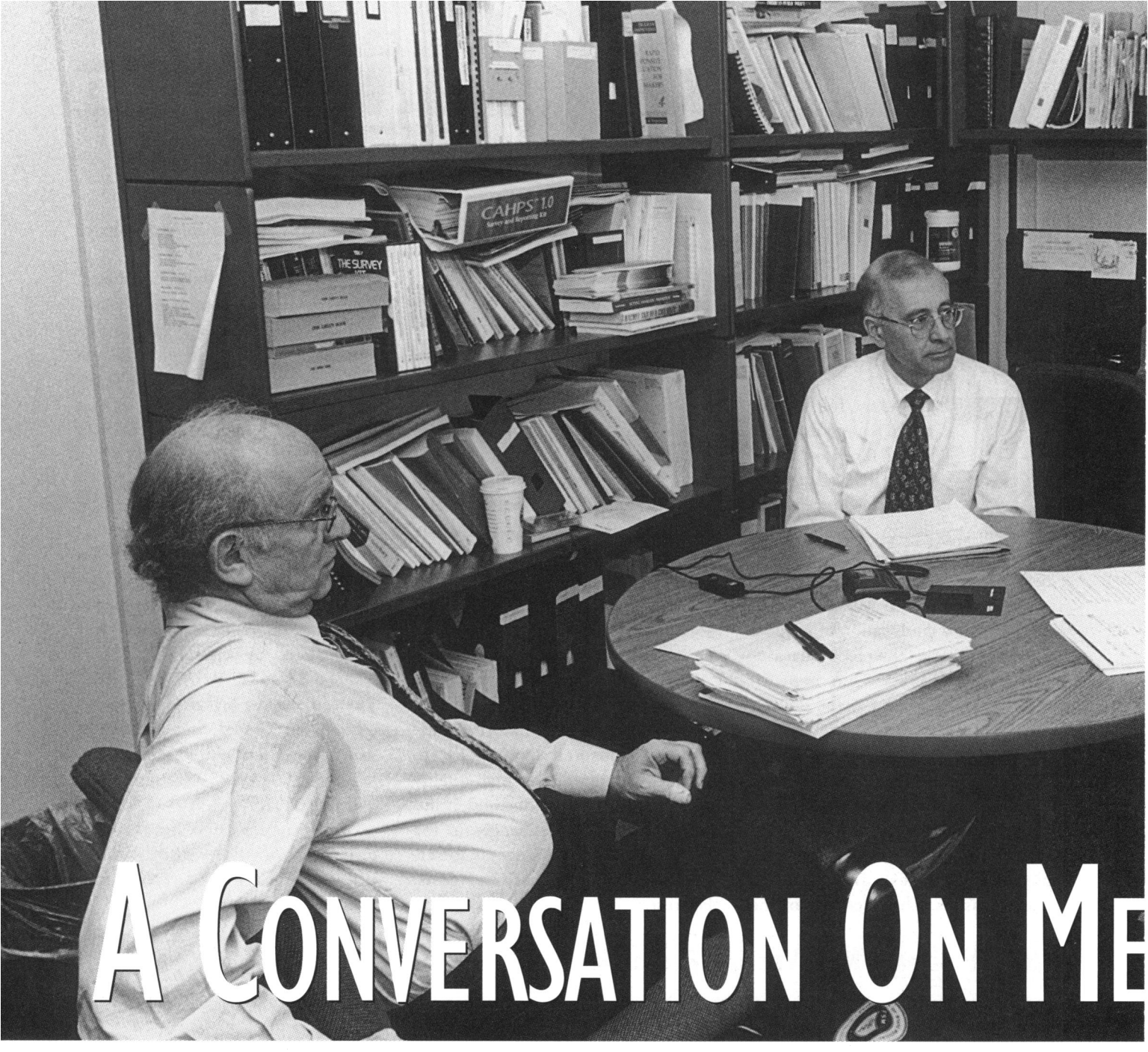
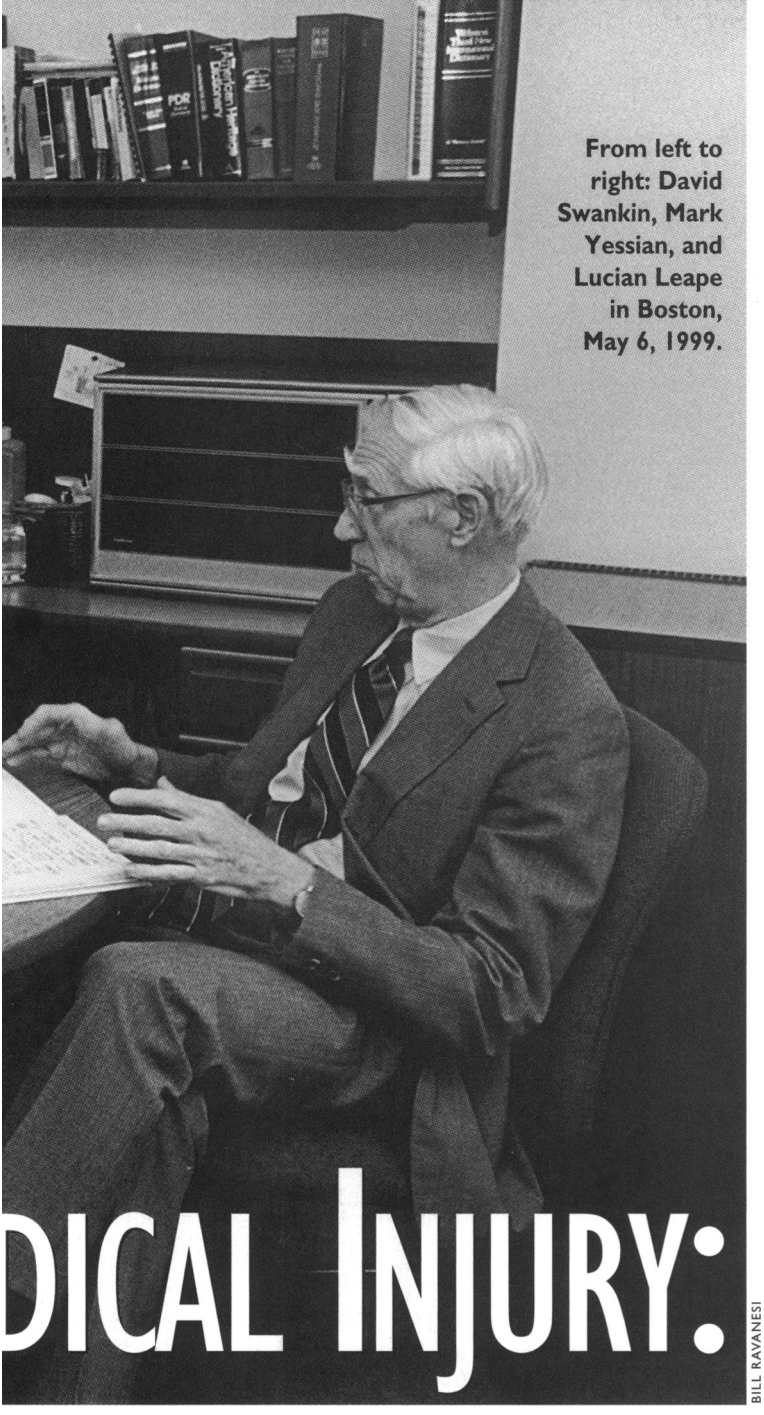


A CONVERSATION ON ME

Lucian L. Leape, MD,
David S. Swankin, JD,
and
Mark R. Yessian, PhD

Medical injuries are adverse events attributable to the medical management of patients. During the past quarter century, two large-scale studies have examined the incidence of such events in hospitals. The first, an analysis of approximately 20,000 records of patients hospitalized in California in 1974, found that adverse events occurred in 4.5% of hospitalizations and negligent adverse events in almost 1% of cases.[1] The second study, in which researchers reviewed about 30,000 records of patients hospitalized in New York State in 1984, revealed comparable proportions.[2] The Harvard team that conducted the New York study drew on the data to estimate that in 1984, among the 2.6 million admissions to New York hospitals, there were about 98,000 adverse events, of which approximately 37,000 involved negligence (substandard care).[2]



From left to right: David Swankin, Mark Yessian, and Lucian Leape in Boston, May 6, 1999.

