Summary of Testimony

The Institute of Medicine’s To Err Is Human is a strong reminder of the extent of error in medicine and a promising conceptual blueprint for improving patient outcomes. Its general patient-safety approach is to de-emphasize blaming individuals for errors and injuries in the fashion of legal liability or professional discipline. Those systems probably help, but do not prevent the high level of avoidable error that many investigators have found.

Instead, errors can be reduced further by focusing on how systems within which individuals operate can help support good clinical decision-making and keep slips or lapses by caregivers from reaching patients and causing harm. Shielded from blame, individual practitioners are meant to communicate freely about problems, helping to find solutions through analysis of errors and development of fail-safes and other safeguards. Methods emphasize the positive of avoiding injury for patients and seek to actively support all practitioners to do ever better rather than penalizing a few of them for being substandard.

This is a very exciting development for protecting patients. Implementing these emerging approaches is a great challenge. One recommendation of the IOM panel was to encourage learning about safety from cross-institutional reporting systems for errors, which are now inhibited by fears that data will be discovered in liability lawsuits. Federal legislation is proposed to protect the voluntary reporting of ordinary injuries and "near misses"—errors that did not cause harm this time but easily could the next time. Not dissimilarly, aviation near misses are confidentially reported and can be analyzed by anyone. This seems a good idea, and for near-miss data, confidentiality would not deny liability claimants any information now available.

Another recommendation is to set national minimum standards for mandatory reporting to states of serious injuries and deaths from error in hospitals. These reports would not be confidential, unlike the typical existing state program. This recommendation is understandable as a quest to balance the patient-safety approach of confidentiality with the broader social demands for outside accountability. Too much openness could drive information underground, however. Current state reports seem to fall well short of estimated reportable problems. Further investigation of how well existing systems work seems appropriate, not immediate federal standards. In the meantime, progress can be made on the substantial work of developing a coherent framework for uniform reporting.

Outside pressure needs to be maintained on medical providers to improve, as complete voluntarism is unreliable. Without impacting the existing liability system one way or the other, quality standards, more demanding buyers of care, and regulators who emphasize patient safety principles could also help. Wherever possible, pressures should be positive in tone, emphasizing processes for improvement.

It’s premature as yet to impose mandates and sanctions. Better approaches will become feasible as more is learned about success.

Thank you for inviting me to testify today on "Medical Errors: Improving Quality Care of Care and Consumer Information." My testimony addresses voluntary and mandatory reporting of information about errors and associated confidentiality issues.

The Emergence of Patient Safety. Researchers on injury and liability issues have long recognized that medical injury and medical error occur too often. If they were a disease, they would have their own Institute at NIH. Moreover, injuries far exceed traditional efforts to fix them—medical peer review, regulatory
discipline, or legal liability and risk management. Fortunately, many injuries not prevented by current oversight systems nonetheless seem preventable.

Better prevention requires a new mix of information, motivation, and implementation. The big question now is what mix of policy tools can best address prevention in various medical settings, for various types of care and their characteristic problems. Observers and policy makers differ in their conceptualization of problems and in the emphasis they would put on different policy tools. I urge you today to consider that a multiplicity of tools may be appropriate, each in their own way, but that we proceed carefully and avoid working at cross purposes.

This hearing continues the lively debates sparked last November by the Institute of Medicine (IOM) report *To Err Is Human.* This book has performed an extremely valuable service. More successfully than any of the prior efforts on which it builds, the IOM panel has highlighted existing knowledge on the extent of preventable injury, mainly in hospital care. This alone has put patient safety higher on the policy agenda than ever before. This is an extremely exciting and important development.

Better yet, the book describes emerging methods of preventing medical errors from hurting patients and lays out a vision of patient safety as an alternative approach to error. The book focuses more on systems design and operation than on individuals. It emphasizes the manifold nature of errors and how prevention calls for developing and implementing a variety of techniques to identify problems and achieve solutions. It also seeks to de-emphasize retrospective blame finding as a policy tool in favor of front-end safety design, catching errors before they can reach patients, and building in self-monitoring and continuous improvement for the future.

