MEDICAL ERRORS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

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CONTENTS

MEDICAL ERRORS

THURSDAY, FEBRUARY 10, 2000

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, D.C.

The Subcommittee met, pursuant to notice, at 9:40 a.m., in room 1310, Longworth House Office Building, Hon. Bill Thomas (Chairman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
February 3, 2000
No. HL–11

Contact: (202) 225–3943

Thomas Announces Hearing on Medical Errors

Congressman Bill Thomas (R–CA), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold a hearing on the prevalence and nature of medical errors in the health care system. Additionally, proposed strategies to ensure patient safety through the reduction of errors will be discussed. The hearing will take place on Thursday, February 10, 2000, in room 1310 Longworth House Office Building, beginning at 9:30 a.m.

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

Since Medicare's inception, a variety of measures have been utilized to help ensure the quality of medical care received by Medicare beneficiaries (e.g., Peer Review Organizations). Recently, the Institute of Medicine (IOM) released a report, *To Err is Human: Building a Safer Health System*, that has brought the issue of patient safety to the forefront of health policy discussion. This report cites studies that estimate the annual number of deaths resulting from medical errors in the United States to be at least 44,000, and possibly as high as 98,000. This number equates to the eighth leading cause of death in the nation and is more than the amounts attributed to auto accidents, cancer, or AIDS.

The statistical data included in the IOM study were derived from the hospital inpatient environment. As the country's largest insurer, Medicare Part A is the primary source of funding for services provided in these locations. Authors of the IOM study recommend several potential strategies for government, industry, consumers, and health providers to reduce medical errors. Additionally, the authors encourage Congress to create a national patient safety center to develop new tools and systems in order to address persistent problems.

In announcing the hearing, Chairman Thomas stated, "As Congress prepares to act on patient protection legislation, we must examine the problem of medical errors this year. After all, isn't the ultimate patient protection to prevent deaths from medical errors? Congress should not complete patients' rights legislation without examining potential solutions to prevent patients from dying due to medical errors. I look forward to this hearing to learn how Congress might develop solutions that will help protect seniors and all other patients in the health care system."

FOCUS OF THE HEARING:

The hearing will provide the opportunity to hear from the administration, advisory bodies, and providers on why medical errors occur and what possible solutions could be utilized to prevent them.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Any person or organization wishing to submit a written statement for the printed record of the hearing should submit six (6) single-spaced copies of their statement, along with an IBM compatible 3.5-inch diskette in WordPerfect or MS Word format, with their name, address, and hearing date noted on a label, by the close of business, Thursday, February 24, 2000, to A.L. Singleton, Chief of Staff, Committee on Ways and Means, U.S. House of Representatives, 1102 Longworth House Office Building, Washington, D.C. 20515. If those filing written statements wish to have their statements distributed to the press and interested public at the hearing, they may deliver 200 additional copies for this purpose to the Subcommittee on Health office, room 1136 Longworth House Office Building, by close of business the day before the hearing.

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All statements and any accompanying exhibits for printing must be submitted on an IBM compatible 3.5-inch diskette in WordPerfect or MS Word format, typed in single space and may not exceed a total of 10 pages including attachments. Witnesses are advised that the Committee will rely on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. A witness appearing at a public hearing, or submitting a statement for the record of a public hearing, or submitting written comments in response to a published request for comments by the Committee, must include on his statement or submission a list of all clients, persons, or organizations on whose behalf the witness appears.

4. A supplemental sheet must accompany each statement listing the name, company, address, telephone and fax numbers where the witness or the designated representative may be reached. This supplemental sheet will not be included in the printed record.

The above restrictions and limitations apply only to material being submitted for printing. Statements and exhibits or supplementary material submitted solely for distribution to the Members, the press and the public during the course of a public hearing may be submitted in other forms.

Note: All Committee advisories and news release are available on the World Wide Web at "http://waysandmeans.house.gov".

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202–225–1721 or 202–226–3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Chairman THOMAS. The subcommittee will come to order. I want to thank everyone and apologize in advance for the unusually small room. This is the committee hearing room for House Administration. I am chairman of that committee and we rarely see this many people. It went from the District of Columbia, where you had no one. House Administration at least filled some of the seats.

For centuries, healers have taken the Hippocratic oath, and we will hear this a number of times today. First, do no harm. Based upon the Institute of Medicine's report, not necessarily a significantly new report, but for some reason, either timing in a slow news cycle or the reaction or overreaction of some institutions to its presentation, it has become front-page news.

This committee, and I believe this chairman and the ranking member, are not always interested in being the first with a piece of legislation. The rush to legislation has begun in this particular area. I have always been an advocate of get it right rather than get it first. However, it seems to me in reading the report and in reading the testimony today, there are clearly some steps that can be taken of an organizational or structural nature that would create a more fertile field for the continued development of error correction structures or systems. To the degree that the patient protection conference continues to be delayed, there may very well be an opportunity to present in a measure that will move relatively rapidly through the system.

I was amazed to find that after I suggested this at the Hospital Association last week at their convention, that a member, not of this committee but a colleague of mine from California, suggested that dealing with procedures to reduce the number of patients killed would be a poison pill in the patient protection legislation, and I just find that ironic, because if there is anything fundamental to first do no harm, it is first do not kill. If there is something that can be done, I do not know why we do not move as expeditiously as possible.

This morning, I really want to have as clear an understanding as we can bring to the issue about what is being done to prevent errors, but more importantly, what we can do to prevent these mistakes, and a know a number of folks are going to tell us that there has been a flurry of activity in recent years, while at the same time I have heard criticisms of the IOM report that the data is old, it has been around a long time. If that is the case, then why was there not a flurry earlier? My assumption is it is because it got more news than it ever has before.

So in the course of this hearing, I hope we will learn why the current medical error reporting systems apparently are not working and what changes need to be made. Our objective, obviously, should be to make changes that result in more effective, accurate, and timely systems for reporting medical errors.

We are going to start with Dr. Christine Cassel, who will provide an overview, given her unique history on the Institute of Medicine's recommendations, and then we will hear from Ms. Linda Connell, who directs the Aviation Safety Reporting System at NASA and who, coincidentally, is a nurse and may be able to provide some cross-fertilization between what is usually used as an example of an extremely successful model, based on her experience and involvement in the other world.

We also want to learn about the characteristics of the internal reporting system used by the Veterans Health Administration, followed by witnesses that will describe other approaches that are currently being used or that should be put in place to correct medical errors.

I look forward to the session. As I said, our goal is to see if there are not some initial steps that can be made relatively briefly. I do not think we need to wait until we reinvent an entire national system, but I will be very sensitive to the statements made about what should not be done or cannot be done, because even if the number of accidental deaths is not 100,000, even if it is 50,000, even if it is 40,000, i.e., you pick the number, the current system is and will be unacceptable without fundamental and systematic change.

With that, I will yield to the gentleman from California for any opening remarks he might wish to make.

[The opening statement of Chairman Thomas follows:]

Opening Statement of Hon. William M. Thomas, a Representative in Congress from the State of California

For centuries, healers have taken the Hippocratic Oath to "first do no harm." Yet, it seems that patients have reason to question their safety as they participate in today's health care system.

Last November, the Institute of Medicine issued a report on patient safety and the staggering number of medical errors that occur in our nation's hospitals. As Congress prepares to act on patient protection legislation this year, I can think of no better reason to examine why these errors occur and how we can reduce the number of people who die from them. Some of my colleagues on the other side of the aisle have called this issue a "poison pill"in patients' rights legislation but, isn't reducing medical errors the ultimate patient protection?

This morning, I want to learn why people are suffering and dying from medical errors and what can be done to prevent these mistakes. We are not here to debate the number of errors, or the methods for calculating them. Even one death from a medical mistake is one too many. In the course of this hearing, we will learn why the current medical error reporting systems apparently are not working and what changes need to be made to prevent people from dying due to medical errors. Our objective should be to make changes that result in more effective, accurate, and timely systems for reporting medical errors.

We will start with Dr. Christine Cassel, who will provide an overview of the Institute of Medicine's recommendations. Then we will hear from Ms. Linda Connell, who directs the Aviation Safety Reporting System at NASA, which has been cited by many in the quality field as a model system for reporting medical errors. We also will learn about the characteristics of the internal reporting system used by the Veterans Health Administration, followed by witnesses who will describe possible approaches to drive down the number of medical errors. I look forward to an informative session that helps us understand how we can protect and improve the safety of the health care system for all patients.

Mr. STARK. Thank you, Mr. Chairman, for calling this hearing. As the Institute of Medicine report tells us, medical errors result in injury and death to thousands of patients each year and billions of dollars in wasted costs. It is time for the health care industry to catch up with the rest of the world in preventing errors.

Much information reported by the IOM, as you point out, has been known for some time. This recent report focuses our attention and helps us realize that it is time now to address the problem.

We find, for example, that the dialysis program is the MD–80 of the medical world. In 1997, we called for quality standards and HCFA is still working on the standards. That is three years. It is way past time for these standards to be implemented.

Some dialysis centers are needlessly killing people today, and we have the data to show it, and yet HCFA and other regulators were

not doing anything about it. So how many airplane crashes do we need to have in the medical delivery system before they wake up?

The quality of care has never been a priority in Medicare, Mr. Chairman, and it certainly is not a priority in any of the managed care plans outside of Medicare. I believe that it is time that we make it a priority, and improving quality and preventing errors ought not to be partisan. I doubt if it will be. We want to improve that, and I look forward to working with you on this issue and I hope we can act on it this year. Thank you.

Chairman THOMAS. Thank you. I would now ask Dr. Cassel and Ms. Connell to come forward. There are a number of medical professionals who are concerned about this, and I will tell you only that some of us may even have to apologize ahead of time in terms of our terminology, because we may use the vernacular in discussing what is going on, and if the reference is that people are dying and being killed, there may be some terms that are used which somehow insulate you. I know in the spy business they used to talk about it as termination.

It is, I think, partly necessary to confront the fact that what is happening in the system is that people are dying from medical errors. The argument that if they are being killed, there is some willfulness to it, is a concern I have because a willful refusal to change procedures when people are dying reaches a very interesting philosophical debate point about whether or not the system is killing people.

Mr. STARK. Mr. Chairman?

Chairman THOMAS. The gentleman from California.

Mr. STARK. By way of, I guess, apologizing for a harsh word, I would like to describe it in layman's terms. Going to the hospital, for example, is a dangerous trip. The difference in my mind, at least, is that if people are allergic, as I am, to penicillin, and if the person at the hospital asks me before I have an operation and I say, no, I am not, or I forget to tell them, or I am not wearing that little wrist bracelet, and I have a reaction, that is not the medical delivery system's fault; it is mine. Now, if I do not know whether I am allergic, that is different.

Also, if the medical system forgets to ask, that, to me, is negligent or wrong. That is something in the system that is wrong, and I think those kinds of errors could be fatal. We certainly should be able to eliminate the errors where they forget to ask. What we can do to educate the populus, I think that is beyond our ability, but I would like to draw that difference. Thank you.

Chairman THOMAS. I appreciate it. An educated consumer is a goal that all of us want because that would help significantly.

[The opening statement of Mr. Ramstad follows:]

Opening Statement of Hon. Rep. Jim Ramstad, a Representative in Congress from the State of Minnesota

Mr. Chairman, thank you for calling this important hearing today to discuss the issue of medical errors within our health care system.

Like all of my colleagues here, I was troubled to hear of the high number of medical errors that occur in our nation every year. The amazing and hard-working people who make up the health care industry in America—these people who have dedicated their lives to the health and welfare of those around them—are human and that means errors will happen. But the sheer numbers of errors is staggering.

I know every physician, nurse and health care provider at any level is ready and willing to help us combat the prevalence of errors in the system. That's why we do not seek to blame anyone for these errors at this hearing today, and why we need to carefully identify ways to reduce the number of errors and establish a system for analyzing the problems and learning how to prevent future mistakes.

I still believe the answers to these tragic issues lie within the health care industry itself, but I look forward to hearing the testimony of those coming before us today on how we can work together in an appropriate fashion to ensure errors and near-misses are reported, analyzed and prevented.

Mr. Chairman, thanks again for calling this critical hearing.

We have your written testimony, and without objection, it will be made a part of the record and you can address us in any way you see fit in the time you have available. Dr. Cassel?

STATEMENT OF CHRISTINE K. CASSEL, M.D., MEMBER, QUALITY OF HEALTH CARE IN AMERICA COMMITTEE, INSTITUTE OF MEDICINE, PROFESSOR AND CHAIRMAN, HENRY L. SCHWARTZ DEPARTMENT OF GERIATRICS AND ADULT DEVELOPMENT, MOUNT SINAI SCHOOL OF MEDICINE, NEW YORK, NEW YORK, AND DIRECTOR, GERIATRIC RESEARCH EDUCATION AND CLINICAL CENTER, VETERANS AFFAIRS MEDICAL CENTER, BRONX, NEW YORK

Dr. CASSEL. Thank you. Congressman Thomas, Congressman Stark, and members of the committee, I am pleased to be here with you today to address this important topic.

Chairman THOMAS. Dr. Cassel, let me tell you that although it is a pretty room, the acoustics are not real good and these microphones are very unidirectional. You need to speak directly into it. Thank you.

Dr. CASSEL. I am an internist and geriatrician and professor and Chairman of the Henry L. Schwartz Department of Geriatrics and Adult Development at the Mount Sinai School of Medicine and Director of the Geriatric Research Education and Clinical Center at the Bronx Veterans Affairs Medical Center. I tell you this because in my field of geriatric medicine, it is an area that is one of the highest risks for complications of medical care. Errors are a small part of those kinds of complications.

Today, I am pleased to be here representing the Institute of Medicine's Committee on the Quality of Health Care in America and our recently released report, "To Err is Human: Building a Safer Health System."

Our committee concluded that medical mistakes rank eighth among the leading causes of death, ahead of traffic accidents, breast cancer, and AIDS. The good news is, we strongly believe that it is possible to achieve at least—at least—a 50 percent reduction in errors over the next five years. The knowledge and technology exists to prevent many of these mistakes.

No physician or nurse wants to hurt patients, and doctors, nurses, and other health workers are highly trained to be careful and take precautions. They are held and they hold themselves to high standards. Paradoxically, it is precisely this exclusive focus on the individual as the source of mistakes that makes health care so unsafe.

Errors are seldom due to carelessness in the sense of lack of trying hard enough. More commonly, they are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them. They can be prevented by designing systems that make it hard for people to do something wrong and easy for them to do it right.

Safe industries, such as aviation, chemical manufacturing, and nuclear power learned this lesson a long time ago. While insisting on training and high standards of performance, they recognize that these alone are insufficient to ensure safety. They also pay attention to factors that affect performance, such as work hours, work conditions, information technology, team relationships, and the design of tasks so that errors are difficult to make. They create safety by design. Health care must do the same.

To address this serious issue, our report puts forth a comprehensive strategy for government, industry, consumers, and providers all to take action. The strategy calls for four major things.

One, the creation of a Center for Patient Safety within the Agency for Health Care Research and Quality to provide leadership, invest in research on medical errors, and build prototype systems to improve safety, and disseminate this information on best practices.

Two, establishment of mandatory and voluntary reporting systems. A nationwide, State-based mandatory reporting system is needed to collect information on the most serious errors that result in death or permanent harm and to use this information to better understand the factors that contribute to errors, to encourage health care organizations to take necessary steps to prevent future errors, and to keep the public informed about safety issues. Voluntary reporting systems focusing on errors that result in lesser or no harm, what the aviation industry calls near misses, should be encouraged by extending peer review protections to the data and information in these systems.

Third, strengthening the standards and expectations for improvements in safety that are set by accrediting and licensing organizations, group purchasers, and professional groups.

And fourth, creating safety systems inside health care organizations, including integrated health plans, hospitals, nursing homes, and outpatient facilities.

As you said, Mr. Chairman, the response to the IOM report has been phenomenal. This report received nearly saturation coverage in the national media. There were more than 100 live and taped appearances of committee members on local television and radio stations. In a recent survey conducted by the Kaiser Family Foundation, 51 percent of Americans closely followed the news of this release. Steady news coverage of this critical issue continues.

Since the release of this report, questions have been raised regarding the recommendation, especially regarding two of our recommendations, one pertaining to the Center for Patient Safety and the second pertaining to mandatory and voluntary reporting systems. I would like to focus a few more words of my testimony in these two areas, but I would be happy to answer your questions about any part of the report.

The Center for Patient Safety. Meeting this safety challenge, we feel, requires leadership and action at a national level. Attention

and resources are critical to making safety the number one priority of other health care industries. Unless something like the Center for Patient Safety is created to keep attention focused on these issues and to enhance the base of knowledge and tools, meaningful progress is going to be very difficult.

The Center for Patient Safety is not intended to be a regulatory or standard-setting body. It is expected to track progress and issue an annual report to the President and to Congress on patient safety and to enhance knowledge of safety by funding research into the application of safety sciences to health care and the development of prototype systems.

At present, there is no national visibility for this issue outside of this alarm in the recent press. There is no stimulus or encouragement for health care organizations to get better at implementing safe practices. We will not achieve safety unless we know what we are striving for. We, therefore, need to set national goals like the U.S. Preventive Services Task Force or Healthy People 2000.

The need for research is enormous. This is a new kind of research for the health care world to take on. The funding for this research has to be at a meaningful level in order to make a difference, and this is the agency that is responsible for our nation's health care quality information. It is an appropriate place to do that.

Let me say a couple more words about the reporting of errors. Our committee believes there should be both mandatory and voluntary reporting systems. We understand many of the problems that have been raised about mandatory reporting systems, but we believe that without some kind of mandatory system, we will not know the rate of errors and we will not know if we have improved them. We must also be responsible to the public in this sense. The mandatory reporting will give us this information, will make us responsible to the public, and as importantly, will require that all health care organizations make some level of investment in this important area which will create a level playing field for health care so that people who spend money on this will not be penalized.

The voluntary reporting is equally important, and I want to just say that these kinds of less-harmful errors are much more difficult to identify, and if we encourage voluntary systems, we can find ways like the aviation industry has to identify the so-called near misses and to improve our performance in the absence of harm to patients. These voluntary systems should be afforded legal protections from data discoverability in order to allow the free exchange of information within those systems.

