The Value of Clinical Practice Guidelines as Malpractice "Safe Harbors"

Timely Analysis of Immediate Health Policy Issues
April 2012

Randall R. Bovbjerg and Robert A. Berenson

Guidelines hold promise for cutting wasteful defensiveness, but practical feasibility limits their reach. Their importance could grow if changes in payment rules or responsibilities changed provider or patient thinking about the desirability of additional procedures.

Introduction

Health care costs too much in the United States. One problem is overservice driven by physicians' fear of lawsuit for failure to use all available modalities to diagnose or treat a patient. Reliable clinical guidelines promise to help by authoritatively stating standards of good care in advance. They also have political appeal as a compromise malpractice reform. Democratic notables including President Barack Obama have endorsed the concept, a number of physician groups are receptive, and some thought leaders promote the idea. Better standards can also promote accountability.

Can such guidelines serve as liability safe harbors for caregivers who practice at the optimal level, protecting them from the risk of being second-guessed in a courtroom years later for not doing more? And will that protection reduce defensiveness and overutilization? The short answers: Following a good guideline should provide some liability protection, to an extent that will likely increase with time. But creating safe harbors will be difficult, and in practice, no harbor can be totally safe. Moreover, guidelines are not a silver bullet for defensiveness, but rather an addition to the policy armamentarium available to address overutilization.

Over time, greater understanding of available medical options and their relative merits will probably help curb overutilization, especially if joined to other controls or incentives. Improved appreciation for how added services add medical risks and other costs should help modify today's expectations that more care is almost always better than less. In turn, such developments could alter how future judges and juries will react to conflicting expert evidence and how they will see the desirability of signaling caregivers to leave no stone unturned in caring for patients. If so, guidelines will have much larger impact in the decades to come.

What are Clinical Practice Guidelines?

According to the Institute of Medicine, "Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options." (Graham et al. 2011, p.4; see note 6.) As an example, the National Guideline Clearinghouse guideline NGC-8118 addresses the "diagnosis and treatment of chest pain and acute coronary syndrome" (see *www.guideline.gov*).

Why Are Clinical Guidelines Attractive as a Policy Reform?

Federal policy has for some years encouraged comparative effectiveness research and guidelines development.[1] The 2010 health reform law also relies on preventive guidelines from an independent Task Force to define the preventive benefits that insurers must pay in full.[2] A confluence of developments has boosted interest in guidelines: They promise a rare trifecta—better medical quality, more cost restraint through limits on liability's influence over medicine, and a potential avenue for political compromise on malpractice reform. A win-win-win.

Improving quality: A long line of research has found substantial gaps between the care that patients should get and what is actually provided[3]—a quality "chasm," according to the Institute of Medicine (IOM).[4] Too often, patients get too much care (providing unnecessarily sophisticated radiology), too little care (forgetting an appropriate diagnostic test), or the wrong care (prescribing too high a drug dosage).[5] Guidelines could improve matters by reliably indicating what works best for each type of patient in each set of circumstances. Two 2011 IOM panels explained how to develop trustworthy guidelines by

Robert Wood Johnson Foundation
Urban Institute

operationalizing findings from "systematic reviews" of the most credible research on the comparative effectiveness of alternative clinical approaches.[6]

Containing costs, especially wasteful defensive medicine: Provision of inappropriate services not only reduces quality, but it also increases costs.[7] A particularly inappropriate type of care is "defensive medicine"—extra tests and procedures done principally to forestall lawsuits or defend them if brought.[8] Physicians perceive great liability exposure for omissions or delays if a bad outcome occurs, even if its likelihood was very small at the time of care and even if additional services would have added little or no clinical certainty.[9] Such fears promote "gold plating" of care—adding services that may look good at the time to a worried patient or to a jury or judge in a courtroom years later, but that have little or no clinical utility. Practitioners have long reported such wasteful defensiveness.[10]

Until recently, medical practitioners' strong belief that defensiveness greatly increases spending lacked strong empirical evidence,[11] and very large dollar figures were asserted with very little documentation.[12] Recent research finds that caps on awards and other "tort reform" limits slightly lower medical spending—by about 1 percent of health spending, much of which is taken to show reduced defensiveness[13]—although findings of zero defensive spending also exist.[14]

Side-stepping routinized political battles over malpractice reform: Republicans and Democrats have long battled for and against caps and other limits on litigation. If guidelines could effectively reduce malpractice fears, they would address the key Republican concern with defensive expenditures.[15] This prospect encourages some Democrats to see safe harbors as a useful malpractice compromise,[16] although no deal is in sight.[17]

What Recent Proposals Would Use Guidelines to Reform Medical Liability?

In June 2009 President Obama called for "broader use of evidence-based guidelines" that could "scale back the excessive defensive medicine reinforcing our current system of more treatment rather than better care."[18] Other Democratic notables agree that doctors should get a "safe harbor" against malpractice lawsuits when they follow established best practices.[19] Some provider groups have also shown interest,[20] and further support comes from opinion leaders and some researchers, with both conservative and liberal perspectives.[21]

A Paradigm Shift for Guidelines?

There is a broad policy consensus that evidence-based guidelines should play a more prominent role in guiding medical decisions, as evidenced by the two recent IOM panels.[1] However, David M. Eddy, MD, PhD, and other thought leaders have raised concerns that guidelines applicable to populations offer only a first approximation of individually appropriate care.[2] The increasing ability and willingness to measure genetic biomarkers,[3] to recognize differences in patients' behavior and their values and preferences, and to make more precise diagnosis and treatment decisions for individuals, supported by electronic health records and "risk calculators"—all these developments raise questions about the long-term value of population-based guidelines for individual treatment decisions, no matter how accurate as general conclusions.

Dr. Eddy's "Archimedes" model postulates both quality and cost improvements from shifting from population to individualized guidelines.[4] A move toward individualized guidelines would undermine the rationale for deference to population-based ones through safe harbors, substituting individual standards of appropriateness that could deter overservice. Eddy's approach deserves serious attention, as he was a seminal promoter of evidence-based medicine.[5] Yet any such paradigm shift remains uncertain and in any case will take time to occur, making it appropriate for this brief to focus on today's conventional, population-based guidelines.

---

[1] Eden J, Levit L, Berg A et al (eds). *Finding What Works in Health Care: Standards for Systematic Reviews*. Washington, DC: National Academies Press, 2011; Graham R, Mancher M, Wolman DM et al (eds). *Clinical Practice Guidelines We Can Trust: Committee on Standards for Developing Trustworthy Clinical Practice Guidelines*. Washington, DC: National Academies Press, 2011. The reports were called for by the Medicare Improvements for Patients and Providers Act of 2008, Public Law 110-275, July 15, 2008. Additional translation and integration into decision support tools may be needed to make guideline effective, as noted in Avraham R. "Private Regulation," *Harvard Journal of Law & Public Policy*, 34(2):543–638, 2009.

