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MEDICAL MISTAKES

JOINT HEARINGS

BEFORE THE

SUBCOMMITTEE ON
LABOR, HEALTH AND HUMAN SERVICES,
AND EDUCATION, AND RELATED AGENCIES

COMMITTEE ON APPROPRIATIONS

THE

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

AND THE

COMMITTEE ON VETERANS' AFFAIRS

UNITED STATES SENATE

ONE HUNDRED SIXTH CONGRESS

FIRST AND SECOND SESSIONS

SPECIAL HEARINGS

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MEDICAL MISTAKES

MONDAY, DECEMBER 13, 1999

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:30 a.m., in room SD–138, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senator Specter.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning. The hour of 10:30 having arrived, the Committee on Labor, Health, Human Resources, and Education of the Appropriations Committee will proceed with our hearing.

On November 29, the Institute of Medicine issued a report entitled "To Err is Human: Building a Safer Health System," which cataloged an enormous number of medical errors which occur at our health care delivery system hospitals and doctors offices. Now, this had followed some rather dramatic disclosures about medical errors.

A prominent health reporter in the Boston Globe, Betsy Layman, died from an overdose during treatment in Florida. Mr. Willy King had the wrong leg amputated. Two large studies, one conducted in Colorado and another in Utah, found adverse events occurring in about 3 to 4 percent of hospitalizations, respectively, and the projected estimates are that as many as 44,000 Americans may die each year from medical errors. These errors comprised the fifth leading cause of death in the United States, with the costs estimated in the range of $20 billion a year.

The study of the Institute of Medicine recommended that the Agency for Health Care Research and Quality receive an appropriation initially of some $30 million. That agency is funded by this subcommittee, and it was decided that we should push ahead with the hearing at an early date, even though the Congress is in recess at this time, so that we may investigate the issue and proceed with the dialogue, hopefully being in the position to introduce legislation on this subject when the Congress reconvenes in late January.

There are a number of agencies, really, to be heard from on this matter, and today's hearing will really just begin the dialogue, but the issue has been raised. In addition to the Agency for the Health Care Research and Quality, a number of other agencies funded through the initiation of this subcommittee may also have an im-

portant role to play, such as the Health Care Financing Administration, the National Institutes of Health, which received an enormous increase in funding, some $2.3 billion this year, to a total of almost $18 billion a year, the Centers for Disease Control, the Health Resources and Services Administration, the Administration on Aging, Substance Abuse, and Mental Health Administration, and also the surgeon general's office.

I might say parenthetically, I talked to Dr. Satcher last week about that very important report on mental health, which is to be released today, and the advanced billing show that to be a matter of enormous concern, and, again, a subject which has been funded through this subcommittee, having enormous implications, which we may have a hearing on later and address those issues.

STATEMENT OF DR. JOHN EISENBERG, DIRECTOR, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. A fuller statement will be admitted for the record, but to proceed at the earliest moment with our very distinguished panel of witnesses, I would like to call at this time Dr. John Eisenberg and Dr. Mary Wakefield to be our initial witnesses. Dr. Eisenberg is the Administrator of the Agency for Healthcare Research and Quality, the agency called upon by this study to take the lead in addressing these serious issues. Dr. Eisenberg was chairman of the Department of Medicine of Physicians, and Chief at Georgetown University, and before that was the Chief of General Internal Medicine at the University of Pennsylvania, a graduate of Princeton, Washington University, St. Louis School of Medicine, and the Wharton Business School. That is quite a varied background, Dr. Eisenberg. Thank you for joining us here today, and the floor is yours.

Dr. EISENBERG. Thank you, Senator Specter. Mr. Chairman, when I read the Institute of Medicine's report on patient safety and errors in the health care system, I, like every physician, had some reminiscences. It brought back some memories.

I recall the woman whom I took care of; we had had a pap test done to screen her for cervical cancer. The result was suspicious, but I never knew that, because I never got the report back, and I did not realize that I had not gotten the report back until she called me and asked about the report.

I tracked it down. I found out it was suspicious. We followed it up, and fortunately, it turned out not to be anything serious, but that was a near miss, and it was a near miss that could have been a tragedy, had she not called me, had she not taken part in detecting and preventing errors. That happened at the University of Pennsylvania, when I headed the General Internal Medicine Division there. It is a great hospital, as you know, but even at the best institutions, errors happen.

Senator, when I spoke at three medical school graduations last spring, I asked all of the students who were graduating, and I asked all of the faculty to raise their hands if they had ever made a mistake in taking care of a patient, and every single student raised his or her hand, and every faculty member raised his or her hand. So we have established the fact that these errors exist; we

have established that the best physicians at the best institutions make mistakes.

What the Institute of Medicine's report has done, has been to alert us to the magnitude of this problem, to point out to us that if it were a disease, it would be the eighth leading cause of death in the United States. But if it were a disease, Senator Specter, I think we would call it an epidemic.

Senator SPECTER. Dr. Eisenberg, did you say the eighth leading cause of death——

Dr. EISENBERG. The eighth leading cause.

Senator SPECTER [continuing]. Not the fifth leading cause of death?

Dr. EISENBERG. Not the fifth. The eighth. It is somewhere between 44,000 and 98,000 deaths per year, is what the IOM has estimated. Now, that is bad news, but there is some good news, and the good news is that these errors can be prevented.

If this were a disease, then let us think about what we would do. We would attack it with the best research that we could muster, we would put resources into translating that research into improved practices, and it is going to take resources, and it is going to take teamwork in order for us to respond to this problem.

I want to commend you, Mr. Chairman, and the other Members of the Senate and the House of Representatives for recently taking what I think is a significant and very timely step in November to reauthorize our agency and to rename it from the Agency for Health Care Policy and Research to the Agency for Healthcare Research and Quality, or AHRQ, as we will call it.

The name quality in our name is very important, because this is an issue of health care quality. Errors and even near misses, like the one that I had, are not new problems, but they have finally gotten the attention that they deserve.

Congress did show foresight in raising the awareness of medical errors as an important part of the health care quality agency through that legislation that reauthorized our agency and renamed it. You gave AHRQ not only the authority, but you gave us the responsibility to carry forward many of the error prevention recommendations in the Institute of Medicine's report.

Now, while an investment is going to be required to make system improvements to reduce medical errors, I think we can be confident that it will also reap substantial benefits. In the long run, when these medical errors are prevented, the IOM estimates that we could save as much as $8.8 billion that is spent on health care today. The research we have sponsored shows that many adverse drug reactions and events can be prevented if appropriate systems are put in place.

I recall, for example, in the mid-1980s, when at Penn, our faculty developed with the Philadelphia College of Pharmacy and Science, one of the first systems to detect adverse drug reactions, and these kinds of systems are now being computerized, but Senator Specter, it is more than just about drug errors.

In fact, the Institute of Medicine found that while about 10 percent of the errors clearly involve drugs, 12 percent of them were the failure to prevent an injury, and 17 percent were diagnostic mistakes, like the one that I almost made.

While the statistics of errors are astonishing to many and they are distressing to all of us, it is very important for us to remember that the IOM emphasized that this is a problem of the health care system, not incompetent careless individuals.

Our approach to medical mistakes has to change from the old mode of name them, blame them, and shame them, to one of looking at systems, finding out what the root causes of these errors are, and then sharing information so that those errors are not repeated. Like the patients that they care for, health care professionals are human, and we humans are not perfect. As the IOM report recognized, to err is, in fact, human.

Now, research has shown us that errors exist, and we need to understand the dimensions of those errors, but we cannot stop just by counting the errors. We have to evaluate why they occur, and then we have to develop systems in order to prevent them. Our new name, AHRQ, is symbolic of the need to develop an arc or a bridge between the problem and its solution, between what we know and what we actually do in health care.

Let me give you one example. Our agency funded a study that tested whether emergency rooms could put together dedicated chest pain observation units, which could reduce the number of people who are mistakenly sent home even though they have had a heart attack. These units have specially trained staff, they have dedicated equipment, and they have validated treatment protocols that have led them to reduce the number of people who are sent home mistakenly by as much as 100-fold, says the research.

We can learn from the aviation industry, as we know, and we know that in health care more can be done as well. Some of the earliest research, in fact, in error reduction in health care was done in anesthesia. Applying the lessons of that research has allowed anesthesiologists, the people who provide anesthesia for surgery, to reduce their error rate by about seven fold.

We have seen, in the Department of Defense and in the Department of Veterans Affairs, programs that show that improvements can be made in reducing errors, but if we are going to reduce errors in health care, Senator Specter, we are going to have to share information on those practices and share information on effective solutions, but we cannot share information if we do not have information. What the Institute of Medicine's report told us is that we can help change the culture of secrecy surrounding medical errors into a culture of education and improvement.

I want to thank you and your colleagues for providing our agency with the funding that you mentioned earlier in fiscal year 2000. That, combined with our new authorizing language, is going to allow us to make a down payment on research in this critical area.

We have already expanded our commitment to research in reducing medical errors. We are going to fund about $2 million in research on medical errors and patient safety this year, identify opportunities for further research that we can carry out in the future, and continue supporting a very exciting new initiative, the Centers for Education and Research in Therapeutics (CERTS). You may have seen the article about CERTS in the *Wall Street Journal* on Friday, which will help to reduce adverse events from drugs, and

we are going to support activities to translate that research into better practice.

We are going to continue to collaborate with the American Medical Association, with the National Patient Safety Foundation, and with many other colleagues who have been providing leadership in this area. Last week, as you know, President Clinton directed the Quality Inter-agency Coordination (QUIC) Task Force to review existing medical errors and patient safety issues in Federal health programs, and to test the feasibility of our implementing the Institute of Medicine's recommendations.

Secretary Shalala co-chairs the QUIC, and she has made a personal commitment to improving health care quality. Secretary Shalala and Secretary Herman have directed me as the operating chair of the QUIC, and as the head of the lead agency in quality, to focus our attention on this issue. At 8:30 this morning, when we had members of every Federal agency involved in this issue come together to talk about what we can do. We have already begun to take steps toward reducing medical errors.

We are going to work with the Institute of Health Care Improvement to look at ways of reducing errors in Federal programs, and we are going to continue to recognize and to emphasize that the issues of reducing medical errors and improving patient safety are critical and timely. We need to be sure that the proposed solutions address the real problem, the problem at its root, which is the system, rather than blaming individuals.

We need to improve the system, so that health care providers can have an opportunity to provide high-quality health care that they were trained to provide in a safe and an effective environment. We look forward to working with the Congress to gain control of this epidemic of medical errors, and to improve the quality of health care for the American people.

Mr. Chairman, I want to thank you for this opportunity to discuss this important issue and to continue to work with you and your staff in the area. Thank you.

Senator SPECTER. Thank you, Dr. Eisenberg.

With respect to the listing as to eighth highest or fifth highest, the statistics which I have from the Institute of Medicine and Centers for Disease Control put the medical errors, with as many as 98,000, in fifth place behind heart disease, cancer, stroke, and obstructed lung disease, and ahead of pneumonia, influenza, diabetes, auto accidents, suicide, and kidney disease, which round out the top ten. So whether the figure is five or eight, it is——

Dr. EISENBERG. That is right.

Senator SPECTER [continuing]. An enormously significant figure.

Dr. EISENBERG. I think one of the reasons we do not know exactly how many there are is because we do not have systems to understand how many errors are occurring and to understand where they are occurring as well as we should. If we could do better research in this area, we could probably clarify for you whether it is number five or number eight.

Senator SPECTER. I had a chance meeting at New York City with Dr. Eugene Flam, a very distinguished surgeon formerly from the University of Pennsylvania, and somebody that I have had personal contact with, and we were discussing the range in statistics, and

a question was raised as to whether they may be inflated, if we cannot put a more precise tabulation on them. Do you think that that is a possibility?

Dr. EISENBERG. I know Gene well, having worked with him when we were both at Penn, and I suspect that from his perspective these estimates of errors may be more frequent than he sees himself, but I think for the nation as a whole——

Senator SPECTER. Because he makes fewer errors?

Dr. EISENBERG. I would not be surprised. But I think for the nation as a whole, these numbers, if anything, are conservative. The numbers that I have heard would suggest that the numbers of the IOM, the 44,000 to 98,000 deaths per year, are, if anything, on the low side.

Senator SPECTER. One suggestion has been made that as a result of the legislation which was signed into law just last week by the President, the omnibus appropriation bill, which gave you clear authority, your agency, that it might be unnecessary to have additional legislation, that you might be able to handle it within the existing framework of established law. What is your view about that?

Dr. EISENBERG. We can certainly do more than we have done in the past, and I think the authorizing language that we have gives us just that authority.

It gives us authority to conduct a more aggressive program of research; it asks us to create a national report on health care quality by the year 2003, and we have to respond, and we look forward to responding to that authorizing language. Whether we should do more than the authorizing language already allows us to do is something that our department and the entire administration is looking at very, very seriously. Over the next several weeks we are going to look at it carefully, get back to the President about what we should do and what we can do even beyond the authorities that we already have.

Senator SPECTER. Well, when there was a call on the part of the Institute of Medicine to start off with an additional funding source of $30 million, and then to elevate that to $100 million, I think it likely that to get that kind of additional congressional support there is going to have to be a lot more concern in Congress, which may require some additional legislation and some additional congressional focus.

Dr. EISENBERG. We look forward to talking with you about that legislation, what it might allow us to do, and the kinds of resources that it would require.

Senator SPECTER. When you talk about mistakes, and then say that they are systemic, it is almost a suggestion that they are not individual matters, and you used the illustration of someone coming into the hospital with chest pains, the errors of not knowing when there is a heart attack, and then a system change led to a significant reduction in those errors, tell us a little bit more about that. What exists before you have a system change that the people who examined patients for chest pain would not be aware of the criteria to make a determination as to whether it is or is not a heart attack?

Dr. EISENBERG. When errors occur, they sometimes occur because of the fact that people are not aware or they are not knowledgeable of what they might want to do. The first step would be to be sure that we translate to them the information that has been made available about what works and what does not work.

Sometimes it helps for them to have guidelines that are written by professional societies or other knowledgeable groups, based upon the research about what they——

Senator SPECTER. Well, do not the people who conduct those examinations have guidelines?

Dr. EISENBERG. Sometimes they have guidelines. We——

Senator SPECTER. Sometimes they do not.

Dr. EISENBERG. Sometimes they do not.

Senator SPECTER. Why not?

Dr. EISENBERG. Sometimes they are not easily accessible.

Senator SPECTER. Guidelines are not easily accessible.

Dr. EISENBERG. Sometimes they are not. We, in fact, have just started——

Senator SPECTER. What is their basic training before you get to the guidelines?

Dr. EISENBERG. The first step is to understand the pathophysiology, the cause of the problem, and the treatments.

Senator SPECTER. If somebody comes into the hospital and has a chest pain, who customarily sees that person, somebody in the emergency room?

Dr. EISENBERG. Somebody in the emergency room almost always would see that person if they show up in the emergency room. However, they may go to their personal physician's office, and that physician, or the person in the emergency room, may not see very many patients with this problem.

If we can make a guideline readily available, which we have done that through AHRQ's a National Guideline Clearinghouse (on the web), then that will help. But even with the guideline, you need to have a system in place whereby the laboratory result comes back quickly and accurately.

Senator SPECTER. Is the EKG standard in an emergency room, where somebody comes in and complains of chest pain?

Dr. EISENBERG. If the suspicion on the part of the clinician is high enough, an EKG would be standard, yes.

Senator SPECTER. How do you define suspicion high enough on the part of the physician?

Dr. EISENBERG. What the average physician will do will be to use what he has read, or she has read and experienced, and say, "this seems likely enough to me that I better look into this and get a cardiogram. " If that physician has a decision support system, which is a fancy way of saying a mechanism of helping the physician not just rely on his own memory, or what, then I think with that kind of system in place, we can get the best information to the doctor right away, rather than relying on our remembering everything in the frenzy of an emergency room setting.

Senator SPECTER. Can you generalize on the quality of the physicians available at emergency rooms across America?

Dr. EISENBERG. I think that the physicians who work in emergency rooms around this country are remarkable clinicians, work-

ing in very difficult and unpredictable situations. They do not know what is going to come in, and they know that it may be very important.

Their job is to figure out whether it is a very important problem or a problem that can be taken care of easily. That is the remarkable task of judgment that exists in an emergency room, and anything we can do to put systems or support programs in place to help them make those judgments better, will help improve the quality of care patients receive.

Senator SPECTER. Well, would you say that the hospitals customarily take very strong measures to be sure that the physicians in the emergency rooms are up to the wide variety of problems that they see?

Dr. EISENBERG. I think they do what they can with the resources that they have available.

Senator SPECTER. Well, actually, that is different, to do what they can with the resources that they have available. How frequently are they left to medical personnel who are in training, as opposed to experienced physicians?

Dr. EISENBERG. The requirements of the Joint Commission of Accreditation of Health Care Organizations and the requirements of all the residency review groups require that any physician in training be supported and backed up by a physician who is fully trained and experienced in this area.

Senator SPECTER. On the spot?

Dr. EISENBERG. Immediately available. As well as having nurses and other health professionals with experience. What I mean by the hospitals doing what is within their resources is the other support that they could provide them.

For example, a computer system. We know that we have the capacity to develop computer systems that would provide support to clinicians making decisions that exceeds the capacity of many hospitals today.

What we need to understand is why those computer systems have not spread more rapidly, which ones work, and which ones really make a difference in the issue that you are addressing. We need to understand how we can make computers more available in emergency rooms and hospitals around the country more quickly.

Senator SPECTER. Well, that is just the beginning, Dr. Eisenberg. There are just so many questions and so many issues, but thank you for those observations.

STATEMENT OF MARY WAKEFIELD, Ph.D., MEMBER, QUALITY OF HEALTH CARE IN AMERICA COMMITTEE, INSTITUTE OF MEDICINE; DIRECTOR, CENTER FOR HEALTH POLICY, RESEARCH AND ETHICS, GEORGE MASON UNIVERSITY

Senator SPECTER. We turn now to Dr. Mary Wakefield, the Director of the George Mason University Center for Health Policy and Ethics. She served on the Institute of Medicine Committee, which issued the report on medical safety, and is here to discuss the findings and implications of that report.

Previously, she served as a commissioner to the Medicare Payment Advisory Commission, and prior to her current position at George Mason she worked as Chief of Staff for Senators Quentin Burdick and Kent Conrad, from North Dakota.

Welcome, Dr. Wakefield. I also note an R.N. beside your name, registered nurse. Thank you for being here, and we look forward to your testimony.

Dr. WAKEFIELD. Thank you. Good morning, Mr. Chairman. My name is Mary Wakefield, and I direct the Center for Health Policy, Research, and Ethics at George Mason University, in Fairfax, Virginia.

As an aside, as you noted, many years ago I was sitting on the other side of the dais as a staff member to one of your former colleagues, and even though I am appearing on this side of the table, I just want to tell you it is a privilege to be back here in a room that I had actually spent a great deal of time as a staff member.

Today, however, I am here representing the Institute of Medicine's Committee on the Quality of Health Care in America, which recently released the report "To Err is Human: Building a Safer Health System." Joining me today is Dr. Janet Corrigan, Director of the IOM Quality of Health Care in America Project.

Patient safety is a tremendously important issue, and one that deserves urgent attention. Our health-care system in this country is the best in the world. We are living longer and are healthier than at any time in the history of humankind, but our health-care system is also under enormous strain, made evident by the number of medical errors plaguing us. The human cost is high. Based on the findings of one major study, 44,000 hospital patients die each year as a result of medical errors, and another study puts the number even higher, at 98,000. Even using the more conservative figure, medical mistakes, as you and Dr. Eisenberg indicated, would rank eighth among the leading causes of death, ahead of traffic accidents, breast cancer, and AIDS.

It is important to note that while errors may be more easily detected in hospitals, they afflict every health care setting: day-surgery and outpatient clinics, retail pharmacies, nursing homes, as well as home care. Moreover, some 7,000 patients die each year from medication errors that take place both in and outside of hospitals, and that number exceeds the annual rate of death from workplace injuries. These stunningly high rates of medical errors are simply unacceptable in a medical system that promises first to do no harm.

So, it is against this discerning backdrop that our committee undertook its study, and having spent substantial time reviewing the literature and examining the data, we have determined that no single entity is at fault, and furthermore that finger pointing and placing blame would be a pointless exercise.

Instead, we emphasize that reducing the high rate of medical errors will require rigorous changes throughout the entire health care system. Here, we are talking about system-wide change. Our report puts forward a comprehensive strategy for government, industry, consumers, and providers all needing to take action.

Taken together, our recommendations represent a systematic way to design safety into the process of care. They should be evaluated after five years to assess progress in making the health system safer. With adequate leadership, attention, and resources, improvements can be made.

To quote the report: "It may be part of human nature to err, but it is also part of human nature to create solutions, to find better alternatives, and meet the challenges ahead."

In order to meet those challenges, we must first face facts. Our health care system is a decade or more behind other high-risk industries in its attention to ensuring basic safety. The risk of dying in a domestic airline flight or at the workplace has declined dramatically in recent decades, in part because of the creation of Federal agencies that focus on safety. Drawing on that model, we urge Congress to create a center for patient safety within the U.S. Department of Health and Human Services.

This center would set national safety goals, track progress in meeting them, and invest in research to learn more about preventing mistakes. It also would act as a clearinghouse, an objective source of the latest information on patient safety for the nation.

For example, if a health care organization improves safety, its practices should be shared with a broad audience, and the center would help provide the needed channel to distribute that information. This center would not have regulatory authority.

Administratively, Congress would need to spend between $30 million and $35 million to set up the center, and it should be housed within the Agency for Health Care Research and Quality of HHS. Funding would need to grow to at least $100 million annually, or put another way, one percent of the $8.8 billion in health care costs attributable to preventable adverse outcomes.

At the same time, we recommend that a nationwide, mandatory public reporting system be established at the Federal level and implemented by State governments. Currently, only about a third of the States have mandatory reporting requirements, and yet this information is critical if we are to learn, in any systematic way, about medical treatments that lead to serious injury or death.

We also believe that the public has a right to know about errors resulting in serious harm, and that this information should be made available to the public with appropriate safeguards for protecting patient and provider confidentiality.

Health care organizations should also be encouraged to participate in voluntary reporting systems. These systems focus on medical mistakes that do not result in serious consequences. The IOM Committee does recommend Federal legislation to protect the confidentiality of these data when the information is collected and analyzed solely for the purpose of improving safety.

This would encourage the growth of voluntary, confidential reporting systems so that practitioners and health organizations can correct problems before serious harm occurs. Without such legislation, fears that reported information might ultimately be subpoenaed and used in lawsuits could discourage participation by practitioners and health care organizations.

A top-down system will not be enough to bring about the kind of fundamental changes needed to improve patient safety. Pressure from all directions will be necessary. That is to say public and private purchasers of health care insurance, including businesses buying coverage for their workers, should make safety a prime concern in their contracting decisions. Doing so will create financial incen-

tives for health care organizations and providers to make needed changes.

One reason consumers do not push harder for patient safety is that they assume accrediting and certifying organizations and local and State regulators do it for them. Regulators and accreditors should make patient safety a key component of their oversight programs. For most health care professionals, for example, there is no assessment of clinical performance once they get their licenses to practice. Licensing and certifying bodies should implement periodic reexaminations of doctors, nurses, and other key providers, based on both competence and knowledge of safety practices.

At the same time, the U.S. Food and Drug Administration also should increase its attention to public safety. As the agency that regulates prescriptions and over-the-counter drugs, it should make every effort to eliminate similar-sounding drug names, and confusing labels and packaging that foster mistakes. Numerous studies have documented errors in prescribing medications and dispensing by pharmacists as well as unintentional mistakes on the part of patients.

Reducing medication errors also will require that all hospitals and health care organizations implement proven safety practices, such as the use of automated drug ordering systems. Medication errors occur frequently in hospitals, yet many have not implemented known methods for improving safety.

Health care organizations must create an environment in which safety becomes a top priority. This culture of safety means designing systems geared to preventing, detecting, and minimizing hazards and the likelihood of error, not finding and attaching blame to individuals.

This requires creating and adequately funding systems to monitor safety. We urge the adoption of well-understood safety principles such as designing jobs and working conditions for safety; standardizing and simplifying equipment, supplies, and processes; and avoiding reliance on memory.

Because the know-how exists to prevent many of these mistakes, we strongly believe it is possible to achieve at least a 50 percent reduction in errors over five years. The majority of medical errors do not result from individual recklessness, but from basic flaws in the way the health care system is organized. Equipment controls that differ from one manufacturer to another, or from year to year, can contribute to errors.

Stocking patient care units in hospitals with drugs that are potentially lethal unless diluted before being administered has resulted in deadly overdoses. Illegible writing in medical records has resulted in the administration of a drug for which the patient has a known allergy.

More generally, medical knowledge and technology advance so rapidly that it is difficult for practitioners to keep up, and the health care system itself is evolving so quickly that it often lacks coordination. For example, when a patient is treated by several practitioners, those practitioners often do not have complete information about the medicines prescribed or the patient's illnesses.

Mr. Chairman, our report emphasizes there are no "magic bullets." No one part of this plan will be sufficient to bring about the

degree of change needed. Dramatic improvement requires comprehensive change involving all parts of the system.

Thank you for this opportunity to testify. I would like my statement put in to the record. I would be happy to answer any questions the Committee may have.

Senator SPECTER. Thank you, Dr. Wakefield.

When you state a 50 percent reduction within 5 years, that is a very tall order. Where do you get that? That is just not a figure pulled out of the air. What statistical base do you have for that expectation?

Dr. WAKEFIELD. Well, we base that on having reviewed the research that identifies both errors that have been committed, their sources, and what we know about how improvement in systems of care can actually occur. So in other words, a lot of the errors that are already occurring within health care delivery systems could be solved by the use of procedures that some facilities already have in place.

So in some cases, in many cases, as a matter of fact, a lot of the solutions to these problems are simply not disseminated throughout the health care delivery system. So part of what we looked at were the causes of those errors, and whether or not with the investment of a number of different organizations and initiatives, those that we identified in our series of recommendations, once brought to the table, we think that that, in fact, could result in at least half of those errors being eliminated within 5 years.

Senator SPECTER. Well, that is a good statement as to what you hope to do methodically, but how do you get to a 50 percent figure?

Dr. WAKEFIELD. It is an aim that, after a deliberation across the members of the committee, we thought was a tall order, a challenge, but an aim that if the resources of stakeholders with an interest in solving these problems are brought to bear, that it should be an achievable order.

Senator SPECTER. It is more than an aim, it is your expectation——

Dr. WAKEFIELD. Yes, it is.

Senator SPECTER [continuing]. That is what you say will happen.

Dr. WAKEFIELD. Yes, it is.

Senator SPECTER. To the extent that you could document that, we would be very interested. When you talk quantifiably about a success rate, and then we can turn that into dollars and cents when you have the figures as to how many billions of dollars it costs by these medical errors, that would be very helpful.

One of the items that you enumerate is well known to just about everybody, and that is the illegible writing issue. How are you going to handle that? It is a very common experience for all of us patients to hear doctors brag about how illegible their writing is when we get a prescription and go off to the pharmacy. How are you going to do that?

Dr. WAKEFIELD. It is a problem. There are systems that have been put in place in some health care delivery organizations. They operate on the use of computerized order entry systems. So rather than having to rely on Dr. Eisenberg's handwriting, for example——

Senator SPECTER. How is your handwriting, Dr. Eisenberg?

Dr. EISENBERG. It needs help.

Dr. WAKEFIELD. Assuming that Dr. Eisenberg needs help with his handwriting, we would ask him to actually enter that prescription on a computer, so that you eliminate the possibility of a nurse, a pharmacist, or some other health care provider misreading what he has written.

Senator SPECTER. To what extent is that done now, prescriptions entered on computers?

Dr. WAKEFIELD. There are hospitals, for example, that have incorporated those kinds of computer systems within their health care facilities, but there are many health care facilities that have not.

Senator SPECTER. Well, regrettably, I have been in a few hospitals, but I have never had a prescription entered on the computer, but that is done——

Dr. WAKEFIELD. Yes, that is correct.

Senator SPECTER [continuing]. To a significant extent?

Dr. WAKEFIELD. Yes, there are hospitals that have purchased and incorporated computerized order entry systems. There are many hospitals, as I mentioned, and other health care delivery systems that have not, even clinics, for example.

Senator SPECTER. Mandatory reporting requirements seems to me to be a very salutatory, very good idea, because if there is mandatory reporting, then the hospital, doctor, has to identify where a mistake is being made, and that is the first step to correcting it, if there is a report on it. People do not like to report mistakes, for good reason, so there is a real incentive to not have to report it, not to make it to have something that you do not have to report to start with.

What kind of resistance do you expect from hospitals, the American Hospital Association, the American Medical Association, the people who would be called upon to really face up to significant errors on that kind of a mandatory reporting system?

Dr. WAKEFIELD. Well, I guess perhaps, Senator, since I believe you have some representatives from those organizations they will probably be telling you what they think of that particular provision, but I would say that from the committee's perspective we thought it was an extremely important one.

We felt that mandatory reporting of very serious errors, errors and errors that result in patient death, ought to be operationalized, and that that mandatory reporting will help to hold the systems of health care accountable for the care that they provide and the safety that they ensure for their patients.

Senator SPECTER. Following hearings by this subcommittee, which also has jurisdiction over education funding, legislation was enacted fairly recently requiring colleges and universities to report campus crime.

There was enormous resistance to that, so that if the crime occurred on the sidewalk within the university complex, it was excluded, and we had to pass supplementary legislation to correct that and put some teeth and some fines into action by the Department of Education, but that, I think, is a core issue and one which there is going to be resistance. We are going to have work on that one very carefully.

Your first recommendation was the creation of a center for patient safety within the Agency for Health Care Policy and Research. Do we really need another bureau?

Dr. WAKEFIELD. Well, we are not recommending establishing a brand new agency, we are recommending the establishment of a center within an already existing agency to provide a very sharp focus to addressing issues around patient safety and error reduction.

Senator SPECTER. When we looked at the proposal for the national health policy in 1993 we had a chart that was more complicated than the New York subway system. We had about 100 new agencies and new jobs for about 50 agencies, even a new sub-box.

Do we really need that, Dr. Eisenberg? Do you have enough bureaus, agencies, without creating another center for patient safety within your agency?

Dr. EISENBERG. Well, we are looking at the IOM's recommendation to determine what we ought to recommend within the administration about the creation of a new center. I think there are certain elements about what the IOM has recommended that go undisputed.

The first is that there ought to be a place in government that has the responsibility for sponsoring the research and analyzing the data that exists. The second is that it ought to be an agency that has a focus on research, and it is not a regulatory agency. The third is that it not be separated from the rest of the quality agenda.

I agree with those three criteria, so I am comfortable with the idea that the responsibilities that the IOM has laid out rest within the Agency for Health Care Research and Quality, and we are going to look at what the right organizational framework for that vesting of responsibility ought to be.

Senator SPECTER. Well, you have a very impressive report, Dr. Wakefield. Where can people get a copy of this report if they want to pursue your recommendations?

Dr. WAKEFIELD. The Institute of Medicine will be making those reports available, within the National Academy of Science. It will also be on the Web, www.nap.edu.

Senator SPECTER. Well, it is very interesting, you start off at the top first, "Do no harm," and I just asked Dr. Chatta to find out where that comes from, and it is in the oath of Hippocrates, that even before you start to help you seek to avoid hurting, which is very interesting. When we patients go, that should be our first area of concern.

Well, thank you very much for your testimony. That gives us a good launching pad, and we will doubtless be talking to some more.

STATEMENT OF RAY McEACHERN, PRESIDENT, ASSOCIATION FOR RESPONSIBLE MEDICINE, TAMPA, FL

Senator SPECTER. I now call our second panel. Our first witness on this panel is Mr. Ray McEachern, President and co-founder, with his wife, Patricia, who is joining us on the panel, of the Association for Responsible Medicine, based in Tampa, FL.

Mrs. McEachern suffered permanent disability as a result of a medical error, bringing them to found the organization to inform patients about the need to protect themselves from such injuries.

Mr. McEachern served in the Peace Corps, at the Office of Economic Opportunity, and worked with former Secretary of Defense Dick Cheney at the Cost of Living Council, and is a graduate of Florida State University. Welcome, Mr. McEachern, we look forward to your testimony.

Mr. MCEACHERN. Thank you, Mr. Chairman. I appreciate the opportunity to testify. As you said, my name is Ray McEachern. My wife and I, Patricia, founded the Association for Responsible Medicine about five years ago. As a report from the IRM says, "To err is human." Of course, the second corollary of that statement is "To cover up is a crime." That is the message I am here to deliver.

I have heard the phrase, "It is not about fixing blame. It is about fixing the system," so often it appears to have become a mantra. I agree that it is not about fixing blame, but unless our first concern is the patient instead of the provider, we will never fix the system. Human beings make errors. Human beings can at times be negligent. Human beings sometimes lack the skill or concern that can lead to unintended outcomes. Systems for preventing human beings from making deadly mistakes must be designed with a focus on human nature.

When the system is to blame, then no one is responsible. I reject that notion. Health care providers are responsible adults. The concern should not be to protect the health care providers, or more precisely, their insurance companies, the concern must be to find ways to prevent injuries from being covered up.

When mistakes are covered up, no system can be designed to prevent them. An effective system for preventing error must recognize the human tendency to deny our own responsibility when things go wrong, it must provide an incentive to learn the humility that comes from admitting our own errors, and it must get rid of those who do not learn.

My wife and I learned about medical injury the hard way in 1992 when a catheter got tangled inside her carotid artery. There was no report made of that error, as was required by law, because as the doctor testified a few years later in a deposition, and I quote, "No one gave me the report form."

The nightly news is filled with reports of automobile accidents and diseases like breast cancer and AIDS, but when a human being suffers a perforated artery during an angiogram or a perforated bowel during a C-section, there are no reports on the nightly news or anywhere else for that matter.

In fact, the Florida Hospital Association had the Florida law changed in 1998 so that mistakes like perforations of organs would no longer have to be reported. That change was just another example of how the foxes are allowed to guard the hen house.

If anyone doubts my analogy about the foxes in the hen house, just take note of the fact that the speaker of the Florida House of Representatives is none other than the former general counsel and chief lobbyist for the Florida Medical Association.

For several years, my wife and I have argued that a national hospital safety board should be established with the power to audit

hospital reports of adverse incidents, infections, and mortality, and publish those reports by hospital name. A system for reporting errors is long overdue, but we must not let those foxes that have been guarding the henhouse, because that would just give the public a little thin chicken soup. That is the kind of reporting system we are going to have if we leave it in the hands of the hospital and doctor associations.

The reporting system must be mandatory and its results must be open and accessible to the public. There must be penalties for failure to report that are meaningful and more to be feared than the financial consequences or the public outcry of the mistake itself. There must be a mechanism for informing the public that allows us to select those providers that have the best records.

Let the marketplace reward those hospitals which have the best patient care records and they will, I assure you, make sure that their staffs include only the best trained and the most concerned health care professionals.

Florida's mandatory error reporting system is designed to protect the reputation of the doctors, and the hospitals, and the bank accounts of their insurance companies. After more than 14 years of confidentiality that is supposed to encourage reporting, the reporting system is a virtual scofflaw.

As an example, one Florida hospital, whose name I am not privileged to know, because of the confidentiality laws, changed its annual report in 1996 from the 10 or 20 they probably reported to approximately 1,700 medical injuries after a training audit was conducted by the agency in Florida that licenses hospitals. Because that hospital was required to report accurately, they had, that one hospital, reported 37 percent of al the iatrogenic injuries reported by all Florida hospitals that year.

The other 200 hospitals in Florida were involved in a massive coverup of human injury that the Harvard study would estimate to be at least 60,000 people. The State government is aiding and abetting the cover-up by hiding the identity of the wrongdoers, by allowing the same doctors to repeatedly make error after error without losing there license, by dismissing our complaints without any investigation, and by passing so-called tort reform laws that slam the courthouse door to the people who would dare to question the care they have received.

If I could somehow give voice to the hundreds of thousands of tongues that have been silenced forever by medical injuries, or if I knew how to give motion to broken bodies that no longer have the capability to fight for themselves, I think there would be a demonstration in the streets of Washington that would rival the demonstration that was recently held in Seattle.

The people who were medically injured are silent, and it is not because they do not care, it is because they are in despair.

Now, I have made some specific recommendations, Mr. Chairman, and I hope this committee will seriously consider those, and I thank you for the opportunity to speak.

STATEMENT OF PATRICIA McEACHERN

Senator SPECTER. Well, thank you very much, Mr. McEachern. If you are willing to do so, we would be interested to know more

about the specific situation about Mrs. McEachern, which has obviously motivated you to be very, very active on this line. Mrs. McEachern, we welcome you here——

Mrs. MCEACHERN. Thank you.

Senator SPECTER [continuing]. And look forward to your statement. We do not want to pry, obviously, but to the extent you feel comfortable telling us what happened to you, we are interested to know that.

Mrs. MCEACHERN. OK. The doctor that I gave approval to run a catheter up, he is the doctor that committed the same thing that happened to me 6 or 7 months prior to somebody else. I did not know it. What he did was he let a resident do the procedure without my approval. The resident did not know what he was doing. He had never done it before.

He got the catheter tangled and it caused my knee to be paralyzed on the right-hand side, my leg and my arm. There are other things, my speech, and things like that.

Senator SPECTER. Was the doctor present when the intern performed the catheterization——

Mrs. MCEACHERN. He said he was.

Senator SPECTER [continuing]. Or the resident, rather.

Mrs. MCEACHERN. The resident was the one that performed it, and the doctor said he was present, but I do not know for sure that he was.

I do not think that a person should be allowed to have somebody do the work on them that you have not approved. The doctor was the one who I had approved to do it, and the resident did it. I did not give the approval.

Senator SPECTER. When did you find out that the resident rather than the doctor had performed that procedure?

Mrs. MCEACHERN. My husband was the one that found out.

Mr. MCEACHERN. Actually, it was learned later that evening from another doctor that what had happened, that she had been stroked, that is a term in the hospital industry, they talk about stroking their patients as if they were stroking a cat, but they do not mean that kind of stroking.

"They stroked your wife," he said, "during the angiogram." Several weeks later, of course, I found out the doctor was who was supposedly supervising the angiogram, and then talked with him. He admitted that he had allowed a resident physician to do it.

Senator SPECTER. Did he say he was present at the time?

Mr. MCEACHERN. He did not say that—he did not deny that he was there. In other words, I did not ask him on that particular issue. I do want to observe, though, that while I was talking to him in the hospital he was outside an operating suite, and operating room suite, where another patient may have been undergoing the same kind of procedure.

In other words, I do not know for a fact what he was supervising or supposed to be supervising at that time, I do know that 6 months prior he had been sued for the exact same kind of error that had occurred with my wife, because he let another resident physician perform it, and since then he has been sued for several other things. I might also admit, even with Florida's mandatory reporting system of errors, he did not report the error, he also has

recently falsified records that were submitted to our Department of Health for entry on the Internet concerning his malpractice record.

So what I am saying is that doctors are just like the rest of us, we do not like to admit our mistakes, and if there is any way we can get away with it, denying them or keeping them from becoming public, they will do so, unless we have an effective system with teeth in it.

Senator SPECTER. Mrs. McEachern, what damages or injuries did you sustain?

Mrs. MCEACHERN. My right leg is paralyzed and my right arm is paralyzed. I have a numbing sensation in my face. I am going to have to be on medicine the rest of my life, so I will not have seizures. I am also on Prozac, a depressant.

What I would like to say is that this is so hard for a person to have something like this happen. I was fortunate to have a family to care for me, but there are so many people out there to have this done to them that have absolutely nobody, and the medicine that they put you on is so expensive that the people have to go on Social Security, and they just do not have the money to buy, so they are, you know——

Senator SPECTER. Did you institute legal action against the doctor?

Mr. MCEACHERN. We were very, very fortunate, sir. As the Harvard study reports, only 2 percent of the people who were negligently injured ever file a lawsuit, by medical mistakes. That was an observation, based on research in the Harvard study.

Senator SPECTER. What was the result of that lawsuit?

Mr. MCEACHERN. We won our lawsuit. It took 4 years. We were only able to find a lawyer to accept our case after visiting many different lawyers that turned us down.

We, by perhaps the grace of God, found a lawyer, who for 25 years had been a radiologist, a doctor, in other words, before he became a lawyer. He understood exactly what happened to my wife as soon as he saw the X-rays. He never batted a eye when he saw that and accepted the case.

Senator SPECTER. Was the case settled, or did you have to go through the——

Mr. MCEACHERN. Well, as is common, the insurance company and the doctors denied it until about 2 weeks before a trial was scheduled. The doctor settled just before that, the trial began. The medical school, which was also in the lawsuit, because of the intern, continued to deny it and went to trial, and we got a jury award of $1.7 million in damages from the jury.

Of course, there is a cap, very common in all of medical malpractice throughout the country. There was a cap on awards for medical malpractice for the medical school of $200,000. In our case, it is $100,000, where if there were two injured parties, myself and my wife, then it is $200,000.

So that is one reason it is so hard to get a lawyer. With the caps that tort reform has instituted nationwide, and, of course, sovereign immunity-type caps, which are also very common, most people, even if they know they are negligently injured in a hospital, are not able to find a lawyer.

Senator SPECTER. Thank you very much, Mrs. McEachern, and thank you, Mr. McEachern.

STATEMENT OF DIANE ARTEMIS, FALLS CHURCH, VA

Senator SPECTER. We now turn to Ms. Diane Artemis, of Falls Church, VA, currently a senior business process engineer, specializing in international organizations. She suffered from a hip joint disease, and endured problems as a result of—well, she will describe it herself. She has over 25 years of experience in managing technical projects. She was a captain in the air force, and holds a B.A. in English and a master's degree in public administration.

Thank you for joining us, Ms. Artemis, we look forward to your testimony.

Ms. ARTEMIS. Thank you, Mr. Chairman. In the interest of saving time, I would like to skip the details of what happened to me, and instead, merely summarize that in May of 1993, I——

Senator SPECTER. That is fine, Ms. Artemis. Do it any way you like.

Ms. ARTEMIS. In May of 1993, I had total hip replacement surgery, due to left hip dysplasia. What followed was a sad comedy of errors that resulted in five trips into the operating room to correct surgery.

This had started when, after surgery I was being escorted to the toilet by a med tech, which is someone who does night duty at many hospitals without LPN or RN credentials. The med tech caught me, a freshly operated hip replacement patient, and somehow got me back into bed, and afterwards I underwent spasms, the hip replacement prosthesis tore through my sutured tissue, and lodged in the muscle tissue of my left thigh.

Over the next 3 months it formed heterotopic ossification, which was caused by the breakdown of traumatized muscle tissue into calcium shards, and this hardened around my left hip. I eventually underwent total reconstructive surgery of my left hip, and I would have, had I not been young, athletic, and fit, been left crippled or probably dead from what had happened to me.

I would respectfully mention that there was a Journal of American Medical Association magazine report on December 4, 1994, that estimated the amounts of deaths per year in this country, upwards of 180,000, rather than 98,000, and many, many more from injuries.

I will skip to some of my conclusions that I made after what happened to me, and I respectfully submit them to the chairman and subcommittee for your consideration.

In addition to the multiple surgeries and the 3 months lost from work that the medical errors caused me, please consider that the cost of a routine hip replacement with rehabilitation and implant included is normally $12,000. The total cost to my insurance company for these multiple surgeries, rehabilitations, and out-patient treatments was nearly $200,000.

Did the surgeon or hospital administrator responsible for training and hiring staff have any incentive to do it right the first time? No. Apart from the personal integrity and competence a patient would they would have, both doctor and hospital profited from every mistake which required repeated surgeries, stays, drugs,

equipment, X-rays, and therapies. Please remember, this was not an HMO or managed care medicine, this was private, fee-for-service medicine all the way.

Did my insurance company have an incentive to contest the charges? No. When I contacted them, they claimed that contesting the charges would be more expensive than simply paying whatever was billed.

So, to whom is a doctor or a hospital administrator accountable? To you? To me? To the government? To other doctors? No one, really, I found. On paper they may be accountable to a State medical board or the Joint Commission on the Accreditation of Health Care Organizations, the JCAHO, but these boards and the JCAHO are merely doctors and administrators policing their own.

JCAHO inspections are announced several months in advance and well-prepared for by a hospital staff. In the case of a medical board investigation of a patient complaint, unless there is evidence of drunkenness or egregious social misconduct, a doctor or administrator will usually be vindicated by his peers.

Can an individual gain access to complaints lodged with the medical board or State insurance corporation to judge for herself whether to take a chance on a particular doctor or hospital? Not in your life? Had I been able to review patient comments about my surgeon, I never would have chosen him. Although technically competent, with superb credentials, his history of incompetent aftercare made him a poor choice.

It is remarkable to me that I can find out more about a plumber by contacting the Better Business Bureau and viewing its open file of consumer comments than I can about a doctor who is going to cut open my body. Choose a doctor by word of mouth? How many people did I know who had had a total hip replacement? Even if I were to find and ask a prior patient, how could I evaluate his opinion or circumstances without viewing the doctor's or hospital's performance in the aggregate?

Does the individual fare any better when she wants to research a hospital's safety record, protocol for handling hip replacement patients; that is, an X-ray required when a patient falls, and assess the level of staff training provided to ensure that a hospital's staff is qualified to treat someone, in my case, recovering from hip replacement surgery? I was placed in a ward whose primary service was head trauma, head trauma rehabilitation, rather than hip replacement rehabilitation.

It is my experience that the hospital administrator, if he responds to such requests for information at all, will quote a list of legal citations a mile long prohibiting the release of this information. Other industries which impact human health, safety and the environment are compelled by disclosure laws to provide such data to the public, as well as to State, local, and Federal inspectors.

The chemical, pharmaceutical, automobile, manufacturing, aviation, et cetera, et cetera, industries all must submit to OSHA and EPA inspections and share their safety records and operating procedures with the public.

How has the medical industry and its personnel obtained these exemptions? Do they impact our health and safety any less? Are

they more prone to be sued than are the chemical, aviation, or other regulated industries?

Tort reform is another issue; we are talking public safety here, but as previously mentioned, only 2 percent of these cases ever make it into court, and for a variety of reasons, it is difficult to find attorneys willing to take on these cases.

As the shocking statistics of 100,000+ deaths per year—and several hundred thousand more injured by negligence or inadequate staff training—show, it is time the medical industry opens its books to public scrutiny of its patient-handling protocols, safety records, and training requirements.

Additionally, any citizen ought to be able to obtain a copy of any complaints filed against a doctor or hospital. Let the consumer have the right to know and judge for herself. After all, our lives are often in their hands and our salaries and insurance costs pay their bills.

I would respectfully add that we have to get beyond an us versus them mentality with doctors and hospitals covering up their mistakes and refusing to acknowledge them. In the chemical industry, for example, unless one causes egregious loss of life and property, an error in operations is not penalized if (1) it is properly recorded and (2) corrective action immediately taken.

Unless doctors and hospital officials are willing and able to admit their mistakes, learn from them, and promptly correct them, we will widen the chasm of distrust between them and us, and watch the percentage of our Gross Domestic Product spent on medical care skyrocket.

I sincerely hope that these hearings help foster a culture of public service and safety in the medical community. I would respectfully suggest the subcommittee consider the creation of medical industry best practices, enabling doctors and hospitals to benchmark their performance against other countries, other industries, and each other. The consumer would benefit by being able to make an informed and objective choice.

Our Nation would benefit by lower overall medical costs to repair damages caused by negligence or carelessness, and less time lost from work. If we work together with our doctors and hospitals to define and improve the standard of care, combined with our technological know-how, we will finally achieve a medical system that can be the envy of the world.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you very much, Ms. Artemis. You say that you had expenses of some $200,000 for what should have cost $12,000.

Ms. ARTEMIS. Yes, sir, close to it.

Senator SPECTER. How many separate operations did you have?

Ms. ARTEMIS. I was in the OR five times, and three times was cut open.

Senator SPECTER. That was on a procedure, which according to your understanding, should have been accomplished with a single operation.

Ms. ARTEMIS. Yes, sir. Mine was very uncomplicated. The original surgery took less than an hour. Very simple.

Senator SPECTER. Did your insurance company pay all of these charges?

Ms. ARTEMIS. My insurance company, I was extremely blessed to have a very generous insurance company, also provided for 12 weeks of rehabilitation care and nursing home care, because I do not have family members to care for me.

Senator SPECTER. Have you had any permanent disability or permanent problems resulting from the operations?

Ms. ARTEMIS. Yes, sir. I have lost most of my major muscle tissue in the left hip sockets. The reconstructive surgery I had was to put together my hip in a new way to allow me movements, and also when I inevitably need replacement of the prosthesis head, the plastic prosthesis head, I may at that time be a cripple.

Senator SPECTER. But you did not consider any legal action against anyone.

Ms. ARTEMIS. No, sir. Actually, I did. My treatment surgeon volunteered to be an expert witness for me, but because both he and my surgeon who performed the operation were adjunct professors at the same medical university, he would only go to court and testify that there was negligence, but he would not name my provider by name. There is a statute of limitations of 2 years, and it expired at the end of the 2-year term.

Senator SPECTER. What efforts had you made to determine the qualification of the doctor who performed the initial operation?

Ms. ARTEMIS. The doctor who performed the surgery was the chief of orthopedic surgery at a very prestigious university hospital. He had done thousands of these procedures. He was well known, well published. I asked to speak to several of his previous patients, and they all thought he was a wonderful, wonderful surgeon.

Senator SPECTER. Well, we will be getting into this subject in great detail. When a doctor or a hospital is obligated to report mistakes, there is a little different issue as to reporting lawsuits or claims which were filed, which were not determined to be mistakes. If there is a judgment issued, and if there is a verdict, then there is a conclusion of an error. If there is a claim made, that does not prove an error until the matter is investigated further.

Your point is you would like to see—or what would you like to see? What would you like to see reported so that you would have a better idea? What could you have found out about the doctor in your case, had you had a range of possibilities?

Ms. ARTEMIS. Well, the original surgeon I chose was from a very prestigious practice specializing in joint replacement surgeries, so I presumed that he was superbly qualified. His credentials were excellent.

Senator SPECTER. Have you heard after the fact that he had been sued——

Ms. ARTEMIS. Yes, I have.

Senator SPECTER [continuing]. In the past?

Ms. ARTEMIS. In searching for attorneys to take on the case, I came across—because I was not crippled, dead, or brain damaged, I had attorneys do underwriting of what they could potentially gain in a case, and I was—because I was young, and healthy, and walking again, I was of low value, so I was interviewing various attorneys, and found in talking to them that they, indeed, had been ap-

proached by patients for this particular surgeon, but for various reasons did not go any further, but I did learn that he had had a track record of this sort of behavior.

In addition, one of my neighbor's father was an anesthesiologist who practiced with this surgeon, and I had heard that he had had a number of disciplinary actions for throwing equipment across the operating room. So I had heard over the months that he had this reputation.

Senator SPECTER. The insurance company took no action either to recover their $200,000 in losses.

Ms. ARTEMIS. No, sir. They claimed that fighting, litigating, going to court potentially would ultimately cost them more time and resources than just paying the bills.

Senator SPECTER. Thank you very much, Ms. Artemis. Thank you.

STATEMENT OF DEBRA MALONE, VAIL, CO

Senator SPECTER. We now turn to Ms. Debra Malone, an intensive care nurse from Avon, CO, 11 years of experience in her profession. Her father, Dr. Karl Shipman, was an internal medicine specialist in Denver whose medical situation was a resulting death from a series of errors in his care, and was extensively chronicled in their local press.

We welcome you here, Ms. Malone. I note that you are a graduate of the University of Colorado at Boulder. Thank you for joining us, and we look forward to your testimony.

Ms. MALONE. Thank you. My name is Debra Malone, and I am honored to speak to you today. I am here to tell you about my father's death. My 64-year-old father, Dr. Karl Shipman, broke his wrist when he fell off a ladder in 1997. The fracture required surgical repair with an external fixator. His death was as a result of a staph infection that began in his healing wrist and spread into his spine, eventually causing multi-system failure. What should have been routine treatment became a series of medical missteps and misdiagnoses that resulted in the death of a wonderful man.

There were opportunities for medical intervention that could have saved my father's life that went unrealized. The spreading infection in his wrist and spine was misdiagnosed as back strain during several office visits. The swollen wrist was characterized as normal.

Physical therapy was the prescribed treatment. The orthopedic physicians never took vital signs or conducted basic lab tests that could have indicated the presence of an infection.

Under the care of these physicians, my father's condition worsened. When I insisted that he be admitted to the hospital, he was admitted to the 600-bed hospital in Denver, where he practiced internal medicine for 35 years. The day he entered the hospital he still had a fighting chance to recover from the infection that was now becoming critical. Unfortunately, the errors were to continue for another 22 hours. Time had proved crucial.

Even with lab tests indicating a very sick man, diagnosis and treatment were slow, at best. He spent the night in the intensive care unit under the care of a float nurse, who was not trained in the IC setting. This unqualified nurse was working with a medical

intern who was only months out of medical school. Together, they failed to recognize the severity of my dad's deteriorating condition.

Important changes in his cardiac rhythm were not addressed. Medication errors occurred. Antibiotics were missed. Haldol, an anti-psychotic medication, was inappropriately given to my father for his new onset of confusion. He was, in fact, severely hypoxic from impending respiratory failure. The tending physician was never notified.

I was at my father's bedside during this nightmare. In the middle of the night, when my initial questioning turned to adamant concern, I was removed by the nursing staff and told to get some rest. By the morning, my father was in decompensated shock, cardiovascular collapse, and respiratory failure.

At this time, the intensivist, who was a board-certified critical care physician, immediately intervened. He rapidly recognized the dire situation and began heroic efforts to save my father's life. After this night, my father never spoke again. He died 18 days later.

The pain of our loss is compounded by the knowledge that his death was probably preventable. As a nurse, I was extremely disturbed by the entire sequence of events. Because of my expertise within the ICU, I live with the feeling of having let my father down by not more forcefully challenging the inadequate care given that first crucial night.

What became even more upsetting was the stonewalling, defensive posture the hospital took when I attempted to address these issues with them. The risk management office assured me that they had reviewed the case and found nothing wrong with the care my father received.

After this, HCFA investigated and found several areas of deficient care, and has placed the hospital under continued investigation for the next year. This action was just short of revoking over $100 million in Medicare funding.

Medicine is complex. We cannot expect perfect outcomes in every situation, but our profession is not doing everything it can to assure the best possible outcomes at all times. My father's case illustrates the need for better supervision of medical residents, better nurse staffing, and better guidelines for appropriate nurse assignments.

An important change that I have been advocating is the reorganization of physician resources in an intensive care unit. The Society of Critical Care Medicine supports what is commonly referred to as a closed or highly structured ICU system.

In this system, a board-certified critical care physician, otherwise known as an intensivist, is the team leader for every patient admitted to the ICU.

They are in the ICU to oversee patient care and education of house staff 24 hours a day, 7 days a week. They coordinate the plan of care with the other physicians on the case, thus eliminating fragmentation that often results in inefficient and unsafe care.

It is well documented that this system significantly increases staff efficiency, decreases patient mortality, and lowers hospital costs. Unfortunately, despite this evidence, many hospitals, includ-

ing the one my father was admitted to, failed to utilize this invaluable system.

Thank you for listening to my story and for your dedication to improving patient safety.

Senator SPECTER. Thank you very much, Ms. Malone. When you testified about what you concluded to be the inadequate care given to your father, you described a float nurse and an intern. Precisely, what is a float nurse?

Ms. MALONE. A float nurse is a nurse who works on another unit, has another specialty of care, and is brought into another unit to work that night. They are floated into another unit.

Senator SPECTER. Was your father in the intensive care unit at that time?

Ms. MALONE. Yes. I believe a lot of this is resulting, and I say it frequently, is the result of nursing staff shortages. They are minimally staffed, and if someone is sick, or patients are moved to the ICU, or to the OB unit, or whatever unit it is, managed care, or many hospitals now, will, instead of paying bonuses or overtime for nurses, or seeking more qualified nurses from an agency, maybe an intensive care nurse from an agency that is more costly, they will bring in another nurse from another unit, which is not their specialty.

I believe that nursing is very highly specialized now, which is, you need to be cross-trained, but you cannot move as easily from one unit to another.

Senator SPECTER. Well, when your father was in the intensive care unit and you were there with him, how much attention did he receive from the float nurse and the intern? How much could they care for him, considering the other responsibilities they had at the same time?

Ms. MALONE. I believe my father was probably that nurse's only patient. In the intensive care unit, it is usually one-to-one nursing—one patient to one nurse, possibly two patients to one nurse.

Senator SPECTER. How about the availability of the doctor?

Ms. MALONE. The medical intern was called at one point, and did come in to see him at one point, but it was never supervised by an attending physician or somebody else that could have directed more appropriate care for my father's condition.

Senator SPECTER. Well, was there an attending physician?

Ms. MALONE. The attending physician was at home sleeping. The problem at this hospital, and at many institutions throughout the country, is that the attending physician will directly supervise the medical intern or resident.

Direct supervision is a pretty loose term, because I failed to see how direct supervision occurs when an attending physician is at home sleeping, or 30 minutes away seeing office patients.

Senator SPECTER. Well, the question that I had raised with Dr. Eisenberg to start, we were just on the point about the emergency room, was the adequacy of the care. We were talking about the situation with chest pains, and how familiar the emergency person would be there, and there have been some grave problems about reductions in funding for the Federal Government under certain of our legislative initiatives.

We just made an adjustment to legislation 2 years ago, adding some $10 billion to hospital reimbursements, and there is no question about the escalating costs of medical care, but these are all parts of the issue which the Congress has to consider, and the Congress has a significant responsibility here, but the question in my mind is, what is the quality of care there and how good are the people.

An intern is obviously limited as to the training, and background, and professionalization. You did raise an objection in the middle of the night——

Ms. MALONE. Yes.

Senator SPECTER [continuing]. And they told you, in effect, to go home. Tell us a little bit more about what happened.

Ms. MALONE. Well, I was quite upset. I was very exhausted. I had just flown in from an international trip. I did not know that it was a medical intern just months after medical school. I did not know that this nurse had never been oriented to the ICU. I was in a very large ICU. Most of my nursing experience is in small rural areas. This hospital had been a part of my life since I was a year old. I have trusted this hospital. I placed all my trust in them. I was a daughter at the bedside.

Senator SPECTER. How old was your father?

Ms. MALONE. He was 64 years old, still practicing medicine full time, married for 40 years.

Senator SPECTER. You say HCFA had the capacity to have——

Ms. MALONE. Right.

Senator SPECTER [continuing]. Taken action to——

Ms. MALONE. Well, after a year of grieving and despair, I finally contacted a patient advocacy group. Even as a nurse, I did not even know—in your grief you do not even know how to report anything. I finally contacted a patient advocacy group, and they gave me instructions.

So I went through the reporting process. I reported it to the nursing board, to the medical board, and to the health board. HCFA investigated, and it received quite a bit of media attention, and quite a bit of change was effected from this.

Senator SPECTER. Tell us about the change, if it did lead to improved procedure. What exactly did happen?

Ms. MALONE. It was mostly administrative procedures for showing nurse competencies, reporting of medical errors for medical residents. I did not see necessarily a huge change to prevent it from happening, it was almost more in the reporting thing. I would like to see changes, system changes that prevent it from happening so we do not even get to the reporting phase.

It is interesting to note—the medical board and the nursing board are still reviewing the case. It is interesting to note that in the State of Colorado, the Colorado State Medical Board has no jurisdiction over medical interns or residents.

Senator SPECTER. Was any consideration given to legal action in your merit?

Ms. MALONE. Yes. This is not a decision taken lightly by my family. My mother is a nurse, I am a nurse, and my father was a doctor. These were all colleagues and friends that we were pursing

legal action. We took almost 2 years to file a wrongful death suit. We went up almost to the statute of limitations.

It was difficult to find competent attorneys that you felt comfortable with taking this case. The cap for wrongful death in Colorado is $250,000.

For a medical resident, it is only $150,000, and you had to file within 6 months, because a medical resident is a government employee, and we did not know this at the time. So the medical resident is under government immunity from a lawsuit and from disciplinary action from the medical board.

Senator SPECTER. What happened to the lawsuit?

Ms. MALONE. We are just in the starting stages of it. Two years ago my father died on November 8.

Senator SPECTER. So the lawsuit is pending at this time.

Ms. MALONE. It is pending. We just filed, and we are starting the proceedings. The procedure, to go down that painful road, we had to fight tooth and nail for restitution for pain, suffering, and death.

Senator SPECTER. Well, thank you very much, Ms. Malone, Ms. Artemis, Mr. and Mrs. McEachern. The subcommittee would be interested if you would take the time to read this report, and we can get you copies, and tell us from your own experience what you think of these recommendations, or what else you would recommend from your own experience.

This is the sort of a matter where there ought to be broad public comment to see what remedial action ought to be taken. People who have been a part of the system and have had problems are very important, and we are going to be hearing from the professionals at all levels, but we would be very interested in your thinking.

Do you have a final comment, Mr. McEachern?

Mr. MCEACHERN. I just wanted to ask, Mr. Chairman, if you saw the recommendations that we have submitted. We submitted seven recommendations with our presentation.

Senator SPECTER. I have seen them, and they will be shared. My colleagues could not be here, so Senator Harkin, who is the ranking member, is very much concerned about this, as are all the colleagues. We do have them and we will circulate them, and we are considering them.

Mr. MCEACHERN. I would just like to make one final observation that there is a gentleman in the audience here today who is the president of a company here in Gaithersburg, MD. The name of the company is HT Medical. They make patient simulators.

We should not be training and maintaining the staff of physicians on human beings, not at least until they have been qualified on some other non-human object, and patient simulators are the way to go. We would not send a man to the moon without his knowing how to fly there and back. We should not allow a doctor to operate on a patient without his having taken all the steps necessary on a patient simulator.

Senator SPECTER. Well, if that gentleman would contact my office, we would be interested to talk to him. Thank you all very much.

STATEMENT OF DR. NANCY DICKEY, IMMEDIATE PAST PRESIDENT, AMERICAN MEDICAL ASSOCIATION

Senator SPECTER. I now turn to our final panel, Dr. Nancy Dickey, Ms. Anne Shea, Mary Foley, Dr. Stan Smullens, and Dr. Martin Merry. Dr. Nancy Dickey is immediate past president of the American Medical Association, family physician from College Station, Texas. During her presidency of the AMA, Dr. Dickey helped create the National Patient Safety Foundation and currently serves on the executive committee of the foundation. She earned her medical degree from the University of Texas Medical School at Houston. Thank you for joining us, Dr. Dickey. You are our lead witness.

Dr. DICKEY. Thank you, Mr. Chairman. Good morning.

The AMA appreciates the opportunity in your calling this hearing, and for us to talk about the IOM report. The elimination of errors is a high priority for the AMA, and we have been a pioneer in the effort to reduce errors and improve the quality of the nation's health care.

For example, in 1996, the AMA joined with other leaders to convene the Annenberg conference, which was the first multi-disciplinary conference on errors, and in 1997, we established the National Patient Safety Foundation, which is an independent not-for-profit organization that brings virtually all of the stakeholders together.

We fund research, have tried to write curricula, and so forth. We are pleased, in fact, that the NPSF was acknowledged in IOM report as a leader in this area.

I assure you, as I assure my patients, that the AMA will continue our efforts to eliminate health care errors, and as an association founded on the commitment to improve the quality of medical care, any error that harms a patient is one error too many.

We believe that true reform has to include all components of the health care system, hospitals, nurses, pharmacists, manufacturers of drugs and devices, physicians, and others all have to work together to identify, study, and solve system-wide problems that could cause errors.

Equally important is the necessity to transform our culture of blame and punishment, a culture being one that tends to suppress information, to a culture of openness and information sharing, and one that says that the right thing to do is put the information on the table.

We are pleased that the IOM report recommends such an approach to reducing errors, in which punitive efforts are rejected, and efforts to create a culture of safety are recommended.

The IOM report, however, recommends a mandatory reporting system. We have serious concerns with this approach. Past Federal efforts to collect data on physicians and other health care providers in the name of quality improvement have had a negative effect on efforts to create an environment that fosters trust and open communication.

Like the successful FAA model for reporting errors, we believe that guidelines for a national reporting system should, at a minimum, include a non-punitive mechanism for reporting incidents, post-incident review, and federally guaranteed protections from discovery for all aspects of voluntarily reported information.

System-wide trusts and communication are fundamental elements for successful reform. This can be achieved first by acknowledging that the vast majority of health care system errors are not intentional and have to be distinguished from truly negligent behavior. The focus should be on reforming the system, not on punishing the individual.

I thank you for the opportunity and will share my time, if I can, with Ms. Shea, from the Patient Safety Foundation.

SUMMARY STATEMENT OF ANNE SHEA

Senator SPECTER. Ms. Shea, welcome.

Ms. Shea is the Chief Operating Officer and Acting Executive Director of the National Patient Safety Foundation. First some background. Her MBA is from Lake Forest Graduate School of Management. Welcome, and we look forward to your testimony.

Ms. SHEA. Good morning. My name is Anne Shea, and I am the Chief Operating Officer and Acting Executive Director of the National Patient Safety Foundation. The mission of the 2½-year-old nonprofit foundation is to measurably improve patient safety in the delivery of health care.

In order to do this, the NPSF concentrates on four principle areas: Research, communication, education, and applications in learning. We try to cover the full range from analysis of what the problem is, to practical solutions. Therefore, the NPSF is a forerunner and a companion to the concerns expressed in the IOM report.

In fact, in "To Err is Human," the National Patient Safety Foundation is often mentioned as an example of what is needed. Quote, "The National Patient Safety Foundation may be able to serve a resource and dissemination role, and NPSF is well positioned to translate concerns and findings about patient safety between many different parties."

This evaluation coincides with our own self understanding. We are well positioned to contribute significantly to our common goal of patient safety. In particular, we are well positioned to become one of the centers for excellence that the report recommends. Our initiatives connect very closely with the overall direction of the IOM report.

Let me give you a sense of what we are doing. We have convened a group of national authorities concerned with reducing medication errors and have identified 41 challenges. We are now in phase two, which focuses on implementation. We are initiating a national call for solutions that is scheduled to be announced in the next 30 to 45 days. This initiative is in conjunction with the Joint Commission on Accreditation of Health Care Organizations.

With the support of the AHCPR, now called AHRQ, we are conducting a cataloging patient safety research project that will document the extent of patient safety research, as well as identify the gaps in existing knowledge. We have in place a clearinghouse of multi-disciplinary literature relevant to patient safety. This brief overview provides some idea of what we are doing.

With committed leadership, a strong infrastructure, and diversified programming, we are looking forward to working with the IOM and other interested parties to increase patient safety. Thank you.

Senator SPECTER. Thank you, Ms. Shea. Dr. Dickey, in your prepared statement, and you covered this part of it, and your full statement will be made a part of the record, you talk about guidelines for a national reporting system, which should, at a minimum, include a non-punitive mechanism for reporting incidents, and a federally guaranteed legislative protection from discovery for all aspects of this information.

Now, we have heard testimony from a number of witnesses here today who wanted to have access to find out about their doctors and their hospitals. Would this information be available to such prospective patients, as you see it?

Dr. DICKEY. I think part of the problem that we see today can be highlighted by looking at the successful FAA reporting. When that system combined the regulators and the reporting, and did not promise to be non-punitive, it was used very little. It was only when——

Senator SPECTER. It was used for what?

Dr. DICKEY. It was used very little by pilots. It was only when they were guaranteed confidentiality, and when there was a promise that if you called and reported a potential problem, there would not be a punitive action, that it began to accumulate the kind of data that has led to a great deal of the safety progress in aviation.

One of the problems that occurs today is that when an error or even a near miss, as Dr. Eisenberg talked about, occurs, getting people to talk about it openly is difficult, because it is an invitation to a liability lawsuit, which is time-consuming, expensive, and oftentimes encumbers somebody's time and money, even when there was not any negligence or intent of harm there.

We believe that a reporting system that allows us to investigate near misses has to encourage people to come forward openly and not threaten that if, indeed, they put issues on the table, the first likelihood is that they will go to court, and then they may or may not get around to what happened at the near miss or even at the error that occurred.

Senator SPECTER. So your answer is no.

Dr. DICKEY. Well, clearly, the information needs to be available at some point to patients, because we believe patients ought to be able to make a choice, but we believe that the information has to be put in the proper format.

I think if we looked at Massachusetts, where the medical association partnered with the State board to create a profile of information about physicians, when there is an opportunity to put information into a format that gives patients full information, that physicians have supported making information available to patients, but to do it in a piecemeal fashion, to suggest that because a physician has been sued it is an incompetent physician is not fair information for patients to be making a hundred percent of their judgments on.

Senator SPECTER. Well, when you talk about punishment, I structured the question as the people who testified here today, who wanted to know about how their doctors performed. Ms. Diane Artemis wanted to know about the quality of her medical service. Now, she is not going to sue. She has not been treated.

So when Ms. Artemis is looking to see what this hip replacement doctor, she is looking at it for preventative measures, she is not about to sue. Why not have that available to Ms. Artemis.

Dr. DICKEY. We believe that you should have available information about whether your physician has performed the procedure, what the outcomes of the procedure are, that is, successes of that procedure. In fact, the AMA has a program called AMAT that would, when fully developed, make information about outcomes and performance of individual physicians available to patients, but——

Senator SPECTER. If the reporting requirement called upon the hip replacement physician to report mistakes, should not the prospective patient have access to that information about those mistakes?

Dr. DICKEY. I think it depends on what you call mistakes, Senator, because I think the problem here is——

Senator SPECTER. Well, help us define it. That is what we are looking to you to do.

Dr. DICKEY. I agree with you, and I think part of my concern, and my heart goes out to each of the people we heard from today, and I am obviously responding only to a brief summary of what I have heard happen, but the surgery appeared to have gone well, if I heard the story correctly.

It was a fall after surgery that created this series of problems for the patient. Now, was the surgeon responsible for the fall that happened afterwards? Does he or she have to report that error, despite the fact that Ms. Artemis had a different outcome than she should have rightly expected?

Those are the kinds of questions that I think are terribly important to physicians, to hospital administrators, to nurses who want to be sure our patients get safe care, but at the same time want to be sure that our patients get good information.

Senator SPECTER. Well, if the case has gone all the way through litigation, and a judgment, and a jury's determination that a doctor was at fault so that it is established as to liability, how about that information? That is not just a claim. That is not just a speculation. That has already been traditionally determined. Do you think that ought to be made available to prospective patients?

Dr. DICKEY. The AMA policy is that that information ought to be available only if it is within a package of information that helps explain it. In other words, we are not supportive of opening up things like the national data bank.