In short, the IOM panel presents a very attractive vision of patient safety as a general approach, with specific examples from a few clinical areas. Actually getting clinicians and clinical managers to act in this fashion is a tall order. There are many real-world examples of significant progress, but there is a long way to go. Another tall order is balancing the social demand for external accountability with the prescription to downplay blaming. In short, more is known about problems than about what approaches to improvement works best. But that’s normal. The ability to diagnose problems always runs ahead of the ability to prescribe cures.

Speaking personally, my own research for twenty years addressed malpractice mainly as a matter of law and liability insurance. I wrote about how those systems perform, and how actual and proposed reforms affect that functioning. A particular interest has been no-fault alternatives, which have the potential for efficiencies as well as for sending clearer signals to practitioners about the extent and nature of medical injuries. It has long troubled me that medical-legal research has always found significant levels of preventable injury—starting with the first systematic study of medical injury and negligence in the early 1970s.

My own first project specifically on injury prevention began just two years ago. Since then, I’ve learned much more about the practical issues of making changes in clinical and administrative systems to protect patients. One very recent advance is that "patient safety" is now readily understood to mean protecting patients from medical injury in many ways. Only two years ago, even well informed clinicians and risk managers usually thought of "safety" as having to do with hazard-free premises—well lighted parking lots, non-slippery stairwells, clearly marked fire exits, and the like. "Risk management" usually meant defending against lawsuits and coping with other legal system demands on clinicians, like Medicare compliance issues. There was little attempt to actively address any factor that might hurt patients.

All this seems to be changing as some medical leaders are learning more about promoting safety, not just avoiding malpractice. Efforts are underway in many institutions across the country, not just hospitals but also large physician groups. This type of work is much more exciting in terms of direct improvements for patients than lots of debates I've been in about law and insurance or the pros and cons of tort reform.

**Learning from Reporting Systems across Institutions.** This morning, the main topic is the potential role for medical error reporting. Sharing information across sites through reporting can help build the knowledge base for improvement. One must start with information about how different types of medical errors occur and how they reach patients in order to begin to prevent them. Medical providers have important information—what clinicians knew and did or didn’t do, the circumstances of a case, the environment in which it occurred. One key to improvement is to be able to study occurrences, errors that led to injury or might have done so. Much can be learned by self study and literature review, especially in hospitals or large physician groups. Sometimes, however, larger scale is needed. Hence the interest in reporting systems to compile information on error in medicine.

Institutional care is the focus of most existing reporting systems and the IOM proposal—especially hospital care. It’s plausible that the need for more information is even greater for non-institutional care, where individual and small groups of practitioners lack the advantages of scale and scope of larger entities. Outpatient care is generally believed to have less potential to hurt patients than more complex hospital care for sicker patients. Still, "failure to diagnose" liability cases are among the more expensive claims, and there are also many issues of follow up and coordination of care among independent offices. Outpatient care, however, remains a raw frontier for safety development.

For the IOM panel, I and my colleague David Shapiro, an M.D., J.D. expert from California, examined some aspects of reporting systems. We researched a number of leading voluntary systems, concerns about their ability to maintain confidentiality, and what existing and potential legal protections could enhance confidentiality. We inevitably also learned about some mandatory programs, though with less detail. Our conclusions are fairly presented in chapter six of the IOM book (pp.94-113): Liability law gives broad scope to litigants to discover information relevant to their claims, or even that might lead to relevant information.
When quality-oriented information is kept confidential within a health care entity (mainly hospitals) and used for peer review purposes, it is typically not discoverable. Risk-management information for defense of claims also has some protection from discovery.

These protections are seldom absolute, however, and sharing data on problems outside the entity raises legal vulnerabilities. Information need not be definitive to be useful. One attorney noted that it is helpful just to know that a patient's hospital chart was submitted to the peer review committee, despite the absence of information about the confidential review or its findings. Just seeing the stamp “referred to peer review” on the chart used to make it much easier to get an expert witness to review the case. Hospitals learned of this effect and stopped using such stamps.