[2] Eddy DM, Adler A, Patterson B et al. "Individualized Guidelines: The Potential for Increasing Quality and Reducing Costs." *Annals of Internal Medicine*, 154(9):627–634, 2011.

[3] Millenson ML. *How Can We Move Clinical Genomics Beyond the Hype?* Washington, DC: The Urban Institute, 2011, *www.urban.org/publications/412426.html* (accessed February 2012).

[4] Eddy DM et al (see note 2 above); Lumpkin JR. "Archimedes: A Bold Step Into the Future." *Health Affairs*, 26(2):w125–36, 2007; Archimedes, Inc. "About Archimedes Inc.," *http://archimedesmodel.com/company* (accessed February 2012).

[5] Eddy DM. "Practice Policies: Where Do They Come From?" *Journal of the American Medical Association*, 263(9):1265–1275, 1990.

There has been less activity on the federal legislative front,[22] but the safe-harbor concept has made it onto the short list of promising malpractice reforms that go beyond caps and other simple limits on traditional tort liability. For example, both bipartisan deficit reduction commissions of 2010 supported safe harbors for adherence to guidelines, along with other reforms.[23]

Moreover, the Obama administration has actively promoted experimentation with patient safety liability reforms. It funded the state of Oregon's guidelines and safe-harbor project.[24] The president's fiscal year 2012 budget sent to Congress in February 2011 proposed a new, larger round of grants for states to develop reforms, specifically focused on safe harbors and two other ideas supported by the deficit reduction commissions.[25] (No state currently has operational safe harbors; they drew much interest in the late 1980s and early 1990s. Maine and three other states tried them to limited extents, after which they fell into disuse or were repudiated.[26])

How Can Guidelines Protect Providers?

The safe-harbor idea is conceptually simple: If practitioners feel that liability exposure prevents them from practicing what they know to be good medicine and makes them instead overutilize low-value services, then good practice needs to be protected against lawsuits. Those who are not practicing good, evidence-based care need help and encouragement to do so.

Following trustworthy guidelines should almost by definition improve medical quality and patient outcomes. And promulgated guidelines are immediately knowable, so that clinicians can rely upon the guidelines in caring for current patients.[27] Guidelines are already admissible in liability cases,[28] to bolster one side's expert in-person testimony or the other's. But today's "plethora of often-conflicting recommendations produced by multiple organizations"[29] undercuts the persuasiveness of any one guideline, so results are still governed by unpredictable jury decisions that foster defensiveness.[30]

Going forward, better evidence and more authoritative guidelines could justify making them safe harbors. Legislation would be necessary, as the hundreds of state appellate courts that create tort law cannot be expected to adopt such a new rule on their own, and certainly not uniformly.[31] The statutes would need to specify the standards to be met for a guideline to qualify for safe-harbor status and also what legal effect that status would have in litigation.

For example, the Healthy Americans Act proposed in 2009 by Senator Ron Wyden (D-Ore.) called for guidelines to serve as "rebuttable presumptions" that care was not negligent.[32] This means that a defendant could theoretically win without presenting any other evidence. Instead, the plaintiff would need to rebut the presumption with expert evidence of their own to convince a jury that medical services had been substandard (judges rule on who constitutes an expert).

Such a presumption does little to increase the practical influence of guidelines in litigation. To proceed with a liability case, claimants must already have expert testimony that services were negligent, which a jury could believe over the presumption. In practice, defendants must therefore actively defend their conduct with their own experts. Defense experts are also needed to introduce guidelines as evidence, explain why they are authoritative, and show how they apply to the facts of the particular case.

The word "safe" in "safe harbor" suggests stronger legislation, to make guidelines *conclusive* evidence of appropriate care. This would go farther than Maine's legislation or Senator Wyden's bill.[33] If safe harbors created an *irrebuttable* presumption, plaintiffs simply could not contend that the guidelines are wrong and that a jury should instead believe a different standard articulated by an expert witness.

Federal legislation in 1972 did something like this. It created Professional Standards Review Organizations (PSROs) as authoritative bodies to set standards for the appropriateness of care paid for by Medicare and protected physicians from later lawsuits for not doing more. The intended guidelines were denigrated as "cookbook medicine" and were not promulgated, but the statutory authority remains for today's Quality Improvement Organizations, the successors to PSROs.[34]

How Would Guidelines as Safe Harbors Prevent Defensive Medicine?

The theory of safe harbors seems sound, as far as it goes. The need for better incentives to practice appropriately is certainly clear, as improvements from research can take a long time to diffuse into general practice.[35] Moreover, medical professionals' vociferousness about defensive medicine suggests that legal incentives are strong enough to help motivate change. Safe-harbor rules hold promise for realigning legal incentives with good medical practice

and promoting fast uptake of proven modes of care.

Guidelines could help reduce disputation not only at trial, but also well before. At the time of service, guidelines could help a caregiver explain to a patient why doing less is appropriate and incidentally could signal that the physician has accepted a form of accountability to independent authority and is not just cutting corners. Should patients nonetheless seek out lawyers to bring suit, an applicable guideline would help the attorneys screen out inappropriate cases—which they are well motivated to do. Even if a lawsuit is still filed, guidelines may shorten the uncertain and unpleasant period of "discovery" during which all the lawyers in a case test out the strengths and weaknesses of their case—and that of their opponents.

Guidelines are meant to constitute very strong evidence, even conclusive evidence, that guideline-compliant care is not *negligent*. They do not address what *damages* resulted from the injury, which are the focus of caps and similar tort reforms. Other reforms thus operate quite independently of guidelines, so guidelines could reform liability determinations with or without any reform to rules on payments.

What Challenges Arise in Designing Safe-Harbor Protections?