Senator SPECTER. Well, I am on a specific issue now. You raised a question about whether it is proved, whether something else is involved, whether it is just a claim. I am talking about something that has been litigated and decided, there has been a judgment through the court process, a final judgment, appeals if any are or in order, or any sought to be taken.

What kind of package would you need beyond that sort of a factual statement be made available to a prospective patient?

Dr. DICKEY. I think patients would need to know how often physicians in that particular specialty get sued, that the fact that your physician had been sued successfully once would perhaps be put in the information that says 98 percent of physicians in that specialty

have been sued successfully once, and if they have been sued 12 times, that may raise your level of concern.

I think that patients need good information to make decisions. I think, unfortunately, piecemeal information may lead them in the direction of bad decisions, because they are not getting the right information to make a decision.

Senator SPECTER. So if there were a fuller picture or a background, a package, do you think under those circumstances we could structure that kind of disclosure?

Dr. DICKEY. I believe and the AMA believes that the patients need to be given information on which to make choices about physicians, hospitals, and procedures, but it needs to be full information. Part of the concern we have expressed in the past, for example, has been that many times the hospitals that have the highest number of bad outcomes are those facilities that take care of the very sickest patients, patients that only a few years ago might not have even been offered the opportunity of a particular operation or a particular potential for cure, because their rate of complications was going to be so high.

Do we want to punish those entities that take on the care of the sickest patients when it may be my spouse or my mother who needs the care, but has a very complicated medical history?

Senator SPECTER. Well, if the hospital chooses to have that information, I think we can structure a reporting system which would give them that opportunity, but if you so delimit it with a level of proof which is unrealistic, then information is not going to be forthcoming to patients.

You have not dealt specifically with the concept of a Federal mandate on risk reporting, or do you support a Federal mandatory reporting system?

Dr. DICKEY. At this time we would not support a Federal mandate. We believe that collecting of information may well advance the ability to do the kind of research that Dr. Eisenberg talked about, that the NPSF attempts to fund, but do not believe at this point that we need a Federal mandate either to have that occur, nor that Federal mandates in the past for that kind of reporting have demonstrated that they improve the situation or improve the quality of the care.

Senator SPECTER. Well, I would respectfully disagree with you about the need for a Federal mandatory reporting system. I think the evidence is on the table for it. To the extent that it could be structured in a way which will give a fuller picture, and not distort the picture, or explain how many doctors in a similar situation have this consequence, or that they treat the sickest people so that the explanations are present to give the doctor's side of it and the hospital's side of it I think is fair.

If you start analogizing it to the Federal Aviation Administration, where you are really dealing with very, very different quantities and qualities, much more than apples and oranges, they are both fruits, but if you deal with FAA and doctors, I think they are just different, but to the extent that we could accommodate your concerns, I think Congress would want to do that.

We fought this battle on mandatory reporting of crime on college campuses. There was a lot of resentment to that, because it is very

embarrassing, and all sorts of efforts were made to hide it away, but as soon as the requirement came into effect, all sorts of precautionary measures were taken to prevent crime, because colleges and universities did not want to report it. We are well aware in the Congress about the undesirability of too many mandates coming out of Washington.

We do not want a mandate, there are too many of them from Washington's bureaucracy, but you are talking about a problem here which has been pretty well recognized nationally, and my sense is that my colleagues will be looking at some sort of a mandatory system, but we want to accommodate the concerns you raised to give the fuller picture and allow hospitals and doctors to say what is on the other side of it, to give an explanation, so that the consumer, prospective patient, knows the full picture, and can say, well, okay, that happened, but this fellow, this woman, et cetera, is okay.

Dr. DICKEY. Senator, I think it is important that we realize the IOM report, and I know you do, is far bigger than physician interactions with patients. In fact, we have mandatory reporting of those issues that have been adjudicated.

It is the National Practitioner Data Bank, where all lawsuits are ultimately kept. I think here we are talking about where a doctor, or a nurse, or a hospital administrator identifies something, may have not resulted in harm, because something intervened to stop the problem before the patient was hurt.

If we can put that near miss or even the error on the table and talk about how did that happen without fear of spending a half-a-million dollars to defend one of those players in a court of law, we may be able to prevent hundreds of other hospitals, or doctors, or nurses from that error, which may not be stopped the next time.

Senator SPECTER. Well, where you deal with those cases where there have not been damages, you are not going to be sued, if it is a mistake which has not resulted in an error. Well, these are all things that we have to talk about, and this is a very important dialogue.

On this side of the table we are trying to figure out what the facts are and what the public policy ought to be. You men and women know the specifics. You are the experts. Now, we have a pretty good document here to start to work from, so we want to push the envelope.

STATEMENT OF MARY FOLEY, R.N., FIRST VICE PRESIDENT, AMERICAN NURSES ASSOCIATION

ACCOMPANIED BY ANNE SHEA, ACTING EXECUTIVE DIRECTOR AND CHIEF OPERATING OFFICER, NATIONAL PATIENT SAFETY FOUNDATION

Senator SPECTER. Our next witness is registered nurse, Mary Foley, the First Vice President of the American Nurses Association, Director of Nursing at St. Francis Memorial Hospital in San Francisco, earned her nursing degree from Boston University and her master's degree from the University of California, San Francisco.

Thank you for joining us, Ms. Foley, and we look forward to your testimony.

Ms. FOLEY. Thank you, Mr. Chairman, and thank you for this opportunity. I am Mary Foley, First Vice President of ANA.

In the last 3 years I have had the privilege of working as a staff nurse, a director of nursing, and a clinical nursing faculty person, so I feel well rounded. I am proud to represent the American Nurses Association, which is the full-service professional organization representing our 2.6 million registered nurses in the country. We include staff nurses, nurse practitioners, clinical nurse specialists, certified nurse mid-wives, educators, managers, and nurse anesthetists in all of our 53 States and territories.

The ANA appreciates the opportunity to discuss our concerns regarding the topic of patient safety and medical errors. The issue of health care error is one of great importance to the nursing profession. Nurses have substantial contributions to make to the efforts to reduce health care error, and it is critical for us to share our perspectives.

The American Nurses Association agrees with the Institute of Medicine Reports' assertion that the majority of errors result not from human recklessness, but from failures in the health care system, and believes the report reinforces the need to address all systems' issues, including staffing, though the report itself lacks important information on the relationship between system errors and appropriate staffing.

"To Err is Human" describes a fragmented health care system prone to errors and detrimental to safe patient care. This problem is not new to registered nurses or to the American Nurses Association.

In nursing practice, the scope of responsibility, independent judgement, and decision-making has been expanded, while nurses' autonomy and decision-making abilities are more constrained, as management systems focus on bottom-line profits over patient safety and quality.

Nurses are the single largest labor cost for a hospital, and, therefore, a likely target for cuts. Slashes in operating budgets have resulted in reduced utilization of professional nurses and nursing management oversight positions. These traditional management positions have been most directly responsible for assuring that adequate safety and quality systems are in place.

Let me add as well, we are beginning to see shortages of nurses in areas such as critical care, operating room, and emergency room staff, and that will be another consideration for future discussion, I am sure, as we try to provide adequate numbers of nurses, in addition to addressing the systems and the financial systems that have interfered with adequate staffing.

Therefore, one of ANA's major concerns in the health care delivery system relates to the prevention of adverse events, and we must speak to the adequacy and the appropriateness of staffing.

For some time, ANA, the State Nurses Associations, and nurses throughout the country have identified elements of these troubling workplace trends. Separate studies by ANA, the Princeton Survey Research Associates, the American Hospital Association, and the National Coalition of Health Care all reveal that patients and families were concerned about the care they were receiving in acute care institutions.

Adequate numbers of staff are necessary to reach a minimum level of quality patient care services. In 1994, ANA launched its

safety and quality initiative to investigate the impact of health care restructuring on the safety and quality of patient care and the nurses who provide that care.

Central to this initiative is the development of nursing quality indicators, the nursing report card for acute care, and the national data base of nursing sensitive quality indicators. ANA has advocated and participated in the collection of this information, and beleives that this information must be disseminated to be effective.

Therefore, the ANA supports many of the IOM recommendations, including the creation of a center for patient safety. The ANA also supports a call for nationwide mandatory reporting systems. ANA would argue, however, that such a system of reporting and tracking adverse events must not only maintain data on when the errors are occurring, but include information on what organizational valuables are responsible for the errors.

Staffing should be such that the quality of patient care is maintained, the quality of organizational outcomes are met, and that the quality of nurses' work life is acceptable. This focus represents a safety system that was referenced in the IOM report, and it is an example of safer practices at the delivery level.

We have been working hard to pursue strategies that protect patients from preventable errors, and that move organizations away from the traditional search and destroy missions that frequently follow serious health care errors. In addition to our safety and quality initiative, ANA has participated in the President's advisory commission on consumer protection and quality in the health care industry. We are a founding member of the National Coordinating Council for Medication Error Reporting and Prevention, and we are actively involved in the National Patient Safety Foundation, sponsored by the American Medical Association, and the Veterans Administration's National Patient Safety partnership.

We believe that nurses are the quality and safety monitors of health care. We worry about systems that put providers and patients at risk. Today's environment demands that the nursing profession assert its powerful voice in a time-honored role as patient advocate by supporting public policies that protect consumers, enhance accountability for quality, and promote access to a full range of health care services.

ANA will continue to increase hospitals' awareness of and participation in the national data base of nursing-sensitive quality indicators, and will work for the dissemination of that information.

By working together we can further document the link between nurse staffing and patient outcomes in order to make informed data-driven decisions that will allow safe quality patient care to be the norm in all patient care settings.

We appreciate the opportunity to participate in this discussion, and welcome the opportunity to work with you as we address these issues.

Senator SPECTER. Well, thank you very much, Ms. Foley. Initially, what is your evaluation of the adequacy of nurse staffing? It is a big, broad question, but would you care to make a comment on it?

Ms. FOLEY. We are very concerned, as a professional organization. We would be remiss in not saying aloud that we think there

have been forces in the health care system, financially based many times, in terms of reimbursement, inadequacy of reimbursement, decision making that may focus unfortunately on the bottom line of operations.

As an administrator in a facility, I want my facility to continue to operate and to be in existence for another 95 years in the City of San Francisco, and yet, some of that focus I think has been detrimental, I know has been detrimental, to the adequacy of nurse staffing.

I think Ms. Malone spoke very eloquently and personally about an observation that she realized, that nurses, while they may be in short supply perhaps through supply, we know that there have been efforts to reduce the overall budgeted positions of registered nurses in some cases.

I think Ms. Artemis spoke of a med tech who substituted for a professional registered nurse. Perhaps a nurse may not have assisted her to the bathroom that evening, but perhaps it might have been a nurse close by to assist in some of the immediate follow-up care.

I am not sure if that would have changed the outcome, but I would like to believe that the presence of adequate numbers of registered nurses, and the right number, and in the right qualifications will, indeed, make a difference. So we are concerned.

We think the report touches on the delivery level issues, and the fact that staffing is part of the safety system, we think there is a great deal of relevance, and we appreciate the linkage.

Senator SPECTER. Well, here again, if there has to be a disclosure of mistakes, errors, attributable to insufficient staffing, that is motivation not to have insufficient staffing. The cost factor always is very much front and center with the practical problems we are facing.

I am interested to have your views on a mandatory reporting system. We have had a little different view from Dr. Dickey. Is it your thought that there would not be a conclusively chilling effect, but that there would be a reporting of mistakes and errors, even where the reporting person is going to be admitting some potential liability?

Ms. FOLEY. I think as long as there is an avoidance of a blame approach to the individual who has the courage and I believe the professionalism to report, then it would be absolutely appropriate, and we do support it as an organization.

Nurses are often the individuals making out reports. I am sure somebody, I hope somebody documented the fall, for example, of Ms. Artemis. I mean I think that is an example of reporting that we have done. Now, many times those reports go into the risk management file and are internally evaluated.

I know as a nurse administrator I carefully watch the trends of medication errors and falls, and I do not believe that all of them are reported. I am concerned, not just at my own facility, but through out the country, that individuals are fearful of a disciplinary approach, as opposed to a supportive process improvement approach.

If there is an individual who really should not be practicing, I would never hesitate to pursue that as an individual case, but if

there is a system failure, not enough staff, staff who have not been properly cross-trained, an opportunity to be oriented well to the very particular techniques of post-operative total hip care, I mean I think those are very serious system problems.

Yes, the individual might have made the error, but there were individuals such as the administrator and the supervisors who contributed to that error by not allowing the support systems to work.

Senator SPECTER. Well, when you talk about mandatory, so long as it does not involve blame, it is a little difficult not to cross the line.

Ms. FOLEY. It is.

Senator SPECTER. That is what we want to try to do. When we are talking about letting prospective patients know what the doctor has done in the past, then the patient simply does not choose the doctor. So the doctor does have a disadvantage in being ruled out of the case, but not being sued, not being disciplined.

When you talk about disciplinary matters within the hospital, you can encourage the hospital not to discipline, but if the hospital knows that an individual has done something which is egregious, should their hands be tied and not taking some sort of direct action which might involve discipline?

Ms. FOLEY. No, by no means, and I do not mean to mix reporting of events that would help paint the picture of some system problems with those egregious errors. I by no means want to commingle those situations. I think individuals will need to be addressed.

I think the nursing approach is, we have been trying to measure some of the patient outcomes, those indicators that we believe have changed, because of some of the support systems, and those includes falls, and medication errors, and patient satisfaction.

Nurse injury, we are finding, has a close correlation to the number of adequate numbers of staff. We have supported not just the collection of this information, but public disclosure, and dissemination of this data, so that the next time an individual is pursuing the outcome of post-operative care for total hip patients, they may understand more accurately what facilities they might want to select, because nursing believes that only with sharing in the public arena will the consumer be able to make an informed decision.

So we support the reporting. I think we need to work, perhaps, on the detail of what, as you said, gets to that line of egregious individual error and responsibility versus those reports that would help us draw the bigger picture.

Senator SPECTER. Well, when we talk about liability, it is going to be a challenge to try to have mandatory disclosure which is not going to involve some admissions as to legal liability. There is certainly a tremendous amount more that hospitals and supervising within the medical system can do before the case gets to court at all.

The cases which get to court are usually very protracted and with extraordinary discovery, which could be short circuited by administrators to find the problems long before it gets to that kind of judicial determination, a very, very small percentage of matters.

STATEMENT OF STANTON SMULLENS, CHIEF MEDICAL OFFICER, JEFFERSON HEALTH SYSTEM, PHILADELPHIA

Senator SPECTER. We now turn to Dr. Stanton Smullens, Chief Medical Officer for the Jefferson Health System in Philadelphia. He is here representing the American Hospital Association, has served in a variety of leadership posts at Thomas Jefferson University Hospital, including committees on quality improvement, clinical professor of surgery at Jefferson, won the Leon Paris Memorial Award for superior patient care, graduate of Harvard College and Jefferson Medical College, and a personal friend of mine, as is wife, Sarah Case Smullens, seated behind him. Welcome, Dr. Smullens. We look forward to your testimony.

Dr. SMULLENS. Thank you, sir.

Senator SPECTER. It is a great opportunity to have an opportunity to question you, Dr. Smullens.

Dr. SMULLENS. My name is Stanton Smullens. I want to tell you who I am, why I am here testifying today, and why I welcome this opportunity.

Until 2 years ago I was a surgeon and teacher at Thomas Jefferson University in Philadelphia, where I went to medical school, trained, and practiced for many years. I became involved in medical administration, because I felt that doctors and other health care professionals had to work together with hospitals to address the problems confronting health care in America.

In June of this year I became the first Chief Medical Officer of the recently formed Jefferson Health System. The Jefferson Health System is very diverse, and includes over 3,000 physicians, most of whom are in private practice. In many ways, it is a cross-section of the hospitals in the American Hospital Association, and the issues confronting health care.

I am here today on behalf of the AHA, because they realize that the entire health community has to address the serious issues raised in the Institute of Medicine's report on medical safety. I also want to share with you some of what hospitals and health systems are doing in this critical area.

First, I want to reassure the committee and the American public that hospitals safely provide care to millions of patients every year. The people who deliver health care, the doctors, nurses, and others on the health care team are highly trained, receive continuous education, and strive every day to deliver safe and compassionate care. They truly believe in the dictum, "First, do no harm." But health care today is extremely complex, and even our best intentions can have unwanted and unintended consequences.

The IOM report, "To Err is Human: Building a Safer Health System" points out that as good as our systems are for preventing and reducing medical errors of all kinds, we can and must do better.

We applaud the members of the IOM committee on quality of health care in America for developing the report that shines a bright light on the problems of medical errors, and outlines their significance in this country, and are heartened by the quick response this has received.

We agree with the report that says we need to avoid blaming individuals for past errors, and instead, focus on preventing future

errors by designing safety into the system. It stresses two principles that reduce errors and increase patient safety.

First, individuals, by the very nature of being human, are vulnerable to error. Although, individuals are the focus of the error, we have to understand and improve the systems in which people work that make errors more likely. As a result, reducing errors will require us to design and implement systems that are more error resistant.

Second, we have to create an environment where care givers feel they can come forward after an unfortunate mistake is made. There needs to be a non-punitive culture that allows the candid discussion of errors, their causes, and ways to prevent them from happening again. If we cannot discuss our mistakes, we cannot learn from them.

The AHA also agrees with the recommendation that stepped up vigilance is necessary. There are many organizations that specialize in the area of reducing and preventing medical errors. The IOM report focuses on the broad issue of medical safety. This past week the AHA announced an initiative to improve medication safety, since it is one of the most common sources of overall medical errors.

As part of this initiative, the AHA formed a partnership with a highly respected organization in this field, the Institute for Safe Medication Practices. This non-profit research and educational organization is dedicated to reducing the incidents of medication error throughout the health care system, and will provide leadership and technical expertise for AHA's initiative.

In summary, Mr. Chairman, the Institute of Medicine's report is very timely, and causes us to refocus on basic issues.

At a time when great technological change and increasing complexity of health care, I am glad to raise my voice in the efforts to improve the overall safety of our health care system, and as the report notes, the large complex problems require thoughtful, multifaceted responses that will demand the thoughtful collaboration and participation of everyone involved in the health care field, hospital leaders, doctors, nurses, other health professionals, pharmacists, business, government agencies, other organizations, and the public. The AHA is pledged and committed to help its member hospitals and health systems respond to this critical issue.

Thank you, Mr. Chairman.

Senator SPECTER. Well, thank you very much, Dr. Smullens. You are a key official at one of the world's greatest hospitals, Jefferson Medical College. Problems of hospitals everywhere are staggering, in terms of the demands put on you, the medical education, care of indigents, reduced Federal payments, et cetera.

Years ago my oldest sister advised me never to go to a hospital. She really stated do not go unless it is imperative. What goes on in the hospitals which leads to the common problem of infection? When you go into a hospital and you are sicker after you get into the hospital than you were before? That is a very broad question——

Dr. SMULLENS. It is.

Senator SPECTER [continuing]. And one which is on many, many minds when they think about going to hospitals.

Dr. SMULLENS. Well, it is a complicated question, obviously. One of the problems, of course, is that the patients are very sick when they get there, their resistance is lowered, and that in itself is a major problem.

The other problem is that there are a lot of sick people with infections in hospitals, so that the hospital environment does have infection, so that it is very important that policies are in place and that they are followed appropriately to reduce the transmission of infection between patients, and that the infections when they are discovered are treated appropriately.

Senator SPECTER. To what extent are you doctors exposed to this infectious atmosphere, to undesirable consequences?

Dr. SMULLENS. Well, I think that everyone in the health care field, who are treating patients, is involved. There are policies and procedures about isolating infectious patients, treating infectious materials, wearing the appropriate gowns, care of any type of equipment that comes in contact with infected patients. There are policies in place to try and handle this, but it is a constant ongoing problem.

Senator SPECTER. We have heard from Dr. Dickey being opposed to mandatory requirements and Nurse Foley being in favor of them. We are going to hear from Dr. Merry in a few minutes. How do you vote?

Dr. SMULLENS. Well, Pennsylvania has mandatory reporting. I think the real question is how it is used. The recommendation is that the errors be analyzed and that they be looked at in a way that information can be learned from them.

In the case of the fall that was described, the nurses have taken a leading position in having what they call falls assessment for patients, so that if you have a patient who is admitted to the hospital, every patient is analyzed as to what the chances are that they will fall. Certainly, a patient who has just had a hip replacement is at risk for a fall, so that patient would be treated differently than a patient, say, who comes in for some other routine problem.

So that every patient, elderly patients, patients who are frail, there is a false assessment that is made, and, hopefully, hospitals are implementing that. There are categories that you can rate one through four. I think that is the categorization. But the point is, there is this type of system approach to that very problem, so that the understanding—the way that came about was looking at falls, understanding why they occurred, and then setting up these policies in place.

Senator SPECTER. To what extent are consumers able to have access to the mandatory system in Pennsylvania to evaluate a prospective doctor?

Dr. SMULLENS. I do not know the answer to that. I suspect that it is limited. I think that for any consumer, anyone going to a physician, they have to ask. One of the concerns is what Dr. Eisenberg raised, every doctor in that audience raised his or her hand that they had made a mistake. If you set up the situation where people are afraid to seek appropriate care, then you are going to hurt more people than you are going to help by the reporting, so that it is only if the reporting gives information that is helpful in making those decisions that we can go forward, so that I personally

think that anybody going to have any kind of procedure has to open their mouth, ask the doctor have you been sued, have you done this before, will you do the operation. If they do not want any of the training physicians to be involved then say I do not want the training physicians involved.

There is a problem, though, about training the next generation of physicians, and nurses, and other health care professionals. Jefferson has just opened a medical simulation laboratory, and I would be glad to have you come down and see it.

Senator SPECTER. Well, it would be an extraordinary patient who would ask those questions——

Dr. SMULLENS. I know. I know.

Senator SPECTER [continuing]. An extraordinary patient, and it is not an easy line to draw to get the information for the consumer to adequately inform the consumer without opening Pandora's box, but that is what we are going to be wrestling with here.

The considerations of privacy are very, very critical, but I would be interested, and we will pursue it further as to what the impact has been with Pennsylvania's statute, as to how that has worked with respect to a chilling effect or what has happened.

Do you think it is possible—well, you have already said we have that in Pennsylvania. We will have to work from that step, forward.

STATEMENT OF MARTIN D. MERRY, M.D., ASSOCIATE PROFESSOR OF HEALTH MANAGEMENT, UNIVERSITY OF NEW HAMPSHIRE

Senator SPECTER. We now turn to Dr. Martin Merry, South Portland, Maine, Associate Professor of Health Management at the University of New Hampshire, where he teaches quality management, is a private consultant on medical quality, and was medical director at St. Joseph's Hospital in Elmira, New York, as well as project director for the Department of Defense Civilian External Peer Review Program.

He earned his college degree at Cornell and his medical degree from McGill University in Montreal. Thank you for joining us, Dr. Merry, and the floor is yours.

Dr. MERRY. Thank you, Mr. Chairman. As you indicated, my focus upon health care quality as part of my career path is about 25 years old, and from this perspective, I would say to its great credit, the Institute of Medicine has finally brought to center stage the question that has troubled many of us working in health care quality for years; specifically, how can a health care system that achieves literal miracles of cure also generate such stark statistics on errors of medicine.

My intention today is both to address this question and suggest how we might use this moment to launch a renewed, and this time, more effective quality transformation for health care. In my view, Senator Specter, quality legend W. Edwards Deming got it precisely right with his famous 95–5 rule, the notion that 95 percent of quality problems relate primarily to system deficiencies, only 5 percent to people issues.

In keeping with this notion, I can assure the committee that the root cause of errors in medicine is not incompetent doctors, nurses, and health care administrators. These errors are the inevitable re-

sult of an incredibly complex enterprise, namely, modern health care, still structured in a totally inadequate, obsolete, craft model of service delivery.

Fortunately this obsolete model is imploding as we meet, but unfortunately, this implosion is accompanied by a painful cacophony of insurers bleeding red ink, slash-and-burn hospital and health system cost cutting, angry and depressed physicians, burned out nurses, fired administrators, and, yes, inexcusable and intolerable amounts of harm to patients.

Is there any way that we might better understand the seeming chaos that now afflicts health care? I say yes. Approximately 200 years after it began in this country, the industrial revolution has finally arrived in health care. In fact, I agree with a growing number of people who acknowledge that health care is experiencing a simultaneous industrial and information revolution, and this double revolution is asserting itself with vengeance.

During such a profound transformation, there is no neutral ground, we are all either part of the problem or part of the solution. I and my colleagues at the Northland Health Group define being part of the solution as focusing our knowledge and energy on Deming's 95 percent. We seek to address the inadequate systems that now so poorly serve health care professionals, and are the root cause of errors in medicine.

This means commitment to transformation, and specifically to measurement systems that better define quality, information systems that truly support clinicians and managers who wish to actualize evidence-based health care practice, learning systems that help us change our mental models and our behaviors, and finally, payment systems that genuinely reward, and in any case do not penalize performance excellence.

Perhaps most importantly, we are encouraging new form of collaborative leadership. To paraphrase Albert Einstein, we cannot master today's leadership challenges with yesterday's tired and increasingly ineffective leadership models.

All of this requires infrastructure investment among health care provider organizations, even as they witness the disappearing operating margins. My frustration is that we already possess a vast array of underutilized systems tools for addressing these infrastructure issues, as well as many sparkling examples of twenty-first century world class quality in health care.

Let me illustrate. In communities where open surgical biopsy remains the standard practice, craft-model scheduling and operational inefficiencies are such that a woman can experience as many as 30 sleepless nights between the moment she learns of her suspicious mammogram, then finally has a definitive diagnosis. This is not error in medicine.

This is simply a wholly inadequate craft-model health system doing its normal thing, but if the same woman happens to receive her care through Health System Minnesota, the suspicion-to-definitive diagnosis time gap is 2 hours.

Let me be sure we heard the quality message of this example. Using known elements of modern quality management science, Health System Minnesota has reduced sleepless nights for its pa-

tients not from 30 days to 2 days, it reduced the time line to 2 hours, zero sleepless nights.

As Michael Millenson documents in "Demanding Medical Excellence," which I have here, and I think should be the companion volume to the committee's excellent report, information-age health care can and does generate superb quality today.

I reemphasize that we already have the tools to accomplish the transformation revolutionary improvement. A tragedy that outstrips even that of errors in medicine is our failure to disseminate and actualize the knowledge we already possess. In this context, I urge the committee to push even harder for the industrial/information revolution that our health care system must inevitably transit. The report is long on traditional regulatory approaches, such as mandatory reporting, and these all certainly have a role, but it is short on its recognition and support, in my opinion, for leading-edge quality management science.

I urge the Federal Government to elevate its vision beyond that of this report, to move beyond fighting errors, to embracing the best that modern quality management science might create.

Nearly 10 years ago, Paul Starr, author of the Pulitzer-winning, Social Transformation of American Medicine, stated, "No matter how dramatically you think health care has changed in the last decade, now is the time before the revolution. Year by year, the existing system is coming unstuck." He made that statement in 1990.

Error in medicine is a tragic phenomenon of a system now deeply unstuck. We will not solve this problem by attacking it though regulation alone. We will not fix the errors problems until we change health care's culture, and changing culture is not a technical problem, it is a leadership imperative.

We must all work together to foster a transformation that elevates the whole system to a quality culture that simply will not tolerate error. If both the space program and the airline industry can nearly eliminate human errors as a source of injury, can we in health care aspire to anything less?

I applaud the efforts of this committee, Senator Specter, and thank you for this opportunity to share my experience and outlook.

Senator SPECTER. Well, thank you, Dr. Merry. When you used the illustration of 30 sleepless nights awaiting an X-ray for somebody who has some indication of possible breast cancer——

Dr. MERRY. It is actually awaiting a diagnosis, the time between I may have cancer, and I know one way or another.

Senator SPECTER. Well, why so many intervening sleepless nights? It is not a complicated matter to have to test, is it?

Dr. MERRY. It is because we have never really designed our systems around patients. The system heretofore has been designed around physicians primarily.

When I was practicing primary care internal medicine, I would have my primary care patients, we would learn about the diagnosis from the X-ray that there was a suspicion, and I sort of narrowly defined my role as that of getting her to the surgeon, and quite frankly, during those years, this was the seventies, I would like to think I would be more sensitive now, I really did not think a lot about what happened in my busy day thereafter until we got the diagnosis, and I did not have the sensitivity, until I learned what

Health System Minnesota had done, to really be thinking about what that experience was like——

Senator SPECTER. Health Systems in Minnesota got it done in 2 hours.

Dr. MERRY. In 2 hours.

Senator SPECTER. What is at Jefferson, Dr. Smullens, 1 hour?

Dr. SMULLENS. The problem is that, a lot of it is that it is a fragmented system. There is not really a system to deal with it, so the individual——

Senator SPECTER. It is not fragmented at Jefferson, is it?

Dr. SMULLENS. If the patient gets to the surgeon, I would hope it would get done very quickly, but unfortunately, there is a time frame between when the primary care physician gets the report of the X-ray, which may be several days after the X-ray is done, then has to get to the appointment with the surgeon to get the biopsy done, or perhaps with the radiologist.

So it is a sense that there is a time between when the diagnosis is suspected and the patient actually gets to someone who can make the diagnosis.

Senator SPECTER. You are a management specialist, Dr. Merry, so give Dr. Smullens some advice as to how to solve that for Jefferson.

Dr. MERRY. First of all, you would have to really broadly conceive what our duty to our patients really is. In the seventies, when I was in practice, getting the diagnosis was the big thing, but we are now in the 1990s and the time lag, the sleepless night factor, is a part of what we owe to our patients at this level. If we have the capability of producing that, we need to do it.

Interestingly enough, it is higher-value health care, too. It is cheaper to do it faster. That old way of getting them to the surgeon, scheduling the surgery and open biopsy, that is actually more expensive than stereo-technic biopsy, which is one of the technical pieces by which you can get that lag down to 2 hours, but we have to conceive it in a very sensitive and much deeper way than we ever have before, building a system around our patients rather than the physicians and the hospitals.

Senator SPECTER. Well, your suggestion, Dr. Merry, is that quality management is vastly underutilized in American medicine.

Dr. MERRY. That is my statement, yes.

Senator SPECTER. Are there enormous financial savings, too, if the management processes were improved? Must be.

Dr. MERRY. Yes. If we define, as Deming did, quality improvement as process improvement, getting waste out of the system, as designing more efficient systems, as the breast biopsy suggests, that actually is lowering the cost through process improvement, and producing higher quality simultaneously.

I think that that notion has been so jargoned in health care that we do not believe it is really true, but some of your—the members of this committee, specifically Don Berwick, as well as Brent James, have demonstrated that.

Ten years of leadership at Intermount Health System and IHI, that is the truth, we just have not been able to spread that word through the system adequately.

Senator SPECTER. Does this report deal with the issue you raise about improving health management?

Dr. MERRY. To me, it begins to touch on it in the notion of a culture of safety. A lot of this stuff strikes me as being kind of, a little more regulation, and I think it—better regulation I am all for at this point, but it is not the creative challenge, and it is not the kind of stuff that leaders will aspire to.

The culture on safety comes to the closest to what I think are the directions that the Federal Government could do to pull the whole system away from the error problem. Yes, deal with it effectively here, but just establish a higher bar, so to speak, for a cultural shift, that is why I like the word, culture of safety, the problem being that if you have a culture of safety, it makes a big difference whether it is a culture of fear versus a culture of excellence, because the two are incompatible, as Deming very well stated.

Senator SPECTER. Well, tell us a little bit more about how you would approach a culture of excellence.

Dr. MERRY. It is first and foremost a leadership problem. CQI came into health care in 1987 through the national demonstration project. Again, Brent James and Don Berwick were leaders in that movement, and we looked upon it as a technical issue.

If we would learn enough of the tools and techniques, we will do it. We did not understand it the first time around in the late eighties and early nineties. It was a cultural shift of major magnitude.

One of Deming's 14 points was adopt a new philosophy, and we did not fully understand the new philosophy back in the early 1990s, so we went through that wave. I am very encouraged. About the last 6 months I am getting more opportunities to speak about quality, I am getting a receptive ear to quality as a business strategy.

I think it is beginning to sink in, as this kind of industrial information revolution goes through health care. I think we are in a new position of potential receptivity of this message.

Senator SPECTER. Dr. Eisenberg, how does this dichotomy strike you, culture of excellence versus culture of fear?

Dr. EISENBERG. I agree with just about everything that has been said. I think one of the most striking aspects of what Dr. Merry has said is the gap between what we know we can do and what we know we ought to be doing, and our ability to deliver it. In many ways, it is like much of what you know about the science of medicine. We know that mammography works, but we do not know why more women do not receive them.

If we could learn more about what works in developing this culture, and in developing more information about what produces errors, and then see that we could translate that into improved practices, then I believe we would answer the problem that these folks have laid before you today.

Senator SPECTER. Well, I am sort of struck, here we are in Congress seeking to legislate on this report on a culture of fear where we might have some standing, but do we have any standing to legislate on the culture of excellence?

Dr. EISENBERG. We certainly do. In fact, I will go back to what I had mentioned when I had started, which is I think you did legislate on a culture of excellence when you changed the name of our agency to the Agency for Health Care Research and Quality. It was a clear statement by the Congress that you think this is high priority.

Senator SPECTER. Also legislature on the culture of excellence when we handed $2.3 billion to NIH this year——

Dr. EISENBERG. I would agree with that.

Senator SPECTER [continuing]. And $2 billion last year, and a billion the year before.

Dr. EISENBERG Senator Specter, what I appreciate is the fact that you appropriated funds to AHCPR (now AHRQ) to allow us to translate some of the new knowledge gained from the research of the NIH into improved practices. I think the culture is going to require a team effort.

It is going to require the patients and the consumers to come up and speak and have the courage that these folks did today, and it is going to require the courage of the profession to say that we can do a lot better than we have been doing.

Senator SPECTER. Well, I think the Congress is going to legislate on the issue of mistakes, from this report. Senator Kennedy has announced his intention to do so, and Senator Jeffords is the chairman of the authorizing committee, and we are going to be moving toward it here.

When you talk about a culture of excellence, it is a broader range as to whether there is competency here. We can appropriate money, as we have for your agency, or we have for the National Institute of Health, or the Center for Disease Control, but whether we ought to go beyond that, leaving the implementing decisions to you professionals, whether we have anything more to say is a much tougher question.

Well, thank you all very much. This is a very provocative and a very, very important subject. It is obviously life and death, and we wanted to have this hearing as soon as we could, and stay tuned.

CONCLUSION OF HEARING

Thank you all very much for being here, that concludes our hearing. The subcommittee will stand in recess subject to the call of the Chair.

[Whereupon, at 1:03 p.m., Monday, December 13, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

Material Submitted Subsequent to the Conclusion of the Hearing

[CLERK'S NOTE.—The following statements were received by the subcommittee subsequent to the conclusion of the hearings. The statements will be inserted in the record at this point.]

PREPARED STATEMENT OF HON. PETE STARK, U.S. REPRESENTATIVE FROM CALIFORNIA

Mr. Chairman: I would like to congratulate you for your quick action in holding today's hearing, which will educate Members and the public concerning the need to reduce medical errors and improve the quality of care in our nation's health care system.

We too are busily looking into this matter. I am currently drafting legislation to establish a comprehensive quality system—including a provision to curb medical errors. This legislation will require the Secretary of Health and Human Services to establish and maintain a comprehensive system for monitoring, improving, and safeguarding the quality of care for Medicare beneficiaries and to reduce medical errors. Providers will have to join in this effort as a Condition of Participation in Medicare.

The recent Institute of Medicine (IoM) report raises public awareness concerning the need to prevent medical errors and to promote public safety. This also opens the door to a number of critical issues—such as safeguarding health care professionals from accidental needlestick injuries and protecting patients from the improper use of restraints and seclusion. I have introduced legislation this Congress to reduce medical errors in both of these areas and I hope you will include these proposals in whatever legislation you develop and advance.

Earlier this year, I introduced H.R. 1899, the "Health Care Worker Needlestick Prevention Act" with my colleague Rep. Marge Roukema (R-NJ) to ensure that those who care for us don't have to risk their lives to save our lives. Last year, an estimated 800,000 accidental needlesticks occurred in medical facilities from needle-bearing devices. Accidental needlesticks produce the single greatest risk of blood exposure to the HIV virus for health care workers. And infection with the hepatitis B and C viruses may also be transmitted through needlestick. Technology exists to greatly reduce these injuries. Such preventable medical errors involving health care workers must be brought to an end.

In addition, I joined Rep. Diana DeGette (D-Colo.) this year to introduce legislation addressing the use of restraint and seclusion in Medicare and Medicaid psychiatric treatment facilities, facilities for the developmentally disabled, and residential treatment facilities for children. A series of Hartford Courant articles from October 1998 highlighted the misuse of restraint and seclusion in residential facilities over the course of ten years and found that 142 cases of patient deaths were related to the improper use of restraint or seclusion. A General Accounting Office (GAO) September 1999 report on restraints and seclusion identified 24 deaths during fiscal year 1998 related to improper use of restraint or seclusion. Due to currently inadequate reporting requirements, the GAO estimates that the number of deaths is likely to be significantly higher.

This past August, the Administration came forward with new conditions of participation for hospitals concerning the use of restraints, and I commend the Administration for their important, major step forward. Yet, as the GAO notes, we still have further to go. Current Federal regulations do not limit the use of restraint and seclusion in all settings such as residential treatment centers and group homes, and there is no comprehensive reporting system to track injuries, deaths and use of restraint and seclusion.

The "Patient Freedom From Restraint Act of 1999" (H.R. 1313) sets strict requirements for the use of restraints and seclusion and requires treatment facilities to document and report on restraint and seclusion use. H.R. 1313 also requires facilities to report cases of severe injury and death to the state's Protection and Advocacy

Board, and the Secretary of Health and Human Services. By establishing such a reporting framework, the bill intends to reduce medical accidents related to restraint and seclusion use.

The IoM report should prove a catalyst for Congress to take overdue action on preventing deaths by accidents in our nation's health care system. I look forward to working with you and our colleagues on this timely, important issue. Let's work together to end these senseless injuries and deaths.

PREPARED STATEMENT OF THE UNITED STATES PHARMACOPEIA

The United States Pharmacopeia (USP) is pleased to have the opportunity to provide this statement in conjunction with the Senate Subcommittee on Labor, Health and Human Services, and Education Hearing on Medical Mistakes. USP strongly supports Congressional consideration of actions it might take to ensure the significant reduction of preventable medical mistakes that occur throughout the continuum of the prescription, dispensing, administration, and use of medicines. USP further believes that development and execution of federal legislation and regulatory policies, which will direct and guide public and private initiatives at the national, state, and local levels, must be achieved to ensure patient safety from medical mistakes, and to reduce substantively the multi-billion dollars that such mistakes currently cost the health care system each year.

USP comments, offered for Subcommittee consideration, cover the following:

—Information about the U.S. Pharmacopeia's 30-year record of stimulating voluntary health care practitioner reporting and using the analysis of those reports to improve patient safety.

—Background on USP's ability to affect change in drug product labeling, packaging, and nomenclature when such is identified as contributing to medication errors.

—An explanation of USP's new MedMARx™ program—a national, Internet-based, anonymous medication error reporting system, introduced in July 1998, and now used by over 100 U.S hospitals.

—A recommendation for Congressional action that can directly and quickly remove one of the most significant barriers to hospital and practitioner reporting of medication errors.

USP'S MEDICATION ERROR REPORTING EXPERIENCE

Background

USP, founded in 1820, is a private not-for-profit organization whose sole mission is to promote the public health by establishing and disseminating officially recognized standards of quality and authoritative information for the use of medicines and related articles for professionals, patients, and consumers. It is composed of approximately 500 members representing state associations and colleges of medicine and pharmacy, ten agencies of the federal government, and about 75 national professional, scientific and trade organizations, and members-at-large who include members from other countries that recognize USP standards. The USP's expertise as a standards-setting body has been recognized by Congress in the enactment of the Pure Food and Drug Act of 1906, by the Federal Food Drug and Cosmetic Act in 1938, and by the Food and Drug Modernization Act in 1997. USP standards are also referenced in most state pharmacy laws governing practice.

USP began developing drug information, in 1970, as support to its standards-setting activities. The USP DI©, the compendia of USP drug information, is today recognized by the Federal Omnibus Budget Reconciliation Acts of 1990 and 1994 as a reimbursement resource for Medicaid Agencies considering issues associated with off-label uses of medicines and guidance for patient counseling. Based upon its federal recognition, and its reputation as a credible, authoritative, and non-biased source of information developed by approximately 800 volunteer experts, USP DI also serves as a reimbursement resource for insurers and third party payers, and as the basis for drug formulary decisions.

USP practitioner reporting programs

Because of our concern with the quality of drug products on the market, in 1971, the USP co-founded the Drug Product Problem Reporting Program—national program in which health professionals were asked to voluntarily report problems and defects experienced with drug products on the market. Often the product problems or defects had to do with inadequate packaging or labeling—labeling that could lead to confusion on the part of health professionals or lead to errors; for example, similarity in color or design of the label, or look-alike, sound-alike drug names.

Eight years ago, in 1991, USP decided to focus more intensely on the problem of medication errors and what it could do to prevent them. Our focus today is on both the product and on the system in which the product is prescribed, dispensed, administered, and used. USP does not set practice standards per se, but admittedly many of our standards do indirectly affect professional practice and many practice standards are based on USP standards. The USP learned that The Institute for Safe Medication Practices (ISMP) was seeking support of a national organization to bring its program, The Medication Errors Reporting (MER) Program, to the national level. USP agreed to coordinate the national program for ISMP. The MER Program is now one of four USP voluntary, spontaneous reporting programs for health care practitioners. The Program is operated under the umbrella of the USP Practitioner and Product Experience Division.

Since late 1991, the MER Program has received more than 4,000 reports of actual and potential medication errors. We also continue to receive medication error reports through USP's other reporting programs. These reports have identified errors in various health care delivery environments, including hospitals, nursing homes, physicians' office, pharmacies, emergency response vehicles, and home care. By these reports, we have seen that errors are multidisciplinary and multi-factorial. They can be committed by experienced and inexperienced staff, by health professionals, support personnel, students, and even patients and their care givers. Errors can occur anywhere along the continuum from prescribing to transcribing to dispensing and administration. The causes of errors may be attributed to human error, to product names or designs, or to the medication handling and delivery systems in which the products are used and individuals operate and interact. For purposes of voluntary reporting, USP does not seek to limit the types of errors that may be reported, because all information received may have some future value. We do not, however, actively solicit reports of adverse drug reactions.

We recognize that an actual error may be reported as a potential error because of liability concerns, or a facility's risk management policies, so each report is treated with the utmost seriousness by USP, no matter how it is characterized by the reporter. As each MER report is received, it is shared with the product manufacturer and with the Food and Drug Administration. USP does not require, in the MER Program, that the name of the reporter, patient identity, or facility be given. If given, however, USP respects the desire of the reporter to keep their identity confidential and will purge the identity of the institutions or individuals named in the report in accordance with the instructions of the reporter. Reporters are advised of any actions resulting from their report either individually or through USP's Quality Review publications, which are disseminated to all individuals who have reported to the MER Program and are publicly available on USP's web site.

USP'S ABILITY TO AFFECT CHANGE

Encouraging the reporting of errors is only one aspect of USP's efforts to promote safety of the medication use system. USP evaluates and implements, through its standards-setting authority, changes in drug products to prevent the recurrence of errors. The following examples describe some of the changes or other steps taken by USP in response to MER Program reports.

—Death reported due to the accidental misadministration of concentrated Potassium Chloride Injection led to (1) changing the official USP name to Potassium Chloride for Injection Concentrate to give more prominence to the need to dilute the product prior to use; (2) labels must now bear a boxed warning "Concentrate: Must be Diluted Before Use;" and (3) the cap must be black in color (the use of black caps is restricted to this drug only), and the cap must be imprinted in a contrasting color with the words, "Must be Diluted."

—Deaths reported due to the confusion and resultant injection of the anticancer drug, Vincristine Sulfate for Injection, directly into the spine instead of into the vein, resulted in changes in the requirements for packaging by pharmacies and manufacturers preparing ready-to-use doses. Each dose, whether prepared by the manufacturer or the pharmacist, now must be wrapped in a covering labeled "FOR INTRAVENOUS USE ONLY" and that covering may not be removed until the moment of injection.

—Deaths reported due to the name similarity of *Amrinone* and *Amiodarone* have lead USP and the United States Adopted Names (USAN) Council to consider changing the official and nonproprietary names of one, or both, products.

—Deaths reported due to the inadvertent mix-up of neuromuscular blocking agents (which paralyze the respiratory system) with other drugs, have led to recommended changes in standards for labeling and packaging of the therapeutic class of neuromuscular blocking agents.

—MER reports of deaths identified the need to establish dosing limitations for the sedative-hypnotic Chloral Hydrate for use in children, and for the anti-gout drug Colchicine. These dosing limitations have been incorporated into USP DI information in a special section in each drug monograph to caution health professionals on each drug's proper use based upon reports of errors received through the program.

Reported medication errors also have brought about other changes in USP standards and guidance to practitioners. For example, USP has ceased to recognize use of the apothecary system, a centuries old system of measurement, in favor of the metric system in order to avoid misinterpretations that have led to overdoses. USP has made changes in general label requirements for marketed drug products. For example, strengths less than one must be expressed as a decimal preceded by a zero (e.g. 0.1 grams, not .1 grams) to avoid ten-fold-overdoses. USP standards also require that the strength of a product when expressed as a whole number be shown without a zero trailing the decimal to avoid ten-fold overdoses by the lack of recognition of the decimal point (e.g. 1mg, not 1.0 mg).

Prior to the formation of the Food and Drug Administration Office of Post Marketing Drug Risk Assessment, FDA developed a formal mechanism for receiving and evaluating MER reports—the Subcommittee on Medication Errors. USP and FDA also created a joint advisory panel on the Simplification and Improvement of Injection Labeling to reduce medication errors. The Food and Drug Modernization Act of 1997 recognizes product labeling recommendations of that joint initiative.

In 1991, to expand the scope of the MER Program, USP developed a joint program with the National Association of Boards of Pharmacy. The database is maintained by USP and assists each Board of Pharmacy to determine the relative extent of errors in its state and contributes to the overall incident collection effort.

In addition to using the MER program to stimulate changes in enforceable standards and information, USP has used the MER information to develop educational tools for the health professions. In 1993, a curricular resource entitled—Understanding and Preventing Medication Errors—was distributed at no charge to colleges of pharmacy throughout the U.S. USP also has attempted to reach the public directly to teach patients how to protect themselves from medication errors through the development of a public service campaign—Just Ask . . . About Preventing Medication Errors.

USP has worked diligently during the past eight years, particularly in the standards-setting area, to build coalitions among health care organizations and to provide health care expert review of medication errors. In 1995 USP spearheaded formation of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). USP is the founding organization and continues to serve as NCC MERP Secretariat. To date, NCC MERP comprises 17 national organizations and agencies that share a common mission to promote the reporting, understanding and prevention of medication errors. Member organizations include practice organizations of medicine, nursing, and pharmacy, the licensing boards of pharmacy and nursing, organizations of the pharmaceutical industry, the Department of Veterans Affairs, USP, FDA, Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), and the American Hospital Association. In the four years since its inception, the Council has produced internationally recognized work products, such as:

—A standardized definition of "medication error"

—A categorization index to classify medication errors by the severity of the outcome to the patient

—Recommendations to reduce the error prone aspects of prescription writing; product labeling and packaging; and broad recommendations related to the dispensing and administration phases of the medication use process.

The Council is now examining issues of process failures in the use of verbal orders, benchmarking, inter-organizational comparisons, and error rates.

In 1996 USP appointed an Advisory Panel on Medication Errors, an interdisciplinary group of health care practitioners who: review reports submitted to the USP Medication Errors Reporting Program; make recommendations for USP standards-setting; and make recommendations and participate in the activities of the NCC MERP.

In 2000, USP will constitute a new expert committee on "Safe Medication Use" that will fulfill a broader scope of responsibilities of the Advisory Panel that it will replace. The new expert committee will review MedMARx data and provide guidance for the development of best practice solutions that will result in the reduction and prevention of medication errors.

USP'S MEDMARX PROGRAM

In early 1998, USP developed a program for hospitals to report medication errors to a nationwide program. Hospitals were eager to submit reports to USP if it could be done anonymously and in a standardized format that would allow hospitals to track, trend, and compare their data to other participating hospitals. USP's goal was to develop a model for hospitals first, ensure success of the model, then broaden the model to include other health care settings and other types of reporting such as medical error and adverse drug reactions.

On July 27, 1998, USP made MedMARx available to hospitals nationwide. MedMARx (pronounced med marks) is an internet-accessible, anonymous reporting program that enables hospitals to voluntarily report, track and trend data incorporating nationally standardized data elements (i.e., definitions and taxonomy) of the USP Medication Errors Reporting Program, the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), and the American Society of Health-System Pharmacists. MedMARx is structured to support an interdisciplinary systems-approach to medication error reduction and fosters a non-punitive environment for reporting.

Hospitals use the program as part of the organization's internal quality improvement process, thereby extending the "peer-review" group to the group of hospitals in the program. Hospitals review the errors entered by other institutions in "real time" and also can view any reported action taken by another institution in response to the error or to avoid future similar errors. This feature affords institutions the opportunity to examine errors in a proactive manner. For example, the institution can review the error profile of a drug or class of drugs before a product is added to the institution's formulary to determine if certain risk prevention measures or training programs should be instituted prior to the drug's purchase or if the error profile is so serious that the decision to stock the drug is rejected. MedMARx also supports the performance improvement standards of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), which requires institutions to look outward at the experiences of others in order to reduce risk.

Currently 110 hospitals have enrolled in the MedMARx program and other progressive hospitals and health systems are joining rapidly. Profiles of the participants show that hospitals of various types and sizes spanning fewer than 50 beds to approximately 1000 beds are enrolled. MedMARx hospitals include institutions of the Department of Veterans Affairs and the Department of Defense, and state-owned facilities.

The USP commitment to MedMARx is broader than merely collecting data. In the coming year, USP will enroll champion hospitals participating in MedMARx in a long-term project to propose indicators of quality in the medication use process and to identify best practice standards and best process standards for the medication-use system.

A recommendation for congressional action

USP is heartened by the national attention resulting from release of the Institute of Medicine Report—*To Err is Human—Building a Safer Health System.* USP is particularly gratified at the immediate action being taken by Senators Spector and Stevens through the Subcommittee on Labor, Health and Human Services, Education.

Among the IOM Report discussions and recommendations is recognition that the lack of federal and/or state protection of medication error reported information poses a major barrier to voluntary reporting of errors, or potential errors. Health care practitioners are concerned about reprisals and practitioners and systems are concerned about liability. USP believes, therefore, that Congress can make a significant contribution to the development of systems that facilitate voluntary medication error reporting and tracking through immediate consideration of legislation that would protect information developed in connection with error reporting by hospitals and other institutions and health care settings. USP currently is developing such legislative language to present for Senate and House consideration.

CONCLUSION

In closing, we wish to assure Subcommittee members that USP shares with Congress the goal of a safe medication use system. USP has made a public and long-term commitment to working proactively with all stakeholders toward that goal. We particularly look forward to working with Congressional leadership on the issue of confidentiality and other policy issues that will result in greater voluntary reporting, analysis, and system changes to prevent medication mistakes.

PREPARED STATEMENT OF SALVADOR CASTRO, PROFESSIONAL ENGINEER

I am writing you about another facet in the recent disclosure of deaths and injuries caused by medical errors.

It involves dangerous medical devices. It also involves the cover up of ineptness of some of the people in the FDA. There is also the dilemma of a whistleblower.

I am a Whistleblower who stuck his neck out and, like the other whistleblowers, I also paid the price. I was fired. In this case it involved a medical device that could harm the weakest of our society, infants.

As a licensed professional engineer, I am required by law and the code of ethics of an engineer to protect the health and safety of the public.

Late In 1995 I discovered that the company I worked for, Air-Shields/Vickers located in Hatboro, PA, was making an infant transport incubator that had the potential of causing injury or death to a newborn infant. I brought this to the attention of my supervisor, Joe Lassard. I pointed out what the problem was and how it could easily be corrected. I also told him that the FDA should be informed of the situation. He told me that the company knew of the problem but was hiding the information from the FDA. I was appalled at the unexpected response. The modification would actually reduce the cost of the device.

My response was that if the FDA was not informed by the company of this problem, I would. Big mistake! Within a few weeks I was fired as being "Incompetent". In the letter of discharge the Director of Engineering, Jan Wenstrup, stated that "It became very clear that Sal is not able to function in a progressive product environment . . ."

Built into the incubator is a hand ventilation system. It is used to resuscitate an infant in respiratory distress. This hand ventilation system is dangerous because the design is flawed. A pressure relief valve in the system was improperly located in the circuit. It did not protect the infant's lungs from being ruptured. As a result, the pressure displayed on the pressure gage did not indicate the actual pressure being applied to the infant lung.

A few days after being fired, I notified the FDA of the dangerous design. In my letter I explained the problem and its solution.

Two weeks after I was fired, tests were run by Quality Assurance Engineer Joe Bagnell to check my concerns. The data from the test proved that the design was flawed.

Around December 1995, Dr. Mickler, Head of the dept. of Anesthesia at Montgomery County Hospital in Norristown, PA received an infant care unit with the identical hand ventilation system. He informed Air-Shields/Vickers that the hand ventilation system was dangerous. A team from the company was sent to talk with the doctor. Dr. Mickler was able to demonstrate his concerns to the team. The team was not convinced that the design was dangerous. The doctor, frustrated with the company's refusal to admit that there was a problem, called the FDA. The doctor also notified Emergency Care Research Institute (ECRI). The staff members at ECRI are experts in the evaluation of medical equipment. They reported in June 1996 their findings to the hospital industry. They agreed that the hand ventilation system was dangerous. ECRI published its findings in their magazine. In the article they make recommendations on how to correct the problem. The very same recommendations I had made to my supervisor six months earlier. The same information I had sent to the FDA.

The FDA sent investigators, John S. Shea and James P. McEvoy to collect information on the breathing circuit. The two FDA investigators interviewed me in my home. I provided them with a sworn statement of the facts.

The FDA investigators spoke to the company's "experts". The "experts", who had no engineering background, insisted that the circuit was safe. The "experts" told the FDA investigators that the company would not make any change in the breathing circuit design.

A report of the investigation was sent to FDA headquarters outside of Washington, DC. I was able to get an edited version of this report.

I inquired as to what the FDA was going to do about having the problem corrected. I was told, over the phone but not in writing, that the case was closed. FDA determined this based on the fact that they did not have any record of injuries or deaths. The FDA also decided it was not going to insist that the company correct the dangerous breathing circuit.

Under the Freedom of Information Act (FOIA), I requested from the FDA the documentation that involved the 510(k) approval of this medical device. The letter was sent in April 1996. In spite of numerous calls and follow up letters, to this date I have not received the requested information.

Someone in the FDA eventually went back and reviewed the information they had. The FDA came to the conclusion that I was right after all. A recall on incubator was issued October 11, 1999.

It has taken the FDA 43 months to get the company (Now known as Hill-Rom Airshields) to correct the dangerous breathing circuit.

The FDA estimates that the retrofits will not be completed until the end of January 2000.

The horrible fact is that the FDA originally approved this dangerous design in 1989. The FDA 510(k) approval number is K985550. This product has been on the market for 10 years. How could the FDA allow infants to be exposed to this dangerous device for so long?

I can not believe that someone in the medical field did not report this to Airshields or the FDA. This product had been on the market for six years before Dr. Mickler and I brought it to their attention.

Who knows how many babies' lives will be saved because I blew the whistle on my employer and continuously badgered the FDA to have the error corrected..

In the light of the recent disclosures of the cover up of medical errors in hospitals, one has to wonder how many of these victims were helpless infants. We may never know.

The FDA was created to enforce the laws passed by our legislators to protect the public. It is impossible for the limited number of investigators to ferriet out the illegal activities of a few corrupt corporate managers. Who is more qualified to expose shoddy products than the company employees who work with these products?

New Jersey has a law that is called the Conscientious Employee Protection Act (CEPA). The American public would be best served with a similar national law to protect whistleblowers. Employees would be protected from unscrupulous employers who callously break the law. Employers who put Bucks before babies!

I am a member of Institute of Electrical and Electronic Engineers (IEEE). Our organization of 347,000 members has a commitment to ethics in engineering. I have presented my case to two ethics committees, the Member Conduct Committee (MCC) and the Society on Social Implications of Technology (SSIT). They fully support my position. One of the members of the committee sent a letter to the Director of Engineering, Jan Wenstrup for his side of the story. The response of the lawyer is typical of the double-speak one can expect from corporate management. It is reminiscent of the rubbish put out by the CEOs of the tobacco industry.

If you wish, I am willing to talk to anyone in your office in greater detail regarding this matter. It can be here in Philadelphia or in Washington.

MEDICAL MISTAKES

TUESDAY, JANUARY 25, 2000

U.S. SENATE, SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES, COMMITTEE ON APPROPRIATIONS, AND COMMITTEE ON VETERANS' AFFAIRS,

Washington, DC.

The subcommittee and committee met at 9:37 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senator Specter.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The hearing of the Appropriations Subcommittee on Labor, Health and Human Services, and Education will now convene.

As we meet this morning at 9:37, a snow storm is raging in Washington. And word came in that the Government was closed. Some of us had notice that it had been opened, but it was officially closed today. And word also came that the Senate was closed.

Yesterday began the second session of the 106th Congress. But we have had a good response and a turnout for the witnesses scheduled for this hearing. And the witnesses have come from long distances: California, Florida. Dr. Specken drove 8 hours, coming in last night. Only one witness, a Washingtonian, was unable to get out of the driveway. So we will proceed.

It may well be that this will not be the last hearing on the subject of medical errors. Senator Harkin, who could not be here this morning because he was engaged in the Iowa primaries, which were held last night, had wanted to be here. And we have prepared legislation in the field, and the hearings will enable us to flesh out the legislation and perhaps make some modifications. Since we are going to be circulating it in the course of the next several days and hope to introduce it in a week to 10 days, we want to get some comments. And I shall discuss the legislation in due course.

The issue of errors in hospitals has been brought into sharp focus. And I ask unanimous consent—which is not hard to get for two reasons: one, I am the chairman and the other is nobody else is here—that my full statement be included in the record, and I will summarize.

The report of the Institute of Medicine on medical errors has caused quite a reaction in the United States. This subcommittee held its first hearing on December 13 even though we were in re-

cess at the time, because of our consideration of the urgency of addressing the issue.

The Institute of Medicine report chronologed that an estimate between 44,000 and 98,000 hospitalized Americans die each year due to avoidable medical mistakes. The national cost of preventable medical errors is between $17 billion and $29 billion. And the IOM estimates that there could be a 50 percent reduction in errors over the next 5 years.

The Institute of Medicine recommended a mandatory reporting system, which has caused a large number of objections. And we heard them in our December 13 meeting. My own view is that there has to be mandatory reporting if we are to have any results. My own State of Pennsylvania has a reporting system. And we threw a big party in Pennsylvania and nobody came. We require reporting and almost no one is reporting. If there is to be a chance to succeed in identifying these errors and preventing them, I believe, personally, there must be mandatory reporting.

The Joint Commission of Accreditation of Health Care Organizations has recommended voluntary reporting. So the issue is joined and there will be plenty of debate on that subject.

This is a joint hearing with the Veterans Affairs Committee, which I Chair. And I am pleased to note that the Veterans Administration has responded to this problem with a substantial degree of diligence. The Veterans Administration has been plagued with a great many problems. So it is especially pleasing—frankly, refreshing—to find that there has been action here.

Last month, the Veterans Administration Medical Inspector published a report on data from the Patient Safety Registry for events from June 1997 through December 1998. Almost 3,000 adverse events in hospitals and almost 600 of them were sentinel events, classified as loss of life, limb or permanent loss of function. And the VA has already instituted a mandatory reporting system.

Senator Harkin and I have prepared legislation which will call for 15 demonstration projects to report to HHS, to give us some insights as to what will work. On five of the demonstration projects there will be mandatory reporting, with the errors to be held confidential. On five of the other demonstration projects there will be voluntary reporting, with the information to be confidential. And five other demonstration projects will call for mandatory reporting and will mandate that the hospital, the physician who made the mistake, must report that to the patient.

Now, that may appear to some as a rather extreme, drastic, unusual procedure, but Senator Harkin and I have discussed this matter at length, and discussed it with others, and it is our judgment that there is a professional responsibility on the part of the hospital or a doctor, where an error is made which affects the patient, that the patient ought to be notified. That is a professional responsibility.

Beyond the medical profession, it is my personal view that that would apply professionally generally. It is not done because of the obvious human frailty of not wanting to admit an error, which may open up the party to civil liability, or more. But there is no doubt that if the injured party has an attorney and an inkling as to what

has happened, that through litigation and discovery, the professional must and the hospital must make those disclosures.

We have seen a fair number of lost records, missing pages, an intolerable situation, giving rise to the inference of deliberate concealment. Of course we do not find that only in hospitals and medical reports, we find it in corporate papers. We find it in government papers. Our Government Affairs Committee had an extensive inquiry and found key Department of Justice documents with missing pages. But that is an intolerable situation in our so-called civilized society.

So our legislation will be looking for these demonstration projects to give us insights as to how to identify these problems as the first indispensable step toward correcting the problems. The legislation will further provide for an analysis as to how to solve the problems of Federal funding.

For example, there are computers available which can track complex medicines taken by a patient, so many that it is hard to figure out what will cause a problem and hard to figure out what the patient is taking. And that can be reduced, with our modern technology, to the computers to find out. That is just one illustration. And there needs to be an assessment as to what can be done and what its cost will be.

So those are issues which are of vital importance. They are life and death matters. And as chair of the Veterans Committee, we intend to pursue the VA health system, which is one of the largest in the country. And as chairman of the subcommittee having jurisdiction over funding of HHS and HCFA and the health system, we intend to see to it that adequate resources are devoted to identify the problems and to move ahead with the solutions.

I believe it is necessary to get tough on medical mistakes and hospital mistakes with the mandatory reporting. And it is necessary to get tough on requiring professionals to report their errors to their patients. Because where it is life and death, that kind of a resolute sense of urgency and toughness I think has to be followed.

At this point I will submit a statement from Senator Rockefeller IV, ranking minority member of the Committee on Veterans' Affairs.

[The statement follows:]

PREPARED STATEMENT OF SENATOR JOHN D. ROCKEFELLER IV

I applaud the Chairman's leadership on this important issue, but I am sorry this hearing has been scheduled at a time when I have another longstanding commitment away from the Capitol. I ask that this statement be inserted in the hearing record following the Chairman's opening remarks.

The problem of patient safety is staggering—between 5 to 18 percent of hospitalized patients are affected by medical errors; an average of 7 percent of hospitalized patients are affected by medication errors; and there are approximately 2 million hospital-acquired infections per year.

We now know that treatment errors and other problems most often result from imperfections in the health care system—how medical personnel interact with each other, with technology, and with medications. Rarely is a lapse in patient safety caused by a single error, by a health care professional working independently. It's much more complicated than that. Fortuitously, an Institute of Medicine report entitled "To Err is Human: Building a Safer Health System" lays out a blueprint for developing better ways to care for patients.

Late in 1997, I issued a Committee minority staff report on shortcomings in VA's quality management program. That report found that although VA has many good programs and talented personnel, it did not have the systems in place to determine whether or not quality care is being provided, uniformly, at all facilities. I want to remind you that we were looking at the systems in place, not the quality of care provided. A VA Inspector General's report on the same subject included many of the same findings as the Committee minority staff report. Given this recent history, I am so proud that the VA has taken an enormous step forward in dealing with patient safety.

Although this is just the beginning for some to mitigate the potential for medical errors, I am enormously proud that the VA health care system is already ahead of the curve. For each of the Institute of Medicine (IOM) recommendations, the VA has either developed a response or is actively pursuing programs to get at the heart of a very complex problem. I include with this statement a comparison of the IOM recommendations and VA current activity.

For example, the IOM recommends establishing a research agenda, Centers of Excellence, and a method to disseminate lessons learned. The VA has a distinct research program in place and will be kicking off research efforts by focusing on anesthesia issues, human-machine interface, patient falls, and medication errors. VA is also funding Centers of Inquiry at four sites. And the VA updates field personnel with Internet postings and safety alert updates.

And while the IOM recommends a nationwide mandatory reporting system for adverse events that result in death or serious harm, the VA is already developing their own mandatory reporting system. VA has adapted their current error reporting system to collect the standardized information, to conduct an analysis of the data, and to follow up with prudent solutions.

Clearly, the VA is doing much in this area. Generally, I question the need for taking legislative action to force VA to comply with IOM recommendations, which they are already doing.

I recently wrote to the Secretary of Veterans Affairs and asked for the Department's views on the need for legislation. A copy of my letter is attached. If legislation is necessary to enable the VA to do a better job at identifying errors or fixing known problems, I certainly will work with Senator Specter to do that.

While this is an excellent opportunity to tout the good work of the VA, it also provides some cautionary lessons for other health care systems.

First, the quality of the data must be examined. Far too often, faulty data have led VA to incomplete or incorrect conclusions. Sufficient resources must be pumped into data collection activities.

Second, health care groups must find a balance between overly prescriptive and more lax approaches. The VA's Patient Incident Program of old, which was designed to identify the underlying causes of adverse incidents, originally permitted VA hospitals to develop unique lists of events to be tracked. There was no requirement to use any predetermined categories or uniform methods in collecting data. Obviously, this limited what could be learned about the system as a whole. VA has evolved past this more free-flowing approach and is now revising and expanding this system to develop a National Patient Safety Reporting System, which will include specific data elements. It will be based on NASA's successful aviation safety reporting system.

And finally, simply designating a program will not provide the answers. While the glory seems to come with the promise of new and innovative programs, lip service will not help patients. Real results follow implementation, and successful implementation requires adequate funding and staffing. There is no getting around this. Management must also be willing to commit to the future, as results will not be instantaneous.

Again, I thank Senator Specter for his leadership on patient safety. I hope that we can work together to get VA the needed tools. Improving the health care system for veterans, and for all Americans, must be a priority.

A copy of my letter to Secretary West follows.

JANUARY 14, 2000.

Hon. TOGO D. WEST, JR.,
Secretary of Veterans Affairs,
Washington, DC.

DEAR SECRETARY WEST: Your efforts to implement a Patient Safety Initiative, as part of an overall approach to quality, are to be applauded. VA seems to be on the right track to avoiding medical errors in the future. I am pleased VA is in the the process of implementing most of the recommendations included in the recent Insti-

tute of Medicine (IOM) report on medical errors. Of course, much remains to be done.

As you are aware, there seems to be Congressional interest in requiring other Federal health care systems to comply with IOM recommendations. I do not believe legislation is necessary at this time regarding VA compliance. I solicit your views on this.

Clearly, all health care systems have significant error rates, and providers from all settings generally underreport medical errors. Establishing a National Patient Safety Center, the Patient Safety Centers of Inquiry, the reporting system and registry—together with your plans to provide training in the field—should provide a sound basis for the Patient Safety Initiative to move forward.

Mr. Secretary, VA's plans are truly admirable, and I look forward to learning more about this initiative as it continues to move from the drawing board to VA's medical centers. I strongly believe, however, that for this effort to be successful, the necessary resources—in staffing and in dollars—must be devoted to it. For example, I understand that the National Center has nearly a dozen authorized staff positions yet to fill. I hope this process will be completed quickly.

I would like to know more about your plans to encourage voluntary reporting and to improve the quality of the information included in the registry. The Office of Medical Inspector's report on the registry indicates significant problems with data validity and reliability. As you are well aware, incomplete and questionable data is a longstanding problem within VA. Nevertheless, the OMI has provided several concrete recommendations to improve the registry. Please keep me updated on your progress in this area.

Finally, the Patient Safety Initiative is a positive and potentially effective approach to risk management. However, it will fail, in my view, if it is used to attempt to shield poor quality health care providers from the necessary review and sanction that follow the provision of poor and harmful treatment.

Mr. Secretary, I am pleased with your focus on patient safety. With sufficient resources and improved data, I believe we can look forward to dramatic reductions in the medical errors which cause unexpected injury or death. I look forward to hearing about your latest advances.

Sincerely,

JOHN D. ROCKEFELLER IV,
Ranking Minority Member.