In conclusion, let me just say that the core message from safety experts that our committee heard and that I believe you will hear today is to avoid a system that is punitive towards individuals. That will inhibit accurate reporting and it will not reduce errors. The key is creating an environment where teams can be creative about reducing errors, where they have the information to work with, and where the health care systems are accountable to the public. Thank you very much.

Chairman THOMAS. Thank you, Dr. Cassel.

[The prepared statement follows:]

Statement of Christine K. Cassel, M.D., Member, Quality of Health Care in America Committee Institute of Medicine, Professor and Chairman, Henry L. Schwartz Department of Geriatrics and Adult Development, Mount Sinai School of Medicine, New York, New York, and Director, Geriatric Research Education and Clinical Center, Veterans Affairs Medical Center, Bronx, New York

Good morning, Congressman Thomas and members of the Committee. My name is Christine K. Cassel. I am an internist and geriatrician, and Professor and Chairman of The Henry L. Schwartz Department of Geriatrics and Adult Development at The Mount Sinai School of Medicine in New York and Director of the Geriatric Research Education and Clinical Center at the Bronx Veterans Affairs Medical Center. I am here today 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.*

The IOM Committee on the Quality of Health Care in America concluded that medical mistakes rank eighth among the leading causes of death—ahead of traffic accidents, breast cancer, and AIDS. The good news is that we strongly believe that it is possible to achieve at least a 50 percent reduction in errors over the next five years. The knowledge and technology exists to prevent many of these mistakes.

No physician or nurse wants to hurt patients, and doctors, nurses, and other health workers are highly trained to be careful and take precautions to prevent mistakes. They are held and hold themselves to high standards. Paradoxically, it is precisely this exclusive focus on the individual as the source of mistakes that makes health care so unsafe.

Errors are seldom due to carelessness or lack of trying hard enough. More commonly, errors are caused by faulty systems, processes and conditions that lead people to make mistakes, or fail to prevent them. They can be prevented by designing systems that make it hard for people to do something wrong and easy to do it right. Safe industries, such as aviation, chemical manufacturing, and nuclear power, learned this lesson long ago. While insisting on training and high standards of performance, they recognize these are insufficient to insure safety. They also pay attention to factors that affect performance, such as work hours, work conditions, information technology, team relationships, and the design of tasks to make errors difficult to make. They create safety by design. Health care must do likewise.

To address this serious issue, our report puts forth a comprehensive strategy for government, industry, consumers, and providers all to take action. The strategy calls for:

- The creation of a Center for Patient Safety within the Agency for Healthcare Research and Quality to provide leadership, invest in applied research on medical errors, build prototype systems to improve safety, and disseminate information on "best practices" throughout the health care system.
- Establishment of mandatory and voluntary reporting systems. A nationwide, state-based mandatory reporting system is needed to collect information on the most serious errors that result in death or permanent harm, and to use this information to better understand the factors that contribute to errors, to encourage health care organizations to take the necessary steps to prevent future errors, and to keep the public informed of safety issues. Voluntary reporting systems, focusing on errors that result in lesser or no harm (what the aviation industry calls "near misses"), should be encouraged by extending peer review protections to data and information in these systems.
- Strengthening the standards and expectations for improvements in safety that are set by accrediting and licensing organizations, group purchasers, and professional groups.
- Creating safety systems inside health care organizations, including integrated health plans, hospitals, nursing homes and outpatient care facilities.

The response to the IOM report on errors has been phenomenal. The report received near saturation coverage in the national media, including front page and leading news coverage in most of the major national newspapers and television news programs. There were also more than 100 live and taped appearances of Committee members on local television and radio stations. In a recent survey conducted by the Kaiser Family Foundation and Harvard School of Public Health, it was found that *51% of Americans* closely followed news of the release of the report. Moreover, steady news coverage of this critical issue continues.

Since the release of the report, questions have been raised especially regarding the recommendations pertaining to the creation of a Center for Patient Safety and the mandatory and voluntary reporting systems. I would like to focus my testimony

on our Committee's thinking in these two areas, but I would be happy to answer questions about any part of the report.

Center for Patient Safety

Meeting the patient safety challenge will require leadership and actions at all levels, but *national* leadership, attention and resources are absolutely critical to making safety the #1 priority of every health care institution. Experience from other industries, such as aviation, suggests that unless a Center is created to keep attention focused on patient safety and enhance the base of knowledge and tools, meaningful progress is not likely.

The Center for Patient Safety is not intended to be a regulatory or standard-setting body, but it is expected to track progress and issue an annual report to the President and Congress on patient safety, and to enhance knowledge of safety by funding research into the application of safety sciences to health care and the development of prototype systems. The Center would also be responsible for dissemination of information on "best practices."

Goal-setting. At present, there is no national visibility for patient safety, and no stimulus or encouragement for health care organizations to implement safe practices. We cannot achieve safety unless we know what we are striving for. By setting national goals, much like the U.S. Preventive Services Task Force, or Healthy People 2000, the Center for Patient Safety can "raise the bar" for achievement by all organizations.

Research and development. While much is known from prior research and industrial experience about theories of error causation and prevention, relatively little is known about the application of those theories and methods in medical practice. Because principles of safety have been so sparsely used in health care, their usage needs to be studied in a number of applications (medication safety, surgical operations, new technologies, etc.) and in a variety of settings (e.g., emergency rooms, intensive care units, and doctors' offices). The Center for Patient Safety would set a research agenda and fund both intramural and extramural research projects to address those needs. The need is enormous. The funding should be at a meaningful level in order to make a difference.

For its development role, the Center for Patient Safety would lead and facilitate the application of known principles and research findings in the definition of best practices and processes. These would apply to both clinical care and management, and are needed for virtually all systems in health care organizations: medication systems, operating rooms, emergency departments, diagnostic testing, care of the elderly, etc. Some of these activities can, and should, be led by professional societies who can mobilize the expertise and commitment of their members. The Center would also develop methods for consumer education and be responsible for disseminating safety information widely.

The need to develop these research, education, dissemination, and facilitation activities is the principal reason for recommending that the Center for Patient Safety be lodged in the Agency for Healthcare Research and Quality. These functions are similar to those that the Agency has traditionally carried out over the past decade under its quality improvement agenda. It can easily provide both the leadership and the expertise needed by the Center for Patient Safety to establish new programs.

Evaluation. The Center for Patient Safety could also perform the valuable function of coordinating, collecting and analyzing data provided by both voluntary and mandatory reporting systems. It would monitor national progress in improving patient safety and provide an annual report to Congress, including recommendations to health care organizations and the various agencies and associations for improving patient safety. Part of this function might also be served by the newly established National Forum on Health Care Quality Measurement and Reporting.

Reporting of Errors

The IOM Committee also believes there should be mandatory and voluntary reporting systems. Mandatory reporting systems should focus on detection of errors that result in serious patient harm or death. While safety experts recognize that errors resulting in serious harm are the "tip of the iceberg," they represent the small subset of errors that signal major system breakdowns with grave consequences for patients.

Mandatory systems serve three purposes. First, they provide the public with a minimal level of protection by assuring that the most serious errors are reported and investigated and appropriate follow up action taken. Second, they provide an incentive to health care organizations to improve patient safety in order to avoid the potential penalties and public exposure. Third, they require all health care orga-

nizations to make some level of investment in patient safety, thus creating a more level playing field.

We recommended that a nationwide, state-based system of mandatory reporting be established that provides for the collection of standardized information about the most serious errors. Congress should provide funds and technical expertise for state governments to establish or adapt their current error reporting systems to collect the standardized information, analyze it and conduct follow-up action as needed with health care organizations.

The committee believes there is a serious problem of accountability for safety in health care and that current mechanisms for holding health care organizations accountable for safety are inadequate. We use the phrase "holding accountable" not as code for blame and punishment, but to mean insuring responsibility, i.e., making sure that health care organizations are doing everything they reasonably can for patient safety. If mandatory reporting systems are perceived as unfairly punitive, or embarrassing for the organization, compliance will be reluctant and incomplete. But, improvement cannot happen in the absence of reliable data. Reporting, alone, does not improve safety or reduce hazards. Unless reporting is followed by understanding and change, safety will not improve. Investigation of the circumstances surrounding incidents is required to determine the underlying causes. Improvements only occur if the analysis identifies systems failures and they are corrected. Success of the investigation and analysis depends in large measure on the degree to which individuals feel it is safe to participate. Systems that have been most successful in bringing about changes for safety combine mandatory reporting with some degree of confidentiality and protection of individual providers.

Although state governments would be responsible for the mandatory reporting program, this does not mean that a state would have to collect and analyze the data themselves. A state may choose to rely on an accrediting body, a peer review organization or other private sector oversight entity to perform this function. Twenty states already have mandatory error reporting systems. Since the release of our report, a number of others are exploring this option. Flexibility and innovation in implementation is important at this stage of development because states that have existing adverse event programs have used different approaches to implement their programs and a "best practice " or preferred approach is not yet known.

The IOM Committee believes that voluntary reporting systems play a valuable role in encouraging improvements in patient safety and are a complement to mandatory reporting systems. The focus of voluntary systems is usually on errors that resulted in no harm, or very minimal patient harm. Voluntary reporting systems are particularly useful for identifying types of errors that occur too infrequently for an individual health care organization to readily detect based on their own data, and patterns of errors that point to systemic issues affecting all health care organizations. The continued development of voluntary reporting systems should be encouraged, and voluntary reporting systems should be afforded legal protections from data discoverability. The core message from safety experts in other fields is to avoid a system that is punitive towards individuals—it will inhibit accurate reporting and won't reduce errors. The key is creating an environment where teams can be creative about reducing errors, where they have the information to work with, and where the health care systems are accountable to the public.

Thank you for this opportunity to testify. I would be happy to answer any questions the Committee may have.

Chairman THOMAS. Ms. Connell is the Aviation Safety Reporting System Director at the National Aeronautics and Space Administration Ames Research Center, Moffett Field, and, of course, the FAA and the reporting procedure associated with that is held up as a model. But something that some folks may not know, Ms. Connell is also a nurse, so that she has an opportunity to have a comparison of two different worlds, one in which many folk wear blue uniforms with epaulets and the other world in which they have a stethoscope around their neck and a white coat, one which has an open structure of reporting errors, the other one seems to have a degree of secrecy about the fact that errors even occur. Ms. Connell?

STATEMENT OF LINDA J. CONNELL, DIRECTOR, AVIATION SAFETY REPORTING SYSTEM, NATIONAL AERONAUTICS AND SPACE ADMINISTRATION, MOFFETT FIELD, CALIFORNIA

Ms. CONNELL. Mr. Chairman and members of the subcommittee, I thank you very much for the invitation to provide information to you on the Aviation Safety Reporting System, which I will call the ASRS from here on. This system in aviation is a voluntary, confidential, non-punitive safety reporting system that has been contributing to aviation safety since 1996. As the Director of the ASRS for NASA, I will attempt to highlight some of the aspects of this system that may be applicable to the current efforts in health care safety.

The ASRS is a highly successful and trusted program that has served the needs of the aviation community for 24 years. The ASRS was established as a result of a very tragic accident in 1974, not far from here, when TWA 514 collided with a Virginia mountaintop on approach to Dulles. It was discovered in the ensuing NTSB accident investigation that a United Airlines crew had very narrowly escaped the same fate only six weeks prior.

As a result, the NTSB provided a recommendation to the FAA and the ASRS began operation in 1976 under an agreement between the FAA and NASA. This cooperative safety program invites pilots, air traffic controllers, flight attendants, maintenance personnel, and others to voluntarily report to NASA any actual or potential hazard to safe aviation operations.

As the medical community begins to consider the value of reporting systems within their discipline, there are several constructs that are a part of ASRS which could be beneficial. The guiding principles of the ASRS are that it is voluntary, it is non-punitive, and it is confidential. It is voluntary in the sense that any person involved in the daily operations of the system can report to NASA by their choice and describe any event they determine to be important. Although the system solely excludes accident and criminal event reporting, it was decided that the system should not restrict or influence what the people wanted to say about safety or their experiences. This was an opportune decision and has helped to expand the insights into human performance.

The ASRS is considered non-punitive in that the reporters to the ASRS are guaranteed limited immunity by the FAA. The FAA will not use, nor will NASA provide, any information that has been filed with the ASRS in an enforcement action. The FAA will also waive fines and penalties for unintentional violations of any Federal Aviation regulation as long as those violations are reported within ten days to the ASRS and that all criteria written in an advisory circular are met.

All the reports submitted to the ASRS are held in strict confidence. More than 470,000 reports have been submitted since the beginning of the program without a single reporter's identity being revealed in those 24 years. Currently, the ASRS program is receiving approximately 36,000 reports annually.

I would like to point out that the ASRS is a unique safety information system. No other such system, voluntary or mandatory, offers and delivers the complete standard of confidentiality and subsequent anonymity provided by the ASRS program. The successful

longevity of this system and its continuing trust and strength arises almost solely from the proven ability to protect the identity.

It is important to remember that the ASRS is not an investigative system. There are two main purposes under the ASRS function. One is to identify any deficiencies or discrepancies in the system and alert the system. Two is to provide data for planning and safety improvement.

The ASRS has released numerous alert messages concerning potential hazards and important occurrences and they are paid attention to. We also hold biweekly telecons with the FAA in order to highlight any significant report information. These discussions involve information that is fully de-identified by the NASA expert analysts, who are retired airline pilots, air traffic controllers, mechanics, flight attendants.

The long-term purpose for the ASRS is met by the database, which provides de-identified reports that include an extensive narrative section which is a very complete description of the event. Due to the style of reporting and our ability to contact the reporters while processing their report, we are able to find out the "why" of the event, not just a terse description. Once this data is placed into the database, it is accessible to the public.

The ASRS has accomplished over 5,800 database searches for the government, students, research organizations, international organizations, aircraft manufacturers, as well as others not in our discipline, as in nuclear power. The FAA is the top requester of this ASRS information.

There are several factors that could be described as components for success. Briefly, some of these factors are the independence, perceived and actual independence, of the operating organization; the involvement of an advisory group representing the reporter community from the beginning; the availability of expert analysts for the report processing; continuous feedback of information to the reporter communities; and ongoing research utilizing this data.

It is noteworthy as people consider the application of the aviation model to medicine that the ASRS model has generally been accepted in international aviation systems. There are currently seven countries that have operating voluntary systems.

This concludes my remarks, and I would close in stating that we at the ASRS firmly believe that the collection of voluntary reports and the subsequent database provide the most authoritative source of human performance information that exists in aviation. I thank you.

Chairman THOMAS. Thank you very much.

[The prepared statement follows:]

Statement of Linda J. Connell, Director, Aviation Safety Reporting System, National Aeronautics and Space Administration, Moffett Field, California

Mr. Chairman and Members of the Subcommittee,

I am pleased to respond to your request for information on the Aviation Safety Reporting System (ASRS). The ASRS is a model for voluntary, confidential, non-punitive safety reporting that has been contributing to aviation safety since 1976. Some aspects of its applicability to the current efforts surrounding the improvement of healthcare have been addressed in the December 1999 Institute of Medicine report, "To Err is Human: Building a Safer Health System."

The ASRS is a highly successful and trusted program that has served the needs of the aviation community for 24 years. It is available to all participants in the National Aviation System who wish to report safety incidents and situations. The

ASRS was established in 1976 under an agreement between the Federal Aviation Administration (FAA) and the National Aeronautics and Space Administration (NASA). This cooperative safety program invites pilots, air traffic controllers, flight attendants, maintenance personnel, and others to voluntarily report to NASA any actual or potential hazard to safe aviation operations. The FAA, Office of System Safety, provides most of the program funding. NASA Ames Research Center administers the program, assures confidentiality, receives all reports submitted to the program, and sets policies in conjunction with the FAA and a fifteen member industry Advisory Committee.

The ASRS collects and responds to these voluntarily submitted incident reports to lessen the likelihood of aviation accidents. The ASRS data are used to identify aviation system deficiencies for correction by appropriate authorities, support aviation system policy, planning and improvements, and strengthen the foundation of aviation human factors safety research.

The ASRS reporters are protected when they report to this system. NASA and the FAA offer those who use the ASRS program two important reporting guarantees: confidentiality and limited immunity. These guarantees as expressed in Federal Aviation Regulation 14 CFR 91.25 and FAA Advisory Circular 00–46D are offered because this type of safety information is unique and its value can only be obtained as a result of the confidence and trust placed in the program by the reporters. The NASA preaddressed and postage-free form, NASA ARC 277A–D, is used by the aviation reporters to submit information. The reports sent to the ASRS are held in strict confidence. More than 470,000 reports have been submitted since the program's beginning without a single reporter's identity being revealed. The ASRS removes all personal names and other potentially identifying information before entering reports into its database. Currently, the ASRS program is receiving 36,000 reports annually.

The reporters to ASRS are guaranteed limited immunity by the FAA. This means that the FAA will not use, nor will NASA provide, information that has been filed with the ASRS in an enforcement action, and will waive fines and penalties for unintentional violations of Federal Aviation Regulations, as long as violations are reported within 10 days. However, accidents and criminal activities are not protected from enforcement actions, and should not be submitted to the ASRS. In addition to the immunity provisions associated with the ASRS program, reporters often mention other equally important motivations for using the program. The reporters feel increased satisfaction in knowing that they are helping to improve the aviation system by giving safety information to the ASRS and increased understanding of the factors contributing to their safety incident.

I would like to point out that the ASRS is a unique safety information system. No other such system, voluntary or mandatory, offers and delivers the complete standard of confidentiality and anonymity provided by the ASRS program. An indication of the importance of confidentiality is provided by the fact that over 70% of the reports in the ASRS database contain statements revealing human error information. It is not unusual for reporters to discuss their own operational mistakes, mistakes they won't tell others (like other government agencies or organizations), let alone the reasons why it happened. Confidential incident reporting provides an insight into events from the human perspective that can rarely be obtained through other methods.

