/30/AR2009073004285.html.
[193] The law itself can ban the procedure, or a hospital can refuse to allow a procedure to be performed. Usually this refusal by the law or a hospital is based not on the cost of a procedure but on its experimental nature. *See* 28 USC §301-399a (Federal Food, Drug, and Cosmetic Act) (outlining FDA agency oversight).

As was mentioned above, 30% of Medicare spending is on end-of-life care, of which 50% is spent on the last 60 days of life.[194] Having to follow CPGs, doctors might be more able to resist the compassionate instinct and provide only care which they know is scientifically supported. It is hard to estimate the impact CPGs will have on compassionate care but it may be large. Even if not large, it will definitely be in the right direction.

c. Cost-apathetic care

Cost-apathetic care should be significantly reduced as doctors will have hard science to combat their ignorance. Because of the strong incentives doctors will have to follow CPGs, it will be almost impossible for them to provide cost-apathetic care in any procedure for which CPGs exist. The CPGs will synthesize all current medical knowledge for a given procedure and present it in a way easy for the doctor to follow. Just like a builder following an architect's designs, the doctor will follow the CPGs and provide the patient the optimal level of care based on the latest medical knowledge.

d. Offensive Medicine.

A great deal of skyrocketing healthcare costs may be rooted in offensive medicine (or induced demand). Under the predominant current payment system a doctor is not paid for having a healthy patient but for having performed a set number of tests, procedures or examinations on a patient.

Recently, some have proposed moving from a compensation system based on discrete procedures and tests to a system that pays doctors based on the health of individual patients.[195]

[194] See supra note %%%

[195] Julie Weed, If Doctors Had More Time to Listen, The New York Times, June 6, 2009 (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)

congestive heart failure) a certain amount of money, paid by the insurance company. This money will be allocated to the doctor, and if the doctor is able to keep the patient healthy for less than the insurance company expected, the physician would be able to keep the remainder of the funds.[196] Problems with this solution abound, and include the issue of who will decide if the patient is sufficiently "healthy" and keeping insurance companies from lowering allocations when doctors prove their ability to cut costs. Of course, a fear of allocations being cut may cause doctors to over-report the costs of care, thus returning us once again to the agency issue at which we started.

This type of "capitation" system, where physicians are paid based on the health outcomes of a patient with a given disorder, has been implemented in several areas. The largest trial has been in Medicare and Medicaid, where this system of capitation was recently mandated for both services in 2005.[197] One problem with capitation is that disorders can overlap, making a given patient more expensive to treat than the average patient on which the payment rate is based.

A more advanced version of the same solution to this issue is the Prometheus System, a non-profit consortium that has created something called an Evidence-Based Case Rate (ECR).[198] These ECRs differ from capitation systems in that the ECRs use Clinical Practice Guidelines to inform medical care and many different demographic variables to fine-tune the payments according to more correlative indicators of patient

[196] Kate Pickert, Cutting Healthcare Costs by Putting Doctors on a Budget, Time Magazine, July 6, 2009. (describing a system where a doctor, if given $25,000 on the assumption that the typical patient requires $20,000 to keep them healthy and is was able to reduce costs and keep the patient healthy for $15,000, would double her reward from that particular patient).

[197] Deficit Reduction Act of 2005, Public Law 109-171, Titles V (Medicare) and VI (Medicaid), February 8, 2006; Pauline W. Chen, Getting Off the Patient Treadmill, The New York Times, February 19, 2009 (" . . . in the Deficit Reduction Act of 2005, Congress mandated that the Center for Medicare and Medicaid Services adopt a pay-for-performance plan into Medicare.") These changes from a pay for service system to a capitation system for Medicare began in the early 1980s and defied the predictions of the Congressional Budget Office. The CBO had expected an increase in hospital admission rates once payments were tied to discrete patients rather than procedures, yet after the early reforms hospital admission rates actually declined. See Jon R. Gabel, Congress's Health Care Numbers Don't Add Up, The New York Times, August 26, 2009 ("In the early 1980s, Congress changed the way Medicare paid hospitals so that payments would no longer be based on costs incurred. Instead, hospitals would receive a predetermined amount per admission, based on the patient's primary medical problem. This encouraged shorter stays, led to fewer diagnostic services and reduced administrative costs. The Congressional Budget Office predicted that, from 1983 to 1986, this change would slow Medicare hospital spending (which had been rising much faster than the rate of inflation) by $10 billion, and that by 1986 total spending would be $60 billion. Actual spending in 1986 was $49 billion. The savings in 1986 alone were as much as three years of estimated savings.")