BILL RAVANESI

DICAL INJURY:

Since then, no inquiries of comparable scope have been undertaken. But more narrowly focused studies, using different methodologies, have indicated that medical injury continues as a serious problem. For instance, in 1995, on the basis of a review of about 4000 adult admissions over six months in two tertiary care hospitals, Bates and colleagues reported that adverse drug events occurred at a rate of 6.5 per 100 nonobstetrical admissions.[3] Further, they found that 42% of adverse drug events were life-threatening or serious and that 42% of these were preventable. In 1997, drawing on observations of about 1000 patients admitted to three units of a large teaching hospital, Andrews and colleagues reported that 17.7% experienced at least one serious adverse event and that the likelihood of experiencing such an event increased about 6% for each day of hospitalization.[4]

The general public need not know of these studies to be aware of the problem. Even the casual newspaper reader or television viewer is apt to have come across prominent accounts of patients injured because of poor hospital care. Often described in graphic detail, these events include cases of death or disability resulting from improper medication, botched surgery, inadequate patient oversight, and other lapses in medical management. Moreover, it appears that the public's own experiences provide substantiation for concern about medical injury. In a recent national poll, 42% of the respondents indicated that they have been involved, either themselves or through a friend or relative, in a situation in which a medical mistake was made.[5]

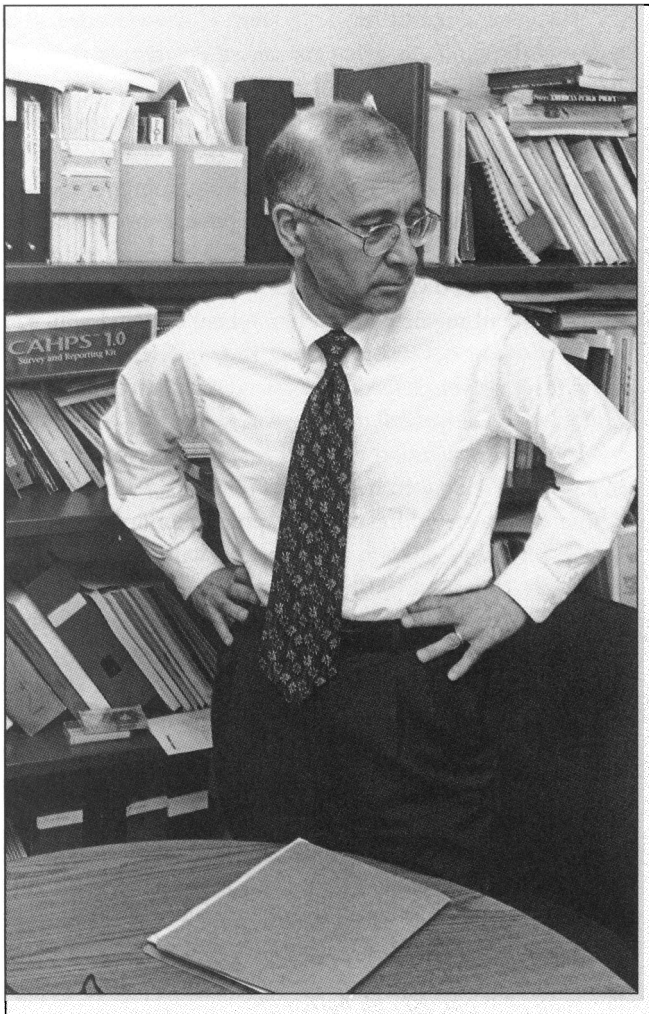
In the conversation that follows, we present the views of a physician, an attorney, and a political scientist, each of whom has been addressing the phenomenon of medical injury for more than a decade. As will be clear, they approach the topic with different emphases, but they share a commitment to consumer protection and to finding a common ground that will enable a concerted, broadly supported effort to reduce the incidence of medical injury.

—The Editors

Lucian L. Leape, the physician, was a key participant in the Harvard study mentioned above. That experience triggered his interest in the medical errors that occur in even the best of hospitals. He has contributed to a number of studies that examine the system bases of errors and has become a leading national authority on the subject. Lucian is Adjunct Professor of Health Policy at the Harvard School of Public Health. He is also a member of the Health Sciences Division of RAND, where he has directed studies of overuse and underuse of cardiovascular procedures. Previously, he was an academic surgeon, most recently as Professor of Surgery and Chief of Pediatric Surgery at Tufts Medical School and the New England Medical Center.

David A. Swankin, the attorney, has extensive experience in working with state boards responsible for the licensure and discipline of physicians and other health care professionals. As President of the Citizen Advocacy Center (CAC), he has devoted particular attention to training and providing support for the public members of these licensure boards. Recently, the CAC issued a model state law on the mandatory reporting of disciplinary actions taken by hospitals against individual practitioners on their staffs. David's broad advocacy background has included service as the first Executive Director of the White House Office of Consumer Affairs and, more recently, as a member of the Pew Health Professions Commission.

Mark R. Yessian, the political scientist, has focused on the quality assurance mechanisms that the federal government relies upon to protect patients. In his capacity as Regional Inspector General for Evaluation and Inspections of the US Department of Health and Human Services, he has produced a number of influential studies addressing the performance of Medicare Peer Review Organizations, the National Practitioner Data Bank, state licensure boards, and hospital oversight bodies. In other roles, Mark has served as the Director of Policy Analysis for the Oklahoma Department of Human Services, as Adjunct Professor of Public Management, and as the co-founder and co-editor of a national human services journal.



BILL RAVANESI

Mark Yessian, in his capacity as editorial advisor to *Public Health Reports*, served as the convener and lead questioner for the conversation.

MY: Lucian, the Harvard medical practice study that you participated in suggests that medical injuries could account, at least in part, for as many as 180,000 deaths in a year. These are far more deaths than are attributable to motor vehicle or workplace accidents. As you've indicated yourself, they are about equivalent to the death toll from three jumbo jet crashes every two days.

Your search for causes has led you to emphasize the significance of errors, and in particular of poorly performing organizational systems that lead to such errors. Why do you feel that this line of explanation is so compelling?

LL: Well, over the last 50 years medicine has become incredibly complex. The old paradigm of the kindly family doctor who made house calls and carried everything he needed in his bag has given way to an incredibly complicated system—one that involves extensive interactions among many different people with many different skills. In the last 15 to 20 years we have certainly progressed, with the tremendous expansion of sophisticated high tech equipment and care. But this development has made it much more difficult for anyone to coordinate care and make sure everything works properly. As a result, we have a lot of dysfunctional systems. We do a lot of things that just don't work well.

Almost every one you know who has been hospitalized can tell of an experience in which something went wrong. Often, it's trivial—they got a medicine a few hours late, or they couldn't get the nurse for an hour, or the meal was cold. But a lot of time it's not so trivial. Just this last Sunday, the *Boston Globe* reported on the terrible experience of a well-known physician, Dr. Paul Ellwood. He received inappropriate care after being injured in a ski accident and was outraged by it. As well he might be. The point is that it is not that unusual.

Now, outside medicine, there are other complex systems that have dealt with this issue, and that we can learn from. One immediately thinks of the aviation field because it has succeeded so well. Last year, not a single person died from an airline accident involving a US airline—not one: 615 million people flew on airplanes and nobody died. Now, pilots aren't better than doctors. They make mistakes, too, but their planes don't crash.