The successful longevity of the ASRS and its continuing trust and strength arises from several factors. First and foremost is the promise of confidentiality which is further reinforced by the 24-year history of proven ability to protect the identity of a reporter. The next important factor is the program's independence, both actual and perceived. NASA, as the "honest broker" between the regulator and the reporter, has been a significant reason the ASRS is trusted and the reports received are honest appraisals of the reporter's performance and that of others in the aviation system. NASA is a research organization with no regulatory authority and, therefore, is perceived as a safe place to report sensitive, possibly self-incriminating, information. NASA's distinct position as an independent government agency with a strong influence on aviation safety policy and practice has been invaluable in instilling trust in the ASRS.

Another important factor is the creation of the ASRS Advisory Committee. This body has assisted the ASRS by providing substantial advocacy, guidance concerning ASRS policy, assurance to reporter communities of bona fide confidentiality, and support for safety change as a result of incident reports. This Advisory Committee has been very crucial from the initial steps of the creation of the ASRS and throughout its history. The Advisory Committee attempts to represent all potential reporter communities, as well as other industry organizations and government. Currently,

this group exists under the NASA Aero-Space Technology Advisory Committee as the ASRS Advisory Subcommittee.

The Advisory Committee has substantially assisted the ASRS in providing another crucial factor important for its success. The importance of feedback to the reporter communities cannot be underestimated. The ability of the ASRS program to convert the aviation community's report input into constructive output is evidenced by the many products produced by the ASRS (see Attachments A & B and <font size="2">http://asrs.arc.nasa.gov). The ASRS has released 2,500 alert messages concerning potential hazards and important occurrences. Approximately 42% of the alert addressee responses indicate that a follow-up action was taken as a result of the safety alert message. A monthly newsletter, CALLBACK, is distributed to over 88,000 recipients which captures and presents safety information from the incidents received by ASRS. The participation of ASRS at significant safety organizational meetings, conventions, and workshops continues to reinforce the participation by these communities. The reporters can see evidence that information provided is utilized for constructive changes to improve safety.

It is noteworthy as people consider the application of the aviation model to medicine that the ASRS model has generally been widely accepted in international aviation systems. There are currently seven countries that have operating voluntary, confidential incident reporting systems. These countries are United Kingdom, Australia, Canada, Russia, Taiwan, Korea, and the United States. Each country has preserved the concepts of voluntary and confidential as the necessary structure to accomplish the receipt of reports. Most countries have provisions for "use immunity" (i.e., prohibition from use in enforcement action), but none have "transactional immunity" (i.e., waiver of disciplinary action). But all countries are very aware of their survivability in relation to confidentiality. As an example to all systems, one country's first system was completely destroyed due to lack of reporting after a breach of a reporter's identity.

As part of the process to protect a reporter's identity, methods for de-identification of the report are crucial. The ASRS employs aviation experts as its report analysts. These people are, in fact, retired aviation professionals who analyze each report and maximize the pertinent safety information available within the report. This analysis process is performed by pilots, air traffic controllers, flight attendants, and mechanics who have each had lengthy careers in aviation. Our system (as opposed to one which has anonymous reporting) has the capability of calling incident reporters and obtaining additional information as well as discussing the safety event with the reporter. When these interactions occur, you have pilots talking to pilots and controllers talking to controllers, etc. This process produces an increase in the validity of the data. We are able to find out the "why" of the event, not just a terse description. The narrative section of the report record is quite complete in its description of the event, as well as the inclusion of key words and coding for retrieval from the electronic database.

The ASRS analysts, as well as providing their expertise and quality assurance, are able to reliably remove information that might identify a reporter. The ASRS places its highest priority on this protection. The goal is to remove enough information to protect the reporter and preserve the safety message from the actual words of the person reporting. This process of de-identification also relates to other topics of interest which include the public release of information and legal discovery. The ASRS database includes the data that has been determined to be most important. Due to limited resources, the ASRS performs a type of triage to determine which reports will be fully analyzed for inclusion in the database. Once this data is placed into the database it is accessible to the public through the ASRS Search Request process, an internet site managed by the FAA (*http://nasdac.faa.gov/safety—data*) or by a private CD–ROM product on the market. The ASRS has accomplished over 5,800 database searches for government agencies, students, research organizations, international organizations, aircraft manufacturers, etc. The FAA is the top requester of the ASRS information. Often, we are asked for information through the Freedom of Information Act (FOIA), but this is not needed, as NASA's ASRS database is openly available.

In relation to legal issues, incidents rarely give rise to the issues of negligence and liability inherent in more serious events, like accidents. The reports are rapidly de-identified, the narrative may be altered when analysts add additional clarifying language, and a report from one reporter (e.g., a Capt.) will be paired with other reports (e.g., a First Officer) describing the same event, etc. These policies and procedures subsequently alter the original report content to some extent. ASRS has been informed that due to this the database report becomes hearsay evidence due to its lack of an identifiable source, which appears to be of less interest in legal cases. The ASRS has been told that in some cases the database reports have been

used to defend a pilot, for example. Instead of the information being used against a person, it has been used to illustrate a potential system flaw that numerous humans have been victim to. Therefore, if the event's reporter does choose to share their experience with the ASRS, they are not faced with the added threat of complicating their own, or their employer's legal position. The de-identification process tends to drive out the fear of reporting.

It is important to note that the ASRS is *not* an investigative system. The information contained in reports is evaluated carefully by experts, but the confidentiality requirements of the system prevent us from obtaining third party verification. The information relating to the existence and character of the phenomenon is relayed to the appropriate organizations in a manner that permits and encourages them to investigate the safety issue further and seek a solution, or implement interim procedures to accommodate the phenomenon until a solution can be identified and instituted. We firmly believe that the ASRS incident database is the most authoritative source of human performance information that exists in aviation today. This program is a paradigm that can be utilized in many other disciplines.

Thank you for providing me with this opportunity to present information on the Aviation Safety Reporting System regarding our efforts and activities associated with improvements in safety. If the ASRS can be of any further assistance to the Subcommittee or its members, please feel free to call upon us at your convenience.

Mr. Chairman, Members of the Subcommittee, this concludes my testimony.

AVIATION SAFETY REPORTING SYSTEM SIGNIFICANT PROGRAM SAFETY PRODUCTS

The following is a listing of the variety of safety products that were accomplished by the NASA ASRS staff:

GENERAL ACCOMPLISHMENTS

- Since the implementation of the Aviation Safety Reporting System (ASRS) in 1976, over 474,000 reports have been submitted by pilots, mechanics, air traffic controllers, cabin attendants, and other aviation personnel.
- The ASRS is the largest repository of aviation human factors incidents in the world.
- The ASRS has an unblemished record of never breaching reporter confidentiality.
- The ASRS has accomplished over 5,800 database searches for government agencies, students, research organizations, international organizations, aircraft manufacturers, etc.
- Since 1976, the ASRS has issued over 2,500 safety alert messages in the form of Alert Bulletins & For Your Information Notices. Approximately, 42% of the addressee responses indicated that a follow-up action was taken as a result of the safety alert message.

OPERATIONAL IMPACTS

- Identified and alerted the FAA Office of Aviation Safety & the NTSB to the wake vortices caused by B757 aircraft. Consequently, the FAA issued a directive requiring increased separation behind B757 aircraft and the issuance of wake turbulence advisories. Identified and alerted the FAA Office of Aviation Safety & the Air Transport Association to the affects of passenger electronic devices on air carrier communication & navigation systems.
- Issued an ASRS Alert Bulletin to the aircraft manufacturer that concerned an L–1011 electrical fire. The manufacturer subsequently issued a Flight Operations Advisory Bulletin to all L–1011 operators.
- Issued an ASRS Alert Bulletin to the air traffic managers at Los Angeles Control Tower and the Southern California TRACON concerning close-in instrument approach changes. The FAA collaborated with various manufacturers to implement a flight management system (FMS) program modification that would promptly display transitions to newly assigned runways.
- Issued an ASRS For Your Information Notice concerning the airport lighting and general conditions of the Pickens County Airport, Jasper, GA. The local FAA Flight Standards office conducted an on-site inspection of the airport and issued a warning notice to the Pickens County Commissioner to take corrective actions within 30 days of the notice.
- Issued an ASRS For Your Information Notice to the Airport Manager of Mitchell International Airport, Milwaukee, WI concerning an unsafe runway incursion incident. The airport authorities subsequently completed a project to install flashing warning lights at key runway intersections.

• Issued an ASRS Alert Bulletin to FAA Headquarters concerning a smoldering passenger's bag in a DC–10 aircraft that was caused by animal-shaped butane cigarette lighters. The FAA subsequently issued a notice to airport security personnel on the toy-shaped lighters.

NTSB ACCIDENT SUPPORT

• A database search of Jetstream–31 aircraft failure incidents was forwarded to the NTSB in conjunction with the Jetstream–31 accident at Raleigh-Durham, NC.
• A database search of EMB–120 aircraft engine incidents was forwarded to the NTSB in conjunction with the EMB–120 accident near Carrollton, GA.
• A database search of Colombian airspace incidents were forwarded to the NTSB in conjunction with the B757 accident near Cali, Colombia.
• Accomplished a database search request for the NTSB in support of the investigation of the MD–11 accident near Halifax, Nova Scotia.

NASA/ASRS RESEARCH IMPACT: A PARTIAL LISTING

NASA/ASRS Research Product or Data	Year	Regulatory/Operational Effects	Cited In
Human Factors Associated with Runway Incursions, C.E. Billings, NASA TM 78540 (ASRS QR#8). An analysis of ASRS incident data.	1978	Used as resource in NTSB and FAA studies of runway transgressions; 1991 FAA study resulted in new procedures and improved runway/taxi marking systems.	• Runway Incursions at Controlled Airports in the United States, NTSB special Investigation Report, (NTSB.SIR–86/01).. • Runway Incursion Plan, DOT/FAA Associate Administrator for System Engineering and Development, ARD–100, January 1991.. • *Pilot Surface Incident Safety Study,* David R. Kelley and J. Glenn Steinbacher, MITRE, report prepared for DOT/FAA Office of Integrated Safety Analysis under the direction of the Associate Administrator for Aviation Safety (March 1993)..
Knowledge of the limitations of the ATC system in conflict avoidance capabilities, William P. Monan, NASA TM 81197.	1978		• *Altitude Deviation Study:gT1 A Descriptive Analysis of Pilot and Controller Incidents , MiTech, Inc. and Carlow Associates, DOT/FAA Research and Development Service, Final Report, October 1992*.
Distraction—A Human Factor in Air Carrier Hazard Events (ASRS QR#9)	1979	Provided data and motivation for FARs Part 121.542 and Part 135.100, "Flight Crewmember Duties" (";The Sterile Cockpit Rule").	• Federal Register, Notice of Proposed Rulemaking, Vol. 45, No. 169, August 28, 1980, p. 57684.. • Federal Register, Final Rule, Vol. 46, No. 12, January 19, 1981, p. 5500.. • Flight Safety Digest, "Accident and Incident Reports Show Importance of Sterile Cockpit Compliance," Vol. 13, No. 7, July 1994, 1–8..

NASA/ASRS RESEARCH IMPACT: A PARTIAL LISTING—Continued

NASA/ASRS Research Product or Data	Year	Regulatory/Operational Effects	Cited In
Probability Distributions of Altitude Deviations, R. Thomas and L. Rosenthal, NASA CR 166339.	1982	First in-depth study of the characteristics of altitude deviations in the ASRS database, including geometry and distribution of altitude deviations..	• *Altitude Deviation Study: A Descriptive Analysis of Pilot and Controller Incidents,* MiTech, Inc. and Carlow Associates, DOT/FAA Research and Development Service, Final Report, October 1992.
Non-Airborne Conflicts: The Causes and Effects of Runway Transgressions, Richard J. Tarrel, NASA CR 177372. An analysis of ASRS incident data.	1985	Used as resource in NTSB and FAA studies of runway transgressions; 1991 FAA study resulted in new procedures and improved runway/taxi marking systems.	• Runway Incursions at Controlled Airports in the United States, NTSB special Investigation Report, (NTSB.SIR–86/01).. • Runway Incursion Plan, DOT/FAA Associate Administrator for System Engineering and Development, ARD–100, January 1991.. • *Pilot Surface Incident Safety Study,* David R. Kelley and J. Glenn Steinbacher, MITRE, report prepared for DOT/FAA Office of Integrated Safety Analysis under the direction of the Associate Administrator for Aviation Safety (March 1993)..
Human Factors in Aviation Operations: The Hearback Problem, William P. Monan, NASA CR 177398	March 1986	Motivated 1986 change to FAA Air Traffic Control headbook order 7110.65) requiring comptrollers to ensure that pilot readbacks are correct. Also Introduced the term "hearback" to the aviation community (subsequently widely adopted);.	• FSF Accident Prevention Bulletin, Vol. 43, No. 10(3), October 1986, "The Hearback' Problem". • *Flight Safety Foundation Accident Prevention,* "My Own Mouth Shall Condemn Me, "Vol. 47, No. 6, June 1990..

Cockpit or Cabin Crew Coordination, Kim M. Cardosi and M. Stephen Huntley, Jr., DOT/FAA/FS–88/1, Final Report. Utilized ASRS data.	February 1988	• Motivated issuance of FAA Advisory Circular 120–48 (7/13/88), "Communication and Coordination Between Flight Crewmembers and Flight Attendants".	.
VFR Flight Near TCAs: Practices, Perceptions & Problems, R. Tarrel, et al (ASRS)	November 1989	Study performed at request of FAA Office of Aviation Safety; believed to have influenced moderation of FAA enforcement posture toward General Aviation pilots.	.
Human Factors of Flight-Deck Checklists: The Normal Checklist, Asaf Degani and Earl Wiener, NASA CR 177549. Findings based on ASRS data.	1990	Published as a mandatory requirement for all FAA inspectors that certify checklists (1995); more than 2,400 copies requested by operational community as the result of CALLBACK summary.	• Incorporated in FAA Advisory Circular 120–64.. • NASA/ASRS CALLBACK, No. 136–137 (Sept–Oct 1990).. • Aviation Daily, November 5, 1990, p. 241.. • USAir Airwaves, December 1990, 12–13.. • Journal of flight engineers (Varig), Vol. 17 (63), 1990.. All Nippon Airlines Journal, No. 149, 17–21, 1991.. • Journal of the United Nations Civil Aviation Organization, Vol. 46 (6), 18–21, 1991.. • Delta Airlines Safety Newsletter, Vol. 6 (1–2), 1991.. • Human Factors, Vol. 35, No. 2, June 1993, 345–359. <.

NASA/ASRS RESEARCH IMPACT: A PARTIAL LISTING—Continued

NASA/ASRS Research Product or Data	Year	Regulatory/Operational Effects	Cited In
"Eliminating Pilot-Caused Altitude Deviations: A Human Factors Approach," Robert L. Sumwalt, in *Proceedings of the Sixth International Symposium on Aviation Psychology,* The Ohio State University.	1991	Described genesis of USAir's Altitude Awareness Program and usefulness of ASRS data in this enterprise..	• "The Development of an Altitude Awareness Program: An Integrated Approach," Thomas M. Granada, Carlow Associates; Capt. Donald H. McClure, ALPA; Capt. James W. Fogarty, USAir, paper presented at the Human Factors Society Meeting, 1991.. • *Altitude Deviation Study: A Descriptive Analysis of Pilot and Controller Incidents , MiTech, Inc.* and Carlow Associates, DOT/FAA Research and Development Service, Final Report, October 1992.
The Use and Design of Flightcrew Checklists and Manuals, John W. Turner and M. Stephen Huntley, Jr., U.S. DOT Research and Special Programs Administration, Final Report. Findings based on ASRS data.	April 1991	Study was supported by six Part 121 and nine Part 135 carriers, and an ALPA survey. Contained recommendations for formatting and content of checklists and manuals, and use by flight crews..	.
"One Zero Ways to Bust an Altitude," Donald George, ASRS Directline. Review of ASRS data on altitude deviations.	Fall 1991	Distribution to an estimated 50,000+ pilots in US. and foreign operations.	• United Airlines excerpted portions of article and distributed to all of its 9,000 pilots in a United Airlines Flight Safety Brief. UAL also reproduced a graphic from the article and made it into a poster for company-wide distribution.. • Article reprinted by TWA, USAir, New Zealand Air, GATCO, Commercial Aviation Safety (UK), and Focus on Commercial Aviation..

"Air Carrier Ground Deicing/Anti-Icing Problems," Robert L. Sumwalt, in *Proceedings of the Seventh International Symposium on Aviation Psychology,* The Ohio State University. Review of ASRS data on ground deicing operations. The author summarized the results of this research in personal correspondence to the FAA in April 1993, in response to Docket No. 26930 (interim NPRM).	April 1993	FAA Advisory Circular 120–60 (5/19/94) contained a provision recommended by the ASRS study and its author requiring an outside-the-aircraft check for icing contamination..	• "Aircraft Ground Deicing Problems: Recommendations from Analysis of ASRS Incident Data," SAE Ground Deicing Conference Transcription of Proceedings, June 15–17, 1993, Salt Lake City, Utah.. • "Incident Reports Highlight Problems Involving Air Carrier Ground Deicing/Anti-icing," Robert L. Sumwalt, FSF Airport Operations, Vol. 19, No. 5, September/October 1993..
A Review and Discussion of Flight Management System Incidents Reported to the Aviation Safety Reporting System, Donald Eldredge, Susan Mangold, and Robert Dodd, U.S. DOT/FAA Research and Development Service. Analysis of ASRS FMA-related database reports	February 1992	Frequently requested by air carrier and aviation industry organizations.	
On the Typography of Flight Deck Documentation, Asaf Degani, NASA CR 177605	December 1992	Published as a mandatory requirement for all FAA inspectors that certify checklists (1995); more than 800 copies requested by operational community as the result of CALLBACK summary.	• Incorporated in FAA Advisory Circular 120–64.. • Human Performance Considerations in the Use and Design of Aircraft Checklists. Federal Aviation Administration, Office of Safety Services-Safety Analysis Division, 1995.. • NASA/ASRS CALLBACK, No. 168 (May 1993)..