Maine's experiment with safe harbors revealed a number of practical challenges. The state's 1990 legislation called on four specialty societies to create guidelines.[36] Development took about three years, and only a limited number were ever created. The promulgated guidelines were also often vague, with many exceptions.[37] Leaving such flexibility for responsible clinicians was not unusual; it simply reflected the state of the art at the time, and the 1992 IOM recommendations did the same.[38] Finally, the promulgated statutory guidelines were not used in many legal disputes. By the end of the decade, the enabling legislation was repealed.[39] Three other states that had shown lesser interest in trying out safe-harbor guidelines also ended their efforts.[40]

Moving forward to 2012, guidelines development has made huge strides. What in 1992 was seen as simple review of key literature by one or more experts has become "systemic reviewing," nearly a discipline in its own right. The 2011 IOM panel on guidelines felt empowered by such advances to set much higher standards for guidelines development. Nonetheless, the panel ended its review of recent history by conceding that clinical practice guidelines still "suffer from shortcomings in the guideline development process, often compounding limitations inherent in their scientific evidentiary bases."[41] Supporters of individualized guidelines also highlight shortcomings in the population-oriented guidelines proposed as safe harbors.[42]

In short, while guidelines' potential is great, much work remains before authoritative promulgation. Using guidelines as safe harbors will face challenges like the following:

It may not be technically feasible to create enough relevant and reliable guidelines fast enough to change medical practice any time soon. This observation may seem surprising, as so many guidelines already exist. To repeat, however, most existing guidelines are not trustworthy, and more precision is needed to develop a safe harbor.[43] Producing guidelines is also resource intensive and will become more so if IOM standards of trustworthiness are expected. One element of trust-building is securing support that is independent of potential conflicts of interest, yet much past effort has relied on interest group funding.

Keeping guidelines up-to-date is a parallel challenge: The speed of medical innovation may outpace the capacities of existing researchers and guideline writers. Not only must many new guidelines be created, but all will need periodic review and potential revision, which intensifies funding challenges.

Medicine has many gray areas not reachable by safe harbors: To be an effective safe harbor, a guideline must definitively indicate what care is to be given and what is not. However, statistical proof seldom creates a bright line between indicated and non-indicated care. Consider prevention guidelines. Strong evidence may support the screening of women above age X for condition A, and also not screening those below age Y. However, between the ages of X and Y, evidence may well be weak and conflicting. Gray areas may be created not only by imprecise scientific knowledge, but also by differences of opinion about, for example, how to value increments of additional knowledge gained by ever more elaborate testing. Such issues of valuation go beyond the scope of this brief.[44]

Popular or interest-group resistance to guidelines can be potent: Such objections may be able to derail guidelines at any stage—in the creation and promulgation of guidelines, even only advisory ones, in the enactment of legislation to make them safe harbors, or in guidelines interpretation by jurors. Many people simply do not agree with

IOM panels and authors of issue briefs that policy should be evidence-driven and that good research constitutes a better basis for clinical decisions than personal experience, practitioner opinion, or popular anecdotes.

One relevant example is that the federal Agency for Health Care Policy and Research was nearly defunded after it followed its legislative directive to create guidelines, some of which threatened the accustomed practices of politically potent medical specialists.[45] The agency survived as the Agency for Healthcare Research and Quality, but stopped issuing guidelines.[46] Another example is the more recent experience of the U.S. Preventive Services Task Force, which makes recommendations about what screening tests and other preventive modalities should routinely be used and paid in full by insurance. Two of the panel's guidelines provoked huge popular backlashes in 2009 and again in 2011. First, accumulated evidence led the panel to cease recommending routine cancer-screening mammography for women at younger ages, then, second, routine prostate cancer tests for men of any age.[47]

Vociferous objections made national news, coming not merely from affected medical specialists and manufacturers but also from lay opinion leaders.[48] Many opponents are convinced that the guidelines do not represent good science but are just trying to save money—unmollified by the contrary explanations of the task force or the lack of cost calculations in most underlying research.[49] Sometimes much simpler guidelines seem almost hardwired into belief structures: Prevention is always good, and more care is always better than less.[50]

Should Safe-Harbor Guidelines be Enforceable Only as "Shields" to Disprove Negligence, and Never as "Swords" to Show Substandard Care?

"Safe" implies that guidelines will fully protect against liability. A contentious issue is thus whether guidelines should put caregivers at new liability risk if they do not comply. Guidelines would clearly help plaintiffs attack under-serving by caregivers, in addition to over-serving. Such use of guidelines as swords rather than shields angers many clinicians. However, existing guidelines are already used in both ways.[51] Moreover, the logic of guidelines is that their safe-harbor status reflects their codification of best medical practice; and the logic of "best" is that less good can lie in more than one direction. Any defense-use-only version of safe harbors also seems less likely to win legislative enactment, as it could no longer constitute a centrist political compromise.

Even if barred from courtroom use, guidelines would still help plaintiffs' lawyers in other ways—for example, in finding expert witnesses to agree with the guidelines' recommendations. Similarly, attorneys and their experts' testimony can use a guideline's underlying systemic review to explain why care was negligent, without specific reference to any guideline. Once knowledge exists, its use can seldom be suppressed.

An important caveat applies here: guidelines can inculpate as well as exculpate. That is their nature because they are developed to determine the right type and amount of service to provide under given circumstances. Such quality promotion is what has engendered so much policy enthusiasm, but another approach exists—guidelines that use research findings to determine what specific types or levels of care are *excessive* because they are *unsupported* by evidence—what some call setting boundary conditions. Thus, a guidelines developer could say that in a particular case there is no evidence that one procedure (e.g., an MRI) achieves better population results than another (e.g., ordinary X-ray followed by watchful waiting in certain cases). Similarly, a drug dosage of X might be known to be beneficial, but one of 2X or higher could be detrimental. Thus, it may be necessary to emphasize the ceiling for appropriate care rather than the target of ideal care to create better safe harbors.

What Hurdles Will Affect the Application of Guidelines as Safe Harbors in Practice?

The targets of guidelines seem mismatched to the grounds of liability claims: Guidelines tell practitioners what plan of care they should choose, so they protect against claimed errors of planning, not of execution.[52] The planning-execution distinction resembles the classic legal dichotomy between errors of omission (e.g., delayed diagnosis from failure to conduct an indicated test) and errors of commission (e.g., a scalpel slipped in surgery). Most commentators on defensive medicine see extra testing as a classic example of defensiveness, and safe harbors most readily deal with allegations that it was negligent to omit such tests. However, although data are not strong, malpractice claims generally allege errors of commission of many different kinds.[53] So even if guidelines work precisely as intended where they

are applicable, the nature of safe harbors will leave many—likely most—lawsuits unaffected.

Finally, even where a guideline seems directly applicable (e.g., indicating that the correct test or radiology was performed), a claim can often be made that the guideline's suggested care was incorrectly executed (e.g., that a test was not performed timely). Similarly, one could argue that although the indicated X-ray was done, the result was ambiguous and should have been reviewed by a more specialized practitioner or followed up with a more sophisticated test.

There will always be battles over whether a particular patient's case should have been an exception to the general guideline: Guidelines themselves have routinely contained exceptions to their general recommendations, notably for special subpopulations or people with particular medical histories. Even if no exceptions are stated, a litigant might try to convince a judge that one must have been intended or should be imposed, in the same way that litigants try to influence how regulations or statutes are interpreted in various cases. The following well-known lawsuit provides a memorable example (see sidebar on *Helling v. Carey*).