COMPARISON OF IOM RECOMMENDATIONS ON PATIENT SAFETY AND VA'S CURRENT STATUS

IOM Recommendations	VA Actions
4.1 Congress should create a Center for Patient Safety (CPS) with the AHCPR. This Center should:	VA led the way in setting up the National Patient Safety Partnership. In 1997, the partnership began with 8 and now has 13 health care organizations as members.
Set national goals for patient safety, track progress in meeting these goals, and issue an annual report to the President and Congress.	VA has set four comprehensive goals, noted in the VHA National Patient Safety Improvement Handbook. (being piloted) (Draft 10–29–99) (VHA NPSIH). It addresses identification of errors, study of errors, safety alerts, and prospective analysis. VA is tracking, by means of a Mandatory and Voluntary Reporting System. (IL 10–99–010, June 29, 1999). VA will provide an annual report, per conversation with Dr. Bagian, the Director of the Center for Patient Safety.
Develop knowledge of errors in health care by developing research agenda, funding Centers of Excellence, evaluating methods for identifying/ preventing errors, and funding dissemination activities to improve patient safety.	VA has research agenda. The first four issues are anesthesia, human-machine interface, patient falls, and medication errors. (These will be applied research). VA is funding Centers of Inquiry for research. Those identified are at VA Palo Alto, CA; Cincinnati, OH; White River Junction, VT; and Tampa, FL. VA is evaluating and is developing a VHA National Patient Safety Improvement Handbook, an Advisory Panel, an oversight committee, and is redesigning its Performance Measurement System for the organization. Evaluations of the program have been done by the Chief Network Office, the Office of the Medical Inspector, the Office of Quality Performance, Patient Care Services, etc. VA has put lessons learned, from patient errors, on its website and updates it with safety alerts.
5.1 A nationwide mandatory reporting system should be established that provides for the collection of standardized info by state govts about adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually of other institutional and ambulatory care settings. Congress should:	VA is performing this function for all VISNs as described in the VHA NPSIH (Draft 10–29–99).
Designate the Forum for Health Care Quality Measurement and Reporting as the entity responsible for promulgating and maintaining a core set of reporting standards to be used by states, including a nomenclature and taxonomy for reporting;	VA is collecting standardized information as described in VHA NPSIH (Draft 10–29–99).
Require all health care organizations to report standardized info on a defined list of adverse events;	VA is requiring that all care, whether given in hospitals, ambulatory care, or other settings is to be reported. (VHA NPSIH)

Provide funds and technical expertise for state govts to establish or adapt their current error reporting systems to collect the standardized info, analyze it, and conduct followup action as needed with health care organizations. Should a state choose not to implement the mandatory reporting system, HHS should be designated as the responsible entity; and designate the Center for Patient Safety (CPS) to:	VA has adapted their current error reporting system (risk management) to collect the standardized information, conduct root analysis, and do followup. Actions to correct errors will be taken as required and lessons learned will be published on the Web. A mandatory reporting system is under development. VHA NPSIH The National Center for Patient Safety is located at 2215 Fuller Road, Ann Arbor, MI, 48105—Tel (734) 930–5890; Fax (734) 930–5899.
(1) Convene states to share info and expertise, and to evaluate alternative approaches taken for implementing reporting programs, identify best practices for implementation, and assess the impact of state programs; and	VA is already involved in initiatives to identify best or model practices and has shared information and expertise with health consumers, patient advocacy groups, the pharmaceutical industry, health care practitioners and organizations, etc. (National Patient Safety Partnership Statement, May 12, 1999).
(2) Receive & analyze aggregate reports from states to identify persistent safety issues that require more intensive analysis and/or a broader-based response.	VA has a system under development to gather reliable data and to analyze aggregate reports from all VISN and medical facilities in order to find prudent solutions to identified problems.
5.2 The development of voluntary reporting efforts should be encouraged. The Center for Patient Safety should:	A VA Expert Advisory Panel on Patient Safety Design is establishing a voluntary reporting system that is confidential, de-identified, and nonpunitive. (Briefing by the Deputy Under Secretary for Health to Senate and House Staff from the Committee on Veterans Affairs, January 4, 2000)
Describe and disseminate info on existing voluntary reporting programs to encourage greater participation in them and track the development of new reporting systems as they form;	The VA Lessons Learned Program, which is on the Web, as well as the use of the VA Performance Measurement System and the VA National Patient Safety Reporting System will all be used to encourage participation in reporting. The National Patient Safety Partnership and the National Center for Patient Safety will track the development of new reporting systems. (VHA NPSIH)
Convene sponsors and users of external reporting systems to evaluate what works or doesn't work well in the programs, and ways to make them more effective;	The National Patient Safety Partnership program, which is made up of 13 members, has held meetings with other health care organizations, pharmaceutical companies, etc. to see what works and what does not work.
Periodically assess whether additional efforts are needed to address gaps in information to improve patient safety and to encourage health care organizations to participate in voluntary reporting programs; and	VA has identified 12 major steps or milestones to address gaps in patient safety. VA firmly supports voluntary reporting or errors. (Significant Milestones in VA Patient Safety Improvement, VA Office of Congressional Affairs, December 20, 1999)
Fund and evaluate pilot projects for reporting systems, both within individual health care organizations and collaborative efforts among health care organizations.	VA is funding and evaluating (through pilot projects) reporting systems throughout the VA and is collaborating with other health care organizations such as JCAHO, AHA, AMA, ANA, AAMC, NPSF at AMA, and IHI-Charter Members, as well as with NASA and ASRA (Aviation Safety Reporting Systems).

COMPARISON OF IOM RECOMMENDATIONS ON PATIENT SAFETY AND VA'S CURRENT STATUS—Continued

IOM Recommendations	VA Actions
6.1 Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality.	For the VA, information from confidential sources or documents are protected by Title 38 (U.S.C.) Section 5705 and restrictions dictated by the Privacy Act—Title 38 (U.S.C.) Section 7332 grant additional protection.
7.1 Performance standards and expectations for health care organizations should focus greater attention on patient safety. Regulators and accreditors should require health care organizations to implement meaningful patient safety programs with defined executive responsibility. Public and private purchasers should provide incentives to health care organizations to demonstrate continuous improvement in patient safety.	The VA has had organizational and executive detailed performance standards for about 5 years and has had specific safety standards for the past 3 years. VA's health care facilities are accredited by JCAHO, CARF, NRC, CAP etc. All of these bodies have patient safety requirements for the organization and its executives. This does not apply to the VA as written, but VA does have safety standards so that it can compete for and provide services to private and public purchasers such as in sharing agreements, and for providing care for those eligible for TRACER, etc.
7.2 Performance standards and expectations for health professionals should focus greater attention on patient safety. Health professional licensing bodies should—	For the past three years, VA has had patient safety performance standards for all health care professionals. This also includes health care executives. VA has an excellent certification and privileging program. This has been attested to by GAO and JCAHO.
(1) Implement periodic reexaminations and relicensing of doctors, nurses, and other key providers, based on both competence and knowledge of safety practices; and	VA requires reprivileging of all physicians and those that require privileges every two years. All those with licenses must maintain primary verification of up-to-date licenses. Re-privileging is based on both the competence and knowledge of staff medical practices as well as on quality of care considerations. These considerations include safety.
(2) Work with certifying & credentialing organizations to develop more effective methods to identify unsafe providers and take action.	VA has been working with the U.S. Public Health Service since 1996 to develop a Federal Credentialing Program that will be an electronically accessible health care practitioner credentialing data base consisting of primary source verification. (Bureau of Health Professions, Health Resources & Services Administration, Public Health Service, HHS, January 13, 2000.—VetPro and FCP) This is one of the first methods used to assure the provision of safe health care. This program will also evaluate the peer review organization.
Professional societies should make a visible commitment to patient safety by establishing a permanent committee dedicated to safety improvement. This committee should—	VA took the lead in establishing the National Patient Safety Partnership Initiative in 1997.

(1) Develop a curriculum on patient safety and encourage its adoption into training and certification requirements;	The VA, working with the National Patient Safety Partnership Program, gave birth to a VA Patient Safety Improvement Oversight Committee, a VA Patient Safety Registry, a VA Patient Safety Improvement Awards Program, a VA National Patient Safety Center, a VA Patient Safety Center of Inquiry, a VA Expert Advisory Panel on Patient Safety, a VA National Patient Safety Improvement Handbook (draft), etc. All of these programs will assist in the development of the foundation of a curriculum for training, planned for every VISN and VA health care facility.
(2) Disseminate info on patient safety to members at special sessions at annual conferences, and in journal articles, editorials, newsletters, other publications, and websites on a regular basis;	VA is frequently cited in various journal articles, editorials, newspapers, and other publications concerning its efforts to improve safety. (During the last two weeks of December 1999, I collected 18 clippings.) VA has a website to disseminate information about lessons learned from patient safety information. The VA, in November 1998, helped to fund and was a participant in the International Patient Safety and Reducing Errors in Health Care Conference at Rancho Mirage, CA.
(3) Recognize patient safety considerations in practice guidelines and in standards related to the introduction and diffusion of new technologies, therapies, and drugs;	VA has developed patient guidelines on numerous health care issues which have set the standards for new technologies, therapies, and drug usages. The whole purpose of these guidelines is the provision of quality care that is safe, above all.
(4) Work with the CPS to develop community-based, collaborative initiatives for error reporting and analysis, and implementation of patient safety improvements; and	Once the Center for Patient Safety has been established, VA will work with it, as it has continued to work with all the members of the National Patient Safety Partnership and other pioneers in this field.
(5) Collaborate with other professional societies and disciplines in a national summit on the professional's role in patient safety.	VA will participate and in fact may be one of the leading group of professionals with considerable experience in this field.
7.3 The FDA should increase attention to the safe use of drugs in both pre- and post-marketing processes through the following actions:	VA agrees that FDA should increase attention to the safe use of drugs and is a continuous collaborator with the FDA in pre- and post-marketing processes.
Develop and enforce standards for the design of drug packaging and labeling that will maximize safety in use;	VA routinely provides information to the FDA on a systematic basis for these types of issues.
Require pharmaceutical companies to test (using FDA-approved methods) proposed drug names to identify and remedy potential sound-alike and look-alike drug names to identify and remedy confusion with existing drug names; and	While this recommendation is under the purview of the FDA, VA notifies the FDA about proposed sound-alike drug names and look-alike drug names as part of it current safety program. This has been in effect as part of the older Risk Management Program that has been renamed the Patient Safety Program.
Work with physicians, pharmacists, consumers and other to establish appropriate responses to problems identified through postmarketing surveillance, especially for concerns that are perceived to require immediate response to protect the safety of patients.	After problems have been identified through postmarketing surveillance, VA notifies the FDA and all of its health care facilities and requires immediate action to eradicate the identified problem and to prevent errors.

COMPARISON OF IOM RECOMMENDATIONS ON PATIENT SAFETY AND VA'S CURRENT STATUS—Continued

IOM Recommendations	VA Actions
8.1 Health care organizations and the professionals affiliated with them should make continually improved patient safety a declared and serious aim by establishing patient safety programs with a defined executive responsibility. Patient safety programs should: (1) provide strong, clear, and visible attention to safety, and implement nonpunitive systems for reporting and analyzing errors within their organizations; (2) incorporate well understood safety principles, such as standardizing and simplifying equipment, supplies, and processes; and (3) establish interdisciplinary team training programs, such as simulation, that incorporate proven methods of team management.	VA has been the leader in establishing the Patient Safety Partnership Program in 1997. It is evident from the VA National Patient Safety Improvement Handbook (Draft 10–29–99) (currently being piloted) that the VA is providing visible attention to safety and is implementing a nonpunitive system. VA is developing a system to analyze errors and is standardizing and simplifying equipment, supplies and processes. The Center for Patient Safety is planning a training program for all VISNs and VA health care facilities at individual sites in the field. The training is planned for small groups so that there can be simulations and one-on-one training.
8.2 Health care organizations should implement proven medication safety practices.	VA is not waiting for any law or development of a Center for Patient Safety as recommended by the IOM. It has its own center and is implementing the program now!

STATEMENT OF MOLLY JOEL COYE, M.D., MEMBER, INSTITUTE OF MEDICINE, COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA

ACCOMPANIED BY LUCIAN LEAPE, M.D., MEMBER, INSTITUTE OF MEDICINE, COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA

Senator SPECTER. We turn now to our first witness. As a matter of informality, I am going to ask all the witnesses to come forward at the same time and sit at the dais together. Our first witness is Dr. Lucian Leape. He serves as a member of the Institute of Medicine, Committee on Quality of Health Care in America, and is an Adjunct Professor at the School of Public Health at Harvard University. Dr. Leape did the original research, published 10 years ago, that first called the issue of medical errors to the public's attention.

And we have Dr. Molly Joel Coye, who serves as a member of the Institute of Medicine, Committee on Quality of Health Care in America, and Senior Vice President of the West Coast office for the Lewin Group, a health care strategic planning, policy research and managing consultant firm. Dr. Coye has previously served as Director of the California Department of Health Services and Commissioner of Health for the State of New Jersey and head of the Division of Public Health at Johns Hopkins School of Hygiene and Public Health.

Welcome, Dr. Leape and Dr. Coye. We look forward to your testimony.

Dr. COYE. Thank you.

Dr. LEAPE. Mr. Chairman, I think it would be nice to have Dr. Coye go first and set the stage, and then I will pick up after that. She originally planned to testify. I am a pinch hitter, but I am happy to do anything I can.

Senator SPECTER. Well, as you like it.

Dr. Coye.

Dr. COYE. Dr. Leape is, as usual, much too modest. He is really the father of work on patient error and patient safety in this country.

I, however, am also here representing the Institute of Medicine and the Committee on the Quality of Health Care in America, which recently released the report, "To Err is Human: Building a Safer Health System." We realize that you have already held a series of hearings—this is the second in a series of hearings—and that my colleague, Mary Wakefield, has testified on behalf of the IOM committee in the past. For that reason, we will only briefly review the IOM's recommendations, and really focus our remarks on the frequently asked questions that have ensued in the last month or so, or two months, since then.

But let me reiterate, first of all, because it is really core and central to our concern that our review of the literature underscores the fact that medical mistakes rank eight among the leading causes of death, ahead of traffic accidents, breast cancer, and AIDS. Furthermore, we believe strongly that it is possible to achieve at least a 50 percent reduction in these errors over the next 5 years.

For that reason, we welcome your interest and support and attention to these concerns. Most importantly, we have knowledge and technology available now, which 10 or 15 years ago was not

available, in order to address these problems. Based on those findings, we offered four major recommendations. The first was to create a National Center for Patient Safety within the Agency for Health Care Research and Quality, to provide leadership, invest in applied research, build prototype systems, and disseminate information on best practices. That is not intended to be a regulatory agency, but a national center for learning and research and dissemination.

Our second recommendation is for the establishment of mandatory and voluntary reporting systems, which is central to the discussion today. We recommended the creation of a nationwide system, which is State based, as a mandatory reporting system to collect information on the most serious errors that result in death or permanent harm in order to use that information to better understand the factors that contribute to errors and to encourage health care organizations to take the necessary steps in order to prevent them in the future. We also encourage the growth of voluntary reporting systems, analogous to the near-miss systems in the airline industry.

Senator SPECTER. How do you distinguish between the mandatory and the voluntary reporting systems?

Dr. COYE. The mandatory system is intended to collect information on serious errors which lead to serious injury or death. The voluntary is for either lesser injury or essentially no injury at all. We learn an awful lot from the errors in which nobody was particularly hurt but we almost hurt someone.

The third recommendation is to strengthen standards through accrediting and licensing organizations and also to encourage group purchasers and professional groups to raise their expectations. And I hope you will hear from, if you have not already, the Leapfrog Alliance of Purchasers, as an example, which includes many large purchasers which are moving rapidly to try to incorporate requirements in their negotiations with health plans for the assurance of patient safety. And creating safety systems inside health care organizations.

Now, the response to our recommendations has been pretty phenomenal. You probably have seen the Kaiser Family Foundation and Harvard School of Public Health poll that found that 51 percent of Americans closely followed news of the release of the report. And coverage continues. We believe, because of that, there is a tremendous opportunity to act. And we would like to take the opportunity today to address some of the concerns and questions that have arisen.

I would like to stress, having not only been health director and commissioner in two States, but a member of the committee over the last year as we reviewed all of the literature in this area, that it is hard to overstate the lack of public understanding of the impact of these errors in medical mistakes. We know a great deal about this, but there has been very slow progress. There is a great need for action in this area. Our recommendations call for national leadership, national attention and resources, to make safety the number one priority of every health care institution.

I would like to turn to Dr. Leape to talk about the mandatory reporting requirements in detail. But before I do so, I would like

to speak specifically to aspects of our report on mandatory reporting that relate also to State health Departments and public health officers interests. The IOM committee believes very strongly that the public has a right to be informed about unsafe conditions and a right to expect health care organizations to respond to evidence of safety hazards by taking whatever steps they need to in order to remedy the situation.

We said in our report that only the institution itself—the hospital, the clinic, the physician's office—can redesign its systems for safety. The majority of effort in improving safety should focus on safe systems, and the health care organization itself should be held responsible. This does not mean that State governments must be responsible for actually operating the mandatory reporting program. The State could delegate to an accrediting body, a peer review organization or another private sector entity the collection and analyzing of data.

So we do not believe that this would be an onerous burden on the States, and it is an important role in experimentation and innovation, because we do not yet know what the best practice for a national system would be.

Let me turn to Dr. Leape, who has spent the last several decades working on this issue.

Senator SPECTER. Is that true, Dr. Leape?

Dr. LEAPE. Thank you, Dr. Coye. And thank you, Mr. Chairman.

Senator SPECTER. Is that true, Dr. Leape, several decades?

Dr. LEAPE. It just seems like it.

Senator SPECTER. If so, how many?

Dr. LEAPE. Well, I was a practicing pediatric surgeon for 20 years and, about 12 years ago, got interested in this subject and have been working since then.

Senator SPECTER. We welcome you here, Dr. Leape. We know of your work and look forward to your testimony.

Dr. LEAPE. Well, thank you, sir.

I want to reinforce what Dr. Coye has said. The committee feels the Center for Patient Safety is the most important thing we can do to advance safety. But I think the focus of the hearing today is on the mandatory reporting requirement, and so we wanted to give you whatever help we could in that area.

I would like to clarify one thing. There are three levels at which reports are made. The first and I think still the most important one is to the patient. And I could not agree more with your statement that this is an unequivocal, clear and important professional obligation.

The first obligation a physician or nurse has is to be honest with the patient, and patients have a right to know. It is part of our ethical canon in medicine, and this is certainly a principle that is upheld and specifically stated by the American Medical Association, the American Nursing Association and the American Hospital Association. They all believe that we have an obligation to be honest with our patients, full stop, period.

The second level of reporting is internal within an institution. And most of us believe this is where real improvement takes place. Tip O'Neil used to say: All politics is local. I think all improved safety is local. Hospitals and health care institutions have to create

safe environments for the people to work in. They have to make sure that the procedures they follow are safe.

So internal reporting is a key feature for that, and we know a lot about that. We know that internal reporting does not happen if it is not safe. That is, if we punish people for reporting errors, they do not report. We know that internal reporting does not happen if it is not productive. That is, if nothing happens. Because reporting alone does not improve safety. Reporting only improves safety if it leads to a response, if it leads to an investigation, if it leads to an analysis on what is found that leads to change. And only when people see that that is what has happened do they feel that it is worth while to report.

This has been the experience of the most impressive and most successful reporting system in the world, which is the aviation safety reporting system. They receive over 30,000 reports a year. And they analyze these reports and they feed back.

I hope you will hear from Charles Billings, if you have not already, the architect of that system. Because what he says is: All reporting is voluntary. People can find ways to get around it if they have to. But they will report and they want to report when it is safe and when it is productive. The success of the aviation safety reporting system I think is eloquent testimony to the validity of Dr. Billing's comments.

The final kind of reporting, in addition to internal reporting within hospitals is external reporting, such as the aviation safety reporting system—voluntary systems which get information to improve safety, and mandatory systems which are used for a very different purpose—accountability. And I think that is where a lot of the confusion has come.

Most of us feel it is very difficult to get both improvement and accountability from the same system. It can work, and it does in some instances. But most of the time it is very difficult. But we think it is absolutely crucial to have a system of accountability. And the committee felt that the way to do this was to require reporting of sentinel events. A sentinel event to us is a bad thing, an injury—not an error—an injury or a death that should not have happened, that we all agree really should not have happened—suicide in a hospital, removal of a wrong leg, maternal deaths.

These are the kind of things that really should not happen. And when they do, they may not mean that anybody has done anything wrong, but they certainly raise the question. They raise the question as to whether the hospital has adequate safeguards to prevent these kind of really serious injuries. The committee felt that these need to be clearly defined and that we need to be quite clear about what we are trying to do with it.

Reporting of sentinel events is after all a very minimal level of safety assurance. We want our regulators, we want our hospitals to do much, much more. But the least we can do is make sure we are finding out about these terrible breaches in our safety mechanisms.

We would suggest that there are several characteristics of such a system. The first is it should focus on events, not errors. Second, reports should be by institution and not by individuals. Individuals can report, but the point is to hold the institutional accountable.

Because only the institution can change the systems. We think that it should be a relatively short list of clearly defined, unambiguous, unfudgeable, unhideable, serious events that everybody knows need to be reported and that are hard to conceal.

They may require investigation from an external body. It turns out, in practice, about a third do and about two-thirds do not. And they may require some significant changes. They rarely require punishment. Most effective external reporting systems do not have to punish; they just have to make it clear they will. And we find that in systems that work, there is no question about the authority, but there is also no question about a constructive, cooperative arrangement that leads to improvement.

And, finally, I think they need to be confidential with regard to individuals, both patients and providers, if we are to make them safe and if we are to make them effective. Now, there are three issues here. One is mandatory notification. Does a health care organization report? And our feeling on that is unequivocal—yes, absolutely, there should be no question about that at all. There is really no legitimate reason to not report these types of things.

The second issue has to do with the response—what do you do when you report? And there we think it is important that the system be such that both the health care institution and the regulator or accreditor respond in an appropriate way. And they should be held accountable to make a response. As I indicated before, only about a third of them probably require a full-scale investigation, but they all need to be notified, and we all need to know what was done.

Finally is the issue of disclosure. And that is a sticking point—which of this information should be disclosed to the public? Hospitals, of course, do not want any of it disclosed because it damages their reputation. This is a very real and important consideration that we should not ignore.

On the other hand, the public has a right to know. And we think the balance is that there needs to be public access to this information both in terms of the fact that the event occurred and in terms of what was found and how it was resolved. We do not think there is much to be served by making available all the details of the investigation and specifically names of individuals. So we would like to see a responsible system. And we think the health care institutions in this country want to do that. And there are good examples out there of how regulators are doing it. But there is not any question in our minds that we need to have this, and I am quite happy to answer any questions you may have.

Senator SPECTER. Thank you very much, Dr. Leape.

Beginning with the basic issue of mandatory versus voluntary, as I said earlier, I believe the mandatory requirements ought to be imposed. But what, Dr. Leape, was the best argument on the other side for limiting it to voluntary disclosures?

Dr. LEAPE. Well, I would go back to Dr. Billings' comment of all reporting is voluntary. And that is, people have tremendous reluctance to report when they get punished. I have spent the last 10 years trying to convince people that we have to quit punishing people for making errors. Because errors are not sins. People are not bad when they make errors. Errors very rarely result in mis-

conduct. But there may be bad systems and those systems that cause the errors. But the reason people do not want to report of course is because it makes them look bad and they get punished for it. Even if you leave out the whole risk of litigation, I think that is greatly overblown.

Senator SPECTER. That is to say that a voluntary system does not work. People do not want to report if it is a matter of their option. And if it is voluntary, then they will not report, as you outlined, human nature on the point, basic human nature. So what is the strongest argument that can be made for those who want to have it on a voluntary basis? Do they structure a rationale that there will be more information or enough information to correct the errors?

Dr. LEAPE. May I show you an illustration? I would be glad to make these available to the committee.

Senator SPECTER. Sure.

Dr. LEAPE. People will report voluntarily when it is safe. And when it is safe means when they do not get punished. What you have here is an example from a single nursing unit in a single hospital in the Midwest, in which the nurse decided to quit punishing people when they reported medication errors. And they had information for the previous year, they had reports in their voluntary system of approximately eight reports a month. It varied, but it was about eight reports a month.

In the month after, she said two things. One is we are not going to punish people. And secondly, we want to find out about our errors so we can do something about them. The next month she received 160 reports—20 times more.

Senator SPECTER. And what punishment had been imposed in the earlier period?

Dr. LEAPE. Well, the punishment is often very subtle. Sometimes, if it is a serious error, people can be fired. If it is less serious, they are reprimanded. If it is less serious, they are cautioned and warned that it should not happen again or they are retrained. Or even if none of those happen, it is made quite clear that they are looked down upon for having made a mistake. There is a social ostracism in health care often. And that has been the single major barrier to improvement. Because we treat errors as sins, because we treat people who make errors as bad people, they hide and they conceal.

And all I am saying to you is when you quit doing that, they will talk about it. And the interesting thing is they want to talk about it, because they want to do something about it, too.

Senator SPECTER. Well, if you have a system which requires that the patient be advised of the mistake, then that opens the door to litigation. The door may be opened later, or may be opened in any event by the patient seeking an attorney who will make inquiries and get compulsory disclosure through the litigation discovery. You support the proposition that there is an obligation, a professional obligation, to notify the patient who has been injured. But does not that involve the principle of punishment, which discourages reporting as you articulate it?

Dr. LEAPE. Well, I do not think there is any way around our fulfilling our ethical obligations. I think we have to do that regardless of the consequences.

Senator SPECTER. Dr. Coye, you had commented about the technology which is available. We would be interested to know what you have in mind. One example which I mentioned was the computerization of a patient's medicine so those who are providing it know what is going on. What other suggestions in the technological field do you have in mind?

Dr. COYE. I can give you two examples, and I think probably that Dr. Leape can give you some examples as well. The first example has to do with the computerized physician order entry systems, which is what you are referring to. And I am not sure if someone has presented this before, but there are actually small hand-held machines, a Palm Pilot or analogous machines, which can have on it enough about the patient's medical history and about the available drugs, about the interactions between drugs, that a physician can write a prescription essentially right there during the interview with the patient and immediately find out if they have made an error.

They do not have to send it to the pharmacy and have the pharmacist catch the error. They immediately can see a screen that pops up and says: This dosage is not the recommended dosage. Or: Are you aware that this patient is also taking these other three medicines, and there is a drug-drug interaction here?

So there are very practical means—some of them have other platforms other than this—in order to alert the physician in real time and prevent some of these errors, as well as the fact that it is then transmitted by computer from the Palm Pilot or from a PC to the pharmacist. And the whole process is from machine to machine, so the opportunity for human error in there is reduced.

Senator SPECTER. Do you have any examples of technology on any other issue than prescriptions?

Dr. COYE. Right now what we have most of what I am aware of is in the prescription area, because that is so critical. One of the big problem areas is that a lot of the work has been done in hospitals. And one of the things we wrestled with is how do get a handle on the size of the error potential in ambulatory.

Most people do not go to the hospital most of the time; they are seeing a doctor in a private office. But there is very good technology now that can analyze the medicines that are prescribed for those patients and that they take and their clinical conditions to show where there are patterns of prescribing that are probable errors and that can actually intervene and reduce those rate of errors.

Senator SPECTER. That is more on prescribing prescriptions. What other errors might be attacked by technology?

Dr. LEAPE. The field that has done the most in improving safety has been anesthesia. And over the years they have made a number of changes, both technological and otherwise. They have looked a lot about how they work together. They have done a lot in terms of team training and how people interact. But they have also put a lot of emphasis on technology.

One thing, for example, is they now require the use of the pulse oximeter, which is a little device that attaches to the finger that continuously records the blood oxygen level. And by doing this and having alarms on that system, the anesthetist gets an early warning if the patient's ventilation is not adequate. They also measure the carbon dioxide coming out in the ventilators. And they have a number of monitors they use. Anesthesia has set up a whole battery of safety procedures that they now routinely follow. They have been an excellent model for this.

Another area that again anesthesia started but is now going into surgery and internal medicine is the use of simulation, in which doctors learn to do procedures on a dummy, so they have their first crash or their first disaster on an artificial patient. And this has greatly improved safety we believe. So I think there is a whole host of things coming down the line.

Senator SPECTER. Dr. Leape, you made one statement that I would like to ask you about. You say that a lot of these errors, these are errors which should not have happened, but it does not mean anyone has done anything wrong. I question the juxtaposition of those two statements. If an error occurred, if an injury occurred which should not have occurred, does not that necessarily mean that if somebody had not made a mistake that would not have occurred?

Dr. LEAPE. It seems that way, does it not?

Senator SPECTER. Well, I am trying to understand your profession, your application. Because your approach is obviously very thoughtful, and I know you have something specific in mind.

Dr. LEAPE. Well, the thing that is impressive when you investigate a serious accident and so forth is the complexity of what is going on and the multiplicity of factors. A case in point that you may have heard of is the death of a child in the Denver Hospital who got the wrong form of penicillin injected intravenously. When that case was investigated, they found 55 system failures. All kinds of things had not worked the way they should. And this is what you invariably find.

You find a physician takes out the wrong kidney, for heaven's sake. But how did that happen? How is it possible that the rest of the team did not realize what was going on? How is it possible that it was not properly marked on the x-ray? How come it was not marked on the patient? Et cetera, et cetera.

And what we are saying is we want to substitute responsibility for blame. They are not the same. We hold everybody responsible. And we want to substitute systems analysis for personal punishment. And the reason for that is really very simple. I am a surgeon. And one thing about surgeons is they are pragmatists. They can have all the theories in the world, but if they do not work and a patient dies, that theory is no good.

So you learn very quickly in surgery to not fool around and to be honest because you get tested every day. And pragmatically, the system of blaming and punishing people and holding individuals responsible has not worked. It has got us what we have today, which is an incredibly unsafe system. Even if you do not agree with our theory, you have got to admit we have got to do something dif-

ferent. And something different is not only soundly based on theory, it works.

And so when you have an egregious accident, what you have to say is: What are all the things that have caused this to happen? One of them may be that that doctor was on for 24 hours. That is a systems failure. No other industry would permit that.

One of the problems may be that for that doctor it was only the procedure for which he was not adequately trained. Right, he should not do that. But what is the system that lets that happen? And that is what we are getting at. These problems are not simple, but they are not because of bad people. We do not have very many bad people in medicine. We have a few, but not very many.

Senator SPECTER. Dr. Coye, one final question for you. It was recently called to my attention that at a major hospital there was a review of a doctor's failure to file an honest report on a procedure. And it was thought that he did so to avoid malpractice liability. And the review board suspended him, saying that had he candidly stated that he had falsified the records to avoid malpractice liability, they would have retained him on the staff. But because he was not candid in admitting that he had falsified the records, that they were going to discharge him from the staff.

What do you think of that kind of a judgment?

Dr. COYE. In the committee, we recognize that the malpractice system is a tremendous barrier in fact to the kind of improvements that are needed. We have a malpractice system that is very, very strong and is not going to be dismantled simply to solve the problems of patient safety. It is not an important means of ensuring the safety of the public, however, in medicine.

Senator SPECTER. It is not?

Dr. COYE. It is not. And it is very important that we not—I am getting into too many double negatives—we not be prevented, as a nation, from doing what we ought to do to reduce patient errors because of the malpractice system. The malpractice system we took in our committee as somewhat of a given. Given that we have a malpractice system, we still have to put in the programs of reporting that are going to be needed to find out more about and track progress in the work on patient safety.

Senator SPECTER. Do you think the medical malpractice system contributes to keeping the medical profession on its toes to avoid mistakes and to avoid malpractice liability?

Dr. COYE. Very minimally I think is the most accurate statement I could make. Again, I would just like to invite Dr. Leape to comment on this. We wrestled with this for quite a long time in the committee. It is quite clear that—I also was COO of a large hospital system in California, and I regulated hospitals for a long time—that we know, and I am sure that you do, too, that a very small proportion of all errors ever wind up in malpractice cases. And so physicians who are worried about legal liability are not necessarily forced to do much about these patterns. And frankly, a lot of it is not something an individual physician can do much about.

Senator SPECTER. Do you think there should be more malpractice cases, then?

Dr. COYE. That is not what we see as the solution.

Senator SPECTER. I thought you would not see it that way. Well, you did not quite come to grips with my question. And it seems to me—and not to belabor the point and we have taken a lot of extra time on the first panel because these are such difficult questions—that you cannot justify falsifying a report because there is an understandable personal interest in avoiding malpractice.

Dr. COYE. Oh, I think we completely agree with that. I am sorry if I did not say that.

Senator SPECTER. That is what the hospital concluded, that if the doctor had said it is a false report because he did not want to be liable for malpractice, he could have stayed on.

Dr. Leape, I have one final question for you. When you went through the enumeration of the various organizations which say there is a duty on the part of the professional to tell the patient about a mistake, are those reduced to codes of ethics among the nurses, among the doctors, among the hospitals?

Dr. LEAPE. My knowledge of these is merely as a recipient, as a practitioner, and you should inquire of those organizations their specifics. But certainly that is my understanding, that hospitals have codes of ethics based on these.

Senator SPECTER. We will do that. I have an instinct that the thought of Federal legislation, mandating doctors and hospitals to tell the patient about a serious mistake is going to create an enormous outcry. And I think it is time that professionals faced up to what you and I and—Dr. Coye, let the record show, is nodding in agreement—that is an adoptive admission, Dr. Coye, you agree with Dr. Leape?

Dr. COYE. I am very comfortable with agreeing.

Senator SPECTER. OK. That professionals have a duty to tell their patients when they have made a mistake. But to mandate that is going to I think cause a great hue and cry. And I think that your quotation of Charles Billings, that all reporting is voluntary because there is a way to avoid it, it all depends upon, if you will pardon me, the punishment at the other end. And I may have a predisposition to that because I spent so long as a prosecuting attorney.

The Federal income tax system is voluntary, but reporting goes way up when the prosecutions go up. White collar crime has a very heavy aspect of deterrence. Barroom killings do not. The punishment is not a deterrent there. And spousal disputes are not. But where people are thoughtful, if there is a consequence and a punishment at the end of it, that kind of a mandate at the end promotes the reporting.

We very much appreciate your being here, Dr. Coye and Dr. Leape. We will study carefully what you have said. And we may be back to you for some more answers. Thank you.

Dr. LEAPE. Thank you.

STATEMENT OF THOMAS L. GARTHWAITE, M.D., ACTING UNDER SECRETARY FOR HEALTH, DEPARTMENT OF VETERANS AFFAIRS

ACCOMPANIED BY JAMES P. BAGIAN, M.D., P.E., DIRECTOR, NATIONAL CENTER FOR PATIENT SAFETY, VETERANS HEALTH ADMINISTRATION

Senator SPECTER. I call now panel number two: Dr. Thomas Garthwaite and Dr. James Bagian. Dr. Garthwaite is the acting Under Secretary of Health, the highest official in the Veterans Health Administration, responsible for the management of the Nation's largest health system, that serves more than 3 million veterans each year and has an annual budget of more than $17 billion. In addition to providing medical care, the VA's health system is the Nation's largest provider of graduate medical education and one of the Nation's largest research organizations.

Welcome, Dr. Garthwaite. It says here that you have served the VA for 25 years, which means you started at a very early age, from your appearance at least. We will not ask you how old you are. We will not mandate a disclosure on your age, but anything you want to volunteer on that subject will be printed in the record.

Dr. GARTHWAITE. Thank you, Mr. Chairman. It is a pleasure to be here to discuss what can be done in patient safety and what the VA has already done.

I think the first thing I might do is read from our Patient Safety Handbook, because of what has been brought out in the previous panel. It says that networks will ensure that their facilities have a process in place to promptly inform patients and their families about pertinent clinical facts associated with injuries resulting from adverse events. It goes on to describe various processes and our responsibility to inform them about their rights both under the Tort Claims Act but also under a separate set of benefits, 1151 benefits. We believe strongly that a frank and open discussion about any medical errors that we discover must start with the patient.

In fact, one of our medical facilities has recently written up their experience, in which they proactively have done this for many years, and track their litigation experience versus other VA's who have done that perhaps less formally. And it indicates that in fact their malpractice payments seem to be somewhat less. They have removed, in a way, the need to punish the health care system for failure to admit that something happened.

I would like to make just a couple of points. The first is about the difference between accountability systems and learning systems. And I think that really speaks to the issue about mandatory and voluntary reporting to some degree.

We have multiple systems in place to try to understand whether a given provider is a bad provider and to take action. We have credentialling systems to understand their training. We have privileging systems to understand if they are currently clinically competent to do what they do. We have administrative investigations when we think there has been an intentional unsafe act. And we have personnel and performance systems in which we can take actions against individuals.

So we have in place many systems, and I think, by and large, they work effectively where we need to use them to take action against practitioners. That, however, is not the major issue in un-

derstanding mistakes. We believe, as Dr. Leape stated, that most people come to work every day to help patients, not to harm patients. And it is a systematic view that is necessary in order to change that.

Let me just give you one example of systems versus people. The prescription prescribing practice involves a series of steps, from a clinician writing an order for a medication—in older systems, handwritten; in newer systems, computerized—and then the transcription of taking that order off the chart, sent to the pharmacy, the filling of that prescription, sending it to the ward, a nurse taking the prescription to the beside and assuring the patient gets that either orally or by injection.

Timing is important. Dose is important. Reading the handwriting is important. Some drugs sound a lot alike. Getting the right drug to the right patient. Some patients have similar sounding names. There are a host of opportunities along that process for error to occur.

If you went today to the Washington VA Medical Center, you would find that 100 percent of their inside orders, their hospital orders, are entered on the computer. No chance for handwriting error. No chance to prescribe a drug that they do not carry. No chance for ordering a dose that they do not carry.

Then, as the drug comes back and is administered by the nurse, instead of the nurse looking visually at the patient and trying to read the arm band, and sometimes at a difficult angle in an imperfectly lit room, they have hand-held devices which they can use—to scan the bar codes both on the patient's wrist band and on the medication. And so at the bedside with this technology today, they can compare what was ordered, which patient is getting the drug, the time of the drug, the dose, and the actual drug. So any potential errors related to the administration of medication are significantly decreased by this new process.

Nurses say: I definitely would not want to go back to the old way of passing out medicines. I like the fact the system will stop me when there is a discrepancy.

So I think it is really about systems. And that is what we have really been about in the VA over the last 3 to 4 years. In 1997, we set out on a mission to improve patient safety in our health care system. The first step was to reach out to others in the health care system. And we were the energy behind forming the National Patient Safety Partnership, which now has 13 very large organizations across health care, where we can get together and discuss what generically should be done.

Then we have added a series of things, and I am not going to bore you with a long list. It is part of our written testimony. But one of the key things we did was to set up a Center for Patient Safety that reports directly to the Under Secretary of Health. So there is no question about who is accountable for setting a system in place. There is no plausible deniability that we did not know that things were unsafe. We want to know at the very highest levels what we can do to make health care safer for veterans.

In fact, what we really would like to do is, first, see a weakness before anything happens. If we cannot do that, then maybe there is a close call. We catch it. We would like to learn from that.

And finally, the worst way to learn, but the one that we want to dedicate ourselves to learn from the first and only mistake, is when we have harmed a patient. And so that is what the system is designed to do, to learn the maximum amount with the least harm to anyone, and then to put into place systems that do not ever let it happen again.

With me today is Dr. Jim Bagian. Dr. Bagian is a two-time astronaut, an engineer and a physician. And he has joined us as the head of patient safety. And as you will see, he has given this a lot of thought and has good ideas about how we can continue along our journey to make VA the safest health care system in the world.

[The statement follows:]

PREPARED STATEMENT OF DR. THOMAS L. GARTHWAITE

Mr. Chairman and Members of the Committees, I am pleased to appear before you to discuss VA's ongoing activities and initiatives to re-engineer its patient ensure the safety of patients who receive care from VA programs. In December 1999, the Institute of Medicine (IOM) released a report "To Err is Human: Building a Safer Health System." The report reviewed existing studies and concluded that as many as 98,000 preventable deaths occur each year in United States' healthcare due to error. The IOM recommended creating a new National Center for Patient Safety that would focus on research and policy related to errors in healthcare, improved error reporting systems, improved analysis/feedback methods, performance standards for healthcare organizations and individuals, and other specific governmental actions. Importantly, they cautioned that the focus must be on creating a culture of safety that will require improving systems, not assigning blame.

VA interpreted the IOM report as a validation of our commitment to improving patient safety in our healthcare system. All of the IOM recommendations applicable to VA have either been in place or were in the process of being implemented prior to the release of the report. While VA has had quality and safety related activities ongoing for many years, it was in 1997 that our formal patient safety program was launched. Leaders in the field of patient safety and medical error outside VA have participated in the design of our system and recognize VA as a pioneer in these efforts.

During 1997, VA intensified its already extensive efforts in quality improvement by launching a major initiative on patient safety. We recognized that programs to improve quality and safety in healthcare often share purpose and corrective actions. However, we believed that patient safety required a new and different approach. We set out to create a new culture of safety in which our employees detect and tell us about unsafe situations and systems as part of their daily work. Once we know about unsafe situations and systems, we are committed to design and implement new systems and processes that diminish the chance of error.

HIGHLIGHTS OF PATIENT SAFETY ACTIVITIES AT VA: 1997-PRESENT

The VA recognized that patient safety is not a VA-specific issue, therefore we asked other health care organizations to join us in an effort to understand the issues and to act for patient safety. As a result, the National Patient Safety Partnership (NPSP), a public-private consortium of organizations with a shared interest and commitment to patient safety improvement, was formed in 1997. The charter members, in addition to VA, included the American Medical Association, the American Hospital Association, the American Nursing Nurses Association, the Joint Commission on Accreditation of Healthcare Organizations, the American Association of American Medical Colleges, the Institute for Healthcare Improvement, and the National Patient Safety Foundation at the AMA. Five additional organizations have subsequently joined the charter members in the Partnership: the Department of Defense—Health Affairs, National Institute for Occupational Safety and Health, the Food and Drug Administration, Agency for Healthcare Quality and Research, and the Health Care Financing Administration. This group addresses high impact issues that are of importance to a broad cross section of the healthcare field in a cross-cutting wayindustry. An example of the Partnership's activity was the establishment of a clearinghouse for information related to the effect of Y2K computer issues on medical devices medically related issues. The NPSP also called public and industry attention to Preventable Adverse Drug Events and promulgated simple actions that patients, providers, purchasers and organizations could take to minimize their

chance of an adverse drug event. The partnership serves as a model of what a private-public collaboration can do to improve patient safety.

In 1998, VA created the National Center for Patient Safety (NCPS) to lead and integrate the patient safety efforts for VA. As the IOM report advises, VA created this center as a commitment to patient safety as a corporate priority with a direct reporting relationship to the Under Secretary for Health. The NCPS employs human factors engineering and safety system approaches in its activities. The first task for the Center was to devise systems to capture, analyze and fix weaknesses in our systems that affect patient safety.

We sought to design reporting systems that would identify adverse events that might be preventable now or in the future. In addition, we sought systems to identify and analyze situations or events that would have resulted in an adverse event if not for either luck or the quick action of a healthcare provider—we call such events "close calls." We believe that "close calls" provide the best opportunity to learn and institute preventive strategies, as they will unmask most system weaknesses before a patient is injured and avoid the liability issues implicit in investigation of injury. This emphasis on "close calls" has been employed by organizations outside of healthcare with great success.

VA consulted with experts (Expert Advisory Panel for Patient Safety System Design) obtaining advice to enhance the design of VA's reporting systems. These experts in the safety field included Dr. Charles Billings, one of the founders of the Aviation Safety Reporting System, as well as other experts from NASA and the academic community. They advised us that an ideal reporting system (a) must be nonpunitive, voluntary, confidential and de-identified; (b) must make extensive use of narratives; (c) should have interdisciplinary review teams; and (d) most importantly, must focus on identifying vulnerabilities rather than attempting to define rates of error. VA has used these principles to design the patient safety reporting systems we have in use or in development.

Based on the expert advice and on lessons learned from our first generation mandatory adverse event reporting, the NCPS has developed a comprehensive adverse event, close call analysis and corrective action program which includes an end-to-end handling of event reports. This system not only allows for the determination of the root causes, but also captures the corrective actions as well as the concurrence and support of local management for implementation. The system includes a number of innovations such as algorithms and computer aided analysis to determine the root cause of adverse events and close calls. The Joint Commission on Accreditation of Healthcare Organizations and the American Hospital Association are currently evaluating parts of the system for use.

The improved event reporting system is being pilot tested in VA's VISN 8. Extensive training is used as the new system is introduced to assure full understanding of the search for the root cause and redesign of the system. To date, response from the pilot site is positive. The quality managers and clinicians using the system believe that the new methods analysis of error will make a significant difference in the care of veterans.

A complementary, de-identified voluntary reporting system is in the process of being implemented. It is patterned after the highly successful Aviation Reporting System that NASA operates on behalf of the FAA. It will be external to VA and will allow employees and patients to report unsafe occurrences without fear of administrative or other action being taken against them.

Based on lessons learned, VA has promulgated specific procedures and policies aimed at reducing risk of error. These include such things as restricting access to concentrated potassium chloride on patient care units, use of barcode technology for patient identification and blood transfusions in operating rooms, and for verification procedures prior to injection of radio-labeled blood products. Based on the observation of a VA nurse when she returned a rental car, VA developed a system for using wireless bar coding to improve medication administration. That system was piloted at the Topeka VA Medical Center and will be in all VA hospitals by June of this year. At least two-thirds of medication errors can be prevented with this system.

In 1999, VA established four Patient Safety Centers of Inquiry. These Centers conduct research on critical patient safety challenges. Activities at the Centers of Inquiry range from fall prevention and operating room simulators to understanding the role of poor communication in patient safety. The Center in Palo Alto, which is affiliated with Stanford University, is a recognized leader in the area of simulation and has been featured prominently in the media. Their simulated operating room allows surgeons and anesthesiologists to train and do research without endangering a patient. VA expects to create additional simulation facilities to train its physicians and other healthcare professionals. One simulator with appropriate staff could train about 600 anesthesiologists and residents-in-training per year. This

means that virtually all VA anesthesiologists/anesthetists can be trained in a year on clinical situations that could not be simulated safely in patients. As a result of analyzing common variations during simulated operations, the center has developed a checklist card of facts that should be kept close at hand. These checklist cards will be attached to all anesthesia machines across VA.

VA is partnering with the Institute for Healthcare Improvement to build learning collaboratives aimed at reducing medication errors, a major issue identified in the Institute of Medicine report. IHI collaboratives will affect several hundred VHA personnel each year. Other IHI collaboratives have resulted in measurable improvements and similar results are anticipated with medication errors.

Another key VA strategy to reduce medical errors involves the development of a new curriculum on safety. VA is moving forward with plans to provide education and training relevant to patient safety not only to those already in practice but also at the medical, nursing, and health professional school level. This will be the first time an extensive safety curriculum will be developed and broadly implemented. VA is particularly well situated to lead the educational effort due to the extensive role it plays in the education of healthcare professionals in the United States. (VA is affiliated with 105 medical schools and up to one-half of all physicians train in a VA facility during medical school or residency.) Additionally, we have instituted a performance goal and measure to provide VA employees 20 hours of training on patient safety this year.

VA instituted a Patient Safety Improvement Awards Program to focus interest on and reward innovations in identifying and fixing system weaknesses. Not only does this produce ideas for patient safety improvements that might otherwise go unnoticed but it further reinforces the importance that VA places on patient safety activities.

In 1995, VA instituted a Performance Measurement System that uses objective measures of patient outcomes to set goals and reward achievement. Since 1998, VA has incorporated a performance goal and measure for its executives for accomplishment in patient safety activities. Last year, each network had to implement three patient safety initiatives to be fully successful and six initiatives to be outstanding.

Other performance goals and measures assess the use of Clinical Practice Guidelines. By holding entire medical centers and geographic networks responsible for measured outcomes, we are able to institute reminder systems and redundancies that lead to dramatic improvements in performance. For example, patients who receive medications known as "beta-blockers" following a heart attack are 43 percent less likely to die in the subsequent two years and are rehospitalized for heart ailments 22 percent less often. A goal of providing this therapy to 80 percent of eligible patients has been set in the private sector, and recent medical literature reports rates of use as low as only 21 percent in some settings. In the VA, over 94 percent of heart-attack patients receive this life-saving medication.

Another example of the power of using systems rather than relying on individual adherence to clinical guidelines is in immunization. It is estimated that 50 percent of elderly Americans and other high-risk individuals have not received the pneumococcal pneumonia vaccine despite its demonstrated ability to minimize death and hospitalization. VA's emphasis on preventive healthcare has led to achieving pneumonia vaccination rates that exceed standards set for HMOs by almost 20 percent and nearly double published community rates. Similar accomplishments have been achieved in providing annual influenza vaccinations.

We believe that patient safety can only be achieved by working towards a "culture of safety." Patient safety improvement requires a new mindset that recognizes that real solutions require an understanding of the "hidden" opportunities behind the more obvious errors. Unfortunately, systems' thinking is not historically rooted in medicine. On the contrary, the field of medicine has typically ascribed errors to individuals and embraced the name-blame-shame-and-train approach to error reduction. Such an approach by its very nature forecloses the opportunity to find systems solutions to problems. Other industries such as aviation have recognized the failings of this approach and over many years have succeeded in transitioning from a similar blame and faultfinding approach to a system-based approach that seeks the root causes of errors. VA realized how pivotal culture is to improving safety and in 1998, conducted a culture survey of a sample of employees. Of interest, the shame of making an error was a more powerful inhibitor of reporting than was fear of punishment. Employees readily forgave mistakes in others but were intolerant of their own. We plan to survey culture broadly in VA for several years to track the progress of our efforts.

VA created a database of adverse events and asked our Medical Inspector to review it. The report has been widely, yet often inaccurately, quoted or critiqued in the media. The database was created to discover common and important adverse

events in order to focus our efforts in patient system redesign. Commonly, the media assumed that all the adverse events (and deaths) were due to error. They were not. Neither the report nor the database cataloged which adverse events were preventable with today's state of knowledge and therefore could be characterized as errors. For example, most of the adverse events were falls, suicides and parasuicidal events (attempted suicides, suicide gestures), or medication errors. It is not possible with today's knowledge to operate a national system of nursing homes and acute-care hospitals treating the elderly and chronically ill without a number of falls. Yet, we know that it is important to look for common factors to allow us to reduce the frequency of falls in the future. Similarly, psychiatrists have tried unsuccessfully to predict which patients will commit suicide. By looking at our data we hope to be able to predict high-risk patients in the future and therefore be able to prevent suicides. We have already learned that men with a recent diagnosis of cancer, who live alone and who own a gun, are more likely to commit suicide. We hope to study the use of additional interventions in this subgroup of patients at high risk of suicide.

CONCLUSION

With no successful models in large healthcare systems to guide us, VA turned to other high risk, high performance industries to learn principles for safety. We have borrowed both methods and people from safety-conscious settings such as aviation and space travel and from underutilized disciplines like human factors engineering. These efforts have already produced significant improvements in VA, and we believe will do the same in all healthcare settings.

We would prefer that all of healthcare had begun to address the issue of patient safety long ago. For too long, the emphasis has been on holding individuals accountable and hoping that well-intended and well-educated professionals wouldn't make human mistakes. As the IOM aptly states in the title of its report: "To err is human." We are pleased to be on the leading edge as healthcare takes a systems approach to patient safety. We are anxious to discover new ways to make VA and all healthcare safer. We appreciate your support of these efforts and intend to keep you fully informed of our progress.

Senator SPECTER. Dr. Bagian, Dr. Garthwaite has pretty much made my introduction of you unnecessary, but that will not stop me from doing it. You are the Director of the Veterans Health Administration's National Center for Patient Safety, a Diplomate of the American Board of Preventive Medicine with a specialty in aerospace medicine. And you chair the VA Expert Advisory Panel on Patient Safety System Design. You were a NASA astronaut for over 15 years. You have extensive experience in aviation-related safety programs.

You have a very impressive background, Dr. Bagian. We look forward to your testimony.

Dr. BAGIAN. Thank you, Mr. Chairman. It is a honor to be here today to have the chance to speak with everyone here.

As Dr. Garthwaite said, the VA has, for quite some time, taken a very proactive role at looking at patient safety and errors and their role. I could not agree more with many of the things that were said by the previous panel about the IOM report. We in fact feel like we have either done or have in the process of implementation virtually everything that is applicable in that report, and we could not applaud it more.

I thought I would go over some of the high points of what we are doing right now and maybe some of the rationale. And then, if you have questions, certainly we would answer them.

The way I first became involved with the VA and doing this was chairing the Expert Advisory Panel on Patient Safety System Design you mentioned. And with my background, I have often recognized that medicine did not necessarily take advantage—not just the VA, medicine in general—with many of the systems designs for safety that occur in other industries, both in the industrial world

as well as aviation and space flight, where quite a bit has been done. And you have already heard about the aviation safety reporting system.

Our job when we first were tasked was to come and look at, how will we construct reporting systems to really learn what is going on? And one of the primary things there is what barriers might exist there. Because you cannot really begin—and it is not reporting, I should say, in itself. Reporting is kind of worthless if you do not do something about it.

If it just goes into a black bureaucratic hole, where people fill out reports and they do not see the benefit of what they have reported in their system, they see improvements made, changes being made, feedback that it has even been read, people do not want to continue to report. And it is not just to have a requirement. People want for things to be better. They want to have an effect. But when they feel like it is fruitless, they tend to be discouraged and you do not really glean the best that you can from your folks.

When they talk about high performance organizations in the organizational psychology world and when they talk about industries, they talk about mainly space flight and aviation which are two of the ones that standout. They do not talk about medicine. They talk about industries. We are not talking about individual companies. These are the ones that do it well. And they talk about how people feel free to talk about the unthinkable, the things that people would be embarrassed about. And they try to remove that.

So we had a panel. And Dr. Charles Billings, who you heard mentioned before, who is basically the architect or one of the fathers of the aviation safety reporting system, was on that panel, as were others, from NASA and from other institutions. And we asked them to identify, what are the characteristics of a reporting system that makes it successful? And in aviation, up until about the mid-seventies, there was not a lot of reporting. When a report was made, basically it was responded to by fine, suspension, things like that. So many things did not get reported.

When they put what is called a de-identified system in place, where you do not identify the individual reporter but it is used for systems-level stuff, as Dr. Leape mentioned, they have over 33,000 reports a year, that have been going on for close to 25 or 30 years now. And it is because the individuals do not worry about individual punishment. They think that they can actually report something that they have concern about.

Now, in that particular program, it is only open to close calls, essentially, not actual accidents. That was because of the situation that evolved at the time. It was not because they would not like to look at everything.

In our system, we have a mandatory system that you have heard briefly about and we have a voluntary component as well. And we think mandatory is important. And you have to look at what you are using it for. Is it for accountability or improvement? And we realize both are important, very important. You cannot ignore one versus the other.

In our mandatory system, we look at it. And if we see that an act is even thought to be what we call an intentional unsafe act—and in our handbook you can read the definition if you would like,

but it basically is those things that appear to be intentionally unsafe—not proven beyond a shadow of a doubt. If on first review it appears it was a deliberate, unsafe act, if it was a criminal act, if it was an act that involves substance abuse, alcohol abuse on the part of the care-giver or if there was alleged patient abuse, those are not covered in our safety system. They go in our administrative system where they are thoroughly investigated, so that if punishment is required or other administrative action can be taken. However, if it does not meet that hurdle—and most do not—they are on the other side. And that is where we look for the true systems issue, where we try to correct the systems. But it is not about who did what.

And if you go in the aviation world in an accident investigation, for example, the first words out of somebody's mouth are not: Whose fault is it? And I kiddingly call it the "f" word. We do not use the "fault" word. That is not how you start. Because if you begin the investigation by saying, Whose fault is it, you tend to look for whose fault it is and you miss the richness of what else went on—the long chain of events that you heard Dr. Leape refer to a few moments ago.

But if we look at systems, you may find individuals. And if we do at any time, we can throw it back over that way. We worked with our Office of Medical Inspector, the Office of Health Inspection, unions, everyone else. And everyone thought that was a very fair and equitable way to do it, to really give us both pieces. But it is not enough just to have a voluntary system, because that gives you large systems-level things. But also the mandatory does that. But you want voluntary, because, as we found, the culture is very important.

And you have heard that referred to in some ways. And it is really the essence of the organization. You can have a number of rules and procedures, which are all very important and we would not want to minimize their importance, but it is important that the people want to do the right thing and feel that it is safe, as you heard Dr. Leape mention, safe that they feel that they can do it.

We did cultural surveys and published them. And one of the first ones published in the Annenberg proceedings, the safety meeting in 1998. And we found, for instance, that they talk about the punitive aspect. Punitive is not strictly that you will be fired or suspended or anything like that. It is also embarrassment, shame. We found that about half the people—and this is not just within the VA—half the people feel that if they make a mistake that they are ashamed.

Yet only 4 percent say that they would hold it against someone else if they make an innocent error. So it says we have a long way to go. Because it is the shame and the embarrassment that really stands in our way.

So we have put both systems in place. We have put in a voluntary system in place because it has been shown—and that was in the news in the last couple of weeks, when you heard there was a statement by the President about trying to change the way aviation safety systems are going to report. That was not talking about the ASRS, that was talking about another system that was identified, but how to take the punishment out because you get different

messages from both. And if you only have a mandatory system, you will get information that is good. But if you do not have the voluntary, you will miss some. So that one cannot operate absent the other. They both are complementary.

And one final thing is in these systems, it is not about the numbers. Because you are never really sure of the denominator. It is about identifying the vulnerabilities of your system. Because once you identify a vulnerability, you do not have to say, are there a thousand cases of this? Once you see one that is wrong, that you think is wrong, you correct it.

I will give an example of potassium chloride that you may have heard, where patients may have inadvertently had it injected—not just in the VA, but anywhere. It is a problem that is known. And the VA went out, over a year ago, and we said, we recognize that it is a problem. We did not say we have to do some study about what percentage got it.

We said, this is a systems problem. Take it off the floor and put it in the pharmacy so this cannot occur. Make it easier for people to do the right thing and not that they have to remember to be careful. That is a bad system. So we have changed that and we think that is the essence of reporting, to identify vulnerabilities, so we can then actually take actions. And that is what we hope to do.

Senator SPECTER. Thank you very much, Dr. Bagian and Dr. Garthwaite.

Dr. Bagian, you talk about de-identifying on near misses, where that encourages the party to come forward and say what has happened. But you reject that for actual mistakes. Why do you reject it for actual mistakes?

My instinct is to be in favor of identification. But when you make the point that the de-identifying stimulates reporting because nobody knows who did it, then the question arises in my mind as to whether it might be better to have all this information to improve the system than to be able to identify the person who made a mistake. So why not carry the de-identification system beyond near misses to actual mistakes?

Dr. BAGIAN. Thank you for that question. I need to clarify what I said. Actually, the system we have is slightly different than the IOM's, where they take the actual sentinel event, which is the serious injury, permanent injury, death, versus the near misses, close calls. We say both our mandatory system and our voluntary system take all comers, that we do not just segregate and say, oh, if it is a close call, it is less important.

In fact, it has been shown I think in many places that close calls are often the best way to learn about things, to prevent things. The whole point is prevention. And we often say that experience is the best teacher, but it is also the most expensive. If we can learn in a way that did not require an injury, but we knew one could have occurred, we then foreclose the possibility of one.

In our system, we look at both. So what happens is, in the mandatory side, we do have the identification. We have a system where we know who reported what.

Senator SPECTER. Well, the question is, why not have the identification? Because you might get more information if you did not identify even where there have been the serious errors.

Dr. BAGIAN. Yes, we have, too. We have a de-identified system that is being planned and which is not fully rolled out yet, the voluntary system, which is de-identified. We have the mandatory system which is. And we realize that there are some, you are right, that may be deterred from reporting. And I certainly expect that we will not get a report of everything that goes on, for a number of reasons. But we think you have to have both.

The identified system lets you focus very specifically on that particular area and understand it in great depth. The de-identified voluntary system gives you other information which you may learn things from. And FAA can give you numerous examples where, in their identified system, they have learned certain things, but in the de-identified, their voluntary ASRS system, they learn other things. And they are complementary. And one does not repudiate the other, but they reinforce each other.

Senator SPECTER. They might learn more if they had all de-identified.

Dr. BAGIAN. Well, I will give you an example. Suppose you knew in a de-identified system that—we will take one outside of medicine—but suppose you knew that there was a system at the high school where your children go to school, and they said, we know that 55 percent of high school juniors are drinking after school. We do not know if it was your high school junior, but we know 55 percent. You go back and you look at your kids and you go—if you do not like them drinking after school; I would not—and you try to figure out, well, is it them or not and what do you do? You are not sure exactly the corrective action or if one is even needed for your child.

On the other hand, if you know that your child did that, you would do something different. You might say, hey, Brian, I know you have been using some of what I think is questionable judgment. Let us talk about this and let us deal with this.

On the one hand, you might miss the opportunity to improve something or try to put pressure on somebody to behave in a different way which is inappropriate. So one focuses your attention and allows you to do certain things, but because of the bright spotlight they may not be reported in all cases. On the other hand, the other one gives you the chance to see those ones that nobody wants a spotlight on, but they kind of would like the thing to be handled generically. And you can learn from both.

That does not mean it does not also cause you to look, even from the de-identified, to look more closely at the particular individuals that you even wonder, are we prone to vulnerability in an area, and then you can further, in a prospective manner, inspect those. So it identifies vulnerabilities, which is the real key.

Senator SPECTER. Well, these considerations call into question the basic philosophy of where the best public policy lies. Dr. Coye testified that the malpractice system helps only minimally. There are many people who believe that, and perhaps most of them are doctors and hospital officials who believe that.

As a practicing lawyer who has been on both sides of the plaintiffs and defense work—happily not too much because I was successful in getting out of the practice of law—and for a long time chose to be a prosecuting attorney as opposed to being in private

practice—but in the experience I have had, as I say, both representing plaintiffs and defendants in personal injury cases, has persuaded me that the system is a deterrent. That when there are major errors disclosed on manufacturers of a variety of products, they change the way they do it. They do not want to be hit with big liability verdicts.

It may be that however big the verdicts are they are minuscule compared to the corporate profits. And that brings in the big argument about punitive damages which rages in these halls all the time.

And on medical malpractice, my sense has been that the awards do focus the attention of the doctors and the hospitals on the problems and that it does have therapeutic effect, it is a deterrent, there is a real value in it. But when we start to talk about turning the system upside-down, so to speak, and trying to correct the big problems on systems changes—so if you had a lot of reporting, you might be able to have better public policy at the end of the rainbow—it still does not take care of the individual who was injured and how you compensate that individual for the loss that individual has suffered.

And in the medical malpractice field, catastrophic injuries occur all the time. So that it is a matter of millions of dollars to provide for somebody who has been injured that way for the balance to compensate their injuries. But that is why I push on the de-identification issue which you talk about.

Dr. GARTHWAITE. Mr. Chairman, if I might. As we look at it internally, we keep it identified under a quality assurance protections. But then there is a point at which we attempt to de-identify it and share it broadly. We have a Web page that has every small and large lesson we have learned locally. And then we have a committee that reviews those and decides which things are absolutely system issues versus local issues and need to be implemented in the system.

So as we attempt to communicate the things that we learn broadly, we do not feel it is about punishing a person who had the honesty to bring it forward. It is really about what is the issue and how do we fix it. And so I think that is a key piece.

Senator SPECTER. Let me ask you a specific question related to that. In the context of VA self-reporting of medical errors, it is my understanding that VA hospital names are not revealed. Which leads to the question as to why not, if the VA patients should know that a particular hospital had reported errors? This goes to Dr. Bagian's point about which school has the high school drinking. Parents would like to know that.

Dr. BAGIAN. Just to clarify the way it works. It is complex, but not that complex.

Senator SPECTER. Try us. We might understand it.

Dr. BAGIAN. Absolutely, Mr. Chairman, I know you will. The way it works in the mandatory system, and let us just talk about that. When it is reported, it has the institution's name on it. There is an identifier. So if we need to go back and get more information, we know who the people involved are. That is the people, and I mean people from practitioners, care-givers.

Senator SPECTER. We identify the VA hospital?

Dr. BAGIAN. Internally, absolutely, yes, sir.

Senator SPECTER. No, but for the patients?

Dr. BAGIAN. Yes, for the individual patients, as Dr. Garthwaite said, it is our policy and requirement that if a patient is injured through a medical error or in any way, suffers untoward effects, we will do that.

Senator SPECTER. But suppose somebody is not injured, if you have a very bad result at the Veterans Hospital in Tuscaloosa—which is outside of Pennsylvania so I can speak freely—should the veterans who are going to Tuscaloosa know that there are a lot of errors so they can choose to go somewhere else?

Dr. BAGIAN. On the safety side, we do not post the errors that way.

Senator SPECTER. Why not?

Dr. BAGIAN. There are several reasons. One is that unless you get down to the point where you risk—we risk adjust for errors. And I will give you an example. One of the things I know—I have talked to Dr. Leape about this earlier—is one of the things people think for mandatory reporting, you know, you might pick certain types of things, like say maternal death during labor, or whatever you might want to report, and if you looked at something like that and you just looked at the box score, like how many deaths occurred in Tuscaloosa, if that is the one you want to use as the illustration, and they just give you a number—and we had four in the last year—is four a lot? Is four too many?

If Tuscaloosa was the regional high-risk maternity care place, you might expect there might be more deaths because the acuity, the severity of the illness with those people is much higher. Whereas the ambulatory care clinic down the street does not really see women in labor. And they would say, oh, we have not had any. Would that mean you should go there?

Senator SPECTER. Wait a minute. You are saying you are not going to tell which hospital it is because there may be extenuating circumstances?

Dr. BAGIAN. Well, we think that there are two things. In the safety—and we tried to draw this thing about the intentionally unsafe act versus not—in order to build trust in the system—and trust is really paramount for people being willing to come forward to address the problems—safety has to be looked at that it is looking for systems changes. To publicly say, from the safety—I am telling the safety side; Dr. Garthwaite can talk about the VA in total—but from the safety side, we felt it was very important that we not be looked at as we are the stick.

If it is looked at like that, on the one hand, they do not know—it is like they are flipping a coin—and we report this——

Senator SPECTER. OK. So you keep it confidential to get better reporting you suppose is a higher value than letting them know for the prospective patients?

Dr. BAGIAN. We think so for big systems, yes, sir.

Senator SPECTER. Let me move on to a couple of other questions which I want to cover here, because we are running very late. And these are very important and complex subjects.

Dr. Garthwaite, you identify the specific language—and we are going to be tracking that with other organizations—which has a mandate that the errors be reported. Would you repeat that?

Dr. GARTHWAITE. What I read?

Senator SPECTER. Yes, read that to us again, please.

Dr. GARTHWAITE. We have a whole chapter.

Senator SPECTER. Do not read the whole chapter.

Dr. GARTHWAITE. So networks will ensure that their facilities have a process in place to promptly inform patients and their families about pertinent clinical facts associated with injuries resulting from adverse events, assuring them that measures have been taken to maintain life and minimize disability and discomfort.

Senator SPECTER. Adverse events being defined as hospital or doctor errors?

Dr. GARTHWAITE. And beyond.

Senator SPECTER. Dr. Garthwaite, do you think there is any greater response for doctors and hospitals to report their errors because they are not liable to suit because of the Federal Tort Claims Act and the individual doctor and the hospital and the Federal Government is not liable? You have a very different system of liability for confessing error.

Dr. GARTHWAITE. Yes, I think we do. And we enjoy a greater degree of public scrutiny, which is appropriate for a federally funded health care system.

Senator SPECTER. Public scrutiny?

Dr. GARTHWAITE. I mean in terms of oversight that we have.

Senator SPECTER. Oversight by the Veterans Affairs Committee? Piercing oversight by the congressional committees?

Dr. GARTHWAITE. One of our goals is to be an organization characterized by exceptional accountability. And we have not shied away from that. I think that is why we have a patient safety system.

Yes, there is a difference. You can sue the United States Government. We do report individuals for their role when payments are made. Not all the time, but about half the time, after a peer review panel looks for their contribution. There is a disincentive for us, I think, to admit publicly when bad things happen, just as there is in the private sector. We are trying extremely hard to improve the image of the VA health care system in terms of quality.

Senator SPECTER. Dr. Bagian, let me ask you one final question. Yesterday's New York Times reports your saying, quote: There needs to be some level of national reporting. But to allow disclosure of hospital names and practitioner names would be counterproductive. It would inhibit reporting and drive the problems further underground.

First, were you accurately quoted?

Dr. BAGIAN. I think that is the general gist. They were not using a recorder at the time, but I think it is reasonably accurate. Contextually, I think that is true.

Senator SPECTER. Are you not saying there that you are against mandatory reporting of errors, identifying the specific hospital and practitioner?

Dr. BAGIAN. No. What I said was I think we have to have our eyes open and that it can have a chilling effect. You have to decide,

is the need for people to know worth maybe the unintended side effect that you drive things underground and therefore do not learn? We can look at other systems. In aviation that was the case and they learned very little.

Senator SPECTER. You say it is counterproductive. Overall, do the advantages outweigh the disadvantages in your mind?

Dr. BAGIAN. The advantages of?

Senator SPECTER. Of reporting specific hospital errors and practitioner errors.

Dr. BAGIAN. Yes, sir. If our goal is to increase patient welfare and minimize injuries due to error, I think if we create fear in people, they are going to be less candid about coming forward. That is human nature. And I think there is ample evidence in reporting systems in this country and others, especially in aviation, that would show that to be true.

Senator SPECTER. So are you in favor of reporting?

Dr. BAGIAN. I am in favor of reporting, yes, sir.

Senator SPECTER. With specific names of the practitioners and the hospitals?

Dr. BAGIAN. In the case where it was not what we would call an intentionally unsafe act, we would think that that is counterproductive. I will speak for myself.

Senator SPECTER. Well, the rabbit is in the hat. If you call it an intentionally unsafe act, that is subject to generous interpretation by the doctor.

Dr. BAGIAN. Well, it is not the doctor that makes the judgments.

Senator SPECTER. Oh, yes, it is, if there is a report. The doctor either reports or does not.

Dr. BAGIAN. But other people also report things. When a report is reported, there are very complex issues that many people are involved in. It is not just the reporter that is involved.

Senator SPECTER. But others do not have access to the same knowledge that the person who makes the mistake does. The language which Dr. Garthwaite read imposes an obligation on the doctor to tell a patient where there has been something that has been wrong.

Dr. BAGIAN. That is true. Yes.

Senator SPECTER. So that is in variance with your quoted statement that it is counterproductive to disclose the names of hospitals and practitioners.

Dr. BAGIAN. The point there was that if you disclose those things—it is not saying that one may not, but it is saying you have to have your eyes open. That if the goal is to try to have greater candor so we can understand what is going on, to change it, we might have a chilling effect. And I think that has been shown in other places. And it was just a statement of opinion borne out by other experience with similar reporting systems.

That when you make it where it becomes public embarrassment—as was pointed out, it is not the fact of saying that we would write some legislation that says you could not be liable for tort or whatever else. It is actually the whole shame issue, which probably weighs at least as large overall as anything. And public ridicule is not necessarily a strong inducement.

Going back to what you said before, sir, I think you are exactly right—the issue about tort and liability as far as motivation, there certainly is some motivation there. But I think there is also information that would argue that, besides the motivating factor, that people practice in some cases defensive medicine——

Senator SPECTER. I would like you to supplement your oral testimony with a memo to the committee on your ultimate conclusion, whether you do or do not favor disclosure of hospital names and practitioner names or not.

Dr. BAGIAN. I would be happy to do that.

Senator SPECTER. Because I do not think the record is clear on this point.

Dr. BAGIAN. I would be happy to do that.

[The information follows:]

At the hearing of the Senate Committee on Veterans Affairs and the Committee on Appropriations, Subcommittee on Labor, Health and Human Services, and Education on January 25, 2000, the question posed was whether I thought that the public "disclosure of hospital and individual practitioner names in conjunction with some form of national reporting would be counterproductive." Specifically, did I think that such action would tend to "drive problems further underground." I appreciate the opportunity to provide further information in this regard.

If the purpose of the reporting that is contemplated is to provide knowledge that can be used to improve systems design and prevent future errors and injuries; then I believe that public disclosure of identities related to errors that were not of a malicious or intentionally unsafe nature is counterproductive. I say this because public disclosure does little to improve the systems level type issues and will appear and be perceived as punitive on some level. The punitive atmosphere that this would create would be in line with the traditional "train and blame" approach that has been the standard operating procedure in medicine for too long and has given us the system that we are currently trying to change.

Studies that have been done about safety culture in medicine have indicated that fear of shame plays a substantial role in people's reticence to report. The experience of the aviation industry has indicated that protection of individual and corporate identities has been vital to the success of their programs, most notably the Aviation Safety Reporting System (ASRS). A real world example exists where another country tried to emulate the ASRS system and inadvertently divulged the identity of one of the reporters. The result was that the system ceased to function and was disbanded due to lack of participation for years.