NASA/ASRS RESEARCH IMPACT: A PARTIAL LISTING—Continued

NASA/ASRS Research Product or Data	Year	Regulatory/Operational Effects	Cited In
On the Design of Flight Deck Procedures, Asaf Degani and Earl Wiener, NASA CR 177642. Findings based on ASRS data.	June 1994	Published as a mandatory requirement for all FAA inspectors that certify checklists (1995); 200 copies requested from NASA as the result of CALLBACK summary.	• Incorporated in FAA Advisory Circular 120–64.. • *Human Performance Considerations in the Use and Design of Aircraft Checklists.* Federal Aviation Administration, Office of Safety Services-Safety Analysis Division, 1995.. • NASA/ASRS CALLBACK, No. 184 (Sept 1994)..

Chairman THOMAS. We have a vote on now and we are running short of time, given the distance from the floor that this hearing room is, so I would ask for our witnesses to allow us to recess and I would like to reconvene at 10:25.

[Recess.]

Chairman THOMAS. I want to thank you both for your testimony. During the debate on patient protection, which has passed both houses and is now in conference, there was a common reference to a movie, I think it was "As Good As It Gets," and the throw-off lines about HMOs. It was obviously art and a work of fiction, but somehow, it was representative of the truth.

I was struck by another movie called "Malice" in which Alec Baldwin plays a surgeon and there is a discussion going on in which there was great concern about the question of life hanging in the balance and the comment was that, well, they had better pray to God, and Alec Baldwin said that they had better pray to me because I am God.

Now, that was as much a fictional script as "As Good As It Gets," but I think it also focuses, as art often does, in a non-statistical way, on a general belief that, to a certain extent, one of the reasons there has been some great difficulty in getting the kind of error structure in place in the medical community is because of that type of an attitude. Is there any truth, any relevance to that? Is there any indication that the argument is that, after all, medicine is primarily an art and great artists have to be left alone so that they can do the best they can in a difficult environment?

Dr. CASSEL. Well, there is—I do not know so much about the art component. I think medicine is a skill and it deals with uncertainty and it deals with science and technology. It also deals with human beings, as we were talking about earlier.

Chairman THOMAS. I believe all of those are true in the aviation industry.

Dr. CASSEL. That is right.

Chairman THOMAS. Would you say, Ms. Connell, that that is probably a good profile of some fairly egotistical pilots who think they are really good at what they do?

Ms. CONNELL. They are highly trained and highly skilled.

Chairman THOMAS. Yes.

[Laughter.]

Ms. CASSEL. But, Mr. Thomas, I think it is also true that the culture of medicine has held physicians and nurses accountable as individuals for getting it right all the time. It has not been so much a systems approach. One specialty——

Chairman THOMAS. So if you do not get it right, do not talk about it?

Ms. CASSEL.—it is your fault. Do not talk about it, because it is your fault, and do it better next time. One specialty has begun to address this with remarkable success, and that is anesthesiology, which has recognized the high-risk environment in which they work and has begun actually to take some lessons from aviation to look at team interaction, to look at identifying——

Chairman THOMAS. Is there not a real world result, and that is the——

Ms. CASSEL. And there is a real world result.

Chairman THOMAS.—the insurance costs for that specialty have dropped dramatically because of the structure.

Ms. CASSEL. Dramatically, right. So it can be done.

Chairman THOMAS. Now, I understand there was some complaint or difficulty about that because what they really did was try to do a look-back dealing with history in trying to shape where they go forward. That may be difficult, but obviously, it is not impossible.

Ms. CASSEL. That is right.

Chairman THOMAS. And by stating that it is there does not mean other specialties could not adopt exactly the same procedure?

Ms. CASSEL. Probably not exactly the same procedure, because——

Chairman THOMAS. Roughly?

Ms. CASSEL.—other specialties operate in a different context. For example, my specialty, geriatric medicine, is not in the operating room. We are in the community. We are in nursing homes. But the same principles of being willing to sit down with your colleagues and talk about potential mistakes and how to prevent them can be applied just as well.

Chairman THOMAS. Ms. Connell, obviously, the statement that I made that you had an organization that is always used as an example of how to do it right, but you also have been historically involved in the medical community. Based upon your knowledge, is there no transferability, is there modest transferability, or is there significant transferability in what you have been doing in aviation to a medical model?

Ms. CONNELL. My experience in medicine basically finished in 1986 and I have been inactive since that time. But when I became involved in the ASRS, I just intuitively saw ways in which this kind of information could transfer into medicine. I think it could significantly contribute to information systems that can help health care look at the human factor component.

Chairman THOMAS. Dr. Cassel, you indicated in your opening statement and kind of emphasized that you think you can have at least a 50 percent reduction over five years, but in the report, there was an allusion to what occurred in the aviation industry, that, in fact, since the middle of the century, it has been reduced by more than a third. That is a 40-year period.

Are we in danger of creating a self-fulfilling failure if we are talking about we are going to get a culture structure reculturalized as well as a reporting system in place and do it so that you can reduce them by 50 percent, or is the opposite true, things are so sloppy and so disorganized with no structure whatsoever that any structure at all could produce a 50 percent reduction in five years?

Dr. CASSEL. Well, it is not so much that the situation is as bad as you describe, but there is some very low-hanging fruit in this area. There are some things that could be done fairly easily that could achieve quite dramatic reductions in errors.

Chairman THOMAS. Then why have they not been done?

Dr. CASSEL. In part, they have not been done because the goals have not been so clearly articulated and because the resources have

not been there, and let me give you an example. Medication is a place where a lot of error occurs. As Mr. Stark said——

Chairman THOMAS. Do we have any ability to quantify that, what percentage of the deaths occur from the medicine side versus operating room, for example?

Dr. CASSEL. There are hundreds of studies looking at error rates, and particularly problems with medications, and they come up with different numbers and some of our extrapolations used in the report come from those studies.

Chairman THOMAS. My concern is I do not necessarily want to quantify to simply look at a number and then compare where the greatest failure is, but it seems to me that if we are going to try to put some structure in place, you would kind of like to go to where, as you say, the low-hanging fruit orchard is.

Dr. CASSEL. Let me tell you a story. Last week, I was a consultant to a major academic health center in the country that wanted to do something. It was a senior management retreat. They wanted to do something about this errors issue. And their debate in looking at the medication issue was, should we think about in the current competitive environment spending huge amounts of money on big new information systems, or should we simply put a pharmacist on rounds with the medical team every morning, because that has been shown to be very effective, as well.

Now, those are the kinds of discussions that I think we ought to be encouraging people to have, and we quite frankly, I think, need to try out both models. It is very clear that computerized order entry helps this problem, but it is also very clear that those are huge expenditures in the current environment and the same improvement can be achieved other ways.

Chairman THOMAS. I will tell you, it is kind of frightening to read some of the stories that we are beginning to focus on. You will recall the number of infant deaths because of the failure to keep household cleaning items away from children and where you place them on the shelves and keeping latches closed, and it sounds like hospitals are just now discovering that concentrated potassium chloride kept at a lower shelf level will result in deaths.

This seems incredible, based upon all of the other safety discussions in the home, in the workplace. I mean, you go to any area that requires you to wear a hard hat and there is a sign on the wall that proudly says, we have had no accidents for X number of days. Now, the problem is, in hospitals today, it would be we have a sign that says, we are proud to say there have been no deaths for X number of hours, but they do not talk about that in terms of a culture of trying to get it right.

Dr. CASSEL. The potassium chloride issue has now been widely addressed because it was so obvious and such a quick fix, if you will, that made a lot of sense, similar to things that the anesthesiologists learned when they looked at their practices.

One of the differences here is the liability environment and the fact that a hospital internally may decide to do some of these things, but they are sure not going to write articles about it for the popular press and say, look what we accomplished by reducing these errors because of that liability environment.

I just want to say that that is a very complex area that our committee recognized we did not have the capability to address, but I think that should be another major step that we address——

Chairman THOMAS. Well, my concern is I do not think the liability is all that difficult. I think we may get into a discussion in terms of mandatory versus voluntary scope of information circulation, but Ms. Connell, do you not think that that was absolutely critical to the success of your structure, that whole ability to depersonalize the information and create an environment in which people had a comfort level that when they reported it, and I imagine at the beginning, it was fairly difficult. It is a chicken and an egg. How do you do it?

Ms. CONNELL. I do not see large disparities over what I am hearing and what I know of the history of the ASRS. The extensive history is published in a NASA publication, and you can read in here some of the dilemmas that were being considered at that point in time, and one of them is this legal liability issue and how to get beyond it. The other is how do you encourage people to report and take the chance kind of thing. Even with the promises, how will they know?

And one of the strategies used by the founders, Dr. Billings, Dr. Renard, Cheney, and Harding, is that they involve the trusted individuals in the industry, so they are union heads and representatives, they are pilot organizations, they are traffic organizations, flight attendant organizations, that went to their communities and said, we have looked at this thoroughly and in depth and we bona fide it as a system that will work. We have great promise for it. We would encourage you to support it by submitting. And if you have any difficulty with the program, I am the person you can talk to.

Chairman THOMAS. Just a couple of examples and then I will yield to my colleague. Everybody is familiar with a pilot and copilot getting ready, say, to take off, and notwithstanding the fact that they have spent thousands of hours in that seat and perhaps hundreds and even thousands of hours in that particular aircraft, they have a checklist and they go down the checklist systematically on items that you would think were old hat to them, and, in fact, they are, but they go down in a systematic way.

That seems to me something that could be carried to a number of areas in which you think you are following a procedure, but perhaps it is not as structured. Let me give you a more controversial example.

I am quite sure that the question of installing a device which would monitor not only all of the telemetry in the aircraft but the actual voices of the pilots in a stress situation was not universally accepted. Nevertheless, one of the more dramatic aspects of this amazingly public effort to find out what went wrong was recovering the black box and analyzing what occurred.

Could you not talk about an analogous situation of having a black box in the operating room which would collect all of the telemetry and perhaps video cameras, so that instead of trying to recreate an event from hearsay or third-party testimony after the fact, you would have a medical black box that you could examine to determine exactly what happened. But most importantly, you

would have a graphic teaching tool to show firsthand what you do not do. Is that an idea that might be transferrable to medicine?

Ms. CONNELL. It is difficult for me to say. The black boxes—

Chairman THOMAS. I am going to ask Dr. Cassel in just a minute, so——

Ms. CONNELL. Okay. Accident investigation with the NTSB is a very intensive and in-depth investigation, and I am just not familiar with what depth investigations occur on the medical side and whether that is a cost that would provide a large benefit. That is something they would have to assess. But in aviation, it was resisted and it was resisted by the pilots who are sitting up front, having every word recorded and every change in throttles recorded.

But they did adopt it eventually as the accident prevention mentality. In other words, if we do, you know, have an accident and we do not survive, at least someone will know what has happened and we can prevent the next one. So it was an altruistic professional kind of argument that basically won over the day. It has still and is still remains a controversial issue in aviation in terms of it getting in public hands and getting outside of the walls of the accident investigation.

Chairman THOMAS. Dr. Cassel, I know that as well as being on the IOM, you are professor and Chairman at Mount Sinai Medical Center in terms of a well-respected teaching hospital. As I mentioned to you earlier, there were indications that doctors were not as adequately trained in a bedside manner in terms of the way in which they addressed patients, and there was some discussion of changing the curriculum to make sure that they were a bit more responsive in their communications.

Has there been any change in the teaching curriculum about the Alec Baldwin syndrome and that there needs to be a commitment in an altruistic and a professional way to let people know what happened when errors are being made, or is there still this cult of secrecy developed and promoted in these teaching hospitals?

Dr. CASSEL. There have been a number of changes in medical curriculum to try to teach the students to interact on a whole range of scales in a better way with the patients, and as importantly, with the other members of the team, and that is part of what we have learned from these lessons from the aviation industry.

There are probably specific environments, such as trauma units or operating rooms, where models like the black box might be useful, but in general, I think they are more useful for teaching purposes. We, for example, have some experience at Mount Sinai in using videos of medical students and residents interviewing patients and then talking with their colleagues about the management of the case, and then we do sort of a post-mortem on that interaction. We say, well, look how you were putting down that nurse and that nurse could not tell you what really needed to be said about that patient.

So that kind of sort of an autopsy of the behavior, if you will, and taking it apart and having the faculty, the teachers, examine that with the students can really help. I have seen some very helpful videos of cockpit interactions when I was Chairman of the American Board of Internal Medicine saying doctors could learn a lot

from how they sort of break down and examine the hierarchial behaviors in those settings.

Chairman THOMAS. I am just slightly concerned about your use of terms, post-mortem and autopsy in those situations.

Dr. CASSEL. I am sorry.

[Laughter.]

Chairman THOMAS. The gentleman from California.

Mr. STARK. Thank you, Mr. Chairman.

Dr. Cassel, Ms. Connell, thank you for your testimony. I wanted to ask you, Dr. Cassel, in the IOM report, there is discussion about a national center to fund research and conduct analysis of the data, and I do not find any mention of a plan or a suggestion that we require hospitals to take action. We in Congress are now talking about education. We are forcing schools and principals to have a plan of action to improve the results of training kids.

Ought we not to require, not just suggest, I think, a hospital to have a plan? The plan might be more intensive or less intensive, depending on the hospital's record, of how they are going to reduce errors and have targets to achieve that. Should we not, as part of that plan, include investigations where there is a serious or fatal accident to find out why the accident happened and add corrective measures to the plan and then follow up to make sure the corrective actions are taken?

In other words, without the question of mandatory or voluntary reporting, ought there not to be some kind of required system? If hospitals already write up errors and get A-pluses, obviously, it would not be as much of a burden. If a hospital is way behind the curve, it might be more of a burden. Could you discuss how you think that would work and would it be helpful?

Dr. CASSEL. I think it would be very helpful. I would just also want to add that whatever we are thinking about for hospitals, we should also be thinking about for nursing homes——

Mr. STARK. Okay.

Dr. CASSEL.—another very high-risk environment that actually has more beds in the United States than hospitals do any given day.

Mr. STARK. I will lump them all together, as well.

Dr. CASSEL. Secondly, I think what you are describing is not what we envision as being a function of the Agency for Health Care Quality, which is to support research and setting some goals for the nation, but, in fact, could be done by any number of means. Some of the accreditation processes that are currently in place, perhaps Medicare standards and expectations.

But the most important thing about requiring institutions to document their approaches to improving the rate of errors, or not the rate of errors, but the occurrence of errors and to learning from those is that there be a level playing field, that this not be something that is held against the system. The example you are going to hear later about the Department of Veterans Affairs, that there was a front page article in the New York Times that the VA has more errors than any other system, well, it is because they are doing a better job of reporting.

Mr. STARK. Right.

Dr. CASSEL. But the public does not understand that, and so we need to make sure that the playing field is level if we are going to require all of the institutions to do the same thing.

Mr. STARK. Or universal? Would you say——

Dr. CASSEL. Yes, even that. That is right.

Mr. STARK. Why has the industry not done it up until now?

Dr. CASSEL. Well, that is——

Mr. STARK. The hospital and nursing home. Why——

Dr. CASSEL. Why has the hospital industry not?

Mr. STARK. Yes.

Dr. CASSEL. I think the answer to that is a very complex one and it is analyzed in some detail in our report. It has to do in part, as Mr. Thomas suggested, with the culture of medicine and the emphasis on the individual. I believe that the liability environment is a big, big piece of this, and I also believe that the competitive marketplace in which no hospital wants to go public saying, we are doing our best to prevent errors, that is not a big selling point in the marketplace. So until we require everybody to do the same thing, it is not going to happen.

Mr. STARK. Let us switch to your profession. Several years ago, many years ago, it was suggested that we require physicians to recertify, be tested, say, every seven years. Now, most of the specialty groups do require that. The AMA came off the wall and said, oh, my God, you cannot do that. We will do it voluntarily. Well, you know what voluntarily means.

We require pilots to be tested. We require lawyers to be tested. We require real estate brokers to be tested. Cops have to go out and shoot their guns every so often. We in Congress are tested, good point.

[Laughter.]

Mr. STARK. Is there anything so awful about suggesting that a physician, because of the rapid change in technology, ought to go back periodically and be recertified? Would that help?

Dr. CASSEL. We did not address this in detail in the report, but I will tell you my personal opinion is not only is there not something so awful about it, I think it is essential for our health care to be accountable to the public, as you point out, in this current environment of rapidly advancing science and also requiring physicians to know something about the systems that they work in and how to improve those systems.

Certification boards do now require episodic recertification, but having just finished a year as chairman of one of those boards, I can tell you that we did not feel that a sit-down paper and pencil test every seven to ten years is really enough, either. We need more performance measures. We need what—the aviation industry does it every six months, I believe, in simulators. We need much more practice performance evaluation in addition to cognitive knowledge.

Mr. STARK. One quick question, Ms. Connell.

Ms. CONNELL. Yes.

Mr. STARK. The VA system has a voluntary reporting system that permits employees and patients to report occurrences and protects them. Should any error reporting system permit confidential

reporting by employees and patients or anybody else without fear of action being taken against them?

Ms. CONNELL. I am not sure I could answer that question without knowing deeply the VA system.

Mr. STARK. You have it in your system? Do you have a confidential reporting system——

Ms. CONNELL. Ours is a confidential reporting system at the national level.

Mr. STARK. And there is no fear of action being taken against somebody who reports, right?

Ms. CONNELL. Not now. We have proven over 24 years that that is impossible with the structure the way it is.

Mr. STARK. So you say that is important to your structure?

Ms. CONNELL. It has been important in keeping the flow of information increasing and continuing.

Mr. STARK. Thank you.

Chairman THOMAS. I thank the gentleman. We may need to do two rounds, so we will try to maintain the clock as we move through, not withstanding the chairman's unwillingness.

Does the gentlewoman from Connecticut wish to inquire?

Mrs. JOHNSON. Thank you, Mr. Chairman, and my apologies to some of the later speakers. I have to chair a hearing at 11:00, so I will not be able to stay through the whole hearing.

I was very interested, Dr. Cassel, in your comment that errors are seldom due to carelessness or lack of trying hard enough and that, in fact, what we are looking for is safety by design. I think that is very, very important. I represent a manufacturing part of the country. I have seen what has happened as a result of system change, first through total quality management and then due to this ISO 9000. I had one of my hospitals say to me recently, why are you doing this? Do you not understand, we are going through ISO 9000. We have to because GE wants every one of its contractors to be ISO 9000 and we take care of GM employees. I did not know that.