Whenever you say that, somebody will say, "Well, planes are different from people." That's true, but we are not talking about the patient; we are talking about what we caregivers do and how we do it. When you look at a complicated system like flying an airplane or running a nuclear power plant or landing airplanes on aircraft carriers, you see each has a number of things to make it work and to reduce errors. In health care, we need to see if we can apply some of the same approaches. The evidence so far is encouraging.

MY: You've offered good grist for conversation. Before we react, let me give David a chance to add his perspective to the mix. David, in addressing this issue of medical injury, you have been more inclined to use the term substandard care rather than medical error and to note that part of the problem is attributable to individual practitioners—physicians, nurses, other health care professionals—who have deficiencies in their own practice skills and/or knowledge bases. Please elaborate.

DS: I think Lucian is on the right track. The points he makes about errors and organizational systems are very

important. However, when you look at the whole ball of wax, there are two other basic issues that must be considered if we are to make serious progress in reducing the incidence of medical injury.

First, as reflected in your question, you have to acknowledge that some of those things that go wrong in medical care happen because of the presence of substandard professionals—because of people who do not meet minimum standards that any of us as patients would have a right to expect. I'm not referring to professionals who have just had a bad day or who have made a mistake, as any of us can do. I'm referring to people who have no business practicing, at least not without adequate supervision or until they have brought their competence up to par. These are people you would not want working on you or anyone in your family, whatever system they were working in. We have to do something about them.

My second point is that if we look at the quality oversight bodies that are out there now, what we see is essentially a non-system. If we were beginning today, we would never build the kind of oversight system that now exists. Each of the state boards responsible for licensing individual health care professions functions in isolation, each focused on its own profession. Take a nursing home. You are going to have 8, 9, 10 different types of licensed professionals in there, each of them licensed by a separate entity.

On top of that you have numerous other federal and state agencies with regulatory responsibilities and various private oversight bodies responsible for accreditation of nursing homes, hospitals, managed care organizations, and other entities. Again, each operates independently.

Going back to Lucian's analogy with the airline industry, it has occurred to me that if we regulated airlines the way we do health care, we would have 50 state boards regulating pilots. We would have 50 different boards regulating mechanics. We would have still different organizations that regulate the airports, still others that regulate the air traffic controllers. And on it goes. You know, if that were the kind of oversight system that existed, I wouldn't want to fly.

It is also worth noting that pilots must demonstrate competency on a continuing basis.

LL: Every six months.

DS: And health professionals have no comparable requirement. As a result, I think we can feel that as consumers we are more protected from substandard pilots than from substandard health care practitioners.

MY: Both of you are talking about systems, but I hear you talking about systems in different terms. I hear you, Lucian, talking about systems within organizational settings, most especially hospitals.

LL: Right.

MY: You want to focus on the system of care that's provided in the hospital setting and to hold the hospital leadership accountable for it. (This, by the way, is in accord with the directions set forth by the Joint Commission on Accreditation of Healthcare Organizations.)

On the other hand, you, David, are focused much more on the oversight system (or non-system) that functions external to the health care organization: the licensure boards, the accreditation bodies, and the myriad of other regulatory entities responsible for oversight.

DS: I think we need both. I think we need systems within health care organizations, and then I think we need a system of external oversight that works.

LL: It's not an either/or. It's both. We have concentrated our work on systems within hospitals, but I think it's quite evident to all of us that all of the systems and "The System" are of a piece and we need to work on all of it. Because what happens in the regulatory arena, in the tort area, in the licensing boards, in education and training, in privileging and credentialing, all have very powerful effects on hospitals' ability to change their internal systems and to deal with marginally competent people. So you can't look at any of them in isolation.

It is possible to make some process changes, some task definition changes, and other kinds of systems changes in isolation. And it's worth doing so. But we cannot create a culture of safety that adequately protects patients without involving everything in the big, capital letter System. So I don't have any disagreement at all, and as a matter of fact, we are trying to get people to see beyond their walls and to work on that.

I think it should be stated that changing systems, that is, looking at process changes, looking at training for teamwork, setting standards, and doing all those things, really does work. The aviation model is fantastically successful, and part of the question is how do you translate that into health care? When you change major systems, you can see a very substantial improvement. Take the system of unit dosing of prescription drugs that was introduced in the 1970s. Instead of the nurse in a hospital calculating what the dose was going to be, measuring it out, and administering it, the pharmacist does the calculation and measuring in the pharmacy and sends up medication ready to go, each single dose prepared for the patient. That change cut dosing errors by over 70%.

Computerized physician order entry, a system in which physicians enter the orders on a computer instead of writing them down, has reduced serious medication errors by as much as 80%.

Internal changes are critical to making health care safe, but they alone aren't going to create a culture of safety; that takes a very fundamental realignment in the way we think in organizations. That, in turn, is very much related to the external environment. Right now there's an atmosphere of fear that inhibits innovation, inhibits dealing with reality, inhibits getting reports and understanding errors. As long as doctors and nurses in hospitals are fearful of what they do, it's very difficult to get them to act.

MY: Fearful because of the litigation concerns?

LL: Fear on all levels. Physicians and nurses internalize very high expectations; that is, we are taught from day one that we are not to make mistakes. Therefore, when doctors and nurses make mistakes, they feel guilty, they feel shame. They don't think of an error as being caused by the system. They think it's entirely their fault. That's the way I was when I practiced surgery. If I made an error, it never occurred to me it was anybody's fault but mine, that there might be something in the system that led me to do it. There's a tremendous amount of internal guilt and shame. And, there's a lot of judgmental behavior toward one another, especially, it seems, in nursing. Nurses, like everyone else, make errors. They are reprimanded and punished quite regularly. Nurses are very tough on each other.

Overlying that for physicians is the malpractice threat. If they make a serious mistake and people find out, they'll be sued. Being sued isn't about losing money; they all have insurance. It's about character assassination. It's going through a process in which you will spend a long time listening to people tell the world what an awful person you are. It's a very strange way to compensate people for injuries.

MY: Let me go back to the issue of errors and substandard care. David was mentioning that there are some poorly performing practitioners who function outside the system...

LL: No, no, it's a systems problem.

MY: OK, explain, if you would, the problem of the "bad apple" in the system context.

LL: OK, case in point. A surgeon does something really awful, takes off the wrong leg, or even worse. What do you hear in the hospital? "I knew that was going to happen someday."

MY: Meaning that that physician would mess up?

LL: Yes. "I knew that was going to happen with him someday." Well, if you knew, why didn't you do anything about it? The answer? There's no mechanism for doing anything about it. The people working in the hospital know who the dangerous doctors are. The people in practice know. Maybe in the case of an individual physician working in an isolated office out in a small town of 300, nobody knows how bad he is, but in any other circumstance—in an office with three people, in a hospital with a staff—people know who the marginally competent people are.

By the way, I prefer to use the term "marginally competent," since no one's incompetent. It is different levels of competency we are talking about. In essence, what we are talking about is substandard care.

The crux of the problem is we don't have an effective "system" for dealing with problem physicians. For several reasons, we do not have a system that can investigate and find out what the problem is and do something about it. One is we tend to think in black and white. We tend to think in terms of removing a physician from the staff or leaving him alone to do what he wants to do. Instead, we could think more constructively in terms of graded responses, such as restricting privileges, monitoring, and remedial training. We don't do that nearly enough. Hospitals don't tend to think of that as their job. So, they consider the "bad apples" in terms of firing them or just leaving them alone, until they get into enough trouble to get the attention of a licensure board or a malpractice attorney.

A second defect of the current system is that physicians have shied away from the self-governing responsibility that is part of their professional code. Part of being a professional is to take responsibility for self-regulation. It is a moral responsibility because patients assume that we look after their best interests. Physicians have shied away from this kind of internal review for a number of reasons. One obvious one is that they don't want to point fingers. Another one of course, has to do with realistic concerns about liability. When you try to discipline a physician on your staff, the first response is he files a suit against you. A suit is usually based on restraint of trade, or something of that sort.