[198] Prometheus Website: ECR Playbook, http://www.prometheuspayment.org/playbook/index.htm

costs than capitation alone.[199] While both capitation or the Prometheus system are solid alternatives to the pay-for-service system, there is a danger that either system might deter useful procedures if a physician feels that they could cut costs by ordering fewer clinically indicated procedures.

A somewhat similar approach has been taken recently by the Medica health insurance company, the second-largest Minnesota insurer, which has teamed up with a group of Minnesota clinics to work towards holistic patient health rather than crisis-based problem-solving, by using evidence-based practice guidelines.[200] By shifting the focus towards patient health, physicians are incentivized financially (rather than professionally or ethically) to ensure good results from their contacts with patients.[201] Together, both sides, insurer and clinic, are working to increase patient enrollment and decrease the numbers of individuals and companies that are dropping out of the health insurance system entirely.[202]

By encouraging evidence based CPGs both the Prometheus System and Medica health insurance company go a long way towards a regime of Private Regulation, and in a way are evidence for its feasibility. However, while efficient in combating offensive medicine, the lack of immunity to providers and the lack of liability for suboptimal CPGs makes them ineffective in combating defensive medicine and medical errors, respectively.

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

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[199] Prometheus Website: Frequently Asked Questions, "Isn't this just capitation in disguise?" http://www.prometheuspayment.org/FAQs/index.htm#b6 ("In capitation, providers take the risk that they may have a sicker patient panel than average or that their condition or disease mix can be more unfavorable in terms of resource use per patient than the average. The PROMETHEUS Payment® model avoids this problem by (1) constructing the payment rates in a way that reflects the cost of what is clinically relevant to the patient's condition, appropriate differentials in resource use by the condition, disease or procedure and (2) adjusting those ECRs® to account for the relative severity of the patients cared for under this system.")

[200] David Welna, Minnesota Experiment Puts Patient Health First, NPR, September 3, 2009, http://www.npr.org/templates/story/story.php?storyId=112488466. And see Medica Website: Visitor Resources Fact Sheet, http://www.medica.com/C2/Factsheet/default.aspx

[201] *Id*.

[202] *Id*.

in the private market as well. Kaiser Permanente, as a large health plan, sets up payments for individual "medical groups" so that the physicians in the groups are receiving salaries.[203] Both the Cleveland and Mayo Clinics pay their doctors a salary rather than basing reimbursement on the number of patients seen and procedures performed.[204]

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

iv. Not Enough Reliable Scientific Information Exists To Make The Endeavor Worthwhile.

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

[203] Kaiser Permanente Website, Frequently Asked Questions About Our Medical Care, https://members.kaiserpermanente.org/kpweb/faqmedcare/entrypage.do.
[204] Kevin Sack, For Two Health Care Systems, a Priceless Presidential Testimonial, The New York Times Prescriptions Blog, September 10, 2009, http://prescriptions.blogs.nytimes.com/2009/09/10/for-two-health-care-systems-a-priceless-presidential-testimonial/.

guidelines only for those procedures which are conducive to evidence-based improvement. Under the PR regime, guidelines will be written only for medical procedures that are complex and carry with them high risk of failure with significant adverse consequences. For example, improved guidelines for obstetrics, surgery, missed diagnosis, and medication could have a tremendous impact, as these key clinical areas account for approximately 80 percent of all claims in the United States and an even larger proportion of total indemnity costs.[205] Additionally, the lack of information will be less of an issue under the PR regime because, unlike now, private firms will have the financial incentive to fund the high quality research necessary to make evidence based guidelines possible.

v. Contracting with private experts might be too expensive.

The costs associated with the PRR, including those required to develop and apply new evidence-based-medical practices, may lead some to wonder whether the project is simply too expensive for a single hospital to bear. After all, process is labor intensive and requires a team of experts conducting research and potentially observing hospital's conduct over potentially several months. First, as was mentioned earlier the market already uses private experts to some extent. There are several private and public entities which constantly write guidelines. Second, to the extent the proposed regime is expensive, a possible solution is to have MCOs (hmos, ppos, etc), Medicaid and Medicare share costs because after all they bear the medical costs associated with both defensive medicine and medical accidents.

c. Legal Concerns

i. Can Courts Really Apply The Ex-Ante Perspective?