Any litigant can demand to be treated as an exemption to a guideline's general rule. Because each case is heard separately, judges or juries lack comparative context within which to weigh the appropriateness of such a claim.[54] Similarly, the facts of what happened could be argued to differ from the circumstances specified in the guideline.

How often claimants will be able to claim an exception from a seemingly applicable guideline is not certain. One can surmise that the likelihood will be higher where a guideline is more advisory than prescriptive, where it itself acknowledges that underlying research evidence is not worthy of the highest score, or where it is vague rather than specific, leaving much wiggle room for later interpretation. If the case for individualizing guidelines progresses in the literature and in esteem among expert witnesses, that development will further facilitate courts' allowing exceptions to general, population-oriented safe harbors.

Judicial rulings could also prevent effective application of safe harbor rules for litigation: Plaintiffs can litigate the validity of safe harbors, which are not of their own making, unlike safe harbors in other areas of law.[55] Some courts might find safe harbors unconstitutional, just as caps on awards and other legislative limits on court-made tort doctrine have sometimes been invalidated.[56] Alternatively, judges might choose to interpret safe harbor legislation in a way that retains more traditional power for judges to control the law of tort.[57]

Safe harbors cannot keep caregivers completely safe from having to appear in court: Although guidelines may discourage most suits and provide a solid defense to those

Helling v. Carey[1]

The plaintiff in this 1974 decision argued that the defendant ophthalmologist had been negligent in not giving her a simple eye pressure test for glaucoma until it was too late to prevent her tunnel vision. The guideline-like prevailing standard of care at the time was to routinely test people seeking corrective lenses only if they were at least 40 years old. That standard was based on research showing that glaucoma affected 2 to 3 percent of older patients but only one person in 25,000 at younger ages; and the plaintiff was only about 23 when she first sought corrective lenses in 1963.

The trial judge instructed the jury that it must rule for the defendant if it found that there was such a medical standard, essentially making it a completely safe harbor.[2] The jury complied, and the plaintiff lost at trial, then again on appeal. However, the state's Supreme Court reversed the lower courts, in a much-discussed ruling.

One might think that the reason for not following the guideline absolutely would have been that the plaintiff had repeatedly returned seeking help for eye pain until the age of 32. This could easily have fit within a recognized exception to the general rule, which did "require pressure tests if the patient's complaints and symptoms reveal to the physician that glaucoma should be suspected."[3] The state's Supreme Court instead went much further, ruling that the medical standard was irrelevant: Ordinary prudence alone required the provision of a safe, reliable, and inexpensive test where the condition tested for was so harmful.

---

[1] 83 Wash.2d 514, 519 P.2d 981, 67 A.L.R.3d 175 (1974, Supreme Court of Washington).
[2] The actual 1974 legal ruling overturned the traditional judicial rule that medical custom sets the standard of care. However, the practice on glaucoma testing was universal, effectively amounting to an authoritative guideline.
[3] *Helling v. Carey* (see note 1 above) Wash.2d at p. 516, P.2d, at p. 982.

brought, defendants may still have to go to court to assert that defense. Safe harbors cannot provide the complete immunity from suit in malpractice cases that they can elsewhere. For instance, the Office of Inspector General of the Department of Health and Human Services has absolutely guaranteed hospitals it will not challenge their subsidies of physicians' obstetrical malpractice insurance in underserved areas as illegitimate kickbacks.[58] The enforcement agency has thus promised not even to begin proceedings.

However, patients make no such promise about safe harbor guidelines; and any one of them can sue, and then hold out for a trial. There, defendants will have to prove, at a minimum, that the guideline is authoritative and that the facts of their case match its specifications. This prospect may not commonly occur, but it needs to be mentioned because medical practitioners so greatly detest appearing in court.

How Much Could Safe-Harbor Guidelines Reduce Medical Overspending?

Research suggests that caps and other limits reduce medical spending by somewhat under 1 percent.[59] However, no good research shows just how various liability exposures translate into defensive actions. Yet policy analysis still needs to assess how well nonconventional reforms like safe harbors would work. As a start, the following observations seem relevant.

Guidelines could somewhat reduce liability exposure and fear, but less than the strongest conventional limits: Caps and other limits are known and trusted by doctors—whatever their policy merits—whereas guidelines are novel and untrusted. Guidelines thus seem apt to have less influence than caps. Moreover, caps, limits on time to bring suit, and the like apply *across the board*, to all cases. In contrast, guidelines by definition target very specific circumstances, *only a fraction* of all claims. Caps are the strongest conventional reform, and although they might seem to apply only to a small subset of very large claims, behaviorally caps also affect smaller cases because they reduce plaintiff lawyers' negotiating leverage. With caps, they can no longer credibly threaten to win very large awards at trial. There is no such spillover impact beyond the specific targets of guidelines.

Caps not only lower liability premiums, as all proponents note, but they also provide another extremely valuable but little-appreciated benefit: Caps greatly reduce the probability that even a single award could exceed the limits of a doctor's liability coverage and put the doctor into bankruptcy.[60] That is a very powerful threat, and guidelines provide much less thoroughgoing protection.

Defensiveness is partly engendered by generalized fears, and hence may be little affected by specific guidelines: Some amount of defensiveness seems to derive from vague fears about the unpredictability, and power, of an ever-evolving U.S. tort system. Substantial unpredictability and occasional sudden change is inherent in a system of personal-injury rules created by judges and administered by juries listening to idiosyncratically chosen experts. Where even one case may have career-ending potential, some defensiveness seems independent of the specific tort regime and frequency of litigation where a caregiver practices.

One suggestive indicator of this phenomenon is that the level of legal fear reported by surveyed physicians tends to be similar across states, in large part independent of their varying legal climates.[61] Certainly, the popular medical press and specialist liability newsletters rapidly give national dissemination to any single state's unfavorable results, raising fears in jurisdictions wholly untouched by the actual law (favorable legal rulings seem less newsworthy). One often hears of a Connecticut case while interviewing an informant in Colorado, for example.[62] Safe harbors would not address such generalized fears, only identified types of low-value services. Full insulation from liability would require comprehensive reform that replaces it with a new and different system of dispute resolution and compensation—a topic beyond the scope of this brief.

Even without defensiveness, other strong pressures encourage overservice: Defensiveness is not the single root cause of overutilization. Other influences come from medical practitioners, patients, and social culture, including the fear of bad publicity, professional perfectionism, and peer pressure.[63] Consumer demand can lead to overservice, if only for reassurance. Fee-for-service insurance payment, at favorable prices, is an important enabling factor for both providers and patients.[64]

Liability interacts with such other influences. Sometimes consumers pressure physicians for extra care that professionals consider excessive. For such patients, an implicit threat to sue is a useful "club" for getting what they want. Other times, physicians prescribe care that patients do not value. For such clinicians, liability

may constitute a convenient rationalization to provide the care, assuming that insurance payment makes the service free for the uninterested patient. Conjoined with all of these influences is a general societal belief that more is better—held not just by doctors, but also by patients, judges, and jurors. These multiple causes of overutilization suggest that liability reforms would be most useful if conjoined with other reforms that target overservice.