This illustrates a key observation about data on errors. People are very reluctant to report on themselves or colleagues unless they have a reasonable expectation of confidentiality. Whatever one's views about the appropriateness of open confession of error, it is a practical reality that few medical practitioners want to do it within what they perceive as a litigious or vengeful environment. All our interviewees at reporting systems stressed the importance of confidentiality in getting practitioners to report; fears of legal and other repercussions are very strong. All said they thought reporting of errors falls vastly short of the true extent of error.

It is difficult to get people to discuss potential failures at all, much less report them to regulators empowered to discipline them, especially if litigators may also get hold of them. Hesitation is built into behavior even without disclosure. Note, for example, that the first information a liability insurer or hospital risk manager often gets that something may have gone badly wrong in patient care is an inquiry or notice of suit from a patient's attorney. Reporting by the practitioners involved has traditionally been very low—even though they are contractually obligated to report claims, even though they're reporting only to the people whose job it is to defend them, and even though the reports are internal and confidential.

Stronger confidentiality protections would probably improve voluntary data sharing. That's why the IOM panel recommended new federal legislation. If cross-state reporting is to expand greatly, this may indeed be required. There are existing legislative models of confidentiality protection on which to base new rules, including those applying to peer review and to the National Practitioner Data Bank. The panel recommended a decentralized approach, as different expertises and scales of operation are appropriate for different types of problems—drug errors, blood transfusions, emergency medicine, and so on.

Many states have created mandates for hospitals to report serious injuries to a state regulatory agency, often along with other matters, including epidemics and fires. Typically, a case is confidential unless the agency takes formal action against the institution. Legal requirements and conditional confidentiality may plausibly increase reporting overall, though this is undocumented. But it seems clear that even a long-standing mandate, as in New York or California, elicits only a few thousand reports of unnatural deaths or serious injuries a year (see Appendix D of the IOM book, pp. 210-217). The rate of error and serious injury found by hospital chart review in those states is far higher. Mandatory reporting may or may not find more problems than does the liability or peer review system.

For purposes of learning from reported mistakes, incomplete reporting may not be critical. A clinical or administrative manager at hospital X can see that others also have a lot of problem Y and hence decide to take action. An area for much greater work is how to report or otherwise generalize knowledge about solutions as well as problems.

Reporting systems cannot measure the true incidence of particular problems, however, because they don't know either of the two key factors: They cannot count how many errors truly occurred (say, in a state or in a type of hospital). Nor do they know how many patient encounters it took to generate the observed level of reported cases. For this reason, it's a bit troubling that incomplete systems can be used to discipline medical providers.

**Reporting Systems as Motivators of Change.** This observation leads to a second issue about safety—how to motivate change among doctors and hospitals. Here, the IOM panel touched briefly on the importance of corporate leadership (chapter eight, pp. 143-144) and appeals to professionals' desire to excel in quality, now including attention to error prevention. These are good things. However, considerable outside pressure seems needed as well. It's taken a long time, after all, for most medical leaders to begin to accept that major improvements seem possible, despite all the rhetoric about American medicine as the best in the world. And complacency about performance continues; many hospital executives seem to think they are doing enough about injuries already.

Enter state regulators as motivators. The threat of sanction after investigation of a reported serious occurrence is surely meant to encourage change. How well this works goes beyond the scope of the IOM book and is worthy of much more attention. How well staffed and funded are the relevant agencies? What are their capabilities to investigate, especially promptly and outside their home offices? How much are individual cases studied as against patterns of problems? Can regulators recognize when other factors than error affect reporting (e.g., nurses' labor dispute with hospital)? What sanctions do regulators use? How much acceptance is there of the appropriateness of their findings among the regulated entities? Do the regulatees in fact change? How do regulators try to generalize advice to the industry at large? The questions go on and on.