The last set of criticisms deal with legal issues. To start, one may wonder whether courts, conditioned to apply ex-post and ad-hoc analysis, can really change their skin and apply an ex-ante perspective.[206] The answer is that creating a new tort called

[206] *See supra* pp. 14-24 (discussing the problems with the current tort law system.
[206] *See supra* pp. 14-24 (discussing the problems with the current tort law system.

"negligent guidelines" and defining it from the ex ante perspective should at least be an improvement over the current regime in that it distances courts from an identified patient and an identified doctor and make them face statistical patients and statistical doctors. One would hope that within short time courts will get it right.

ii. Aren't We Losing The "Information Updating" Benefit That Tort Law Provides?

Because the required legislation would fundamentally change medical malpractice, there is a worry that the information updating benefit present in tort law would be lost. Both professors Robert Rabin and Richard Nagareda discussed separately the "information updating" effect of tort law.[207] No doubt there are examples of tort litigation "eliciting information about risk and aberrant conduct," as Rabin puts it; tobacco litigation, he notes, is probably the best example of plaintiffs' lawyers unearthing this vital information.[208] The relevant analysis is one of comparative institutional advantage. The current experience is not encouraging. It takes about 17 years for new good knowledge (one generated by randomized controlled trials) to be incorporated into practice, and even then application is highly uneven.[209] Recall that under the PR regime the hospital gets immunity for only a few years, and that, in addition, the PR firm does not have the state-of-the-art defense. These factors should take care of the information updating concern in a much quicker, more consistent, more rational, more systematic, and more scientifically reliable way.

d. Political Concerns

i. Would Private Regulation Lead to "Pulling the Plug on Grandma."

In order to achieve the legal changes necessary, the PRR would have to be politically palatable. First, and also present in the wider debate about healthcare reform, is the issue of rationing. Will guidelines ration care and keep sick people from being

[207] Shuck, *supra* note 64, at 17.
[208] *Id*.
[209] INSTITUTE OF MEDICINE, *supra* note 1, at 13.

treated? It is true that guidelines incorporate rationing, but healthcare must be, and is currently being, rationed. It is economically impossible and unethical to provide unlimited care to everyone. If a drug for cancer costs $50,000, but only prolongs one's life by a few months, then there must be a rational way to determine whether this drug is worth providing. If resources were unlimited, then it would be worth doing anything that can save or prolong lives. However, rising costs have put Medicare on the brink of insolvency[210] and President Obama has stated "ever-escalating healthcare costs" are "the most significant driver by far of our long-term debt and our long-term deficits."[211] Once we acknowledge the impending budget constraints, and the rationing that these constraints will require, we must only decide what would be the best use of our healthcare dollars. In fact, the argument against rationing ignores the fact that, being a scarce resource, healthcare is already rationed, only less visibly and based on a prospective patient's ability to pay.[212] If we decide that the $50,000 cancer drug will not be covered, then those who suffer from that particular cancer may die. But, the same holds if we decide to cover the drug. If the drug is paid for the result would be higher health insurance premiums which some people will not be able to afford. If people cannot afford health insurance, and therefore not afford healthcare to treat their diseases, they are more likely to die from those disease.[213] This is rationing too, only by a different criterion—the ability to pay.

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[210] Senate Finance Committee, *Description of Policy Options: Financing Comprehensive Health Care Reform: Proposed Health System Savings and Revenue Options*, May 20, 2009, http://finance.senate.gov/Roundtable/complete%20text%20of%20financing%20policy%20options.pdf (last visited Sept. 1, 2009).

[211] *See* Whitehouse.gov, The Briefing Room, The Blog, *Health Care Reform: 'Urgency and Determination,'* May 13, 2009, http://www.whitehouse.gov/blog/Health-Reform-Urgency-and-Determination/ (last visited Sept. 1, 2009).

[212] *See* [212] Peter Singer, *Why We Must Ration Health Care*, N.Y. TIMES MAGAZINE, July 15, 2009, at MM38.

[213] *Id*. In a study conducted by the Urban Institute using data from the U.S. Census Bureau, researchers found that as many as 165,000 people likely died due to lack of insurance in the time period between 2000 and 2006. Sara Lubbes, *Thousands of U.S. Deaths Attributed to Lack of Health Insurance*, THE COMMONWEALTH FUND, January 11, 2008, at 1. As stated by the study lead, Senior Researcher Stan Dorn, "This is all a question of common sense. Nowadays we know that medicine can save your life and if you have to choose between food and medicine, for instance, you're playing Russian Roulette with your health." *Id*.