Therefore, if the purpose of national reporting is to gather information for improvement, we should not publicly disclose identities. On the other hand, if the purpose is to mete out some sort of punishment then disclosure will facilitate that. It must be recognized that such disclosure will probably result in the drying up of most meaningful reporting.

I appreciated your questions on the day of the hearing as inquiries to fully understand the issues and I offer this in the spirit of conveying that the options available are about more than whether reporting is mandatory or voluntary. If there is any other information that you or your staff desire, please do not hesitate to contact me. This is a vitally important issue and I am happy to assist in whatever way is useful.

Senator SPECTER. One final question for you, Dr. Garthwaite. The medical inspector's report was dated June 15, 1999, but the committee was not notified of it or provided copies until December 13th, which was the same date that U.S. News & World Report published a story of its report in its edition dated the 13th. So it must have been out before the 13th. Why did the committee get such late notice?

Dr. GARTHWAITE. I do not know. We will examine that and tighten up our distribution.

[The information follows:]

Medical Inspector reports have been routinely treated like the internal working documents that they are. They are used to fix local and/or systemic issues in the

delivery of care. We have not routinely distributed them to our oversight committees. We have supplied them when requested and the Medical Inspector routinely meets with SVAC and HVAC staff. The Medical Inspector's report, entitled "Special Report, VA Patient Safety Event Registry: First Nineteen Months of Reported Cases, Summary and Analyses, June 1997 through December 1998," was issued on July 15, 1999. Copies of the report were distributed to the Office of the Under Secretary for Health at that time. In August and September 1999, copies of the report were sent to each facility and Veterans Integrated Service Network (VISN) in the VHA system. The Medical Inspector presented the report at VHA's monthly Quality Management Integration Council meeting on September 1, 1999.

At an October 27, 1999 meeting with Senate Veterans Affairs Committee staff, the Medical Inspector mentioned the report. At that meeting, it was agreed that staff from both the Senate and House Veterans Affairs Committees should be briefed on the contents of the report. The Medical Inspector's briefing for the two Committees took place on December 13, 1999. 1 am sorry that this briefing did not occur sooner.

Senator SPECTER. Were you aware that the committee got notice after the fact?

Dr. GARTHWAITE. No, I was not aware of that. I apologize for that.

Senator SPECTER. Well, I think you are moving in the right direction. It is not without its complications and difficulties. And these are issues we are going to be wrestling with for some time. But I am glad to see the VA moving ahead.

We fought very hard to get the extra money last year. We finally succeeded. But it was a hell of a battle.

Dr. Garthwaite and Dr. Bagian, if you would wait around until after the hearing, I want to have a private word or two with you on another subject.

Dr. GARTHWAITE. I would be happy to.

Dr. BAGIAN. Yes, sir.

STATEMENT OF JOSEPH DONAHEY, CIRCUIT COURT JUDGE, PASCO COUNTY, FL

Senator SPECTER. Our third panel is Judge Joseph Donahey and Dr. Ralph Specken. Judge Donahey is a Circuit Court Judge for the Sixth Judicial Circuit in Florida since 1995. He is a former criminal defense attorney. He spent 38 years in the justice system as a lawyer and judge. He is a member of the Florida, American and Federal Bar Associations. The introduction says: Although a true Floridian, Judge Donahey was born in State College, Pennsylvania, where his father started a strip coal mining business.

Judge Donahey, I think that this is undue editorial license for my staff to call you a true Floridian, when I would say you are a true Pennsylvanian. The place of birth governs. You can dissent from that, but that may be the official committee view.

Judge DONAHEY. Senator, I bleed blue and white when Penn State plays.

Senator SPECTER. I am glad you made my point so effectively.

Would you introduce the beautiful woman to your left? And I am looking forward to your testimony.

Judge DONAHEY. Yes, sir, this is my wife Tina, who is in fact a true Floridian.

Senator SPECTER. Okay, 50/50. That is not too bad.

Thank you very much for joining us, Judge, and we look forward to your testimony.

Judge DONAHEY. Thank you, sir. Very simply, or as simply as I can make it. On January the 11th, 1999, I was fully sighted. I went in as a patient to Tampa General Hospital for lower back surgery. I had disks virtually gone between L–2–3, 3–4, 4–5, L–5 and S–1. It was major surgery. I had done quite a bit of time checking out, trying to find out where to go.

I had been referred by one of my former law partner's husband, who was a physician in Clearwater, to a neurosurgeon with a wonderful reputation, who refused to touch me, referred me to another neurosurgeon at Tampa General Hospital with a reputation for having just magnificent hands and wonderful technique and who could solve my problem, if anybody could. I went to see him. I consulted with him. I was assured that he felt they could deal with the problem, that they could resolve it, and that I could get back to going back on the tennis court and doing things that I enjoyed doing physically, like chopping wood at my cabin in North Carolina, et cetera.

Very confident. I was very pleased. And I went into surgery again January the 11th, fully sighted. Ten hours, I came out blind. Never had I ever heard from anybody anywhere that loss of vision was a potential side effect or a potential result of such surgery.

In the informed consent that preceded the surgery I was told that I could die. I was told that I might end up a paraplegic. I was told that I might have drop-foot in my left leg or something like that. These things rarely occurred, but never, ever a mention of loss of vision.

I emphasize that because post-surgery I learned that in fact this physician had had this similar result three times prior to mine. One of those results was just within 30 to 40 days prior to my surgery. In fact, the day I consulted with him and he was giving me—predicting prospectively what was going to occur, I have since learned that he had a meeting with his last patient, who suffered an impairment of vision from surgery a month before.

Obviously, when the anesthesiologist and I came out of the anesthesia were saying, how many fingers do I have up, and I could not see fingers, it was quite an experience.

Several things that I think are important to what you are doing here today. No. 1, this doctor did not inform me that he had had these results in three cases before. And by the way, my loss of vision is bilateral, both eyes—his previous three cases were only loss of vision in one eye, which they seem to feel was far less significant. I was not told that they had had that result. I have since learned that risk management at Tampa General Hospital did not know that he had had these results.

Now, he is the lead neurosurgeon on that hospital staff, and yet risk management/quality assurance assures me that they have never heard of these results at their hospital before. And we know that that simply is not true.

Post-surgery I have learned some other interesting things. The first is that he did not perform my surgery. And I went to him because of the buildup and the recommendation and because of the assurances he gave me personally of how he developed the technique, of how he has trained other physicians around the country to do this rather unique surgery, but that he felt it could be done.

As it turns out, he did not do it. It was a resident who performed the surgery. He was supervising.

The interesting part of it is that he was not supervising just my surgery, but he was supervising surgery in an adjoining surgical suite. He was floating back and forth between the two.

In this type of surgery, with the length of the surgery—and by the way, he told me that the surgery would last from 5 to 6 hours. His physician's assistant told me that the surgery, the actual surgery, would only last about 4 and a half hours. The other hour or so that he talked about was with the anesthesia, preparation and coming out of the anesthesia. The surgery actually lasted 10 hours.

My suggestion would, or my suspicion would be, that the fact that he did not do it himself but had a resident do it and the fact that he was floating back and forth, supervising two suites, may well have lengthened the procedure. That is very important because my loss of vision is directly attributable to their failure to maintain the oxygen and red blood cell level during the course of the surgery, depriving my optic nerves of oxygen, resulting in the neuropathy and the loss of vision.

Were there warning signals? Yes, absolutely. We have now had this situation reviewed. Warning signals, there were big flags waving everywhere. I now know that when they initially administered the anesthesia that my blood pressure dropped dramatically. They did nothing. The anesthesia was not being administered by the anesthesiologist that I was told would be doing it, but by a resident.

So the anesthesiologist was floating back and forth between the same two surgical suites. It turns out that the resident surgeon and the resident anesthesiologist apparently did not know what to do. I do not know whether they were cowered by the fact that they had these sages that were supervising them, that they did not want to approach them, they did not want to tell them.

I do not know what caused them to not react as they should have, but they did not. And as a consequence, after I was strapped in, the blood pressure had recovered. When they flipped me over, the blood pressure dropped again. All during this time the red blood cell count—or when the surgery started, I started losing blood.

By the way, I had provided two pints of my own blood for them to give me the transfusions during the course of the surgery if it became necessary. I was assured that it would not, but if it became necessary. As it turned out, they did not give me the blood during the surgery even though the blood cell count went below acceptable levels. They did not give it to me until post-surgery, when they found out I was blind.

I sat here and I listened to this testimony about reporting and whether it should be reported and whether or not it should be identified. Let me assure you, Senator, I have had my wife in Rochester, Minnesota, at Mayo for surgery. I was seeking the best place to go to get my surgery done. It was complex. I knew that. It was difficult. I would not have hesitated for a moment to go to Rochester or to Duke or to a number of other places—all of which were available to me. I chose this doctor and this facility because of what I was told and, as it turns out, because of what I was not told.

And what I was not told was that this physician, this surgeon, had had three cases of vision impairment in the 18 months preceding my surgery.

Senator SPECTER. Well, Judge Donahey, thank you for sharing your experience with us. It was a very poignant and unfortunate story.

Before asking any questions, I just want to turn to Dr. Specken. But I would be interested to know what your status now is with respect to your eyesight.

Judge DONAHEY. I cannot see.

Senator SPECTER. You cannot see.

Judge DONAHEY. There is a bright light up here. And there is another one over here. I every now and then get just a bit of form of where you are. I think you are right there.

Senator SPECTER. Well, you appear to have eye contact, but that is deceptive from my view, not from yours.

Judge DONAHEY. I do that in the courtroom. I try to follow voices.

Senator SPECTER. What is the prognosis?

Judge DONAHEY. This is it.

STATEMENT OF RALPH SPECKEN, M.D., NEW YORK, NY

Senator SPECTER. Well, I have some questions for you, but first we are going to turn to Dr. Specken. He is a Consulting Psychiatrist for the New York City Human Resources Administration, Attending Psychiatrist at Hollisford Hospital. He is here to give us his own medical expertise, but also testify about his harrowing experience with losing his 23-year-old son because of an information breakdown within the medical system.

Thank you for joining us, Dr. Specken, and for what I understand was a harrowing drive down here, some 8 hours from New York City. We appreciate your being here. Would you introduce your companions?

Dr. SPECKEN. To my left, Ms. Pearl Korn. Pearl is known as one of the deans of the photojournalist community, doing some of the early work in Rumania and Northern Ireland. She was damaged by medical malpractice.

To my right is my life partner, Stephanie, the brains of the family. I am the mouth, so I will talk. I am very persuaded by this systems notion. In all seriousness, it is an honor to be in the same room as Dr. Leape. In the history of the 20th century, he is going to go down as one of the giants in medicine, really. So it is an honor to be here.

Thank you for your concern about our 8-hour drive down. But since I am persuaded by systems theory, I have to tell you something. I ran a couple of red lights getting over here. I did not do it intentionally. I did not want to do it, but it happened. I assume I will suffer no punishment for this, and I promise I will not do it again. If I do it, I will tell about it and we will try to work out a better system so that this sort of thing does not happen.

Senator SPECTER. You have not been sufficiently specific to identify jurisdiction or venue. Judge Donahey is going to counsel you.

Dr. SPECKEN. You will see that I am very well aware of this. I am not completely convinced of the indemnity, but I am trying to break new ground here. After all, with the 21st century and sys-

tems. But, with all seriousness, it is very important to very careful with that word, and not to abrogate personal responsibility to the world of the computer disk and whatnot.

It was almost 6 years ago today that Seth's mother walked into his bedroom where the chart from the hospital lay and figured out how he died. I am going to mention the name of the hospital, since it is the world's largest and wealthiest and most important in many ways—New York Presbyterian Hospital, then Columbia Presbyterian Hospital, in the City of New York.

Seth died essentially from an act of what should have been called second-degree homicide. It was not intentional, but the acts that were taken against him were such that the prudent physician would have known better. Stephanie's reading of the chart set upon a whole series of motions, set about a lawsuit, set about our Web site, which was known as medmalpractice.com. I will give Ms. Taylor a copy of that if she has the fortitude to read through it.

From that Web site, as far as I know, came the first analogy between medical error and the situation in the airline industry. We found, Stephanie and myself, that the risk of dying in an airplane is something like 1 and 1 million. The risk of dying from a cause unrelated to your illness in a hospital in New York is approximately 1 in 323. Few of us would get on airplanes gingerly if we faced that sort of risk, 1 in 323.

But, in any case, time has moved on. I am abbreviating this section of my talk, because it is not my main interest in speaking to you, Senator. But I wanted to fill you in on what has happened with the case. Shortly prior to trial, mysteriously, one of the lawyers resigned, thereby ending the trial. In a very Byzantine series of events, the chief lawyer coerced us into signing a general release, which incidentally put the lie to one of the hospital's charges against me.

And then a further series of Byzantine events—I took on the role of being a pro se lawyer and defeated the aim of the chief lawyer, who was actually one of the best litigators in New York, to have a guardian appointed over me, to enforce the settlement. And we have submitted a pro se motion to have this settlement vacated—not on the grounds of the money, but on the grounds of the fact that we have been forced into silence about what happened to Seth.

In all of this I have made great connections with folks around the country, such as Pearl. You should know, and probably do know, that there are groups developing around the country. You met with Ray McAetrin. Our group in New York City, founded by Irene Corrina, who has been on national television, is called Pulse of New York, is attempting to get mandatory disclosure of a physician's malpractice history. It is meeting great resistance in the State legislature.

Through all of this I have become a minor expert in medical malpractice law and, really, I can speak about it with some expertise. I can totally support Dr. Coye's perception. It is a very poor system. I do not want to use extreme, inflammatory words. It is a broken system. It is a system which must be replaced. The average medical malpractice victim in this country is impoverished, living on welfare, in great poverty. That is the average medical malpractice victim.

One out of seven cases, from Dr. Leape's work, come to the law. A minimum of those come to trial—oftentimes the wrong cases. It is a very bad system. And all of this is in preface to what I wanted to say today. And here is what I want to say.

It is very important that the members of the committee become aware of the fact that there are other countries that are well ahead of us in the study of this problem. Three specifically come to mind—Sweden, Germany, and New Zealand. And I am going to give some references to the staff that should be explored. The predominant thinker in this area was a German professor, now passed on, Dieter Deeson, who, in 1988, put together a compendium of comparative malpractice law around the world, which should inform the committee of other vistas in this area. It is very important for your future deliberations.

Because, as I say, our malpractice system essentially is broken and should be discarded. It benefits the insurance companies. It benefits the medical malpractice lawyers. To the victims, it presents a sort of casino environment, where a handful are rewarded handsomely, the bulk receive nothing, and even those that are rewarded oftentimes are coerced into silence.

So I would like to give a brief proposal in this whole area. Contrary to the National Academy—and, incidentally, as far as I know, I was the first one to propose this National Patient Safety Board on our Web site 3 years ago—but in any case, this National Patient Safety Board, in what I think should be the system of the future, must become a regulatory agency analogous to the National Transportation Safety Board. This agency should adopt systems that encourage accountability, regulation and strict enforcement. People are people. They are going to respond to these issues.

The current system of regulation is State-based, with various medical boards in the State. Ours is called the Office of Professional Medical Competency. Other States have medical boards. These are, as you will hear from the victim communities, very problematic organizations in many ways.

As one of our State board directors told me recently in the committee meeting, they are receiving literally thousands and thousands of complaints that they cannot field. They do not have the staff to deal with these complaints. They are backlogged for years. And overlying all of this, these boards are largely dependent on the physicians making the ultimate decisions. In other words, in our board, the decisions as to malpractice are made by three people, two of them who are physicians.

These medical boards should be altered to become subsidiaries of the board in Washington. And then something that will make the doctors happy in my proposal, I am for strict tort reform. I think we have to move into a system of strict tort reform, moving into the German and Swedish system of schedules of payments, that victims are compensated essentially by the government with a payment schedule—not as much as they receive in the malpractice system, but something. So that once a malpractice is identified, the issue of medical malpractice lawyers is not present. The payment is made for the medical misadventure.

Where I will come to blows with my colleagues, however, comes from my understanding of the German system, in which it is their

experience that fully 22 percent of what is called negligence is deemed criminal negligence and immediately goes into what amounts to a criminal medical system of jurisprudence in which there are specially trained judges with knowledge and interest in medicine who deliver true criminal penalties when it is due. And this is approximately 22 percent of the time.

Medicine to be practiced in Germany therefore becomes somewhat of a high risk profession, but with much better safety.

Senator SPECTER. Dr. Specken, your suggestion is that medical malpractice cases result in criminal sanctions?

Dr. SPECKEN. No. No. I am saying that looking at negligent cases, over the spectrum of negligent cases, 22 percent of them would fall into what they perceive as their criminal realm. It has to do with their concept of due diligence.

Senator SPECTER. Are those cases then prosecuted criminally?

Dr. SPECKEN. They all are. And doctors go to jail in Germany, something which is unheard of here. But I spoke to a German lawyer, and he was aghast when I explained our system to him. He could not understand why we tolerated this system of indemnification of doctors. And I could bring to you something Ray McAetrin said when he came before the committee, if the anger in the victim community ever gets unleashed, Seattle, the experience in Seattle, will become a mild thing compared to what could happen with that anger.

Senator SPECTER. Dr. Specken, what happened to your son, if you are comfortable telling us? I do not want to press you, but if you would tell us what happened to your son with his medical treatment, we would be interested to know.

Dr. SPECKEN. Yes. Seth was restrained illegally for a period of over 60 hours in an inappropriate withdrawal from Zanax medication, which I had been prescribing to him for panic disorder. The hospital staff, which was largely run by trainees and interns, did not know how to withdraw an individual and used restraints.

Senator SPECTER. And you lost your son?

Dr. SPECKEN. And Seth died in a bathroom, naked and alone.

Senator SPECTER. Judge Donahey, you have had a fair sized criticism of the medical malpractice system today. You have had a lot of experience in the judicial system obviously as a jurist, a lawyer. Do you have litigation pending against the doctor?

Judge DONAHEY. Well, you would be interested in knowing that another thing that I did not know prior to my surgery was that my surgeon was a full-time professor at the University of South Florida Medical School and therefore is covered by sovereign immunity in the State of Florida, both the hospital and him.

Senator SPECTER. Covered by immunity for what he does in the operating room?

Judge DONAHEY. Yes, sir sovereign immunity in the State of Florida protects you. So yes, there is litigation. I am going to pursue the litigation not because I have the potential of recovering some amount of money, but more because I think this matter needs to be brought to light. I was really appalled when I found out that quality assurance and assigned risk at the hospital did not know that he had three prior patients that had suffered vision impairment.

You might be interested in knowing also that since then I know that there has been a debate going on in the quality assurance at Tampa General Hospital to determine whether or not they should add to the informed risk statement for patients that are undergoing lower back surgery the loss of vision or the impairment of vision as a potential result.

This doctor who is in charge of the department refuses to permit that to be added. And the justification that he gives is that if you were to put it in the informed risk to be read to patients, that patients who legitimately need this surgery would choose not to have it.

Senator SPECTER. Judge, did you consider asking this doctor any questions about what the worst result he ever had was or had he been sued or something which a direct question might have drawn some information for you?

Judge DONAHEY. No, I did not ask that question. I should have. Hindsight certainly suggests that I should have.

Senator SPECTER. Well, it is a tough question to ask as a patient. No matter how much prescience you have or how much experience you have, that is not an easy question to ask.

Judge DONAHEY. Well, let me tell you what I have found out post-surgery. Post-surgery, there is no recordization, no suit that has ever been filed against him as a result of the previous three cases, or of any other cases. He does not have any cases. Now that tells us what? It tells us real simply that if there have been claims, they have been settled. They have been settled quietly prior to the filing of suit and a stipulation and condition of that settlement is that the settlement not be revealed. And you know that occurs all the time.

In Florida, our medical malpractice system requires that you do your investigation before filing the suit. You have to give notice of intent to file the suit. You have to have affidavits by other physicians supporting the finding of medical malpractice before you can file a suit. If you do not do all of that, first of all, your suit is subject to being dismissed; and, second, the lawyer who files the suit is subject to a counterclaim himself for liability.

Senator SPECTER. Judge Donahey, I would be interested in your views. We are going to have to terminate this hearing shortly.

Judge DONAHEY. Yes, sir.

Senator SPECTER. I would be interested in your views as to whether you agree with the Institute of Medicine that there ought to be mandatory reporting?

Judge DONAHEY. Absolutely.

Senator SPECTER. And mandatory disclosure to the patient of anything that went wrong?

Judge DONAHEY. Absolutely. Senator, it is a patient's right to be informed. It is a patient's right to make a fully informed decision as to where to go and where to seek his or her medical treatment. And you can only do that if you have available to you a full disclosure of the history and the background and the performance of the particular facility and physician that you are talking to.

Senator SPECTER. Dr. Specken, do you favor mandatory disclosure by hospitals and doctors of their errors?

Dr. SPECKEN. This dimension of the discussion is putting the cart before the horse. What we need first is a new system of regulation, which has to do with a well-functioning local medical board that in turn, in a hospital, manages a quality assurance office.

Now, I am in full agreement with Dr. Leape and Dr. Coye and Dr. Garthwaite and Dr. Bagian on a certain point—definitely there are cases which are true accidents that happen to doctors, although I was the first to bring up the analogy to the airline industry in medical mistakes. I am also the first to say it is a poor analogy. Doing medicine is infinitely different than flying a plane. It is infinitely more difficult. The best of doctors is going to make a mistake. It should be the determination ultimately of what is served by releasing that information.

Senator SPECTER. You may be right about a restructuring of a great many things, but that is unlikely to happen. We are going to be faced with a narrower question as to whether we are going to mandate hospitals and doctors to report their mistakes.

Dr. SPECKEN. And in that case, do it now. It is overdue.

Senator SPECTER. How about reporting to the patients?

Dr. SPECKEN. Absolutely. It is overdue. There is so much death because of this, it should be done.

Senator SPECTER. We are going to have to conclude now. And you have my thanks, Judge Donahey and Dr. Specken, for coming from Florida and from New York. I am very sorry to hear about your son, Dr. Specken; I have a couple of my own. And I am sorry to hear about your blindness, Judge Donahey. You seem to comport yourself well when you look at the chairman. And you probably have a bead on some of the witnesses in your courtroom. I think they will not know you cannot judge their demeanor by your presentation.

Your wife is nodding in the affirmative, so you are making the best of a very tough situation.

The subcommittee will be pursuing this matter further. There will be additional hearings. Senator Harkin asked me to announce that he will be cosponsoring the legislation which I have described. There is a great deal more we have to find out, but we are determined to take a strong stand against these kinds of errors.

That concludes the hearing. And Dr. Garthwaite and Dr. Bagian, if you would step forward, I would appreciate it.

Thank you all very much.

Dr. SPECKEN. Thank you for the opportunity, Senator.

Judge DONAHEY. Thank you, Senator.

CONCLUSION OF HEARING

Senator SPECTER. Thank you all very much for being here, that concludes our hearing. The subcommittee and committee will stand in recess subject to the call of the Chair.

[Whereupon, at 11:29 a.m., Tuesday, January 25, the hearing was concluded, and the subcommittee and committee were recessed, to reconvene subject to the call of the Chair.]

MEDICAL MISTAKES: ADMINISTRATION RESPONSE AND OTHER PERSPECTIVES

TUESDAY, FEBRUARY 22, 2000

U.S. SENATE, COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS, AND THE SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, COMMITTEE ON APPROPRIATIONS,

Washington, DC.

The joint hearing convened at 9:36 a.m., in room SD–430, Dirksen Senate Office Building, Senators Frist and Specter, presiding.

Present: Senators Frist, Specter, Hutchinson, Collins, Kennedy, Dodd, Harkin, Bingaman, and Reed.

OPENING STATEMENT OF SENATOR BILL FRIST

Senator FRIST. Good morning, and welcome to this joint Senate hearing of the Committee on Health, Education, Labor, and Pensions, and the Appropriations Subcommittee on Labor, Health and Human Services, and Education, on the topic of "Medical Errors: Administration Response and Other Perspectives."

Today's hearing, as most of you know, is the fourth and last in a series on the finding of an Institute of Medicine report entitled "To Err is Human: Building a Safer Health System."

I would like to thank Dr. John Eisenberg for appearing before the committee on behalf of the administration to offer the response of the Quality Interagency Coordination Task Force on Federal Actions to Reduce Medical Errors and their Impact.

We will also hear from the Veterans Administration on their implementation of a National Patient Safety Program and from other health care professionals who have spent a great deal of time and effort studying the issue of quality improvement.

I applaud the Institute's efforts to highlight patient safety as a major concern in America's health care system. The report states that medical errors are the eighth leading cause of death in the United States, with as many as 98,000 people dying per year. More people die from medical mistakes than from motor vehicle accidents, AIDS, or breast cancer.

There are several schools of thought on how to prevent these mistakes. Some say that sanctioning those health professionals who are not doing their job is the answer. But even the best-trained, the best doctors and nurses, make mistakes during even the most routine of tasks.

Clearly, the root cause of medical errors is more systemic, and examining and improving the systems that ensure patient safety

would seem to be more effective in reducing the number of medical errors than solely reprimanding any one individual or group.

One implication of a system view of error reduction is that the responsibility for safety lies with the people who organize and run those systems. This also implies that in order to achieve systemic improvements, we must facilitate and encourage communication between the different disciplines within the health care delivery system. Doctors, nurses, pharmacists, hospitals, researchers, regulators, accreditation bodies and health plans must all be involved in systems improvement.

The report calls for strong mandatory reporting efforts in order to identify these errors, analyze the patterns, and discover ways to prevent the problems from recurring, as well as a system of voluntary reporting. Standards and expectations should be raised, the report states, to encourage health care professionals and organizations to focus on and develop patient safety programs.

The report also recommends creating a new Center for Patient Safety through the Agency for Health Care Quality and Research, and providing initial funding of $35 million for the Center. While the President's budget calls for an additional $20 million in funding for patient safety research and pilot projects, more may be needed in order to address a problem of this magnitude.

We also need to allow for confidentiality through peer review protections for information that is voluntarily submitted regarding medical errors. I believe the Federal Government is uniquely positioned to provide the necessary protections against the inappropriate disclosure of data collected for the purposes of error reduction.

I am pleased that the report of the Quality Interagency Coordination Task Force supports the extension of peer review protections to facilitate reporting of errors in a blame-free environment.

Once the information is collected and analyzed, either through AHRQ—we will be hearing that acronym over the course of the day—or another deemed institution such as the Joint Commission on Accreditation of Health Care Organizations, recommendations on ways to prevent errors need to be developed and disseminated throughout the health care industry. It is my hope that the recommendations will be incorporated into future survey instruments by organizations such as the Joint Commission, the accrediting body responsible for hospitals and other inpatient health care settings.

We are especially fortunate to have with us today a witness from the Veterans Administration. As they indicate in their testimony, all of the IOM's recommendations applicable to the VA have either been in place or are in the process of being implemented. Based on their findings, the ideal reporting system must be nonpunitive, voluntary, confidential, and de-identified.

I support their conclusion that patient safety can only be achieved by root cause analysis and building a true culture of safety. Our committees' common goal is to identify and support approaches that increase knowledge about why medical errors occur and to apply that knowledge to improve patient safety.

This series of hearings has provided the committee with an understanding of the problems associated with medical errors and the

recommended solutions. I anticipate the development of bipartisan legislation creating a health care system quality improvement framework to address these problems. A number of members of this committee, including Senators Kennedy, Jeffords and Dodd, have already expressed interest in joining all of us in that effort.

At this hearing, we will hear from health care professionals and thoughtful leaders who have spent a great deal of time studying this issue. They will speak to the current State of patient safety, share with us recent developments in improving the quality of care, and give us their recommendations about what should be done.

I appreciate everybody coming. As you can see, Senator Jeffords is not with us; his plane has not yet arrived, and therefore, I am chairing this hearing. We will insert Senator Jeffords' prepared statement at this point.

[The statement follows:]

PREPARED STATEMENT OF SENATOR JAMES JEFFORDS

Good morning, welcome to this joint Senate hearing of the Committee on Health, Education, Labor, and Pensions and the Appropriations Subcommittee on Labor, Health and Human Services, and Education on the topic of "Medical Errors: Administration Response and Other Perspectives."

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I applaud the Institute's efforts to highlight patient safety as a major concern in America's health care system. The report states medical errors are the 8th leading cause of death in the United States, with as many as 98,000 people dying per year. More people die from medical mistakes than from motor vehicle accidents, AIDS, or breast cancer.

There are several schools of thought on how to prevent these mistakes. Some say that sanctioning those health professionals who aren't doing their job is the answer. But even good doctors and nurses make mistakes during the most routine of tasks. Clearly, the root cause of medical errors is more systemic. Examining and improving the systems that ensure patient safety would seem to be more effective in reducing the number of medical errors than reprimanding any one individual or group.

One implication of a system view of error reduction is that the responsibility for safety lies with the people who organize and run those systems. This also implies that in order to achieve systemic improvements, we must facilitate and encourage communication between the different disciplines within the healthcare delivery system. Doctors, nurses, pharmacists, hospitals, researchers, regulators, accreditation bodies, and health plans must all be involved in systems improvement.

The report calls for strong mandatory reporting efforts in order to identify these errors, analyze the patterns, and discover ways to prevent the problems from recurring, as well as a system of voluntary reporting. Standards and expectations should be raised, the report states, to encourage health care professionals and organizations to focus on and develop patient safety programs.

The report also recommends creating a new Center for Patient Safety through the Agency of Healthcare Quality and Research (AHRQ) and providing initial funding for the Center of $35 million. While the President's budget calls for an additional $20 million in funding for patient safety research and pilot projects, more may be needed in order to address a problem of this magnitude.

We also need to allow for confidentiality—through peer review protections for information that is voluntarily submitted regarding medical errors. I believe the Federal Government is uniquely positioned to provide the necessary protections against the inappropriate disclosure of data collected for the purposes of error reduction. I am pleased that the report of the Quality Interagency Coordination Task Force supports the extension of peer review protections to facilitate reporting of errors in a blame-free environment.

Once the information is collected and analyzed, either through AHRQ or another deemed institution, such as the Joint Commission on Accreditation of Health Care Organizations, recommendations on ways to prevent errors need to be developed and disseminated throughout the healthcare industry. It is my hope that the recommendations would be incorporated in future survey instruments by organizations such as the Joint Commission, the accrediting body responsible for hospitals and other inpatient healthcare settings.

We are especially fortunate to have a witness at today's hearing from the Veteran's Administration. As they indicate in their testimony, all of the IoM's recommendations applicable to the VA have either been in place or are in the process of being implemented. Based on their findings, the ideal reporting system must be non-punitive, voluntary, confidential and de-identified. I support their conclusion that patient safety can only be achieved by root cause analysis and building a culture of safety.

I believe our committees' common goal is to identify and support approaches that increase knowledge about why medical errors occur and to apply that knowledge to improve patient safety. This series of hearings has provided the committee with an understanding of the problems associated with medical errors and the recommended solutions. I anticipate the development of bipartisan legislation creating a health care quality improvement framework to address these problems. I am pleased that a number of members of the Committee, including Senators Kennedy, Frist, and Dodd, have already expressed interest in joining me in that effort.

At this hearing we will hear from health care professionals and thought leaders who have spent a great deal of time studying this issue. They will speak to the current state of patient safety, share with us recent developments in improving the quality of care, and give us their recommendations about what should be done. Thank you all for coming.

Senator FRIST. We will hear opening statements from Senator Specter, Senator Kennedy, and Senator Harkin; then we will go to the first panel and then give the other members the opportunity to make opening statements after the first two witnesses, if that is all right.

Senator Specter.

Senator SPECTER. Let me yield to Senator Kennedy. Today is his birthday. And beyond it being his birthday, he is the senior member here.

OPENING STATEMENT OF SENATOR EDWARD M. KENNEDY

Senator KENNEDY. That is very kind. Watching what has been happening on the national political scene, this kind of hospitality and generosity is very welcome.

I have to recognize that it is Senator First's birthday as well, so the stars are lined up in some particular way.

Senator FRIST. We had better be productive.

Senator KENNEDY. Senator Frist, I was born 200 years after George Washington, and I have always tried to make something out of that but have never been able to do much with it. In any event, I thank the Senator and my chairman and also Senator Specter.

As Senator Frist has pointed out, we are very fortunate to have together the two committees, one the authorizing committee, the other the appropriating committee, that have worked very closely on health care policy issues. I think that that is really the way that this process should work.

I think all of us are enormously impressed with the Institute of Medicine recommendations, which are very powerful and very thoughtful and very compelling. We received these just several weeks ago and members are enormously interested and concerned about the problem of medical errors. The administration has re-

sponded in the last few days, giving us an update on their own recommendations, which are extremely thoughtful and have, I think, a great deal of substance. Obviously, they will probably be the subject of differences in how to approach this, but they really respond in a very timely way to these issues which are of such great importance.

So at a time when perhaps there is some question about whether the Congress is off to a shaky start in terms of how much has been achieved and accomplished, I think that this area of public policy is one where we have seen very substantial recommendations from our colleagues on the various committees, and we look forward, Mr. Chairman, to working with you and those on the other committee in moving ahead with this legislation.

We regret that Senator Jeffords is not here. But we can talk in a bipartisan way, and I know that myself, Senator Dodd and others look forward to working very, very closely.

I also want to welcome Dr. Arnold Relman from Massachusetts, who will be appearing on our second panel. He has had a very distinguished record in academic medicine, at the University of Pennsylvania, as well as at Harvard and with the New England Journal of Medicine. He has not only thought a great deal about these issues but has also been instrumental in working in our own State of Massachusetts at addressing how to improve patient safety, so we have some practical guidance from him, as well as from a very outstanding group of witnesses today.

Mr. Chairman, I want to thank you at the outset. I think you have outlined in a very important way some of the various considerations we need to address. We have one approach that has been employed by the Veterans Administration by implementing a mandatory reporting system and developing a voluntary reporting system to ultimately achieve the greatest kinds of protections for American consumers. That is really what we are trying to accomplish. This is an extremely comprehensive and demanding subject matter, but it is one that demands action.

PREPARED STATEMENT

I would like to put my full statement in the record.

I am somewhat disappointed with our friends at the American Association of Health Plans. Instead of joining in a rather thoughtful, productive discussion on how we can best act together to reduce and prevent medical errors, the Association continues to argue against accountability for patient abuse. So I was very disappointed in their recommendations. However, the other reports and suggestions have been, I think, enormously thoughtful and productive. I look forward to working with you and the other members to implement an effective medical error reduction program to protect American families, which we know is our charge and responsibility.

I thank you.

Senator FRIST. Thank you, Senator Kennedy.

[The statement follows:]

PREPARED STATEMENT OF SENATOR EDWARD M. KENNEDY

I commend the Chairman for holding these important hearings on medical errors. We have learned a great deal from our witnesses, and I look forward to our efforts to improve the current system and prevent as many medical mistakes as possible.

I particularly welcome Senator Specter to our hearing. He's been an effective leader on this issue, and I look forward to his testimony.

After speaking with many providers and patients, it is clear that we need better data on medical errors, why they occur, and how to prevent them. It also seems clear that many providers will not take the steps necessary to improve patient safety unless they are held accountable in some way for implementing those steps.

Reporting offers one way to obtain needed information about medical mistakes. The programs in existence today vary widely some are voluntary and others are mandatory. Some have protections against disclosure and others do not. The Veterans Administration has developed a mandatory reporting system, and is implementing a voluntary system, as well. It's likely that no single data collection method can provide the broad range and depth of information we need to prevent as many medical errors as possible.

Another major challenge is to commit the necessary resources to all aspects of the problem, including research and education. The Institute of Medicine set a goal of a 50-percent reduction in medical errors within 5 years. That recommendation contemplates an initial increase of $35 million in the budget of the Agency for Healthcare Research and Quality, with progressive increases up to $100 million at 5 years.

Finally, any legislation put forward will not effectively reduce medical errors unless it holds institutions accountable for implementing practices and standards that improve patient safety. The public deserves meaningful information about how well individual health care institutions perform on patient safety measures, so that patients can make informed choices.

Each of these aspects of the medical errors problem is important. These issues must be given high priority by this session of Congress.

I also commend the President, the Vice President, and the members of the Quality Interagency Coordination Task Force for an outstanding job. The Administration's proposal is an effective plan to reduce medical mistakes and improve patient safety, and it will allow progress while Congress prepares to move forward.

Finally, I must also comment on the testimony by the American Association of Health Plans. I am disappointed in both the tone and content. Instead of joining in a thoughtful and productive discussion on how we can best act together to reduce the occurrence of preventable medical errors, the Association continues to argue against accountability for patient abuse.

Nevertheless, I'm optimistic that Congress will act quickly to solve the glaring problem of medical errors, and I look forward to working closely with my colleagues to meet this urgent challenge.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator FRIST. Senator Specter.

Senator SPECTER. Thank you very much.

This is a very important hearing by the authorizing committee, the Senate Committee on Health, Education, Labor, and Pensions, and also our Appropriations Subcommittee on Labor, Health and Human Services, and Education, tackling this issue of enormous importance.

On November 29, the Institute of Medicine came down with its report that there are almost 100,000 deaths annually due to mistakes in hospitals, and there has been very, very prompt action. A series of hearings has already been held in our subcommittee in December, as well as in this authorizing committee. Senator Harkin and I introduced legislation on February 8. The President has acted with an Executive Order, and today, we will have the report of the Quality Interagency Coordination Task Force as directed by the President, and later today, President Clinton will hold an event in the Executive Office Building, and many of us will be present at that time to really tackle this matter of overwhelming impor-

tance, as well we should in light of the fact that more than 300 people die each day from hospital mistakes. So this is something that we ought to be working on and working on expeditiously.

The issue as to how it is going to be handled is not an easy one. My own view is that mandatory reporting is necessary. There is considerable resistance to mandatory reporting, but the President's Task Force has made a suggestion that the mandates be by category and not identifying institutions or individuals. There may be a way to accommodate mandatory reporting without having a chilling effect to discourage people from reporting.

The legislation which Senator Harkin and I have introduced calls for demonstration projects along three lines. One is voluntary reporting with confidentiality, with five institutions doing that; five more institutions would have mandatory reporting with confidentiality; and a third group of five institutions would have mandatory reporting with disclosure to the injured patient.

It is my own view that there is a professional responsibility by doctors and hospitals to tell people when they have been injured. I would extend that to lawyers and architects and professionals of every sort. I think that is a professional responsibility. It may be that in the long run, the disclosure of errors can lead to a way to deal with this problem which would be different from the current tort system of medical malpractice, and perhaps those who are injured could be compensated in some other way, like perhaps workmen's compensation without respect to fault. That is a long way down the road, but the business of identifying the mistakes is really very, very important.

I agree with Senator Kennedy about the cooperative nature of what we are doing here, not only the committees, but both sides of the aisle, Republicans and Democrats. I was a little bit concerned to see in the morning's press that the president of the American Hospital Association, which had been invited to the White House event, has decided not to attend. I think that that is not proper. I think we all ought to participate, and we all have our views, but they are not necessarily in concrete. Our duty is the American people and to the patients who are entitled to medical care without being victimized by mistakes. And toward that goal, we are pledged to move ahead.

I am delighted now to yield to my very distinguished colleague from Iowa, my partner on the subcommittee, Senator Harkin.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Thank you very much, Senator Specter. I want to thank you and of course, Chairman Jeffords, Senator Kennedy, and Senator Frist for holding this important hearing on medical errors. I really think everything has been said, and I do not know how much I can add, other than to just reiterate for emphasis' sake that this is costing us a lot in our society—estimates of $17 to $29 billion a year just in terms of monetary cost. But how do you estimate the cost for patients and their families when a diagnostic test is misread, a drug is given that is known to cause an allergic reaction, or a surgery goes awry? These costs are inestimable, and they also further erode the trust that Americans have in our health care system. It is bad enough to have to go into a hospital for surgery—

and Dr. Frist can probably speak to this a heck of a lot better than I can—but all of us who have gone through that or who have had family members go through it know the apprehension, the fear of the unknown. When you add to it the knowledge that so many errors are being made compounds, I think, the anxiety that people have when they seek medical help.

I just want to make one thing clear from my viewpoint. That is, as I have looked at this along with Senator Specter, I am convinced that no one individual and no one institution is at fault. I do not think you can put a finger on something and say this is it. We have the best-trained and most sophisticated health care work force in the world; we have skilled, conscientious doctors and nurses and pharmacists, many of whom are working under tremendous pressure and time constraints. I believe the problem is very complex, and I believe it is a systemic problem—it is something in the way the system works—so I think we are going to need some comprehensive solutions and rigorous changes that will address this in a very comprehensive manner.

As Senator Specter said, he and I recently introduced the Medical Errors Prevention Act of 2000. The one thing I would say about the administration's approach—and I will be asking the witnesses about this—there is no money provided in the President's budget to go out to the States to help them set up these reporting systems. Senator Specter and I provide for that in our proposed legislation. We provide grants to the States. I do not see that in the administration's proposal.

Finally, I will just say that some years ago, we had a similar problem facing us in the aviation industry. The level of errors was unacceptably high. But we had a major national initiative; we put sufficient resources into research and training and systems solutions. I think we have altered the culture and processes of aviation so that the errors and risks have been dramatically reduced. That does not mean that airplanes do not crash—of course they do—but it is nothing like it used to be. And now we know how to pinpoint and find the errors more rapidly than we did, say, 20 years ago.

I think that that same kind of approach must be applied here, and that is what Senator Specter and I have tried to do in our legislation.

Thank you very much, Mr. Chairman.

Senator FRIST. Thank you, Senator Harkin.

Senator Collins.

OPENING STATEMENT OF SENATOR SUSAN M. COLLINS

Senator COLLINS. Thank you, Mr. Chairman.

Mr. Chairman, I am very pleased to participate in this fourth hearing today on how we can reduce the number of medical errors in this country. I am particularly interested in hearing from representatives of the Veterans Administration. In my home State of Maine, we have a Veterans Hospital at Togas that recently received a lot of publicity in regard to two serious medical errors that occurred there, including one case where a very unfortunate gentleman had his prostate inappropriately and unnecessarily operated on.

So we know that these problems and errors do occur, whether in VA hospitals or in other hospitals throughout our country. In fact, the VA recently issued a report that showed nearly 3,000 cases of medical mistakes or adverse events involving more than 700 patients who died while hospitalized or shortly thereafter—those were the major findings of this report. In contrast with the past VA practice of trying to cover up or minimize such errors, however, the VA has adopted a new approach of encouraging employees to come forward to fully disclose the mistakes and to learn from them as a means of enhancing patient safety.

So I think we can learn from the experience of the VA about whether the actions that have been put in place are reducing medical errors and whether they can serve as a model for other hospitals as well.

I appreciate the opportunity to participate today. Thank you.

Senator FRIST. Thank you, Senator Collins.

Senator Reed.

OPENING STATEMENT OF SENATOR JACK REED

Senator REED. Thank you, Mr. Chairman.

Mr. Chairman, let me just thank you for hosting this hearing. It is an interesting topic, and I am eager to hear from today's witnesses.

I yield back.

Senator FRIST. Thank you, Senator Reed.

Senator Bingaman.

OPENING STATEMENT OF SENATOR JEFF BINGAMAN

Senator BINGAMAN. I agree with Senator Reed, Mr. Chairman. Thank you for holding the hearing, and I am here to hear the witnesses.

Thank you.

Senator FRIST. Those were good, short opening statements by the last two.

Senator Dodd.

OPENING STATEMENT OF SENATOR CHRISTOPHER J. DODD

Senator DODD. Thank you, Mr. Chairman. Let us keep it moving in your direction and keep this moving.

I will put an opening statement in the record, Mr. Chairman, and when the time for questioning comes, I will make some further comments.

Senator FRIST. Thank you.

[The statement follows:]

PREPARED STATEMENT OF SENATOR CHRISTOPHER J. DODD

Mr. Chairman, I'd like to thank you both—Senator Jeffords and Senator Specter—for convening this joint hearing, the final in a series of three that the Health and Education Committee has held on the topic of medical errors. I am pleased that the committee is looking carefully and thoughtfully at this troubling issue and I'm delighted to be working with the Chairman, Senator Kennedy, Senator Frist and other members of this committee to draft legislation to address it.

As we are all now aware, a recent Institute of Medicine study has revealed a major health crisis—not a deadly new virus or another tear in the safety net—but a crisis of human error. According to the IOM, medical mistakes, ranging from il-

legible prescriptions to amputations of the wrong limb, are responsible for as many as 100,000 deaths a year.

Most Americans feel confident that the health care they receive will make them better—or at the very least, not make them feel worse. And in the vast majority of circumstances, that confidence is deserved. The dedication, knowledge and training of our doctors, nurses, surgeons and pharmacists in this country is unparalleled.

But, as the IOM reports starkly notes, our health care system is showing some cracks. If we are to maintain public confidence, we must respond quickly and thoroughly to this crisis.

As we near the end of the series of hearings that the committee has held on this topic, having heard from government officials, academic experts and health care providers, the questions to be addressed are now clearly outlined for the us: Should error reporting should be mandatory or voluntary? Should reports, once made, should be disclosed to the public, and, if so, in what form? Should information in the reports be out of the reach of malpractice attorneys, and if so, how? Who should collect the information? And how should the information, once collected, be analyzed and disseminated to improve patient care?

The task before us is straightforward and I am hopeful that the legislation we are drafting through the committee process will be ready for introduction in the next few weeks.

I would like to end by stating my concern about continuing attempts to use the medical errors issue to divert attention from the Patents Bill of Rights (PBOR). I am surprised and disappointed by the arguments being made that solving the medical errors crisis alone is all that is needed to improve the quality of health care in this country. Doctors inadvertently harming patients and insurers deliberately withholding medically necessary care are equally important, but distinct, issues—addressing one does not obviate the need to address the other. I think the American people understand that and I hope those working on this issue understand it as well.

Again, Mr. Chairman, I thank you for placing this issue high on the committee's agenda. And, I thank Senator Specter and Senator Harkin for their interest and leadership on this issue. I look forward to working with you all in a bipartisan manner to find a solution.

STATEMENT OF DR. JOHN M. EISENBERG, DIRECTOR, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND OPERATING CHAIR, QUALITY INTERAGENCY COORDINATING TASK FORCE

Senator FRIST. I have the pleasure of introducing our first panel this morning. Once again, we will be welcoming Dr. John Eisenberg, who is director of the Agency for Healthcare Research and Quality, or AHRQ. The reason I keep stressing that is for those of us who have been around a little bit, we have followed the agency, and in the reauthorization last year, the name was changed, and with a lot of working together and a lot of foresight, it was exactly for this reason, where the focus is very much on quality and research.

Dr. Eisenberg has held his current post since 1997. His agency is the lead Federal agency charged with conducting and sponsoring research to improve the quality, the appropriateness, the effectiveness of health care services and to improve cost and access to care.

Dr. Eisenberg also serves as Senior Adviser to the Secretary on Quality at the Department of Health and Human Services. His career includes a variety of positions in academia and Government. Prior to being appointed to AHRQ, Dr. Eisenberg was chairman of the Department of Medicine and physician-in-chief at Georgetown University. He has also been chief of the Division of General Internal Medicine at the University of Pennsylvania. He has held a number of key positions in the research community, physicians' associations, and in the clinical practice of medicine.

Dr. Eisenberg, we are pleased to have you with us once again.

Dr. EISENBERG. Thank you—I suppose I should say "Messrs. Chairmen"—for the invitation to join you today. I am pleased to be here to discuss the response of the Quality Interagency Coordination Task Force, or QuIC, to the Institute of Medicine's report entitled, "To Err is Human: Building a Safer Health Care System."

I want to take a moment to make a personal comment about what a pleasure it is to be in a hearing where Dr. Relman is testifying. He was the chairman of medicine at the University of Pennsylvania when I was a resident, and when I went to him and said, "I would like to be a clinician, but I also want to do research related to health care improvement," he said, "That is great—why don't you study at the Wharton School?"

As Senator Frist will attest, it is not always that you get encouragement like that at that stage in your career when you want to do something unorthodox, so I want to thank him for that. Were it not for his encouragement, I would not be here today. After the testimony, others can decide if that is a good thing or not, but I do want to thank him for getting me started in this area.

Senator FRIST. Dr. Eisenberg, pull the microphone just a little bit. These are very directional microphones, so during the hearing, I will keep repeating that so people in the back can hear as well.

Dr. EISENBERG. The QuIC was created by President Clinton in 1998 when he received the final report of his Quality Commission in March of that year. This organization, the QuIC, or Quality Interagency Coordination Task Force, brings together every Federal agency that is involved in health care quality so that we can collaborate and coordinate all of our efforts to improve quality. It is chaired by Secretary of Health and Human Services Donna Shalala and by Secretary Alexis Herman of the Department of Labor. I serve as its operating chair, and Dr. Garthwaite is one of its key members. I testify today not so much in my role as director of the Agency for Healthcare Research and Quality but as the operating chair of the QuIC. Later today, as has been mentioned, Secretaries Shalala and Herman will present the response of the QuIC to the President at a White House ceremony.

What I would like to do now is submit for the record our report—other copies are available here today—entitled, "Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact." And doing what counts is very important, because we think that not only should we count what is happening, but we need to do what counts in order to improve patient safety in response to that.

The Institute of Medicine report certainly shocked the Nation. Newspapers and television nationwide covered the story; they reported that 44,000 to 98,000 Americans were dying each year as a result of preventable medical errors, in hospitals. Clearly, those numbers reflect a problem of near epidemic proportion.

The administration has had a longstanding commitment to improving health care quality and to improving patient safety, and my written testimony details at length a number of existing Federal efforts that are underway to reduce the medical errors that exist and to improve patient safety in this country. But we do not think that that is enough; we think more needs to be done.

The Institute of Medicine proposed a four-tier approach to reducing medical errors and called for a national goal of reducing the number of those errors by 50 percent in 5 years. We agree with that goal, we fully endorse that goal, and we are going to work to achieve it with the following steps which are also, in a corresponding way, four steps, as a part of our strategy.

The first step is to create a national focus on patient safety. The Institute of Medicine recommended and we endorse the establishment of a research center on patient safety within the Agency for Healthcare Research and Quality, or AHRQ. This new Center for Quality Improvement and Patient Safety will support research, especially extramural research, and it will support the kinds of centers of excellence in patient safety research that we have sponsored in biomedical research. This center is also going to support studies to determine the best way to translate research findings into practice and will do that in partnership with both the public and private sectors.

The center at AHRQ will also have the responsibility for integrating these efforts into the Agency's broader quality agenda, recognizing that patient safety is part of the broad agenda of quality in this country. It will include support for centers for education and research in therapeutics and the National Report on Quality, which both of your committees have urged us to do by mandating in our reauthorization and by providing appropriations to get the program started. The President's fiscal year01 budget includes $20 million to support this center's initial activities.

The second step is to establish reporting systems nationwide. This will help us to achieve complementary goals of, first, accountability to the public, and second, a learning environment for the health care industry. We firmly believe that the American public has the right to know how safe its health care system is and what is being done to make it safer. So following the IOM's recommendations, we will work to promote a nationwide system of State-based mandatory reporting programs to gather this information.

We believe that this mandatory data should collect information on errors that result in death or serious harm, and we agree with the Institute of Medicine that this data should be reported to the States by health care systems and then reported to the public without identification of patients and without identification of health care professionals.

But we think we should do more than that. We believe that we should do more, especially to find the best way to be accountable to the public which wants so much for its health care system to be safe. The Health Care Financing Administration, for example, will undertake several initiatives. First, it will develop a pilot program with a State that has a mandatory system to determine what the best way is to report these preventable adverse events, the events that should never occur. HCFA will also require as part of its conditions of participation that hospitals participate in mandatory programs and that the over 6,000 participating hospitals in the Medicare program participate in those programs and demonstrate that they have a patient safety program in place. HCFA will also work with a peer review organization not develop a mandatory reporting system that will remain confidential in order to help hospitals and

health professionals learn how to prevent errors through improved systems in up to 100 hospitals.

Now, similar to these activities from the Health Care Financing Administration as a value-based purchaser, another Federal value-based purchaser, the Office of Personnel Management, will instruct the almost 300 health plans in the Federal Employees Health Benefits Program to include error reduction and patient safety initiatives beginning in the year 2001, so that its call for proposals this year will include that requirement.

To fulfill both the learning objectives and the accountability objectives, the Federal agencies that deliver health care, like those that purchase health care, will make a commitment to establish reporting systems and to be sure that they do everything they can to improve patient safety. For example, the Department of Defense will soon implement a mandatory but confidential reporting system in its hospitals and clinics that will be modeled after the ones developed by the VA that Dr. Garthwaite will be describing.

Agencies other than the purchasers and providers of care will also contribute to patient safety. The CDC and the FDA, which currently run reporting systems that provide opportunities for learning how to prevent adverse events, are going to be able to ensure even more in the future that the health care system is publicly accountable for safety. These efforts are going to be strengthened by activities like the FDA's extension of mandatory reporting requirements for blood banks and establishments that deal with blood products, from the 400 today to the entire 3,000 that are involved in blood banking and the delivery of blood products.

In every one of these programs, no matter which part of the Federal role in health care quality we are addressing, partnerships are going to be key. Whether it is the researchers or the providers or the purchasers or the regulators of health care in the Federal Government, partnerships with hospitals and health professionals and patients are going to be absolutely critical.

To make these partnerships work, we believe that one of our first steps should be to work with the National Forum for Health Care Quality Measurement and Reporting, also known as the Quality Forum, which is a private sector standard-setting body that was launched by Vice President Gore and is now an independent membership organization. It will identify a basic set of patient safety measures and a set of proven patient safety practices, based on good evidence about what works, that should be reported by every hospital. The Quality Forum's recommendations will be used to guide the Federal reporting systems, such as the one that the Health Care Financing Administration will develop.

We believe that these reporting systems should include just the most serious events that are preventable, the deaths and serious adverse events, in the mandatory and publicly disclosed system, but we also believe that it is important for us to give the public information on whether health care delivery organizations are responding to those errors by adopting patient safety practices.

We are going to work with the Forum closely to determine how best to disseminate this data to the public and to asset the States and others who want to do a better job in understanding what the most effective data collection and data dissemination methods are.

The Agency for Healthcare Research and Quality will lead a research and evaluation effort to study those existing mandatory reporting systems and to develop recommendations for their improvement.

We hope that these activities will inform and encourage the State efforts as well as private efforts. It is our goal that mandatory reporting systems should be in place in all 50 States within 3 years. Within 3 years, the QuIC will review the evaluations of the State programs that I have described, assess their impact, see how they can work best, assure that the reporting requirements help and do not hinder reporting and patient safety, and recommend whether further Federal action is needed.

In addition to these mandatory systems, both those on very serious adverse events that are publicly reported as well as those that remain confidential, the QuIC also agrees that there is a place for voluntary reporting. This voluntary reporting should focus on a broader array of information, including what are called "close calls" which might have been intercepted in time to prevent patient injury; to identify and to learn from those close calls, and from the pattern of those errors. We know from other industries like aviation that confidentiality is a vital feature of this type of reporting system, and it is critical in order to encourage widespread cooperation. We will evaluate the effectiveness of these voluntary systems, including the VA's soon-to-be-implemented voluntary system.

Also learning from the aviation experience, the QuIC believes it is important that peer review protections that are now available to the peer review organizations be extended to others who are working on confidential reporting systems, whether they are mandatory or voluntary; but these protections should never deny an individual information from his or her medical record, nor should it limit the normal process of discovery of the original records. The QuIC believes that patients and their families, as Senator Specter said, should be told about serious events that occur to them or to their family members, and we believe that the entire Nation should follow the lead of the VA and the Defense Department, who are putting that principle into practice.

In addition to these reporting and research initiatives by Federal purchasers, the third step recommended by the Institute of Medicine was to set performance standards and expectations for safety at both the health care organization and individual provider levels. We agree with the IOM's recommendation that the States have a key role not only in reporting but also in assuring the competence of health care professionals and the licensing of institutions. The QuIC also recognizes the critical role that professional societies play, as do accrediting organizations, and we are prepared to offer technical assistance and collaboration to professional societies and accrediting organizations to be sure we promote the models of best practices and patient safety. This year, for example, the Department of Labor will work with private sector employers and employees to incorporate patient safety into purchasing decisions.

The administration also agrees with the IOM's recommendation——

Senator SPECTER. Dr. Eisenberg, could you summarize at this point, please?

Dr. EISENBERG [continuing]. I will—to increase the attention to safe use of drugs. The FDA will expand its programs of reporting in order to improve reporting of adverse events and also to be sure they are safe.

Finally, we believe that the QuIC should make every effort possible to join you in commending the Institute of Medicine's panel for its excellent and thoughtful report. The Institute of Medicine has challenged each of us to be safer, to build safer systems of health care that prevent those human errors from turning into human tragedies.

PREPARED STATEMENT

The QuIC and all of its participating agencies represent the capacity of the Federal public sector's commitment to do better—as researchers, as purchasers, as providers, as regulators, and so on—and we stand ready to work with the Congress so that we can work with our fellow public sector agencies, with the States, and with the private sector to reduce medical errors and make American health care safer for everyone. That is the only way that we are going to meet this challenge.

Thank you very much.

Senator SPECTER. Thank you very much, Dr. Eisenberg.

[The statement follows:]

PREPARED STATEMENT OF HON. JOHN M. EISENBERG

INTRODUCTION

I am very pleased to be here today to discuss the response of the Quality Interagency Coordination (QuIC) Task Force to the recent report of the Institute of Medicine on medical errors, To Err Is Human: Building a Safer Health System. The QuIC is chaired by HHS Secretary Donna E. Shalala and Labor Secretary Alexis Herman; I serve as its operating chair, and I testify today in that capacity.

President Clinton has a longstanding commitment to improving health care quality and protecting patient safety. In 1998, he created the QuIC to focus Federal efforts to improve health care quality and appointed Health and Human Services Secretary Shalala and Labor Secretary Herman as co-chairs. When the IOM report was released, the President requested that the QuIC evaluate its recommendations and provide recommendations for further action to prevent medical errors.

Later today, Secretaries Shalala and Herman will formally present the response of the QuIC to President Clinton at a White House ceremony. I would now like to submit a copy of that report—Doing What Counts for Patient Safety: Federal Action to Reduce Medical Errors and Their Impact—for the record. Before I outline its details, I would like to discuss briefly the issue of medical errors and ongoing Federal efforts to improve patient safety.

The IOM report shocked the Nation. Newspapers and television nationwide carried the story that anywhere from 44,000 to 98,000 Americans die each year as a result of preventable medical errors in hospitals. Many more are permanently or temporarily disabled, and still more experience minor or no ill effects, but nonetheless have been victims of medical errors. In addition, because of limited data, we don't know about the rate of medical errors that occur in health care settings outside of hospitals.

Clearly, the numbers we do know reflect a problem of near epidemic proportions.

Many of the findings described in the IOM report are not new. Perhaps the most significant contribution of the report has been to bring the information together in one place, draw it to the attention of the American public, and issue a call for action.

FEDERAL EFFORTS

To say we know about the problem, begs the question, "What have we done to address medical errors?" The answer is we've done quite a bit, but much more can and should be done.

In early 1997, the President established the Advisory Commission on Consumer Protection and Quality in the Health Care Industry, and appointed Secretaries Herman and Shalala as co-chairs. The Quality Commission released two seminal reports focusing on patient protections and quality improvement. Also consistent with the Quality Commission's recommendations, Vice President Gore launched the National Forum for Health Care Quality Measurement and Reporting. The "Quality Forum" is a broad-based, widely representative private advisory body that develops standard quality measurement tools to help all purchasers, providers, and consumers of health care better evaluate and ensure the delivery of quality services. In addition to the work and significant potential of the QuIC and Quality Forum, other Federal agencies have made significant efforts to reduce medical errors and increase attention on patient safety.

The Quality Commission, in its final report to President Clinton, highlighted medical errors as one of the six quality challenges facing the American health care system. On December 7th, he directed the QuIC to evaluate the IOM report and present to him its own recommendations for reducing medical errors and improving patient safety. Those recommendations are in the report I've just submitted for the record.

I would like to note, however, that Federal efforts to improve patient safety predated the Quality Commission's deliberations and the IOM report. A few highlights:

—The Agency for Healthcare Research and Quality, which I direct, sponsored landmark research into the frequency and causes of medical errors and testing techniques designed to reduce them. This research was used by the IOM panel in its deliberations.

—The Centers for Disease Control and Prevention (CDC) collect data on such adverse events as hospital-acquired infections, and the Food and Drug Administration collects data on errors related to drugs and medical devices, one of the most frequent sources of medical errors. These agencies then report findings back to health care providers and medical manufacturers to assist them in taking action to prevent similar occurrences.

—The Departments of Veterans Affairs and Defense have instituted computerized physician order entry systems, a proven deterrent to errors caused by drug interactions. The VA, which also has one of the world's largest and most advanced computerized patient record systems, has created an error reporting system and is using bar code technology for medication administration and blood transfusions, all in the name of reducing medical errors.

—The Health Care Financing Administration's (HCFA) "Conditions of Participation" for Medicare provider facilities addresses quality of care. VA uses its purchasing power to demand safe packaging and labeling of the drugs it buys. And the Office of Personnel Management (OPM) announced it will require meaningful patient safety programs in all health plans in the Federal Employees' Health Benefits Program to implement patient safety initiatives beginning in 2001.

But, as I stated earlier, more should be done.

QU IC RESPONSE

The IOM proposed a four-tiered approach to reducing medical errors and called for a national goal of reducing the number of errors by 50 percent in 5 years. We fully endorse that goal, and we will work toward achieving it with the following strategy:

The first step is to create a national focus on patient safety. The IOM recommends, and we endorse, the creation of a Center for Patient Safety within the Agency for Healthcare Research and Quality.

The President has included an additional $20 million in his fiscal year 2001 budget for AHRQ to conduct research on medical errors reduction, including creating a new Center for Quality Improvement and Patient Safety. Those funds will be used to develop national goals, invest in an aggressive research agenda, convert findings into improved health care practices, and educate patients about their safety. The Center—or CQuIPS will perform these functions in partnership with both the private and public sectors and integrate these efforts into the Agency's broader quality agenda.

The second step is to establish reporting systems nationwide. In order for there to be an effective, coordinated approach to reducing medical errors, we need much more information than we have now, in comprehensive and useful formats. Our objective will be to achieve the complementary goals of accountability to the public and a learning environment for the health care industry. The IOM recommended establishment of nationwide reporting systems that contain both mandatory and voluntary components as the means to gather this information.

We agree, and will pursue the development of a well-designed patient safety program that includes reporting systems that hold health care systems accountable for delivering high-quality care and provide valuable information for decisionmakers to use in making our health care system safer.

It is important to note that the QuIC believes that any legislation or administrative intervention in this area should not undermine individuals' rights to redress for criminal activity, malpractice, or negligence. The QuIC does not support legislation that would allow safety reporting systems to serve as a shield for providers engaging in illegal or negligent behavior.

The American public has the right to know how safe its health care is and what is being done to make it safer. We support the development of standardized, State-level mandatory reporting systems that include both mandatory and voluntary components. We believe the mandatory data systems should collect information on errors that result in death or serious harm to individuals. We also believe that the data should be aggregated by the States and reported to the public grouped by health system without identification of patients or health care professionals. This should provide the public with information that it deserves about the quality of care without compromising patient privacy.

To fulfill both the accountability and learning objectives, the Federal agencies that deliver health care are also taking action to establish reporting systems. The Department of Defense will soon implement a reporting system in its hospitals and clinics modeled on the one used by VA. Dr. Garthwaite will be describing VA's system in a few minutes. Federal agencies such as the CDC and FDA currently run reporting systems that provide opportunities for learning how to prevent adverse events and ensure that the health system is publicly accountable for safety. These efforts will be strengthened by the FDA's requirement for blood banks and establishments dealing with blood products to report errors and accidents.

In addition, we will ask the National Forum for Health Care Quality Measurement and Reporting, the private-sector, standards-setting body launched by Vice President Gore, to identify a basic set of patient safety measures and proven patient safety practices. We will encourage reporting systems to include information on whether health care delivery organizations have adopted these practices in the information made available to the public. We will work with the Forum to determine how best to disseminate the data to the public. To assist States and others in understanding the most effective data collection and use practices, AHRQ will lead an effort to evaluate existing mandatory reporting systems and develop recommendations for improvement.

HCFA, through its Peer Review Organizations (PRO) Program, will test the effectiveness of developing a data collection and technical assistance function to help hospitals identify error-prone practices and modify their medical delivery systems to reduce or eliminate errors. This will be tested in up to 100 hospitals that volunteer to participate in this model mandatory reporting system. Funding for these pilot projects will be derived from existing resources in the President's fiscal year 2001 budget for PROs.

We hope these activities will inform and encourage State efforts to implement reporting systems. It is our goal that mandatory reporting systems be in place in all 50 States within 3 years.

We also agree there is a place for voluntary reporting systems designed to collect a broader array of information, including close calls that were intercepted in time to prevent patient injury, identifying and learning from patterns of errors. We know from other industries, like aviation, that confidentiality is a vital feature of this type of reporting system, in order to encourage widespread cooperation.

We will evaluate the effectiveness of current voluntary reporting systems, including the VA's soon-to-be-implemented voluntary reporting system nationwide that will identify, evaluate, and take steps to prevent errors in its facilities.

If the first and second steps are to create a national focus on patient safety, and to establish both mandatory and voluntary reporting systems, the third step is to set performance standards and expectations for safety at both the health care organization and individual provider levels as recommended in the IOM report. We agree with the IOM's conclusion that the States have a key role in assuring the competence of health professionals. The QuIC also recognizes the importance of professional societies and accrediting organizations, and we will offer technical assistance, and as well as promote models of best practices in patient safety.

We can, and will, however, take positive steps toward ensuring that health care organizations implement patient safety programs. HCFA will publish regulations requiring hospitals participating in the Medicare program to have ongoing medical error reduction programs in place. That alone will affect over 6,000 hospitals nationwide. The OPM will instruct the almost 300 health plans in the Federal Employees

Health Benefits Program to include error reduction and patient safety initiatives beginning in 2001. This year, the Department of Labor will work with private-sector employers and employees to incorporate patient safety into purchasing decisions by including information on medical errors in the educational material disseminated through its Health Benefits Education Campaign.

Third, the Administration also agrees with the IOM recommendation to increase the attention given to safe use of drugs and medical devices, and the President has increased the FDA's funding level for pre- and post-marketing oversight in his fiscal year 2001 budget request.

Finally, the IOM urged that health care organizations make a commitment to continuous patient safety improvement. We couldn't agree more. Within the Federal community, VA and DoD—leaders in the patient safety area—have implemented a variety of innovations to enhance patient safety, including enhanced safety training for staff, use of computerized medical records, and adoption of automated prescription order entry systems. This summer they will lead a QuIC initiative to test strategies to improve patient safety in "high hazard areas," like labor and delivery rooms, emergency rooms, operating rooms and intensive care rooms.

CONCLUSION

I would like to commend the IOM panel for its excellent and thoughtful report. Its recommendations are vitally important to the safety of the American people. We agree with each of its recommendations, and the QuIC report details how we will address them. The QuIC and all its participating agencies stand ready to work hand in hand and with our fellow public-sector agencies, States, and the private sector in a collaborative effort to reduce medical errors and make the American health care system safer for all. That's the only way we will meet this challenge.

This concludes my prepared remarks. I will be happy to respond to any questions you may have. Thank you.

Senator FRIST. Senator Specter will introduce Dr. Garthwaite.

STATEMENT OF DR. THOMAS LEONARD GARTHWAITE, DEPUTY UNDER SECRETARY FOR HEALTH, DEPARTMENT OF VETERANS AFFAIRS

Senator Specter. Dr. Thomas Garthwaite is Acting Undersecretary for Health at the Department of Veterans Affairs. He specializes in endocrinology and has served the Veterans Administration for some 25 years. He has a bachelor's degree from Cornell University and an M.D. from Temple in Philadelphia.

Dr. Garthwaite testified at last month's hearing on medical errors, held jointly by the Veterans Affairs Committee and the Subcommittee on Labor, Health and Human Services, and Education. The Veterans Administration implementation of the National Patient Safety Program with the disclosure of medical mistakes has been a forerunner in this field, and Dr. Garthwaite had some important testimony to offer at last months' hearing and I know is an important witness again here today.

Senator SPECTER. Now we turn to Dr. Garthwaite.

Dr. GARTHWAITE. Mr. Chairman and distinguished members of the committees, thank you for inviting us here today to testify on the critical issue of patient safety.

In 1996, President Clinton demonstrated his leadership and commitment to improving our health care system by establishing the Advisory Commission on Consumer Protection and Quality in the Health Care Industry. Actions taken by the President on recommendations of the Commission have led to a new focus and cooperation within the administration to improve health care quality, and I believe Dr. Eisenberg has just detailed that cooperation quite well.

In 1997, the Department of Veterans Affairs began a major initiative to establish a system and a culture to improve the safety

of our health care system and, by sharing our results, to improve health care safety for everyone. Our written testimony details our extensive efforts to date. I would like to comment on VHA's plans for the next couple of years.

First, we will continue to implement safety measures. Medication errors are among the most common errors in medicine. We anticipate that a bar code system for medication administration will prevent over two-thirds of medication errors. We plan to have this system in all VA medical centers by this June.

In the high-risk and intensive environment of an operating room, time can be of the essence. An anesthesia reminder list of important facts has found to be helpful in emergency situations. We will place such a check list on every anesthesia machine in the VA this year.

We have found that suicide is among the most common unexpected causes of loss of life during or immediately after hospital discharge. We have developed new guidelines on the treatment of depression and will promulgate their use throughout the VA this year. We are also organizing a Suicide Summit to bring together experts on depression and to spotlight this altogether too common tragedy.

In addition to implementing these and other safety measures, we will continue to expand and hone our comprehensive safety program. We will expand our National Center for Patient Safety. This Center leads our efforts in implementing and improving our mandatory and voluntary reporting systems, educating the work force in root cause analysis, in creating a culture of safety, in analyzing the root cause of error and of close calls, and in design and implementation of improved systems of care.

We will continue to fund our four Patient Safety Centers of Inquiry. These Centers currently target their safety research on organizational issues and training, on fall prevention, and the development of safer hospital rooms, on human factors engineering, including the interactions among health care workers and between workers and their machines, and on training in safety with an emphasis on the use of simulators for research and competency testing.

In addition, each of our Quality Enhancement Research Initiatives will add patient safety to their goals and objectives. These research initiatives seek to move health services research to the bedside by targeting the effects of providers and systems on patient outcomes.

We will add staff dedicated to patient safety. We estimate adding 190 full-time-equivalent employees to our current composite effort of 294. In addition, we have a goal that half of all full-time staff will receive 20 hours of training in patient safety this fiscal year. This represents a commitment of over $39 million and 1.6 million man-hours of training.