So there are a lot of systems changes going on institutionally, and for us to adopt a mandatory reporting system, and I have never seen one that does not get to be punitive and does not, especially on top of malpractice and competition, foster as much cover-up as is possible.

I think we have an enormous opportunity here to use the certifiers, the system, the office to help gain an understanding of what systems do improve safety, which has been something we have not been willing to look at and have not put the resources in, and then there are many ways in which we can get them to design it. The thing I hear most often in my hospitals is, do you understand that we have to reimburse for this drug, not because you require it but because it is the state of medical practice and we have to do it, and when is Medicare going to notice that we have to do this and up their reimbursements.

So I worry about the emphasis on mandatoriness when there is so much we have not done, and I think this issue of reporters being absolutely free to just talk about something they saw—I saw a hospital go from individual insurance to the institutional self-insur-

ance and then physicians did say, I do not think the way you are dealing with that case is really so hot.

So I think we have an enormous opportunity here, but I think the confidentiality is terribly important. Someplace to report is very important, an office. How do we get visible some of the systems demands that, frankly, are being made in every other sector of the economy for quality, and safety is just a part of quality, but remember, OSHA made this mistake. OSHA came in—the original OSHA law was X, Y, Z. When it began to work was when we got OSHA consultation and without danger, you could get an OSHA person to come into your workplace and say, what are the problems here, and they were not allowed to come back and penalize you if you changed it within six months.

So there is just such an enormous void here and the systems are so lacking because so many of our laws discouraged system views, and these are not bad people and we are never going to wipe out all mistakes. So I do not want—we found this out when we reported death rates in hospitals, and I had a VA hospital in my district and the director had the good sense to come to every one of the members of the Congressional delegation and make an appointment and sit down and say, I am going to provide services to very disturbed veterans and we are going to have problems. He said, the reason we do not have problems now is nobody will take care of them. So he opened his doors to the most severely distressed soldiers with very serious psychiatric problems and so on. Yes, he had a couple of batteries. Over the years, he had a couple of hangings and those kinds of things. But, boy, the lives he saved, the stories he can tell.

I will be interested to look at your report and see more clearly where you want mandatory reporting and why, but there is just such a wide-open opportunity here for rapid improvement if we are able to integrate systems and approaches and spread the knowledge of them, and I worry about that.

Dr. CASSEL. I very much agree with your concerns and I would really welcome your input on this process. The committee spent a lot of time examining this issue and it is very aware of the potential for mandatory reporting having a negative effect, a silencing effect, if you will, and that is why we keep emphasizing this level playing field aspect of it.

But we already have more than 20 States that have some form of mandatory reporting. There is experiments, if you will, out there at the State level that the Agency for Health Care Quality could, in fact, look at, see what seems to be working, what does not seem to be working, and follow that, and that is another reason why we call for this at the State level rather than in some uniform Federal way and then to learn from those individual experiences.

The last thing in the world that you want is for a health care institution not to take care of the high-risk people, not to engage in a trauma unit because they are afraid that they are going to get in trouble for doing that.

Mrs. JOHNSON. Right. I thank you and I thank the chairman for inviting you and also you, Ms. Connell, from the aviation system, because your system is very, very interesting and I always sort of wondered, how is it that we are able to have quite as safe an air

traffic system as we do, a remarkable record, when people are people and errors happen, so thank you for your good work.

Ms. CONNELL. Thank you.

Mrs. JOHNSON. Thanks, Mr. Chairman.

Chairman THOMAS. I thank the gentlewoman.

Does the gentleman from Washington wish to inquire?

Mr. MCDERMOTT. Thank you, Mr. Chairman. Sitting here thinking about having practiced medicine, it seems to me that the issue we are discussing here has really two parts. One is, what do you do about the individual who has had a medical error occur in their treatment, and then what do you do about the system?

I think that it is important for us in trying to fashion any kind of government response to that that we keep those clearly in mind, because my remembrance of the AMA responsibility for a doctor, I mean, it is that a doctor is required to be honest with his patient in spite of the fact that there may be, in fact, a legal responsibility or a liability may come out of it. Is that correct?

Mr. MCDERMOTT. I believe that is part of the code of ethics.

Mr. MCDERMOTT. Yes, it is, Section 8.12. I just want to get it in the record, that a doctor does not have the luxury of not telling a patient just because he is afraid of a lawsuit, and that is a responsibility that he or she has to deal with.

[The information was not received at the time of printing.]

Dr. CASSEL. And that gets at another response to Congressman Johnson's question of why did we make this recommendation for mandatory reporting, understanding all of the challenges inherent in that, but that there is fundamentally this responsibility to the public which we felt was the overriding concern.

Chairman THOMAS. Would the gentleman yield on that point, since you are a practitioner and you are discussing this as two doctors and those of us who are watching, do you believe that, notwithstanding whatever number point subsection that is, that it is, in fact, working, that people do follow it?

Mr. MCDERMOTT. I have no way of telling. I suspect that it goes on a lot more than we know because I suspect that in most cases where there is not a lawsuit brought, it is because the physician said to the patient, we made a mistake here. We did this, we did that, and we are going to correct it. Then the patient does not have to go to the legal system to get it corrected. So I do not know how you would—it would be very hard to say what the statistics are. I am sure there are physicians who do not tell.

Chairman THOMAS. I am sorry to interrupt, but my biggest concern is that I know we are going to hear from folk that, you know, we are professionals. We are on top of it. We have written statements. We have rules. Did you not have those five years ago and ten years ago and do you not have them today, and here this report comes out. My concern is that if we do not really look at it systematically this time, we may not get the impact of publicity that has occurred and we will not be able to make the changes that need to be made. That is one of my concerns about citing items that are already on the books and have been there for some time.

I thank the gentleman for yielding.

Mr. MCDERMOTT. What I said at the outset was, you had to talk about individual responsibility as physicians and then you have to

talk about how you bring about systemic change. I, actually, early in my career when I was in the State legislature, worked in a PRO, so I pulled charts out of hospitals all over the State of Washington and looked at them and looked at what was going on. We looked at all the deaths in hospitals during a given period to see. So I have been in that process.

The question, I think, is in the mandatory reporting. Do you then publish that this happened and this happened, or do you design a system by which you make the PRO deal with this both in investigating the root cause, why are there infections in the operating room or why are there whatevers going on, and then have a corrective action? Do you give that responsibility to them and say, it is your job to do this and see what happens?

My view is that I am reluctant—the first rule of medicine is, above all things, do no harm, and I am afraid that if you start posting on the wall of every hospital everything that has gone on in the hospital, you will do neither the patients nor the physicians nor the hospital any good. So I am curious about if you think, from looking at your study, whether giving the responsibility for this, mandatorily reporting to the PRO every problem and then make them go out and do an investigation and do a corrective action, would that solve the problem or at least come at the problem in a reasonable way?

Dr. CASSEL. I do not know if it would solve it, but it seems a reasonable strategy to examine because the PROs are in place and they are charged with quality. They do not, however, by and large, have the technical analytical expertise to do the kinds of root cause analysis that aviation gives us as a model.

That is why your example exactly, of why listing a list of something on the wall of any institution is not going to be what matters here. What is most valuable from the aviation example are these complex stories. These are complex issues involving lots of different people, communication, packaging, every dimension of a very complex industry, and so if you are going to ask the PROs or any other body to do this, there would really have to be the resources to get the analytical strength to make sense out of these stories so that they can be learning experiences to improve the situation.

Mr. MCDERMOTT. Simply mandatorily reporting and publishing a great book of medical errors for the country——

Dr. CASSEL. That will not do, no.

Mr. MCDERMOTT.—would not move the issue forward?

Dr. CASSEL. No, and in general, quantitative reporting is not going to tell us much about this because we never can know what the denominators are. So to try to measure how many we have got this month and how many we have a year from now of some sort of error in some geographic location is not really going to tell you what you need to know. You really need to dig down deeper and look at the human factors involved.

Mr. MCDERMOTT. Let me just ask, if you indulge me for just a second longer——

Chairman THOMAS. I will indulge you.

Mr. MCDERMOTT. Thank you. I like to be indulged.

Chairman THOMAS. The gentleman's time has expired.

[Laughter.]

Mr. MCDERMOTT. The question of medicine has changed dramatically since I began practicing in 1963, and what one of the changes is, that there are not three nurses on every floor, as there used to be. There is one nurse perhaps covering a couple of floors with some nurse assistants or licensed practical nurses or whatever and technicians operating at all sorts of levels. In your study, was there any attempt to refine where the errors occurred, what kind of categories they fell into, besides medication errors? I mean, the idea of putting a pharmacist on the team going around is a cost to the hospital, and under the present conditions, no hospital is going to pay a pharmacist to walk around for following 20 doctors going through rounds.

Dr. CASSEL. Well, some actually are because it costs less than the kinds of information systems that use computers to identify drug-drug interactions or somebody's handwriting, the nurse made a wrong interpretation of what the medication was. Those kinds of problems can be avoided by information systems, but for some hospitals, they think they are better off having human beings interact in teams. Ideally, of course, you would like to have both, but what you are describing with the change in the kinds of staffing in hospitals is a response to this very competitive environment that we are in and people trying to deliver much more high-tech care and to do it with as few people as possible.

And that, to my mind, is an environment in which we should be even more interested and more concerned about these kinds of errors and hold ourselves more accountable, because there is all this reengineering going on. Now, we have seen this happening in industry and much of it has actually been for the better. They have gotten more efficient and produced better-quality products. So it is not necessarily a bad thing, but if you are not following and reporting what you are doing, you are not going to know whether you are getting better or not.

Mr. MCDERMOTT. I guess, Mr. Chairman, the reason I raised this whole thing is that having watched the change in hospitals, it is hard for me to know how you can train somebody at the community college for 30 days or 90 days or maybe a semester or maybe even a year to then come in and give one little slice of the treatment without looking at the whole rest of what is going on. I mean, that person cannot possibly know because they have only been trained to look at the thing they are to do.

Dr. CASSEL. Right.

Mr. MCDERMOTT. That is where I have the——

Dr. CASSEL. That is where we need to look at the human investment the same way that industry does, to say these people are not widgets to be inserted into a health care system. They are a valuable part of the team and you invest in their ongoing education and in their ongoing communications with the other people involved.

Mr. MCDERMOTT. Thank you, Mr. Chairman.

Chairman THOMAS. All that may be true, but it is rather frustrating when I continue to hear that one of the problems is that someone cannot read someone's handwriting. Now, I rent a car and I pull up, and by the time I have turned the auto off, opened the trunk, and retrieved my luggage, someone who is probably being paid pretty close to the minimum wage can hand me the total-

ization of the time, the mileage, the dollar amounts. There is a little computer that they use to assist them.

Now, someone better not tell me that this world is so complicated and so difficult that you cannot create a palm-held interactive drug relationship of what is on that chart and that any of those very simple requirements like, hey, guy, type the Rx, the computer can do it for you today. To sit here at this level on the seriousness of this issue and say the problem is somebody's handwriting on an Rx tells me exactly how far we have to go with this culture that we have been talking about.

Dr. CASSEL. And what you describe does exist in many places. It just does not exist everywhere, and——

Chairman THOMAS. And the problem is, there is no systematic collection of data, there is no systematic confidentiality, and there is no willingness to share in a confidential way as there is, for example, in the aviation industry.

Does the gentleman from Louisiana wish to inquire?

Mr. MCCRERY. Thank you, Mr. Chairman. In fact, that is part of what I was going to pursue, is the use of technology and why we are not making greater strides in the use of technology in terms of patient protection, if you will. It seems to be a word or phrase that is bandied about a lot in Washington these days, so let us talk about patient protection.

Is it necessary for the Federal Government to intervene here and mandate the use of certain technologies like these hand-held machines that are available, I believe, in which you type in, or actually just push a few numbers or letters and the prescription pops up, the interactions pop up, the patient's records are on there for other drugs that he or she is taking. Should we mandate that those things be used by doctors on their rounds in hospitals? It is for patient protection.

Dr. CASSEL. It certainly is, and the broader answer that I believe to your question about should the Federal Government do something is yes. Now, as Mr. Thomas said, I think the very important question is what exactly would really make the most difference and be the most productive role for government intervention, and there are a number of different approaches to that.

Let us remember that the computer process is also not infallible, as we have been actually learning about Internet activities just this week. But even the thing about pushing the button, people also do push the wrong button. So the human factor—you can never escape the need for the human factor's dimension of this kind of work.

But I think that information technology is very promising for reducing errors and improving quality of care, but it is expensive. I have been sitting at the table at a number of different health care organizations with discussions about the competitive environment, how many hundreds of millions of dollars they spend on information technology, and where is that going to come out of. So that is where part of the tension, the inevitable tension will be.

Mr. MCCRERY. What is the role of the government, the Federal Government, in establishing a system of reporting disclosure of errors and near misses? Do we have a role? Should we implement a nationwide system of mandatory or voluntary disclosure?

Dr. CASSEL. Our reports suggest that there be a nationwide expectation or standard of reporting from every State and that the States get help from the Federal Government in implementing these systems and evaluating them and improving them going forward.

Mr. MCCRERY. Only about a third of the States, as I understand it now——

Dr. CASSEL. Currently have that.

Mr. MCCRERY.—have those, so why should we not mandate it from Washington?

Dr. CASSEL. Our reports suggest that you do that, but that you not mandate exactly the same system for every State because we do not know yet how best to do this and we can learn from what the States have been doing.

Mr. MCCRERY. Since you are at a teaching hospital, one thing that I get from people often, Mr. Chairman, is why do doctors in residency programs have to stay up so many hours? Is that not dangerous? Why do you force them to work hours on end? Nobody else does that. Pilots cannot do that. In fact, pilots have just the opposite. They have to take off. They have to take off from their job. They also have to take off, but——

[Laughter.]

Ms. CONNELL. In order to land, they must take off.

Mr. MCCRERY. Yes. But why is that? I am just curious, so I can answer all these people that bug me about this.

Dr. CASSEL. Now here, you will get my personal opinion. I think that medical training has been unreasonable and actually dehumanizing in those dimensions. It is getting better. The State of New York has very clear rules about how many hours a resident can work. But we still get arguments from physicians who say that the most important thing for the physician is to learn to work under stress and to learn the continuity of care, so you are responsible for one patient over a period of time in the illness.

Chairman THOMAS. Dr. Cassel, I am sorry to interrupt you, but on that basis, do you think it is primarily driven by economics, that is, it is cheap labor——

Dr. CASSEL. No.

Chairman THOMAS.—or it is part of the hazing process to join the culture?

Dr. CASSEL. Those are my two choices, those answers?

[Laughter.]

Dr. CASSEL. I do not think it is because of economics. I think it is part of the culture of being a tough guy and getting it right no matter how stressed you are. I think this——

Chairman THOMAS. And learning how to not report it if you do not get it right.

Dr. CASSEL. Well, that probably has been part of that, and that is why I think this is something else we can learn from aviation, exactly what you suggest, that we probably do need to recognize that to err is human and that humans are fallible and that humans need to go to sleep periodically.

Mr. MCCRERY. In conclusion, Mr. Chairman, I just want to say that I agree with Mrs. Johnson that, or at least I think this is what she concluded, that much of the problem is systemic and we really

have to look at the reasons for the system, if not promoting errors, certainly putting in place systems that do create errors and afford the possibility for errors in greater numbers than we should.

I really do not think that it is the individuals' faults. It is not the doctors' faults as individuals. But it is a systemic problem, but I do think that it is a culture, as part of the system, that has grown up over the years and the teaching hospitals, the medical schools, I think, are going to have to play a large role in correcting this culture and reversing some of these things that have been put in place by the system.

Mr. Chairman, my time has expired, but this is very interesting. I appreciate the testimony.

Chairman THOMAS. I thank the gentleman. We may do a second round, but I did want Ms. Connell to respond, because as I understood your testimony on the structure that you oversee, it is just kind of open-ended and whoever wants to report gets to report. You were talking about, what was it, 36,000 reports.

My guess is, if it were an open-ended reporting system in the medical structure, you would probably be overwhelmed and so perhaps there is a question of volume. But to what extent do you believe it has been fundamentally important in building the system to let every individual in the system believe that they can make a difference if they choose to make a difference?

Ms. CONNELL. There definitely is a human concept there that people need to feel empowered, to feel engaged, to feel they can make a difference, and this system has provided that.

Now, in all honesty, of all the information I receive, there is some percentage I cannot use because it does not fit into what we can do something about. But that does not mean I do not accept it.

Chairman THOMAS. I will go to the gentleman from Florida, but it seems to me that the reporting of information which is not all that useful is a minor problem compared to the enabling position of people believing that they can inform. I hear immediately, oh, we cannot do that because it is just going to be too much volume, and you immediately then begin a hierarchial structuring of who is important, what is important, who counts in the system and who does not, and I think that has been one of the fundamental problems in medicine, that there is this hierarchial structure and I do not think folks realize it when they begin saying, oh, there is no way we can create a system like the FAA where everybody reports.

Just create a system of dealing with that volume, because one of the fundamental enabling aspects of a system, I think, is to be able to say, hey, anybody in this structure who feels strongly enough, on a confidential basis, let us have it. I think that probably would break down the culture of medicine almost as fast as anything else we could do.

Ms. CONNELL. And we have learned a lot by taking that perspective, because—

Chairman THOMAS. I understand the volume problem, but boy—

Ms. CONNELL.—you cannot anticipate what you are going to hear, but you have to be ready to listen.

Chairman THOMAS. You can if you can judge who is important and who is not to the system.

Ms. CONNELL. But some rather innovative solutions to problems have come from an Embry Riddle student looking at an issue. So it is pretty wide open.

Chairman THOMAS. But it is the mental concept, the willingness to accept even the least in the system's report that there may be of some value. That, again, is part of that culture that has been built into medicine, that is not going to work.