Concluding Discussion

Defensive overutilization is a real problem, and guidelines as legal safe harbors appear to offer a partial solution. Beyond their face validity as a liability fix lie a number of problems for safe harbors. Not all care is amenable to the creation of guidelines, and there are practical limits on how many guidelines can be created and how quickly. Implementing guidelines as a safe-harbor legal defense also faces challenges. Consequently, legislated safe harbors are unlikely to contribute much in the near term to bending the curve of increasing medical spending.

By their nature, the quality-promoting guidelines now in vogue mainly provide guidance on what typically constitutes the best care for an entire population. Accordingly, they seem most suited to applications where they can be applied in an aggregate fashion. For example, it seems relatively easy to use guidelines as benchmarks for reducing payment to practitioners whose usage of diagnostic imaging far exceeds the applicable guideline. It is much harder to use a guideline to deny care to a particular patient, who can always argue that their case is an exception to the general rule. Malpractice cases always focus on an individual—a Ms. Helling and all her particulars—not on a general population in the fashion of systematic research reviews and guidelines. Moreover, if the emerging paradigm that guidelines should be replaced with individualized advice takes hold, its rationale may also encourage assertions that a particular case should be seen as an exception to a general guideline.

To better reduce defensiveness by defending against assertions that not enough was done, guidelines may well need to set *ceilings* of reasonableness beyond which care is clearly inappropriate, not *targets* for all care to meet. This appears to be a less common goal of scientific guideline production, and if done would by definition apply only to a subset of cases.

Safe harbors also seem most likely to be useful as adjuncts to other interventions that target overutilization, whether driven by consumer education or incentives, provider risk-sharing, health plan controls, or government directives. Then the legal protection simply makes compliance with the other effort more likely. The safe harbor does not have to carry the full load of changing behavior by itself. A utilization ceiling for payment, plus legal protection, was the approach taken by 1972 PSRO legislation for Medicare, a tactic worth another look.[65] In any case, no single silver bullet can cure defensive overutilization because the tendency to gold-plate care is driven by many factors.

Finally, to succeed in reducing defensiveness and overutilization, guidelines need to win popular support. Invocation of scientific authority alone will likely fall short, both in doctors' offices and in courtrooms. This seems clear from the recent firestorms of consumer protest over guidelines for mammography screening and prostate cancer tests. People can be told to apply guidelines but find a way around them if they lack popular legitimacy or seem to cut corners.

Conversely, better informed and motivated patients might more often seek out evidence-based guides on their own. Then, popular media could have a larger role to play than legal reform. *Newsweek*'s teaching readers when to say "no" to more medicine[66] may reach more patients and jurors than safe-harbor legislation. Over time, more general use of scientifically valid guidelines, especially as ceilings, may alter the more-is-always-better bias of many Americans, whether caregivers, patients, or jurors. Then, guidelines will naturally move into the courtroom, as a familiar and accepted influence on standards of care. Such evolution lacks the quick-fix appeal of legislation, but seems likely to be more influential and sustainable.

Regardless of the fate of guidelines as safe harbors, it remains important to press forward with generating good, evidence-based advice for clinicians and patients. Over time, it will become increasingly important for cost to be included in the evidence base as well. Then guidelines could protect against stinting as well as overutilization.

The views expressed are those of the authors and should not be attributed to the Robert Wood Johnson Foundation, or the Urban Institute, its trustees, or its funders.

About the Authors and Acknowledgments

Randall R. Bovbjerg, JD, is a senior fellow and Robert A. Berenson, MD, is an institute fellow at the Urban Institute. The authors thank Brian K. Atchinson, P. Divya Parikh, David W. Shapiro, and Lawrence E. Smarr for their helpful comments and suggestions. This research was funded by the Robert Wood Johnson Foundation.

About the Urban Institute

The Urban Institute is a nonprofit, nonpartisan policy research and educational organization that examines the social, economic, and governance problems facing the nation.

About the Robert Wood Johnson Foundation

The Robert Wood Johnson Foundation focuses on the pressing health and health care issues facing our country. As the nation's largest philanthropy devoted exclusively to health and health care, the Foundation works with a diverse group of organizations and individuals to identify solutions and achieve comprehensive, measurable and timely change. For 40 years the Foundation has brought experience, commitment and a rigorous, balanced approach to the problems that affect the health and health care of those it serves. When it comes to helping Americans lead healthier lives and get the care they need, the Foundation expects to make a difference in your lifetime. For more information, visit *www.rwjf.org*.

Notes

[1] The Omnibus Budget Reconciliation Act of 1989 directed the Agency for Health Care Policy and Research to develop guidelines and asked the Institute of Medicine to help define the methodology. See Field MJ and Lohr KN (eds). *Guidelines for Clinical Practice: From Development to Use.* Washington, DC: National Academy Press, 1992.

[2] Section 2713 (Coverage of Preventive Health Services), Patient Protection and Affordable Care Act, Public Law 111–148, 124 Stat. 119-1025, 2010, gives the responsibility to the U.S. Preventive Services Task Force, an independent entity supported by the Agency for Healthcare Research and Quality, *www.ahrq.gov/clinic/uspstfix.htm* (accessed February 2012).

[3] Schuster MA, McGlynn EA and Brook RH. "How Good Is the Quality of Health Care in the United States?" *Milbank Quarterly*, 76(4):517–563, 1998.

[4] Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the Twenty-first Century.* Washington, DC: National Academy Press, 2001. For other work of the IOM Committee on Quality of Health Care in America, see *www.nap.edu/catalog.php?record_id=12610* (accessed February 2012).

[5] Chassin MR. "Quality of Care: Time to Act." *Journal of the American Medical Association*, 266(24):3472–3473, 1991.

[6] Eden J, Levit L, Berg A et al (eds). *Finding What Works in Health Care: Standards for Systematic Reviews*. Washington, DC: National Academies Press, 2011; Graham R, Mancher M, Wolman DM et al (eds). *Clinical Practice Guidelines We Can Trust*: *Committee on Standards for Developing Trustworthy Clinical Practice Guidelines*. Washington, DC: National Academies Press, 2011. The reports were called for by the Medicare Improvements for Patients and Providers Act of 2008, Public Law 110-275, July 15, 2008. Additional translation and integration into decision support tools may be needed to make guideline effective, as noted in Avraham R. "Private Regulation." *Harvard Journal of Law & Public Policy*, 34(2):543–638, 2009.