We will continue to fund the VA Quality Scholars Program. This unique fellowship in quality and safety is currently available for 10 physicians per year at five VA facilities affiliated with academic institutions. It is designed to promote the academic awareness of safety design issues in medicine.

Underlying our comprehensive program for patient safety are several key principles. We believe that the institution delivering

care has a responsibility to assume that individuals will make errors. Those institutions must find the systems that allow the errors to occur and improve the design of those systems. The new designs might either prevent error or minimize the impact of error.

We also believe that those institutions must share their lessons learned; otherwise, each system is doomed to harm a patient to learn the very lesson previously learned in another institution. All institutions have a responsibility to detect the less common cause of error related to incompetent providers and to take appropriate action.

In VA, we believe that we must, first, openly inform patients or family about their errors; second, have a system of mandatory, but not punitive, reporting and analysis of adverse events within a process protected from public disclosure of individual patients and practitioners; third, have a complementary voluntary system of reporting which in other systems, like aviation, has been shown to provide additional important information; fourth, to analyze those adverse events and close calls for possible systemic fixes and new standards; fifth, and critically important, to implement new standards rapidly and universally across our health care system; and sixth, to share our important lessons and improvements with other health care institutions in VA and outside.

VA has chosen to use its unique position as a publicly accountable national health care system to lead in the effort to ensure the safety of patients. We also will use our strength as a major research and educational organization to conduct research on safety and to add human factors and organizational design to the curriculum of clinical and administrative students in VA.

PREPARED STATEMENT

It is the opportunity to learn from a single mistake that all health care must embrace and which underlies the need for event reporting systems. VA has established such systems. We believe that we must share our lessons learned broadly but also hope to learn from the experience of others.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF HON. THOMAS L. GARTHWAITE

Mr. Chairmen and Members of the Committees, I am pleased to appear before you to discuss VA's ongoing activities and initiatives to ensure the safety of patients who receive care from VA. In December 1999, the Institute of Medicine (IOM) released a report "To Err is Human: Building a Safer Health System." The report reviewed existing studies and concluded that as many as 98,000 preventable deaths occur each year in United States' healthcare due to error. The IOM recommended creating a new National Center for Patient Safety that would focus on research and policy related to errors in healthcare, improved error reporting systems, improved analysis/feedback methods, performance standards for healthcare organizations and individuals, and other specific governmental actions. Importantly, they cautioned that the focus must be on creating a culture of safety that will require improving systems, not assigning blame.

VA interpreted the IOM report as a validation of our commitment to improving patient safety in our healthcare system. All of the IOM recommendations applicable to VA have either been in place or were in the process of being implemented prior to the release of the report. While VA has had quality and safety related activities ongoing for many years, it was in 1997 that our formal patient safety program was launched. Leaders in the field of patient safety and medical error outside VA have

participated in the design of our system and recognize VA as a pioneer in these efforts.

During 1997, VA intensified its already extensive efforts in quality improvement by launching a major initiative on patient safety. We recognized that programs to improve quality and safety in healthcare often share purpose and corrective actions. However, we believed that patient safety required a new and different approach. We set out to create a new culture of safety in which our employees detect and tell us about unsafe situations and systems as part of their daily work. Once we know about unsafe situations and systems, we are committed to design and implement new systems and processes that diminish the chance of error.

HIGHLIGHTS OF PATIENT SAFETY ACTIVITIES AT VA: 1997-PRESENT

VA recognized that patient safety is not a VA-specific issue, therefore we asked other health care organizations to join us in an effort to understand the issues and to act for patient safety. As a result, the National Patient Safety Partnership (NPSP), a public-private consortium of organizations with a shared interest and commitment to patient safety improvement, was formed in 1997. The charter members, in addition to VA, included the American Medical Association, the American Hospital Association, the American Nurses Association, the Joint Commission on Accreditation of Healthcare Organizations, the Association of American Medical Colleges, the Institute for Healthcare Improvement, and the National Patient Safety Foundation at the AMA. Five additional organizations have subsequently joined the charter members in the Partnership: the Department of Defense—Health Affairs, National Institute for Occupational Safety and Health, the Food and Drug Administration, Agency for Healthcare Quality and Research, and the Health Care Financing Administration. This group addresses high impact issues that are of importance to a broad cross section of the healthcare industry. An example of the Partnership's activity was the establishment of a clearinghouse for information related to the effect of Y2K computer issues on medical devices. The NPSP also called public and industry attention to Preventable Adverse Drug Events and promulgated simple actions that patients, providers, purchasers and organizations could take to minimize their chance of an adverse drug event. The partnership serves as a model of what a private-public collaboration can do to improve patient safety.

In 1998, VA created the National Center for Patient Safety (NCPS) to lead and integrate the patient safety efforts for VA. As the IOM report advises, VA created this center as a commitment to patient safety as a corporate priority with a direct reporting relationship to the Under Secretary for Health. The NCPS employs human factors engineering and safety system approaches in its activities. The first task for the Center was to devise systems to capture, analyze and fix weaknesses in our systems that affect patient safety.

We sought to design reporting systems that would identify adverse events that might be preventable now or in the future. In addition, we sought systems to identify and analyze situations or events that would have resulted in an adverse event if not for either luck or the quick action of a healthcare provider—we call such events "close calls." We believe that "close calls" provide the best opportunity to learn and institute preventive strategies, as they will unmask most system weaknesses before a patient is injured and avoid the liability issues implicit in investigation of injury. This emphasis on "close calls" has been employed by organizations outside of healthcare with great success.

VA consulted with experts (Expert Advisory Panel for Patient Safety System Design) obtaining advice to enhance the design of VA's reporting systems. These experts in the safety field included Dr. Charles Billings, one of the founders of the Aviation Safety Reporting System, as well as other experts from NASA and the academic community. They advised us that an ideal reporting system: (a) must be nonpunitive, voluntary, confidential and de-identified; (b) must make extensive use of narratives; (c) should have interdisciplinary review teams; and (d) most importantly, must focus on identifying vulnerabilities rather than attempting to define rates of error. VA has used these principles to design the patient safety reporting systems we have in use or in development.

Based on the expert advice and on lessons learned from our first generation mandatory adverse event reporting, the NCPS has developed a comprehensive adverse event, close call analysis and corrective action program which includes an end-to-end handling of event reports. This system not only allows for the determination of the root causes, but also captures the corrective actions as well as the concurrence and support of local management for implementation. The system includes a number of innovations such as algorithms and computer aided analysis to determine the root cause of adverse events and close calls. The Joint Commission on Accredita-

tion of Healthcare Organizations and the American Hospital Association are currently evaluating parts of the system for use.

The improved event reporting system is being pilot tested in VA's VISN 8 and VISN 22. Extensive training is used as the new system is introduced to assure full understanding of the search for the root cause and redesign of the system. To date, response from the first pilot site—VISN 8—is positive. The quality managers and clinicians using the system believe that the new methods analysis of error will make a significant difference in the care of veterans.

A complementary, de-identified voluntary reporting system is in the process of being implemented. It is patterned after the highly successful Aviation Reporting System that NASA operates on behalf of the FAA. It will be external to VA and will allow employees and patients to report unsafe occurrences without fear of administrative or other action being taken against them.

Based on lessons learned, VA has promulgated specific procedures and policies aimed at reducing risk of error. These include such things as restricting access to concentrated potassium chloride on patient care units, use of barcode technology for patient identification and blood transfusions in operating rooms, and for verification procedures prior to injection of radio-labeled blood products. Based on the observation of a VA nurse when she returned a rental car, VA developed a system for using wireless bar coding to improve medication administration. That system was piloted at the Topeka VA Medical Center and will be in all VA hospitals by June of this year. At least two-thirds of medication errors can be prevented with this system.

In 1999, VA established four Patient Safety Centers of Inquiry. These Centers conduct research on critical patient safety challenges. Activities at the Centers of Inquiry range from fall prevention and operating room simulators to understanding the role of poor communication in patient safety. The Center in Palo Alto, which is affiliated with Stanford University, is a recognized leader in the area of simulation and has been featured prominently in the media. Their simulated operating room allows surgeons and anesthesiologists to train and do research without endangering a patient. VA expects to create additional simulation facilities to train its physicians and other healthcare professionals. One simulator with appropriate staff could train about 600 anesthesiologists and residents-in-training per year. This means that virtually all VA anesthesiologists/anesthetists can be trained in a year on clinical situations that could not be simulated safely in patients. As a result of analyzing common variations during simulated operations, the center has developed a checklist card of facts that should be kept close at hand. These checklist cards will be attached to all anesthesia machines across VA.

VA is partnering with the Institute for Healthcare Improvement to build learning collaboratives aimed at reducing medication errors, a major issue identified in the Institute of Medicine report. IHI collaboratives will affect several hundred VHA personnel each year. Other IHI collaboratives have resulted in measurable improvements and similar results are anticipated with medication errors.

Another key VA strategy to reduce medical errors involves the development of a new curriculum on safety. VA is moving forward with plans to provide education and training relevant to patient safety not only to those already in practice but also at the medical, nursing, and health professional school level. This will be the first time an extensive safety curriculum will be developed and broadly implemented. VA is particularly well situated to lead the educational effort due to the extensive role it plays in the education of healthcare professionals in the United States. (VA is affiliated with 105 medical schools and up to one-half of all physicians train in a VA facility during medical school or residency.) Additionally, we have instituted a performance goal and measure to provide VA employees 20 hours of training on patient safety this year.

VA instituted a Patient Safety Improvement Awards Program to focus interest on and reward innovations in identifying and fixing system weaknesses. Not only does this produce ideas for patient safety improvements that might otherwise go unnoticed but it further reinforces the importance that VA places on patient safety activities.

In 1995, VA instituted a Performance Measurement System that uses objective measures of patient outcomes to set goals and reward achievement. Since 1998, VA has incorporated a performance goal and measure for its executives for accomplishment in patient safety activities. Last year, each network had to implement three patient safety initiatives to be fully successful and six initiatives to be outstanding.

Other performance goals and measures assess the use of Clinical Practice Guidelines. By holding entire medical centers and geographic networks responsible for measured outcomes, we are able to institute reminder systems and redundancies that lead to dramatic improvements in performance. For example, patients who receive medications known as "beta-blockers" following a heart attack are 43 percent

less likely to die in the subsequent two years and are rehospitalized for heart ailments 22 percent less often. A goal of providing this therapy to 80 percent of eligible patients has been set in the private sector, and recent medical literature reports rates of use as low as only 21 percent in some settings. In the VA, over 94 percent of heart-attack patients receive this life-saving medication.

Another example of the power of using systems rather than relying on individual adherence to clinical guidelines is in immunization. It is estimated that 50% of elderly Americans and other high-risk individuals have not received the pneumococcal pneumonia vaccine despite its demonstrated ability to minimize death and hospitalization. VA's emphasis on preventive healthcare has led to achieving pneumonia vaccination rates that exceed standards set for HMOs by almost 20% and nearly double published community rates. Similar accomplishments have been achieved in providing annual influenza vaccinations.

We believe that patient safety can only be achieved by working towards a "culture of safety." Patient safety improvement requires a new mindset that recognizes that real solutions require an understanding of the "hidden" opportunities behind the more obvious errors. Unfortunately, systems' thinking is not historically rooted in medicine. On the contrary, the field of medicine has typically ascribed errors to individuals and embraced the name-blame-shame-and-train approach to error reduction. Such an approach by its very nature forecloses the opportunity to find systems solutions to problems. Other industries such as aviation have recognized the failings of this approach and over many years have succeeded in transitioning from a similar blame and faultfinding approach to a system-based approach that seeks the root causes of errors. VA realized how pivotal culture is to improving safety and in 1998, conducted a culture survey of a sample of employees. Of interest, the shame of making an error was a more powerful inhibitor of reporting than was fear of punishment. Employees readily forgave mistakes in others but were intolerant of their own. We plan to survey culture broadly in VA for several years to track the progress of our efforts.

VA created a database of adverse events and asked our Medical Inspector to review it. The report has been widely, yet often inaccurately, quoted or critiqued in the media. The database was created to discover common and important adverse events in order to focus our efforts in patient system redesign. Commonly, the media assumed that all the adverse events (and deaths) were due to error. They were not. Neither the report nor the database cataloged which adverse events were preventable with today's state of knowledge and therefore could be characterized as errors. For example, most of the adverse events were falls, suicides and parasuicidal events (attempted suicides, suicide gestures), or medication errors. It is not possible with today's knowledge to operate a national system of nursing homes and acute-care hospitals treating the elderly and chronically ill without a number of falls. Yet, we know that it is important to look for common factors to allow us to reduce the frequency of falls in the future. Similarly, psychiatrists have tried unsuccessfully to predict which patients will commit suicide. By looking at our data we hope to be able to predict high-risk patients in the future and therefore be able to prevent suicides. We have already learned that men with a recent diagnosis of cancer, who live alone and who own a gun, are more likely to commit suicide. We plan to study the use of additional interventions in this subgroup of patients at high risk of suicide.

CONCLUSION

With no successful models in large healthcare systems to guide us, VA turned to other high risk, high performance industries to learn principles for safety. We have borrowed both methods and people from safety-conscious settings such as aviation and space travel and from underutilized disciplines like human factors engineering. These efforts have already produced significant improvements in VA, and we believe will do the same in all healthcare settings.

We would prefer that all of healthcare had begun to address the issue of patient safety long ago. For too long, the emphasis has been on holding individuals accountable and hoping that well-intended and well-educated professionals wouldn't make human mistakes. As the IOM aptly states in the title of its report: "To err is human." We are pleased to be on the leading edge as healthcare takes a systems approach to patient safety. We are anxious to discover new ways to make VA and all healthcare safer. We appreciate your support of these efforts and intend to keep you fully informed of our progress.

ATTACHMENT 1

NCPS HANDBOOK

[DRAFT—NOT FOR GENERAL DISTRIBUTION]

VHA NATIONAL PATIENT SAFETY IMPROVEMENT HANDBOOK

Foreword

It has been reported in the medical literature that as many as 180,000 deaths occur in the United States each year due to errors in medical care, many of which are preventable. In order to take actions that will improve this situation, it is necessary to have a clear picture as to what is actually happening so that appropriate steps can be taken that will prevent such occurrences. For this prevention effort to be effective, it will be necessary to establish methods of gathering and analyzing data from the field that will allow the formation of the most accurate picture possible. It is believed that only by viewing the health care continuum as a "system" can truly meaningful improvements be made. A systems approach that emphasizes prevention, not punishment, as the preferred method to accomplish this goal will be used. Armed with this type of information the most appropriate conclusions can be drawn from which prudent solutions can be formulated, tested, and implemented. Ultimately, this effort can be successful only if emphasis on safety and responsibility for improving it resides at all levels of the organization. This activity requires a true team effort. People on the frontline are usually in the best position to identify a number of issues and their solutions while those in managerial roles are often in positions that allow the implementation and wide dissemination of lessons learned. Only by creating and/or maintaining open lines of communication can the improvements developed be successfully implemented. If we don't work together, real success will not be possible. If we are not receptive to changing our way of doing things, we can't succeed.

What we're talking about here is building a "culture of safety". Such a cultural change does not happen over night. It can only happen as a result of countless efforts on everyone's part to approach the way we look at things differently. We must constantly question if we can do the things in a better, more efficient, and safer manner. We must never let "good enough" be good enough. We must be relentless in our pursuit of finding ways to improve our systems. We don't believe people come to work to do a bad job or make an error, but given the right set of circumstances any of us can make a mistake. We must force ourselves to look past the easy answer that it was someone's fault to answer the tougher question as to why the error occurred. It is seldom a single reason. Through understanding the real underlying causes we can better position ourselves to prevent future occurrences. As has been said, "Experience is the best teacher" but is also one of the most expensive teachers as well. To minimize that expense we must communicate the lessons we learn throughout the system so that others can learn from our experience without forcing them or our patients to learn these same things unnecessarily through their own bitter experience. While we do a good job now and should be proud of the service we provide, there are always ways we can do it better in the future.

The VA is in an exciting position in the field of healthcare. We have the opportunity to lead the way in improving the overall care patients receive through the Patient Safety Initiatives that exist now and that will exist in the future. The impact we can have is enormous but to do this requires courage on our part. I use the word courage because to report events that not only resulted in actual problems but also those situations, referred to as a "close call', where problems were averted but the potential for an actual incident did exist is not the status quo in healthcare or most other industries. It will require us to learn not to look to fix blame but rather to look to answer the questions what, why, and how do we prevent it. This will require trust on everyone's part and that won't and can't happen over night. It will be the product of many small steps and small victories. But to happen at all, we have to have the courage to take the first steps and remain committed to the overall goal of improving safety in the way we provide care to our patients and run our system. We are sailing into uncharted waters and will no doubt have to make many changes as we learn. The important thing is that we begin the journey or else we condemn ourselves and our patients to the realm of "good enough".

JAMES P. BAGIAN, M.D., P.E.
Director, VHA National Center for Patient Safety.

VHA NATIONAL PATIENT SAFETY IMPROVEMENT HANDBOOK

1. Purpose

The Patient Safety Improvement (PSI) Handbook's purpose is to provide a clear roadmap that can be used to guide the VHA in the accomplishment of its goal of minimizing the chance of the occurrence of untoward outcomes consequent to medical care. Through the use of procedures, methods, clarifying examples, and appropriate feedback loops at all levels of the organization (with accompanying rationale) it is hoped that this overall goal can be achieved. Incorporation of a widely understood methodology for dealing with these safety related issues will allow for clearer more rapid communication of information both up and down the organization thus speeding the process of safety improvement. For this to occur, training must take place to complement the contents of this handbook, reading it alone is not sufficient.

2. Scope

This handbook will delineate what type of events are to be considered and how they should be dealt with as well as defining the disposition of events not covered by this handbook. It will also specify the method by which the need for conducting a root cause analysis will be determined and what the procedure for communicating related findings throughout the organization is. These procedures will address the management component as well as the frontline needs.

3. Definitions

a. *Adverse Events*.—Adverse events are untoward incidents, therapeutic misadventures, iatrogenic injuries or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic or other VHA facility. Adverse events may result from acts of commission or omission (e.g., administration of the wrong medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment, etc.). All adverse events require reporting and documentation in the National Patient Safety Registry (NPSR), however, the type of review is determined through the Safety Assessment Code (SAC) Matrix scoring process, as outlined in Appendix SAC. Some examples of more common adverse events include: patient falls, medication errors, procedural errors/complications, completed suicides, parasuicidal behaviors (attempts/gestures/threats), and missing patient events.

b. *Sentinel Events*.—Sentinel events are a type of adverse event. Sentinel events, as defined by JCAHO, are unexpected occurrences involving death or serious physical or psychological injury, or risk thereof. Serious injury specifically includes loss of limb or function. Major permanent loss of function means sensory, motor, physiologic, or intellectual impairment not previously present that requires continued treatment or life-style change. The phrase "risk thereof" includes any process variation for which a recurrence would carry a significant chance of serious adverse outcomes. Sentinel events signal the need for immediate investigation and response. Some examples of sentinel events include: death resulting from a medication error or other treatment related error; suicide of a patient in a setting where they receive around-the-clock care; surgery on the wrong patient or body part regardless of the magnitude of the operation; and hemolytic transfusion reaction involving the administration of blood or blood products having major blood group incompatibilities. (Note: Events considered to be JCAHO "sentinel events" are included in the catastrophic cells of the SAC Matrix.)

c. *Close Calls*.—A close call is an event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention. Such events have also been referred to as "near miss" incidents. An example of Close Calls would be: surgical or other procedure almost performed on the wrong patient due to lapses in verification of patient identification but caught at the last minute by chance. Close Calls are opportunities for learning and afford the chance to develop preventive strategies and actions. Close Calls will receive the same level of scrutiny as adverse events that result in actual injury. All Close Calls require reporting and documentation in the National Patient Safety Registry (often referred to as "the Registry"), however, as for adverse events, the SAC Matrix scoring process and score determines the type of review.

d. *Intentional Unsafe Acts*.—Intentional unsafe acts, as they pertain to patients, are any events that result from: a criminal act; a purposefully unsafe act; an act related to alcohol or substance abuse, impaired provider/staff; or events involving alleged or suspected patient abuse of any kind. Intentional unsafe acts should be dealt with through avenues other than those defined in this handbook (i.e., Administrative Investigation (AI) or other administrative channels as determined by the Fa-

cility Director). Guidance on what to do when criminal acts are suspected is described in paragraph 5.d. Intentional acts will be entered into the National Patient Safety Registry along with the results of any review or investigation as they pertain to patient safety. (This will ensure that preventive patient safety measures, where appropriate, can be shared and/or instituted across VHA.)

e. *Root Cause Analysis (RCA)*.—Root Cause Analysis is a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls. This specific type of focussed review known as a Root Cause Analysis will be the form of focussed review that is used for all adverse event or close calls requiring analysis since it further refines the implementation and increases the quality and consistency of our focussed reviews. To avoid confusion, the term Root Cause Analysis (RCA) will be used to denote this type of focussed review and will adhere to the guidelines provided in this handbook (see Appendix RCA).

NOTE: The term Root Cause Analysis needs to be used in documents so that they will be confidential under Title 38 United States Code (U.S.C.) 5705 and its implementing regulations.

RCAs have the following characteristics:

1. the review is interdisciplinary in nature with involvement of those closest to the process;
2. the analysis focuses primarily on systems and processes rather than individual performance;
3. the analysis digs deeper by asking "what" and "why" until all aspects of the process are reviewed and all contributing factors are (progressing from looking at special causes to common causes), and;
4. the analysis identifies changes that could be made in systems and processes through either redesign or development of new processes or systems that would improve performance and reduce the risk of event or close call recurrence.

To be thorough, an RCA must include:

1. a determination of the human and other factors most directly associated with the event or close call and the processes and systems related to its occurrence; (there is rarely only one underlying cause)
2. analysis of the underlying systems through a series of "why" questions to determine where redesigns might reduce risk;
3. identification of risks and their potential contributions to the event or close call, and;
4. determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist.

To be credible, an RCA must:

1. include participation by the leadership of the organization (this can range from chartering the RCA team, to direct participation on the RCA team, to participation in the determination of the corrective action plan) and by individuals most closely involved in the processes and systems under review;
2. be internally consistent (i.e., not contradict itself or leave obvious questions unanswered), and;
3. include consideration of relevant literature.

Appendix RCA provides details about RCA structure, process and outcomes.

4. Goals

The goals of the PSI Program are to prevent injuries to patients, visitors, and personnel, and to manage those injuries that do occur to minimize the negative consequences to the injured individuals. The way this will be accomplished is by taking small steps in the way we do things so that we establish the level of faith and trust in our system to let these behaviors become a true part of us. This will and should be a never-ending process. In this way a "culture of safety" can be formed. The key building blocks for accomplishing these goals are:

a. Comprehensive identification and reporting of all adverse events, Sentinel Events, and close calls (see paragraph 5).

b. Reviewing adverse events, Sentinel Events, and close calls to identify underlying causes and system changes needed to reduce the likelihood of recurrence (see paragraph 6). The determination of cause will be aimed at the system issues not directed at use as a punitive tool. The requirements for initiating a review will be determined by the priority scheme as defined by the Safety Assessment Code (Appendix SAC).

c. Disseminating patient safety alerts and lessons learned regarding effective system modifications throughout VHA (see paragraph 6) in an effective manner.

d. Prospective analysis of service delivery systems before an adverse event occurs to identify system redesigns that will reduce the likelihood of error.

5. Identification and Reporting of Adverse Events, Sentinel Events, and Close Calls

a. Each VISN will ensure that its designated facility manually or electronically reports at least the following events:

1. Adverse Events (see Definitions, paragraph 3a).
2. Sentinel Events (see Definitions, paragraph 3b).
3. Close Calls (See Definitions, paragraph 3c).

b. Facility staff will also report any unsafe conditions of which they are aware, even though the conditions have not yet resulted in an adverse event or close call. These would include potential system weaknesses that were identified through prospective hypothetical analyses ("what if" types of questions) using techniques such as failure modes and effects analysis (FMEA).

c. Adverse events, Sentinel Events, and Close Calls shall be reported within the facility to the risk manager (or other appropriately designated party) within 24 hours of their detection. The risk manager (RM) will then use the Safety Assessment Code Matrix (SAC) to determine what action is required. This action could range from reporting to the VISN, National Center for Patient Safety (NCPS), and JCAHO with associated RCA performed and corrective action plan, to a decision to do nothing at the present time due to the low priority accorded the event from its SAC score. Appendix SAC details how the SAC score is used and paragraph 6 shows the procedure that will be followed for handling events that are reported along with the associated time constraints and products required as well as to what organization reports will be made. Events affecting personnel, visitors, and groups of patients as well as individual patients are covered here as well. If a safety alert to other facilities seems needed, this should be indicated (this is covered in the Appendix RCA).

If in the course of conducting a RCA it appears that the event under consideration is the result of an Intentional Unsafe Act the RCA team will refer the event to the facility director for appropriate further consideration as is described in paragraph 3.d. above. In such a situation the RCA team will then discontinue their efforts, since the facility director will have assumed the responsibility for any further fact finding or investigation, while still maintaining the information they have already collected confidential as per Title 38 United States Code (U.S.C.) 5705. This means that members of the RCA team in question could not serve on an AI team that might be convened by the facility director to consider this particular issue.

d. If a crime is suspected to have been committed, appropriate officials should be notified as soon as possible by management (see Title 38 Code of Federal Regulations (CFR) Sections 14.560 and 14.563, MP–1, Part I, Chapter 16 and MP–1, Pt. I, Ch. 2, subpar. 208.02). To the extent possible the surrounding area should not be disturbed so that evidence is available for review by the police and other authorities. However, care needed by the patient should always be provided as quickly as possible, regardless of its effect on the site. As required by 38 CFR Sections 14.560 and 14.563, allegations of crimes against the person or property, or other non-fraudulent criminal matters shall be referred to the Regional Counsel, who will then refer the matter to the appropriate law enforcement agency. Serious crimes (felonies or misdemeanors) committed on hospital or domiciliary grounds must be reported directly to the United States Attorney or local agent of the Federal Bureau of Investigation. Allegations of fraud, corruption or other criminal conduct involving VA programs and operations must be referred to the Office of the Inspector General. Notification should also be given to the Deputy Assistant Secretary for Security and Law Enforcement and to the VISN office. The VISN office will inform the CNO.

If a crime is suspected to have been committed, facility security and medical staff may need to assist law enforcement agencies with preserving evidence (e.g., blood alcohol levels, weapons, controlled substances). Local policies and procedures for maintaining the chain of custody of evidence apply in those instances.

e. Staff who submit close call and adverse event reports will receive feedback on the actions being taken as a result of their report. The feedback should be of a timely nature and come from the risk manager (or other appropriately designated party). Prompt feedback to reporters has been credited in other reporting systems with being one of the cornerstones that establishes trust in the system in that it demonstrates the seriousness and commitment on the part of the system to the importance of the reporting effort. The bottom line here is for the reporters to be made acutely aware that their effort of reporting was not just a paperwork drill. The nature of this feedback can range from a simple acknowledgement that the event is under consideration, to providing information as to the corrective action that is planned or has been accomplished.

f. Each VISN and facility will adopt strategies to motivate and facilitate staff identification and reporting of adverse events and close calls, even when staff errors contributed to the event. Emphasis should be placed on the value of close calls in identifying needed system redesigns. Identification and reporting of adverse events and close calls, including those that result from practitioner error, need to be a routine part of everyday practice. Employees need to understand that human errors are commonly due to systems type problems. They especially need to understand that the most conscientious, knowledgeable, and competent professionals can make errors.

g. The National Patient Safety Registry will be used to track and monitor reported events. The field will accomplish initial entry of data into the Registry. This is so the accuracy of the data recorded will be as high as possible and avoids translation and transcription errors that could occur if this function was accomplished at some other level in the organization. Further, it is intended that the data entry should occur at the facility level, where technically possible, for the same reasons as described above.

6. Review and Analysis of Reported Events

a. A procedure has been worked out so that the review and analysis system for handling reports proceeds in an understandable manner and takes into account the various requirements of the VHA and accrediting organizations. The process is schematically outlined in Figure 1.

The following description will "walk you through" the chart above. The first step taken by the RM after any required immediate action is to assign a SAC score (see Appendix SAC) that then defines the further actions that are necessary.

Events receiving a score of 2 or 1 will be acted on as thought appropriate by the facility. You will need to either eliminate, control, or accept the risks associated with these events. These actions can range from performing an RCA to no further action required.

All events receiving a SAC score of 3 will receive either a traditional RCA or an Aggregated Review as described below and the initial report of the event will be entered into the Registry where it can be accessed by the VISN, CNO, and the NCPS.

A quarterly Aggregated Review may be used for three types of events. The three types of events are: falls; medication errors, and; parasuicidal behavior (see Appendix Aggregated Reviews). The use of aggregated analysis serves two important purposes. First, greater utility of the analysis (i.e., trends or patterns not noticeable in individual case analysis are more likely to show up as the number of cases increases). Second, it makes wise use of the RCA team's time and expertise. The NCPS will use this information to compare to other data it has and determine if any immediate action as far as the issuance of alerts, etc. is indicated. It must be noted that any event may be subjected to a traditional RCA even though it is in a category that is permitted to use the aggregated approach if this course of action is thought to be appropriate. Further, events that are in those categories that are eligible for Aggregated Review and have received a SAC score of 3 based on what has occurred rather than a potential/risk thereof will have a RCA performed and not be allowed to use the aggregated approach.

If the event in question is an actual adverse event meeting the JCAHO definition of Reviewable Sentinel Event the facility will then make the determination if they will report it within 5 calendar days of occurrence to the JCAHO (this may entail consultation with other entities, such as the VISN, as is defined by local policy) as is indicated by the first dotted line in the chart. In either case, the event receives an RCA and results are reported to the Registry and if previously reported to the JCAHO, to them as well. The report of the outcome of the RCA will be completed within 45 calendar days and forwarded as described above.

It is worthwhile noting that only two reports might result, that is the one before the RCA is performed and that after the RCA is completed. This was specified so as to reduce the burden on the frontline folks to that which was already required of them to prioritize (SAC score) and do their RCA.

To summarize, facilities have the option to report to JCAHO as explained in JCAHO policy. The RCA report delineated in Appendix RCA will be used and will be retained by the facility even after the results have been entered into the Registry so that they can be made available for future review as required.

The point where the real benefit of this entire process will be realized is after the RCA is completed and the corrective actions that can be taken to prevent the future occurrence of similar events are defined and implemented. These corrective actions will fall into the categories of eliminate, control, or accept and the rationale for selecting one approach over another should be documented. Once implemented, a plan for evaluating the effectiveness of the implemented change must be enacted to in-

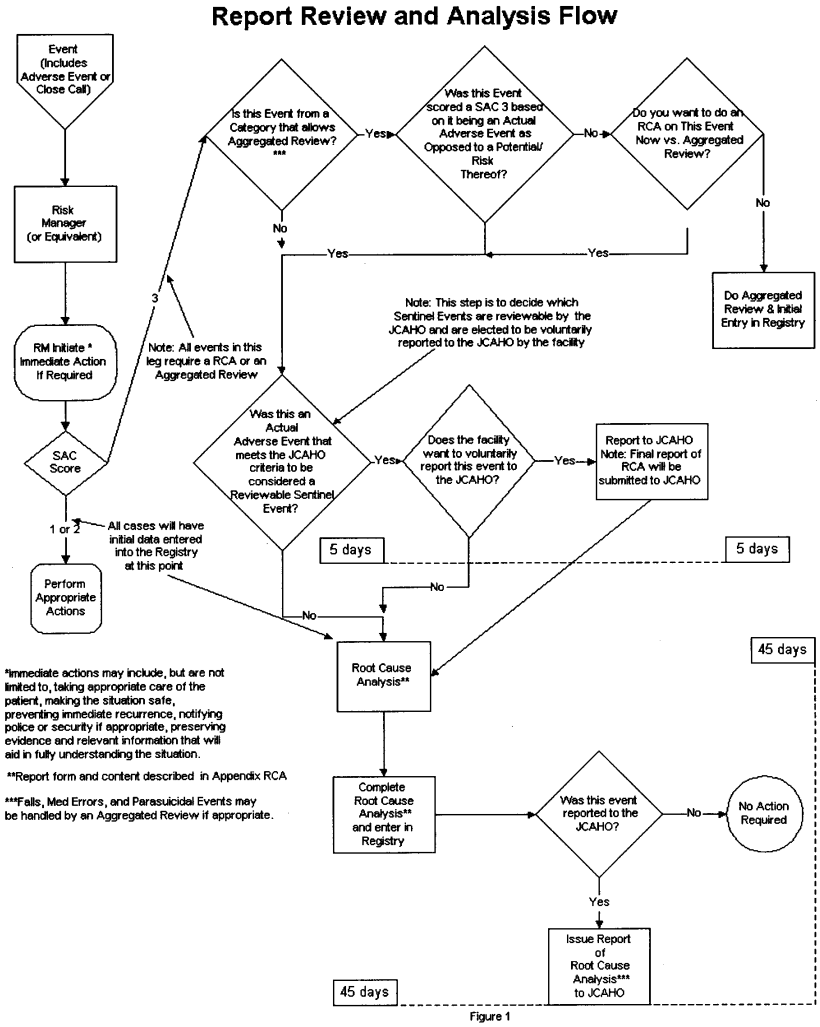


Figure 1

sure that this change has the desired effect and the subsequent results communicated to the VISN and NCPS (see Figure 2) through entry in the Registry or other appropriate means.

As noted above, all events will be entered into the Registry. In this way all events reported will be captured in the Registry even if they have SAC scores less than 3 while remembering that 3's will receive RCA's as described above. Accordingly, the opportunity will then exist to better understand the system and appropriately focus our attentions in the future.

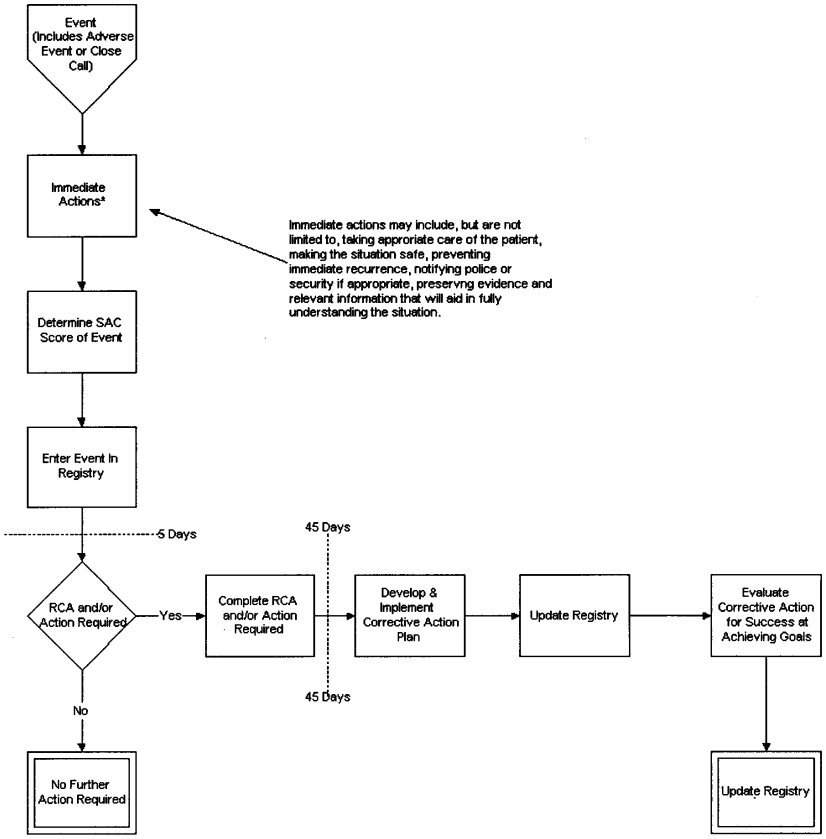
b. The NCPS will be responsible for disseminating the lessons learned and alerts from the RCAs and the Registry. The NCPS will also develop methods that the field may find advantageous to implement based on this and other information.

c. The NCPS will chair the PSI Oversight Committee (PSIOC) which will be comprised, at a minimum, of a representative of Office of Quality and Performance (OQP), Office of Medical Inspector (OMI), Chief Network Officer (CNO), and Patient Care Services (PCS). This committee will meet monthly to:

1. Review data from the registry for trends.
2. Review RCAs and AIs of selected cases from the Registry where indicated to guide future policy development.

Figure 2

Overview of Work Flow for Event Reporting and Follow-up



3. Review selected process improvements for general applicability and disposition.

4. Recommend topics that deserve further examination or issues that require further action. This could include recommendation of quality or performance measures to address issues that have been identified.

5. Assign follow-up responsibility for issues identified in activities (1) through (4). Note: The input of subject matter experts will be obtained as needed.

d. The Office of Medical Inspector shall monitor RCAs and AIs to assess their adequacy and to identify problems with processes of care which warrant attention. The OMI may conduct reviews and site visits at the request of the Secretary of Veterans Affairs, the Under Secretary for Health, the Deputy Under Secretary for Health, the Inspector General, veterans and their families, the VISNs and medical facilities, and other stakeholders, such as Congress and Veterans Service Organizations. The OMI also may conduct reviews and site visits based on its own judgement.

7. INFORMING PATIENTS ABOUT ADVERSE EVENTS

a. Background Information

1. VHA is obligated to inform patients and their families, only as authorized by applicable confidentiality statutes, about injuries resulting from adverse events and the options available to them. There is also evidence that patients desire acknowledgment of errors from their caregivers and that doing so reduces

the likelihood that patients will take legal or administrative action. Any information disclosed must not come from documents and data protected by Title 38, United States Code (U.S.C.), Section 5705. Also, in addition to the restrictions dictated by the Privacy Act, certain information generally cannot be revealed even after a patient's death under 38 U.S.C. Section 7332, and includes information related to the patient's treatment for substance abuse (including alcohol), sickle cell anemia disease, and HIV status.) Furthermore, the patient's name and home address cannot be released under certain circumstances to individuals other than the patient. Questions about release of information to the patient and the patient's family should be referred to the facility's Health Information Service, who may consult with the Regional Counsel, where applicable.

2. The two primary options available to injured patients or their survivors are claims for compensation under 38 U.S.C., Chapter 11, Section 1151, and tort claims under the Federal Tort Claims Act, Title 28 U.S.C., sections 1346 (b), 2671–2680.

(a) Claims under 38 U.S.C. Section can result in payment of monthly benefits for additional disability or death incurred as the result of VHA facility care, medical or surgical treatment or examination, if the disability or death was proximately caused by negligence or an unforeseen event. Claims under section 1151 provide for the payment of a monthly benefit based on the percentage of disability and eligibility for VA medical care. Claims for 1151 benefits are processed by VBA Regional Offices.

(b) Tort claims may result in a settlement by Regional Counsels, General Counsel, United States Attorney, or in a judgement if a Federal court determines that negligence by medical practitioners caused injury or death (and jurisdictional requirements are met). The claimant frequently receives money in a lump sum payment, but structured settlements, which can include annuities, medical trusts, future payments, and reversionary interests, are also used where appropriate. Tort claims can result in monetary awards for pain and suffering, which are not necessarily included in veterans benefits. Tort settlements or judgements can also be used to provide for family members in ways that veterans benefits statutes do not allow. However, an attorney is usually retained, and attorney fees capped at 20 (administrative settlements) to 25 (litigation) percent of the damages reduce the award the veteran or survivors receive. Tort claims are processed by the Regional Counsels.

(c) Veterans and survivors may pursue both section 1151 and tort claims. However, if both claims are successful, 38 U.S.C. Section 1151 benefits will be offset until the amount that would have been paid equals the amount of the tort claim settlement or judgement.

b. Communication with Patients Regarding Adverse Events

1. VISNs will ensure that their facilities have a process in place to promptly inform patients and their families, consistent with the legal requirements and restrictions as stated in paragraph 7.a. above, about pertinent clinical facts associated with injuries resulting from adverse events, assuring them that measures have been taken to maintain life and minimize disability and discomfort. Typically the attending physician or designated member of the treatment team will be the ones to communicate with the patients or family initially.

2. VISNs and facilities will ensure that their staff provide appropriate and timely communication with patients and their families regarding adverse events that involve potential organizational liability. Potential organizational liability should be assessed based on discussions with practitioners and the Regional Counsel. The patients and their families shall be advised of appropriate remedial options. These options should include locally available interventions (e.g., arranging for second opinions, expediting clinical consultations, inpatient admission) and referral of patients to the 38 U.S.C. Section 1151 claims process and the tort claims process.

3. One mechanism to facilitate such communication is a standing PSI group, e.g., the Chief of Staff or designee, Regional Counsel, Veteran's Benefit Counselor, patient representative, and PSI staff, that assesses liability issues and coordinates conferences with patients and families. To provide prompt responses, the group needs to be able to meet on short notice. Another approach is to have PSI staff assume these responsibilities with support and consultation from facility management and Regional Counsel.

4. A collaborative relationship between Regional Counsel and VA medical center staff is necessary to ensure that appropriate and timely communication with patients occurs. Each VISN should ensure that their staffs develop an understanding with its Regional Counsel regarding the procedures for obtaining Regional Counsel input prior to discussing an adverse event with a patient.

8. TORT CLAIMS

a. Each facility shall ensure that its staff conduct peer reviews of all new tort claims and share the findings with their Regional Counsel.

b. State licensing board and National Practitioner Data Bank issues will be coordinated with the office of the Director of Medical/Legal Affairs.

APPENDIX—CLOSE CALL SYSTEM DEFINITIONS

WHAT IS A CLOSE CALL?

1. A close call is an event or situation that could have resulted in an accident, injury or illness, but did not. Close calls can involve patients, staff or visitors. Close calls can occur in patient care settings and anywhere else in a VA facility.

2. We have all experienced close calls on the job. A few examples are listed below.

—A nurse almost gives an overdose of insulin, but recognizes and prevents the error when double-checking the order. (During the double check, they realize that they had confused the "U", for units, with a "0".)

—An environmental management employee notices a jug of industrial strength cleaner mistakenly left in the shower stall on a locked psychiatric unit. They return it to proper storage before any patient can use it inappropriately.

—On the way to the parking lot, a motor pool employee notices that a barricade, preventing anyone from using a sidewalk under repair, has fallen down and been shoved aside. The employee replaces the barricade and then notifies engineering service of the hazardous situation before anyone trips and falls.

WHAT IS NOT A CLOSE CALL?

1. There are a few events or situations that are not close calls. These events or situations are handled through administrative review or investigation. These excluded events or situations are: Intentionally unsafe acts; Criminal acts; Acts related to alcohol or substance abuse, impaired provider/staff; and Events involving alleged or sustained patient abuse.

APPENDIX—THE JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS' (JCAHO) DEFINITION OF REVIEWABLE SENTINEL EVENTS THAT MAY BE REPORTED TO JCAHO

The following criteria define the subset of sentinel events that are voluntary reportable, at the facility's discretion to the Joint Commission. Only those sentinel events that affect recipients of care (patients, clients, and residents) and that meet the following criteria fall into this category:

1. The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition,[1] [2] or

2. The event is one of the following (even if the outcome was not death or major permanent loss of function):

a. Suicide of a patient in a setting where the patient receives around-the-clock care (e.g., hospital, residential treatment center, crisis stabilization center).

b. Infant abduction or discharge to the wrong family.

c. Rape.[3]

d. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities.

e. Surgery on the wrong patient or wrong body part.[4]

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[1] A distinction is made between an adverse outcome that is related to the natural course of the patient's illness or underlying condition (not reviewable under the Sentinel Event Policy) and a death or major permanent loss of function that is associated with the treatment, or lack of treatment, of that condition (reviewable).

[2] "Major permanent loss of function" means sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or life-style change. When 'major permanent loss of function' cannot be immediately determined, applicability of this policy is not established until either the patient is discharged with continued major loss of function, or 2 weeks have elapsed with persistent major loss of function, whichever occurs first.

[3] The determination of "rape" is to be based on the healthcare organization's definition, consistent with applicable law and regulation. An allegation of rape is not reviewable under the policy. Applicability of the policy is established when a determination is made that a rape has occurred.

[4] All events of surgery on the wrong patient or wrong body part are reviewable under the policy, regardless of the magnitude of the procedure.

Note: As JCAHO policies are dynamic, it is important to be sure that the most recent JCAHO Sentinel Event Policies and definitions are used in making any determination.

APPENDIX—AGGREGATED REVIEWS—FALLS, MEDICATION ERRORS AND PARASUICIDAL BEHAVIOR

Background.—Quarterly Aggregated Reviews, completed within 45 days of the end of the quarter and conducted by a chartered RCA Teams, may be used for three types of reported events or close calls (potential 3s). All actual SAC 3s require individual RCAs. The three types of aggregated reviews are: falls; medication errors, and; parasuicidal behaviors.

The use of Aggregated Reviews serves two important purposes. First, greater utility of the analysis (i.e., trends or patterns not noticeable in individual case analysis are more likely to show up as the number of cases increases). Second, it makes wise use of the RCA Team's time and expertise.

Of course, a facility may elect to perform an individual RCA rather than an Aggregated Review on any of these three types of adverse events or close calls that they think merits that attention, regardless of the actual SAC score.

A tailored real-time minimum data set (Aggregated Review Log) will be compiled for falls, medication errors and parasuicidal behaviors by designated staff in follow-up to reported events or close calls, during each quarter. Capturing this data may require medical record review, medication administration record review, and brief discussion with staff members most knowledgeable about the events or close calls. The Aggregated Review Logs will be provided to the designated RCA Teams as soon as they are convened, and will serve as their initial data source. (By using these logs, the RCA Teams may not routinely need to retrospectively consult individual patient profiles or individual medical records.)

It is anticipated that by utilizing this aggregated approach and building the reviews over succeeding quarters, common themes may be more readily identified and the effectiveness of actions taken to prevent these events or close calls from happening again may be more easily evaluated.

Descriptions of each Aggregated Review Log are provided below, and copies of the Logs are attached to this Appendix.

Falls.—Falls are defined according to local/facility definition.

An individual RCA will be performed for any reported inpatient or outpatient fall occurring on facility property that results in an actual SAC 3, for all enrolled patients.

Reported falls and close calls on facility property (potential 3s) involving enrolled patients will be included in an Aggregated Review on a quarterly basis (completed by the RCA Team within 45 days after the end of the quarter). These Aggregated Reviews will be entered in the Registry.

The following elements are included in the Falls Aggregated Review Log:

—Case (1 . . . X)

—ID# (First Initial, Last Initial, last 4 SSN)

—Age

—Sex

—Event (Day, Date, Time)

—OPT or INPT/Unit (designation of inpatient or outpatient status at time of event, and if inpatient, unit where the patient was assigned at the time of the event)

—Functional & Cognitive Factors (a listing of factors related to falls, requires a "yes"/"no" response for all applicable items: prior fall; designation as "high risk" for falls; needs assistance with ADLs mobility, transfer, toileting, dressing, eating; gait or balance limitations; incontinent; confused/memory limitations; related medical conditions; medication effect, and; other)

—Assistive Devices (a listing of devices related to falls, requires a "yes"/"no" response for all applicable items: cane; crutches; transfer device; walker; wheelchair; bathing device; mechanical lift; eye glasses; hearing aid, and; other)

—Communication Issues (a short list of areas where communication or information exchange can break down, requires a "yes"/"no" response for all applicable items: staff to staff; staff to patient, and; staff to family/other)

—Environmental Factors (a listing of physical plant issues related to falls, requires a "yes"/"no" response for all applicable items: use of restraints; use of protective devices; inadequate footwear; bed siderails; floor condition; obstacles; fall while the patient was reaching for a needed item; inadequate patient or family/other education; unfamiliarity with the environment; inadequate lighting, and; other)

—What Happened & Treatment Plan Changes (free narrative)
—Comments (free narrative)

Medication Errors.—Medication errors are defined according to local/facility definition.

An individual RCA will be performed for any reported inpatient or outpatient medication error that results in an actual SAC 3, for all enrolled patients.

Reported medication errors or close calls (potential 3s) involving enrolled patients will be included in an Aggregated Review on a quarterly basis (completed by the RCA Team within 45 days after the end of the quarter). These Aggregated Reviews will be entered in the Registry.

The following elements are included in the Medication Aggregated Review Log:
—Case (1 . . . X)
—ID# (First Initial, Last Initial, last 4 SSN)
—Age
—Sex
—Event (Day, Date, Time)
—OPT or INPT/Unit (designation of inpatient or outpatient status at time of event, and if inpatient, unit where the patient was assigned at the time of the event)
—Processes Related to Event (a listing of key steps in the medication process, requires a "yes"/"no" response for all applicable items: ordering; transcribing; dispensing; administering, and; documenting)
—What Happened? (a listing of medication errors, requires a "yes"/"no" response for all applicable items: medication given despite known allergy; omission; overdose; incorrect patient identification; incorrect medication identification; incorrect dose; incorrect route; incorrect schedule, and; equipment failure)
—Medication (name/dose/route/schedule for the correct medication, and, the actual/close call medication)
—Treatment Plan Changes (free narrative)
—Comments (free narrative)

Parasuicidal Behaviors.—There are two primary categories of suicidal events: completed suicides, and; parasuicidal events (i.e., any suicidal behavior with or without physical injury—short of death—including the full range of known or reported attempts, gestures and threats).

An individual RCA will be performed for any completed inpatient suicide (at the time it occurs) and for any completed outpatient suicide (at the time of facility notification) for all enrolled patients. In other words, all actual known suicides of enrolled patients will receive a RCA. And, all actual known suicides of enrolled patients will be reported in the Registry.

All reported parasuicidal events or close calls (potential 3s) involving enrolled patients will be included in an Aggregated Review on a quarterly basis (completed by the RCA Team within 45 days after the end of the quarter). These Aggregated Reviews will be entered in the Registry.

The following elements are included in the Parasuicidal Aggregated Review Log:
—Case (1 . . . X)
—ID# (First initial, Last initial, last 4 SSN)
—Age
—Sex
—Event (Day, Date, Time)
—OPT or INPT/Unit (designation of inpatient or outpatient status at the time of event, and if inpatient, unit where the patient was assigned at the time of the event)
—Date of Last OPT TX (date of most recent prior outpatient treatment, this does not include an appointment that was scheduled but was a "no show")
—Diagnoses (a listing of current/active diagnoses)
—Tx Team (a short list of treatment team options, for providers that were assigned to the patient at the time of the event, requires a "yes"/"no" response for all applicable items: mental health/psychiatry; specialty/sub-specialty, and; primary care)
—What Happened? (free narrative)
—Family & Other Supports (free narrative)
—Treatment Plan Changes (free narrative)
—Comments (free narrative)

Appendix—Safety Assessment Code (SAC) Matrix

Severity Categories

Key factors for the severity categories are: extent of injury; length of stay; level of care required for remedy, and; actual or estimated physical plant costs. These four categories apply to actual adverse events and potential events (close calls). For actual adverse events, assign severity based on the patient's actual condition.

If the event is a close call, assign severity based on the most likely "worst case", systems level scenario. (For example, if you entered a patient's room before they were able to complete a lethal suicide attempt, the event is catastrophic, because the most likely "worst case" is suicide.)

Catastrophic	Major
Patients with Actual or Potential: Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying condition (i.e., acts of commission or omission). Suicide (inpatient or outpatient) Rape Hemolytic transfusion reaction Surgery/Procedure on the wrong patient or wrong body part Infant abduction or infant discharge to the wrong family Death or major permanent loss of function that is a direct result of injuries sustained in a fall; or associated with an unauthorized departure from an around-the-clock treatment setting; or the result of an assault or other crime	Patients with Actual or Potential: Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying conditions (i.e., acts of commission or omission). Disfigurement Surgical intervention required Increased length of stay of more than 3 patients Increased level of care for more than 3 patients
Visitors and Staff: Death; or Hospitalization of 3 or more (includes outpatients) [1]	Visitors More than 3 visitors requiring evaluation and treatment Staff More than 3 lost time or restricted duty injuries or illnesses Equipment or facility Damage more than $100,000 [2]

Moderate	Minor
Patients with Actual or Potential: Increased length of stay for up to three patients; or Increased level of care for up to three patients.	Patients with Actual or Potential: No increased length of stay or increased level of care
Visitors Evaluation and treatment for up to three visitors.	Visitors Evaluated and no treatment required or refused treatment
Staff Less than three lost time or restricted duty injuries or illnesses.	Staff No lost time or restricted duty injuries or illnesses
Equipment or facility Damage more than $10,000 but less than $100,000.	Equipment or facility Damage less than $10,000

[1] 29 CFR 1960.70 requires each federal agency to notify OSHA within 8 hours of a work-related incident which results in the death of an employee or the in-patient hospitalization of 3 or more employees.

[2] The Safe Medical Devices Act of 1990 requires reporting of all incidents in which a medical device may have caused or contributed to the death, serious injury, or serious illness of a patient or another individual.

Probability Categories

Like the severity categories, the probability categories apply to actual adverse events and close calls.

In order to assign a probability rating for an adverse event or close call, it is ideal to know often it occurs at your facility. Sometimes, the data will be easily available because it is routinely tracked (e.g., falls with injury, medication errors, etc.). Sometimes, getting a feel for the probability of events which are not routinely tracked will mean asking for a quick or informal opinion from staff most familiar with those events. Sometimes it will have to be your best educated guess.

HOW THE SAC MATRIX LOOKS

Severity & Probability	Catastrophic	Major	Moderate	Minor
Frequent	3	3	2	1
Occasional	3	2	1	1
Uncommon	3	2	1	1
Remote	3	2	1	1

Frequent—Likely to occur immediately or within a short period of time (may happen several times in 1 year).

Occasional—Probably will occur in time (may happen several times in 1 to 2 years).

Uncommon—Possible to occur in time (may happen sometime in 2 to 5 years).

Remote—Unlikely to occur (may happen sometime in 5 to 30 years).

How the SAC Matrix Works:

When you pair a severity category with a probability category for either an actual event or close call, you will get a ranked matrix score (3 = highest risk, 2 = intermediate risk, 1 = lowest risk). These ranks, or Safety Assessment Codes (SACs) can then be used for doing comparative analysis, and, for deciding who needs to be notified about the event.

Notes:

1. All known reporters of events, regardless of SAC score (1, 2, or 3), will receive appropriate and timely feedback.
2. The Risk Manager (or designee) will refer adverse events or close calls related solely to staff, visitors or equipment/facility damage to relevant facility experts or services on a timely basis, for assessment and resolution of those situations.
3. A quarterly Aggregated Root Cause Analysis may be used for three types of calls (this includes all events or close calls other than actual SAC 3s, since all actual SAC 3s require an individual RCA). These three types are: falls; medication errors, and; parasuicidal behavior. The use of aggregated analysis serves two important purposes. First, greater utility of the analysis (i.e., trends or patterns not noticeable in individual case analysis are more likely to show up as the number of cases increases). Second, it makes wise use of the RCA team's time and expertise.

Of course, the facility may elect to perform an individual RCA rather than Aggregated Review on any adverse event or close call that they think merits that attention, regardless of the SAC score.

ATTACHMENT 2

NATIONAL PATIENT SAFETY PARTNERSHIP STATEMENT REGARDING ITS INITIATIVE TO REDUCE PREVENTABLE ADVERSE DRUG EVENTS—MAY 12, 1999

Various studies have shown that adverse drug experiences or events affect between 2 and 35 percent of hospitalized patients. Preventable adverse drug events represent a significant subset of these, if not a large majority of them. Little is known about the incidence of adverse drug events in outpatients, although they have been shown to be a significant cause of hospitalization and, consequently, increased health care costs. Indeed, adverse drug events are a cause of increased healthcare costs in all care settings.

For this initiative, a preventable adverse drug event (PDE)[5] is defined as an event that can be anticipated and forestalled and that will cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding

[5] The differences between a PDE and the Food and Drug Administration's (FDA) broader statutory definition of an adverse drug experience or event should be recognized. The National Patient Safety Partnership's principal interest is advancing practices that prevent adverse events whereas the FDA's principal interest is understanding drug/drug interactions and the biologic activity of drugs so they are fully labeled. At 21 CFR section 314.80 FDA defines an adverse drug experience as any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.

or dispensing; distribution; administration; education; monitoring; and use.[6] Overall, PDEs are a serious public health and medical care problem because of the large number of drugs, doses, and drug treatment regimens currently available and the many changes in the manner that healthcare is provided today.

The National Patient Safety Partnership is a public-private partnership dedicated to improving healthcare in general and patient safety in particular by reducing adverse events and untoward outcomes of healthcare or healthcare-related processes. The members of the Partnership believe there are significant patient safety improvements that can be made through the prevention of avoidable adverse events associated with the prescribing, dispensing and administering of medications.

The members of the National Patient Safety Partnership believe that prevention of medication-related adverse events will be maximized when the outcomes of specific actions for improvement can be reliably predicted based on a strong body of evidence. It realizes that the current evidence base needs strengthening and believes that iterative improvement accompanied by outcomes analysis can advance the state of the science toward that goal. Based on current knowledge, the Partnership has identified a number of "best practices" or "model practices" that could substantially reduce the potential for occurrence of PDEs, and the Partnership calls on healthcare consumers, patient advocacy groups, the pharmaceutical industry, healthcare practitioners and healthcare organizations to make a commitment to adopt the practices listed below and to work together to implement them, as well as to develop additional ways to reduce PDEs.

MODEL PRACTICES TO PREVENT ADVERSE DRUG EVENTS [7]

Current Best Practices For Patients/Consumers

The members of the National Patient Safety Partnership believe that all patients should be actively involved in their care and decisions concerning their care. There are many actions that patients can take, but the following two are stressed as ways to ensure that medication-related information is exchanged in a way that increases the probability of safe care.

1. Patients (or their personal advocates) should always inform their physician or other healthcare practitioner of all medications they are taking (NB: This includes prescription medication, over-the-counter medication and dietary supplements.) as well as about any and all allergies or previous adverse drug experiences they have experienced before accepting any new medication. Patients should not assume that information previously provided has been communicated or has been considered prior to a medication being prescribed or administered.

2. Patients (or their personal advocates) should request information about medications in terms that they can understand, both at the time the medication(s) is/are being prescribed and when they are received. This applies to prescription and over-the-counter medications. Patients should ask for information about the intended use or purpose of the drug, possible drug-drug interactions, potential hazards associated with taking several medicines (e.g., more than 3 drugs at the same time), and about changes in the appearance of any medications they have been taking (such as when a prescription refill is a different color from what had previously been taken). Before accepting or receiving a prescription, the patient should always ask the following questions:

—Is this the drug my doctor (or other health care provider) ordered? What is the trade and generic name of the medication?
—What is the drug for? What is it supposed to do?
—How and when am I supposed to take it and for how long?
—What are the likely side effects? What do I do if they occur?
—Is this new medication safe to take with other over-the-counter or prescription medications, or dietary supplements, that I am already taking? What food, drink, activities, dietary supplements or other medication should be avoided while taking this medication?

In addition, at the time prescription medications are received from pharmacies, patients should ask if the drug they are receiving is the one their doctor or other

[6] Adapted from the USP Quality Review—Definition of Medication Errors.

[7] The ordering of these "Best Practices" is not intended to suggest relative importance. The "Best Practices" are identified on the basis of eight techniques or criteria that have been shown to be important in reducing errors in general and medication errors in particular. The eight criteria are (1) ensuring timely access to information; (2) standardization; (3) simplification; (4) reduced reliance on memory; (5) reduced reliance on practitioner vigilance; (6) broad application; (7) cost effectiveness of the intervention; and (8) established success of the intervention. The 16 practices are used in the Institute for Healthcare Improvement Breakthrough Series.

health care provider ordered and ask that both the trade and generic names be listed on the prescription label.

Current Best Practices For Providing Organizations and Practitioners

The members of the National Patient Safety Partnership believe that healthcare organizations and practitioners are committed to safeguarding patients and call upon both organizations and individual practitioners to further advance the following practices and to support and advocate for these actions in areas and organizations in which they are not utilized.

3. Educate patients, family members and other caregivers about all medications (both prescription and over-the-counter, including dietary supplements) that are used. (Emphasis should be placed on the hazards of polypharmacy, drug-drug interactions and possible adverse effects.) Patients and caregivers should be encouraged to ask for information about all medications and dietary supplements, especially when new medications are prescribed or changes in medications are made.

4. Prominently display critical patient information, such as drug allergies and medication regimens, on every patient record.

5. Emphasize the need for dose adjustment in children and elderly patients. In some elderly patients, a reduction in dose may be required because of age-related changes in body mass and organ function.

6. Limit accessibility to and control the use of highly toxic or other high-hazard drugs such as potassium chloride or concentrated epinephrine.

7. Insist on the development and use of protocols for highly toxic or hazardous drugs or those with a narrow therapeutic range. (Computerized drug order entry systems can be especially important in facilitating this with alerts, restrictions or suggestions for safer substitutes.)

8. Computerize drug order entry whenever possible. If computerized drug order entry is not feasible, then use pre-printed order forms for drugs in inpatient settings and, where appropriate, in ambulatory care settings.

9. Utilize pharmacy-based intravenous (IV) admixture programs.

10. Avoid the use of abbreviations whenever possible; if abbreviations are used, they should be standardized throughout the organization and their use minimized.

11. Standardize approaches and processes for drug storage locations, internal packaging or labeling and delivery, and require use of the standardized approaches and processes.

12. Use unit dose drug distribution systems for inpatient care; also use such systems for outpatient care, where appropriate.

Current Best Practices For Purchasers

The members of the National Patient Safety Partnership believe that while most of these practices advocated in this initiative would cost little or nothing to implement, they do recognize that an investment will be required for some and call upon healthcare organizations and the pharmaceutical industry to make any needed investment in the interest of patient safety.

13. Require machine-readable labeling, such as a barcoding system, complete with pertinent information such as lot number and expiration date.

14. Preferentially purchase products that have labels with name of drug, concentration and warnings prominently displayed and that otherwise incorporate human factors evaluation into naming, labeling and packaging processes. (For example, the use of large type or contrasting colors to avoid look-alike packaging or unheeded warnings.)

15. Preferentially purchase and utilize "unit of use" packaging in inpatient settings; also use such packaging in outpatient (ambulatory care) settings, where appropriate.

16. Preferentially purchase intravenous (IV) solutions with contents and concentration prominently displayed on both sides of the container.

Even Better Practices in the Future

Finally, the members of the National Patient Safety Partnership believe it is imperative that the healthcare and pharmaceutical industries launch and sustain collaborations directed toward systematic approaches to the prevention of PDEs. The Partnership challenges these industries to seek opportunities for research and to seek collaborations to identify better practices in the future, to prioritize practice interventions, and to define practices that can predictably effect improvement in terms of increased safety and cost-effectiveness. Integral to such an activity is a non-punitive culture that encourages reporting of adverse or unexpected events to relevant oversight bodies, including internal quality management systems and regulatory agencies, and that provides feedback about resulting lessons learned and system changes aimed at preventing future such events. To be truly successful these

activities must be ongoing since no solution that is found to any problem can be thought of as the "solution for all time". A spirit of continual and relentless examination and reexamination will be necessary to insure that our processes and techniques are appropriate today and that they continue to evolve as necessary to be appropriate in the future as well.

ATTACHMENT 3

VHA DIRECTIVE 99–031—JULY 14, 1999

THE AVAILABILITY OF POTASSIUM CHLORIDE FOR INJECTION CONCENTRATE USP

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy regarding the use of potassium chloride for injection concentrate USP.

2. BACKGROUND

a. In recent years, numerous reports have been published in the medical literature of adverse events and deaths caused by errors in the use of potassium chloride for injection concentrate USP. This matter has been discussed on numerous VHA Headquarters pharmacy conference calls. Many facilities have already removed potassium chloride for injection concentrate USP and other hypertonic injectables from patient care areas.

b. VHA policy requires that a pharmacy-managed IV admixture program be responsible for the labeling, preparation, and distribution of IV admixtures. Understanding that some IV admixtures may not be prepared by the Pharmacy Service, practices and policies must be in place to ensure the IV admixtures not prepared by the Pharmacy Service are compatible with the policies that govern the pharmacy-prepared IV admixtures.

3. POLICY: VHA policy regarding potassium chloride for injection concentrate USP is as follows:

a. Potassium chloride for injection concentrate USP will not be stored on any wards, intensive care units, surgical suites and similar sites as ward stock.

b. Potassium chloride for injection concentrate USP will only be utilized as part of a pharmacy-managed IV admixture program; therefore, storage of the medication will be in the pharmacy and is the responsibility of the Pharmacy Service.

c. To meet patient needs, the use of manufactured "pre-mixed" large volume solutions, including those with potassium chloride, may be used in conjunction with a pharmacy-managed IV admixture program.

4. ACTION

a. All Department of Veterans Affairs (VA) medical facilities will ensure that any potassium chloride for injection concentrate USP is removed from all wards, intensive care units, operating suites, and clinics.

b. All VA medical facilities will establish medication use policies that include guidance regarding safe handling of potassium chloride for injection concentrate USP. Additionally, these policies shall specifically state that it is VA policy not to have potassium chloride for injection concentrate USP and other hypertonic injectable solutions on the wards and similar sites, that normal or routine VA practice is for IV solutions to be mixed centrally, that cardioplegic solutions are prepared by, or supplied by, Pharmacy Service only, and that unit dose drug distribution is required for inpatient areas.

c. At VA medical facilities that perform heart transplant and open heart surgery, cardioplegic solutions are to be prepared by, or supplied by, the Pharmacy Service.

(1) Those solutions prepared by Pharmacy Service will be hand-delivered to the operating room (OR) by Pharmacy Service. These solutions are to be clearly labeled, "For Cardioplegia Only" and contain the patient's name. They may be secured in one location in, or adjacent to, the cardiac surgery suite, i.e., the OR automatic medication dispensing machine or the locked perfusionist's cabinet. Access is to be limited to the cardiac surgeon, cardiac anesthetist and/or cardiopulmonary bypass technician (perfusionist) and the OR pharmacist.

(2) The Chief, Anesthesia Service is responsible for:

(a) Identifying the secure location in the cardiac surgery suite;

(b) Assuring that access is limited to those individuals requiring access to this highly concentrated therapeutic agent;

(c) Ascertaining that the correct solution is used in the correct patient (as in the use of blood or blood products);

(d) Providing for the disposition of any unused cardioplegic solutions; and

(e) Developing, publishing, and maintaining a local policy that assures the accountability and safety of the drug.

5. REFERENCE: None.
6. FOLLOW-UP RESPONSIBILITY: The Chief Consultant for Pharmacy Benefits Management Strategic Healthcare Group (119) is responsible for the contents of this directive.
7. RESCISSIONS: Directive 98–026, is rescinded. This VHA Directive expires July 31, 2004.

THOMAS L. GARTHWAITE, M.D.
Acting Under Secretary for Health.

ATTACHMENT 4

VHA DIRECTIVE 98–049—NOVEMBER 5, 1998

BAR CODING PATIENT WRISTBANDS

1. PURPOSE: This Veterans Health Administration (VHA) Directive defines policy for bar coding a patient's full social security number on the patient identification wristband.
2. BACKGROUND: The requirements for a Blood Product Verification function, in response to a working group review of "system" changes which would reduce blood transfusion errors in the operating room, have been developed. The group proposed that a universal identifier be bar coded onto the patient identification wristband. A revision to the Veterans Information Systems Technology Architecture (VistA) Surgery software package necessitated that as of February 1, 1998, a bar code that displays the patient's full social security number must be printed onto the patient identification wristband.
3. POLICY: It is VHA policy to issue to each patient on hospital admission a patient identification wristband on which there is a printed bar code displaying the patient's full social security number.
4. ACTION
a. All patients reporting for hospital admission or ambulatory surgery must be issued a patient identification wristband that contains the patient's full name, social security number and a bar code that displays the patient's full social security number.
b. Printers capable of generating wristband bar codes must be installed in locations that process patients for hospital admission and ambulatory surgery.
c. Additional information, e.g., ward designation, is optional. If the ward designation is used, it will refer only to the ward identification and will not reference the professional service specialty.
4. REFERENCES: VHA Manual M–1, Part I, Chapter 4.
5. FOLLOW-UP RESPONSIBILITIES: The Director, Health Administration Service (10C3), is responsible for the contents of this VHA Directive.
6. RESCISSIONS: VHA Directive 97–064 is rescinded. This VHA Directive will expire on November 5, 2003.

KENNETH W. KIZER, M.D., M.P.H.
Under Secretary for Health.

ATTACHMENT 5

VHA DIRECTIVE 98–033—JULY 16, 1998

TRANSFUSIONS PERFORMED IN OPERATING ROOMS

1. PURPOSE: This Veterans Health Administration (VHA) Directive established policy for the identification process to be used in all VHA operating rooms, (inpatient and ambulatory) prior to the administration of blood or blood products.
2. BACKGROUND: VHA policy has established standard operating procedures (SOPs) to be used when transfusing blood products. These include specific visual verification by two individuals that the unit of blood or the blood product is in fact the one that has been assigned to this particular patient. The Standard Form (SF) 518, Blood or Blood Component Transfusion, documents this process. Nevertheless, there have been rare blood product transfusion related deaths in VHA Operating Rooms (OR) due to patient and/or blood product identification errors. As part of VHA's patient safety policy to provide high quality, safe, appropriate health care, this policy introduces the requirement to perform an additional independent mechanical verification of the identity of the patient and the blood product. This me-

chanical process utilizes the Veterans Health Information Systems Technology Architecture (VistA) software to read the bar coded identification on the blood product. This will be performed in addition to the current visual verifications. The visual identification by two individuals and this mechanical check will provide an error proof identification process.

3. POLICY: All laboratories in facilities performing surgery must have implemented and use the VistA Blood Bank Package. The identity of each unit of blood and blood products will be entered into the VistA Blood Bank files. At the time the blood product is assigned to an individual, the assignment information must also be entered into the VistA Blood Bank files. Each Veteran Integrated Service Network (VISN) will ensure that all facilities performing surgery have implemented this policy by August 1, 1998.

4. ACTION

a. All patient wristbands will be printed with the bar coded full Social Security Number (SSN) of the patient.

b. All inpatient or ambulatory surgery operating rooms in which procedures are performed which will, on some occasions, require the transfusion of blood products shall be equipped with bar code readers for direct interaction with the VistA Surgical package.

c. When a patient enters the OR, the patient's full SSN bar code on the wristband will be machine read and entered into the VistA Surgical files as a component of the surgical menu options.

d. Should the patient require blood or blood products, two members of the surgical team will visually validate that the blood product is correct for that specific patient. Specifically, they will match the name and SSN on the patient's wristband to the information on the SF 518 and match the information on the blood product to the information on the same SF 518.

e. Upon completing the visual validation, the blood product will then have its identifying bar code mechanical scanned. If the resulting computer message indicates that the database does not have an assignment of this particular unit to this particular patient, a warning message will be displayed indicating that the staff must personally verify that the specific blood product unit is appropriate for this specific patient prior to administration.