The third problem is discipline is almost always ad hominem. It comes down to the chief of the division saying, "You're not adequate. Shape up or ship out." That's one person against another person. A better way would be to have individuals define themselves—that is, to have standards for professional practice that everyone

knows and to have measures that determine whether practitioners are meeting them. Then an individual practitioner and everyone else knows whether or not he meets the standards.

Now, in saying this, I might as well be on Pluto. We don't have anything close to that in most of our hospitals. We completely lack internal systems for identifying and dealing with people who are marginally competent. That's a very major systems problem.

DS: Let me ask you a question. Take the best hospital that you can think of, one where you would say peer review really does work.

LL: I don't know of any.

DS: You don't know of any?

LL: No.

DS: That's surprising.

LL: I've trained and practiced in some of the best hospitals. When I was a resident, they would send us in to operate with a certain surgeon to keep him out of trouble: a staff surgeon who had a huge practice. They always picked their best resident to go with him, to make sure he didn't do anything wrong.

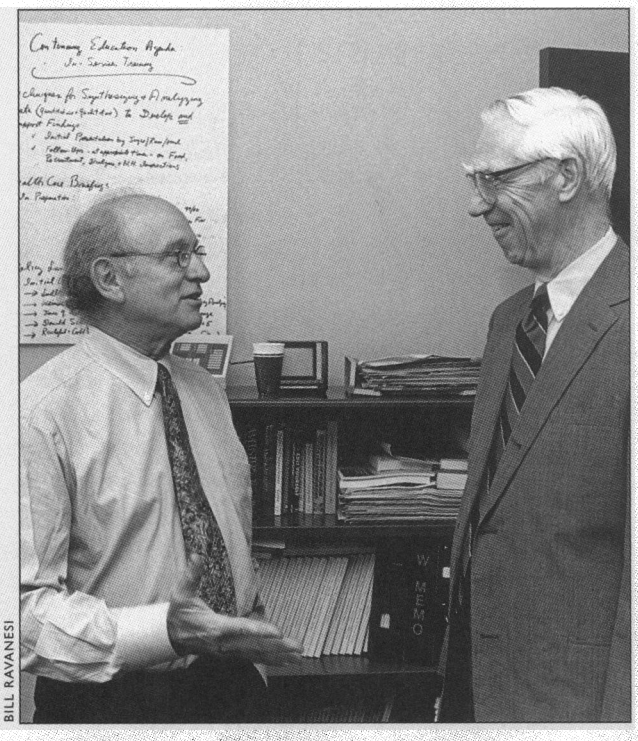
I'm not saying there aren't any. Mayo Clinic may have it. I've never been there. Mayo does a lot of things well and they may well have a good system for this, but the hospitals I've been in have not had one.

DS: Your answer about the poor state of peer review and of hospital systems for dealing with the marginally competent helps explain why disciplinary action reporting laws seem to have so little effect. I'm thinking of the federal law that requires hospital disciplinary actions that are taken against members of the staff and that are above a certain threshold to be reported to the National Practitioner Data Bank (so that other hospitals and state licensure boards will be able to find out about these individuals). I'm also thinking of similar state laws that call for hospital disciplinary actions to be reported to the state licensure authorities. You would think that hospital leadership would have some sense of obligation to let regulators know about those individuals who could cause harm to their patients.

LL: Right, no question about it.

DS: It's a culture in which you don't turn people in. You don't tattle. You don't tell.

LL: It's called self-preservation. People don't file reports if they're going to get in trouble. And in our current system, that's what happens. If you tell, you get in trouble.



BILL RAVANESI

"As consumers, we [may be] more protected from substandard pilots than from substandard health care practitioners."

—David Swankin

DS: It seems me that there are many types of errors that are clearly controllable through system changes. For example, with proper systems in place (including backup systems) it seems to me that we should be able to practically eliminate medication errors.

LL: That's right.

DS: But what about the cases where the underlying problem is not a process or technological or organizational issue, but essentially one of competence? How do you impose system controls in those cases?

LL: Let me try to make a couple of points here. The first is that I happen to think that of the serious errors that hurt people, the percentage that are due to incompetence is very small. Nobody knows for sure. It's almost impossible to get a measurement. But my hunch is it's 1% or 2%. Some people say it's 5% or 10%. But it's certainly not more than 10% and it's certainly not less than 1%. So it's in that range. For that reason, many of us have said, let's apply Sutton's Law and go where the money is. Let's work on the other 95%.

My second point is that anything you do to reduce errors of people who are competent also reduces errors of people who are incompetent. The computerized order entry system at Brigham and Woman's Hospital that has reduced medication errors by 80% has reduced the medication errors of the marginally competent doctors by 80% too. So there is much to be said for making a safe system, one that will ensure safety regardless of who's working in it. Which isn't to say you don't also deal with the people who are the problem.

So, you might ask, "What is your system for making sure you have competent people?" And the answer is, we don't have one. We don't have every-six-months testing like pilots do. We don't have a system for identifying pathologists, cardiologists, internists, or others who are marginal.

Now, let me add that any process that is observational—that involves a person looking at something—is going to have a significant error rate. We've got a paper coming out about errors made in the reading of angiograms, which decide whether you have coronary bypass surgery. Twenty percent error rate! Studies on interpreting electrocardiograms—17% error rate. Studies on chest X-rays—15% of pneumonia is missed. Anything that's observational has a substantial error rate, not 1% or 2%, but more like 15% to 20%.

The obvious answer in these situations is to have two independent observations. That'll cut errors by about 90%.

"The crux of the problem is we don't have an effective 'system' for dealing with problem physicians."

—Lucian Leape

MY: At an increment in cost...

LL: Exactly. So what price safety? Without some built-in redundancies (as airlines have), we will tolerate error rates that are much too high. The review of angiograms I just mentioned took place in New York State, where the state allows only 31 hospitals to do bypass or angioplasty. They are concentrated, mostly in medical schools. We looked at the work of superb cardiologists, good people. We took their angiograms and gave them to other cardiologists to read them blind. Twenty percent error rate!

So if you really want to deal with that issue, I would say the priority is not to search for the bad guys. What you really need is to have double readings of everything. Would it cost more? You bet it would. But all the evidence is that overall it costs less to do it right. If you have all the money coming out of the same pocket and you look at all the costs, quality pays every time.

DS: At the same time, we need to draw on the regulatory powers of the state to call for continued compe-

BILL RAVANESI

tency assessment for physicians, just as we do for pilots. To me this is an essential complement to the kind of system changes you call for, Lucian. Further, I would add that this approach need not be punitive in its thrust. Those who are found to be short of the mark in their competency testing should be given opportunities to take remedial training to maintain their credentials.

MY: Let me focus on one concrete thing here that Lucian already mentioned to see if we can take it a step or two further in terms of any possible solutions. I'm thinking of the privileging and credentialing actions of hospitals. You have already suggested, Lucian, that from your own experience they do not appear all that effective. From my own work in this area, I can document how superficial this process can be.

One indication of this sort is in the hospitals' response to the National Practitioner Data Bank. The federal law establishing the Data Bank requires hospitals to send to the Data Bank any disciplinary actions they take against practitioners that affect their clinical privileges for 30 days or more. We found that in the first three years of the Data Bank's operation about 75% of the hospitals in the nation had not reported a single disciplinary action. Subsequent studies have shown that a low level of reporting continues.

I'll offer another example, this one from inside a hospital system. Awhile back I was at a community hospital discussing hospital privileging practices with a number of the physician leaders of the hospital. During the course of the conversation, one of the physicians brought up the example of an orthopedic surgeon who has not performed a certain complicated surgical procedure for two or three years and suggested that he should not be granted privileges to perform that procedure or at least should be granted privileges only with a mentor present during the operation.

LL: And what did they say?