[7] Young PL, Saunders RS and Olsen LA (eds). *The Healthcare Imperative: Lowering Costs and Improving Outcomes: Workshop Series Summary*. Washington, DC: National Academies Press, 2010.

[8] Ball JR. "Project, The Malpractice Threat: A Study of Defensive Medicine." *Duke Law Journal*, 1971:939–993. Extra tests constitute "positive" defensive medicine, which is the focus of safe-harbor guidelines. "Negative" defensive medicine means omitting valuable care out of liability fears, such as giving up obstetrical practice. See also U.S. Department of Health, Education and Welfare. *Report of the Secretary's Commission on Medical Malpractice.* Pub. No. (OS) 73-88, Jan. 16 (Washington, DC: DHEW, 1973), p. 14.

[9] Physician Insurance Association of America. *Aortic Disease Claims Study: Special Focus on Aortic Aneurysm and Aortic Dissection.* Rockville, MD: PIAA, 2011. Legal doctrine applicable in many states allows damages for even the "loss of a chance" of successful treatment. See "Tort Law—Loss of a Chance Doctrine—Massachusetts Supreme Judicial Court Accepts Loss of a Chance in Medical Malpractice Suits.—Matsuyama v. Birnbaum, 890 N.E.2d 819 (Mass. 2008)." *Harvard Law Review*, 122(4):1247–1254, 2009.

[10] U.S. Congress, Senate Committee on Government Operations, Subcommittee on Executive Reorganization. *Medical Malpractice: The Patient Versus The Physician*. 91st Cong., 1st Session. Washington, DC: U.S. Government Printing Office, 1969.

[11] Office of Technology Assessment, U.S. Congress. *Defensive Medicine and Medical Malpractice*. OTA-H-602, Washington, DC: U.S. Government Printing Office, July 1994, *www.wws.princeton.edu/ota/disk1/1994/9405/9405.pdf* (accessed February 2012); Congressional Budget Office. *Medical Malpractice Tort Limits and Health Care Spending*. Pub. No. 2668. Washington, DC: Congressional Budget Office, 2006.

[12] Califano J Jr. "Billions Blown on Health," *New York Times*, Wednesday, April 12, 1989, p. A25.

[13] Congressional Budget Office. "Letter to Sen. Orrin G. Hatch," October 9, 2009, *www.cbo.gov/ftpdocs/106xx/doc10641/10-09-Tort_Reform.pdf* (accessed February 2012). The CBO estimated savings from new federal tort reform of about half of 1 percent, but that omits similar savings already achieved by state reforms.

[14] Sloan FA and Shadle JH. "Is There Empirical Evidence for 'Defensive Medicine'? A Reassessment." *Journal of Health Economics*, 28(2):481–91, 2009.

[15] Office of the Assistant Secretary for Planning and Evaluation. *Confronting the New Health Care Crisis: Improving Health Care Quality and Lowering Costs by Fixing our Medical Liability System*. Washington, DC: Department of Health and Human Services, 2002, *http://aspe.hhs.gov/daltcp/reports/litrefm.pdf* (accessed February 2012).

[16] Daschle T and Nather D. *Getting It Done: How Obama and Congress Finally Broke the Stalemate to Make Way for Health Care Reform*. New York, NY: Thomas Dunne Books/St. Martin's Press, 2010.

[17] Democrats continue to see tort limits as unfair, while Republicans see them as curbs needed to rein in legal excesses and continue to promote limits, as in the Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2011, H.R. 5, January 24, 2011, *http://thomas.loc.gov/cgi-bin/bdquery/z?d112:h.r.5:#* (accessed February 2012).

[18] American Medical Association. "President Obama's address to the AMA." (Presented at the 2009 Annual Meeting of the AMA House of Delegates, Chicago, IL, June 15, 2009), *www.ama-assn.org/ama/pub/news/speeches/obama-speech-2009-annual.page* (accessed February 2012).

[19] Daschle T and Nather D (see note 16 above).

[20] American Academy of Orthopaedic Surgeons. *Position Statement: Medical Liability Reform.* Position Paper, No. 1118. Rosemont, IL: AAOS, *www.aaos.org/about/papers/position/1118.asp* (accessed February 2012).

[21] Orszag P. "Malpractice Methodology," *New York Times*, Thursday, October 21, 2010, p. A39, *www.nytimes.com/2010/10/21/opinion/21orszag.html* (accessed February 2012); Avraham R. "A Market Solution for Malpractice," *New York Times*, Tuesday, March 29, 2011, p. A31, *www.nytimes.com/2011/03/29/opinion/29Avraham.html* (accessed February 2012); Blumstein JF. "Medical Malpractice Standard-Setting: Developing Malpractice 'Safe Harbors' as a New Role for QIOs?" *Vanderbilt Law Review*, 59(4):1017–1049, 2006.

[22] Safe harbors are not a prominent legislative proposal. The February 2009 health reform proposal of Senator Ron Wyden (D-Ore.) did call for state-level malpractice reforms, including a safe harbor provision, Healthy Americans Act, S.391, 111th Cong. (2009), sect. 712. However, the Senate bill that became the Affordable Care Act (see note 2 above) specifically denied seeking any substantive change in medical liability, even in authorizing state experimentation, sec. 399V–4. Similarly, the House-passed version of federal health reform, the Affordable Health Care for America Act, 111th Cong. (2009), H.R. 3962, also included a "savings clause for state medical malpractice laws," sect. 261(c), assuring that nothing in the bill was meant to alter state medical liability law. Republicans in both houses continue to promote only conventional tort reform, notably the HEALTH Act of 2011 (see note 17 above).

[23] Debt Reduction Task Force. *Restoring America's Future*. Washington, DC: Bipartisan Policy Center, 2010, co-chaired by Sen. Pete V. Domenici (R-N.M., 1973-2009) and Alice M.

Rivlin, PhD (D-D.C., first Director of CBO, 1975-83), *www.bipartisanpolicy.org/projects/debt-initiative/about* (accessed February 2012); National Commission on Fiscal Responsibility and Reform. *The Moment of Truth: Report of the National Commission on Fiscal Responsibility and Reform*. Washington, DC: Executive Office of the President, 2010, co-chaired by Erskine Bowles (D-N.C., White House Chief of Staff 1997–98) and Sen. Alan K. Simpson (R-Wyo., 1979-97), *www.fiscalcommission.gov/sites/fiscalcommission.gov/files/documents/TheMomentofTruth12_1_2010.pdf* (accessed February 2012).

