Private and Competitive Regulation of Medicine

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Health care costs in the U.S. are estimated to be $2.4 trillion dollars per year, around 17 or 18 percent of GDP and twice as much as any other country.[1] Many blame malpractice liability and the defensive medicine it induces. The simple answer for those like Rep. Michael Burgess, the Health Caucus Chair, is to cap damages to injured patients.

Damage caps will surely limit the dollar costs of medical malpractice liability insurance and potentially of medical care, but that in itself does not make them a good idea. The point of liability is to induce optimal care-taking and it would be tragic if limiting liability reduced the quality of medical care. Medical errors are already associated with 98,000 deaths every year, more than twice the deaths from car accidents by some estimates.[2]

What to do? Instead of simply capping damages, we should seek malpractice reform that encourages compliance with evidence-based medical practices. Today, it can take up to 17 years for physicians to implement proven procedures, according to the Institute of Medicine.

President Obama has hinted that he favors making medical liability reform part of broader healthcare reform,[3] and in his recent primetime press conference, he stressed the need not only to lower costs but also to focus on evidence-based medical practices. Part of the solution, according to the incoming president of the American Medical Association, is exempting doctors from liability if they follow medical guidelines.[4]

The problem with such an exemption—and it's significant—is that most guidelines do not work. They fail to incorporate evidence-based-medicine because they are not produced under the appropriate incentives. Without the proper incentives, cost savings and patient safety cannot be achieved and immunity for doctors cannot be justified.

Instead, private firms could create evidence-based guidelines and offer liability protection to complying doctors. This type of private regulation regime that I describe below could decrease malpractice lawsuits and increase patient safety.

WHAT IS WRONG WITH THE CURRENT SYSTEM?

Most commentators agree that current signals from the courts are weak. There is

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simply not enough correlation between outcomes in courtrooms and actual medical negligence. As a result, tort law misses what many argue is its primary target: incentivizing optimal behavior. Improving the judicial system, for example by establishing health-courts, is controversial and politically difficult. Nor can incorporating existing medical practice guidelines into malpractice law solve the problem.

Current guidelines provide little help to doctors. The federal government, liability insurance carriers, third-party payers—such as HMOs—and various medical organizations—such as the American Heart Association—presently create guidelines for medical practice. Unfortunately, these organizations struggle to provide guidelines that optimize care and minimize costs. A recent study found that only half of all cardiac guidelines are based on scientific evidence.[5] The guidelines fail because one or more of the following problems ensues: the entities that write them lack resources, have financial incentives to maximize their self-interest at the expense of the social pie, or lack financial incentives to invest in the continual improvements necessary to keep pace with quickly evolving medical fields. In 2001, a study examined the validity of clinical guidelines developed between 1990 and 1996 by the U.S. Agency for Healthcare Policy and Research.[6] It found about two-thirds of the guidelines were out of date with current research.[7]

Exemplifying the self-interest problem are guidelines written by liability insurance carriers which often externalize costs on patients, HMOs and other healthcare insurers. Liability insurance carriers would require doctors to perform yearly mammograms to prevent breast cancer, even if such a requirement unnecessarily wastes medical resources, because the liability carriers do not bear the costs of extra mammograms but do bear the costs of malpractice lawsuits arising from the late diagnosis of breast cancer. This is the problem of defensive medicine which is believed by many to account for up to 9% of total healthcare costs.[8] 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.

Another troubling problem arises out of the strong ties between many of the professional organizations promulgating guidelines—and the clinical practice studies on which they rely—and drug or medical device companies. These businesses stand to benefit greatly if the guidelines recommend use of their products. A 2002 study involving 192 guidelines found that 58 percent of the authors surveyed had received financial support for their clinical research from pharmaceutical manufactures.[9] About one-fifth of respondents believed their coauthors' recommendations were influenced by their relationships with these companies.[10] (Interestingly, even the authors of the study had attended events sponsored by or received money from pharmaceutical companies.[11])

Compounding the problem, the organizations which produce guidelines are not subject to financial liability for their recommendations. Not surprisingly, many doctors suspect the guidelines do not reflect untainted, evidence-based advice. A recent study found that more than 50 percent of doctors say they pay no attention to the guidelines.[12] It is easier and more profitable for physicians to base their practice upon tradition, experience, prior medical school classes now outdated, or discussions with friends and colleagues.

IS THERE A PRIVATE MARKET ALTERNATIVE?

A market of guidelines produced by *private firms* could create a gold standard for patient care. The firms would compete to sell their guidelines to doctors and hospitals and in turn offer their clients a safe harbor from medical malpractice lawsuits, provided that the guidelines are followed. The private firms, unlike current organizations that create guidelines, would be held liable for promulgating sub-optimal guidelines. They would strive not only to reduce costs in order to sell their guidelines, but also to maximize patient safety to avoid liability. The private firms would have a strong interest in continually funding objective scientific research to create evidence-based medicine in order to achieve their twin goals of cost savings and patient safety. Granting immunity to doctors who follow such guidelines would go a long way toward meeting the nation's goals of minimizing healthcare costs while maximizing patient safety.