MY: One of the other physicians sitting around the

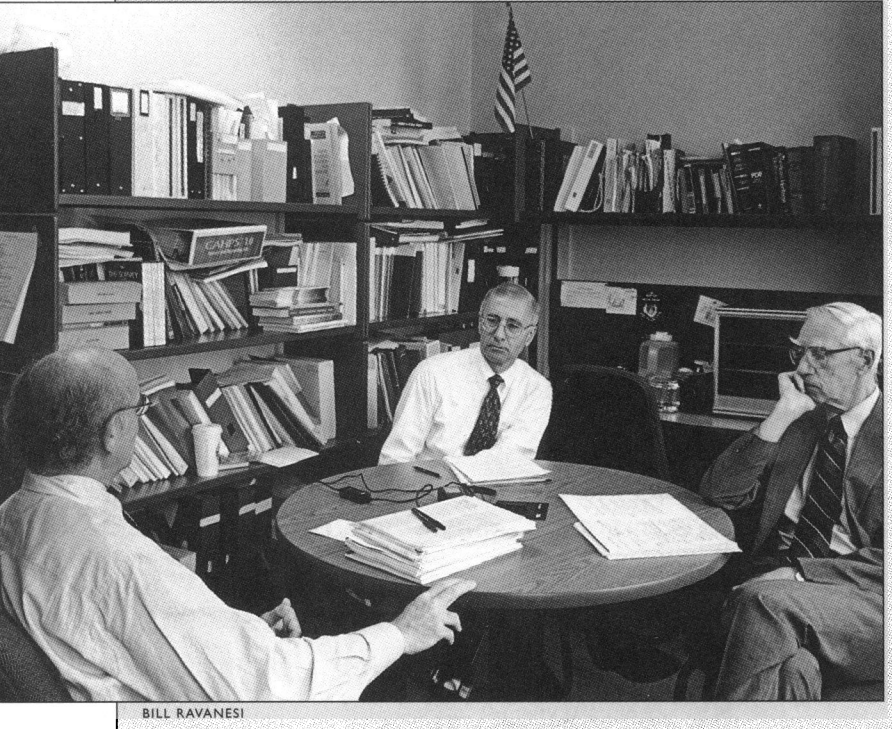
table said, "Well, who would notice? Who would know, on the outside?" And this is with me, an outsider, sitting in the room. This must call for more than just finding a fix in the malpractice liability system. How do we get serious attention to this issue of hospital privileging and credentialing?

DS: There's a model out there that I would love to see pursued. It's the approach that is used in most states to respond to impaired physicians—those with alcohol or drug problems. This approach, in its general outline, involves personalized assessments and treatment programs. Based on the assessment, some physicians are required to stop practicing while in treatment. Others may be allowed to continue to practice during their treatment if they present no harm to the public. And, as long as they remain in good standing in the impairment program, their participation is kept confidential. So, if I were in a hospital and wanted to know if my doctor was in an impairment program, I would not be able to find out.

I know that this approach has some flaws. (At the Citizens Advocacy Center, we are developing a set of standards to be sure that these impairment programs are held properly accountable.) It is also strange for me to advocate it since we have been closely associated with calls to strengthen mandatory reporting laws. But, I ask, if we can develop such a mechanism to deal with impaired practitioners, why can't we do the same with many of those practitioners whose impairment is not related to drugs or alcohol but to some deficiency in their skills or knowledge? Earlier, Lucian called for more graduated responses to marginally competent practitioners rather than the just choosing between the dump-him or do-nothing options. Hospitals, licensure boards, and others could find that the impaired practitioner programs offer a lot of lessons on how they can best deal with marginal performers.

This is quite different from the thrust of mandatory reporting laws which offer a legal way to tell regulators about practitioners with questionable skills. I strongly support such laws because we do not have in place a viable alternative to protect the public. But as we discussed before, I acknowledge that mandatory reporting does not tend to be very effective. I'd like to start pursuing ways in which we could build systems, maybe based on impairment programs, that would take poorly performing individuals on a case by case basis and help them improve their practice skills to acceptable levels. And it can be done in a confidential manner if the system we build is accountable. That is both our opportunity and our challenge.

MY: David, I like what you are saying, but I worry about this being done confidentially. I'm not sure that is neces-



BILL RAVANESI

"The fact that so many people feel that something bad can happen to them in a hospital because of their hospital care is shocking."

—David Swankin

sary. As a consumer/patient, I would probably like to have the right to know if my physician is in such a program.

DS: But a good, accountable intervention program will make an initial decision on whether the physician should continue practicing as the remedial effort goes on. So there is a concept of public protection that needs to be built into any accountable program.

One development that is consistent with this notion is the early intervention approach that some state medical boards are beginning to explore. In these cases, as boards become aware of physicians who may have certain practice deficiencies, they put them on an educational track rather than a disciplinary one. They send them off to various places for evaluations, with the idea of developing a targeted program of educational corrective actions geared to their particular deficiencies. They do this before the physician has hurt anyone, and before he has been brought before the board to face disciplinary charges. We are just at the front edge of this, but it holds much promise in my opinion.

LL: This reminds me of a couple of quotes. One is from Tip O'Neill, the former Speaker of the House of Representatives, who said that "all politics is local." In that spirit, I would say all quality improvement is local. The government, and the regulators, and the licensing boards cannot improve quality. What they can do is not get in the way, set standards, and create a climate where it can happen. They cannot make it happen. Which is another way of saying if the people who are going to make it happen don't believe, don't buy in, don't accept, don't internalize it, it isn't going to happen. That's the fundamental thing wrong with mandatory reporting.

Look at it at a micro level and then extrapolate it. At Massachusetts General Hospital, where we did a little study, we found through our detailed look a whole bunch of adverse drug events. But very few of them had been reported as incidence reports. As a matter of fact, the reporting rate was about 5%. So 95% were not reported. To understand why, we convened three separate panels: front-line nurses, quality improvement nurses, and managers. They all agreed that the incidents should have been reported, but offered three reasons why most were not: (*a*) It takes too much time. (*b*) It is likely to get someone in trouble. (*c*) Nothing happens anyway. Which of course is why they don't make the time, because if nothing is going to happen, why should I waste my time with it? Now I would submit to you that that's the answer for all reporting, at any level. So, if you want voluntary reporting: it can't take too much time, it can't hurt somebody, and something's got to happen.

The second quote is from Charles Billings, a physician who developed the Aviation Safety Reporting System. He said, "All reporting is voluntary." People don't report unless they want to and believe in it. Well, it's also voluntary if they know they're going to get found out anyway; so they "voluntarily" report an incident. The flip side is, if they will be punished, nobody will report something they can hide. And, you know, we can hide most of it.

The model that we're all wrestling with—and saying, "How can we do this in health care?"—is the Aviation Safety Reporting System. This system does not focus on accidents. Accidents get investigated. It focuses on near misses, errors. Errors are what you learn from. (You can learn from accidents, but you can learn even more from errors.) So pilots can do something really awful, such as almost crashing with another plane, but they will be immune from discipline if they report within 48 hours.

What happens then? An experienced pilot looks at the situation, analyzes it, thinks about it, relates it to other similar reports, and then comes out with a recommendation. The pilots then say, "You know, when I reported that there was a problem with runway lights that were confusing and they had two other reports about those lights, they changed the lights!" That's what we need in health care.