5. REFERENCES: None.

6. FOLLOW-UP RESPONSIBILITY: Agatha Francis, Enforcement officer (115) is responsible for the contents of this directive. Questions may be directed to (202) 273–8420.

7. RESCISSION: This VHA Directive expires July 16, 2003.

KENNETH W. KIZER, M.D., M.P.H.
Under Secretary for Health.

ATTACHMENT 6

VHA DIRECTIVE 99–003—MARCH 4, 1999

ADMINISTRATIVE PRACTICES FOR ENSURING SAFE INJECTION OF RADIO-LABELED BLOOD PRODUCTS

NOTE: Changes have been incorporated into this directive so this Change 1 to VHA Directive 99–003 stands as a complete document.

1. PURPOSE: This directive articulates Veterans Health Administration (VHA) current policy regarding the administration of all radio-labeled blood products (e.g., Indium-111 labeled white blood cells, Technetium 99m—HMPAO labeled white blood cells, Chromium-51 labeled red blood cells, and Technetium 99m labeled red blood cells) to patients.

2. BACKGROUND: The prevalence of blood-borne diseases such as hepatitis and human immunodeficiency virus (HIV) require that specific and controlled procedures be utilized to protect patients from needless risk when blood samples are removed, tagged with radio-pharmaceuticals, and re-injected for diagnostic or research purposes.

3. POLICY: According to Title 10, Code of Federal Regulations (CFR), Parts 19, 20, 21, 30 and 35, and Department of Veterans Affairs (VA) Manual MP–2, Part XX, responsibility for developing local policies for the control and supervision of the administration of radio-labeled blood products is assigned to the VHA medical facility's constituted Radiation Safety Committee (RSC).

4. ACTION: To avoid misadministration of radio-labeled blood products and ensure safe injection practices, the following procedures are to be followed:

a. A written requisition from a physician shall be obtained for the procedure, and the physician shall verify the request on the patient's chart or computerized patient record.

b. The patient's identity shall be verified with the participation of two healthcare personnel by two of the following measures when obtaining a blood sample: by confirming the patient's name and Social Security Number (SSN), examining the wrist and/or armband, and querying the patient as to their identity by asking for spelling of their name. NOTE: Do not merely ask if the patient is "X" and accept a "YES" response. If available, employ bar code verification should be utilized.

c. The original blood product container shall be identified with an adhesive label bearing the patient and/or recipient's full name, SSN, date, and signature of the person drawing the blood. Where and when available, bar code verification shall be utilized.

d. Prior to the administration of the prepared radio-labeled blood product, the container that is clearly labeled with an adhesive identification label, the patient's identity shall be again verified by two individuals by two different measures, including bar code verification, as appropriate. Ideally, one or both individuals who initially identified the patient should be present at the time of administration of the blood product.

e. A copy of VA Form 10–0130, Administration of Radio-Labeled Blood Products, is attached for local reproduction. After the initial distribution is received, additional stock may be obtained from the Forms and Publications Depot through normal channels. This form documents the preceding identification procedures and should be completed in the sequence described and remain part of the patients nuclear medicine record.

NOTE: The radio-pharmaceutical vendors may provide forms accompanying the agent. Such forms do not eliminate the need for Nuclear Regulatory Commission (NRC) records or VA Form 10–0130.

f. The performance plan for each nuclear medicine technologist shall emphasize the importance of assuring patient safety by including patient identification and verification prior to the administration of all radio-labeled blood products by requiring 100 percent compliance in the performance of this function.

g. Each nuclear medicine technologist shall receive a copy of the policy, receive appropriate training, and sign to verify that the policy and procedure have been reviewed and are understood. Annual mandatory reviews of the policy and procedure with each employee shall be documented.

h. Any misadministration of a radio-pharmaceutical product must be reported via the facility Patient Safety Improvement Program mechanism through the Quality Management office and, if criteria are met, the NRC.

5. REFERENCES: Title 10 CFR, Subpart A, 35.1 and 35.33.

6. FOLLOW-UP RESPONSIBILITY: The Director, Nuclear Medicine and Radiation Safety Service (115B) is responsible for the contents of this directive. Questions should be directed to Deputy Director, Nuclear Medicine Service, Ann Arbor, MI at (734) 761–7885

7. RESCISSION: Circular 10–93–005 is rescinded. This VHA directive and change 1 will expire on February 3, 2004.

KENNETH W. KIZER, M.D., M.P.H.
Under Secretary for Health.

ATTACHMENT A

ADMINISTRATION OF RADIOLABELED BLOOD PRODUCTS

Patient Identification

Patient: _____ , _____ _____
Last First Middle Inital

SSN: ____-_____-_____

Procedure Information

Procedure: _____

Requested by:_____ M.D.

Approved by: _____ M.D.

Patient ID Verification
(check two)

____Patient spelling of full name

____Patient ID bracelet

____DOB by patient matched record

____Address by patient matches record

____SSN by patient matches record

____Patient is non-responsive
provide source of data
_____

Sample Collection

The patient named above has been correctly identified, and the blood container receiving the blood sample is correctly and clearly labeled with the patient name, SSN, procedure, and date.

Witnesses

(1)_____
Name

_____
Position

(2)_____
Name

_____
Position

_____
Date

Label Preparation

The blood sample for the procedure requested above has been correctly identified, the sample has been labeled, and the product added to a correctly and clearly labeled container.

Witnesses

(1)_____
Name

_____
Position

(2)_____
Name

_____
Position

_____
Date

Label Reinjection

The patient named above has been correctly identified, the patient identification on the labeled blood product corresponds to the patient identified and the product has been reinjected.

Witnesses

(1)_____
Name

_____
Position

(2)_____
Name

_____
Position

_____
Date

ATTACHMENT 7

DEPARTMENT OF VETERANS AFFAIRS,
VETERANS HEALTH ADMINISTRATION,
Washington, DC, July 9, 1998.

IL 10–98–015

UNDER SECRETARY FOR HEALTH'S INFORMATION LETTER

VHA PATIENT SAFETY IMPROVEMENT AWARDS PROGRAM

1. The Veterans Health Administration (VHA) is committed to improving healthcare quality in VHA treatment facilities and in the healthcare industry overall.

2. One important element of the Department of Veterans Affairs (VA's) healthcare quality improvement effort is its Patient Safety Improvement Initiative. This initiative includes, among other things, promulgating the Patient Safety Improvement Directive (formerly entitled the Risk Management Directive, VHA Directive 1051); establishment of the Forensic Medicine Strategic Healthcare Group; inclusion of patient safety-related measures in the Veterans Integrated Service Network (VISN) Directors performance agreements; creation of the National Patient Safety Partnership; provision of funding and other support for industrywide conferences and expert working groups on patient safety; establishment of a new health system management fellowship aimed at developing clinical leaders in healthcare quality improvement; and funding new quality of care clinical research projects.

3. Historically, the healthcare industry has not viewed itself as a high-risk industry and has not utilized the same type of rigorous, systematic review of each adverse event or untoward outcome as has been done in other high-risk industries like aviation and nuclear power. For example, there is no oversight entity for the healthcare industry like the National Transportation Safety Board that deconstructs and analyzes each airline accident to isolate the critical causative factors and to develop approaches to minimize future occurrences through technical design changes, system or process changes, or improved training. Similarly, unlike the nuclear power industry, healthcare has not widely used detailed process engineering that carefully analyzes alternative scenarios to prospectively establish the safest, most risk-free method to handle potentially hazardous situations. The aviation and nuclear power industries have controlled the risk of adverse events by focusing meticulous attention on the design of their operating systems to make it difficult for personnel to make mistakes, and easy to correct mistakes before they result in an untoward outcome. The result, contrary to public perception, is that these high-risk industries have reduced their risk of an adverse event 1,000 to 10,000 times lower than what occurs in healthcare. Clearly, one of the major challenges facing healthcare today is to become a "high reliability" industry such as aviation and nuclear power generation.

4. While various indicators suggest that the veterans healthcare system has a better record on patient safety than the healthcare industry overall, adverse events or untoward outcomes resulting from medical treatment occur too frequently at VHA facilities. VHA is committed to systematically identifying and analyzing these occurrences in an effort to reduce their frequency to the lowest level possible. VHA is uniquely positioned in the United States to serve as a national laboratory to find solutions to patient safety problems and to lead national efforts to improve patient safety. Illustrative of VHA's unique characteristics are the fact that VHA has medical treatment facilities located in every state; is a fully integrated healthcare system; has mechanisms in place to capture the relevant patient safety data; is intimately involved with physician and other health professional training; has a widely acclaimed research program; and is open to widespread scrutiny by virtue of it being a public system.

5. As a further way of identifying the root cause(s) of adverse outcomes and developing improved processes or procedures to minimize potential patient safety risks, the VHA Patient Safety Improvement Awards Program was established.

6. The Patient Safety Improvement Awards Program is designed to increase the emphasis on this important aspect of clinical practice by financially rewarding individuals, teams, services or institutions which identify adverse events or potential patient safety situations and improve processes or practices that minimize or eliminate the risk of an untoward outcome. The awards are intended to provide an incentive to employees to develop and document improved processes and to export them as "best practices" throughout the veterans healthcare system, and the healthcare industry.

7. The VHA Patient Safety Improvement Awards Program will provide a financial reward ranging from $500 to $25,000, along with other recognition, to recipients.

The exact amount of the award will depend upon the extent to which the improved process can be adopted in, or adapted to, other patient care settings and the severity of the potential hazard it reduces or eliminates. Larger rewards shall be targeted for improvements that reduce or eliminate life-threatening risks and have system-wide application. Award nominations will be accepted in the following categories:

a. Direct Care Provider Category—Individual or Team

(1) This category recognizes submissions from individuals or teams which provide direct, hands-on clinical care to patients, and which can identify and implement steps to lessen the likelihood of medical errors, adverse outcomes or anomalous clinical occurrences. It is expected that this category will generate the largest number of award submissions. Individual or team nominations in this category may include persons who provide indirect care or support.

(2) Individuals and teams are eligible for awards of up to $5,000 in this category.

b. Indirect Care and Support Activities Category—Individual or Team

(1) This category recognizes submissions from individuals or teams which provide indirect clinical support, such as pharmacists or laboratory personnel, or which provide support activities making the overall environment safer, such as safety specialists or bio-medical engineers. It may also include activities which eliminate risk from the various processes supporting the provision of patient care such as Medical Records or Information Resources Management.

(2) This is established as a separate category in order to focus attention on these indirect care and support activities as a potential source of patient safety improvements.

(3) Individuals and teams are eligible for awards up to $5,000 in this category.

c. Single Service or Product Line Category

(1) This category recognizes submissions from discrete organizational entities, such as the Medical Service or Surgical Service, or product lines, such as an Ambulatory Care Service Line, which has developed and implemented policies, procedures, or training which significantly improves the level of patient safety throughout the organizational element. The specific processes, approaches, or behaviors must be reflected in the overall operation of the service or product line.

(2) Services or product lines are eligible for awards up to $10,000 in this category.

d. Multiple Service, Facility or Institutional Category

(1) This category recognizes submissions that involve two or more services or that are from a complete entity on an organizational basis, e.g. Medical Center or Outpatient Clinic. It recognizes programs that permeate the entire operation of the facility, either through changes in culture, total process engineering, or other systematic approaches. The award submission would have to demonstrate significant, sustained improvements to patient safety over a baseline, and also demonstrate that accidents and misadventures were reported in a full, complete manner.

(2) Institutions are eligible to receive awards up to $25,000 in this category.

e. Equipment, Tools or Supplies Categories—Individual or Team

(1) This category recognizes individuals or teams which identify equipment, tools or medical supplies which eliminate risk or otherwise significantly improve patient safety. Given the widespread availability of information on such items, awards under this category must demonstrate a high level of initiative, i.e. locating and identifying a very new or little known item, or recognizing that a modification to an item currently available could make it safer.

(2) Individuals or teams are eligible for up to $2,500 in this category.

8. Individuals, teams, services or institutions are invited to submit descriptions of their safety improvements. Submit six copies of each nomination to the VHA Headquarters Management Support Office (10A2A), ATTN: Dot Brady, 810 Vermont Avenue NW, Washington, DC 20420. Nominations from field activities are to bear the endorsements of the Medical Center Director and Network Director. Submissions from VA Central Office activities are to bear the endorsement of the appropriate Chief Officer. Final approval of nominations will be made by the Office of the Under Secretary for Health. Submissions should be limited to no more than ten pages and should include at least the following items:

a. Name of nominee, address, phone number and telefax number

b. Nomination category

(1) Direct Care Provider Category—Individual or Team.

(2) Indirect Care and Support Activities Category—Individual or Team.

(3) Single Service or Product Line Category.

(4) Multiple Service, Facility or Institutional Category.

(5) Equipment, Tools or Supplies Categories—Individual or Team.

c. Nominator's name, title, address, phone number and telefax number

d. Description of the specific event or circumstance(s) that triggered the process or system improvement

e. Description of the specific and/or general safety hazard eliminated

f. Description of the approach used to develop the new process; i.e., whether based on a retrospective review of a specific incident or based on prospective review or process reengineering

g. Estimate of the potential number of untoward incidents that could be avoided if adopted throughout the system, or assessment of the applicability of the new process at other VA health care facilities and its impact on patient injuries at those facilities

h. Listing of specific equipment, supplies, or staff training required to implement the revised process or system improvement

NOTE: Photographs, flow charts or diagrams, floor plans, blueprints or other materials that help illustrate the proposal are welcome, and may be submitted with the narrative justification.

9. Proposals will be judged on the following criteria:

a. Severity of the safety hazard eliminated,

b. Potential frequency of the hazard eliminated,

c. Elegance of the solution, in terms of simplicity and investment or maintenance required,

d. Clarity of the analysis of cause of incident or misadventure, and

e. Evidence that solution was effective in reducing hazard

10. This is an on-going program with no limit on the number of awards. Proposals which are not selected for national recognition but which have merit will be referred back to the VISN or facility for recognition at the local level.

11. For additional information, please contact Dot Brady (10A2A), Management Support Office, on 202–273–8873.

KENNETH W. KIZER, M.D., M.P.H.
Under Secretary for Health.

Senator FRIST. Thank you, Dr. Garthwaite.

Dr. Garthwaite, before coming to the U.S. Senate, I spent 10 years working in VA hospitals doing heart surgery. One thing that was interesting to me in doing heart surgery in VA hospitals, both in Tennessee and on the West Coast, was the protection of an individual from the tort system—not protection, but separation. It is unique, and as we talk about the VA system and we talk about 5,500 other hospitals that are outside that system, I think it is important for us to at least address the issue.

First of all, the VA falls, correct me if I am wrong, under the Federal tort system, and individual physicians working for the VA cannot be sued for medical errors; is that correct?

Dr. GARTHWAITE. That is correct, as long as they are operating within their job description and their assigned duties.

Senator FRIST. Which is very different from outside the VA system. Could you comment, and again, this goes back to what Dr. Eisenberg mentioned in the report about this blame-free environment, how important is that different, more protected environment, in terms of the willingness to participate in reporting medical errors and mistakes, based on your experience and what you have heard?

Dr. GARTHWAITE. I am sure it must play some role, although if we do make a payment on behalf of a provider, we have the responsibility, when we determine the care was substandard, of reporting them to the National Practitioner Databank. So there are some consequences for individual providers who are deemed to have provided less than standard care.

I think an other distinct difference is that we employ most of our physicians. Some are on contract, but most of our physicians are employed directly by the VA. That sets up an employer-employee relationship and a supervisor-supervisee relationship which are relatively unique to the VA.

Senator FRIST. And do you feel the blame-free environment makes people more willing to come forward and report errors?

Dr. GARTHWAITE. I think it can and should, although I would say that, for instance, in our report of 3,000 which Senator Collins alluded to, those were in fact 3,000 adverse events; many of them were not actual errors, but events which were unanticipated which we felt demanded further investigation. The same is true with the deaths associated with those adverse events.

We received a fair amount of encouragement from the press about that, but we also received some not so flattering commentary about the number of errors occurring in the VA health care system.

I only say that because it is not just whether or not there is a tort action that really suppresses people from coming forward; it is often the shame, in the sense that you have done less than you set out to do, and the embarrassment for doing less than you believe you can do. That is very important in keeping people from bringing forward and discussing errors.

We did a survey of our staff, and in fact, shame significantly outranked fear of punishment as a reason for not sharing medical mishaps.

Senator FRIST. I think you are exactly right. That sort of peer pressure is something which cannot be understated in medicine today, which means more disclosure can make the system work better. It does not have to be just punishment and taking people into the courtroom. I think that is very important; many people do not understand that.

Dr. Eisenberg, as you know, we worked very hard in this committee on the reauthorization of the Agency for Healthcare Research and Quality, signed into law this past year. What we attempted to do was refocus the entire Agency on quality issues, quality improvement, recognizing that we do not have the answers to all these difficult challenges; that the pace of science and health care delivery is moving quickly, and therefore, you have taken that charge, and it is now written into law. Part of what we wrote into it was this reduction of medical errors before the IOM report, and we granted the Agency very broad authority, however, funding issues we must continue to address. You were very clear in your opening paragraphs that you were speaking today not primarily wearing your hat from the AHRQ, but I am going to ask you to put it on and tell us what effect the recommendations will have on your agency and specifically, do you believe that we need to create a new center within AHRQ to accomplish what has emerged—the IOM recommendations or the recommendations that will be put forward today by the administration.

Dr. EISENBERG. My AHRQ hat is on now. You are correct in your comment about the fact that we have been thinking about the issue of errors for some time. In fact, the Agency funded investigators in Massachusetts looking at the issue of errors as early as the first part of the preceding decade, in the nineties, and it was much of

the work that was funded by the Agency which led to an understanding of what the risk is and what the number of deaths is. So this is part of an ongoing project for us, and it is also part of our ongoing quality agenda.

I think, though, that the Institute of Medicine report has had a very positive effect for all of us who are concerned about the need for more research in health care quality, because it has taken an issue which has been difficult to explain and has made it feel more real to people. It has taken a part of the quality challenge for this country and it has made it very clear to Americans that while we have very good health care, we could have better health care. It has also made it clear to them that there is a lot that we do not know about how we could have better health care, and that we need more research in this area, both to understand the causes and to understand how we can improve care.

I have often thought that if health care quality were a disease, and it were listed as the fifth or eighth leading cause of death, that people would not hesitate for a moment in calling for a major research agenda. Now that the quality agenda has taken more life through the issue of patient safety, I think it is easier for us to explain the rationale for a major national agenda in health care research.

Senator FRIST. What about the new center?

Dr. EISENBERG. On the center, we applaud the Institute of Medicine's recommendation and agree with it. We believe that a new center can be created within the Agency, building on what we have as the Center for Quality Improvement, so that it would expand the scope of that center to become a Center for Quality Improvement and Patient Safety, with a broader scope and a broader set of responsibilities.

Senator FRIST. Thank you.

Senator Specter.

Senator SPECTER. Thank you very much.

Dr. Eisenberg, starting with the good news, there has been a recommendation of $20 million in funding from our subcommittee, and I believe Senator Harkin and I will lead the way in providing that funding for you.

I was pleased to hear you say that you agree with the thought that I expressed that there is a professional responsibility to tell the patient when an error has been made by the hospital. My question is whether you agree with me that there should be a mandatory requirement as a matter of law. There is no doubt that a patient has a right to get the information when an error has been made, or full disclosure if a patient seeks to exercise that right in court. Would you agree that there ought to be a provision that where there is a patient who has suffered death or acute injury, that should be disclosed to the patient or to the estate?

Dr. EISENBERG. The QuIC has taken the position that it is the obligation of the individual clinician and the hospital to tell the individual about that event. We really have not taken a position on whether that requires a Federal law, or even States laws, for that matter, but we certainly believe that at a minimum it is a professional responsibility.

Senator SPECTER. Well, I would ask you to take a look beyond. There is a mandatory requirement for reporting in Pennsylvania, for example, by hospitals, but there is relatively little. I note that you have called for reporting by the States as opposed to the Federal Government, and I believe that that is a matter which requires some analysis. You have also noted that the 6,000 hospitals funded by HCFA would have a mandate which goes pretty far on having a Federal responsibility.

There is a little more of an inclination to report when it is a Federal responsibility, a Federal mandate, perhaps backed up by loss of payments from HCFA, for example. There is an analogy in the campus reporting where we found that the obligation of universities and colleges to report crimes on campus was disregarded in substantial measure. That legislation came through our subcommittee, and we have since added some pretty tough penalties.

Do you think that ultimately, there will have to be a stick as well as a carrot to get compliance by those who have an obligation to report on a mandatory basis?

Dr. EISENBERG. I think that the State systems as they currently exist demonstrate the fact that in their diversity, we do not know enough about how to collect this data, and we do not know how to report it at this point. What we need to do is look at the States systems, and we need to work with the States to demonstrate how this process can work best.

If in 3 years, we find that States have not adopted a mandatory reporting system, we will have by that time learned which of the States' programs work best, how they work best, and the QuIC will report back to the administration with recommendations about how to go beyond the current proposal if that is necessary.

But we are optimistic that with Federal help through, for example, the Quality Forum helping to standardize the kinds of measures that ought to be used, the States systems can work.

Senator SPECTER. Perhaps the demonstration projects that Senator Harkin and I have recommended, with five institutions on voluntary confidential, five on mandatory confidential, and five on mandatory with a statutory obligation to tell the patient, will give us some insights there.

Let me ask you one final question, Dr. Eisenberg, before turning to Dr. Garthwaite, if I have sufficient time. The president of the American Hospital Association, Richard Davidson, is reported in today's New York Times as saying they were not going to attend the White House event today "because we thought that there was an agreement with the White House in a public-private partnership, but there has been little or no consultation."

Before Senator Harkin and I introduced our legislation, we consulted with many of the national agencies, including the American Hospital Association, and while they did not like the idea of mandatory reporting, they did have some good ideas on technology.

When President Clinton proposed his national health plan late in 1993, and we had the very heated debate in 1994, there was considerable concern—really, criticism—by the private sector of lack of consultation. My question to you is what do you plan to do, if anything, to try to bring on board groups like the American Hospital Association to try to get cooperation from the private sector, which

I think is going to be necessary if there is going to be what Mr. Davidson calls "a change in the culture in hospitals"?

Dr. EISENBERG. Well, we look at this process as beginning, not ending, and we have stated very clearly in the report that we want the consultation of the States, of the private sector, including the hospitals, the medical community, and the nursing community, as we lay out the implementation of the principles that we have established. But a careful read of this report—and I am sure the hospital community will read it carefully—will demonstrate that these are principles that are established, and we do not pretend to know exactly how these programs ought to be implemented. In fact, that is the gist of my response to you about the State programs. We think we have a lot to learn from the States and from the hospitals about how to implement a mandatory reporting system so that it encourages and does not discourage the reporting process.

Senator SPECTER. My red light just went on, Dr. Garthwaite, but I have you on the record from our last hearing. Thank you for joining us.

Senator FRIST. Thank you, Senator Specter.

Senator Kennedy.

Senator KENNEDY. Thank you very much, and I thank the panel.

At the outset, I listened to my friend Senator Frist talk about what has happened in the military. We have what we call the Feres doctrine, which is another way of stating what has been reviewed earlier today about the limitations on the ability of our servicemen and women to recover damages for tort-related injuries. That is a longstanding doctrine that I think may be worthy of review at some time—I do not know if we want to get into it today, because we have had extensive hearings in the Armed Services Committee over a period of time, and I think there are some legitimate questions about that doctrine. The protections that exist now were basically adopted because we had a war situation and did not want to have people involved in conflict having to think twice about how they were going to treat servicemen and women. We have had a long period of peace now, and, therefore, the continuation of liability protections is a legitimate issue.

You also have in the military certain protections for whistleblowers, which we do not have in the private sector at the present time, which permit information to be brought forward. Service personnel who report possible violations of law or negligence are protected, which is enormously important.

The whistleblower protections for medical personnel have not been included, although we attempted to include them in our Patients' Bill of Rights. This remains an important issue.

Basically, in my limited time, I want to ask about the prescription drug benefit program. One aspect of this issue involves various adverse drug reactions that particularly affect our elderly population. We know that our senior citizens have a heavy utilization of prescription drugs. I am very hopeful that we will get action in this Congress on an extended prescription drug benefit. But we also want to make sure if we are going to do that that we give adequate protections to our seniors to avoid the kinds of adverse drug reactions that various studies have reported.

Could you tell us how important you think making sure that we provide at least some protection, perhaps along the lines of a pharmacy benefit, for seniors? How important is that, and how important will that be, as there is an increasing reliance on prescription drugs? As a result of these studies, what are you recommending we do in order to make sure we provide protections for seniors, and how important is it that we pass a prescription drug benefit program?

Dr. EISENBERG. The issue of patient safety and medications in the elderly is a very critical issue. We know that as many as 7,000 of the people who die each year from errors die because of drug errors, and we think that about one out of every ten hospitalizations occurs because of a prescription drug-related issue.

There are three ways which we think we ought to approach this issue. The first one does relate to your point about a drug benefit, that is, when drug benefits are offered, they are often managed by organizations like a pharmaceutical benefits manager. If that is the way a drug benefit is organized, that would provide us with an opportunity to have a safety program embedded in the prescription and dispensing process.

We understand from pharmaceutical benefit managers that they do have programs in place to enhance patient safety, to provide utilization review to the clinicians as well as education. But in addition to that, we think the FDA plays a key role in its reporting systems, to enhance its reporting systems, to develop standards so that drug packaging and labeling and the naming of drugs is safer.

And third, we believe it is very important to understand what the risks are of adverse events, and the Centers for Education and Research in Therapeutics at AHRQ will provide us with a mechanism for enhancing that knowledge.

So to your question, we believe it has to be a multifold way of addressing it, and a drug benefit would give us an opportunity to address it head-on.

Senator KENNEDY. Dr. Garthwaite.

Dr. GARTHWAITE. I would just add that often we think of errors as errors of commission, but errors of omission are important in terms of patients' overall quality of care. The use of beta-blockers and aspirin after a heart attack has a significant effect on preventing the next heart attack and preventing hospitalization and extending life. Some private sector studies suggest that that happens as infrequently as 21 percent of the time. We have been able, though the use of systems, reminders, and education of our providers, to get the VA up into the 90 percent of administration of beta-blockers and aspirin. So the availability of drugs can be critical.

Senator KENNEDY. Dr. Eisenberg, you mentioned the importance of educating patients so they can make informed decisions. Will the Office of Personnel Management rate health plans and institutions participating in the Federal Employees Health Benefit Program on how well they perform in medical error reduction and meeting patient safety standards and make that information available to participants? We have about 10 to 11 million people involved in that program at the present time, and I am interested in whether you have thought about that and what suggestions you may have.

Dr. EISENBERG. Yes, we have thought about it. The Office of Personnel Management intends to have a requirement that plans describe the systems that they have in place and that that be made available to individuals in the book that describes the plans as Federal employees choose those plans.

OPM does not have a plan right now to rank or rate programs, but rather, to report the degree to which they exist. In addition to that, OPM uses the Consumer Assessment of Health Plans Survey that was developed by AHRQ to educate Federal employees about the satisfaction of other Federal employees and people who use health plans, and we believe that patient safety and the satisfaction with patient safety and the experiences with patient safety could be embedded in that as well.

Senator KENNEDY. Thank you.

I thank the chair.

Senator FRIST. Thank you, Senator Kennedy.

Senator Harkin.

Senator HARKIN. Thank you, Mr. Chairman.

I want to focus on just two areas. Dr. Eisenberg, your plan sets up 100 demonstration projects where reporting will be mandatory for those institutions that volunteer to participate in the demonstrations, but you do not require other hospitals to do the same. I am just wondering, given the authority that HCFA has to determine which providers can participate in Medicare, why don't you go further? You have a big stick there with HCFA, so why don't you go further?

Dr. EISENBERG. Well, HCFA has proposed several initiatives, with one guiding principle, which is that it needs experience, and it wants to get that experience as quickly as possible, about how these systems work, when they work the best, and how to design a system that might go beyond the first demonstration project.

So the program to which you are referring is a program that would be a demonstration project with a peer review organization; it would have mandatory reporting, but it would be confidential, and 100 hospitals would participate in it. We believe that very soon after the institution of a program like that, we would know more about how a broader system such as you describe should be instituted so that it has more effect.

Senator HARKIN. Why aren't you taking the approach that Senator Specter and I have in our bill? We propose looking at different types of systems rather than just the one system.

Dr. EISENBERG. We would be more than happy to sit down and talk with you about expanding beyond the one program that the Health Care Financing Administration has proposed at this point, to explore whether more would be appropriate.

Senator HARKIN. Second, we included in our bill a provision for demonstrations on best practices, and I do not see that in your proposal. Now, there is a lot of information out there, and some places are doing really good work. I do not have all the information at my fingertips right now, but I have been informed of some unique approaches at the Latter Day Saints Hospital in Salt Lake City—they are supposed to be faxing me a lot of information. I understand they have really moved way ahead in this area. I would hope again

that you would expand your request to include demonstrations on best practices.

Dr. EISENBERG. That is a critical issue for us. In fact, in the proposal that we have before your committee, there is $11 million requested for the Agency for Health Care Research and Quality to study whether the best practices really are best, how they compare to their alternatives so we can prove that they are best rather than just assert that they are best. That $11 million will enable us to fund research like the research at LDS Hospital, which in fact our agency had funded earlier, demonstrating that programs can work. LDS tells us that eight other hospitals are now coming to them, asking them for advice, and we are proud of that because we funded the initial research, and that shows that the research can be translated into practice. So it is a large part of what we see as the research agenda in this area, and we have requested $11 million for what we call the "translating research into practice" part of the safety agenda.

In addition to that, we will have evaluations of programs such as those that the VA and the Defense Department are instituting.

Senator HARKIN. So you have requested $11 million—run that by me again—what are you going to do with that money?

Dr. EISENBERG. The total request for the Agency's patient safety initiative is $20 million. Of that, $5 million would be spent on new knowledge in this area, $4 million would be spent in developing new tools to implement that new knowledge, and $11 million would be spent in the area that you are describing, which is evaluating best practices and getting those best practices translated and disseminated and into the field, to see how we can get them disseminated as quickly as possible.

We think the $11 million is a good down payment on the suggestion that the Institute of Medicine has made.

Senator HARKIN. Thank you very much, Dr. Eisenberg.

Thank you, Mr. Chairman.

Senator FRIST. Thank you, Senator Harkin.

While we are talking about the money, could you just answer one question for me. The $20 million, you walked through, and I think that is very important. The Institute of Medicine specifically said $35 million. What do they recommend that you are not doing? The Institute of Medicine report said $35 million a year for 3 years; is that correct?

Dr. EISENBERG. That is right.

Senator FRIST. And the President has recommended $20 million. What is the difference? Should we be doing more, and what are we leaving out?

Dr. EISENBERG. Well, the Institute of Medicine's recommendation was for $35 million in the first year and $100 million within 5 years in this area. We are currently spending about $4 million in this area, so the total is about $24 million, not the $35 million that the Institute of Medicine had recommended.

I do not think there is a major area that the IOM suggested that we work on—whether it is understanding root causes or developing measures or evaluating outcomes and effectiveness of these programs—that we are not doing. It is simply an issue of the mag-

nitude of the investment and the degree to which we can address those issues.

Senator FRIST. I think that is something that Senator Specter and we need to come back to—because if it is this big, and as Senator Harkin said, there are more things that we need to be doing, we need to do that.

Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

Dr. Eisenberg, the emphasis in both the Institute of Medicine report and your recommendations is on patient safety and reducing medical errors in the hospital setting, and yet a great deal of health care is now being delivered outside of hospitals, whether in ambulatory care clinics or physicians' offices. Have you taken a look at whether there are similar problems in those settings—it seems to me we have every reason to believe there are problems in these settings as well. Has there been any attempt to address medical errors outside the hospital setting?

Dr. EISENBERG. There has not been enough. We think, as you do, that there are a number of adverse events which are preventable which occur outside hospitals, and because of that, we think we ought to take several steps. One of them is to start with hospitals, because we know we have ways in which we can institute improvement programs there. The VA and the DOD have shown us that.

Second, we know that many hospitals are a part of broader systems, and throughout our report, we describe a way of addressing this challenge, not just from hospitals but systems of care, so we can look at the system no matter where the patient is—whether the patient is vertical or horizontal, walking or in the hospital, we can address this issue.

And third, we place a major emphasis on the importance of information systems, because whether a patient is in the hospital or out of the hospital, we need to have data on what is happening with that patient, and our information systems in the health care industry lag far behind the information systems that are available in many other industries like aviation or even banking, where more data is available and more is known.

If we could have better information systems, then I think I would be able to give you a more satisfactory answer to your question, because we would know more about what is happening in the outpatient setting.

I think Senator Kennedy's question gets to that as well with regard to outpatient use of drugs.

Senator COLLINS. A second question that I have for you, Dr. Eisenberg, concerns the burden on small hospitals versus large hospitals of some of the new requirements that we are talking about. My State is typical of many. We have the 600-bed Maine Medical Center in urban Portland, and our smallest hospital is a 14-bed hospital, the Charles A. Dean Hospital in rural Greenville. Obviously, we want to have quality patient care no matter where it is delivered. But those hospitals—that tiny hospital versus the large—by Maine standards—hospital—face very different challenges. As we look at this issue and how best to address it, is there a way to take into account the size of hospitals and the burden of

certain reporting requirements, so that particularly rural hospitals that are fragile financially already are not pushed over the brink?

Dr. EISENBERG. There is, and we have thought about that very seriously because we agree with you that it is an important issue, and there are several ways of addressing it. One is for us to emphasize how we are only asking that the reporting that is mandatory and publicly disclosed reporting be on those events which are preventable, very serious events, and avoidable deaths. One of our concerns is that in small hospitals like the ones that you describe, the number of those events will be small, and the number of events occurring that are not quite as serious will still be small.

Any single event that should never happen should never happen, no matter how big or how small the hospital. But if we are looking at events that might be related to more serious events, like a wrong prescription that might be caught, what Dr. Garthwaite called a "close call," we are concerned that if we were to require mandatory reporting on those, the reporting burden could be substantial. Therefore, we think that what we are proposing is doable and is feasible in the short term. And second, we believe that for hospitals like that, we need to put programs together, for example, with the Quality Forum, that will help them understand what the measures are that they should be measuring so they don't have to reinvent the wheel in every, single hospital.

Senator COLLINS. Thank you.

Dr. Garthwaite, I have been concerned for some time, and I know you are well aware of this, about the cutbacks at the VA hospitals across this country, particularly in the Northeast and particularly at Togas in Maine. I have been concerned that the cutbacks are going to reduce veterans' access to care, but they also threaten to jeopardize the quality of care. When you have a situation as we do in Maine where there are currently no oncologists, when physicians complain repeatedly to us about the pressures of seeing ever greater numbers of patients in ever shorter amounts of time, when there are long waiting periods for treatment—it paints a picture that raises serious questions in my mind as to whether we are creating the kind of environment that is conducive to medical errors.

Aren't the kinds of staff reductions and cutbacks that we are seeing at Togas and at other hospitals likely to increase rather than reduce the kinds of medical errors that you are working so valiantly to try to reduce at VA hospitals?

Dr. GARTHWAITE. Well, I certainly hope not. We are attempting to reduce nondirect care providers in most of the areas where we find our expenses exceed other areas of the country in terms of how much it costs to give a certain unit of care. But I think your point is a valid one both in the VA and in the health care sector in general, and that is that as there are increasingly intense pressures to decrease the cost of health care, that can lead to staffing issues.

One of our Patient Safety Centers of Inquiry will look specifically at staffing mixes and staffing ratios and others and whether or not the number of staff and how busy they are has contributed as a root cause to any of the adverse events that we uncover.

So I think it is a very valid point. I think it is not just a VA issue, but a general issue, and we think it is a very important one to examine.

Senator COLLINS. Thank you, Mr. Chairman.

Senator FRIST. Thank you, Senator Collins.

Senator Reed.

Senator REED. Thank you very much, Mr. Chairman.

Dr. Eisenberg, in your testimony, you have indicated that this summer, QuIC will begin to test strategies to improve patient safety in high hazard areas. Are you aware of the ongoing work between the Department of the Army and certain military and civilian hospitals. I am aware of this program, which is called med teams, because a lot of the research is taking place at Rhode Island Hospital. Through med teams, hospitals are taking the techniques the Army has used to develop training for aviation crews and applied them to emergency rooms, and it seems to be working quite well.

Could you comment on the med teams program and more generally about the adaptation of some of military crew training techniques to medicine? And one other point—medical errors seems to be, following a point Senator Harkin made, more of a systemic problem, but in many respects, it might be similar to group crew training problem. In medicine today, despite the skill and the extensive training of individual physicians and nurses, the breakdown might arise from the fact that they cannot work together as a cooperative crew or team. Please comment Dr. Eisenberg, if you could.

Dr. EISENBERG. The QuIC has provided us a wonderful opportunity for Federal agencies to learn from each other, and the example that you give is a terrific example of just that. We have learned from the Defense Department about how it is learning from systems that have been put into place for other purposes and how they can be applied to systems in the health care system, and as opposed to having individuals independent, that a well-organized, systematic approach that is goal-oriented can help us to address those issues.

In fact, the Defense Department has the lead in helping us to develop what is called a "breakthrough series" in reducing errors in high-hazard environments. We are going to be doing that with the Institute for Health Care Improvement in Boston. There will be a number of Federal agencies—the VA, the DOD, the Public Health Service agencies will all be participating in this. It is a way we can learn from the Defense Department's experience in the area that you described.

Senator REED. And to elaborate, is it your sense that this notion of crew training might be a way to handle some of the problems, being experienced by our highly trained physicians, technicians and nurses. I guess it begs the question: Are some of these problems the result of poor teamwork rather than lack of individual skills?

Dr. EISENBERG. Many of them are the result of poor teamwork and poor systems that undergird the teams. In the best American hospitals, both of those issues have been addressed. We have teams that are working together in a very well-organized way. In fact, team care and shared decisionmaking are themes in the patient safety area in hospitals around this country. But even that is not enough if they do not have the underpinning of an information sys-

tem to help them communicate with each other and understand what the data is about their patients.

Senator REED. Dr. Garthwaite, do you have a comment?

Dr. GARTHWAITE. I would just say that we have a simulator for an operating room at the Palo Alto VA, affiliated with Stanford University, and when they bring in a team and put them through an emergency, they tape record from every angle and all the communication and then play it back to get exactly what you have suggested, in that people do not realize how imprecise the communication is and what their actions are like when they are taken out of that situation and they get to watch and critique themselves.

So that whole human factors analysis is going to be critical to solving some of these issues.

Senator REED. And Dr. Eisenberg, I presume your plans are to take this already existing knowledge and technique, the simulations, and deploy it into the hospital setting—is that at the core of what you are doing, or at least should it be?

Dr. EISENBERG. You have heard Dr. Garthwaite describe the VA's intentions. We, as Federal agencies, do operate some hospitals—those that we have talked about today, the VA and the DOD, as well as the Coast Guard, the Bureau of Prisons, Indian Health Service—all of whom are participating in this program. In those institutions where we provide care, we intend to implement these programs as quickly as we can. But we want to do what we can to stimulate and help the private sector.

Senator REED. And in that regard, your testimony also suggests that OPM, for example, is going to urge all 300 private health plans in the Federal Employees Health Benefits Plan to include error reduction and patient safety measures. Urging, suggesting, persuading—at what point do you recommend that they do things like put all of their surgeons and surgical teams through this type of crew-oriented training?

Dr. EISENBERG. The Office of Personnel Management at this point believes that by making the information available to Federal employees and letting Federal Employees make decisions about the choice of plans or hospitals and whether or not they have patient safety programs in place, that will be a very forceful incentive for those plans and those hospitals to put those programs into place.

We will evaluate that, and if it does not work, we may come back to you and say it did not work, we need something else. But at this point, we believe that that is the right first step.

Senator REED. It just seems to me, reflecting the number of hospitals in my State, and there are only a few, I suspect that they will write in their brochure that they have these techniques if they in fact do, and the question is whether or not they are up-to-speed. I think it is hard for a layperson to make the distinction along those lines, but at least it is a first step.

Dr. Garthwaite, you have already done some work in VIS-8 and VIS-22 about close call reporting. I feel particularly moved to ask this question today as the pilot of my plane this morning came back with a flashlight to make sure the landing gear was down, and as he walked back to the front of the plane, I said, I wonder if they are reporting that as a close call.

Can you comment on the VA's close call reporting system?

Dr. GARTHWAITE. Yes. We learned from our initial forays into adverse event reporting that it was not just sending out a policy and hoping people read it and understood what it really meant, or that our caregivers really had any intrinsic knowledge about how to do a root cause analysis. So in rolling out the new system, we have done extensive education and targeted two pilot health care networks, one in Florida and one in Southern California—I think that is what you are referring to.

Senator REED. Yes.

Dr. GARTHWAITE. The one in Florida has been up for about 3 months, and we have gotten very good feedback. In fact, other networks have asked to move up their dates of implementation somewhat, because this seems to work much better than the older system.

I think the key is the total education, the immersion in the computer-aided analysis system that walks people through what a true root cause analysis is. We hope to learn even more as we implement this, but we believe that it is going to make a major difference.

Senator REED. My time as expired, but just quickly—they are in fact reporting close calls?

Dr. GARTHWAITE. Yes. We think we should hear about errors and close calls both in our mandatory and in our voluntary systems. We would rather have too much information and error on that side at the present time until we begin to understand it. I really only takes knowing about an error to learn from it. You do not have to learn the same lesson six times or 12 times—it is not how frequently you learn it—you have got to find it, design a fix, and implement that systematically.

Senator REED. Thank you, Doctor.

Thank you, Mr. Chairman.

Senator FRIST. Thank you, Senator Reed.

Senator Hutchinson.

Senator HUTCHINSON. Thank you, Mr. Chairman.

I would like to pursue the voluntary versus mandatory a little bit, Dr. Eisenberg. My understanding was that the administration initially had supported voluntary reporting requirements and that now, the plan calls for mandatory, at least in the case of death and serious injury. Am I correct that there has been a switch in thinking in the administration?

Dr. EISENBERG. No, that is not correct. We did support voluntary programs, and we still do, but we had not taken a position prematurely, nor announced a position prematurely, on whether we were supporting and how we were going to support mandatory programs.

What you might have read was that at the time, we were not prepared to announce what our findings were going to be because we thought we ought to come to you and announce them here. So that was not accurate.

Senator HUTCHINSON. From your statements today during the questioning of Senator Harkin, I just wonder how strong is the commitment to mandatory, because when he suggested a multifaceted approach where there would be mandatory voluntary, you indicated a willingness to negotiate that and discuss that, so that

seems to me to be somewhat of a retreat from a blanket commitment to a mandatory system.

Did I misunderstand something there, or could you expand on that?

Dr. EISENBERG. We think that a mandatory system is necessary. We think, however, that the whole spectrum of reporting activities should be undertaken and that we should evaluate how they work best, and even within mandatory systems, we believe that there should be confidential systems of mandatory reporting and mandatory systems that should be disclosed.

We have not retreated from anything—in fact, our position on mandatory systems that are to be disclosed is that there ought to be a nationwide, State-based system of mandatory and disclosed reporting on major events that are either——

Senator HUTCHINSON. Wouldn't that preclude Senator Harkin's, where you would have—obviously, if you are doing voluntary, it is not mandatory, so if you are doing both——

Dr. EISENBERG. As I understand that proposal—and I should say that the administration has not had a chance to review it or take a position on it—but as I understand it, they propose to go beyond the cautious approach of just having mandatory reporting of major life-threatening or life-ending events, to look at what more we can do than that and to evaluate those in short order.

We agree with that, that we need to evaluate more than just the mandatory reporting of major events.

Senator HUTCHINSON. The New York Times story today that was referred to by Senator Specter earlier said that the President's initiative leaves some important questions unanswered, among those, what is the Federal role in the proposed new reporting system, and will the States get additional money to catalog and analyze reports of errors.

When you were talking about the $20 million and putting a new mandate on the States regarding reporting and their role in that, will there be any incentive or any assistance for the States in this new obligation?

Dr. EISENBERG. There will. The $20 million that we were describing is for the research part of this and not for the implementation part. We do think it is very important, though, that we assist the States in implementing these programs, first through asking the Quality Forum to come up with a core set of measures so there is some standardization, and the States do not have to all struggle to find out what a good set of measures ought to be.

We also want to help the States to evaluate what those programs are, bring the States together in the convening role of the Federal Government, and help them to learn from each other. Once we know what works best, then we can help the States to move forward and implement those programs that are most effective.

Senator HUTCHINSON. You mean move forward in the sense of assisting them with funding at some point?

Dr. EISENBERG. Well, we have not taken a position on that, because we do not know what the best system would be. But I trust that when we do know that, we will come back to work with the Congress to evaluate how much it would cost to implement a program like that and whether it should be funded federally or not.

Senator HUTCHINSON. In that same New York Times article, Dr. Nancy Dickey, former president of the AMA, is quoted as saying that they are "opposed to mandatory reporting and that it may well drive underground the very information you need to improve safety. A number of States have mandatory reporting, and there is no evidence that they have greater safety or fewer errors."

Would you respond to that concern, both that it might drive that information underground and that in States that have mandatory reporting, there is no evidence that you have fewer errors?

Dr. EISENBERG. I will. First, we do not think that having mandatory reporting of events that the doctors and the hospitals should disclose to the patients anyway is going to drive anything underground, because they should have reported it to the patient in the first place. So none of this should have been secret. The kinds of events we are describing are the events of deaths that were avoidable, or a major event that causes the patient a lifetime or long-term problem, and as we have already discussed, that should be disclosed. So we are just talking about reporting those events which have already been disclosed.

Second, in response to your question, do we know if these programs work or not—no, we do not. We do not know how well they work or when they work best. So the comment that is quoted is on target. We need to know a lot more about these programs, and there is no way we are going to learn more about them unless we have them, and we can evaluate them very carefully.

The final thing I want to say is that the American Medical Association should take great pride, I think, in the fact that it has taken a very professional approach to this issue of patient safety, raised the issue, and recognized the responsibility of the profession for doing just what the VA and the DOD have been doing and translating that to the Nation as a whole to learn from errors as well as to make them available to the public.

Senator HUTCHINSON. My time is almost up, but I would have thought that in the States that have had mandatory reporting requirements, there would be some indicators, some evidence, that in fact we have a better track record there as far as the serious adverse events than in States that do not have that. Are you saying there has been no analysis, so there is no evidence?

Dr. EISENBERG. It is not that there has been no analysis; it has been that there is very little. Our agency, as you know, is a small agency, and our research budget is likewise small, but we have funded a few projects, one of which looked at the New York system and demonstrated that in New York with mandatory reporting of cardiovascular deaths, there was a reduction subsequent to that in deaths from cardiovascular surgery. In Pennsylvania, we found that the reporting system existed, but it was not disseminated widely to the public, and the public by and large did not know about it.

So those two research projects that we have sponsored tell us that programs can work if you extrapolate from that research; they do not work if you do not do anything with the information. It is that kind of research that we think we need to sponsor to look at other States' programs to find out how they can work best.

Senator HUTCHINSON. Thank you.

Thank you, Mr. Chairman.

Senator FRIST. Thank you, Senator Hutchinson.

Senator Dodd.

Senator DODD. Thank you, Mr. Chairman.

This is very interesting, and I appreciate the opportunity to listen to the witnesses and to our colleagues.

If I could jump ahead, since we have another panel coming up. Someone has suggested that in fact there is not much need for a Patients' Bill of Rights, that if we could deal with the issue of proper reporting of medical errors, that would alone suffice—that the pursuit of patients' rights is a misguided effort in Congress. I disagree with that, but I would like to ask you, Dr. Eisenberg, to comment on it because you may not have the chance once you leave that microphone. And there is a distinction in my view between a physician committing an inadvertent error that causes serious injury or death and a deliberate decision by a health care plan to deny health care coverage. That is how I see it. I think there is a fundamental distinction. I think both issues are very important, and I do not see how one necessarily supplants the other. I wonder if you might just take a moment and comment on a coming witness' position on that issue.

Dr. EISENBERG. I cannot comment on his position because I have not heard it, but I will comment on your statement. I think it is so important for us to recognize that to get high-quality care delivered to Americans, they need to have health care insurance, and we in the administration have taken very strong positions, as has the Congress, to improve access to insurance. We also believe that once you have insurance, you need to have access to care, and that is what the Patients' Bill of Rights is all about—just because you have insurance, you may not have access to the necessary care, and we want to be sure that that happens.

But even if we have a Patients' Bill of Rights, and even if people have access to care, what we are talking about today is what happens when people do have access to care and to be sure that they have access to high-quality care.

So the way we look at it is, in a sense, as three legs of a stool. In order for us to have high-quality care, we have got to have insurance so that people are covered; we have got to have access to the necessary services; and then, once you get access to those services, they have to be safe services, error-free services, and high-quality services. So they are separate issues, they are separate parts of the same story of trying to get high-quality care to the American public.

Senator DODD. And one does not replace the other.

Dr. EISENBERG. No. They are all necessary.

Senator DODD. Dr. Garthwaite, I see you nodding your head, but do you want to add anything to that?

Dr. GARTHWAITE. No. I would agree. We try to set the same kind of system within the VA. It is very important that decisions about what is a covered service are made openly and publicly and are adequately disclosed to the patients.

Senator DODD. Senator Hutchinson has left, but he raised some good questions about the mandatory vs. voluntary approaches—and I apologize as one of the last people to ask you the question here,

but it was still somewhat uncertain in terms of what we mean by mandatory reporting.

First of all, I realize this is a work in progress as you describe it, but I would like to try to get some clarity on this if I could. Mandatory for whom? Mandatory for hospitals—for doctors—for pharmacists? Who does that cover? When you use the word "mandatory," what is the universe that you are talking about there?

Dr. EISENBERG. First, the universe is defined by what it is that needs to be reported in a mandatory way. It is a system responsibility to assure that those reports are being made. We believe, as was the implication of the question earlier, that this is a team issue, that it is not the responsibility of any one group or any one clinician, but it is the responsibility of the system to be sure that mechanisms are in place to be sure these reports occur, and that people feel safe in doing that reporting.

Some of the reporting will be confidential. Some of the mandatory reporting will be confidential. But the definition of who does the reporting is really driven by what it is that they are reporting about, if it is surgery, or if it is a drug, or if it is some other part of health care.

Senator DODD. On the question of confidentiality, I think there is an implication in the minds of some people, care, that if you say "mandatory," there is the question of confidentiality—once something is mandatorily reported, there is an assumption, and I do not think without some justification, that once it has to be reported, you have no assurance that that information is going to be held in confidence. Once a larger universe has that information, to what degree is there a sense that you are- not going to be subjected to unwarranted lawsuits, for instance, which is a concern that many have.

Dr. EISENBERG. That is a critical part of this proposal, that the confidentiality be serious, that there be peer review protections extended to those who are organizing and holding these databases of errors or breaches of patient safety, and that we not fear the discovery of those secondary databases. They should not be discoverable. We do not want those databases to be available to people who just want to go on a fishing expedition to find examples of errors. The charts are available, and they will always be available, I hope, to anyone who has the right to look at them; but we do not think these secondary databases where we are collecting the errors that have occurred should be disclosed. There should be peer review protections of those.

Senator DODD. Are you recommending any penalties for unwarranted disclosure of information for those who might do so?

Dr. EISENBERG. We have not been so specific as to recommend what the penalties are, and we recognize that that is an area in which we are going to need to work very closely with you and the Congress to develop a mechanism for implementing those peer review protections.

Senator DODD. Of course, the other side of that—and again, I realize it is a bit of an unanswered question—is that if there is a pattern—if it is an inadvertent mistake, that is one thing—if it becomes a pattern that shows up, at what point do you then decide that holding information confidential then places patients at sig-

nificant risk by protecting information that should otherwise be in the public domain so that patients and their families can make intelligent decisions about who provides care?

Dr. EISENBERG. We believe that if the events are serious enough that they need to be disclosed, as the ones that you have described would be, that they ought to be disclosed to the public, but that mostly, these events are avoidable errors that will sometimes lead to an adverse event, but that not all adverse events, of course, occur from an error. Some of them occur despite the best medical care that could have been provided.

Because of that, we want to emphasize the aspect of learning from errors, whether it is a mandatory or a voluntary system, and we do think that we need to count on the medical profession, its accrediting organizations and professional societies to do just what you have said, which is to act on that information. But we do think that some of that information needs to be held confidential so that the reporting is full and complete.

Senator DODD. My time is up, but Mr. Chairman, could I ask just one other question of Dr. Garthwaite?

Senator FRIST. Yes, go ahead.

Senator DODD. On the bar-coding that you do at the VA, that is a best practice method, and I just wondered how expensive that is to do. Could an individual hospital bar-code? Is there enough technology available today that you could do it at a relatively low cost?

Dr. GARTHWAITE. Yes, I believe there is. It is never completely free. We have 173 medical centers, and to implement it in all of those, the actual hardware is probably $25 million. But it will save money, too, in the fact that a lot of extended hospitalizations are due to giving the wrong dose or the wrong timing of medication and so forth; a lot of hospitalizations are the result of adverse administrations.

So we think there are some savings to be had. There is a significant expense to training, but I think that overall, it is such a common error, and the effects on our pilot study were to dramatic in reducing the number of errors that it is worthwhile. And I assume the price will come down, as it does with everything else in electronics.

Senator DODD. Thank you. I have overextended my time, Mr. Chairman, and I thank you.

Senator FRIST. Thank you very much.

I know we need to move to the second panel, but let me just say, Dr. Eisenberg, that I appreciate your three-legged stool approach to quality, and I think it is very important, because in each of the medical errors hearings that we have had, we have had the Patients' Bill of Rights come up, and then the question of should you separate the two or not—and the real answer is that you need to look at all these issues together.

I do think it is important for my colleagues as much as others to understand that that approach to quality of medicine was very much a part of the Patients' Bill of Rights bill that was marked up by this committee, that was taken to the Senate floor, that passed the U.S. Senate, that is currently being talked about as the Patients' Bill of Rights in our conference. I say that because the authorization for AHRQ, the emphasis on quality, the only legislation

last year to pass on medical errors, which is part of AHRQ, started in this committee and was debated. And when we looked at the bills that were on the Senate floor last year for a Patients' Bill of rights, medical errors was part of the Senate-passed bill; the reauthorization for AHRQ was part of the Senate-passed bill and was not a part of the other bills that were debated on the floor and was not a part of the Patients' Bill of Rights in the House.

I say that because a lot of people do not know it. Ultimately, we ended up pulling that out, passing it at the end of last session so that we could keep moving ahead, and as demonstrated today, I think that your leadership in AHRQ addresses this larger picture of quality where, yes, we have a Patients' Bill of Rights, we have insurance, we have access, but we have got to address people who get into the system and minimize the errors that are there.

Let me just ask one thing that I think will clarify things for me, and then we will move to the second panel. I am a heart transplant surgeon in Nashville, TN, and I have patients who come in from all around Tennessee in a field that is pretty new, transplantation. We are using drugs that people who are going through medical school now are trained to use, but most physicians are not accustomed to using cyclosporin, which is a fairly new drug—15, 20 years old—and they certainly do not know the interactions with other drugs. So I transplant a patient, send him back to a small town in Tennessee, where they go back to work and live a normal life—but they are on seven, eight, nine, ten different medicines. The family practitioner in that area sees a sore throat, starts erythromycin, does not realize that cyclosporin and erythromycin interact, and all of a sudden, the erythromycin drives the cyclosporin levels up, the kidneys shut down, adverse reaction, possible death. There is an 11-bed hospital there in the country—a typical small rural hospital of 11 beds, as Senator Collins said. How would the system under the recommendations being made today by the President, and conceptually, based on your discussions, work? Is it reported through hospitals, or who does the reporting? Is that 11-bed hospital responsible for collecting that data? And then you have the emphasis on States. Whom do they report it to? Do they report it to the Department of Public Health in Tennessee, which does not have the organization or the administration or the focus now? And then, once it gets to the State with this mandatory reporting, does it come to AHRQ, does it come to you, where basically, we are talking about funding, or does it go to the FDA or to the NIH? Where does this data eventually go?

Dr. EISENBERG. First, that example that you gave is certainly an avoidable error and one that should not have occurred. The first question, then, is would that have been defined by the Quality Forum as one of those select examples of a reportable event that should be reported to the States.

Every State may want to choose the events that it decides are reportable, but we are going to ask the Quality Forum to help the States to look at those which have an evidence base.

Senator FRIST. And that has not been defined, or do we have definitions out there right now?

Dr. EISENBERG. That is right; we do not. And if you look through the Institute of Medicine report, they describe every State's definition, and they are all different.

The Quality Forum will be a special place for this to happen, I think, because it brings the hospitals, the hospitals, the physicians, the purchasers, the consumers, and the providers all together to decide what the appropriate list should be. So that would be the first question.

Second would be yes, the report would occur through the hospital as we see this system developing. As I mentioned earlier, perhaps when we see how well that system works and how it can work best, that could be expanded to systems of care, but right now, we think it should start with hospitals.

Senator FRIST. Even if the patient is not hospitalized?

Dr. EISENBERG. If the patient is not hospitalized, the way the reporting system would currently work, I do not think that that would be picked up.

Senator FRIST. That is fine. Please continue.

Dr. EISENBERG. I do not think any of us see that as where we would like to end, but that is at least where we are starting.

Where would it go? In each of the States, there is a different mechanism for who collects the data in the State, so each State would decide that independently.

What would happen to the data after that? I should say that in addition to this reporting that you are describing, I think you will hear later from the JCAHCO about a different kind of reporting system which that hospital might want to report to that would not go just through the State but would be through the accrediting organizations, and Dr. O'Leary can comment on that.

Then, finally, what would happen to the State data, you asked. We believe that we should have a mechanism for polling the data nationally so that we can help the States compare their experiences with other States, but it should be de-identified—it ought not to have the name of the individual patient or the name of the individual clinician. And when it comes to the national dataset, in fact, the hospitals ought to be coded so that they are relatively de-identified, too, but the State would be able to break that code and find out how the States are doing, how the hospitals are doing.

We believe that that could be done at AHRQ in our research role to help the States to analyze that information, but without any regulatory responsibility for doing so.

Senator FRIST. I know we have to move to the next panel, but that really helps me walking through it, because there are so many different points at the local level all the way up. On the last one with AHRQ—and you said it in the last sentence, but I want my colleagues to be aware—conceptually, I do not think we want AHRQ to be in the regulatory business—and I do not know, if this is the system that we decide upon, where is the appropriate repository? We need to be thinking at least 5 years out or 10 years out where we want it to be. And then, is it going to be mainly a research institution, or is it going to be a regulatory institution, or is it both?

Dr. EISENBERG. That is a critical issue. In the aviation area, the decision was made to split out the regulation from the research

role, and that information goes to the research group, ont to the regulatory group, who then inform the regulators about where the problems may be, but it is a separated process.

Senator FRIST. Thank you. We need to move to the second panel——

Senator DODD. Just one more question, Mr. Chairman.

You raised the issue earlier—and I appreciate your going through this last issue step-by-step—we are losing 100,000 people each year, and I do not know what direction those numbers are heading in and whether that is static or continues to go up each year, but it is not an insignificant problem that we are dealing with here. I am not interested in watching yet another agency of the Federal Government become a regulatory agency—I like to leave as much at the State level as possible—but I can see a patchwork developing here that could be very uneven in terms of what degree of confidence people would have about whether or not they are going to be in good hands in making decisions depending on what State they are in. Particularly today, with the mobility of medical technology, where people go to different places because, for example, it is known that in Tennessee, there is a better heart surgeon, or in Philadelphia, there may be a better brain surgeon, so people move around a lot, and now, if you add to that that you have to concern yourself with whether each State is going to have better recordkeeping so I can make a good decision about whether my brother or my sister or myself will be in good hands, I get uneasy about that approach. I understand the rationale for it, but——

Senator SPECTER. Senator Dodd, if you are going to talk about Philadelphia, you are going to have to talk at greater length.

Some of us have an obligation to be——

Senator DODD. I know that, but just as to the last point on the question of cost.

Senator SPECTER [continuing]. Let me just make one statement here. Some of us have an obligation to be at the White House at 12:10, and we have four more witnesses to hear from as well as questions.

Senator DODD. I understand.

You are not going to answer it here today, but on the point that Senator First was raising, I would be very interested in some cost analysis of what this is going to cost States, because ultimately, I can see the issue coming back to us in terms of what dollars we are going to provide States. I presume you do not have the answer to that today. Senator Hutchinson raised it, and Senator Frist did so implicitly, and I would like to know what you are anticipating in terms of the cost of this if the States are going to do it.

Senator FRIST. OK. Thank you both very much. We appreciate it.

Let us now call the second panel forward, and Senator Specter, why don't you begin with the introductions? Let us go through all four introductions and the move straight into the testimony.

I will ask everyone to try to keep your testimony to 5 minutes and try to summarize. It will be made a part of the record—and then we will continue with questioning, recognizing that people do need to get to the White House.

Senator Specter.

STATEMENT OF DR. I. STEVEN UDVARHELYI, SENIOR VICE PRESIDENT AND CHIEF MEDICAL OFFICER, INDEPENDENCE BLUE CROSS, PHILADELPHIA, PA, ON BEHALF OF THE AMERICAN ASSOCIATION OF HEALTH PLANS

Senator SPECTER. Our first witness will be Dr. Steven Udvarhelyi, senior vice president and chief medical officer for Independence Blue Cross and its affiliated companies, Keystone Health Plan East and AmeriHealth in Philadelphia. Dr. Udvarhelyi has extensive experience in the managed health care industry and serves on several panels concerned with quality in health care. He received his M.D. from Johns Hopkins and his B.A. from Harvard.

Senator FRIST. Thank you, Senator Specter.

Dr. UDVARHELYI. Good morning, Chairman Frist, Chairman Specter, and members of the committee.

My name is Dr. Steven Udvarhelyi, the chief medical officer for Independence Blue Cross in Philadelphia, PA, and I thank you for the opportunity to testify today on the very important issue of patient safety. I am testifying on behalf of the American Association of Health Plans, which represents more than 1,000 HMOs, PPOs, and similar network plans that provide health coverage to more than 150 million Americans.

Independence Blue Cross, my company, serves approximately 2.7 million individuals in Southeastern Pennsylvania and offers a full range of health insurance products including Medicare, Medicaid, and commercial health plans.

The Institute of Medicine report, "To Err is Human," has performed an important service by raising the public's awareness about the longstanding problem of medical errors. But it is important to not that preventable medical errors are neither a new nor a newly-discovered phenomenon. For example, in 1984, the Harvard Medical Practice Study looked at over 30,000 hospitalizations in New York and found that about 3,000 patients suffered serious complications from preventable medical errors. Based on this, the authors estimated that over 27,000 individuals die each year in New York alone as a result of preventable adverse medical events.

So if the evidence on the proliferation of medical errors is not new, then why have we not been able to effectively improve patient safety? The answer has to do with the atmosphere in which physicians, hospitals, and other health care providers function. When a mistake occurs, we are all eager to point the finger at someone, and our current liability system promotes this culture of blame.

Both the Institute of Medicine and President Clinton's Advisory Commission have noted that fears of litigation negatively impact error reporting. In fact, there is really no doubt that the current culture of blame inhibits the identification of medical errors and in so doing helps perpetuate them.

Mandatory reporting of medical errors by itself will not necessarily lead to a reduction of errors or better outcomes for patients. We must first create an environment that encourages the reporting of errors and then enables all participants in the health care system to learn from mistakes in an effort to prevent them from occurring. A central characteristic of this environment must be malpractice reform to reduce the punitive consequences of reporting. And I agree with Senator Specter's earlier comments that

such reforms should address how to compensate injured individuals.

Other elements of the new environment that must be embraced if we are to move away from the current culture of blame and toward improved patient safety include confidentiality and a nationally-based reporting system. There must be strong confidentiality protections in place for any error reporting system, whether voluntary or mandatory, again in part so that reports cannot be used as a basis for initiating or pursuing liability claims. Additionally, data should be reported and analyzed in the aggregate wherever possible.

We need a national rather than a State-based system to promote uniform reporting and to enable us to identify the underlying systematic causes of medical errors. Only in an environment with malpractice reform, strict confidentiality, and nationally-based reporting do we believe that mandatory reporting for medical errors is appropriate.

Implementation of an error reporting system also raises a number of other important issues, including what type of errors should be reported, who will be able to report those errors, what type of information should be included in an error report, and who will have access to the data and how will it be used.

In conclusion, the American Association of Health Plans wholeheartedly supports the goals of the Institute of Medicine committee to decrease errors and develop a systemic approach to prevent their recurrence. We also believe that if the Institute of Medicine report has shown us nothing else, it has demonstrated that the current debate over patient protection legislation needs to be viewed in a new light. As noted by the IOM and President Clinton's Advisory Commission, the current liability system deters the reporting of errors. Expansion of such a system, as proposed by the Norwood-Dingell bill, would do nothing to promote improved patient safety.

PREPARED STATEMENT

Chairman Frist and Chairman Specter, we are committed to working with your committees and all the stakeholders involved in this issue to develop an effective way to identify errors and use that knowledge to improve patient safety.

Thank you for the opportunity to provide testimony today. I would be happy to answer any questions at the end.

Senator FRIST. Thank you, Dr. Udvarhelyi.

[The statement follows:]

PREPARED STATEMENT OF I. STEVEN UDVARHELYI

Good morning Chairman Jeffords, Chairman Specter, and members of the committee. My name is Dr. I. Steven Udvarhelyi, and I am Chief Medical Officer at Independence Blue Cross in Philadelphia, PA. Thank you for the opportunity to testify today on the very important issue of patient safety. I am testifying on behalf of the American Association of Health Plans, of which Independence Blue Cross is a member. AAHP represents more than 1,000 HMOs, PPOs, and similar network plans providing care to more than 150 million Americans. AAHP member plans are dedicated to a philosophy of care that puts patients first by providing coordinated, comprehensive health care.

Independence Blue Cross serves approximately 2.7 million subscribers and members in Southeastern Pennsylvania. Our company offers a full range of health insurance products: fee-for-service indemnity plans in conjunction with Pennsylvania

Blue Shield; Personal Choice, a Preferred Provider Organization; Blue Choice, another PPO; Keystone Health Plan East, our commercial HMO; Keystone 65, our Medicare HMO; Personal Choice 65, our Medicare PPO; and Security 65, our Medicare Supplemental coverage. We also contract with the state of Pennsylvania to provide HMO coverage for Children's Health Insurance Program (CHIP) eligible children in our region, and in partnership with Mercy Health Plan we offer Medicaid HMOs, Keystone/Mercy Health Plan and AmeriHealth/Mercy Health Plan.

Mr. Chairmen, patient safety is an issue that must be addressed if we are to improve the quality of health care in the United States. The Institute of Medicine (IOM) report has performed an important service by raising the public's awareness about the long-standing problem of medical errors and we applaud the Committee's goal to improve patient safety.

My testimony will address the issue of patient safety, focusing on the following four areas:

(1) The historical context of errors in medicine;

(2) How our current environment prevents effective identification of errors;

(3) Types of changes that must be made to create an environment that is supportive of error identification and improved patient safety; and

(4) Additional questions raised by error reporting initiatives.

HISTORICAL CONTEXT

Preventable medical errors are neither a new nor newly discovered phenomena. Awareness of this issue dates back many years, with studies documenting the problem reaching back as far as the 1950's. For instance:

—In 1976, the U.S. House of Representatives' Subcommittee on Oversight and Investigation of the Committee on Interstate and Foreign Commerce issued its report, "Cost and Quality in Health Care: Unnecessary Surgery." The Subcommittee, in citing the scientific literature, estimated that there were some 2.4 million unnecessary operations every year, with as many as 11,900 deaths attributed to these unneeded operations, and thousands more seriously injured.

—The Harvard Medical Practice Study, which looked at over 30,000 hospitalizations in New York State in 1984, found that nearly 3,000 patients suffered serious complications from preventable medical errors. This study projected that approximately 27,000 individuals die each year in New York hospitals alone as a result of preventable medical errors. (Brennen et al, 1991)

—"Giving medication to the wrong patient or to the right patient in an incorrect dosage or at the wrong time is commonplace in hospitals, nursing homes and other health care settings." This is based on findings from six different research studies published between 1986 to 1990. (Bogner, Human Error in Medicine, 1994)

With respect to patient safety, it is important to understand what health plans can do. For example, health plans have credentialing requirements so that only qualified providers participate in our networks. Health plans provide information to providers on "exemplary practices" that are based on medical and scientific evidence, and perform technology assessments to understand what the risks and benefits are of new and emerging medical technologies and interventions. Health plans utilize centers of excellence—hospitals and other health care centers that have gained an expertise in a specific area such as cardiac care—to promote patients' access to the institutions and professionals who are leaders in their respective fields.

However, it is important to note that health plans do not perform the surgery, prescribe or administer the drugs, and are not in the physician's office or the operating room when care is delivered to patients. Accordingly, it is health care professionals who know when an error has occurred and who are in the best position to evaluate and decrease errors. This sentiment is echoed in a 1994 book entitled, Human Error in Medicine.

—"[T]o explore the operational context for error, it is necessary to have information about the elemental unit of the provider, the patient and whatever medical treatment device(s) or medication were used at the time of the error. . . . Such a system cannot be developed without input from those who understand the situation and can identify the factors that induce errors: the medical care providers." (Bogner, Human Error in Medicine, 1994)

"CULTURE OF BLAME"

The question we all must ask ourselves based on the above examples and the findings of the IOM report is why, when we have evidence of the proliferation of medical errors, have we not been able to effectively improve patient safety?

In order to answer this question, we need to look at the atmosphere in which physicians, hospitals and other health care providers function. When a mistake occurs, our society is quick to look for someone at whom to point the finger, and, in the case of medical errors, the finger is often pointed at the individual provider. However, most medical errors result from a series of often subtle events in the systems that deliver care, and not from the negligence of individual practitioners or institutions. Obviously, a "culture of blame" is not conducive to the identification and reporting of errors-the essential precondition for understanding why an error has occurred and what changes are necessary to avoid its repetition. This was noted by both the IOM and President Clinton's Advisory Commission on Consumer Protection and Quality in the Health Care Industry in 1998.