Given the wide range of unanswered questions, the appropriate federal action at this point seems to be to learn more about what states are doing and accomplishing rather than to mandate federal minimum standards. According to news reports, the Administration has decided to oppose mandatory, open reporting at this stage. I agree with that position.
Proponents of traditional and expanded litigation normally assert that motivating preventive efforts is their key contribution—what lawyers call deterrence. This must be at least partly true: The highly successful anesthesiology guidelines, even the patient safety movement itself, was partly a reaction to liability pressures. Formal research has found little evidence of deterrence, however. Support for the hypothesis that exposure to fault liability promotes safety comes from some studies comparing no-fault with fault-based systems for auto accidents. Yet the tie between lawsuits and motivation to promote safety seems weak. Hospitals and other entities within a particular jurisdiction all face the same basic legal rules, yet they differ greatly in their willingness to tackle patient safety as a management priority. Moreover, to repeat: whatever the level of deterrence has been accomplished by liability pressures, it hasn't done enough to protect patients. And it tends to inhibit open sharing of data and methods for safety, even internally.

One last comment here: Regulation and litigation are not the only tools available to motivate change. It's appropriate for buyers of health care to demand much more of providers. That is another major topic on its own. It seems possible to start with some outcomes measures, such as rate of late discovery of cancer, and more pressure for providers to adopt processes thought to help reduce errors. Again, to the extent feasible, at this stage of development it seems preferable to emphasize support for improved processes rather penalties for poor outcomes. Hospital accreditation is doing some of that already, but buyer pressure offers another useful approach, one barely touched upon in the policy debate thus far.

**Implementing Change.** Changing clinical and administrative processes to protect patients calls for good management, beyond good information and motivation to act. It is one thing for leaders or outside experts to proclaim devotion to patient safety and discuss methods in general terms, quite another to make changes in everyday practice. It is notoriously difficult to manage health care providers, and the appropriate system to manage is not clear, especially outside of hospital-based and large physician group practice. Very few private entities have anything like the corporate organization of Veterans Affairs, where top leadership has begun substantial change. Management issues merit much more attention.

Readers will note that this testimony has become sketchier as it proceeds from theory to actual implementation of change. There is a reason for that. Theory is running ahead of practice. Much remains to be learned, but the promise is bright.

**Other points.** Two other points deserve brief mention. First is the relation to pending patient protection proposals. On their face, patient safety initiatives like those on extra-institutional reporting systems in no way foreclose any legislative option on patient protection. Indeed, one can argue that they similarly help patients, and "root cause" style analysis might help elucidate problems of resource allocation under managed or unmanaged care. There is one concern. One patient protection goal is to increase access to state courts in personal injury lawsuits against health plans. Any resulting increase in litigation will have spill-over effects on providers. Any increase in exposure of problems could exacerbate the disincentive to report errors or to cooperate in management efforts to change internal culture.

This testimony noted how reporting data on errors might be encouraged by shielding reports from use in today's personal injury lawsuits. A complementary approach is to change the broader legal environment that practitioners now find so daunting. Tort reform to end the open-endedness of legal damage awards is one approach, considered but not enacted at the federal level. Non-monetary losses like pain and suffering and punitive awards are the types of damage that can lead to exceptionally high awards. Defense interests have long sought flat "caps"; sliding scales proportionate to loss would be better. One might try to condition such liability protection for providers on their making progress in patient protection—as an alternative safeguard. Further thinking is needed to develop a workable proposal.

An even broader liability reform with patient safety implications would be exclusive enterprise liability—that is, shifting liability for medical injuries from individual practitioners to responsible organizations. This could remove the fear of personal liability from individual health care workers, eliminating this disincentive to report errors, although they may still face peer pressure or sanctions from their organization. Another proposed reform, no-fault compensation for medical injuries, might promote error-reporting by reducing the fault system's adversarial inquiry into blameworthiness. Workplace injuries to employees are handled within a combined no-fault, enterprise-liability system, typically funded by self-insurance or experience-rated coverage that is thought to produce systems analysis. Employers are protected from personal injury litigation by workers (injury to clients or customers are still subject to tort claims), but must pay workers limited damages on a no-fault basis under the state law of Workers' Compensation. Safety is augmented by separate regulation and data reporting under the federal Occupational Safety and Health Act. These options are worth mentioning for completeness, though they extend beyond the scope of this hearing and these subcommittees.

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**Other Publications by the Authors**

- Randall R. Bovbjerg