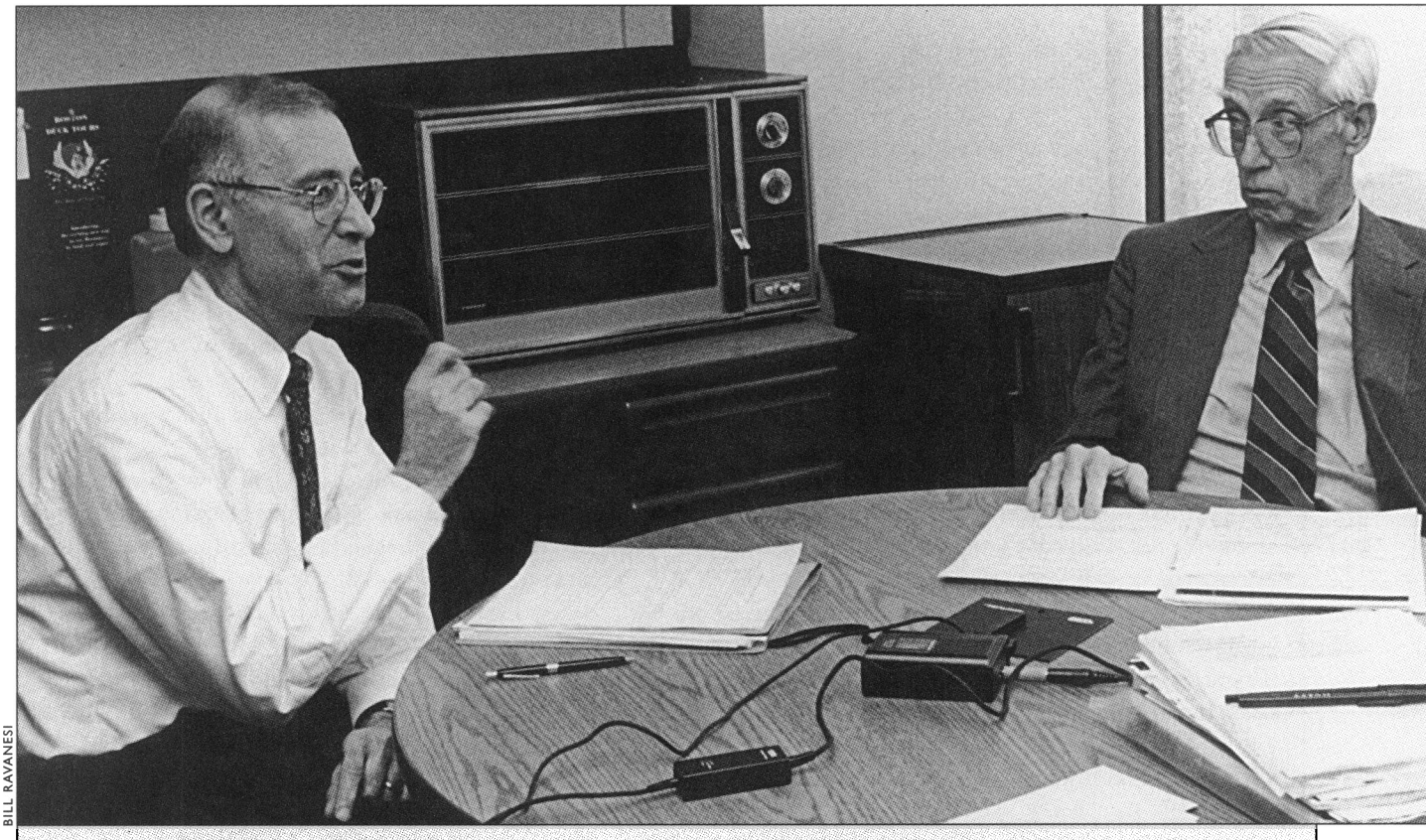
In the future, I think we are going to see more and more mandatory reporting in health care. We've got Massachusetts legislators making that noise right now. They are all upset because of a recent *Boston Globe* series on medical errors in Massachusetts hospitals. They say that it is very nice that you are doing all these things to get at the system causes of errors, but we are going to have to strengthen the reporting system. I'm afraid that in the next five years we are going to have a wave of increased mandatory reporting, with punishments.

MY: We see this development around the issue of abuses in psychiatric hospitals, where there have been a number of highly publicized reports of the use of restraints leading to patient deaths.

LL: Right.

MY: In situations of that sort, how can we expect that they can be handled in a confidential way? Isn't that the equivalent of the airplane crash, where you have a very public investigation?

LL: Here's what we need to do. There are two reasons to report. One is for judgment—that is, to make sure everything's right. The other is for improvement. There are two kinds of things to report. One is events, and the



BILL RAVANESI

other is errors. Errors are not events. It's only an event when someone gets hurt.

Now, there is no question in my mind, and I think among most health professionals, that the state has a right and an obligation to require that untoward events get reported: unexpected deaths, removal of the wrong limb, you fill in the blanks. They should be reported because they are suggestive that maybe there is something wrong in the system. We should have that. But when you start talking about reporting errors, that's a different matter because you're starting to make a judgment that an error is blameworthy when 95% are not blameworthy.

DS: I totally agree with that. As a practical matter, when something terrible happens in a hospital, it is difficult in this day and age to assume that information about that development can or should be kept confidential.

In the model mandatory reporting law we developed, we decided to focus on an even smaller universe than adverse events—that is, on the universe of disciplinary actions that hospitals have actually taken against practitioners on their staffs. We recognize that it's only the tip of the iceberg, but it's a tip consisting of individuals who could well pose harm to patients. It is a cost-effective place for regulatory bodies to focus their attention. Situations involving errors that are caused by mistakes and not by substandard practitioners, I agree, should remain confidential. But that assumes we have in place a system that can differentiate between the two causes.

I recognize that this mandatory reporting approach doesn't address the problem of those marginally competent practitioners who aren't working in hospitals. But if we can make some real progress with those practitioners who are institution-based, that would be an important step.

MY: But couldn't you say that the mandate to report disciplinary actions gives hospitals less incentive to take actions in the first place or at least to take actions that are not reportable? Some have explained the minimal reporting to the National Practitioner Data Bank in these terms.

DS: That may well be true. But when a hospital removes a physician's privilege to practice, it has obviously concluded that the physician does not meet its standards of quality. So what happens? The physician leaves the hospital and practices somewhere else. As a friend of mine once said, he's never seen a physician who was kicked out of a hospital driving a taxi for a living. That is why we need mandatory reporting—because no matter how well the removal of privileges protects the

"If we are to get significant political action in support of system reforms...more common ground must be found."

—Mark Yessian

hospital, it doesn't protect the public, who will continue to be subject to the risk of harm that substandard doctor poses. So with all its flaws, mandatory reporting of substandard practitioners is the only protection we have, unless and until we develop an accountable system for health care like the one we have developed for airlines.

MY: I want to introduce a related point that I've been anxious to get in here. Each of us wants health care organizations to change in ways that make a serious dent in the incidence of medical injury. At the core, we want these organizations to do the right thing in protecting patients and in making themselves accountable for the care they provide.

But all organizations are biased toward the status quo, toward a standard way of doing things. For major change to occur in their routines, it usually takes some externally induced pressures and some conflict, often generated by a sense of outrage at some existing conditions or some terrible event. We all remember the situation at the Dana Farber Cancer Center a few years ago in which a *Boston Globe* reporter who was a cancer patient died because of a chemotherapy overdose. The resultant publicity over this case triggered many reforms at the Center that quite likely would not have happened if this had been treated as an internal matter.

How important is this kind of public disclosure and sense of outrage to achieve the kind of system reforms we want?

LL: There's not much question that it has an effect. More than once in talks I have said that we wouldn't be here today if it hadn't been for Betsy Lehman (the *Globe* reporter mentioned above). But my concern is that it could very easily have perverse effects. An unleashed public outrage, I think, is a greased pig in a china shop. I'm very concerned about that. And that's why I don't look upon it as a policy tool.

There is something else important to mention here. Something that gets no press attention. It is that doctors and nurses don't like to hurt people. When they have the opportunity to redesign their work so they don't make mistakes, they take to it eagerly. I have now worked with 65 or 70 hospitals that are working on their medication systems. They're not doing it because of any external threat. For the most part, they are not hospitals that have had bad episodes. They're not doing it because it's going to save them money; in fact, it's costing them money. They're not doing it because any regulatory apparatus is telling them they have to do it. They're doing it because they see a potential solution to a problem that bothers them, which is making mistakes in the administration of medication.