[24] Agency for Health Care Research and Quality. "Medical Liability Reform and Patient Safety, Planning Grants," June 2010, *www.ahrq.gov/qual/liability/planninggrants.htm* (accessed February 2012); Office for Oregon Health Policy and Research. "Overview of the Agency for Healthcare Research and Quality's Medical Liability Reform and Patient Safety Planning Grant," April 14, 2011, *www.oregon.gov/OHA/OHPR/GRANT/docs/MedLiabGrantOverview_4.14.11.pdf* (accessed February 2012).

[25] The $250 million new grants program, if ever enacted by Congress, will be run by the Department of Justice in conjunction with the Department of Health and Human Services. The dollar amount is a line item in the budget. Details appear in Department of Justice. *FY 2012 Performance Budget, Office of Justice Programs*. February 2011, pp. 180–182, *www.justice.gov/jmd/2012justification/pdf/fy12-ojp-justification.pdf* (accessed February 2012). The Affordable Care Act also contained a provision providing for state demonstrations, although with very restrictive provisions. These proposals went unimplemented; see Norman B. "Malpractice reform efforts stalled," *Politico*, Monday, November 7, 2011, *www.politico.com/news/stories/1111/67780.html* (accessed February 2012).

[26] The policy climate of two decades ago is well described in Hall MA. "The Defensive Effect of Medical Practice Policies in Malpractice Litigation." *Law and Contemporary Problems*, 54(2):119–145, 1991. Maine, Florida, Minnesota, and Vermont had plans to create safe harbors in the early 1990s. See U.S. Government Accountability Office. *Medical Malpractice: Maine's Use of Practice Guidelines to Reduce Costs*, October 1993, *http://archive.gao.gov/t2pbat5/150172.pdf* (accessed February 2012). All four states dropped their efforts by late in the decade, according to Mello MM and Kachalia A. *Evaluation of Options for Medical Malpractice System Reform*, Medicare Payment Advisory Commission, No. 10–2, April 2010, *www.medpac.gov/documents/Apr10_MedicalMalpractice_CONTRACTOR.pdf* (accessed February 2012).

[27] Professor Blumstein (see note 21 above), among others, emphasizes this aspect of guidelines.

[28] Hall MA (see note 26 above); Recupero PR. "Clinical Practice Guidelines as Learned Treatises: Understanding Their Use as Evidence in the Courtroom." *Journal of the American Academy of Psychiatry and the Law*, 36(3):290–301, 2008.

[29] Graham R et al (eds) (see note 6 above), p. 21.

[30] Kelly DC and Manguno-Mire G. "Commentary: *Helling v. Carey*, Caveat Medicus." *Journal of the American Academy of Psychiatry and the Law*, 36(3):306–9, 2008.

[31] For a longer argument on this point, see Hall MA (see note 26 above); the collectivity of judicial precedents is known as the "common law."

[32] Healthy Americans Act (see note 22 above), sect. 712. Specifically, states were to be rewarded for enacting tort reforms that create a "presumption of reasonableness" for a board-certified defendant's adherence to a guideline of their specialty society or listed in the National Clearinghouse, unless "rebutted by a preponderance of the evidence" presented by the plaintiff.

[33] The Maine legislation allowed participating doctors to use the guidelines created by four state specialty societies as an affirmative defense, see Hall MA (see note 26 above); the former *Maine Revised Statutes Annotated*, chapter 24, sec. 2971–2978 (1990) were repealed in 1999; Maine Revised Statute Title 24: Insurance Subchapter 9: Medical Liability Demonstration Project, p. 145, *www.mainelegislature.org/legis/statutes/24/title24.pdf* (accessed February 2012).

[34] See Blumstein JF (note 21 above) and the sources that it cites.

[35] A frequently cited lag is 17 years, mentioned for example in President Obama's 2009 speech to the AMA (see note 18 above), and the IOM volume on quality (see note 4 above), p. 13. The original source for this statistic is frequently attributed to Andrew BE and Boren SA. "Managing Clinical Knowledge for Health Care Improvement," pp. 65–70 in *Yearbook of Medical Informatics 2000: Patient-Centered Systems*, Bemmel J and McCray (eds). Germany: Schattauer Verlagsgesellschaft mbH, 2000. But diffusion can occur much more quickly, see Docteur E and Berenson RA. "How Will Comparative Effectiveness Research Affect the Quality of Health Care?" Quick Strike Series, Timely Analysis of Immediate Health Policy Issues. Princeton, NJ: Robert Wood Johnson Foundation, February 2010, *http://rwjf.org/pr/product.jsp?id=55759* (accessed February 2012).

[36] U.S. Government Accountability Office (see note 26 above). For example, one guideline for anesthesia provided that "These standards may be exceeded at any time based on the judgment of the responsible anesthesiologist."

[37] U.S. Government Accountability Office (see note 26 above); see anesthesia guideline number 3 at p. 44.

[38] Field MJ and Lohr KN (see note 1 above).

[39] Personal communication from Brian K. Atchinson, then the state's insurance commissioner.

[40] Mello MM and Kachalia A (see note 26 above) reviewed this experience, but evidently had little documentation to work from and provided only limited detail about what happened and why. Minnesota, for one, not only failed to implement safe harbors, but also enacted legislation specifically outlawing their use in liability cases.

[41] Graham R et al (eds) (see note 6 above), p. 2.

[42] Eddy DM, Adler A, Patterson B et al. "Individualized Guidelines: The Potential for Increasing Quality and Reducing Costs." *Annals of Internal Medicine*, 154(9):627–634, 2011, especially discussion of their references 3–5.

[43] Relman AS. "Medical Guidelines and Malpractice," *New York Times*, Saturday, October 23, 2010, p. A20, *www.nytimes.com/2010/10/23/opinion/l23orszag.html* (accessed February 2012); Shiffman RN. "Quest for a Gold Standard for Guideline Development." (Presented to IOM Committee on Developing Trustworthy Clinical Practice Guidelines, Washington, DC, November 9, 2009), *www.iom.edu/Activities/Quality/ClinicPracGuide/2009-NOV-09/Agenda.aspx* (accessed February 2012).

[44] Most commentators on defensive medicine believe that it includes low-value services as well as useless or wasteful services engendered by legal fears. Differences of opinion on what constitutes low- as against acceptable-value services may be better handled by policymaking on benefits or on payment methods, or by utilization review or patient preference under tiered benefits than by malpractice law, but safe harbors might make it easier to implement such different forms of oversight.

[45] Field MJ and Lohr KN (see note 1 above).