Ms. CONNELL. And I have to say, the support at the highest levels. The FAA under David Hinson made it very clear that all organizations would have safety departments that report directly to the CEO. They elevated safety as something very important, and there are, and we have managed to translate this to people. The economic advantage of putting money into safety far outweighs the accidents.

Chairman THOMAS. I thank the gentleman.

The gentlewoman from Florida.

Mrs. THURMAN. Thank you, Mr. Chairman.

Dr. Cassel, I am interested to know, is this the first time that this medical error issue has really hit this country?

Dr. CASSEL. Well, that is a wonderful question. No. Nothing in this report is new information. We did a very thorough examination of existing literature, and actually, we did not even go as far back as some other studies that have been done in the 1980s or 1970s that we were aware of. So it is not new information.

Mrs. THURMAN. Okay.

Dr. CASSEL. And that is why it is interesting that it has gotten the response that it has. I think some of that has to do perhaps with the current concern about the quality of care and the so-called managed care backlash and the environment of concern about patient protections, but I think it also has to do with having an organization like the Institute of Medicine look very systematically at this issue and package it in a way that sort of makes sense of it.

Mrs. THURMAN. The reason I asked is because in Florida, and I am going to tout Florida here a little bit because I think Florida has been a real leader in this issue. We were the first state to implement any kind of adverse incident reporting programs. We did that in 1975 and then we expanded it again in 1985.

I guess part of the question, with the recommendations that have been made and the fact that there are some 20 States that have actually put some kind of review system in place; what have we learned from those? Are we analyzing the information from those States that have implemented reporting programs? Has this been included as part of the proposal that is being put forward to us? Have we looked at the statistics of what happened before they did this to what they are doing today to what works in those States in reducing errors?

I am just a little concerned that we are going to get so overpowered with some new regulatory something this, something that, when we have some models out there that potentially might be working. Because I think this is an issue that you have to move quickly on to make something happen and why would we reinvent what are we doing if it is similar to some of these States in their reporting mechanisms and what can we do quickly that can make a difference?

Dr. CASSEL. Some of our data did come from State-level studies exactly as you described, but there has not been an attempt at a national level to really follow over time what has occurred in those States, for example, that have some sort of mandatory reporting or that have other kinds of error reduction or patient safety strategies in place. That is one of the functions that we think that the Agency for Health Care Quality could take on, is to figure out how most accurately to really study those things.

This is not traditional health care research. That is the other thing we need to learn from these other industries, that our approaches to even looking at quality of care research do not have the same dimensions that some of these other industries do in looking at the root cause analysis, for example, and sort of qualitative analysis. So that why I think we do need some very concerted research to exactly draw those lessons from people who are doing the right thing and are making progress, but we really do not know how to study it or explain it.

Mrs. THURMAN. Maybe to the chairman and others, we know that there are some things working out there. Are there things legislatively? For example, I think Florida is the only one now that through the practice acts makes risk managers in hospitals go through classes and have to be accredited for their practices. So we have done some things in those areas and those seem to be working. It just seems to me that we need to learn from some of those things.

I know that talking about some of the technology issues, in Florida, for example, they are putting information on the Web. For example, information about medication safety is already up and running. And yet we are sitting here talking today that this is a major problem in this country. Wrong site surgery, restraint injury, these things are happening.

I think part of it is that we need to make sure that some of this information is getting out. I think we also need to be talking to our State legislators who can put some of these quality boards in place immediately to take care of some of these situations. It is a pretty dismal thing to think that we have been talking about this for a long time and only 13 States have even looked at anything at this point.

Dr. CASSEL. I think it is actually more 20 or 22 at this point, so it is a little bit more promising, but I think there are things to learn from the States. You are absolutely right.

Mrs. THURMAN. Thanks.

Chairman THOMAS. I thank the gentlewoman.

Does anyone have a burning desire to ask another question? The gentleman from California is burning first.

Mr. STARK. Thank you, Mr. Chairman.

Dr. Cassel, I have a hunch that we are going to hear some complaints during the course of the day about the costs of any program that we may encourage or require, and it is my sense that the health care costs due to preventable events is somewhere between $8 and $15 billion a year, or something like $2 billion a year, I have heard even, just through inappropriate or adverse drug events which have to be corrected.

The National Quality Forum on its Internet site estimates that 30 percent of the acute care patients and 20 percent of the chronically ill patients receive care that is contraindicated. I guess that means unnecessary, or may be unnecessary.

So ought the savings to the hospitals from preventing errors which may cause them to have to keep people longer—they are only getting a DRG payment, so if they do it wrong, obviously, it will cost them more than getting it right the first time—can you comment on the costs versus savings of any kind of program we might undertake to require all of the providers to be more involved in a system of reporting and corrective action?

Dr. CASSEL. I certainly can comment on that. But before I do that, I think we always have to remember that cost is not the first reason for addressing this issue. That first do no harm has to do with protection of patients first and foremost, and even if it did cost more it would be worth doing.

But having said that, I think the cost issue is one that needs examination, but it is not quite as straightforward I believe as you describe it. For example, a hospital as a unit may gain or lose money if it improves its error rate depending on how that plays out in the DRGs. Because some patients who become very ill from a medication complication then may go home or may go to a nursing home and the hospital itself may not end up bearing the cost burden of that.

The entity that is likely to save is Medicare when you look at the whole picture of patient care. I think it is harder to know whether a single individual hospital would gain or lose in a single year let us say from implementing some of these strategies.

Mr. THOMAS. The gentleman from Washington.

Mr. MCDERMOTT. Thank you, Mr. Chairman. I am sitting here trying to figure out how to design this, because I think everybody wants to make it better. I remember the difficulty that the Agency for Healthcare Quality, they went through a sort of near-death experience here in the Congress around their analysis of certain procedures and whether or not they were effective and so forth.

So as I think about putting this issue in their box and saying, this is something new we would like you to do, I would like you to distinguish something or at least talk about it, the whole question of confidentiality protections versus medical liability.

If we require mandatory reporting, every hospital in the United States must report to the Agency for Quality Health Research any incidents of medical errors. Can that information then be used in a lawsuit against the hospital or the doctor or whoever? Or is it in fact—would it be possible to make it confidentially protected in such a way that it could be used for the purpose of systemic analysis and recommending changes? Or would it simply be a repository from which whoever would say, I think there is some information over there we need for the lawsuit?

Dr. CASSEL. Several important points. First, we do not recommend that the Agency for Healthcare Research and Quality become the regulatory agency because they need to, exactly as you say, to be free to really examine all of the data and set some goals for the Nation, and look ahead and invest in the research necessary to know how best to do this. So that is not a regulatory function

that makes sense to place there, and as you point out it puts their most important function at risk, which is to support learning or about how to improve quality.

Secondly, I think that a serious look at the liability environment is essential in really trying to answer this question. As I say, our existing IOM committee does not really have the capability to do that. But something like an IOM study about the whole environment of liability and how does it relate to quality or how does it inhibit quality. I tend to think that some very interesting strategies such as no-fault approaches to adverse events that happen in health care would compensate more people who are harmed at less cost, and it would get the money to the people who have been harmed rather than to the attorneys who are trying to find the cases.

As you probably know, in one of the important studies here it was identified that only something like 1 percent of people who were harmed by negligence actually ever even were involved in a lawsuit. And the ones who did get compensated got compensated 10 years later. So that does not seem to me to say that our current liability environment is really protecting the patients. So from my point of view I think we need a much more expansive look at this whole situation.

Mr. MCDERMOTT. Thank you, Mr. Chairman.

Mr. THOMAS. The gentleman from Louisiana.

Mr. MCCRERY. That would be a great hearing for us to have, Mr. Chairman. I would like to pursue that, but I will not today.

The matter that Dr. McDermott brought up earlier is an interesting one, this issue of cost savings that have been implemented by health care institutions, whether it is hospitals or health care plans or whatever. And if I am not mistaken, the data that you studied is 10 years old; is that right?

Dr. CASSEL. Much of it is.

Mr. MCCRERY. Much of it is 10 years old?

Dr. CASSEL. Yes, eight to 10 years.

Mr. MCCRERY. I do not know when all this cost saving took place but it is possible that it had not really reached its zenith 10 years ago and you still might have had two nurses on duty instead of one and those kind of things. So it may be hard to tell. It may be useful to do a new study or collect new data and study that in light of the changes that have taken place.

But I wonder if you have, upon going through all that material, have you reached any conclusions or even developed any opinions on the quality of care today as opposed to say 10 years ago because of cost-saving matters that have been brought into play in the health care institutions? Do you have any comments on that? And if you did not look at that and you did not develop any——

Dr. CASSEL. We did not specifically look at trends over time in this study and I think that the data does not really exist to allow us to do that. That is one of the reasons we think that the research in this area is so vitally important, and that we have some ability to look at trends over time and set some goals for ourselves as a nation. So that would be, to my mind, one of the most important things we can do. If we do not know whether it is getting better or worse, it is going to be hard to fix it.

Mr. MCCRERY. So your panel did not reach any conclusions as to the deleterious effects, if any, of the various cost-saving devices that have been implemented by health plans?

Dr. CASSEL. That was not one of the things that we looked at. There is some literature in the health services research arena trying to look at changes in health care financing and the effects on quality. It requires very sophisticated studies so there are not a lot of really definitive ones in that area. But the current environment of concern about health care quality I believe is going to allow us to really make much better use of that kind of research.

Mr. MCCRERY. Thank you, Mr. Chairman.

Mr. THOMAS. The gentlewoman from Florida have any questions?

Mrs. THURMAN. No.

Mr. THOMAS. I did want to just briefly follow up. Ms. Connell, you heard the statement that they have the goal of a 50 percent reduction in five years. Do you think that that is really a realistic target based upon your experience in changing a culture, which I think is probably more sympathetic to resolving errors? That is not the right way to say it, but you know what I mean.

Ms. CONNELL. You have got a large system, there is no doubt about it. It is real hard to say. We have a goal at NASA under a NASA safety program right now which was driven by the Gore Commission goal to reduce aviation worldwide accidents 80 percent in 20 years. We are looking at that in terms of how are we going to do that when we have an accident rate that is already pretty low and we have a lot of data.

Mr. THOMAS. I certainly do not want to discourage anyone, but I also think if we are going to go into this we have to set some realistic targets so that goals are met in a realistic way. For example, the only legislation that has been introduced so far is a piece of legislation on the Senate side that is setting up three demonstration projects, vanilla, chocolate, and swirl, and they are going to report in five years. So good luck on voluntary compliance to meet your 50 percent if that is the direction that we are going to be going.

My other really big concern, especially when we are talking about mandatory and the role of Government and the rest is that I have found that Government is really good being the sovereign at requiring people to report what.

And what I am hearing, and I hope as we move into this next panel that what is not going to get us there. It has got to be an analysis structure that goes into the why with as much data available as possible, and that that is not always conducive when you want to, even in a non-punitive or litigiousness situation, point the finger at people and reward those who do well and try to stop those who do not do well. That tends to be the direction, notwithstanding the desire, of a mandatory system and a structure of, we have got to get data.

Qualitative analysis thoughtfully done may in fact produce better results in my opinion than a whole lot of quantity mandated because somebody wants to do something about the problem. Any reaction to that?

Dr. CASSEL. I would just heartily endorse the emphasis on the qualitative aspect of the data.

Ms. CONNELL. So would I.

Mr. THOMAS. Notwithstanding the fact that you want everybody to participate in the system because, one, you do not know where the qualitative data is going to come from. But secondly, in my opinion, the openness of that system is what creates the willingness to, within the quantity, get the quality.

Dr. CASSEL. Yes.

Mr. THOMAS. I want to thank the panel very much. We took some time, but I just thought the unique backgrounds of both of you and the perspective that you might bring to this would set the tone and I appreciate very much your willingness.

Now I would ask the defendants to approach the bench.

[Laughter.]

Mr. THOMAS. Oh, I am sorry. The next panel is Dr. Michael Langberg, senior vice president of medical affairs, chief medical officer of Cedars-Sinai in Los Angeles, on behalf of the American Hospital Association. And Dr. Thomas Reardon, president and executive committee member of the American Medical Association.

We have a vote underway. It is a 15-minute vote. If we can get both of your testimony in, your written testimony will be made a part of the record, and if you will address us in the time that you have, which if both of you take five minutes we will have enough time to vote. I believe it is going to be difficult to do, and if we are not successful in doing it then we will recess and come back.

Dr. Langberg, do you want to start?

STATEMENT OF MICHAEL LANGBERG, M.D., SENIOR VICE PRESIDENT OF MEDICAL AFFAIRS, AND CHIEF MEDICAL OFFICER, CEDARS–SINAI HEALTH SYSTEM, LOS ANGELES, CALIFORNIA, ON BEHALF OF THE AMERICAN HOSPITAL ASSOCIATION

Dr. LANGBERG. Mr. Chairman, and members of the committee, my name is Dr. Michael Langberg. I am the senior vice president for medical affairs, chief medical officer for Cedars-Sinai Health System in Los Angeles. The Cedars-Sinai Medical Center is the largest not-for-profit acute care hospital in the western United States, and together with more than 2,000 physicians associated with our system, Cedars-Sinai provides care to an urban population of considerable diversity.

I have spent almost all of my professional career at Cedars-Sinai as a general internist. Since 1996, I have served as its chief medical officer and am responsible for overseeing systemwide quality initiatives and information systems. I have developed a deep knowledge of the complexity of modern health care and have a broad background in improving the quality and safety of the patient experience.

I am here today on behalf of the American Hospital Association. The AHA realizes 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.

To begin, I would like to remind the committee and the American public that hospitals provide care to millions of patients safely every year. The people who deliver health care, the doctors, the nurses, and others, are highly trained, receive continuous edu-

cation, and strive every day to deliver safe and compassionate care. They do believe in the dictum, first do no harm. But health care today is extraordinarily complex and even our best intentions can have unwanted and unintended consequences.

The IOM report, To Err is Human, points out that as good as our systems are for preventing and reducing medical errors of all kinds, we can and we must do better. We applaud the members of the IOM committee for developing a report that shines a bright light on the problem of medical errors and are heartened by the quick response this has received.

We agree with the report in urging all to avoid blaming individuals for past errors, and instead to focus on preventing future errors by designing safety into the system. It stresses two principles that we have learned, reduce errors and increase patient safety.

First, to err is human. We must understand and improve the systems in which people work to make errors less likely. As a result, reducing errors requires us to design and implement more error-resistant systems.

Second, we have to create an environment where caregivers feel they can come forward when an unfortunate mistake is made. We need to create a non-punitive environment that allows for the candid discussion of errors, their sources, their causes. If we cannot discuss our mistakes, we cannot learn from them or prevent them in the future.

The AHA also agrees that stepped-up efforts are needed. There are many organizations today that specialize in the area of reducing and preventing medical errors. We at the AHA are working with some of these experts.

In December, the AHA announced an initiative to target and improve medication safety. Why? Because medication related errors are one of the most common sources of all medical errors.

As part of this initiative, the AHA formed a partnership with the highly respected organization in this field, the Institute for Safe Medication Practices. This non-profit research and educational organization and its president, Michael Cohen, have been dedicated for over 25 years to the continual reduction of medication errors throughout the health care system. We are pleased that they will provide leadership as well as technical expertise for the AHA's initiative.

As part of our effort we will share with every one of our members successful practices for improving medication safety. We have already sent out a quality advisory on improving medication safety to our 5,000 hospital and health system members. This advisory includes background on the issue, resources our members can turn to for help, and a three-page list of successful practices for improving medication safety.

We will follow up on how these successful practices are being implemented with a medication safety awareness assessment. We will also serve as a clearinghouse for information and resources, and are planning a national summit involving other organizations and hospital leaders to discuss widespread efforts to improve medication safety.

In summary, Mr. Chairman, the IOM's report is timely. It brings together a number of stakeholders all at the same time to collec-

tively address this important issue. As the report notes, large, complex problems require thoughtful, multifaceted responses. The AHA has pledged and committed to help its member hospitals and health systems respond to this critical issue.

I will be happy to answer questions.

[The prepared statement and attachments follow:]

Statement of Michael Langberg, M.D., Senior Vice President for Medical Affairs and Chief Medical Officer, Cedars-Sinai Health System, Los Angeles, California, on behalf of the American Hospital Association

Mr. Chairmen, I am Michael Langberg, M.D., senior vice president for medical affairs and chief medical officer of Cedars-Sinai Health System in Los Angeles. I am here today on behalf of the American Hospital Association's (AHA) nearly 5,000 hospital, health system, network, and other health care provider members. We are pleased to have the opportunity to testify on an issue of critical importance for hospitals and the patients and communities they serve: the Institute of Medicine's (IOM) report on medical safety, and what hospitals and health systems are doing to improve patient safety.

The Cedars-Sinai Health System includes a number of physician officers distributed across the Los Angeles metropolitan area. Cedars-Sinai Medical Center is the largest not-for-profit acute care hospital in the western United States. Together with the 2,000 physicians associated with our system, Cedars-Sinai provides care to an urban population of considerable racial, ethnical, social, linguistic, religious and economic diversity.

I have spent almost all my professional career at Cedars-Sinai on the faculty in General Internal Medicine, originally as Director of Medical Education. In 1996, I assumed the role of chief medical officer overseeing system-wide quality initiatives and information systems. I have developed a deep knowledge of the complexity of modern health care, and have a broad background in improving the quality and safety of the patient experience. I believe that much of what is outlined in the IOM report is accurate. The report has focused attention at a time when many other activities are under way to address these issues, which many of the members of the IOM panel first brought to national awareness several years ago.

BACKGROUND

For thousands of years, healers have lived by the motto primum non-nocere—first, do no harm. The nurses, doctors, and others on the patient care team in hospitals strive every day to deliver the safe, compassionate care that patients deserve. But in today's complex, high-tech world of medicine, 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.

THE IOM REPORT AND HOSPITALS

We applaud the members of the IOM Committee on Health Care in America for developing a report that shines a bright yet objective spotlight on the problem of medical errors. The IOM report is important, outlining the significance of the medical error problem in this country.