So there's a tremendous amount of energy, motivation, and drive for improvement.

Having said all that, what, then, can be done from the outside? I would suggest that we haven't even scratched the surface in terms of facilitation by regulators. Boards of medicine, boards of nursing, and departments of public health ought to be setting standards for safe practice and making sure they're being enforced. What has the board of nursing in Massachusetts done about nursing hours and workloads? Zero. Nurses shouldn't be allowed to work double shifts. Pilots can't fly two shifts in a row. The nursing board reacts to bad apples, and they throw them out. But what they should be doing is setting standards for safe practice and calling on the hospitals to enforce them.

If you believe, as I do, that improvement is local, then we're talking about facilitating and enabling hospitals and other local health care providers to make improvements. There are two major external developments that could have substantial leverage in facilitating local improvement. One is the development of national standards. We need a national medical standards board that addresses everything to do with health care: indications for medication, hours, work loads, anything you want to talk about for safety. We need somebody, for example, to say that all patients with heart attacks should receive beta blockers after-

wards. We don't need a national enforcing system, because many of these things will be self-enforcing. But now we don't have the standards to enforce.

The second key external development that could make a big difference is to put the liability responsibility on the institutions instead of on individuals. If you want to have only safe doctors practicing in a hospital, make the hospital liable for the consequences of their actions. Enterprise liability. I would take it to the next step: enterprise compensation. Those are two very different things, and they always get mixed up. It seems to me that if I go into a hospital and the hospital hurts me, the hospital ought to pay for that. It is has nothing to do with negligence, errors, or anything like that. If I get hurt as a result of treatment and I lose wages for six months, the hospital should pay for that.

MY: Who would make the determination as to whether you were hurt because of injury?

LL: There are ways to do that, but that's another conversation.

This approach of holding the hospital liable for compensation would wipe out 90% of the medical tort actions. Which is fine, because the tort system doesn't work anyway. People would still have the right to sue.

If the hospitals were also liable for negligence, then they would have some incentive to do something about it and they would set up some mechanisms. Now, they need help from outside. They need standards. They need a mechanism, a board of licensure to which they can refer the impaired physician for counseling and training, and so forth. That's what I mean by enabling and facilitating. The licensing boards ought to be doing a lot more to work with the hospitals to deal with the problems. Tell the hospitals: "Here are standards, here's the kind of monitoring you want to do," require them to submit reports on their monitoring, and help them deal with the problem. But give them the responsibility to do it. And I think the best way to do that is to give them the financial responsibility for injuries.

MY: OK, Counselor. Your turn.

DS: I want to respond to a few things Lucian has said. First of all, I completely agree on the national standards issue. We took the same approach on the Pew Health Professions Commission when we addressed scopes of practice. It's nonsensical to have 50 different scopes of practices in 50 different states. So, amen on that.

On the issue of the press and sense of outrage it can help generate among the public: consumer groups, as you know, use the press a lot in this way. I don't want to totally dismiss the role the press and media in general can play in facilitating the kind of reforms we want. By heightening public concern, media attention can help break through the kind of organizational status quo Mark was talking about earlier. It can add to the impetus for reform and help sustain it. To trigger the kind of reforms we seek to address errors and substandard practice, we can't just look to the health care professionals or stakeholder organizations. We need the public to demand them.

LL: I don't know how you get the public to do that.

DS: I don't know how, either. But I really do think the media can get to the public better than you or I can. Perhaps part of the challenge is to help the media become as informed as possible.

Lastly, on the matter of enterprise liability, I totally agree there ought to be enterprise liability. I just don't want it by itself. I like individual liability. I don't like the tort system, but I don't like doing away with individual liability when it's called for.

LL: Nobody would do away with that. If a doctor did something egregiously negligent, he could be sued. That's different.

DS: In that context, then, I agree that we should have enterprise liability so long as it is in addition to individual liability. Which is why well-functioning licensure boards need to be recognized as a critical part of the safety net consumers have a right to expect.

MY: The New York medical practice study that Lucian participated in ended up recommending enterprise liability, in good part because it found that the medical malpractice system failed to identify most of the cases of actual liability.

LL: Fewer than 2% of the cases.

DS: Look at the world of HMOs now and all the reform efforts being proposed to protect patients. What's the one thing that the managed care industry hates the most? Liability. They can take most of the other reforms being proposed to protect patients, but they certainly don't want to take "you can sue us" as part of any reform package. So what's the conclusion? That must be the one that really matters.

LL: Right, right! It must be important.

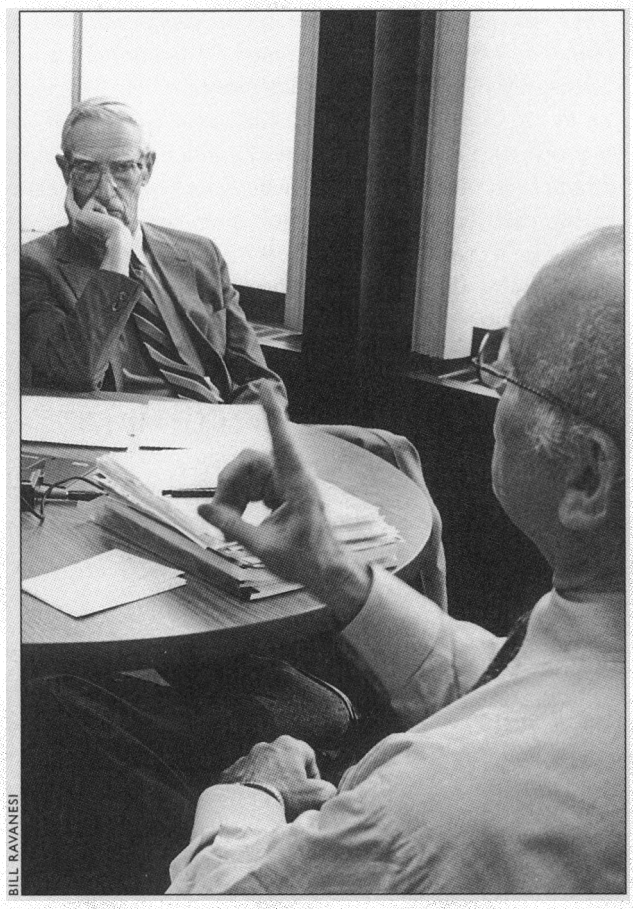
Right now, a quarter of all the many costs cost associated with medical injury comes out of patients' pockets, out of the pockets of individuals who are not insured for the loss. All we're talking about is, who's going to pay? And how it's going to be paid for. No one wants enterprise compensation. The hospitals don't want to take it on because they don't want to have to pay for it. They can't get their rates raised; in fact, they are going down. And you want us to pay for more, they ask? The doctors don't want to give the hospitals more power over them. The insurers don't want to lose the business. The trial lawyers don't want to lose the business. There's no constituency. It's dead on arrival. The hospitals don't want it, the patients don't know about it, the doctors don't want it, the lawyers don't want it, the insurers don't want it. Who wants it? Just folks want it.

MY: As we wind down, let me open up one more issue. Notwithstanding our varied perspectives here, we have substantial agreement among us both on the causes of medical injury and on what kind of corrective actions should be taken.

But the larger political discussion on these matters tends to be much more polarized than our conversation. On the one side, you have those who stress individual accountability and call for more aggressive and more public actions in going after the bad apples. On the other, you have those who emphasize organizational accountability and urge system improvements largely outside the public limelight.

At root, if we are to get significant political action in support of the kind of system reforms (internal and external) that we have called for here, it seems to me that more common ground must be found. It seems to me that we must learn how to explain the reform proposals to lay people, to the media, to elected officials, and others in ways that give them confidence that we are on the right course. We must assure them that while we are not simply placing our trust in health professionals and organizations to do the right thing, neither are we taking a highly regulatory path to impose change. How do we do that? How do we find the right language? The right balance? The right way to market these ideas?