Consequently, the question is how best to spend society's healthcare dollars.[214] The answer does not necessarily lead to pulling the plug on grandma, as some might put it, but must be determined based on how society wants to distribute a finite resource.[215] Guidelines will simply incorporate society's moral and political preferences;[216] optimal guidelines will reflect what society considers proper. The PRR does not require grandma to be harmed unless society decides the resources are better spent elsewhere.

Moreover, the PR regime will be adaptable to peoples' preferences between money spent now on insurance premiums and money spent later on health care. Under the PR regime, there could be several levels of guidelines, say platinum, gold, silver and bronze, which reflect larger benefits for higher premiums. To facilitate effective competition, those standards need to be consistent across the industry. One way to regulate those standards would be by the legislature determining the amount of money each level has to spend per QALY. Suppose that gold means that the CPGs are committed to spending at least $50,000 per QALY, whereas silver spends only $40,000. If a person pays the gold premiums she will go to a hospital which provides a gold standard of care (and gets the drug for cancer). If the person instead pays for the silver standard, then she will not have a complaint when her insurance refuses to pay for the drug.

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

The last criticism is whether the PRR, relying on private, profit-driven companies to regulate healthcare, could ever win political support. Could these private companies

[214] This question is not unique to the healthcare context. Government agencies consider various safety measures must put a price on human's life in order to evaluate whether or not the safety measure is worth the candle. The Department of Transportation uses $3 million (in 2002 dollars), the EPA uses $7.2 million (in 2005 dollars) and the FDA uses $5 million per life saved (no dollar year reported). *See* Lisa Robinson, *How US Government Agencies Value Mortality Risk Reductions*, 1 REV. ENVIR. ECON. POLICY 283 (2007).
[215] Critics of President Obama's healthcare reform argue that his plan rations healthcare and might lead to pulling the plug on grandma. *See* Planet Money, *Obama Says His Health Plan Won't 'Pull The Plug On Grandma*,' NPR.org, http://www.npr.org/blogs/money/2009/08/obama_defends_health_insurance.html (last visited Sept. 1, 2009).
[216] *See supra* note 10.

ever achieve the kind of credibility that would make legislators comfortable in enacting such a regime? Those who share this concern may argue that it is better to work with already recognized bodies, such as the AHRQ and IOM committees, but make sure they are better funded to keep guidelines up to date, and cleansed of corporate influence. To answer this objection, it is important to consider that given the bad reputation guidelines written by these institutions currently have, it may actually be easier to get political support for a fresh start, rather than for doing more of the same.[217] Even if enough funding could be provided (and there is no reason to believe the government could systematically provide better funding than the market), there is still a fact of life which can never go away-- the mix of corporate finance and medical innovation. As long as this mix exists—and for good reasons, it always exists– then it would be nearly impossible to over-come parties' financial self-interest in the healthcare industry. The PR regime takes this fact of life as given, and attempts to align the private financial interest with the social ones.

V. BEYOND MEDICAL MALPRACTICE

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

In contrast, those who favor private tort liability emphasize supposed informational advantages of courts, the social laboratory advantages of federalism, and the socially beneficial information discovery function of tort law. They argue that courts

[217] *See supra,* page 27.

are more impartial because courts are less likely to suffer from agency capture or principle-agent problems. Finally, they appeal to the importance of the compensation goal that tort law more directly achieves.

Surprisingly, it seems that none have suggested regulating medical guidelines by way of ex-ante *private* regulation. Ex-ante private regulation would occur when firms, which I called Private Regulators [PR], contract with an industry or a particular industry player to write detailed guidelines regulating some conduct, fit for such guidelines.

I argued that a private regulation regime (PRR) combines most of the advantages of public regulation and private law while discarding most of the drawbacks. Specifically, the PRR engages unbiased experts as repeat players in determining optimal conduct from the ex-ante perspective. Public agencies are held accountable, at best, to the government or the media, and they normally cannot be sued for damages for their regulations.[218] Private regulators, in contrast, would be held financially accountable. Unlike courts that perform an ex-post analysis which is subject to hindsight and other biases, a Private Regulator Regime would operate from the ex-ante perspective, taking into account not only the costs of conduct (which courts usually do observe) but also the benefits to others (which courts, operating from the ex-post perspective, usually do not). Unlike public regulation regimes, a private regulation regime is not susceptible to interest group politics. Also, a Private Regulation Regime allows for competition and experimentation with various guidelines in a way which ex-ante single-agency public regulation could never allow.