—Patient safety is "hindered through the liability system and the threat of malpractice, which discourages the disclosure of errors. The discoverability of data under legal proceedings encourages silence about errors committed or observed. Most errors and safety issues go undetected and unreported, both externally and within health care organizations." To Err Is Human, Institute of Medicine, 1999

—[P]erhaps the most significant deterrent to the identification of errors is the threat of costly, adversarial malpractice litigation." President Clinton's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, Final Report, 1998

Direct evidence of the impact of litigation on patient safety is not hard to find. In considering Joint Commission on Accreditation of Healthcare Organizations (JCAHO) policy to require reporting of all "sentinel events" that occur in hospitals (defined as all unexpected occurrences that resulted or could have resulted in a patient's death or serious injury), the American Medical Association (AMA) House of Delegates determined it could not support the requirement due to the fear of lawsuits such reporting would generate. Clearly then, we need to replace the "culture of blame" that inhibits the identification of medical errors, and in doing so, perpetuates them. In its place, we need to create an environment that encourages the reporting of errors and enables all participants in the health care delivery system to learn from mistakes in an effort to prevent them from recurring.

CREATING AN ENVIRONMENT SUPPORTIVE OF PATIENT SAFETY

Identifying medical errors is the first essential step to improving patient safety. Mandating reporting in a vacuum, however, will not lead to better outcomes. To again quote from Human Error in Medicine, "It is imperative that an atmosphere be created in which medical care personnel can freely provide data about errors and near errors they experience." As an example of how a supportive environment can promote effective reporting, the federal Aviation Safety Reporting System has established incentives and safe harbors that contribute to the reporting of almost 20,000 errors each year. Aviation officials point to a system that is viewed by workers as confidential and non-punitive. What we can learn from the experiences in the aviation industry is that there are many factors that will impact the success of measures to improve patient safety and they must be considered in order to develop an effective policy.

Accordingly, AAHP believes that the following elements must be embraced if we are to move away from the culture of blame, encourage health care providers to report medical errors, and put our health care system on a path toward improving patient safety.

—Error reporting is tied to significant malpractice reforms. Fear of litigation has interfered with efforts to identify medical errors. The culture of blame pervades every aspect of medicine, from affecting patient safety to increasing medical costs by encouraging the practice of "defensive medicine." In order to promote a more positive environment for reporting and identifying medical errors, we need to enact malpractice reforms applicable to health care claims.

—Reported information is strictly confidential. While the IOM report supports confidentiality for errors not defined as "serious adverse events" we feel there must be strong confidentiality protections for both mandatory and voluntary effort-reporting systems, in part so that reports themselves cannot be used as a basis for initiating or pursuing liability claims. It is critical to recognize that failing to adopt a policy of strict confidentiality for error reports simply means that errors will not be reported, and therefore will go uncorrected, leading to more unnecessary patient injuries. Precedent for maintaining the confidentiality of reported errors already exists in state peer review laws and regulations.

—Analyzed data is reported in aggregate. While researchers will need access to the identity of the individuals and institutions who have committed an error for

the purpose of analyzing the data, public reports should not use any individually or institutionally identifiable information.

—Data is reported to a national entity. The IOM recommends that data be collected on a state-by-state basis. However, this would complicate the ability to easily access data and to identify system-wide trends. A national system, based on uniform data collection, is needed to identify the underlying systemic causes of medical errors.

—Data is used and not warehoused. Error reports are useless if they are not analyzed and if the resulting information is not fed back to those providing for and delivering health care. The entity that receives error reports should have the capability to analyze them and to make the reports available to bona fide research organizations for analysis.

Only under a new environment including malpractice reforms and strict confidentiality do we believe mandatory reporting for serious adverse events attributable to medical error is an appropriate and effective way to begin to reduce medical errors. Such reporting must be tied to incentives to change current behavior of under-reporting errors, if we are to make headway in promoting patient safety. In the absence of these changes our efforts to begin to address the problem of medical mistakes will be hindered.

OTHER ISSUES RAISED

Error reporting raises a host of other issues that must be addressed before policy makers move ahead. To list a few:

—What type of errors will be reported? Not all errors are of such gravity to require mandatory reporting. The national entity responsible for data reporting standards should set priorities for errors subject to mandatory reporting.

—Who will be able to report errors? Will patients or their family members, in addition to medical professionals, be viewed as a source of error reporting?

—What other type of information would be included in an error report? There will need to be clear parameters on what type of information is necessary to track medical errors. Even with confidentiality provisions in place, the error reports will be based on material that may be extremely sensitive to all involved parties.

—Who will have access to the data and how will it be used? There will be broad interest in obtaining the data, and it is critical to ensure that the data is only used for the purposes of improving patient safety.

These are just a few the questions that would need to be addressed before any error reporting system could be implemented.

CONCLUSION

In conclusion, patient safety remains a serious health care quality concern and must be afforded proper attention. AAHP enthusiastically supports the direction and goals of the IOM committee to decrease errors and develop a systematic approach to prevent recurrence. But we do question how Congress can promote the reporting of errors on the one hand and support the expansion of a flawed liability system on the other. If the IOM report has shown us nothing else, it has demonstrated that the current debate over "patient protection" legislation has been misguided at best. The current liability system, as noted by the IOM and President Clinton's Advisory Commission, deters the reporting of errors. Expansion of such a system, as proposed by the Norwood-Dingell bill (H.R. 2990), would do nothing to promote efforts to improve patient safety.

Health plans will continue to maintain their role of supporting those who actually deliver care physicians, hospitals and other health care providers. The commitment of providers is critical to this undertaking, but the commitment of other stakeholders-patients, purchasers, regulators and health plans-is also important. We must work together to develop an effective way to identify errors and use that knowledge to improve patient safety and prevent future errors from occurring.

Mr. Chairmen, AAHP is pleased to continue to work with the committee as you examine the issue of patient safety. AAHP and its member plans remain committed to upholding high standards of patient care, which include supporting efforts to decrease medical errors. We welcome the Committees' interest in these issues, and we thank you for providing us the opportunity to testify today.

STATEMENT OF DR. THOMAS R. RUSSELL, EXECUTIVE DIRECTOR, AMERICAN COLLEGE OF SURGEONS

Senator SPECTER. I am happy to introduce Dr. Tom Russell, recently named executive director of the American College of Surgeons. Dr. Russell is a general surgeon who specializes in colon and rectal surgery. Since 1980, he has served as chairman of the Department of Surgery at California Pacific Medical Center, with which he has been affiliated since 1975. He is also a clinical professor of surgery at the University of California San Francisco and has been affiliated with a number of hospitals in the San Francisco area. Dr. Russell is a member of many professional and medical societies and has published extensively on scientific and educational topics in surgery.

It is a pleasure to have you with us, Dr. Russell.

Senator FRIST. Dr. Russell.

Dr. RUSSELL. Mr. Chairman, Senator Specter, it is a real pleasure to be here. My name is Tom Russell, and until very recently, 2 months ago, I was a busy practicing surgeon in San Francisco, and I have recently been in the health care environment personally, teaching residents.

I am now executive director of the American College of Surgeons, and on behalf of the 62,000 Fellows of this College representing all surgical specialties, I am honored to be here to present to these two distinguished Senate committees.

Patient safety is not a new topic for our organization. I am proud to say that for the entire 87 years of the College's history, patient safety and quality of care have been of paramount importance. Our work in this area is described in some detail in my written statement—I will not bore you with our past history or what our future plans are.

While we have done much in the past, we recognize that much yet needs to be done. The recent Institute of Medicine report gives us the impetus to re-look at what we are doing, and the College leadership, the staff, and our committees are now reviewing this report to see what additional steps our professional organization must take to enhance patient safety in this country's hospitals.

Let me now turn specifically for the sake of time to some of the specific key recommendations of the IOM report. One urges that the Congress pass legislation extending peer review protections to data related to patient safety and quality improvements. The College strongly supports this position. It would greatly enhance the current peer review system's work in evaluating errors, identifying patterns of poor care, and addressing health care system problems—and I underline "system problems."

This was actually recognized even before the IOM report. Last June, the Medicare Payment Advisory Commission, or MedPAC, called upon Congress to "enact legislation to protect the confidentiality of individually identifiable information relating to errors in health care delivery when that information is reported for quality improvement purposes."

In making this recommendation, MedPAC did not attempt to distinguish between different types of adverse events. In fact, MedPAC argued that "reporting incidents of preventable errors in health care delivery is unlikely to become routine practice as long

as providers fear that the information they disclose can be used against them in a punitive manner."

Therefore, the College believes that legislation extending confidentiality protections to all data and work products related to patient safety and quality improvements is a step that is likely to bear immediate dividends, particularly in creating the culture in the hospital and the health care setting for reporting of events.

A second recommendation calls for a nationwide mandatory reporting system. The College has some concerns about this and wishes to know more of the details. We believe it is unfortunate that the IOM committee concluded that the information collected through mandatory reporting should not receive the same level of confidentiality protection as that received through the voluntary reporting process. This makes it appear that the purpose of a mandatory reporting system may be punitive in nature—a perception that seems unlikely to foster the quality improvements that we are all looking for.

Second, the Institute of Medicine report calls for narrowly defined mandatory reporting systems, but stops far short of providing those important details. The College believes that more work is needed to identify the data that should be collected and how such data should be used. It will be critical to ensure that the time and effort involved in submitting information be used effectively and patient safety improvement occur. Reporting of data alone will do nothing to improve the system; the loop must be closed. Without this assurance, the College believes it would be a waste of taxpayers' dollars to create yet another mandatory reporting system and data repository.

This cautious approach, I might add, should in no way prevent progress on patient safety.

A third IOM recommendation stresses that voluntary reporting efforts should be encouraged. We could not agree more. In fact, we believe that a wide variety of voluntary reporting systems should be encouraged. In this regard, the Federal role could be one of providing the funding needed to develop and test a variety of voluntary reporting systems and other patient safety initiatives. The Agency for Health Care Research and Quality, AHRQ, seems well-positioned to play a role provided it is given adequate resources to do so.

To conclude, I want to assure Senator Specter that the American College of Surgeons wants to participate in this activity. The American College of Surgeons has a longstanding history in patient safety, beginning in 1918, when it initiated the Hospital Standardization Program, which you know today as the JCAHO.

I could enumerate all of our activities as far as training the young doctors in medical school and what we do in residency training for all surgical specialties, how we relate to the American Board of Medical Specialties, what we do for ongoing CME education, what some of our committees do with respect to trauma and cancer care in this country. We are forming a framework to develop lifelong learning for physicians throughout their professional lives so they can remain competent, and we are obviously very interested in public education and making certain the public knows

about surgery and how to select surgeons and what to expect from an operative procedure.

PREPARED STATEMENT

We look forward to working with Congress, with these committees and with the administration and other interested professional groups to ensure that patients receive the highest quality care possible.

Thank you very much.

Senator FRIST. Thank you, Dr. Russell.

[The statement follows:]

PREPARED STATEMENT THOMAS R. RUSSELL

Mr. Chairman and members of the Committee, my name is Thomas Russell, MD, FACS and I am the Executive Director of the American College of Surgeons. On behalf of the 62,000 Fellows and other members of the College, I would like to thank you for this opportunity to offer the surgeon's perspective on the IOM report entitled "To Err is Human: Building a Safer Health System." The American College of Surgeons is a scientific and educational association of surgeons that was founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. The College has a longstanding interest in patient safety and we look forward to working with Congress, the Administration, and other interested parties to assure that patients receive the highest quality of care.

ACS INVOLVEMENT IN THE ISSUE OF PATIENT SAFETY

Patient safety is an important issue, but certainly not a new one. From its founding, the College has devoted considerable attention to the issue of patient safety and we recognize that our work will never be done. As others have said, any error that harms a patient is one error too many. However, in discussing the issue of patient safety, we believe it would be a mistake to act as if the issue has simply been ignored. The IOM report itself takes note of a wide variety of programs and initiatives, some of them of a longstanding nature, that have focused on patient safety issues. For example, Appendix E of the report acknowledges that "[s]urgical morbidity and mortality (M&M) conferences began early in the twentieth century as a standardized case report system to investigate the reasons and responsibility for adverse outcomes of care." As noted in the IOM report, the Accreditation Council for Graduate Medical Education now mandates weekly M&M conferences "at which, under the moderation of a faculty member, surgical residents and attendings present cases of all complications and deaths."

I thought it would be appropriate and useful, at the outset, to outline briefly at least some of the College's own work on patient safety and related matters. In 1918, the College initiated a Hospital Standardization Program in an effort to ensure a safe environment and an effective system of care for surgical and other hospitalized patients. That program ultimately led to the establishment of what is known today as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). This commitment continues through the College's representation on the JCAHO board, as well as through other programs and initiatives conducted by a number of College committees and departments.

The College has been intimately involved in the education of surgeons at the undergraduate, graduate and continuing medical education levels. For example, the College's Committee on Emerging Surgical Technology and Education studies the implications of innovations in surgical methods and helps develop policies to promote appropriate training for surgeons and protect the welfare of the surgical patient. The College also sponsors a wide variety of courses, specifically including those aimed at assuring the safe and effective use of new technologies, such as stereotactic breast biopsy, diagnostic breast ultrasound, and sentinel node biopsy in the management of breast tumors.

Another innovative program is administered by the College's Committee on Continuing Education to help surgeons maintain their skills and stay abreast of current practice standards. This program is the Surgical Education and Self-Assessment Program (SESAP) and provides practicing surgeons the opportunity to stay abreast of current standards in surgical practice by reproducing the diagnostic and treatment challenges faced in the practice of surgery.

I might add that it is unfortunate that the rigor with which surgeons and other physicians are trained, examined and board certified, involving the oversight of Residency Review Committees (RRCs), the Accreditation Council for Graduate Medical Education, the American Board of Surgery and the other members of the American Board of Medical Specialties, and other bodies, is generally unknown to the general public. Fellows of the College are nominated to serve on these various oversight and standard-setting bodies and play an active role in their deliberations. Of special note is ongoing work to develop a framework for evaluating a physician's continuing competence in the areas of patient care, professionalism, interpersonal and communications skills, medical knowledge, practice-based learning and improvement, and systems-based practice. All of this is being considered in the context of a physician's maintenance of board certification.

For nearly 20 years, the College's Committee on Operating Room Environment conducted a biennial symposium for operating room team members. These education programs routinely emphasized the need for team communications to ensure safety in the operating room environment, as well as infection control practices, identification and elimination of hazards in the operating room (e.g., electrical, fire), how to deal with difficult behaviors in the operating room, uses of computer-based technology to enhance patient safety in the operating room, training and credentialing operating room team members and other personnel, and data collection and quality improvement.

Additionally, the College has published a Patient Safety Manual as a guide for implementing a systematic approach to quality assurance and risk management in hospitals. The manual focuses on a systems approach to patient safety that includes: analyzing quality of care data; peer evaluation of data; determination of corrective action; and, communicating the results with all affected parties. The College is in the process of updating the manual yet again.

On the subject of trauma care, the College sponsors a number of programs to improve the care of the injured patient. These include a national trauma registry and advanced trauma life support (ATLS) courses.

Another College-sponsored activity worth noting is the annual data set collected as part of the National Cancer data base, which looks at cancer care in approved hospitals and provides feedback to individual institutions, allowing them to compare their practice with the national aggregate. This is the largest cancer database in the country, and operates without the benefit of any federal funding.

In an effort to collaborate with a variety of health care professionals on the issue of patient safety, a representative from the American College of Surgeons serves on the Board of the National Patient Safety Foundation. As you know, the foundation is a broad-based partnership that serves as a forum for addressing a wide spectrum of patient safety issues through four core strategies: research, prevention, communication and education.

In response to the IOM report, the College is planning to devote special attention to the issue of patient safety during our next Clinical Congress, an annual event attended by approximately 18,000 people.

Finally, in today's world, patients must become active partners in their own medical and surgical care. In an effort to assist patients to be as knowledgeable and informed as possible in choosing their surgeons, the College has long supported an active public information program. The purpose of the program is to provide the public with information on what distinguishes surgeons from other physicians, what to look for in examining a surgeon's credentials, questions to ask before consenting to an operation, and so on. This long-standing commitment to public education is a major priority of the American College of Surgeons.

In short, for the last 87 years, the College has emphasized patient safety and quality of care. We, therefore, strongly support recommendation 8.1 of the recently released IOM report, which calls upon health care organizations to make patient safety a priority.

ACS VIEWS ON THE RECOMMENDATIONS MADE BY THE IOM

The IOM report includes a wide variety of recommendations. For purposes of this hearing, the College would like to focus upon several of them.

Extending Peer Review Protections

I'd like to begin by discussing recommendation 6.1. This recommendation urges the Congress to pass legislation extending peer review protections to data related to patient safety and quality improvements that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality.

Peer review can be an effective tool in evaluating errors, identifying patterns of poor care, and addressing health care system problems. Unfortunately, the current peer review system is handicapped in that peer reviewers are not consistently guaranteed the appropriate confidentiality protections that are needed for them to effectively complete their work. Health care professionals will not be receptive to reporting errors to any reporting system if there is a belief that this information could be used against them in future litigation. This handicap will cause these systems to remain ineffective.

In its June 1999 report, the Medicare Payment Advisory Commission (MedPAC) called upon the Congress to "enact legislation to protect the confidentiality of individually identifiable information relating to errors in health care delivery when that information is reported for quality improvement purposes." I think that it is important to note that, in making this recommendation, MedPAC did not attempt to distinguish between different types of adverse events, and went on to observe that "[s]uch a law would neither help nor harm individual patients who are injured (compared with the status quo), but should help patients collectively by fostering the reporting of data that can be used to reduce the incidence of avoidable errors in the future." In fact, MedPAC argued that "[r]eporting incidents of preventable errors in health care delivery is unlikely to become routine practice as long as providers fear that the information they disclose can be used against them in a punitive manner."

To sum up, the College believes that if Congress is able to do only one thing this year to address patient safety concerns, it should be to adopt legislation that extends peer review protections (i.e., confidentiality protection and protection from discovery) to all data and work products related to patient safety and quality improvements. In our view, this is the step that is likely to bear immediate dividends with respect to patient safety. Among other things, it should encourage the development and successful operation of voluntary reporting systems, another IOM-recommended step and one discussed a bit later in these remarks.

National Center on Patient Safety

Recommendation 4.1 of the IOM report calls for the creation of a new Center for Patient Safety. This center would set national goals for patient safety, track progress in meeting these goals, issue an annual report on patient safety, and accomplish other assigned tasks. While the American College of Surgeons would not object to the establishment of such a National Center, we would suggest that the Congress carefully review the existing authority given to the recently reauthorized and renamed Agency for Healthcare Research and Quality (AHRQ). We believe that AHRQ might already be well positioned to address patient safety issues.

In fact, several members of the Health, Education, Labor and Pensions Committee have already pointed this out. For example, Senator Frist, who is a Fellow of the College, has been quoted as saying that the problem of medical errors can be addressed by the Congressionally mandated Centers for Education and Research on Therapeutics, university-based centers that would provide research and education programs on drug safety issues and other issues involving therapeutics. It may well be, then, that what is lacking is not a new center, but rather, additional funding to permit AHRQ to support a wide variety of patient safety research and pilot projects. In fact, given the current state of our knowledge about patient safety, we believe that more research and demonstration projects-conducted by a wide range of organizations, including physician specialty societies—would be extremely important.

We would, of course, encourage AHRQ or any other entity involved in patient safety to ensure that the physician community has an opportunity to provide appropriate input with respect to planned or potential initiatives.

Mandatory Reporting

This brings me to recommendation 5.1, which calls for a nationwide mandatory reporting system that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. Under the recommended approach, hospitals would be the first entities required to report. Further, the Forum for Health Care Quality Measurement would promulgate and maintain a core set of reporting standards (including a nomenclature and taxonomy for reporting). If a state did not implement the reporting system, the U.S. Department of Health and Human Services would assume the responsibility. Quite importantly, this recommendation assumes that the reported information would not be protected from public disclosure.

The College has a number of concerns about recommendation 5.1. First, we believe it is most unfortunate that the IOM committee chose to recommend that the information collected through mandatory reporting should not receive the same level

of confidentiality as that received through a voluntary reporting process. The purpose of collecting information on adverse events should be to improve patient safety by correcting system errors, not by punishing individuals who have committed some unfortunate error. This systems approach would appear to be the model followed in the case of airline safety, where the Aviation Safety Reporting System is held out as a model for voluntary, confidential, and non-punitive safety reporting. Curiously enough, in its report, the IOM Committee itself emphasizes that non-punitive systems for reporting and analyzing errors should be implemented. It is unfortunate, then, that the IOM Committee did not follow this belief throughout the entire report. This inconsistency makes it appear that the chief purpose of the mandatory reporting system is punitive, a perception that seems unlikely to foster quality improvement efforts.

Second, the IOM report notes that "the focus of mandatory reporting systems should be narrowly defined," but it stops short of specifying what such systems should cover. As you know, there are several reporting systems now in place, and the College believes that much more work is needed to identify which data should be collected-whether in a mandatory or voluntary reporting system. We would be pleased to assist in such a study. We would, for example, be interested in finding ways to minimize reporting burdens. Moreover, I am sure this committee would agree that it will be critical to ensure, especially in any mandatory reporting system, that the time and effort involved in submitting information and doing something with it (e.g., providing meaningful feedback to those who submit data) is likely to lead to patient safety improvements. Without this assurance, the College believes it would be a tragic waste of taxpayer dollars to create yet another data repository.

Third, the College is concerned about the state-based nature of the recommended mandatory-reporting system. This recommendation would lead to 50 reporting structures and data repositories. These state-based systems would by their very nature be "different". These differences could include different reporting requirements and different public disclosure policies. Moreover, in at least some cases, individual states might not have the necessary resources to make effective use of reported information or even to operate the data collection effort.

Given all these concerns, the College urges Congress to defer adoption of recommendation 5.1. Our cautious approach to this recommendation is predicated on the belief that overlaying the current system with more regulation, restrictions, disclosures, and punishment could, unfortunately, divert and dilute efforts to focus on systems improvement and problem-focused education for well-meaning health care providers who, by their very nature, are human. In particular, we believe that it is premature, at best, to talk about whether any mandatorily reported information should-or should not-receive confidentiality protections until we know what this information is, its validity, and so on.

Voluntary Reporting

Recommendation 5.2 stresses that the development of voluntary reporting efforts should be encouraged. The College could not agree more. The IOM Committee is absolutely right when it says that "voluntary reporting systems are an important part of an overall program for improving patient safety and should be encouraged." In fact, we believe that a wide variety of voluntary reporting systems should be encouraged. Some could be strictly internal to a particular organization. Others could involve reporting to some independent entity, which would analyze the data and help identify steps likely to reduce or eliminate future errors, or ensure that the reporting entity has conducted a disciplined process to understand the reason(s) for a particular error and the ways to prevent its recurrence.

As the IOM report states, there are currently a number of voluntary reporting entities including the sentinel event reporting system conducted by the Joint Commission on Accreditation of Healthcare Organizations, the Medication Errors Reporting Program, the MedMARx program and the Department of Veterans Affairs Patient Safety Initiative. In addition, a number of healthcare organizations have developed their own internal voluntary reporting systems. Further, as noted earlier, error reporting systems are found in other areas, such as aviation safety. No doubt, these and other still-to-be-created reporting systems have much to teach us.

In short, the College strongly supports recommendation 5.2 and believes that the federal government can certainly play an important role in encouraging voluntary reporting of adverse outcomes. However, as we emphasized at the outset, we believe very strongly that the confidentiality of reported information must be assured if the goal is an effective reporting system. In addition, we believe that it would be inappropriate, at least at this time, for the federal government to dictate how these voluntary reporting systems should be conducted or what information they should collect.

Role of Professional Societies

Among other things, recommendation 7.2 urges the creation of a permanent committee devoted to patient safety by professional societies, such as the American College of Surgeons. Such committees would develop a curriculum on patient safety, disseminate patient safety information through various channels, and take other actions. I think this recommendation unfortunately makes it appear as if professional societies have been ignoring patient safety issues, which is certainly not true in the case of the College and many other professional societies. For many years, the College has had a number of committees addressing the issue of patient safety. Some of the fruit of this work was alluded to at the beginning of this statement. However, in response to the IOM's recommendations, the College will evaluate whether it would be better to centralize patient safety-related work into a single committee. It is quite possible, however, that we will conclude that, due to the wide scope of patient safety issues, surgeons and surgical patients are better served by having several committees, rather than just one, responsible for this work. I have shared the IOM report with several existing committees within the College as well as our 12 advisory councils. Their review of the IOM report may well suggest additional steps that the College should take to address patient safety concerns.

Medication Safety Practices

The last recommendation I would like to address is 8.2, which calls upon health care organizations to implement proven medication safety practices. Among the practices highlighted in the IOM report is physicians' use of a computerized order entry system for prescription drugs. Such systems are already in use in many hospitals and have generally been well received by physicians and proven themselves effective and efficient in handling patients' prescription drug needs. The College, therefore, supports their use. However, we believe that the Congress should recognize that computerized order entry systems for prescription drugs do involve considerable up-front costs for hospitals, and that the current financial pressures being felt by most hospitals could understandably dampen their enthusiasm for incurring these costs.

CONCLUSION

As I stated in the beginning, the American College of Surgeons has a longstanding interest in patient safety and we look forward to working with Congress and other interested parties to ensure that patients receive the highest quality care. I hope that you find our input useful in shaping future policies. I would now be pleased to respond to any questions you might have.

STATEMENT OF DR. DENNIS O'LEARY, PRESIDENT, JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, CHICAGO, IL

Senator SPECTER. Dr. Dennis O'Leary, also on this panel, is president of the Joint Commission on Accreditation of Health Care Organizations. Prior to joining that Commission, Dr. O'Leary served as dean of clinical affairs at the George Washington University Medical Center and vice president of the University Health Care Plan. He has an M.D. from Cornell and a B.A. from Harvard.

Thank you, Mr. Chairman.

Senator FRIST. Dr. O'Leary.

Dr. O'LEARY. Thank you.

I am Dr. Dennis O'Leary, president of the Joint Commission on Accreditation of Health Care Organizations, and I am very pleased to address you today concerning medical errors. This is perhaps the most pressing health care issue of our time, and I applaud the efforts of both of your committees in this area.

The Joint Commission accredits over 18,000 organizations whose services include acute care, long-term care, ambulatory care, behavioral health care, laboratory services, and home care. Since 1996, we have played a leadership role in encouraging error reporting and analysis. This Sentinel Event Program has provided us

some unique lessons learned that we would like to share with you today.

Dramatically reducing the number of errors will take a concerted effort by all responsible parties who participate in and oversee the delivery of health care. This coordinated approach must necessarily bridge the public and private sectors.

We believe that medical error reduction is fundamentally an information problem. With this in mind, we suggest that five critical, information-based tasks are essential to an effective error reduction strategy.

The first task is the creation of a blame-free, protected environment that encourages the systematic surfacing and reporting of serious adverse events. Fear of reprisals, public castigation and loss of business will continue to impede the reporting of serious errors unless we provide incentives for making mistakes known to accountable oversight bodies. Today, the "blame and punishment" orientation of our society drives errors underground. Indeed, we believe that most medical errors never reach the leadership levels of the organizations in which they occur.

If we are to better understand the epidemiology of medical errors, we must create a protected, blame-free environment that permits access to information about their scope and nature. Further, it is imperative that any medical error reporting program operate under a pragmatic and carefully crafted definition of what constitutes the serious adverse event.

The second task is the production and protection of credible root cause analyses of serious adverse events. When a serious error occurs, there must follow an intensive, no-holds-barred vetting of all of the causes underlying the event. These root cause analyses, which we believe hold the critical answers to future error reduction, focus primarily on organization systems. Unfortunately, most reporting systems, both voluntary and mandatory, fail to require or encourage the performance of root cause analyses.

Not surprisingly, organizations are hesitant to share these root cause analyses with the Joint Commission or anyone else. We must recognize that preparing a document that lays bare the weaknesses in health care provider systems is akin to writing a plaintiff's brief. Therefore, we cannot expect uniform preparation of these documents without Federal protections against their inappropriate disclosure.

The third task is to implement concrete, planned actions to reduce the likelihood of similar errors in the future. The principal derivative of a root cause analysis is an action plan that focuses on improving the organization systems related to the serious adverse occurrence. It is essential that implementation of this action plan be monitored and confirmed by an independent oversight body. We view the monitoring of planned systems changes in organizations as a key element of public accountability. Therefore, we believe that any public sector error reporting program must provide for the sharing of relevant adverse information with responsible accreditors.

The fourth task is the establishment of patient safety standards which health care organizations must meet. We believe that all quality oversight bodies should have explicit requirements that

make the identification and management of medical errors a high priority for organization leadership. The Joint Commission implemented such standards in January 1999 in order to bring both visibility and focus to the problem. These standards expect organization action on both medical error crashes and near misses in the delivery of patient care.

The last task is dissemination of experiential information to all organizations at risk for adverse events. To have a positive impact on patient safety, information gleaned from the analyses of errors must be widely disseminated to help all organizations reduce the likelihood of adverse events. The Joint Commission does this through its continuing series of Sentinel Event Alerts. To date, we have issued alerts on medication errors, wrong site surgery, restraint-related deaths, blood transfusion errors, inpatient suicide, infant abductions, and postoperative complications. Such dissemination activities are highly dependent upon having good information and adequate resources to reach health care decisionmakers. This is therefore an area where more effective public-private sector collaboration is highly desirable.

Finally, it must be understood that access to error-related data and information undergirds and drives this overall system of accountability and oversight. The Congress should, therefore, support coordination of error reduction strategies and the sharing of relevant data amongst all of the responsible public and private sector oversight bodies.

PREPARED STATEMENT

The Joint Commission's Sentinel Event Program has identified the critical information-based tasks that are essential to solving the medical error problem. But this program also illustrates the harsh reality of the litigious atmosphere in health care that creates major barriers to the surfacing and reporting of error-related information. It is abundantly clear that without Federal legislation, the Joint Commission's error reporting program and others like it will continue to fall significantly short of their intended goals.

Thank you.

Senator FRIST. Thank you, Dr. O'Leary.

[The statement follows:]

PREPARED STATEMENT OF DENNIS O'LEARY

I am Dr. Dennis O'Leary, President of the Joint Commission on Accreditation of Healthcare Organizations. I am pleased to have the opportunity to address the Senate Committee on Health, Education, Labor and Pensions regarding medical errors. The frequency and gravity of medical errors is perhaps the most pressing health care quality issue of our time.

The Joint Commission is the nation's oldest and largest standard-setting body for health care organizations. We accredit over 18,000 organizations that provide a wide range of services, including hospitalization; long term care; ambulatory care; behavioral health care; laboratory services; managed care; and home care. Based on its broad experience, the Joint Commission has a panoramic view of the strengths and weaknesses inherent in our health care delivery system. We believe that the problem of medical errors is endemic to the way health care is carried out, but that health care providers have the tools and the commitment to sharply reduce their incidence.

My testimony will focus on the task that we believe must be carried to reduce errors nationwide. The release of the Institute of Medicine's report, "To Err is Human: Building a Safer Health System," has galvanized the professional and pol-

icy making communities around this critical set of quality issues. Such synergy of purpose among the key stakeholders is a prerequisite for successfully addressing complex, multifactorial problems that we face today. Dramatically reducing the number and seriousness of errors will take a concerted effort—particularly including a willingness to share information—by all who participate in and oversee the delivery of health care.

The goal for the country should be to find ways to increase knowledge about why errors occur and to apply that information in a manner that will enhance patient safety. On the surface this sounds simple, but success will in fact require a cultural shift in how our society views and treats medical errors. Success will also require a coordinated approach among responsible parties. This coordinated approach must necessarily bridge the public and private sectors.

I would like to stress that medical error reduction is fundamentally an information problem. The solution to reducing the number of medical errors resides in developing mechanisms for collecting, analyzing, and applying existing information. If we are going to make significant strides in enhancing patient safety, we must think in terms of the information we need to obtain, create, and disseminate. With this in mind, we suggest there are five critical, information-based tasks whose completion is essential to an effective error-reduction strategy. In theory, a single organization could perform all of these tasks, but in fact, multiple public and private sector organizations will have roles to play.

The first task is the creation of a blame-free, protected environment that encourages the systematic surfacing and reporting of serious adverse events. Fear of reprisals, public castigation, and loss of business will continue to impede the reporting of serious errors unless we provide incentives for making mistakes known to accountable oversight bodies. Today, the blame-and-punishment orientation of our society drives errors underground. Indeed, we believe that most medical errors never reach the leadership level of the organizations in which they occur. For the typical caregiver involved in a medical error that leads to a serious adverse event, the incentives to report are all negative—potential job loss, humiliation, shunning. It is a small wonder that we know so little about this terrible problem. If we are to get a handle on the epidemiology of medical errors, we must create a protected, blame-free environment that will lead to a more accurate understanding of their scope and nature.

An important feature of the Joint Commission's Sentinel Event Program is the non-punitive reporting environment it seeks to create. Hoping to foster organization cultures that promote error reduction efforts, the Joint Commission has designed its policies not to penalize the accreditation status of an organization that surfaces an error and performs the appropriate due diligence required under the policy. The resulting atmosphere provides incentives that favor the surfacing of information about errors which in contributes to error reduction strategies that can be used by other organizations.

Despite the incentive to report errors to the Joint Commission, the fear of litigation is a significant impediment for the majority of health care providers. Therefore, we have experienced only limited reporting to the Joint Commission's database since it was established in 1996. Indeed, we have found it necessary to create procedural accommodations to protect sensitive error-related information, such as having our surveyors review reported errors onsite rather than having information sent to the Joint Commission's central office. But these manipulations are only stopgap measures that we believe must be replaced by federal protections for error-related information. We urge the Congress to enact such federal protections, because they are as the sine qua non for any effective system of error reporting.

Further, it is imperative that any medical error-reporting program operate under a pragmatic and carefully crafted definition of what is a reportable event. Standardization of the information to be collected is an important prerequisite for aggregating events in a consistent and meaningful fashion. Further, without a pragmatic definition, a reporting program would be flooded with hundreds of thousands of lesser injuries that would overwhelm the system. With this in mind, the Joint Commission has identified a subset of sentinel events [1]—including their nomenclature and taxonomy—that should be reported to the Joint Commission on a voluntary basis.

[1] The Joint Commission defines a reportable sentinel event as an event that has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition, or one of the following: suicide of a patient in a round-the-clock care setting; infant abduction or discharge to the wrong family; rape; hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities, or surgery on the wrong patient or wrong body part.

Our definition of a reportable event minimizes the external reporting burden for health care organizations while focusing on the most serious occurrences. The fact that the Sentinel Event program seeks to collect data on the most serious errors, or "crashes," distinguishes the Joint Commission's reporting program from the voluntary programs encouraged in the IOM report, which would, in a protected environment, collect information only on "near misses."

The second task is the production of credible "root cause" analyses of serious adverse events. When a serious error occurs, it is essential that there be an intensive, no-holds-barred vetting of all of the potential causes underlying the event. We call these responses "'root cause" analyses—a term borrowed from the engineering world's orientation to a systems approach both to solving problems and to producing desired outcomes.

A root cause analysis focuses primarily on organization systems and processes, as opposed to individual performance. While an individual is invariably the proximal cause of a mistake in health care, the fundamental causes of the error almost always relate to systems failures distal to the error itself. For example, systems may fail to provide simple checks and balances; or they may lack critical safeguards; or there may be design flaws that actually promote the occurrence of errors.

Root cause analyses are rich learning processes that often elucidate multiple factors that contributed to the error. Many of these are not readily apparent until the root cause analysis is undertaken. The analysis must be comprehensive and thorough, and engage the personnel involved in all aspects of the care-giving and support processes. These are also time consuming investigations, and their complexity may require external technical assistance. The Joint Commission has developed several comprehensive guides on how to conduct a "thorough and credible" root cause analysis, and continues to be the leading source of guidance for health care organizations in this area.

Unfortunately, most reporting systems—both voluntary and mandatory—fail to require or encourage the performance of these intensive assessments. This was evident during our recent review of state reporting programs. A reporting system that ends with the report of the event itself is not a credible program and will not contribute to error prevention.

Root cause analyses also offer extraordinary insights into how processes must change to control undesirable variations, and they tell stories of what systems must be developed to guard against the occurrence of similar human error. Root cause analyses hold the promise of prevention. They are also the necessary substrate from which risk reduction action plans are created.

While reporting is voluntary under our Sentinel Event Program, the production of a root cause analysis following a sentinel event is mandatory. Not surprisingly, organizations are hesitant to share these root cause analyses with the Joint Commission or anyone else. Although many organizations have done so, we must recognize that preparing a document that lays bare the weaknesses in a health care provider's system is akin to writing a plaintiff's brief for purposes of litigation. Therefore, we cannot expect uniform preparation of these documents without federal protections against their inappropriate disclosure.

The third task is implementation of concrete, planned actions to reduce the likelihood of similar errors in the future. The principal derivative of a root cause analysis is an action plan that focuses on improving the organization systems which related to the serious adverse occurrence. It is essential that implementation of this action plan be monitored and confirmed by an independent oversight body. The response to an error does not terminate simply with the report itself or even an analysis of what went wrong.

The Joint Commission monitors the action plans of accredited organizations which have experienced serious medical errors, in a manner similar to the way it monitors any quality of care area in need of improvement. This ensures that there is targeted review of the milestones associated with planned systems changes. In the end, we expect to see an organizational response that results in preventive actions. This monitoring function is a key element of public accountability. The public must have confidence that there is an external body overseeing patient safety issues in the organizations that are delivering their care.

We believe that the public views safety as a threshold concern. While citizens probably do not wish to have detailed data about safety prevention in each health care organization, they should reasonably expect that responsible oversight bodies are acting conscientiously and effectively on their behalf. This includes aggressive and timely follow-up to the occurrence of a serious medical error and holding the organization accountable for making necessary systems improvements.

At the same time, it is error-related data and information that undergird and drive this system of accountability and oversight. Therefore, we believe that any na-

tional response to the IOM report must ensure appropriate data-sharing among all of the responsible oversight bodies which perform any of the tasks discussed in this testimony. Today's health care quality oversight system involves a variety of private sector and public sector players. Efforts should at least be made to better utilize existing structures through improved data sharing, and to encourage the broad dissemination of what has been learned to date from medical mistakes. We must avoid a fragmented, ineffective system where, for example, a given entity is privy to reports of errors, but oversight bodies with public accountability for patient safety are not made aware of or do not have access to this information.

The fourth key task is the establishment of patient safety standards which health care organizations must meet. The Joint Commission has recently established developed explicit patient safety standards for health care organizations beginning. These new standards were specifically created to establish patient safety as a high priority in these organizations.

The new standards require that the leadership of a health care organization establish processes for identifying and managing sentinel events and put these into practice. The standards also require that the organization monitor the performance of particular processes that involve risks or may result in sentinel events, and intensely analyze undesirable patterns or trends in performance. The standards make patient safety a visible responsibility of health care organizations and a requirement for accreditation. Compliance with these new patient safety standards is evaluated through our periodic onsite inspection process.

While most quality oversight organizations can point to existing standards that should, in theory, have an effect on preventable error, we believe that this particular emphasis on organization accountability is critical. We would therefore like to see other accreditors and health care quality oversight bodies include similar patient safety standards in their requirements. Further, it may be valuable to explore ways for oversight bodies to better inform the public and purchasers as to how well organizations are meeting these heightened performance expectations.

The fifth task is to dissemination of experiential information learned from errors to all organizations at risk for serious adverse events. To have a positive national effect on patient safety, information gleaned from errors must be aggregated, analyzed and disseminated to the health care community at large. This can be done at different levels in the health care system.

The Joint Commission has such a program for its accredited organizations. In 1997, the Joint Commission began to issue periodic Sentinel Event Alerts to share the most important lessons learned—known risky behaviors as well as best practices—from its database of error-related information. To date we have issued Alerts in a number of areas, including medication errors; wrong site surgery; restraint-related deaths; blood transfusion errors; inpatient suicides; infant abductions; and post-operative complications.

We are confident that these Alerts have saved lives. Unfortunately, because the full scope and frequency of serious adverse events is not known, we cannot calculate real decreases in error rates with scientific certainty. However, we have some data which illustrates the effects of our Sentinel Event Program in selected areas. For example, we have seen a notable significant effect from our Alert (Attachment B) dealing with the importance of appropriate storage and handling of potassium chloride (KCl)—a substance that is deadly when given in concentrated form and is easily mistaken for more benign substances. In analyzing the causes of KCl-related deaths, it became evident that storage of concentrated KCl on hospital floors was an important cause of unanticipated deaths. In the Alert that the Joint Commission issued on this subject in February 1998, it was suggested that storage of concentrated KCl be limited to hospital pharmacies to the extent possible. The number of reported deaths has dropped from 12 in 1997 to only one in 1998 and one in 1999.

We also believe that significance should be attached to how information is disseminated and by whom. The risks associated with potassium chloride have long been known to practitioners. But when the principal accreditor of provider organizations issued a major alert, it caught the attention of organization leaders and health care practitioners. Moreover, it was clear to the recipients of the information that the Joint Commission would be paying attention to this particular issue and following up during onsite evaluations of the organization's performance. This program of Alerts is an example of the type of vehicle necessary to achieve behavior change in health care organizations.

There is also a need for more research to inform health care evaluators on how to identify "risk" in organizations. We have some knowledge about the relationship of organizational structure to outcomes—for example, team approaches appear to be more effective than hierarchical structures—but the information is very limited. It may be useful to determine whether there are key characteristics of organizations

that makes them more or less prone to errors such as how well they handle new information, communicate among their component services, etc. Investing in demonstrations of shared decision making may also prove fruitful. Shared decision-making tools that bring the latest information to both practitioner and patient could lead to reduced medical errors through more up-to-date medical knowledge, increased patient compliance, and other factors.

CONCLUSIONS AND NEED FOR CONGRESSIONAL ACTION

We believe that the work of the Joint Commission over the last four years provides significant "lessons learned" for policy makers grappling with solutions to the medical errors problem. Our Sentinel Event Program has identified the critical information-based tasks that need to be carried out. In carrying out these tasks under its aegis, the Joint Commission has assuredly prevented additional errors and saved lives.

But the Sentinel Event Program also illustrates the harsh realities of the litigious atmosphere in health care that creates major barriers to the surfacing and reporting of error-related information. It is abundantly clear that no reporting system for serious errors can fulfill its objectives without Congressional help. Without Federal legislation, the Joint Commission's error reporting program and others like it will continue to fall significantly short of their intended goals. This is true whether the reporting framework is public or private; mandatory or voluntary; national, state, or local.

Therefore, we urge that the Congress create statutory protections from disclosure and discoverability of the in-depth, causal information which must be gathered in any mandatory or voluntary reporting program for serious adverse events.

FACTS ABOUT THE SENTINEL EVENT POLICY

The Joint Commission's Sentinel Event Policy is designed to encourage the self-reporting of medical errors to learn about the relative frequencies and underlying causes of sentinel events, share "lessons learned" with other health care organizations, and reduce the risk of future sentinel event occurrences.

A sentinel event is any unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injuries specifically include a loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

Any time a sentinel event occurs, the accredited organization is expected to complete a thorough and credible root cause analysis, implement improvements to reduce risk and monitor the effectiveness of those improvements. While the immediate cause of most sentinel events is due to human fallibility, the root cause analysis is expected to dig down to underlying organization systems and processes that can be altered to reduce the likelihood of human error in the future and to protect patients from harm when human error does occur.

A standard that creates explicit expectations regarding the internal identification and management of sentinel events was added to the Leadership chapter of all accreditation manuals and became effective January 1, 1999.

The Sentinel Event Policy provides an opportunity to expand the Joint Commission's database of sentinel events that occur with significant frequency. The database also categorizes the most common underlying causes of these events and strategies that accredited organizations have used to reduce risk to patients. The Joint Commission regularly distributes to health care organizations information about sentinel events and how they can be prevented through its newsletter Sentinel Event Alert.

Voluntary Self-Reporting of Sentinel Events

Under the Sentinel Event Policy, a defined subset of sentinel events are subject to review by the Joint Commission and may be reported to the Joint Commission on a voluntary basis. Only those sentinel events that affect recipients of care (patients, clients, residents) and that meet one of the following criteria fall into this category.

—The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition.

—The event is one of the following (even if the outcome was not death or major permanent loss of function): suicide of a patient in a setting where the patient receives around-the-clock care (e.g., hospital, residential treatment center, crisis

stabilization center); infant abduction or discharge to the wrong family; rape; hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities; or surgery on the wrong patient or wrong body part.

An organization that experiences a sentinel event that does not meet the criteria for review under the Sentinel Event Policy is still required to complete a root cause analysis. However, the root cause analysis does not need to be made available to the Joint Commission.

Sentinel Events That Are Not Self-Reported

Each accredited health care organization is encouraged, but not required, to report to the Joint Commission any sentinel event meeting the aforementioned criteria for reviewable sentinel events. Alternatively, the Joint Commission may become aware of a sentinel event by some other means such as from a patient, family member or employee of the organization, or through the media.

Whether the organization voluntarily reports the event or the Joint Commission becomes aware of the event by some other means, there is no difference in the expected response, time frames or review procedures.

Joint Commission Response

If the Joint Commission becomes aware (either through voluntary self-reporting or otherwise) of a sentinel event that meets the definition of a reviewable sentinel event, the organization is required to: prepare a thorough and credible root cause analysis and action plan within 45 calendar days of the event, or of its becoming aware of the event; and submit to the Joint Commission its root cause analysis and action plan or otherwise provide for Joint Commission evaluation of its response to the sentinel event under an approved protocol, within 45 calendar days of the known occurrence of the event. The Joint Commission will then determine whether the root cause analysis and action plan are acceptable.

A "for cause" survey will be conducted in immediate response to learning about a sentinel event if the Joint Commission determines that there is a potential ongoing threat to patient health or safety or potentially significant noncompliance with major Joint Commission standards. These surveys occur infrequently and are charged at a rate of $3,500 per day.

Accreditation Watch

If the submitted root cause analysis or action plan is not acceptable or none is submitted within 45 days, the organization is at risk for being placed on Accreditation Watch by the Accreditation Committee of the Joint Commission's Board of Commissioners.

Accreditation Watch is a publicly disclosable attribute of an organization's existing accreditation status and signifies that an organization is under close monitoring by the Joint Commission. The Accreditation Watch status is removed once an organization completes and submits an acceptable root cause analysis.

Failure to perform an acceptable root cause analysis and implement appropriate actions can result in a change in accreditation status, including loss of accreditation. Further, each sentinel event evaluated under the Sentinel Event Policy will be reviewed at the health care organization's next full accreditation survey. This review will focus on how effectively the organization has implemented its risk-reduction activities.

If an organization declines to share any information regarding a sentinel event with the Joint Commission, the organization will be placed on Accreditation Watch and, ultimately, risks the loss of accreditation.

Advantages to Reporting a Sentinel Event

There are several advantages to the organization that reports a sentinel event.

—Reporting the event enables the addition of the "lessons learned" from the event to be added to the Joint Commission's sentinel event database, thereby contributing to the general knowledge about sentinel events and the reduction of risk for such events in many other organizations.

—Early reporting provides an opportunity for consultation with Joint Commission staff during the development of the root cause analysis and action plan.

—The organization's message to the public that it is doing everything possible to ensure that such an event will not happen again is strengthened by its acknowledged collaboration with the Joint Commission to understand how the event happened and what can be done to reduce the risk of such an event occurring in the future.

Disclosable Information

If the Joint Commission receives an inquiry about the accreditation status of an organization during the 45-day root cause analysis period, the organization's accreditation status will be reported in the usual manner without reference to the sentinel event. If an inquirer specifically references the sentinel event, the Joint Commission will acknowledge that it is working with the organization through its sentinel event review process.

The Joint Commission will not disclose legally protected sentinel event-related information to any other party and will vigorously defend the legal confidentiality of this information, if necessary, in the courts. If subpoenaed for sentinel-event related information, the Joint Commission will not release this information, and again, after notifying the health care organization, will vigorously defend its position in the courts.

Submission of Root Cause Analysis and Resulting Action Plan

The Joint Commission has initiated a number of procedures to protect the confidentiality of sentinel event information shared by accredited organizations and in the Joint Commission's possession.

—The Joint Commission advises health care organizations not to provide patient or caregiver identifiers when reporting sentinel events to the Joint Commission.

—An organization that experiences a sentinel event should submit two separate documents to the Joint Commission: (a) the root cause analysis and (b) the resulting action plan. The root cause analysis will be returned to the organization once abstracted information is entered into the Joint Commission database. If copies have been made for internal review, they will be destroyed after the review. Also, once the action plan has been implemented to the satisfaction of the Joint Commission, it will be returned to the organization.

In addition, if the organization has concerns about increased risk of legal exposure as a result of sending the root cause analysis documents to the Joint Commission, the following alternative approaches to review of the organization's response to the sentinel event are acceptable.

—An organization brings root cause analysis documents to the Joint Commission headquarters for review and then takes the documents back on the same day.

—A specially trained surveyor conducts an on-site visit to review the root cause analysis and action plan. The organization will be assessed a charge sufficient to cover the average direct costs of the visit.

—A specially trained surveyor conducts an on-site visit to review the root cause analysis and findings, without directly viewing the root cause analysis documents, through a series of interviews and review of relevant documentation. For purposes of this review activity, "relevant documentation" includes, at a minimum, any documentation relevant to the organization's process for responding to sentinel events and the action plan resulting from the analysis of the subject sentinel event. The latter serves as the basis for appropriate follow-up activity. The organization will be assessed a charge sufficient to cover the average direct costs of the visit.

—Where the organization affirms that it meets specified criteria respecting the risk of waiving legal protection for root cause analysis information shared with the Joint Commission, a specially trained surveyor conducts an on-site visit to interview staff and review relevant documentation to obtain information about the process the organization uses in responding to sentinel events, and the relevant policies and procedures preceding and following the organization's review of the specific event and the implementation thereof, sufficient to permit inferences about the adequacy of the organization's response to the sentinel event. The organization will be assessed a charge sufficient to cover the average direct costs of the visit.

Confidentiality of Information

A Sentinel Events Legal Issues Task Force was created to address the potential remedial strategies that might be employed to minimize the risk of discoverability of specific information pertaining to a sentinel event. The task force assisted the Joint Commission in pursuing federal legislation and developing model state legislation that would reinforce existing protections for sentinel event-related information that health care organizations may share with the Joint Commission.

With the assistance of the Sentinel Event Legal Issues Task Force, the Joint Commission also has identified two contractual arrangements that should substantively address the legal concerns regarding potential waiver of confidentiality protections in certain states. These arrangements involve having the health care organization either identify, through written agreement the Joint Commission as a participating

entity in the organization's peer review or quality improvement activities; or appoint the Joint Commission to the organization's peer review or quality improvement committee.

These arrangements clarify that the Joint Commission is not an external third party in the limited context of an intensive assessment of a sentinel event and, therefore, no waiver of confidentiality protections has occurred by sharing sentinel event-related information with the Joint Commission.

For More Information

The Joint Commission also has taken a series of steps to help organizations better understand the revised Sentinel Event Policy.

A "hot line" is in operation to respond to questions regarding sentinel events. The number is (630) 792–3700.

Sentinel Event Alert, a newsletter that is distributed periodically to all accredited organizations, provides important information relating to the occurrence and management of sentinel events in Joint Commission accredited organizations. Sentinel Event Alert is published as needed and appropriate (e.g., as suggested by trend data) and provides communication regarding the Joint Commission's Sentinel Event Policy, and, most importantly, information about sentinel event prevention.

The Joint Commission's Web site provides additional sentinel event information including the complete Sentinel Event Policy; how to complete a root cause analysis; sentinel event reporting forms; information about relevant publications and education programs; and back issues of Sentinel Event Alert. Go to www.jcaho.org/sentinel/sentevnt__frm.html.

SENTINEL EVENT ALERT

ISSUE ONE, FEBRUARY 27, 1998

New Publication

We are pleased to introduce the first issue of Sentinel Event Alert, a periodic publication dedicated to providing important information relating to the occurrence and management of sentinel events in Joint Commission-accredited health care organizations. Sentinel Event Alert, to be published when appropriate as suggested by trend data, will provide ongoing communication regarding the Joint Commission's Sentinel Event Policy and Procedures, and most importantly, information about sentinel event prevention. It is our expectation and belief that in sharing information regarding the occurrence of sentinel events, we can ultimately reduce the frequency of medical errors and other adverse events.

Initially, Sentinel Event Alert will be mailed to the organization chief executive officers and Joint Commission survey coordinators, however, it is expected that eventually Sentinel Event Alert will be sent via broadcast fax. In the future, staff from the Joint Commission will be contacting your organization to collect appropriate fax and E-mail addresses.

While the topic of this first issue is particularly relevant to acute care facilities, we will share information of relevance to all accredited organizations in future issues.

Medication Error Prevention—Potassium Chloride

In the two years since the Joint Commission enacted its Sentinel Event Policy, the Accreditation Committee of the Board of Commissioners has reviewed more than 200 sentinel events. The most common category of sentinel events was medication errors, and of those, the most frequently implicated drug was potassium chloride (KCl). The Joint Commission has reviewed 10 incidents of patient death resulting from misadministration of KCl, eight of which were the result of direct infusion of concentrated KCl. In all cases, a contributing factor identified was the availability of concentrated KCl on the nursing unit. In six of the eight cases, the KCl was mistaken for some other medication, primarily due to similarities in packaging and labeling. Most often, KCl was mistaken for sodium chloride, heparin or furosemide (Lasix).

Issue For Consideration.—In light of this experience, the Joint Commission suggests that health care organizations not make concentrated KCl available outside of the pharmacy unless appropriate specific safeguards are in place.

ISSUE TWELVE, FEBRUARY 4, 2000

Operative and Post-Operative Complications: Lessons for the Future

Since the Joint Commission began tracking sentinel events nearly four years ago, the Accreditation Committee of the Joint Commission's Board of Commissioners has reviewed 64 cases related to operative and post-operative complications. For each of the events reviewed, a root cause analysis was completed.

Eighty-four percent of the complications resulted in patient deaths, while 16 percent resulted in a serious injury. All of the cases occurred in acute care hospitals. Cases directly related to medication errors or to the administration of anesthesia are not included in this review.

Fifty-eight percent of the complications occurred during the post-operative procedure period, 23 percent during intraoperative procedures, 13 percent during post-anesthesia recovery, and 6 percent during anesthesia induction. The types of procedures most frequently associated with these reported complications included interventional imaging and/or endoscopy, tube or catheter insertion, open abdominal surgery, head and neck surgery, orthopedic surgery and thoracic surgery. Ninety percent of the 64 cases reviewed occurred in relation to non-emergent procedures.

The most frequent complications by type of procedure included the following:

—Naso-gastric/feeding tube insertion into the trachea or a bronchus.
—Massive fluid overload from absorption of irrigation fluids during genito-urinary/gynecological procedures.
—Open orthopedic procedures associated with acute respiratory failure, including cardiac arrest in the operating room.
—Endoscopic procedures (including non-gastrointestinal procedures) with perforation of adjacent organs. Liver lacerations were among the most frequent complications of abdominal and thoracic endoscopic surgery.
—Central venous catheter insertion into an artery.
—Imaging-directed percutaneous biopsy or tube placement resulting in liver laceration, peritonitis, or respiratory arrest while temporarily off prescribed oxygen.
—Burns from electrocautery used with a flammable prep solution.

Complications associated with misplacement of tubes or catheters usually involved a failure to confirm the position of the tube or catheter (usually radiographically), misinterpretation of the radiographic image by a non-radiologist, or a failure to communicate the results of the confirmation procedure.

Root Causes Identified by Hospitals Experiencing These Events

Hospitals identified eight root causes in the 64 cases. Two-thirds of the hospitals identified incomplete communication among caregivers as a root cause, while more than half mentioned failure to follow established procedures.

The six other root causes included the following:

—Necessary personnel not being available when needed.
—Pre-operative assessment being incomplete.
—Deficiencies in credentialing and privileging.
—Inadequate supervision of house staff.
—Inconsistent post-operative monitoring procedures.
—Failure to question inappropriate orders.

Risk Reduction Strategies Identified by Hospitals Experiencing These Events

Organizations that experienced complications identified risk reduction strategies. Eighty percent recommended improving staff orientation and training. Other strategies included the following:

—Educating and counseling physicians.
—Expanding on-call coverage, especially in radiology.
—Standardizing procedures across settings of care.
—Revising credentialing and privileging procedures.
—Clearly defining expected channels of communication.
—Revising the competency evaluation process.
—Monitoring consistency of compliance with procedures.
—Implementing a teleradiology program.

Experts' Recommendations

Experts emphasize that direct communication between physicians and other health care providers is very important in preventing complications. There should be more staff education, a more conscientious style of practice, less emphasis on turf issues, and more respect for all of the members of the surgical team, says Dorothy Fogg, R.N. B.S.N., M.A., senior perioperative nursing specialist for the Center for Nursing Practice, Association of PeriOperative Registered Nurses in Denver.

Regarding complications associated with misplacement of tubes or catheters, Mark Malangoni, M.D., a general surgeon at MetroHealth Medical Center in Cleveland, says the correct placement should be confirmed with a test or x-ray. For example, health care providers could check the positioning of a venous catheter with a chest x-ray and the placement of a feeding tube with an abdominal x-ray.

Malangoni, a member of the American College of Surgeons' Pre-Operative and Post-Operative Care Committee, and Fogg recommend that hospitals review their credentialing and privileging procedures to ensure that physicians have proper training and expertise. Fogg says this is especially important in an area like endoscopy where some surgeons may have limited training and experience or where the procedure to be done is relatively new. Those with less experience should work in tandem with someone on staff who has extensive experience in this methodology and has demonstrated competency in the procedure to be performed.

STATEMENT OF DR. ARNOLD S. RELMAN, PROFESSOR EMERITUS OF MEDICINE AND OF SOCIAL MEDICINE, HARVARD MEDICAL SCHOOL, BOSTON, MA

Senator FRIST. We also welcome Dr. Arnold Relman as the fourth member of our panel. Dr. Relman is a professor emeritus of medicine and of social medicine at Harvard Medical School and also editor-in-chief emeritus of The New England Journal of Medicine—which I receive weekly and keep reading, even in the U.S. Senate. Dr. Relman has been professor of medicine at Boston University School of Medicine, and he was the Frank Worcester Thomas Professor of Medicine and chairman of the Department of Medicine at the University of Pennsylvania School of Medicine. Over a span of almost 30 years, he has published numerous articles in original research, clinical studies, as well as textbook chapters and in recent years has written widely on economic, ethical, legal, and social aspects of health care.

Dr. Relman, it is good to have you with us.

Dr. RELMAN. Thank you, Mr. Chairman.

Thank you for this opportunity to describe how Massachusetts promotes the quality of medical care in its hospitals. I am chairman of the unit in the State Board of Medicine that is responsible for this program, and I will briefly explain how it works.

All licensed hospitals in Massachusetts are required by State law to have approved programs for quality assurance, the most important element in which is a system for reporting all serious mishaps in their medical care. By "serious mishap," we do not necessarily mean mistakes, and we do not necessarily mean mistakes that are preventable. We mean all serious, unexpected outcomes in the course of medical care, whether they are errors or not and whether they are deemed preventable or not. So we cast a very broad net.

These reports are filed quarterly with the Board and must include a full medical account of what happened along with the results of the hospital's investigation into the cause of the incident and the steps the hospital has taken to prevent any recurrences. Each incident report is carefully reviewed by the physician members of our unit with the assistance of our staff nurses. We often request additional information, and sometimes, when a hospital is in trouble, we meet directly with its staff and its medical leadership. Before we close our file on a case, we need to be satisfied that all appropriate remedial steps have been taken where indicated.

Two crucial features of our program make it unique, I believe, and promote its effectiveness. First, as noted already, it is located in our State Board of Registration and Medicine. The rationale for

this arrangement is that medical errors in hospitals or anywhere else, for that matter, cannot be reduced without the full participation of physicians. External regulators who are themselves physicians are most likely to know when hospital physicians are meeting their professional responsibility for peer review, and if the regulators also hold the power of licensure, as we do, they are likely to get the serious attention of the medical staffs of the hospitals.

A second critical feature of our reporting program is that while it is mandated by State law, its information is kept totally confidential and protected by law from subpoena, legal discovery, or introduction into evidence. Moreover, our unit does not share any of its files with other parts of the Board. The rationale for this policy is to encourage hospitals and their medical staffs to be totally forthcoming in their reports to us and to take responsibility for dealing with their own problems without fear of adverse publicity or disciplinary action simply for doing so.

Of course—and it should be understood—our program does not preempt existing State laws and regulations requiring disciplinary action under certain circumstances and disclosure in cases of medical malfeasance, so it does not change our State's policy on informing the public about such matters. And we have, I think, one of the leading State programs in informing the public about the performance of physicians.

We have accomplished a great deal in less than a decade despite serious limitations on our resources and initial suspicions from the provider community that were quite profound. We are now gaining the trust and cooperation of hospitals and doctors and, just as importantly, of their lawyers. So the number and quality of reports that we receive is steadily improving. Meanwhile, our analysis of these reports has identified common causes of potential mishaps, and we are feeding this information back to the hospitals, generally to the State as a whole, or sometimes to a particular hospital.

It is too early to measure precisely the effect of our program on the quality of hospital care. It has been working for half a dozen or 8 years. It is too early to measure, but we have anecdotal evidence that hospitals and doctors are learning how to prevent mistakes. This evidence also supports our conviction that prevention is more effective than discipline or publicity in the reduction of medical mistakes.

Now, what can the Federal Government do to help? This is my personal opinion and has nothing to do with the experience of our Board. In general, I support the Institute of Medicine's recommendation for the establishment of a national mandatory reporting program in all States, and I believe the reports should be anonymous and confidential; that is absolutely crucial, and I echo what has been said before. I also support the idea of creating a Center for Patient Safety within the Agency for Health Care Research and Quality, to act as a repository for standardized information from the States and to study and do research and disseminate the anonymized information.

In addition, I strongly recommend a program of Federal grants-in-aid to the States to help them develop monitoring programs like the one we have—or even better. Few States have the resources to do this alone, and we are not getting the help that we need from

our State, although we are slowly persuading our legislators that it is really worthwhile. I will be just another few seconds, Mr. Chairman. But without the full participation of State boards, no Federal reporting program could succeed. Let me emphasize—you can pass all the laws that you want; you can have all the Federal agencies that you want, but the raw data and the information and the analysis that must be made where the data are obtained—namely, in the health care institutions—that must be at the State level. You cannot do that at the Federal level.

I estimate that the total cost of these State grants might be about $35 to $40 million annually. I am convinced that an investment of this kind would pay huge dividends in improving hospital care throughout the country, and when it is applied to ambulatory institutions, much more broadly, and in reducing the financial burdens of medical mishaps and substandard care.

PREPARED STATEMENT

Thank you for your attention. I have already distributed a booklet to you describing the Massachusetts program in greater detail, but I will be glad to take your questions. With me is Elizabeth O'Brien, who is the nurse attorney in charge of the staff work of our program, and she will make sure that I give you correct answers.

Thank you.

Senator FRIST. Thank you, Dr. Relman.

[The statement follows:]

PREPARED STATEMENT OF ARNOLD S. RELMAN

Mr. Chairman and distinguished members of this committee: I am Dr. Arnold S. Relman, a physician certified in internal Medicine, and Professor Emeritus of Medicine and of Social Medicine at the Harvard Medical School. I am also a former editor-in-chief of the New England Journal of Medicine, and currently a member of the Board of Registration in Medicine of the Commonwealth of Massachusetts. On the Board, I serve as Chairman of its Patient Care Assessment (PCA) Committee, which is responsible for the program in quality assurance and medical error reduction that I want to describe to you briefly.

Here, in bare outline, is how the program works:

All licensed hospitals in Massachusetts are required by state law to have Board-approved program for monitoring and reporting on the quality of their patient care. They submit regular reports on their programs to the Board's PCA Committee, the most important of which is a quarterly report of all major medical mishaps and unexpected serious outcomes as defined in our regulations. I use the term "mishap" rather than "adverse advent", as used by the Institute of Medicine in its recent report, because we take a somewhat broader view of the incidents that need to be reported.

These quarterly reports must include a full, medically coherent account of what happened, the results of the hospital's investigation into the cause, and the steps taken to prevent any recurrences. Such steps might include changes in hospital procedures and organization, remedial education of its staff, or disciplinary actions against individuals involved. All this information is then reviewed and discussed by the four physician members of our PCA Committee, with the help of a small but highly trained staff of nurses. This is, I believe, a unique feature of our program. It is placed in the State Board of Medicine because we believe physicians must be directly involved if a hospital really is serious about monitoring and improving the quality of its medical care.

Another critical feature of our reporting system is that it is confidential and the involved individuals are anonymous. The reports are not used for disciplinary purposes, or shared with the Board's other units. This encourages hospitals to be totally forthcoming in their reports to us, without fear of damaging publicity or disciplinary action. Of course, our program does not pre-empt existing state laws concerning the

disciplining and public disclosure of medical malfeasance, and hospitals are expected to comply with them.

On the other hand, this is not a voluntary program. In my opinion, voluntary programs cannot work very well. The hospitals understand that we have the legal authority to require compliance, although we have so far depended largely on education and persuasion. The leadership of recalcitrant or underperforming hospitals, including the leaders of their medical staff, are invited to meet with our committee for remedial conferences. Our staff are also available to help hospitals with specific questions or problems. As a result, there has been a steady increase in compliance and in the number and quality of the reports we receive. Despite this improvement, we still have not gained a complete picture of all the medical mishaps occurring in Massachusetts hospitals, nor have all hospitals begun to review their care as rigorously as we would like.

Nevertheless our program has clearly achieved some success. We have gained the trust and cooperation of the physicians and administration in most of our hospitals and they are now much more willing to take on the responsibilities of self-regulation. They understand that more is required of them than simply organizing new committees and producing paperwork. Our type of monitoring cannot work unless physicians take direct responsibility for meeting our requirements. That distinguishes our reporting program from most other state reporting systems, which usually involve hospital administrators and non-physician staff and deal more with records than with the substance of medical care.

In the course of analyzing the hospital reports, our committee has identified certain problems in hospital procedures and the organization of medical care that have warranted the issuance of general advisories to all hospitals, as suggestions for improving care and avoiding mishaps. We have also helped numerous individual hospitals with their own problems in quality assurance. It is too early to measure quantitatively the effect of our program on the quality of hospital care, but I believe it is already substantial, and will become increasingly important. We should also be able to accumulate statistical data on the incidence of certain types of medical mishaps and their causes. At present, however, further exploration of these and other possible benefits of our PCA program is prevented by limited resources.

Could federal legislation help with this kind of program? I believe so, and I think appropriate federal help and involvement would pay great dividends in improving hospital care throughout the country and reducing the human and financial burdens of medical mishaps and substandard care.

In general, I support the recommendations in the IOM report for the establishment of a nationwide mandatory reporting system that provides for the collection of standardized information by state governments about medical mishaps that result in death or serious harm. I also agree that a Center for Patient Safety within the Agency for Health Care Policy and Research should be established to administer the collection, analysis and public dissemination of the information—but it is crucial, I believe, that the transmitted information be anonymous and non-identifiable. The IOM estimates of the initial cost of funding the new Center (i.e., 30–35 million per annum) seems reasonable.

In addition to the Center, however, I think it is necessary that there be funds to help states initiate and operate reporting programs that would meet the Center's requirement. The state programs should be mandated through Medicaid or Medicare regulations and should require the full participation of physicians. Probably the best way to do this is through state Boards of Medicine, as we do in Massachusetts. The federal government should make grants available to the state Boards to undertake this work, but it should continue to delegate the regulation of medical care to the individual states, as is now the case. I would guess that the cost of funding the reporting programs in all states might be of the order of 35–50 million annually. This support is essential if there is to be a national center that gathers information from the states. Few states now have the resources to gather comprehensive or reliable information and I do not believe the federal government could or should attempt the task by itself without the participation of the states.

The total cost of such a federal investment would be relatively small and the dividends very substantial, indeed.

Senator FRIST. Senator Specter.

Senator SPECTER. Dr. Relman, you talk about anonymous and confidential. Would you agree that the hospital physician/professional has an obligation to tell the patient about the error?

Dr. RELMAN. Absolutely.

Senator SPECTER. How does that comport with the requirement of confidentiality?

Dr. RELMAN. When the physician talks to the patient and says, "We have made a mistake, and this is what happened," that is the result—it comes back, Senator, to what I said about the difference between unfortunate things that happen—mishaps—and errors. There is a huge number of unfortunate things that happen in a hospital, and our committee is just beginning to get a mind-boggling idea of the variety of things that might go wrong. Many of these are not mistakes, and many of them could not be prevented. So that first, there has to be some understanding of the cause of what happened. Sometimes it is obvious, and the doctor can immediately say to the patient: "We made a mistake"—the wrong medication, operated on the wrong limb, or whatever—and there is no problem about that.

But to conclude that the hospital or the doctor was in error in many other situations requires an analysis, and that analysis takes time. And if it comes to the conclusion that the hospital made a mistake in that case, the patient has a right to know. That is a professional obligation. But there are many, many things that happen that cannot be individualized that way, and the cumulative results I think should be kept confidential so that doctors and hospitals can work on this problem.

Senator SPECTER. Dr. Russell, you talked about a mandatory requirement as being punitive. We are struggling with how to get the information reported, and the President has come to the conclusion that a mandate is necessary, as has his studying task force.

In Pennsylvania, we have a requirement of mandatory reporting, and there is a wide net on obligations of hospitals, nursing homes, health agencies, ambulatory surgical facilities, intermediate care facilities. A very extensive investigative report by The Philadelphia Inquirer disclosed that there was only one report in the course of a year. Now, we are at a little bit of a loss to figure out how to get the reporting done; if a mandatory system is only going to produce a single report, what is the answer? How can we possibly think about a voluntary system, and don't we need to go even beyond the mandate to put some teeth in it—as, for example, the analogy I used at the outset about reporting crimes on campuses, where we found that the colleges and universities were not reporting because they did not want to discourage students from coming to their schools. We had to amend the law to put some sanctions in there. How do we get the information?

Dr. RUSSELL. I think that if mandatory has anything punitive associated with it, it is going to really dampen the ability to get the information.

I think, Senator, the best way to do it is internally. In our hospital, we had a very free reporting system where things surfaced very quickly, and we attempted to handle most of these issues right on the spot. It is a local problem, and you need to create a culture in hospitals, whether they are small or large, or single hospitals or part of a big system——

Senator SPECTER. Let me interrupt you, Dr. Russell. The words "creating a culture" have been used quite a bit. A culture is

generational. A culture is not something that you can legislate. How do you create a culture?

Dr. RUSSELL. I think you got to hospitals where it exists, and it does. I think there are some hospitals that are doing a very good job at this. There are some hospitals where all patients are informed of an error, which we could not agree more with you—this is a code of ethics that we have as a profession.

Some hospitals are doing an excellent job. There are some hospitals that need to improve. And we need to look to our winners and our good systems to get advice on how to do this, but a lot of it—and I am only speaking as an active practicing surgeon, which I no longer am, but I am using my experience of just a few months ago and of 25 years—if you have a good internal system where you promote the information to get out about problems, you have a very good system.