It acknowledges that medicine is delivered by people who are highly trained and receive continuous education to stay on top of their respective areas of discipline. Hospitals and caregivers already work under strict internal quality control procedures, in addition to federal, state, local and independent oversight. Hospitals have important systems in place—checks and balances to reduce the potential for human error. For example, they have quality teams, physicians and nurses who examine unexpected deaths, treatment errors and accidents, to identify and correct the cause. And most hospitals have teams of experts whose sole focus is to develop and oversee safety policies to prevent accidents before they happen.

In addition, there are many organizations that specialize in the area of reducing and preventing medical errors. The AHA is working with several of these organizations so that we can help hospitals and health systems benefit from their knowledge and expertise. Among them: the National Patient Safety Partnership—a public/private partnership of organizations; the National Coordinating Council for Medication Error Reporting and Prevention; and the American Medical Association National Patient Safety Foundation. We're doing this because, as the IOM report points out, a vigilant, ongoing, stepped-up effort to improve patient safety is needed.

We agree with the report that we need to avoid "blaming individuals for past errors" and instead "focus on preventing future errors by designing safety into the system." We also agree that, as the report states, "professional societies and groups should become active leaders in encouraging and demanding improvements in patient safety." The AHA is committed to being just that kind of leader, so that America's health care system does indeed focus not on blame, but on prevention.

The IOM report focuses on the broad issue of medical safety. The AHA, at a White House event in December with President Clinton, announced an initiative to improve medication safety, because medication errors are one of the most common sources of overall medical errors. We used the opportunity to point out that whatever happens at the national level will only be valuable if it helps the women and men like me and those I work with at the Cedars-Sinai Health System—people who are on the front lines of health care—do their jobs even better.

Speaking of action at the national level, we understand the committee's interest in determining whether further legislation is needed to address medication errors. But before moving to consider new legislation, we urge Congress to consider the reporting mechanisms currently in place—by organizations like the Veterans Administration, the Joint Commission on the Accreditation of Healthcare Organizations, and the Institute for Safe Medication Practices—to collect and use information on errors. Congress should know how these current mechanisms work and consider ways to improve them, if necessary, before proposing new reporting systems.

The AHA believes we need to be clear about what our objectives are in collecting information on events that may be related to errors. Reporting should be a tool for reducing and preventing errors. It should be designed to stimulate organizations and practitioners to analyze what went wrong and make the necessary changes to ensure that the mistakes do not happen again. In addition, lessons learned from one error should be widely shared with others. Provider accountability should be tied to these objectives.

The quantity of reports is not nearly as important as the quality. One need not read 500 reports of workers mixing up two similar sounding medications, before it becomes obvious that the two medications need better labeling. Our goal should not be to ensure that every provider report every event, but rather to encourage dialogue to learning.

AHA ACTIVITIES

More than a year ago, the AHA board and many of our hospital leaders attended a national forum in Cleveland. The topic: improving patient care. Though we have long been involved in improving the quality of care provided in the nation's hospitals, we came away from that particular meeting with a strong sense from hospital leaders that, on a national level, we could do more … we needed to address these issues head on.

But the issue of medical error is very broad in scope. We set our sights specifically on improving medication safety—reducing and preventing medication errors that result from things like different drugs being packaged in similar containers, use of confusing abbreviations on labels and prescriptions, illegible doctor handwriting, and more.

Against the backdrop of all this activity came the IOM report, which led overnight to increased awareness of the importance and seriousness of this issue. The release of the report came as we were preparing to kick off our initiative to take a comprehensive look at hospitals' ability to prevent medication errors and help them make improvements where needed.

As part of our initiative, we formed a partnership with a highly respected organization in this field, the Institute for Safe Medication Practices (ISMP). This nonprofit research and education organization is dedicated to reducing the incidence of medication error throughout the health care system, and will provide leadership and technical expertise for the AHA's initiative. ISMP provides independent review of errors reported through the Medication Errors Reporting Program (MERP), which ISMP was instrumental in founding. Through MERP, health care professionals across the nation voluntarily complete pre-addressed mailers or dial a toll-free number (800–23–ERROR) to report actual and potential medication errors with complete confidentiality. As an official MedWatch partner, ISMP shares all information and prevention ideas with the U.S. Food and Drug Administration (FDA) and other professional and policy organizations. Working with practitioners, regulatory agencies, health care institutions, professional organizations, and the pharmaceutical industry, ISMP provides timely and accurate medication safety information and works toward improvements in drug distribution, naming, packaging, labeling, and delivery system design.

The following four objectives are key to our medication safety campaign with ISMP.

Develop a non-punitive process for discussing errors

Most of what has been learned in recent years about how to reduce errors and increase patient safety is based on two principles. First, individuals, by the very nature of being human, are vulnerable to error. Although they are the focus of the error, errors happen because of the systems in which these individuals work. As a result, reducing errors will require us to design and implement more error-resistant systems.

Second, we have to create an environment in which we learn from failure. This requires us to identify an effective mechanism for candid discussion of errors. This cannot be achieved in an environment of punishment or fear. Doctors, nurses and other caregivers should not be penalized for stepping forward after an unfortunate mistake is made. A more open environment can only occur when health care providers are afforded adequate legal protections.

Today, when health care providers are required to disclose confidential internal information to health care oversight agencies, they may jeopardize state law that protects internal quality analysis discussions and expose themselves to crushing legal liabilities. There is no incentive to share this information with others to prevent similar events in other institutions. We believe protections that currently apply to such information should also apply when it's disclosed. We believe that evidentiary, confidentiality and other legal reforms should be considered to help foster an environment that promotes candor.

Candor is absolutely critical if we are to be truly successful in identifying, learning from and reducing not only medication errors, but all medical errors, and making the health care system safer. We need to create a non-punitive culture at all levels that supports the collection of information about errors, along with candid discussion of errors, their causes, and ways to prevent them from happening again. A safe, non-punitive environment will encourage people to report and discuss errors—the first step in lessening the chance they will happen in the first place and making sure they do not happen again.

Share successful practices with every hospital and health system

We sent to every AHA member the attached "Quality Advisory on Improving Medication Safety." The advisory includes background on the issue, a long list of resources our members can turn to for help, and a three-page list of "successful practices" for improving medication safety. Some of these practices can be adopted easily and quickly, such as providing staff with information about ordering, dispensing, administering and monitoring medications, not storing certain concentrated solutions on hospital wards, and helping patients better understand what they are talking, why, and how to use it safely.

Others are longer-term practices that, with time and money, can create significant changes throughout our members' organizations. Among these are the development of a voluntary, non-punitive system to monitor and report errors that might occur within hospitals, and the computerization of medication administration systems.

We compiled the list of successful practices with the help and advice of some of the best experts in the field—including the ISMP, the Institute for Healthcare Improvement, the Massachusetts Coalition for the Prevention of Medical Errors, the National Coordinating Council for Medication Error Reporting and Prevention, the National Patient Safety Partnership and many others.

Develop a "medication safety awareness test" for use by hospitals

To follow up on how the successful practices are being implemented, we are working with ISMP to develop a "Medication Safety Awareness Test" to help our members assess their progress. This tool will also help the AHA get an idea of what other help its members may need, and help us track and demonstrate hospitals' success at improving medication safety.

Serve as a clearinghouse of information and resources for hospitals

The AHA will continue making available to its members up-to-date information on improving medication safety. We will gather information from outside sources and work with other national organizations to develop information and data. We are planning a medication safety "summit," gathering other organizations and hospital leaders together to discuss widespread efforts to improve medication safety. And we will be adding to our Web site (www.aha.org) a special area containing all the information, data, best practices, and other resources we compile in our medication safety improvement campaign.

CONCLUSION

Mr. Chairman, the IOM report is very timely. It comes as America's health care system enters a new century of caring for people. It marks an opportunity for us to rebuild the public's confidence and trust in the health care system they rely on every day. And it reminds us that, despite setbacks, we still deliver the greatest health care in the world.

But it also notes that "large, complex problems require thoughtful, multifaceted responses." Reducing and preventing medication errors, and improving the overall safety of the health care system, will demand the thoughtful collaboration and participation of everyone involved in the health care field: hospital leaders, pharmacists, drug manufacturers, doctors, nurses, government agencies, other organizations, and consumers. America's hospitals and health systems are committed to this effort.

AHA QUALITY ADVISORY

A Message to AHA Members:

Primum non nocere. Above all, do no harm. Healers have lived by this motto for thousands of years. The minimum our patients expect from us is safe and compassionate care when they enter a hospital. And they deserve to get it.

But in today's complex, high-tech world of medicine, our best intentions can have unwanted consequences. And those consequences are contributing to the public's eroding confidence and trust in the health care system.

While the recently released Institute of Medicine study has drawn a lot of attention to medication errors, we have been working on this issue for some time. Following up on discussions with the AHA Board of Trustees and Regional Policy Boards on improving hospitals' accountability to their communities, the AHA is developing an initiative to help you improve patient safety by reducing and preventing medication errors. To provide leadership and technical expertise in this effort, we have formed a relationship with the Institute for Safe Medication Practices (ISMP), a not-for-profit research and education organization dedicated to reducing the incidence of medication error throughout the health system.

This is what you can expect from us in the coming months.

First, we will provide you with strategic and practical advice to reduce the potential for and incidence of medication error. To jump start this initiative, we are attaching several successful practice recommendations compiled from respected sources.

Next, together with ISMP, we are developing a "Medication Safety Awareness Test" that will help you assess your progress on implementing recommendations in your hospital, and that will enable us to track and demonstrate your success at improving medication safety.

The recommendations that follow can greatly improve patient safety. The first set can be implemented immediately; they focus on standardization and simplification of processes that will likely reduce the potential for human error. The second set require changes to existing organizational systems; they will likely require a longer-term implementation plan and may rely on computerization of the physician order-entry and pharmacy dispensing processes.

Here are some ways to get started:

• Consider organizing a senior management team to review and discuss the attached recommendations. This team could include the CEO, chief medical officer, chief operating officer, chief nurse executive, director of pharmacy, risk manager, director of information systems, and others. Some organizations also include patients on this team. Assess your organization's processes as they compare to the recommendations and track your progress on implementing changes.

• Review your policies and procedures for reporting and investigating errors. Create an open, non-punitive culture that evaluates and corrects errors.

• Review information about incidents that occur within your institution and use it to find opportunities for improvement. Consider personally investigating an adverse event yourself, including talking directly with those involved.

• Help your organization's physicians, nurses, and other patient care staff be prepared to respond to patients' questions about adverse medical events and about the general quality of care in your organization.

• Make sure your staff is aware of the tremendous amount of information available from organizations like the ISMP, the Institute for Healthcare Improvement, the Food and Drug Administration, the U.S. Pharmacopeia, the Massachusetts Hospital Association, the National Coordinating Council on Medication Error Reporting and Prevention, the National Patient Safety Partnership, the National Patient Safe-

ty Foundation, the American Society for Health-System Pharmacists, and the American Society for Healthcare Risk Management.

• Lead the way with executive behavior: Declare the goal of safety to be a specific priority of you and your board. Be certain to keep your board and organized medical staff up to date on all the actions you're taking.

Look for more from us in the near future. We'll provide strategic and practical advice on reducing errors, and we'll be your clearinghouse for information and resources. The AHA is committed to helping you create a safer, more effective, and more efficient health care system.

Dick Davidson President

AHA Quality Advisory

IMPROVING MEDICATION SAFETY

Background

Most of what has been learned in recent years about how to reduce medication errors and increase patient safety is based on two principles. First, individuals, by the very nature of being human, are vulnerable to error. Although individuals are the focus of the error, errors happen because of the systems in which those individuals work. As a result, reducing error will require us to design and implement more error-resistant systems. Second, we have to create an environment in which we can learn from failure—a safe, non-punitive environment that supports open discussion of errors, their causes, and ways to prevent them.

These principles have a common denominator—they require the leadership and commitment of senior executives, medical, nursing, and clinical staff to create change within our organizations.

Common Sources of Error

Medication systems in hospitals are complex and multi-layered, involving many steps and many individuals. This complexity increases the probability of failure. While many errors are caught before they can cause harm, it can be tragic whenever a patient's safety is compromised. Error can occur at any stage—prescribing, ordering, dispensing, administering, or monitoring the effects of a medication. According to the Institute for Safe Medication Practices, some common sources of medication error in health systems include:

Unavailable Patient Information:

Critical patient information (diagnoses, lab values, allergies, drug contradictions, etc.) is often unavailable to pharmacy, nursing, and medical staff prior to dispensing or administering drugs.

Unavailable Drug Information:

Pharmacists often are not readily available on patient care units and written resources may not be up-to-date, which can lead to dose miscalculations or ignorance of drug interactions. Because errors occur most often during the prescribing and administration stages, accessible drug information must be readily available and close at hand for all staff who prescribe and administer drugs.

Miscommunication of Drug Orders:

Failed communication is at the heart of many errors. This includes poor handwriting, confusion of drugs with similar names, careless use of zeroes and decimal points, confusion of metric and apothecary systems, use of inappropriate abbreviations, ambiguous or incomplete orders, and, sometimes, conflicts between practitioners.

Problems with Labeling, Packaging and Drug Nomenclature:

Most drugs are dispensed through unit dose systems that parse medications into smaller-sized doses. These systems, however, do not always provide for thorough preparation, packaging, and labeling of medications, with screening and checking by both nursing and pharmacy personnel, and they may not be available throughout every unit in the hospital (e.g., ERs and ICUs). Drug administration procedures often do not ensure that medications remain labeled until they reach the patient's bedside, a frequent source of error.

Drug Standardization, Storage, and Stocking:

Stocking multiple concentrations of the same drug, or storing drugs in look-alike containers or in ways that obscure drug labels, may contribute to error. Lack of safety procedures for use of automated dispensing technology or inadequate check systems may also contribute to errors.

Drug Device Acquisition, Use and Monitoring:

Lack of standardization in drug delivery devices, improper default settings, unsafe equipment (e.g., free-flow infusion pumps), and the lack of independent check systems for verifying dose and rate settings can all contribute to device-related errors.

Environmental Stress:

Environmental factors like lighting, heat, noise, and excessive interruptions, can affect individual performance. The process of transcribing orders is particularly vulnerable to distractions in the environment, as staff transcribing orders are exposed to noise, interruptions, non-stop unit activity, and too-long or double shifts.

Limited Staff Education:

Many practitioners are not as aware as they should be of situations within their own organizations that have been reported as error-prone, or of similar information published in professional literature.

Limited Patient Education:

Medication use is a multi-step, multidisciplinary process that begins and ends with the patient. Patient education about medications—what they are taking, why they are taking it, and how they should take it—is essential to successful medication administration. Patients can be partners in the prevention of error while hospitalized and need to be educated to safely self-administer medications when they go home.

Quality Improvement Processes and Risk Management:

Health facilities need systems for identifying, reporting, analyzing, and correcting errors and identifying trends, and measurement systems for tracking the effect of system changes. Also, organizations need to take into consideration information from outside sources about errors that have occurred elsewhere. But above all, health organizations need to cultivate a non-punitive approach to error that will encourage frank identification and analysis of errors when they occur.

Steps for Improving Medication Safety

These potential sources of error can be controlled if we design safer systems. With this in mind, the AHA has attached to this advisory a list of successful practices for improving medication safety and for improving overall patient safety within our hospitals and health systems. We encourage your team to review this list of recommendations, plan for implementation, and begin to track your progress.

Our Sources

The recommendations were culled from several reliable sources that are leaders in the effort to reduce and prevent medication errors, and we are grateful for their pioneering efforts. This list includes those organizations, as well as other resources for your organization's efforts.

- American Society of Health-System Pharmacists (www.ashp.org)
- American Society for Healthcare Risk Management (www.ashrm.org)
- Institute for Healthcare Improvement (www.ihi.org)
- Institute of Medicine (www.national-academies.org)
- Institute for Safe Medication Practices (www.ismp.org)
- Joint Commission on Accreditation of Healthcare Organizations (www.jcaho.org)
- Massachusetts Hospital Association (www.mhalink.org)
- Massachusetts Coalition for the Prevention of Medical Errors (www.mhalink.org/mcpme)
- National Coordinating Council on Medication Error Reporting and Prevention (www.nccmerp.org)
- National Patient Safety Foundation (www.npsf.org)
- U.S. Pharmacopeia (www.usp.org)

Books

1. Cohen, Michael R., Ed. **Medication Errors.** Washington, D.C. American Pharmaceutical Association. 1999. (*Contains a special chapter on high-alert medications*

and dangerous abbreviations; rich with insight and practical advice on reducing the risk of error.)

2. Corrigan, Janet, et al. **To Err is Human: Building a Safer Health System.** Washington, D.C. National Academies Press. 1999. (*Comprehensive overview of medical error, containing many practical suggestions and recommendations from several trusted sources.*)

3. Leape, Lucian, et al. **Reducing Adverse Drug Events.** Boston, MA: Institute for Healthcare Improvement. 1998. (*Concepts to reduce adverse events and a model for improvement.*)

Patient Information Brochures

1. *Your Role in Safe Medication Use: A Guide for Patients and FamiliesgT1 is available from the Massachusetts Hospital Association at www.mhalink.org*

2. *Partners in Quality: Taking an Active Role in Your Health Care* is available from the Hospital & Healthsystem Association of Pennsylvania at www.hap2000.org

3. *How to Take Your Medications Safely* is available from the ISMP at www.ismp.org

4. *Just Ask!* is available from the U.S. Pharmacopeia at www.usp.org

Information on Safe Medication Practices

From the Institute for Safe Medication Practices

- **ISMP Medication Safety Alert!**
- **Urgent Error Advisories**

From the U.S. Pharmacopeia

- **Dangerous Abbreviations**
- **Practitioner Reporting Alerts**
- **Drug Quality Alerts**
- **Look-alike Sound-alike Name Lists**

From the Joint Commission on Accrediation of Healthcare Organizations

- **Sentinel Event Alerts**

Successful Practices for Improving Medication Safety

EASILY IMPLEMENTED CHANGES (PROCESS REDESIGN)

The following steps can be implemented immediately by hospitals and health systems. They focus on standardization and simplification of medication system processes.

Fully implement unit dose systems

- Maintain and systematically use unit-dose distribution systems (either manufacturer-prepared or repackaged by the pharmacy) for all non-emergency medications throughout the hospital. Unit dose systems should include, in addition to packaging, systems for labeling and order screening.
- Stress the need for dose adjustment in children, older persons, and patients with renal or hepatic impairment.