VI. CONCLUSION

The U.S healthcare system is sick. It suffers from too many medical errors and from too much underuse and overuse. While there is debate whether overuse is primarily driven by defensive medicine or by offensive medicine, no one doubts there is overuse. Since taking over, President Obama has indicated a commitment to seek creative

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

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, costs savings will not be achieved and immunity for doctors from medical malpractice cannot be justified.

I have offered a potential solution which pairs these objectives into a single legislative package. The solution is not, as many have feared, a government which closely regulates the healthcare system, but a system of many "private regulators" which set the gold standard of patient care. As I have demonstrated, a system of *private* regulators competing to provide evidence-based medical guidelines which offer liability protection to complying doctors could dramatically decrease the exorbitant administrative costs of malpractice lawsuits and, more importantly, increase patient safety while reducing overall healthcare costs.

As I have discussed, in order to attract customers seeking to minimize costs, private regulators would have to offer guidelines which compete 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, the fear of 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 current medical guidelines providers, private firm's profit margins would be closely aligned with patient safety so these firms would now have the financial incentive needed to invest in continuous improvement. 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.

My work develops, expands, and further theorizes on some recent ideas raised by others. Silver and Hyman have briefly discussed the possibility of recognizing evidence-

based medicine as an absolute defense against liability.[219] Avraham, Hyman and Silver have suggested using cap on damages awards as a carrot to doctors who comply with evidence-based medicine norms.[220] In the context of internet regulation, Phil Weiser has even suggested that self regulatory organizations overseen by government agencies could utilize the expertise of industry players to induce optimal standards, while still maintaining the appropriate level of legal accountability.[221]

Admittedly, the analysis leaves some important questions open. Private regulation does not solve the problem of compensating victims when they receive optimal care, yet some remote risk materializes. Some may argue that nothing is wrong when people who receive a treatment with a small risk of an adverse outcome, which actually materializes, do not receive compensation. Others may believe this is a problem. There is much to be said about this. Here however, it is sufficient to say that existing regulation and tort law do not fare any better than the proposed PR regime on this issue. Regulations usually ignore the victim, and tort law is often preempted (explicitly or not) by regulations, leaving the victims without any recourse.[222] Even when tort law is not preempted, it does not compensate victims of non-negligent care.

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[219]David A. Hyman and Charles Silver, *The Poor State of Health Care Equality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution?*, 90 Cornell L. Rev. 893 at 990.

[220] Ronen Avraham, David A. Hyman and Charles Silver, *Texas-style Caps on Noneconomic Damages Isn't Smart Tort Reform*, Dallas Star Telegram, July 18, 2009, *available at* http://www.star-telegram.com/245/story/1494028.html (last visited Sept. 1, 2009).

[221]Phil Weiser**,** *The Future of Internet Regulation, U of Colorado Law Legal Studies Research Paper No. 09-02*, Working Paper Series (February 2, 2009). As Weiser explains, the government lacks the ability and expertise to regulate optimally without the help of private regulatory organizations composed of representatives within the field which they are regulating. *Id*. Similar to the PR regime, his proposal necessitates government intervention to enable the creation of private regulatory organizations whose expertise will facilitate an efficient regulatory market.

[222]As noted by Catherine Sharkey, the trend towards increasing federal preemption of state tort claims has created a "troublesome asymmetry with respect to agency decision making: courts appear to grant agencies expansive discretion to interpret or declare the preemptive scope of the regulations they promulgate, whereas agencies are not given corresponding latitude to infer private rights of action under those same regulations." See Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 241 (2007). This issue is demonstrated by recent court decisions holding that, despite agency intent, no private action against agency regulations can either be created or taken away unless congress has provided clear guidance. *Id*. Additionally, even where congress has expressly provided a right for private action against agency regulations, the boundaries for those rights will primarily be interpreted ex-post by the courts, not the agencies themselves. *Id*. Sharkey promotes a more cooperative ex-anti approach which would require agencies and courts to work together to define the boundaries of preemption issues prior to the full enactment of agency regulations. *Id*.

Nevertheless, I hope to have shown that policymakers have a new exciting alternative that goes well beyond capping damages, or throwing more money to professional groups to write regulations. Private regulation deserves to be seriously considered by Congress as it attempts to reform the healthcare and liability systems.