DS: That's probably the hardest single part of it. As Lucian said, we don't have a natural constituency. I think



BILL RAVANESI

"To trigger the kind of reforms we seek to address errors and substandard practice, we can't just look to the health care professionals or stakeholder organizations. We need the public to demand them."

—David Swankin

it still has to be based on expectations. You wouldn't accept it in airlines, but we accept it in hospitals.

When the country doesn't accept something, we try to change it. We don't accept terrible public schools, and while we may not be as far along as we would like, we are giving much more attention to the problem than in a really long time. The fact that so many people feel that something bad can happen to them in a hospital because of their hospital care is shocking.

MY: It seems that we need to appeal to some sense of outrage here. People need to have a certain degree of outrage to want to do something.

DS: I've been involved with safety issues for much of my life, especially in earlier years with respect to occupational safety. One cardinal rule we have always had as we have tried to promote greater attention to safety is: take advantage of everything bad that happens, of incidents where people are harmed. Maybe that is not a great way to do things, but it does provide opportunities for reform.

LL: The problem is that there aren't easy, simple solutions. It's a very complicated problem. We've aired some of it. We need to make significant changes in several different arenas. And the changes are not simple or easy to understand. And so they're hard to package.

MY: Or to capture in sound bites.

LL: Well, that's right. I think it was H.L. Mencken who said that for every complicated problem, there's a simple solution and it's wrong. Worse, yet, I fear that is exactly what we'll get. I fear a move toward mandatory reporting. That isn't going to do anything for quality. That's not going to reduce errors. That's not going to get rid of bad doctors. Zero. All it's going to do is cause a lot more grief. I haven't figured out how to get the right thing to happen, but one way is to look for what I call high leverage points—places where a change has an impact on many other processes.

If we could get a nationals standards board, for example, that would have significant leverage. But how do we get it without getting people upset? I don't know. One possibility might be to emphasize quality of care rather than errors. We could say that everybody ought to get beta blockers after a heart attack, all women sought to get annual mammograms, etc.

Then, when people say, "That sounds good. I'm in favor of that," we could say that we need a standards board. It could lead to increased monitoring and accountability. But we're not going to fire the doctor who didn't order the mammogram. We're not going to fire the doctor who didn't give the beta blocker. We'll just ask, why? Maybe if we took that approach, focusing on quality of care, we could foster a movement for standards. Dealing with errors could be a piece of that. But if we focus on errors, it too easily results in the kind of outrage that leads to simplified solutions, like mandatory reporting laws.

MY: That's because the public tends to view errors in a judgmental way—not just as something going wrong but rather as an act involving some ignorance or carelessness. The dictionary definitions tend to emphasize this latter construction. So, I agree that it could be strategically wise to focus on quality standards rather than errors per se. That would more likely lead to deliberations on how we implement the standards.

At the outset of this conversation, Lucian, you mentioned Dr. Paul Ellwood, widely known as the father of the managed care movement. In a recent speech at Harvard, he was very critical of the entire health care system, fee-for-service included.

LL: He got some miserable treatment himself.

MY: Yes. He described his own bad experience and, as reported by the *Boston Globe*, noted, "Patients can get just atrocious care and can do very little about it." He then went on to say, "I've increasingly felt that we've got to shift the power to the patient." Very interesting point. With the rapid advances in information and medical technology, it seems to me that patients, and not just physician-patients, are bound to become increasingly proactive in their own health care. And as that happens perhaps they—not the health care purchasers or the regulators—will become an increasingly prominent force for quality.

LL: Is that how we got safe flight? Of course not.

MY: But isn't there something different about the consumer/patient participating in his or her own, individualized health care than about sitting as a passenger on a plane full of people?

LL: I'm a thousand percent in favor of patient information, knowledge, and participation. It's all good. As far as I am concerned, it's just good medical practice. That isn't going to get you there, though. That's our job. It's our job to insure safety, not the patient's.

DS: But I don't want to disown the idea. If people think that the health care system we have in the greatest

country in the world, with the most resources, isn't the system we should have, then I think some major changes could happen. I don't think people are there yet. They accept things as they are. If they really did not accept the status quo, then we could see more momentum in reducing the scope of medical injuries.

LL: Very reasonable people disagree about the role of scare tactics in moving public policy. I see more of the danger than the benefit.

DS: I think the political dimension is very important. And that we need a more concerned populace to make the kind of progress we want. In addition, let's not dismiss the role of the media in helping the public become aware of the scope of the problem.

MY: Well, gentlemen, I think this has been enough for one conversation. I've enjoyed it and hope that it triggers many more conversations among our readers on what can be done about a serious national problem.

The views expressed here by Mark Yessian are his own and do not necessarily represent those of the Office of Inspector General or the US Department of Health and Human Services.

Address correspondence to Dr. Yessian, *PHR*, Rm. 1855, JFK Federal Bldg., Boston, MA 02203; e-mail <phr@nlm.nih.gov>

SELECTED CITATIONS RELEVANT TO MEDICAL INJURY AND THIS CONVERSATION

Andrews LB, Stocking C, Krizek T, Gottlieb L, Krizek C, Vargish T, et al. An alternative strategy for studying adverse events in medical care. Lancet 1997;349:309-13.

Bates DM, Cullen DJ, Laird N, Petersen LA, Small SD, Servi D, et al. Incidence of adverse events and potential adverse drug events: implications for prevention. JAMA 1995;274:29-34.

Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, Newhouse JP, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. New Engl J Med 1991;324:370-6.

California Medical Association. Mills DH, editor. Medical Insurance Feasibility Study. San Francisco (CA): Sutter Publications; 1977.

Cohen RA, Swankin DA. Hospital reporting to state regulators and to the National Practitioner Data Bank: what can be learned to improve compliance with mandatory reporting requirements? Washington: Citizens Advocacy Center; 1997.

Gawande A. When doctors make mistakes. New Yorker 1999 Feb 1;40-55.

Leape LL. Error in medicine. JAMA 1994;272:1851-68.

Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, et al. The nature of adverse events in hospitalized patients: results of the Harvard Medical Practice Study II. New Engl J Med 1991;324:377-84.

Louis Harris & Associates. Public opinion of patient safety issues: research findings. Chicago: National Patient Safety Foundation at the AMA; 1997.

Swankin DA. The role of licensing in assuring the continuing competence of health care professionals: a resource guide. Washington: Citizen Advocacy Center; 1995.

Weiler PC, Hiatt HH, Newhouse JP, Johnson WG, Brennan, TA, Leape LL. A measure of malpractice: medical injury, malpractice litigation, and patient compensation. Cambridge (MA): Harvard University Press; 1993.

Yessian M. How can state medical boards compete in the quality assurance marketplace? Federation Bull: J Med Licensure and Discipline 1994;81:102-8.

Yessian M, Greenleaf J. The ebb and flow of federal initiatives to regulate healthcare professionals. In: Jost TS, ed. Regulation of the healthcare professions. Chicago: Health Administration Press; 1997. p. 169-98.

References

1. California Medical Association. Mills DH, editor. Medical Insurance Feasibility Study. San Francisco (CA): Sutter Publications; 1977.
2. Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, Newhouse JP, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. New Engl J Med 1991;324:370-6.
3. Bates DM, Cullen DJ, Laird N, Petersen LA, Small SD, Servi D, et al. Incidence of adverse events and potential adverse drug events: implications for prevention. JAMA 1995;274:29-34.
4. Andrews LB, Stocking C, Krizek T, Gottlieb L, Krizek C, Vargish T, et al. An alternative strategy for studying adverse events in medical care. Lancet 1997;349:309-13.
5. Louis Harris & Associates. Public opinion of patient safety issues: research findings. Chicago: National Patient Safety Foundation at the AMA; 1997. ■