[46] Gray BH, Gusmano MK and Collins SR. "AHCPR and the Changing Politics of Health Services Research: Lessons from the Falling and Rising Political Fortunes of the Nation's Leading Health Services Research Agency." *Health Affairs*, (Suppl.):w3-283–307, June 2003, *http://content.healthaffairs.org/cgi/content/full/hlthaff.w3.283v1/DC1* (accessed February 2012).

[47] Kaplan K. "Three Thoughtful Critiques of the Recommendation Against PSA Testing," *Los Angeles Times' Booster Shots*, October 26, 2011, *http://articles.latimes.com/2011/oct/26/news/la-heb-psa-prostate-cancer-screening-20111026* (accessed February 2012); Kolata G. "Panel Urges Mammograms at 50, Not 40," *New York Times*, November 17, 2009, *www.nytimes.com/2009/11/17/health/17cancer.html* (accessed February 2012).

[48] Milken M. "Why Block a Cancer Test That Saves Lives?" *Washington Post*, Tuesday, October 11, 2011, *www.washingtonpost.com/opinions/why-block-a-cancer-test-that-saves-lives/2011/10/10/gIQAzybedL_story.html* (accessed February 2012).

[49] The Task Force explains its own standards: "Although opportunity costs may be considered in the Task Force's letter grades, financial costs are not. The Task Force understands, however, that many of its audiences are interested in issues of financial cost. In situations where there is likely to be some degree of health benefit, the Task Force searches for information about costs and cost-effectiveness and provides a summary of this information under 'Other Considerations' in its recommendation statement." See U.S. Preventive Services Task Force. *U.S. Preventive Services Task Force Procedure Manual*. AHRQ Publication No. 08-05118-EF, July 2008, *www.uspreventiveservicestaskforce.org/uspstf08/methods/procmanual.htm* (accessed February 2012).

[50] One popular Internet source of consumer health advice comments on the lay public's "almost magical thinking" about mammograms is Polaneczky P. "Breast Health in 2010 and Mammogram Guidelines – What You Need to Know," Better Health Network, January 2010, *http://getbetterhealth.com/breast-health-in-2010-and-mammogram-guidelines-what-you-need-to-know/2010.01.02* (accessed February 2012).

[51] Hyams AL, Brandenburg JA, Lipsitz SR et al. "Practice Guidelines and Malpractice Litigation: A Two-Way Street." *Annals of Internal Medicine*, 122(6):450–455, 1995; Mello MM. "Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation." *University of Pennsylvania Law Review*, 149(3):645–710, 2001. We use the familiar images of shield and sword somewhat reluctantly, as the usage seems subtly misleading. Guidelines are not inherently either defensive or offensive, but both at the same time. The law's terminology of "exculpatory" vs. "inculpatory" may sound unduly legalistic, but it may more accurately convey that the two ways to use guidelines are two sides of the same coin.

[52] An IOM landmark treatise explains, "error is defined as [either] the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (e.g., error of planning)." Institute of Medicine. *To Err Is Human*. Washington, DC: National Academies Press, 2000, p. 45.

[53] Knowledgeable observers often believe that half or more of malpractice cases involve active mistakes of commission, thus mainly outside the reach of guidelines. Supportive early data exist in Sowka MP (ed). *Malpractice Claims: Final Compilation—Medical Malpractice Closed Claims, 1975–1978*. Brookfield, WI: National Association of Insurance Commissioners, 1980, p. 455, Table 6.8. See also Danzon P. *Medical Malpractice: Theory, Evidence, and Public Policy*. Cambridge, MA: Harvard University Press, 1985, pp. 25–28 (assessing 1977 California study findings that "problems of performance" are "overwhelmingly" the responsible mechanism for claims). More recent closed claims data from the Physician Insurers Association of America show that during 1985 to 2010, the largest single category of all claims and of paid claims was "improper performance," an allegation unlikely to be affected by guidelines. "Diagnostic error" is the second-largest category, with about 20 percent fewer claims, but it is unclear to what extent such alleged errors come from omitting tests or imaging (which might be affected by a guideline) as against incorrectly interpreting a such tests or images (not affected). See Physician Insurers Association of America. *Risk Management Review*, July 27, 2011.

[54] Moreover, the incidence of exceptions could be expected to be much higher among litigants than in the general population of patients, since they are selected specifically for their likelihood of winning their lawsuits.

[55] We owe this insight to our colleague Jonathan Sunshine.

[56] Nelson LJ 3rd, Morrisey MA and Kilgore ML. "Damages Caps in Medical Malpractice Cases." *Milbank Quarterly*, 85(2):259–86, 2007.

[57] See *Gates v. Jensen*, 92 Wash 2d 296, 595 P.2d 919 (1979). Interpreting away a statute meant to overturn the court's prior holding in the *Helling v. Carey* case (see textbox on page 6).

[58] See Code of Federal Regulations, vol. 42, §1001.952(o), *www.access.gpo.gov/nara/cfr/waisidx_01/42cfr1001_01.html* (accessed February 2012).

[59] Congressional Budget Office (see note 13 above).

[60] "It only takes one multi-million dollar lawsuit to eliminate my ability to provide for my family," emphasized one physician quoted in Kavilanz P. "Doctors: 5 gripes about the health law," CNNMoney, April 21, 2010, *http://money.cnn.com/2010/04/21/news/economy/health_legislation_factcheck_doctor_gripes* (accessed February 2012).

[61] Jena AB, Seabury S, Lakdawalla D et al. "Malpractice Risk According to Physician Specialty." *New England Journal of Medicine*, 365(7):629–36, 2011.

[62] Varnon R. "Jury awards $58M malpractice suit against doctor," *Stamford (Conn.) Advocate*, Wednesday, May 25, 2011, *www.stamfordadvocate.com/news/article/Jury-awards-58M-malpractice-suit-against-doctor-1395684.php* (accessed February 2012).

[63] On the malpractice context see Ball JR (note 8 above); on overuse generally see Emanuel EJ and Fuchs VR. "The perfect storm of overutilization." *Journal of the American Medical Association*, 299(23):2789–2791, 2008.

[64] Change in the unit of payment, the amount of payment, or the oversight of payouts could make defensive practice less rewarding for medical providers. Such policy changes and safe harbors would be mutually reinforcing, as noted in the concluding discussion. Full discussion of the various policy levers of incentives or controls from consumers, health plans, risk-sharing provider organizations, or government is beyond the scope of this brief.

[65] The enabling legislation is still in force, although PSROs have been renamed. See Blumstein JF (note 21 above).

[66] Begley S. "One Word Can Save Your Life: No! New Research Shows How Some Common Tests and Procedures Aren't Just Expensive, But Can Do More Harm Than Good," *Newsweek*, August 14, 2011, *www.thedailybeast.com/newsweek/2011/08/14/some-medical-tests-procedures-do-more-harm-than-good.html* (accessed February 2012).