For example, in the sentinel event situation that we have at our hospital, the problem is that too many sentinel events are brought forward, and we have to have a committee to determine which is truly a sentinel event. Not very many occur.

Senator SPECTER. Dr. Udvarhelyi, before my red light comes on, let me direct a question to you. I am pleased to hear you talk about an agreement with the mandatory system, if I understood your testimony correctly. You talk about some changes in the malpractice system as well. Is your endorsement of a mandatory reporting system total, or would you condition that on some pre-existing change in medical malpractice—because candidly, it is unlikely that that is going to happen very fast. That is an issue which the Congress has been wrestling with for a long time, and the States have made some legislative changes. But is your endorsement of mandatory reporting unconditional?

Dr. UDVARHELYI. Senator, I think it would be conditioned on changes in the liability, because if the mandatory reporting were to lead to an increase in claims and became a vehicle by which additional claims were brought, and that became the primary use of the mandatory reporting, we think that that would have a counterproductive effect on creating the correct climate and culture to learn from these and to encourage the reporting.

Senator SPECTER. My red light is on, so I will conclude with just a very brief statement—and I am sorry, Dr. O'Leary, that I did not have a chance to pursue with you the "blame-free" issue, but the red lights go on very fast.

We would ask your assistance in our effort to draft legislation or implement the administration of these demonstration projects. Dr. Russell, you talked about identifying data, how you use it, closing the loop. You have been our experts, and we are going to have to rely upon the experts to work with the Federal agencies, the active practitioners, where those in the bureaus may not have the kind of detailed knowledge you have. If we move ahead promptly with demonstration projects, we can find a lot of answers.

The goal of having a mandatory system within 3 years is a fine goal, but it is unlikely to happen if you are requiring it of 50 States; but if we have some experience on the differences between voluntary reporting and mandatory reporting, and even mandatory

reporting with some disclosures, we will then be in a position to try to really understand and solve this problem.

Thank you all very much for coming.

Senator FRIST. Thank you, Senator Specter.

Dr. Udvarhelyi, could you comment on the administration's recommendation for mandating safety plans for all health plans in FEHBP, the Federal Employees Health Benefits Program? Do you support it, do you not support it?

Dr. UDVARHELYI. Senator, I have not yet seen the final proposal that OPM is going to come out with, so it is a little premature for me to comment on specifics. I think health plans can play a supportive role in patient safety. Today we have credentialing requirements to make sure that physicians and hospitals in our networks meet certain requirements, and we think that is an area where we can encourage physicians and hospitals to do more in patient safety.

We also share best practices with them, and we think we can do more there; and we promote patients going to centers of excellence. As you well know, one of the best ways to get a good outcome is to go to a center that has the requisite experience and track record, as opposed to one that does not. We think that these are all ways in which we can assist, but at the end of the day, the care is provided in the physician's office, or the drug is prescribed in the hospital, and we think it is critical to have the support of physicians and hospitals on the front lines to identify errors and to report them. Without their support, a requirement on the health plans to do something without the support of the physicians and other providers is going to be difficult.

Senator FRIST. One of the big challenges is educating broadly. This is system-wide, and as we have talked about today, you cannot point your finger at any one area and say, "Let us fix this, and it will fix the system." The health plans are in a unique situation in that the health plans interact with doctors, nurses, providers, hospitals, rural hospitals, urban hospitals, and I cannot help but think that it is going to fall on your shoulders to take a leading role. It can be accreditation, it can be individual States, it can be Federal law, but we are going to need to look to you to see how, in a way that is consistent with all the other things that you are doing. I guess it is going to be important for you to put certain pressures on there if voluntary is going to work—and mandatory is going to be important, but limited in terms of the full system-wide impact. I think the health plans can play a very important role there, consistent with what you are already doing, but probably reaching out more.

Would you object to in some way—and I know that new mandates are the last thing you want to see—but having every health plan out there at least put in writing to notify patients, prospective patients, what is being done in terms of medical error reduction?

Dr. UDVARHELYI. We would support the dissemination of information about patient safety, certainly. But again, for us to take an active role, one thing we cannot do is change the liability issues ourselves. And if the information is exchanged in ways that are not protected and are not confidential, and we cannot change that, it may be problematic.

Senator FRIST. Well, the confidentiality and the liability everyone has said must be addressed, and to try to fix the system and come out with a range of proposals that does not include that, I think is irresponsible, and we hear that again and again; so how we address it is tough.

Dr. Russell, on the medical errors, we hear the numbers, and it is appalling, and people are surprised. It is inexcusable, given the information systems that we have today in contrast to 30 years ago, where you really can computerize. We have pockets that are doing very well, hospital systems that are doing well, medical centers that are doing very well—you have been a part of many of those as I have in our own practices. Therefore, we should not leave the impression that nothing is being done. The point is we can do a lot more, and we need to figure out how, together, we can do that, private and public sectors.

For my colleagues, in regard to mortality and morbidity, or M and M, rounds—at Vanderbilt for the 10 or 11 years I was there, every week we had M and M rounds; at Stanford when I was there, and at Massachusetts General when I was there, again, it was standard. But I was in academic health centers. Are mortality and morbidity or M and M rounds just at academic health centers, training centers, where residents and fellows are taught? How many hospitals have M and M rounds that might be community hospitals that are not engaged in training? Could you set the perspective for what M and M rounds are?

Dr. RUSSELL. All right. M and M rounds is looking at your results. Now, it is ideal for surgery, because we are doing surgical procedures, and not always do you have good results. But these are not necessarily errors; you have complications. And it is very important, as Dr. Relman alluded, to differentiate complications from an error.

M and M rounds is an effort in surgery to look at the results of operations and at what problems or complications occurred. These occur in teaching hospitals; it is a very important culture to create in young surgeons to assume responsibility, because in surgery, you know, we often make patients sicker than to start with in order to get them well. We set them back a little bit. So we have to be very critical of our results.

I think the Morbidity and Mortality Conference is a great learning tool for young surgeons to set, once again, the culture of responsibility of results from the operations that we do. This can easily be applied in private hospitals, and I think a lot of private community hospitals do Morbidity and Mortality Conference on a monthly basis, where they criticize and critique their results with the idea that they are trying to make the product better.

Senator FRIST. And confidentiality there is not an issue, because you are within a system, and it is mainly physicians and nurses talking together, looking at systems, looking at failure, errors, unexpected outcomes—but in truth, it is pretty much limited to where training is going on—is that right, or is that incorrect?

Dr. RUSSELL. I think it is true that it is where training is going on, but a lot of private hospitals where there is no training get the staff together on a weekly or monthly basis and go over complications that have surfaced in the last reporting period. It is a very

important part of the internal reporting, and you need to create a culture of not just being critical, but rather, a learning experience.

Senator FRIST. Thank you.

Dr. O'Leary, what role do you think States should play in the collection and dissemination of information at the State level based on what you have seen through the JCAHO?

Dr. O'LEARY. We would have no problem with a State-based reporting system. I do worry about standardization of reporting, something that was addressed in the Institute of Medicine report that I did not hear quite as clearly in the QuIC Task Force report. But I think we have to carefully define what is going to be reported and seek to standardize that across the State systems or we will have bad data, for openers.

I think it is also important that the States establish requirements for root cause analyses for those hospitals and other organizations that are going to be reporting to them. I think one of the failures of the current mandatory reporting systems in States to demonstrate improvement is that simply counting cases does not cause improvement. You need to know underlying causes, gather that information, and share the lessons learned out of that. That has been very much the Joint Commission's experience.

I think the other comment about the State reporting systems is that the need for confidentiality is underscored by our experience. If you look at the States that have confidentiality protections, those are the ones that have pretty good numbers of reports, although there is probably still underreporting there. The States that do not have confidentiality protections have very low numbers. That message is pretty clear, and we need to learn from that experience.

I would finally hope that in any system that we create there would be data-sharing amongst the responsible parties. Many of the hospitals involved in my report to the States are accredited by the Joint Commission. We have an active follow-up program. I think the States and the responsible accrediting bodies need to share information among themselves.

Senator FRIST. Thank you.

Dr. Relman, for 6 to 8 years, things have been going pretty well. How many hospitals are there in Massachusetts, roughly?

Dr. RELMAN. About 110.

Senator FRIST. And how many reports do you get a year?

Dr. RELMAN. It is a rising number, which does not mean the care is getting worse. It means that the cooperation is getting better, and the system is really beginning to operate. It is getting better all the time—it is a moving target.

Senator FRIST. Is it 50; 100; 1,000; 10,000?

Dr. RELMAN. It is now between 500 and 600 a year, based on about 15,000 beds. Our estimate is that that represents only about 10 percent or 15 percent of what actually is going on.

Senator FRIST. And it is mandatory.

Dr. RELMAN. Absolutely.

Senator FRIST. And of the 110 hospitals, how many have not reported any, just roughly?

Dr. RELMAN. Two. But they are going to be hearing from us, and they already have. We watch that, and it is remarkable how, if you sit down—our doctors on one side of the table and their doctors and

their president of the board of trustees and the CEO on the other side of the table—and we look them in the eye, and we say, "What is going on here? Are you saying nothing bad ever happens—no unfortunate outcomes—nothing is unexpected?" Then, there is a dialogue. As long as they know that you are honestly telling them this is in confidence, and it is not punitive, and we want to help you do what you know is the right thing to do, you begin to get cooperation.

Senator FRIST. And do you work for the Government—are you a State employee?

Dr. RELMAN. Well, I would not call it that. I am essentially a volunteer. The State of Massachusetts pays me $35 plus free parking for every day that I spend time working for them.

Senator FRIST. And how many doctors, realistically, out in the field, basically looking at clinical errors for the most part and interpreting them and looking across the table—how many do you think you are going to get to do that for $35?

Dr. RELMAN. You have to be old and foolish, the way I am, and a little idealistic. But I think that a lot of my contemporaries who have had full careers in the practice and teaching and research in medicine are available. It is not full-time. It takes about 15 or 20 percent of my time to do—a lot of nights and weekends. I have a lot of contemporaries, at least in Massachusetts, who would like to do that because it is a very satisfying thing to watch your profession get the message and realize that they could really do much better if they were reassured that this was going to be done in a constructive, confidential way. And it does not interfere with any of the existing laws about reporting on convictions and malpractice litigation and so on. All those laws are in place.

Senator FRIST. But it is important for people to understand that when you are talking about medical errors and medical mistakes and judgment, systemwide failure—we are probably talking about some of the most sophisticated decisionmaking in medicine today.

Dr. RELMAN. Absolutely.

Senator FRIST. You are seeing the toughest, I think, when you go from M and M rounds, and you sit there for hours and dissect individual cases. And I guess I wonder, looking at State Governments in all 50 States, whether you are going to be able to pull that sort of expertise for $35.

Dr. RELMAN. If you want to recommend a raise, I would appreciate it.

Senator FRIST. I will. But it is sophisticated, and I commend you for the success there.

But that goes to my next question—in Massachusetts, it is 6 years; you do not get paid very much; you are probably way underfunded for what you are required to do.

Dr. RELMAN. Yes.

Senator FRIST. You have compulsory reporting for not only what we see at M and M rounds, but in every adverse or serious unexpected outcome, which is thousands, I would think——

Dr. RELMAN. We think that in Massachusetts, there are several thousand such episodes, and so far, we are looking at about 500, or perhaps 600 this year.

Senator FRIST. We are talking about the most sophisticated of medicine that is going to require expertise. We are not all going to be able to have Dr. Relman, with your long history.

Dr. RELMAN. We call on consultants, too, on an ad hoc basis when we need them. We do not have all the expertise in our office.

Senator FRIST. And all this is done through the State government.

Dr. RELMAN. The State Board of Medicine.

And the trick is that the doctors know that there are State regulations which say licensees of the State Board of Medicine in Massachusetts are not allowed to practice in an institution that does not have an approved quality assurance program. And we want you to convince us that we should approve your quality assurance program. Furthermore, we can always report bad performances in hospitals to the State Department of Public Health.

Senator FRIST. I had written down a question, and you got to it at the end, about why do you need Federal laws coming in. You have made this progress, and ultimately, you feel strongly that it should be done at the State level, I assume.

Dr. RELMAN. But we need help, and the Federal Government can give us guidelines.

Senator FRIST. You need some money, and you heard me ask earlier, if the administration is serious about mandatory reporting of thousands of errors, making the most sophisticated dissemination of information back, I am not sure it is not a little disingenuous for them to come forward with tiny bits of money, make this mandatory/compulsory reporting requiring the most sophisticated expertise in medicine today at the table, if you can really interpret the data that is coming forward. If you just want to get it out there and disseminate it, that is a different issue, then we are going to have to face the facts of what the resources are going to be.

Your $40 million figure of grants, based on what you have told me, is a nice start. We have not heard that requested by the administration. We are talking about $20 million for overall funding of all research for the 1,155 of Dr. Eisenberg, which does not approach that. And again, it is important—the $40 million——

Dr. RELMAN. This would go to the States.

Senator FRIST. I understand, I understand. Right now, we have how much going to the States—zero, probably, or a few million dollars.

Dr. RELMAN. We do not get any Federal support.

Senator FRIST. I know. We are going to give some to Massachusetts. We need Senator Kennedy here. [Laughter.]

Anyway, I appreciate it, because the program is admirable and demonstrates the overall complexity of it.

On public dissemination of information—in the transplant field very early on, by Federal legislation, we were required to report every transplant that we did. This was early on, 1986. It is probably one of the first fields where you reported the outcome of whom you operated on, what was the outcome, what was life, death, quality of life at 6 months, 1 year and 3 years, infectious disease outcome—all of a sudden, we had all this data reported, and nobody knew what to do with it. Then it winds up in the newspapers, and all of a sudden, transplant centers were very threatened, because

without a real definition of case mix and how difficult the transplant cases you were doing, all of a sudden, if somebody was doing easy ones, their hospital or their transplant program looked real good, and the others looked real bad. So for about 3 years, we really struggled.

Therefore, I am a little bit suspicious based on that experience of just getting raw data, without the sort of expertise that you have been able to demonstrate, and report it to any agency of the Government without a real careful, thoughtful, sophisticated plan. It might be from the private plans, it might be from JCAHCO, it might be from individual hospitals, physicians. And again, the principles are good, but before we get too far along, I think we need to think long and hard about this information coming to the top, how it is digested in a sophisticated way and then disseminated. I think everybody says that that disclosure needs to be there. That is why I want to hear exactly how it is going to be done as we go through. That is why I keep bringing up points like that.

Dr. O'Leary, in your written comments, you talk about error-related information, that Congress should enact again, I am trying to figure out Federal Government versus State Government. You say that Congress should enact Federal protections for error-related information. I think I agree, but what do you mean by that? How broad should these Federal protections actually be?

Dr. O'LEARY. I think the protections should be for the report of the occurrence, a serious adverse event—however we come to a definition of that—and for the root cause analysis, the in-depth investigation of what happened at a systems level within the organization. That is specifically what we are talking about protecting.

Senator FRIST. And in terms of the actual wording of that, you are fairly confident that we could come in with legislation that would circumscribe that, define it and take care of it?

Dr. O'LEARY. I really am.

Senator FRIST. Are there other comments on that whole issue of legislating Federal protection for error-related information? All of you think it can be done? Good.

Dr. O'Leary, you also stated that the problem of medical errors is an information problem—actually, both of you did, Dr. Udvarhelyi as well—and in your testimony, you went through it. Some people, Dr. O'Leary, have suggested that we are not making use of all the information that is out there today. Is that accurate, and is there a role for Congress to make better use of that information?

Dr. O'LEARY. I do not know that we have a lot of useful information in the medical errors arena. A lot of it is locked within organizations. Even getting caregivers to report significant medical errors inside organizations is a problem. That is existing information, but it is not even known to organization leaders, let alone to the Joint Commission or to State agencies or to HCFA or anyone else. And until we know what is happening inside our organizations, we have no ability to leverage the analyses that need to be performed nor to harvest those analyses for lessons learned and to share those broadly across the country. Now, we do that on a very modest scale. Last year, we had 333 sentinel events made known to us, 83 percent of which were self-reported. The root cause analyses that

we required in each of those cases were very rich sources of information, and we publish quarterly something called "Sentinel Event Alert" on a topical error and medical errors, and those are widely read and used, because we can show that in some areas, we have seen a reduction in the frequency with which certain errors are reported—potassium chloride-related deaths being a case-in-point.

Senator FRIST. Dr. Udvarhelyi, on the health plans, again, you are in a unique situation because you are collecting so much information. Most of it is claims information right now, but still, you are the one in the group here whose plans are talking to a range of providers, facilities, nurses, doctors; they have to report to you, and you have to report to them. Most of it is claims, dollars and cents. Is there information that either you are receiving now that would help with the medical errors or that in some way could be de-identified but attached in such a way that it could address medical errors?

Dr. UDVARHELYI. Senator, I do not think that health plans do have access to the type of information that would be useful to identify medical errors. Again, as I said, earlier, we are not there where care is being delivered, and that is where these errors are identified.

I think it is important, as has been said before—there are adverse events which may or may not be due to an error, and then there are errors which may or may not lead to adverse events. In order to have error reduction, you need to understand the totality of errors, including those that do not produce an adverse event. And really, it is the physicians and hospitals that are in the best position, and other health care providers, to know how the decisions are being made, and I agree with Dr. Relman that you need to understand the context of these events from a clinical standpoint, and again, the health plans are not in a good position to do that. We can play a supportive role, but I do not think we are in a very good position at all for reporting.

Senator FRIST. Dr. Russell.

Dr. RUSSELL. I would just like to say that the ideal place is the hospital, because that is where it happened, and that is where it is disclosed. I think that in a lot of hospitals in this country, when something happens, everybody knows about it. That is the environment that you want to create.

For example, in our hospital, maybe once a year, there would be a death in the operating room. I would know that within 30 minutes of the event; the word would get around the hospital. That is the kind of environment that you want to create, so that when something comes up, the right committees get involved, and it is handled internally. It is not hidden; it is opened up to internal discussion, and then, if it needs to be reported to an external organization, that is fine and dandy. But I think it has to start and hopefully can get finished locally, and then by improving the process. That is the ideal way for it to work, and I think there are some hospitals in this country where it works very effectively. We should not always just look at where there are bad cases; we should look at where we have good use of this data, and results come from the analysis, and we should model our programs after that.

Senator FRIST. Thank you.

I am going to wrap it up shortly, but I want to give everybody an opportunity to close with a minute apiece if you would like to.

Dr. Relman, in terms of what other States are doing, do you interact with other States at all?

Dr. RELMAN. No, we do not. But to the best of my knowledge the particular combination of methods and procedures that we follow are unique. I looked at the material that the Institute of Medicine had collected, and none of it resembles what we do. In fact, what is stated as being what Massachusetts does is what the Department of Public Health does, not what we do, and it is quite different.

Senator FRIST. And the Federal role for you is maybe the mandatory, just so every State will have to get in the business—in terms of what the Congress needs to do—and number two was the confidentiality end of it. And third was the grants and other money.

Dr. RELMAN. Yes. And I agree with John Eisenberg that you need to have a center where you receive nonidentifiable information, statistical information. These are the common problems that we are identifying. And then, you need to have some research on whether they can be prevented and what works and what does not.

There is an enormous amount of information on the procedures of health care in hospitals, in clinics, and in private offices, that we have to know about, and we need research. And the Federal Government can support that research—the States cannot afford to do that—and disseminate the results of the research.

Senator FRIST. Is the group that you work with a regulatory agency?

Dr. RELMAN. Yes, we are. We regulate the practice of medicine.

Senator FRIST. Will you close down hospitals if you do not——

Dr. RELMAN. We hope we do not have to, but we have the statutory authority, State authority, to declare that a quality assurance program in a given hospital is not satisfactory. We also have the authority to determine the conditions under which medical licensees can practice. We have never had to exercise that authority, and we hope we do not, and all of our lawyers are not quite sure what would happen if we came to that point. But we do not have to. The hospitals get the word—they do not want it to come to that point—and staffs respond.

Senator FRIST. Thank you.

Dr. Udvarhelyi, do you have any closing comments?

Dr. UDVARHELYI. Thank you, Senator. I would just emphasize that we think there is a role for legislation to create the proper environment and that after that has been done, mandatory reporting is a viable option, and within that context, we think that if we can identify the errors and learn about the root causes, then all parties will be able to make a concentrated effort to reduce their frequency.

Senator FRIST. Thank you.

Dr. Russell.

Dr. RUSSELL. Senator, I would just like to say that I think it is really worthwhile that we are looking at this, but I want to hasten to say that we do a lot of good in hospitals today. The severity of illness of patients in hospitals in this era is amazing, and what we have to do with them, with comorbid problems and a multitude of

difficulties, with new diseases, the ravages of AIDS and the way it affects patients—it is remarkable what health care can do today. So we cannot lose track of that.

We have a good system, but we are going to make it better. So let us not beat ourselves totally over the back on this, because we have to recognize the good of the system and then build on that. Those would be my closing comments.

Senator FRIST. Thank you very much.

Dr. O'Leary.

Dr. O'LEARY. There are two points I want to emphasize. One is the importance of information-sharing regarding medical errors eventually amongst those with a legitimate need to know. The oversight players are the private sector accrediting bodies, the State agencies, HCFA and its subpart PROs.

The accountability surrounding medical errors is not just for reporting or even doing root cause analyses, but eventually for the implementation of action plans to reduce the likelihood of future errors. We cannot tolerate a situation where medical errors are being reported to one place, and we as an accrediting body do not have access to that information and yet are held accountable for improving patient safety through our Federally-deemed status relationship.

I emphasize this point because it is not addressed in the QuIC Task Force report, and we need to assure that there is appropriate information-sharing.

The second issue more briefly is that most of the recommendations in the QuIC Task Force report have significant time lines associated with them, but the thing that can be done now is the enactment of confidentiality protection information for error-related information. Many hospitals tell us that they would report serious adverse events and their root cause analysis to the Joint Commission if they had that protection. That can happen now.

Senator FRIST. Thank you.

Dr. Relman.

Dr. RELMAN. The responsibility for medical care rests clearly with the medical profession and allied professions, the nursing profession and so on. If you are concerned about improving the quality, you have to start by motivating doctors and nurses to do everything they can to look at what they do critically and carefully and honestly, identify what goes wrong or what is unexpected, find out why it went wrong, and then do something about it if it can be done. You cannot be too draconian. You cannot be too bureaucratic. You cannot make too many rules or have too many organizations requiring doctors and nurses and health care personnel to do the right thing.

However, you can make sure that they do it by saying to them: We want you to tell us that you are, and we understand what you are telling us. We know. We have been there. We have done it ourselves. We doctors. We are nurses. You convince us that you are doing the right thing and that you are correcting it.

That is all we can—now, patients have a right to expect that their doctor tells them what they ought to know. That is different from public disclosure. It has got to be confidential. It cannot be just everything done in the public arena. What is between a doctor

and a patient, you know, is private, and that should not transpire in the public arena. But doctors have got to do it, and hospitals have got to do it, and I believe that the Federal Government and the State Government each have a role to play and can be very supportive, because it does take money.

Hospitals, by the way—let me put in a word for the hospitals—are being stressed terribly now, as you know very well. This adds costs. The peer review function costs money and costs time. Quality assurance nurses, reports being filed with agencies and so on—it takes more money and more effort, and they need some help.

Senator FRIST. Thank you.

I want to thank all the witnesses. Today was a joint hearing, and we do not hold joint hearings that often, to bring together the Appropriations Committee's Subcommittee on Labor, Health and Human Services, and Education, with Senator Specter, and Senator Jeffords' committee, the Committee on Health, Education, Labor, and Pensions. I think that that coming together is a reflection of the way this has to be addressed, both in terms of adequate financial resources, which we come back to again and again, and in terms of the appropriate authorizations given to the appropriate agency, which I am delighted that we have come again and again back to the Agency for Health Care Research and Quality, which was very specific, in legislation that originated in this room 2 years ago, that became a part of the Senate-passed Patients' Bill of Rights, that was taken out and passed last year because of the critical importance of addressing quality and medical errors in addition to access and insurance is a critical component of that.

All this together, I think demonstrates what you said at the end, Dr. Relman, that there have got to be a lot of partnerships at the local doctor-patient/nurse-patient relationship, traveling all the way up to the Federal Government, how we collect, how we report, with everything from the health plans to the accrediting agencies to the hospitals to the professional societies out there today. I think it has got to be addressed in very sophisticated, very inclusive and very comprehensive way to achieve what we all recognize can be achieved.

It boils down to accountability and how we can assure accountability at every level, and I think that based on the joint hearing today and the three previous hearings that we have held on medical errors in the HELP Committee, we have a great foundation. Now we need to all again in a partnering way put our heads together, put on paper what needs to be put there, usher it through the United States Congress, and set a framework. Again, I do not think it has to be overly regulatory, but it really does have to lower those barriers where the accountability can flourish.

I think it can be done. I think it is now our responsibility to do just that. It is going to take all of us working together and listening very carefully in a bipartisan, comprehensive way, House and Senate, to accomplish that.

I am sorry the hearing went on for so long, but it was because of the amount of information that we wanted to listen to, collect, and discuss.

CONCLUSION OF HEARING

Thank you all very much for being here, that concludes our hearing. The joint hearing is recessed.

[Whereupon, at 12:35 p.m., Tuesday, February 22, the joint hearing was concluded.]

Material Submitted Subsequent to the Conclusion of the Hearing

[CLERK'S NOTE.—The following statements were received by the subcommittee subsequent to the conclusion of the hearing. The statements will be inserted in the record at this point.]

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS AND THE AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

The American Academy of Orthopaedic Surgeons and the American Association of Orthopaedic Surgeons (AAOS), representing 18,000 members, appreciate Chairman Jeffords and Chairman Specter holding this joint hearing to address patient safety and the recommendations of the recent Institute of Medicine (IOM) report, entitled To Err is Human: Building a Safer Health System. We would like to offer our perspective on the report and welcome the opportunity to work with you and other members of the Subcommittee as you consider appropriate policies with a goal toward reducing medical errors. We would also like to share with you some highlights of our work over the past several years to reduce or eliminate specific types of surgical errors.

We share your concerns and those expressed in the IOM report that ensuring patient safety in hospitals, as well as other practice settings, must be given appropriate attention. AAOS is committed to the elimination of medical errors and has designated this as a high priority in the policies and practices of the AAOS. High quality patient care is the crux of AAOS' Principles of Medical Ethics in Orthopaedic Surgery and we have strived to create an expectation of high quality care and to assist our members in the practice of safe care by making this an important focus of our education program.

More than a decade ago, the AAOS Board of Directors decided to commit significant financial and clinical resources into the development of a Continuous Quality Improvement Program (CQI) to help provide "Best Care" for our patients. The "Best Care" philosophy has been a cornerstone of the strategic plan of AAOS. Accordingly, clinical guidelines have been developed to serve as common treatment protocols for a number of musculoskeletal conditions. Corresponding outcomes instruments allow for the evaluation of patient outcomes, by identifying factors, including medical errors, associated with positive or negative patient outcomes in order to initiate change in the treatment guidelines. This process of Continuous Quality Improvement thus drives treatment toward optimum or "Best Care." The AAOS is a recognized leader in this area.

AAOS also has developed programs to address specific medical errors. In September 1997, AAOS established a task force to examine surgical errors and recommend prevention safeguards for the operating room. The task force developed "Sign Your Site," a protocol whereby before surgery, the surgeon checks the patient's chart and any radiographs, the patient identifies the correct site and side to be operated on, and then the site is marked with the surgeons initials using a permanent marking pen. The surgeon then operates through or adjacent to the initials. AAOS launched a major educational program among its members to eliminate wrong-site surgery, and, by mid-1998, AAOS mailed information to 19,000 operating room supervisors and surgeons in other specialties.

Numerous hospitals throughout the country have responded positively to this campaign, and mandatory "Sign Your Site" programs have been initiated at an increasing number of hospitals. The AAOS has provided information on the "Sign Your Site" program at the request of the Joint Commission on the Accreditation of Hospital Organizations (JCAHO), the Physician Insurers Association of America and other organizations committed to reducing medical errors. AAOS believes that a unified effort among surgeons, hospitals and other health care providers to initiate preoperative and other regulations is helping to prevent surgical error.

Like many similar initiatives, feedback from the "Sign Your Site" campaign offers invaluable insight into the administrative operations of hospitals and other provider institutions to study how to reduce medical errors. What we have discovered in launching this campaign is that such efforts require long-term commitments and resources involving ongoing communication and research to ensure success. From our experience, we would caution you that policies cannot underestimate the planning involved. A comprehensive campaign requires intensive ongoing communication, networking, surveying, monitoring, research, feedback and education. That is one reason that the AAOS campaign was conceived as a multi-year effort.

Since 1990, the AAOS Committee on Professional Liability also has conducted a series of closed-claim professional liability insurance studies, through on-site retrospective review of the records of insurance companies across the country. Most major orthopaedic diagnoses and procedures have been studied, including foot and ankle surgery, spine surgery and spine fusion, total hip and knee replacement, knee arthroscopy, fractures of the hip, femur and tibia, and pediatric problems, in order to assist orthopaedic surgeons in providing optimum patient care. Many articles and two books have resulted from these studies—the purpose and result have been to identify trends in unexpected outcomes and medical errors, to provide risk management, and to promote safe and appropriate surgical practice. This guidance emphasizes thorough patient consent discussions about treatment options and alternatives, risks of treatment, non-treatment, and patient expectations regarding eventual functional ability after treatment.

We commend the IOM for undertaking such an important study. Several critical points have been raised in the report that must not be overlooked when defining appropriate policies. Medical error is a multifaceted, complex issue. The comprehensiveness of the report alone illustrates the daunting task required to determine how to proceed. AAOS believes that:

—Policies must first determine, by supporting research, whether and how current medical error reporting programs, as well as prevention initiatives, have lead to reduction in medical errors.

—Funding must be available to redesign systems based on research findings and costs to hospitals and other providers for implementing these systems must be considered.

—Access to medical error data under the current liability system must be carefully and thoroughly analyzed and mechanisms for reporting must ensure patient and provider confidentiality and expand peer review liability protections.

—Resources must be available to communicate information on patient safety practices to hospitals, other institutional providers, health care professionals and consumers.

—Promotion of a system of Continuous Quality Improvement is among the best ways to provide patients "Best Care" and to eliminate medical errors. The traditional Quality Assurance (QA) method is a judgmental, confrontational and punitive approach, which is likely to negatively impact relations between physicians, patients and government.

Patient safety is paramount and medical error reporting should lead to improvements in patient safety. As the IOM report points out, the underlying objective is to prevent patient harm. An important focus of legislation should be to examine existing mandatory and voluntary reporting systems across the states to determine if and how this information can be utilized constructively to prevent and reduce the number of medical errors. The progress of prevention programs and demonstration projects in reducing medical errors should also be examined. Follow-up is critical. Without some clear direction on how to integrate the results of the research into the health care system, you risk prematurely raising expectations that reporting will lead to a reduction in medical errors. It is disconcerting that, as the IOM report points out, while approximately one-third of the states have implemented mandatory adverse event reporting systems, there is no indication that these systems have resulted in safer environments for patients and this data has not been utilized to assist in reducing medical errors.

The AAOS is encouraged by the IOM report's discussion of the need to create a culture of safety in reporting. If new reporting requirements, whether mandatory or voluntary, are legislated, then the approach should encourage open and candid discussions and disclosures through non-punitive mechanisms for reporting that ensure patient and provider confidentiality and expand peer review protections. Even if the reporting is institution-based and not individual-based, or just voluntary and not mandatory, implications for the availability and use of such data may result in unintended consequences. Discovery rules and statutes governing access, entitlement and use of such information must be carefully scrutinized. Policies must require appropriate definition of the type and use of data necessary for a successful medical

error reporting program, as well as the process for reporting. A successful effort will require careful planning of the many critical components of a reporting mechanism.

The difficulty in finding the right balance to prevent a punitive approach is evident in the IOM report itself. The report seems to send contradictory messages by expounding on the importance of creating a safe reporting environment on the one-hand, yet maintains that confidentiality is not appropriate for mandatory reporting systems. The impact of such reporting systems on patient confidentiality rights and provider peer review laws requires careful scrutiny. The AAOS is particularly concerned with the report's recommendation to proceed with reporting requirements, including mandatory reporting, while recognizing that the current liability system is not conducive to reporting and analysis.

AAOS also believes that physicians and other health care professionals are already held accountable through a well-established punitive-based judicial system, as well as licensing structures and ever-more-complicated accrediting processes. These systems are designed to substantially serve to prevent patient injuries and ensure good quality patient care. We believe all entities involved in making medical decisions should be equally accountable. But additional systems with punitive undertones could defeat efforts to foster an open dialogue on medical error and patient safety.

Federal legislation should recognize the need to proceed with caution and with careful planning before medical error reporting is required or encouraged of hospitals and other health care providers. Consideration should be given to funding studies of existing data of mandatory and voluntary reporting systems, demonstration and prevention projects, and dissemination of information on patient safety. Funding should encourage private/public partnerships in these efforts. Careful consideration of the legal and statutory requirements governing the use of medical information should be required prior to implementation of any reporting systems, regardless of type or scope.

We appreciate the leadership of Chairmans Jeffords and Specter and other members of the Committee and Subcommittee in drawing attention to the findings of the IOM report, To Err is Human: Building a Safer Health System. Please consider consulting with a broad range of the medical community, recognizing expertise in specific areas, and examining and involving efforts already underway through private funding.

Thank you for taking the time to consider our comments. We look forward to working with the Members of these Committees and other Members of Congress as you assess the need for legislation to address medical error reporting.

PREPARED STATEMENT OF THE AMERICAN COLLEGE OF PHYSICIANS—AMERICAN SOCIETY OF INTERNAL MEDICINE

The American College of Physicians-American Society of Internal Medicine (ACP-ASIM), representing over 115,000 physicians who specialize in internal medicine and medical students with an interest in internal medicine, appreciates the opportunity to comment on the report of the Institute of Medicine (IOM), To Err Is Human: Building a Safer Health System. Our membership includes practicing physicians, teaching physicians, residents, students, researchers, and administrators who are dedicated to assuring high quality medical care.

The IOM report highlights unacceptable quality and safety problems in the nation's health care system. The report reveals that more people die each year as a result of medical errors than from motor vehicle accidents, breast cancer, or AIDS. It notes that medication errors alone account for over 7,000 deaths annually. This is a dismal record that exceeds the 6,000 deaths each year due to workplace injuries. Significantly, the IOM report finds that "the problem is that the system needs to be made safer" and indicates that the "problem is not bad people."

The IOM report concludes that the U.S. health care industry lacks a systematic way of identifying, analyzing, and correcting unsafe practices. In order to achieve this end, the report states: "Preventing errors means designing the health care system at all levels to make it safer. Building safety into processes of care is a more effective way to reduce errors than blaming individuals. The focus must shift from blaming individuals for past errors to a focus on preventing future errors by designing safety into the system." The report lays out a comprehensive strategy for addressing these problems. It challenges the profession to make significant changes to achieve a safer health care system. We accept this challenge. ACP-ASIM offers the following comments regarding specific recommendations in the IOM report:

CREATION OF A CENTER FOR PATIENT SAFETY (IOM RECOMMENDATION 4.1)

ACP-ASIM agrees with the IOM recommendation that a highly visible center is needed with secure and adequate funding to set national goals, evaluate progress, and develop and coordinate a research agenda to achieve improvements in patient safety. We firmly believe that such an effort should involve the many private sector initiatives that are also now underway. We concur with the IOM that a coordinated national effort is needed and that adequate and stable funding must be assured. If the center is to be housed in a federal agency, it should be in a non-regulatory agency such as the Agency for Healthcare Research and Quality (AHRQ). A coordinated program for research and achievement of national goals for improvements in patient safety should be as objective as possible and should not be tied to a federal agency with regulatory responsibilities. AHRQ has the expertise and an existing infrastructure for funding research and coordinating activities concerning health care quality. ACP-ASIM, therefore, supports increased funding for AHRQ to accomplish these expanded functions.

MANDATORY REPORTING (IOM RECOMMENDATION 5.1)

The IOM report recognizes the need for both mandatory and voluntary error reporting systems. It explains that mandatory reporting systems are needed to hold providers accountable for their performance. It further advises that mandatory reporting should focus on the identification of serious adverse events (deaths or injuries resulting from medical interventions). The IOM notes that the focus of a mandatory reporting system should be narrowly defined. It recommends that the Forum for Health Quality Care Measurement and Reporting (The Quality Forum), a recently formed public/private partnership charged with developing a comprehensive quality measurement and public reporting strategy, should be responsible for promulgating and maintaining reporting standards.

The IOM report also calls for licensing and accreditation bodies to expand the scope and magnitude to which patient safety is reviewed and evaluated in rendering licensing/accreditation decisions.

ACP-ASIM agrees with the intent of this recommendation, but is concerned about its possible implementation. We strongly agree that physicians have a professional obligation to patients and society to report serious errors resulting in adverse events. It is appropriate that information on serious adverse events be reported to appropriate authorities and that a uniform, national reporting format be developed. We further agree that a public/private sector body, such as The Quality Forum, should be responsible for clearly defining what should be reported and developing the uniform reporting format. However, we are apprehensive about the possible role of the federal government in mandating what is to be reported and what will be done with the data. We urge Congress and federal agencies not to define reporting requirements too broadly or to be overly inclusive. We are concerned that mandatory reporting requirements could be excessively burdensome to institutions and individual physicians. We, therefore, agree with the IOM that a more narrowly defined program has a better chance of being successful.

We also wish to highlight that the IOM calls for devoting adequate attention and resources for analyzing reports of adverse outcomes to identify those attributable to error. The IOM notes that it is only after careful analysis that the subset of reports attributable to error can be identified and follow up action taken. We agree with the IOM that the results of the analyses, not all data that are required to be reported, should be made available to the public.

ACP-ASIM emphasizes that licensing and accreditation bodies considering patient safety issues in making licensing/accreditation decisions should not review every case patient record, but should review representative samples of patient care. Patient safety reviews should be completed within a reasonable time and with minimal disruption or additional administrative burdens for physicians or institutions.

VOLUNTARY REPORTING SYSTEMS (IOM RECOMMENDATION 5.2 AND 6.1)

The IOM calls for voluntary reporting systems to collect information on errors that cause minimal or no harm. It notes that voluntary reporting of less serious errors can identify and remedy patterns of errors and systemic problems. It notes that the aim of voluntary systems is to lead to improvements in patient safety and that the cooperation of health care professionals is essential. The IOM clearly recommends that voluntary reporting systems must be protected from legal discovery. IOM further recommends that Congress pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected

and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality.

ACP-ASIM supports voluntary reporting of incidents that do not result in fatalities or major errors, but could be symptomatic of systemic problems. However, protection of the confidentiality of data is essential to ensure that events involving medical errors or other incidents adversely effecting patient safety are reported and acted upon. Physicians and other health professionals have a responsibility to patients and the public to assure that all actions adversely affecting the quality and safety of patient care are reported and acted upon through a system of continuous quality improvement. However, ACP-ASIM recommends that voluntary quality improvement systems must protect individual confidentiality. The confidentiality of reported data must be protected so that physicians and other health care professionals are encouraged to report all adverse incidents without fear that their cooperation will increase their exposure to law suits for professional liability or other sanctions. Any potential increased exposure to fines, loss of hospital privileges, or even possible loss of medical licensure will discourage physicians from voluntarily reporting "near misses" and other adverse incidents. Consequently, we strongly suggest that any voluntary reporting system must be primarily educational rather than punitive.

Nevertheless, ACP-ASIM acknowledges that physicians have a professional obligation to disclose to patients information about procedural or judgment errors made in the course of care if such information is material to the patient's well-being. Errors do not necessarily constitute improper, negligent, or unethical behavior, but failure to disclose them may. (ACP-ASIM Ethics Manual, 1998, p.8–9)

THE PRESIDENT'S EXECUTIVE ORDER

In response to the IOM report, President Clinton announced on December 7, 1999, that he had signed an executive order directing a task force to analyze the report and report back within 60 days about ways to implement its recommendations. He also directed the task force to evaluate the extent to which medical errors are caused by misuse of medications or medical devices, and to develop additional strategies to reduce these errors. He further directed each of the more than 300 private health plans participating in the Federal Employee Health Benefits Program to institute quality improvement and patient safety initiatives. He also signed legislation reauthorizing the Agency for Healthcare Research and Quality and providing $25 million for research to improve health care quality and prevent medical errors. The AHRQ will convene a national conference with state health officials to promote best practices in preventing medical errors. In addition, the President announced that he was directing his budget and health care teams to develop quality and patient safety initiatives for next year's budget.

ACP-ASIM applauds all of these actions by the Executive branch to address the problems identified in the IOM report.

THE PRESIDENT'S INITIATIVE TO REDUCE MEDICAL ERRORS AND IMPROVE PATIENT SAFETY

On February 22, 2000, the President announced a series of initiatives to reduce medical errors and improve patient safety. ACP-ASIM concurs with the following IOM and Administration recommendations:

—Establish a new Center for Quality Improvement and Patient Safety within the Agency for Healthcare Research and Quality (AHRQ). We agree that the goals of this Center should be to work with the medical profession, hospitals and consumers to develop national goals for patient safety, to track progress on meeting such goals, to promote the transition of research findings into improved practices, and to educate the public. We support the President's budget request to fund the Center.

—Launch new research to implement mandatory reporting of major errors that *cause serious injury or death* to patients, eventually leading to a requirement for standardized reporting of such errors (emphasis added). We share the concerns of other professional and hospital associations that mandatory reporting can do more harm than good if it is designed to punish those who make errors, rather than encouraging cooperation among all stakeholders in preventing errors. The goal must be to enlist physicians, nurses, hospitals and other providers in a concerted drive to prevent major errors, rather than reporting after a patient has been seriously harmed. We are encouraged that the administration calls for the development of patient safety measures by the National Quality Forum and pilot-testing of mandatory reporting systems before uniform nationwide reporting requirements are mandated. We believe strongly that mandatory reporting must remain limited to major errors that cause serious injury

or death to a patient, and we will oppose efforts that may be made by others to broaden mandatory reporting requirements to other types of errors.

—Extend expansion of peer-review and confidentiality protections to encourage development of post-error review processes. In our view, the establishment of such protections is a pre-requisite for an effective reporting system. ACP-ASIM's Code of Ethics clearly states that a physician is obligated to inform individuals and family members when a preventable medical error occurs that causes serious injury or death. We agree with the administration, however, that system shortcomings (root-cause analysis) and subsequent action to prevent such errors in the future should not be "discoverable information" used in litigation. We support the President's call for legislation to protect patient and provider confidentiality in order to encourage post-error review. We also support broader reforms in the medical liability system, including a cap on non-economic damages, than the administration has been willing to support in the past. ACP-ASIM agrees that legislation to protect peer review and confidentiality should be enacted in conjunction with, or prior to, implementation of nationwide mandatory and voluntary reporting systems.

—Encourage the development of voluntary systems and learning from existing systems. Although the IOM's support for mandatory reporting of major errors has been the subject of the most debate, we believe "as does the IOM" that encouragement of voluntary reporting of problems that do not cause death or serious injury to the patient must be a key element of a national strategy to reduce preventable errors.

ISSUES FOR FURTHER REVIEW

The IOM report raises many questions that will require further examination. We urge Congress to consider the following:

—What should be required for mandatory reporting? Should reporting be required only for the most egregious errors involving death or serious injury? How will "serious errors" be distinguished from "less serious" errors? Will mandatory reporting be cumulative, by institutions or by individual physicians?

—To whom should data be reported? Should it be reported to state agencies only, to states and the federal government, or to private agencies?

—What data should be released to the public? For errors causing serious injury or death, what should be the extent of data released? Should everything be reported or just the final analysis? Does the public have a right to know the number of adverse incidents reported by a physician?

—What happens to the information that is reported? Will there be follow-up actions, and if so, will these be released to the public? Who will have access to the raw data, and will there be adequate protections of confidentiality?

—Should licensing bodies use data on errors to deny or revoke physician licenses? Should data on physicians be available to hospitals for consideration in granting or denying hospital privileges?

—How can reporting requirements avoid creating excessive costs and administrative burdens for physicians and health care organizations?

CONCLUSION

ACP-ASIM is strongly supportive of the recommendations of the IOM report, To Err is Human: Building a Safer Health System. The College agrees that far too many preventable errors are committed that do not get reported and that solutions are needed to improve the quality and safety of patient care. ACP-ASIM concurs with the IOM's conclusion that the focus must be the reform of the system, not the punishment of individuals. ACP-ASIM encourages the profession to take up the challenge raised by the IOM to improve the quality and safety of patient care. The College supports setting a national goal of reducing medical errors by 50 percent within five years. Such an achievement will require substantial commitment of resources and effort. Substantial financial costs will be involved, but these may be largely offset by benefits in improved patient care and better health outcomes. Regardless of the costs, the public has a right to expect health care that is safe and effective. The profession is responsible to individual patients and to the public to continuously seek to improve the quality of medical care and make sure that health care services are provided as safely as possible.

The College applauds the prompt initiatives instituted by the President and will look forward to working with Congress in addressing issues requiring legislative action. However, as we have indicated, there are many questions that need to be addressed before a national plan with mandatory and voluntary reporting requirements can be implemented. ACP-ASIM appreciates the deliberation that the Com-

mittee is giving to the IOM report and the opportunity to submit testimony. We are prepared to work with the Congress and the Administration to reduce the number of medical errors.

PREPARED STATEMENT OF THE AMERICAN COLLEGE OF RADIOLOGY

The American College of Radiology (ACR), a professional society whose purpose is to advance the science of radiology in order to improve the health of patients, is pleased to present the following statement regarding its efforts to improve and ensure patient safety.

The ACR has been involved in patient safety relative to ionizing radiation for over 15 years. To that end, ACR has developed three interrelated programs that speak to the characteristics of quality improvement and patient safety in radiology and radiation oncology. Protecting the patient and public are at the heart of these programs that recognize that quality matters, quality varies, and quality can be improved and measured. In light of the recent Institutes of Medicine (IOM) Report on medical errors, ACR believes its expertise in developing peer-reviewed, quality patient safety programs would benefit Congress as it begins to address this serious problem. ACR's programs are summarized below.

ACR ACCREDITATION PROGRAMS

In the mid 1960's, the ACR developed and implemented its first accreditation programs that were designed to evaluate whether radiology practices met certain criteria developed by their peers. These early programs permitted ACR to develop the voluntary accreditation programs of the mid 1980's that follow recognized principles of accreditation law: provide public benefit/safety; available to all practitioners who are able to meet the criteria; valid, credible, reasonable, substantive, procedurally fair, and able to withstand external scrutiny. Further, final written reports and certificates are issued; there is an appeals process in place; corrective action procedures are available to deficient facilities to assist them in meeting criteria; and finally, denial of accreditation to those facilities unable to meet the criteria.

The Mammography Accreditation Program serves as the model for all other programs with the exception of Radiation Oncology. The voluntary ACR mammography accreditation was implemented in 1987 because of identified problems with the quality of mammography images as well as concerns about radiation dose. The following areas are assessed: personnel qualifications for physicians, physicists, and technologists that includes training and education and continuing medical education, clinical and phantom images are scored, and radiation dose is measured. In 1992, the Mammography Quality Standards Act (MQSA) became federal law with oversight provided by the FDA. This program was largely based on that of the ACR and ACR was recognized as an approved accrediting body with some 9000 facilities. Yearly, there is a federal inspection and triennially, accreditation must be repeated. The main outcomes of this program have been:

—Provide consumer information and listing of accredited facilities
—Provide standardized mammography practice across the United States
—Improve the quality of mammography (greatly)
—Decrease the radiation dose by 100 mRads on average
—Provide the mammography report directly to women
—Increase provider education
—Improve the standards for equipment
—Improve the provider list (10–12 percent no longer provide mammography)

Although other ACR programs provide the same kind of improvement, they do not operate under federal mandate. However, as third party payers seek ways to provide quality to their enrollees, all ACR programs have some third parties requiring them as a condition of reimbursement, e.g., Aetna US Healthcare requires all MRI providers to become accredited. The new Nuclear Medicine program incorporates the Nuclear Regulatory Commission requirements.

The ACR has "crosswalked" their program with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and currently has a cooperative agreement with the JCAHO, which recognizes the ACR organizations accredited in radiation oncology. The same process is being pursued for all of the diagnostic programs and, in fact, the mammography program is recognized.

ACR APPROPRIATENESS CRITERIA FOR IMAGING AND TREATMENT DECISIONS

In 1993, the ACR determined that in a changing healthcare environment a premium would be placed on the efficient use of resources including the appropriate

use of radiologic services. Thus the ACR embarked on developing evidenced based, multidisciplinary appropriateness criteria to assist radiologists and referring physicians in making appropriate, initial imaging decisions for given patient conditions. The ACR incorporated into the development process medical guidelines' attributes developed by the Agency for Healthcare Policy and Research (AHCPR) and the Institute of Medicine.

Following literature review and rating, a modified Delphi technique was used by the ten expert panels, based on anatomic sites, to come to consensus. A number of different imaging techniques were rated using a scale of 1–9. Nine being most appropriate. Over 170 conditions and 900 variants have been completed and published. These are reviewed every three year or sooner if warranted by new evidence.

These criteria are being used in research projects, physician ordering systems, utilization management systems to identify outliers for educational purposes and for reimbursement by third party payers. Patients can also use these criteria in discussions with their physicians regarding imaging/therapy. Further, certain of these guidelines are on the AHCPR Guidelines WEB site.

ACR STANDARDS

The ACR Standards for performing radiological procedures attempt to define principles of practice that should generally produce high-quality radiological care. The standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills and techniques as described in each standard. This standardization effort should improve the quality of patient care throughout the United States. Each standard has undergone a thorough consensus process in which it has been subjected extensive review. The ACR believes that these baseline standards are generic and pertinent to any physician performing radiologic procedures regardless of the setting. Existing standards are reviewed every four years or sooner if necessary.

ACR Standards are used in practice policy, by third party payers, by patients, and lawyers. Further, Physicians Insurance Association of American (PIAA) has reviewed radiology closed claims and indicated that ACR Standards serve as very good risk management tools. ACR has addressed issues of communication between radiologists and referring physicians by writing standards for communication for both diagnostic radiology and radiation oncology.

ACR is committed to the continued improvement in the practice and safety of radiologic services provided to the American people. The College would be honored to provide any assistance to the Committee as it begins to address the serious problem of reducing medical errors.

PREPARED STATEMENT OF THE HEALTHCARE PROVIDER CREDENTIALS VERIFICATION ASSOCIATION

Mr. Chairman, and Members of the Committee: I am pleased to submit the following testimony on behalf of the members of the Healthcare Provider Credentials Verification Association (HPCVA). HPCVA is a non-profit organization representing the interests of the credentials verification industry and is headquartered in Washington, DC. HPCVA was formed to work with legislative bodies, regulatory agencies and other organizations in an effort to improve the healthcare provider credentialing process and improve the relationships between providers and our ability to meet requirements of the industry. It's mission is to advance the efficiency, accuracy, and confidentiality in the gathering, maintaining, and reporting of relevant information to healthcare organizations, practitioners, and consumers as part of the solution to improve the quality and reduce the cost of American healthcare.

Credentialing is a very important part of the administration of healthcare in this country. It is through an exacting credentialing process that organizations know that they are offering quality healthcare services to Americans. Credentialing certifies that healthcare providers have the appropriate knowledge and experience to provide care to patients. It is also a way in which organizations can determine whether providers should be hired, have hospital privileges, or be able to participate in a network or managed care contracts. In addition, credentialing can expose those providers who have falsified their applications or documentation.

WHAT IS CREDENTIALING?

Credentialing is the evaluation of providers defined in the Health Care Quality Improvement act. Regulatory organizations such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the National Committee for Qual-

ity Assurance (NCQA) and the American Accreditation HealthCare Commission/Utilization Review Accreditation Commission (URAC) focus on the measurement of compliance to that act which requires a peer review process. At first this process mostly applied at hospitals. Now, with so many more options for the delivery of healthcare, such as, managed care organizations, independent practices, health maintenance organizations, preferred provider organizations and other healthcare organizations, there has been more need for credentialing than ever. JCAHO and NCQA require that all providers with privileges be "recredentialed" very two years in order to ensure that licensure is current and risk of future substandard care to members is minimized.

During the credentialing process, areas of a provider's background and training are verified through a variety of primary sources. This process can be paper and labor intensive as well as time consuming.

Credentialing includes primary source verification of the following:

—Licensure
—Hospital privileges
—Drug Enforcement registration and state controlled drug substance registrations
—Medical education
—Board certification
—Professional Liability insurance
—Liability claims history
—National Practitioner Data Bank (NPDB) queries and HIPDB queries
—Medical board sanctions
—Medicare/Medicaid sanctions

The process begins with the provider completing the application and signing it thereby attesting to its truthfulness and completeness. From the date the application is signed the information must be verified, according to NCQA, within 120 days. The client or healthcare organization then has 60 days to review the file through its peer review process. If the file is not completed and reviewed in these time frames, the Credential Verification Organization (CVO) and healthcare organization are out of compliance as the information is not considered to be current. If the CVO exceeds the 120-day time frame, the attestation document must be resigned and dated in order for the credentialing process to continue.

Discrepancies or incomplete information can relate to the provider's professional history, which addresses any licensure restrictions or revocations, felony convictions, Medicare/Medicaid sanctions, reports to the NPDB, chemical dependency or substance abuse problems, or physical or mental conditions that might limit the provider's ability to provide services. If a discrepancy is noted, the provider must then provide written clarification, including date and signature, which then becomes part of the application.

Once the credentialing process is completed, the information is sent to the client's credentialing committee for peer review. Peer review is the process of reviewing a provider's professional and educational background and experience to make a final determination as to whether or not to accept the provider into the network, or grant privileges because it is determined by the provider's peers that there is no apparent risk of future substandard care that would be a risk to members or patients.

CVOS ARE ACCREDITED

CVOs are accredited or certified by NCQA and URAC that they meet criteria that comply with standards that these organizations have established for the credential verification industry. Every two years accredited CVOs must undergo an additional certification process by any one of these organizations that verifies that the CVO demonstrates and provides the required service to its clients in a manner that ensures continuous quality assurance, handles the provider data in a confidential manner, and has a sound management structure.

CVOs also monitor their own performance by implementing a continuous quality improvement process to ensure accuracy and compliance with regard to the credentialing process and to determine if processes need to be improved in terms of efficiency, quality of service, and customer satisfaction. It is important that established performance measures are monitored, problems are investigated and preventive action taken where necessary. CVOs also recognize the importance of privacy and confidentiality in their businesses and understand its criticality for effective credentialing. This being a concern to the industry, CVOs develop policies that control access to credentialing files to ensure confidentiality of all information and protect it from unauthorized access and tampering.

WHY IS CREDENTIALING IMPORTANT?

Since credentialing provides thorough information on a healthcare provider's background it is invaluable in terms of a way to ensure quality healthcare and helps reduce the costs and risks involved for healthcare organizations if it is not done correctly. As you can see from the credentialing process described earlier, credentialing gives these healthcare organizations a very comprehensive look at a provider's background in order to make a determination with regards to hiring a provider. Knowing a provider's history—whether there are sanctions or there have been abuses or problems in the past, will help to make these decisions thereby reducing the probability of instances of medical errors. There was a situation where a provider responded "no" to the "have you ever been convicted" question. The verification of the license from the state agency included a transcript of a court case where it was clear that the provider had been convicted and spent 30 days in jail for a drug charge. The official record from the courts had been expunged and no record of the case could be obtained from the previous state of residence. It was only through the licensing agency that the information came to light. The provider was placed on extreme probation as a result.

Not only does credentialing serve as a tool for healthcare organizations to learn more about prospective providers under contract, it also serves as a check on providers themselves. Since the provider signs an attestation document as to the veracity of the information on the application and all of the information requested is verified through primary source, the provider must give all of the correct information. Since the process also allows for written clarification, a provider also has an opportunity to explain his/her behavior or practice in those areas that would be flagged. Providers are keenly aware that missing or inaccurate information will be discovered during the credentialing process and are therefore more apt to fully disclose areas of concern or derogatory information on their applications.

ISSUES AFFECTING THE CREDENTIALING INDUSTRY

Credentialing is an invaluable service to the American healthcare system. However, there have been some initiatives that may result in less effective credentialing and thereby lowering the quality of healthcare in this country. The members of HPCVA are concerned about the impact they may have on the healthcare industry.

Often CVOs are required to access the federal government's National Practitioner Data Bank (NPDB) on behalf of clients who are qualified and registered to query. CVOs compare information obtained by NPDB to information obtained by other sources and can quickly discern incorrect information contained in the NPDB. Since organizations are required to obtain this information, it should and must be correct in order for healthcare organizations to make informed decisions about healthcare being provided in their facility. There need to be checks and balances within this system to confirm that the information contained in the NPBD is correct. As we await the implementation of the Healthcare Integrity Protection Data Bank (HIPDB), there are no assurances that this situation will not occur there.

CONCLUSION

In conclusion, credentialing is an important and necessary process in the provision of healthcare in this country. From a risk management perspective, a healthcare delivery organization is responsible for protecting its patients and members from any unreasonable risk of harm. That process begins with selecting the right provider to provide care. Credentialing gives these organizations the data necessary to make that determination.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES

INTRODUCTION

Mr. Chairman and Members of the committee, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to submit a statement on issues relating to the important role that community pharmacies play in helping identify, prevent and reduce medication errors in our nation's health care system.

Founded in 1933 and based in Alexandria, Virginia, the National Association of Chain Drug Stores membership consists of 136 retail chain community pharmacy companies. Collectively, chain community pharmacy comprises the largest component of pharmacy practice with over 97,000 pharmacists. The chain community pharmacy industry is comprised of more than 19,000 traditional chain drug stores, 7,000 supermarket pharmacies and nearly 5,000 mass merchant pharmacies. The

NACDS membership base operates more than 31,000 retail community pharmacies with annual sales totaling over $158 billion including prescription drugs, over-the-counter (OTC) medications and health and beauty aids (HBA). Chain operated community retail pharmacies fill over 60% of the more than 2.73 billion prescriptions dispensed annually in the United States. Additionally, NACDS membership includes nearly 1,400 suppliers of goods and services to chain community pharmacies. NACDS international membership has grown to include 105 members from 26 foreign countries.

I. COMMUNITY PHARMACY HELPS TO IMPROVE MEDICATION USE

Pharmaceuticals and medication therapy management services are among the most commonly used and cost effective medical interventions in the health care system. In 2000, about 3 billion prescriptions will be dispensed to patients by retail pharmacies, with the goal of improving an individual's health and quality of life.

A December 1999 study released by the Institute of Medicine (IOM), "To Err is Human: Building a Safer Health Care System", identified the prevention of medication-related errors as a high priority for all health care organizations, and suggested that "health care organizations should implement proven medication safety practices" (Recommendation 8.2, page 136). This report focused primarily on the incidence of medical errors in the hospital setting. Medical errors can often result in the need for additional medical treatment, costing billions of dollars in additional health care spending, and lost worker productivity.

As primary care health providers, pharmacists have a critical role in assuring the appropriate use of medications and reducing the incidence of medication errors throughout the health care system. Community retail pharmacies have made, and are continuing to make, significant investments in patient care programs, operational processes, computer information systems, and employee training in an effort to build medication safety programs into the products and services that are provided to patients. For example, almost all community retail pharmacy providers already:

Use reliable, real time, computer software programs designed to check prescriptions for duplicate drug therapies, potential drug-drug and drug-allergy interactions, and out-of-range dosing, timing, and routes of administration.

Provide comprehensive written information and verbal counseling to consumers when they pick up their prescriptions, to help them understand how to take their medications. The IOM report said that: "whenever possible, patients (should) know which medications they are receiving, the appearance of such medications, and their possible side effects—patients should also be given verbal and written information about the safe and effective use of their medications"

Provide "reminders" to patients to refill their medications when the refill is due. This helps reduce the incidence of non-compliance with medication therapy, especially for individuals who need ongoing treatment for long-term chronic conditions, such as hypertension, diabetes, and high cholesterol.

Consistent with state pharmacy practice acts, employ well-trained pharmacy technicians, as well as up-to-date technology, such as automated dispensing systems, to reduce the pharmacist's involvement in administrative activities relating to filling the prescription. This allows more time for patient education and interaction by the pharmacist with the patient.

Are available seven-days a week, and in many locations 24-hours a day, to provide prescriptions and over-the-counter medications, or answer questions about health care products and services.

II. COMMUNITY PHARMACY'S RECOMMENDATIONS TO FURTHER IMPROVE MEDICATION USE

Many of the suggestions in the Institute of Medicine's Report focused on improving medication use in the hospital setting. However, many of the strategies suggested in the report can also be applied in the outpatient setting. For example, community retail pharmacy supports the recommendation made in the IOM report that the Food and Drug Administration (FDA) and pharmaceutical manufacturers seek to eliminate "similar sounding" names for pharmaceutical products. This can help reduce confusion in the prescribing and dispensing of certain prescriptions.

IOM REPORT: ENSURE THE AVAILABILITY OF PHARMACEUTICAL DECISION SUPPORT

"Because of the immense variety and complexity of medications now available, it is impossible for nurses and doctors to keep up with all the information required for safe medication use. The pharmacist has become an essential resource in modern hospital practice. Thus, access to his or her expertise must be possible at all times."

The IOM report recognizes the important role of the pharmacist in the health care system. Not only are pharmacists important drug information resources in the hospital setting, they are also important primary health care providers in the outpatient setting.

Moreover, a January 2000 GAO report on Adverse Drug Events[1] said that "increasing the role of community pharmacists in monitoring drug therapy improves patients' compliance" with their medications. The report also said that the role of the pharmacist as advisers to physicians in prescribing drugs should be increased. Based on the recommendation made in the IOM report, and the findings of the GAO, policymakers should consider the following ideas to help improve the use and outcomes of medications:

Recommendation 1. Assure an a supply of well-trained pharmacists to address the pharmacist shortage

Pharmacist Shortage Exists: Pharmacists are uniquely qualified to play an important role in medication therapy management, helping to assure the appropriate use of medications, and the avoidance of medication-related errors. Pharmacists receive, at a minimum, 5 to 6 years of training and education in such subject areas as pharmacology, disease management, and therapeutics.

However, there are currently over 5,000 unfilled chain community pharmacist positions across the country, as well as a shortage in hospitals, and in Federal health care agencies, such as the Public Health Service (PHS). Almost one chain community pharmacy in five has an unfilled pharmacist position. The shortage is expected to increase over the next few years. It will only be exacerbated if some type of Medicare prescription drug program is developed in the near future, since the demand for prescriptions and medication therapy management services will significantly increase.

Assure Supply of Well-Trained Pharmacy Providers: A sufficient number of properly educated and trained pharmacists is necessary to provide medication therapy management services. To help alleviate the current shortage and encourage students to choose pharmacy as a career, policymakers should consider directing additional funds toward pharmacy education. First, policymakers may want to target loan or grant funds specifically for students interested in a pharmacy education. Second, policymakers may want to provide financial assistance for those universities that want to start or expand their own college or school of pharmacy.

Recommendation 2. Incorporate programs and policies into Federal pharmaceutical benefit programs—such as Medicare, Medicaid, and the Federal Employees Health Benefits Program (FEHBP)—that will improve efficiencies and help improve medication use, such as

Requiring pharmacy-based medication therapy management services, such as disease management and medication compliance programs;

Adopting the NCPDP—developed standard prescription drug benefit card for insured patients;

Allowing for electronic transmission of prescriptions to pharmacy providers.

Medication Therapy Management Services Undervalued: Pharmacists are trained to provide medication therapy management services. These consist of a comprehensive range of programs and services delivered by the pharmacist that help assure that patients take their medications appropriately, and as prescribed by their physician.

Community retail pharmacy believes that the provision of medication therapy management services is as important as providing the drug product itself as part of a pharmaceutical benefit. Pharmaceuticals have the potential to result in a significant amount of benefit if used correctly, and the potential for harm if used incorrectly. As prescription medication therapy becomes more potent and complex, the need for these services will significantly increase.

However, the current pharmaceutical distribution system undervalues the contributions made by pharmacist medication therapy management to the health care system. This is because the system provides payment to pharmacists for dispensing pharmaceuticals products, rather than paying for both the product as well as the activities involved in managing the appropriate use of pharmaceuticals in patients.

Policymakers should consider incorporating pharmacy-based medication therapy management programs into Federal prescription drug benefit programs—including Medicaid, Medicare, and FEHBP—as well as payment for these services. Evidence

[1] Adverse Drug Events, The Magnitude of the Health Risk is Uncertain Because of Limited Incidence Data. General Accounting Office, January 2000.

suggests that these programs save money by avoiding drug-related medication problems, reducing the need for hospital stays and other medical services.

Precedent already exists in Federal health care programs for the use of medication therapy management:

In 1987, long-term care facilities receiving Medicaid payments were required to conduct drug regimen review (DRR) for nursing home residents. This was done in response to the need to improve the use of medications in nursing home residents, who are often taking multiple chronic medications to treat serious medical conditions.

In 1993, Medicaid programs were required to adopt a comprehensive program of drug use review (DUR) for Medicaid recipients to assure that prescription medications are used correctly, and to reduce the incidence of adverse drug reactions.

At a minimum, these pharmacy-based medication therapy management standards should include disease state management, medication compliance programs, and comprehensive drug use review. The program may be structured so that it is risk-based; that is, those patients most at risk for medication errors and adverse reactions can be identified and their therapy managed by the pharmacist, in conjunction with the physician.

Moreover, these services should be delivered as part of an integrated approach to patient care. As such, it is important for pharmacists to have flexibility to use patient-identifiable data to interact with health professionals, payers, and others to develop and implement these programs and manage the patient's drug therapy. Requiring separate patient consent to use patient-identifiable information for each activity would severely impair the delivery of these services, and would prove burdensome and costly.

Adopt Standard Prescription Benefit Card: Significant efficiencies in the delivery of prescription drug benefit programs would be realized if "standard" benefit card format developed by the National Council for Prescription Drug Programs (NCPDP) was used by all Federal programs. This standard card format was developed, in part, in response to the health care system's move toward developing uniform standards for electronic health care transactions. These requirements will ultimately enhance efficiencies.

However, there are still literally thousands of prescription drug benefit plans, each with its own "benefit card", many with different formats. Information about the patient has to be entered from these cards into the pharmacy's computer in order for the pharmacist to fill the prescription, creating incredible administrative burdens. This reduces the amount of time that the pharmacist has available for patient care activities. Over 80 percent of the 3 billion prescriptions dispensed by pharmacies—or about 2.4 billion prescriptions—were paid for through these benefit plans.

Two states—Texas and North Carolina—recently required that a "uniform" pharmacy benefit card be used to reduce the time that pharmacies are involved with entering patient data. While these states are to be commended for their actions, it will take several years for all states to adopt this concept. Consistent with HIPAA's goal of administrative simplification in the transaction of health care data, Federal policymakers should facilitate the movement toward this uniform prescription benefit card by taking action at the national level.

Allow for electronic transmission of prescriptions to pharmacies: The IOM report states that:

"Having physicians enter and transmit medication orders on line (computerized physician order entry) is a powerful method for preventing medication errors due to misinterpretation of hand-written orders."

"A host of common shortcuts in prescribing have frequently been found to cause errors. Abbreviations are major offenders because they can have more than one meaning. Putting such information in computerized order entry forms can eliminate such errors."

New technologies exist that allow the physician to send the prescription electronically to the pharmacy provider of the patient's choice. Electronic prescribing helps eliminate ambiguous abbreviations and specifies all elements needed for a complete order—drug name, dosage, directions, and route of administration—reducing the chance for medication-related errors. These technologies have been used in hospitals for years. For example, an October 1998 study in the Journal of the American Medical Association found that when electronic prescribing was used instead of "manual" prescription writing at a prestigious Massachusetts hospital, the medication error rate dropped by 55 percent.

Some electronic prescribing technology also allows the physician to have access to important medical and medication information about the patient. This information

helps the physician determine the best medication for the patient, as well as avoids potential adverse medication events, such as drug interactions, overdoses, and serious side effects.

Federal policymakers should identify ways to incorporate electronic prescription technologies into Federal health care programs. For example, these technologies could be used in the Medicaid and Federal Employees Health Benefits Program (FEHBP), which collectively provide over hundreds of millions of prescriptions each year. Moreover, any new Medicare prescription drug benefit program that is developed should encourage the use of this technology.

Recommendation 3. Provide incentives to states to modernize their pharmacy practice acts, such as allowing greater flexibility in the use of pharmacy technicians and other new technologies

Efficiencies and Technology Help Pharmacists Fill Prescriptions, Provide Patient Care Services: Efficiencies and technology in community retail pharmacy have allowed the pharmacist to spend less time in the administrative tasks of filling the prescription, and more time interacting and counseling the patient about the prescription. Technology can also help to reduce the potential human errors in filling a prescription.

However, a recent study conducted by Arthur Andersen[2] found that pharmacists still perform many tasks in filling the prescription that do not need to be performed by pharmacists. That is, pharmacists are spending over two-thirds of their time on such tasks as computer data entry; counting and packaging medications; resolving prescription insurance program disputes; and other clerical activities. These non-clinical tasks consume pharmacists' valuable time that could be better devoted to patient care activities. With the number of prescriptions expected to increase to 4 billion by 2004, the need for efficiencies in delivering pharmacy services only increases.

New technologies, such as automated dispensing systems, allow the pharmacist to become more efficient in preparing the prescription. Moreover, increased use of pharmacy technicians working under the pharmacist's supervision helps the pharmacist prepare the prescription for dispensing to the patient.

For various reasons, however, many state boards of pharmacy—which regulate the practice of the professions—have been slow to adopt some of these new technologies and efficiencies. Many states boards of pharmacy still expect pharmacists to spend much of their time on non-clinical functions. They often limit both the number of pharmacy technicians that can be on duty at one time, and their scope of their responsibility. This reduces the amount of time available to the pharmacist to manage and monitor the patient's medication therapy.

Enhance Use of Pharmacy Technicians and Technology: Policymakers should provide incentives to states to modernize their pharmacy practice act. For example, pharmacists should have the latitude to determine the nature and scope of the functions of pharmacy technicians working under their supervision. Moreover, pharmacies should be permitted to utilize new technologies, such as automated dispensing systems, that help in the preparation of the prescription.

CONCLUSION

Community retail pharmacy continues to do its part to help assure that prescription medications are used correctly, and the incidence of medication errors is reduced. There are other steps that policymakers can be taken to even further improve the use of medications in both the inpatient and outpatient setting. NACDS and community retail pharmacy looks forward to working with Federal and state policymakers on developing responsible and reasonable approaches to improving the use of medications.

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[2] "Pharmacy Activity Cost and Productivity Study" Arthur Andersen, November 1999.