The following transaction illustrates the private regulation regime. Hospital A contracts with Firm P to write evidence-based guidelines for its emergency room (ER) conduct. Firm P, with expertise in the field, uses existing research and, if necessary, performs new research to develop optimal ER protocols for hospital A. The guidelines will incorporate the hospital's current infrastructure, staff, and budget. Firm P may also provide a five-year plan to optimally improve the protocol on all fronts. If Hospital A lacks the resources to properly comply with the guidelines it may decide not to adopt them and thereby subject itself to existing tort law. If Hospital A does adopt the guidelines, it will be immune from medical malpractice liability for accidents occurring in its emergency room insofar as it follows the guidelines; essentially enjoying what I call a private regulatory-compliance defense.

A patient's only way to receive compensation from Hospital A (or its physicians) is by showing that the hospital did not follow the guidelines. Alternatively, the patient can sue Firm P for writing sub-optimal guidelines that expose patients, ex-ante, to too much risk. Firm P, which would need a financial safety-net such as insurance to get a license to privately regulate, would be held liable if a court determined that it wrote sub-optimal guidelines which caused a patient's harm.

THE REQUIRED LEGAL INFRASTRUCTURE

Such a private regulation regime will require five essential legal components. These components will likely require some type of government reform, a fact which may explain why we do not already see such a regime. First, Firm P must be eligible for patents or some other form of intellectual property protection for its guidelines. Such protection will protect resources spent for research-and-development by preventing others from free riding on Firm P's effort. The current law roughly meets this requirement.

Second, courts will have to adopt some form of a private regulatory-compliance defense. A private regulatory-compliance defense would enable doctors to stop performing defensive medicine because they will no longer be exposed to liability provided they followed a private regulator's guidelines.

Third, Firm P, the private regulator, must be licensed to guarantee its financial solvency in light of the financial risks it faces. Without guaranteed solvency, the contract between Hospital A and Firm P might impose externalities on injured patients. The financial liability Firm P faces is what guarantees that it will not

write guidelines that emphasize cost-savings over patient safety. If Firm P can become insolvent to avoid paying liability it might not fully weigh the harm of sub-optimal guidelines.

Fourth, Firm P must be liable for writing sub-optimal guidelines and the liability must be judged from the ex-ante perspective. That is, Firm P will be found negligent if and only if the guidelines it has written are inefficient under an analysis using evidence-based, objective research to compare the costs and benefits of medical procedures. The analysis must be performed based on the information available prior to the procedure; if there was a 5 percent risk of injury to a patient, then the 5 percent risk—not the injury to a patient—must be the control. This ex-ante perspective, together with competition among private regulators for clients, will guarantee Firm P writes regulations that minimize cost yet optimize safety.

Fifth, courts must disallow the state-of-the-art defense for private regulators. Many states currently allow defendants to escape liability if they can show that their product was state-of-the-art when it was first introduced to the market. Eliminating this defense would force private regulators to continually update guidelines to reflect ongoing research, while giving practitioners reason to rely on the guidelines.[13]

FROM ART TO SCIENCE: FROM ARCHITECTS TO BUILDERS

The proposed private regulation regime will change the way doctors work by moving medicine further down the path from art to science. The relationship between private regulators and doctors will be similar to that between architects and builders. The architect is primarily concerned with design, the builder with execution. Yet, just as architects need builders' feedback before they seal their plans, private regulators will communicate with doctors about the wisdom of their guidelines. Private regulators (the architects) will design guidelines by synthesizing available scientific evidence, regulatory requirements, and tort law. Doctors (the builders) will execute the synthesized guidelines, and be assured that compliance with the evidence-based protocols will shield them from malpractice liability.

Non-governmental organizations, such as Prometheus Payment, Inc., have started penetrating the world of evidence-based medicine. However, their efforts are simply not enough. Congress needs to incentivize private organizations to regulate healthcare. Moreover, private health insurers—while they look with fear at the specter of a public healthcare option—could protect their position in the field by implementing private regulation. They could lower their costs with the happy side effect of decreasing patient injuries and restoring doctor-patient trust. The insurers would thus not only improve their image, but could at last join the doctor's credo: "first, do no harm."

The result is that private regulators will write optimal guidelines based on the best available medical evidence. The market and the legal system will ensure regulators minimize cost and optimize patient safety. The evidence-based guidelines will be frequently updated as new research becomes available. Hospitals and doctors will be incentivized to follow the guidelines because doing so will shield them from liability and because they know the guidelines provide an optimal balance between cost savings and patient safety. In such a regime, one would have good reason

to believe that the law is playing a positive role by increasing patient safety while still reducing excessive costs.

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NOTES

1. See Keehan, Sisko, Truffer, et al. (2008); Reinhardt, Hussey, and Anderson (2004).
2. Chicago Tribune June 15, 2009.
3. See id.
4. Stolberg and Pear (2009).
5. Tricoci, Allen, Kramer, et al. (2009).
6. Shekelle, Ortiz, Rhodes, et al. (2001).
7. Id.
8. Kessler and McClellan (1996, pp. 371–2).
9. Choudhry, Stelfox, and Detsky (2002).
10. Id.
11. Id.
12. See Cabana, Rand, Powe, et al. (1999).
13. Depending on how the market for private regulation develops, especially in its early stages, there may be a sixth requirement which is that hospitals may not be without guidelines at all.

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