Limit the variety of devices and equipment

- For example, limit the types of general purpose infusion pumps to one or two.

Develop special procedures and written protocols for high-alert drugs

- Use written guidelines, checklists, dose limits, pre-printed orders, double-checks, special packaging, special labeling, and education.
- Remove concentrated potassium chloride/phosphate from floor stock.
- Limit the number of possible concentrations for a drug, particularly high-alert drugs like morphine and heparin. Such standardization will allow the use of premixed solutions from manufacturers or centralized preparation of IV medications in the pharmacy.
- Review JCAHO Sentinel Events Alert #11, Nov. 19, 1999. Also, review Chapter 5 of Michael Cohen's 1999 book, "Medication Errors," published by the American Pharmaceutical Association.

Ensure the availability of up-to-date drug information

- Make updated information on new drugs, infrequently used drugs, and non-formulary drugs easily accessible to clinicians prior to ordering, dispensing, and administering medications (e.g., have pharmacists do rounds with doctors and nurses; dis-

tribute newsletters and drug summary sheets; use computer aids; and provide access to formulary systems and other internal resources).

• Review error potential for all new products, including a literature review, before any drug or procedure is approved for use; reassess six months to one year later.

Educate staff

• Provide physicians, nurses, pharmacists, and all other clinicians involved in the medication administration process with orientation and periodic education on ordering, dispensing, administering, and monitoring medications.

• Distribute information about known drug errors from outside organizations like the Institute for Safe Medication Practices (ISMP) and the U.S. Pharmacopeia (USP).

Educate patients

• Patients should be educated in the hospital, at discharge, and in ambulatory settings about their medications, what they are taking, why they are taking it, and how to use it safely.

• Encourage patients to ask questions about their medications.

• Encourage health care providers to work with pharmacists on patient education when patients receive certain classes of medications or are discharged on more than five medications.

Ensure the availability of pharmacy expertise

• Have a pharmacist available on-call when pharmacy does not operate 24-hours a day.

• Make the pharmacist more visible in patient care areas—consider having pharmacy personnel make daily rounds on units, or enter orders directly into computer terminals on patient care units.

Standardize prescribing and communication practices

• Avoid certain dangerous abbreviations (see ISMP and USP for examples); identify a list of unacceptable abbreviations that will not be used in your institution.

• Include all elements of the order—dose, strength, units (metric), route, frequency, and rate.

• Use full names (preferably generic).

• Use computerized reminders for look-alike and sound-alike drug names.

• Use metric system only.

• Use preprinted order sheets whenever possible in non-computerized order systems.

Standardize multiple processes, such as:

• Doses
• Times of administration (for example, antibiotics)
• Packaging and labeling
• Storage (for example, placing medications in the same place in each unit)
• Dosing scales (for example, insulin, potassium)
• Protocols for the use and storage of high-alert drugs

Longer-term changes (systems redesign)

The following steps will require substantial changes to existing organizational systems; they will likely require a longer-term implementation plan and a continual focus on improvement. Many of the recommendations rely on computerization in the physician order-entry and pharmacy dispensing processes.

Develop a voluntary, non-punitive system to monitor and report adverse drug events

• Review policies for how your organization encourages reporting and analyzing errors throughout the institution.

• Encourage open communication and feedback.

• Ensure no reprisals for reporting of errors. Reports will increase if you make it safe to report.

Increase the use of computers in the medication administration system

- Encourage the use of computer-generated or electronic medication administration records.
- Plan for the implementation of computerized prescriber order entry systems.
- Consider the use of machine-readable code (i.e., bar coding) in the medication administration process.
- Use computerized drug profiling in the pharmacy.
- Be a demanding customer of pharmacy system software; encourage vendors to incorporate and assist in implementing an adequate standardized set of checks into computerized hospital pharmacy systems (e.g., screening for duplicate drug therapies, patient allergies, potential drug interactions, drug/lab interactions, dose ranges, etc.).

Institute 24-hour pharmacy service if possible . . .

. . . alternatively, use night formularies and careful drug selection and storage procedures. To facilitate medication distribution after hours, develop policies and procedures to ensure access to consultation with a pharmacist if a pharmacist is not available on-site.

AMERICAN HOSPITAL ASSOCIATION

DECEMBER 6, 1999

Mr. THOMAS. Thank you very much, Dr. Langberg.

Dr. Reardon, welcome once again. Your testimony will be made a part of the record, and if you could do it slightly under five minutes we would be greatly appreciative because we are going to ask questions.

STATEMENT OF THOMAS R. REARDON, M.D., PRESIDENT, AMERICAN MEDICAL ASSOCIATION

Dr. REARDON. I will do my best. Good morning, Mr. Chairman, and members of the committee.

The AMA appreciates your initiative in calling this hearing to focus attention on the major concern to all of us, the safety and quality of care for patients in our health system. The elimination of health system errors is not only a high priority for the AMA, it is an important ethic of the medical profession. We believe that any error that harms a patient is one error too many.

In short, the AMA believes that Congress, States, and the private sector together can achieve significant advances in health system safety and quality without delay. We recommend that Congress do the following.

One, fund research to analyze existing data. This would have an immediate impact on patient safety and provide guidance on designing future data collection methods. Two, fund the Agency for Healthcare Research and Quality, AHRQ, to provide grants for new private sector patient safety research centers across the country.

Three, extend peer review liability and confidentiality protections to those involved in patient safety improvement initiatives. And four, fund AHRQ to disseminate effective patient safety strategies nationwide.

Congress has already taken steps consistent with these recommendations. For example, in the Healthcare Research and Quality Act of 1999 which was just enacted in December, Congress directed the AHRQ to conduct and support research and build public-private partnerships to first of all identify the causes of preventable health care errors and prevent injury in the health care deliv-

ery; develop, demonstrate and evaluate strategies for reducing errors and improving patient safety; and disseminate such effective strategies throughout the health care system.

AHRQ is also directed to coordinate all research, evaluations, and demonstrations related to quality measurement and quality improvement activities undertaken and supported by the Federal Government.

In addition, in the BBA 1997, Congress directed the Medicare Payment Advisory Commission to look at issues related to quality of care for Medicare beneficiaries. Accordingly, the Medicare Payment Advisory Commission's 1997 report to Congress contains a chapter and seven recommendations to Congress addressing the issue of health care errors under Medicare.

One Medicare Payment Advisory Commission recommendation was noted in the IOM is for Congress to pass legislation to protect the confidentiality of individually identified information relating to errors in health care delivery, and that when that information is reported for quality improvement purposes.

The AMA strongly supports the principle under the IOM report that the health care system must be transformed from its existing culture of blame and punishment which suppresses information about errors into a culture of safety that focuses on an openness and information sharing to improve health care and prevent adverse outcomes.

This does not mean that negligent actions should be protected. Accountability for negligent or incompetent actions is already well-established in our health care and judicial systems for physicians and other health care providers. State and Federal courts, State licensing boards, and accrediting bodies such as the JCAHO all function to maintain accountability and standards. Along with accountability though, we must have a system whereby medical professionals can convene to discuss patient safety issues and potential solutions without having their discussions, findings, or recommendations become the basis for lawsuits.

The IOM report recommends a mandatory reporting system for deaths or serious outcomes. However, investing in expensive data collection without clear objectives may in fact divert resources from other, more productive approaches to improve patient safety. We believe that mandatory public reporting could have unintended consequences and elicit less information than a well-designed, well-run voluntary program. In fact, there is no evidence that patients in States that have a mandatory reporting system are any safer than those in States that do not have that mandatory reporting system.

Congress can assist by providing funding to establish extramural research programs that would be administered by AHRQ with centers for patient safety established throughout the country to analyze available data on errors, deaths, and other adverse outcomes. Thus, the AMA strongly supports the IOM report recommendation for Congress to provide the funds and technical support necessary to analyze the information obtained from current error reporting systems and conduct follow-up actions.

The AMA has been working in a concerted effort to accomplish many of the objectives outlined in the IOM report. For example, in

1996 and 1998, the AMA joined with other health care leaders to convene the Annenberg conferences which have already resulted in several initiatives in patient safety that are being undertaken at the State and national level, such as preventing injuries due to medication errors.

In 1997, the AMA established the National Patient Safety Foundation, an independent, not-for-profit organization that convenes forums to discuss patient safety matters and provides grants to stimulate patient safety research. The NPSF was cited several times in the IOM report for its work and is well-positioned to utilize its diverse group of health care leaders and other stakeholders to continue improving patient safety.

I thank you for the opportunity to testify and look forward to your questions.

[The prepared statement follows:]

Statement of Thomas R. Reardon, M.D., President, American Medical Association

Good morning, Mr. Chairman and members of the Committee, my name is Thomas R. Reardon, MD. I am the President of the American Medical Association (AMA) and a general practice physician from Portland, Oregon.

The AMA greatly appreciates Chairman Thomas' initiative in calling this hearing today to discuss the issue of patient safety and the recent report released by the Institute of Medicine (IOM). This IOM Report, entitled *To Err is Human: Building a Safer Health System,* has focused the nation's attention on a major concern to us all—the safety and quality of care for patients in our health care system. We commend the IOM for its efforts in examining the issues of patient safety and quality of care, and welcome the opportunity to work cooperatively with the IOM, Congress, and health care leaders to further advance the quality and safety of patient care.

The elimination of health system errors is not only a high priority for the AMA, it is an important ethic of the medical profession. As an association founded on the commitment of physicians to improve the quality of medical care, **we believe that any error that harms a patient is one error too many.**

And, clearly, the public shares the AMA's concerns. For example, the November/December 1999 Kaiser Family Foundation/Harvard Health News Index reported that 51% of Americans closely followed news coverage on the IOM Report. While much of the information in the IOM Report is not new, there is much that is new and exciting in the private sector's response to the issues raised in the IOM Report. For instance, the AMA has a longstanding commitment to improving patient safety and quality of care, and has been working in a concerted manner, especially in recent years, towards many of the objectives outlined in the IOM Report. Several recent examples of these efforts are the AMA's creation of the American Medical Accreditation Program, the National Patient Safety Foundation, and the Performance Measurement Coordinating Council, and our active participation in the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry and the new National Quality Forum.

We believe that Congress can make a significant positive impact on reducing health systems errors by:

- **Funding research to analyze existing data to determine ways to improve patient safety and provide guidance on the advisability and potential design of future data collection methods;**
- **Funding the Agency for Healthcare Research and Quality (AHRQ) to provide grants for new private sector patient safety research centers around the country;**
- **Extending peer review liability protections to those involved in patient safety improvement initiatives, and confidentiality protections for individually identifiable information reported for health system safety and quality improvement purposes; and**
- **Funding AHRQ to disseminate effective patient safety strategies nationwide.**

Creating a Culture of Safety

The AMA strongly supports the principal underlying the IOM Report that the health care system needs to transform the existing culture of blame and punishment

that suppresses information about errors into a culture of safety that focuses on openness and information sharing to improve health care and prevent adverse outcomes. The AMA also supports the IOM's focus on the need for a system-wide approach to eliminating adverse outcomes and improving safety and quality, instead of focusing on individual components of the health system in an isolated or punitive way.

What can Congress do to help create a culture of safety?

Congress has already taken several steps to help create a culture of safety. In fact, Congress recently passed specific legislative language to reduce errors in the health system. In December 1999, the Healthcare Research and Quality Act of 1999 (P.L. 106–129) was enacted into law to reauthorize the AHRQ (formerly AHCPR). **In Section 912(c) of this law, Congress clearly showed its commitment to reduce errors in the health care system by, inter alia, directing AHRQ to conduct and support research and build private-public partnerships to: "(1) identify the causes of preventable health care errors and patient injury in health care delivery; (2) develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and (3) disseminate such effective strategies throughout the health care industry.**" (emphasis added) Further, by separating this bill from the Senate's patient protection legislation (S. 1344), Congress has sent a clear message on the way to ensure patient safety and quality.

Also, when Congress passed the Balanced Budget Act of 1997 and created the Medicare Payment Advisory Commission (MedPAC), it directed MedPAC to look at issues related to quality of care for Medicare beneficiaries. Accordingly, MedPAC's June 1999 Report to Congress contains a chapter and seven recommendations to Congress addressing the issue of "health care errors under Medicare." In its report, MedPAC recommends that the Secretary of Health and Human Services establish patient safety as a quality improvement priority for Medicare and take steps to minimize preventable errors in health care delivery.

One area where we believe Congress additionally could be helpful would be to enact legislation to expand peer review and confidentiality protections for those seeking to identify safety problems and their solutions, as recommended by the IOM Report. Legislation excluding from liability those engaged in patient safety improvements, similar to the exclusions for biomaterials suppliers contained in the Biomaterials Access Assurance Act of 1998, could be an important step toward a new culture of safety.

MedPAC and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) have made similar recommendations to Congress. The June 1999 MedPAC Report recommends that Congress 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." The IOM Report states that MedPAC's recommendation is a "promising alternative." Likewise, JCAHO recently testified that it has been seeking federal legislative protection to protect from disclosure information developed in response to a sentinel event and shared with an accreditor.

The matter of accountability for negligent or incompetent actions is already well established in our health care and judicial systems for physicians and other health care providers. State and Federal courts, state licensing boards, and accrediting bodies such as JCAHO all function to maintain accountability and standards. However, the very fear of existing legal liability or its misapplication are the greatest hurdles to pioneering patient safety efforts.

For example, when the Anesthesia Patient Safety Foundation was founded, legal liability was a major concern. The creative approach employed by the anesthesiologists was to start by looking at claims that have already been settled or closed. Unfortunately, waiting for a case to settle or close before a problem can be discussed without the fear of litigation needlessly delays important feedback that otherwise could result in an immediate solution. **Congress can help create a culture of safety by allowing medical professionals to convene to discuss patient safety problems and potential solutions without having their discussions, findings, or recommendations become the basis for class action or other lawsuits. If the fear of litigation continues to pervade efforts to improve patient safety and quality, our transformation into a culture of safety on behalf of our patients may never be fully realized**

The IOM Report recommends a mandatory reporting system for deaths or serious adverse outcomes. However, the AMA agrees with the AHRQ, the VA, and many leading organizations and experts on health care matters that mandatory public reporting could have unintended consequences and elicit less information than a well-designed, well-run voluntary program. We believe that other recommendations in

the IOM Report offer more fruitful avenues for Congress to consider at this time. 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. Simply focusing on finding the individuals who contribute to an error completely ignores the epidemiological and health services research approaches that have produced many notable advances in the quality and safety of patient care.

Any approach to improving patient safety should, at a minimum, include a non-punitive mechanism for reporting incidents, post-incident evaluations for identification of system changes to prevent subsequent occurrences, and federally guaranteed legislative protection from discovery for all aspects of information gathered to improve patient safety. System-wide trust and communication are fundamental elements for successful reform.

Non-punitive approaches have yielded useful results in related contexts. For example, Congress should consider the experience of the past several decades in preventing hospital-acquired infections. With the scientific support of the Centers for Disease Control and Prevention and AHRQ, hospital epidemiologists and physicians specializing in hospital-based infectious diseases have systematically undertaken thousands of investigations of endemic and epidemic infections. These studies have been done in a blame-free environment in which learning was the major goal. The infection controllers observed that spontaneous reporting of infections and broad, voluntary surveillance provided misleading information. They recognized the need for targeted surveillance and focused objectives for the infection control program, as well as for simple, clear definitions of infections. Hospital-acquired infection rates have declined precipitously as a result of these efforts.

There is a great danger in oversimplifying the task of assuring patient safety. Like infant mortality, teen pregnancy, and flu virus, patient safety must be approached using the same epidemiological and health services research methods that we use to address other public health problems. Truly effective quality improvement requires intensive surveillance with monitoring, tracking, analysis of variations, assessment of interventions, feedback, and education. Organizations must focus on studying and improving the entire process of care, not just identifying blame. Enumeration of errors without sound scientific analysis is futile, and diversion of scarce resources to cataloguing all errors could be cost inefficient and unproductive.

In other words, more data collection for the sake of having more data, absent specific goals and scientifically designed studies, is unlikely to yield real improvements in patient safety Indeed, investing in expensive data collection without clear objectives may in fact divert resources from other more productive approaches to improve patient safety. As MedPAC stated in its June 1999 Report, "In devising error-reduction initiatives, the program should conduct small-scale tests of approaches that have been developed for other industries as well as for health care before adopting approaches for programwide use."

The AMA's approach to reducing medical errors is similar to that recommended by the IOM in its report. In fact, when the IOM Committee on Quality began to examine this issue, we were pleased that the National Patient Safety Foundation (NPSF) (which shares the AMA's goals to improve patient safety) was invited to discuss its efforts and provide information that contributed to the report. Thus, the AMA welcomes the IOM recommendation for a system-wide approach to reducing medical errors in which punitive efforts are rejected and instead, efforts to create a culture of safety are recommended.

Health Services Research for Patient Safety

The AMA has been a pioneer in the effort to reduce health care system errors and ensure that our patients receive safe, quality health care. For example, in 1996, the American Association for the Advancement of Science, JCAHO, and the AMA joined with the Annenberg Center for Health Sciences to convene the first multidisciplinary conference on errors in health care. The outcome includes several initiatives in patient safety that are being undertaken at the state and national level, such as preventing patient injuries due to medication errors.

Given the importance for this agenda and the imperative for physician leadership, the AMA established in 1997 the National Patient Safety Foundation (NPSF), a broad-based partnership of health care clinicians, consumer advocates, health product manufacturers, public and private employers and payers, researchers, regulators, and policymakers. The NPSF is an independent not-for-profit organization that now serves as the forum for a diverse group of concerned individuals to think and talk about the issues and impediments to patient safety.

The initiatives undertaken by the NPSF are similar to those recommended in the IOM Report. For example, the NPSF has convened a group of national authorities

concerned with reducing medication errors. This group has identified 41 challenges for improvement and is now in an implementation phase. Also, the NPSF has developed an agenda for research that seeks to identify the core issues that should be targeted by the broader research community, and has awarded eight research grants to advance patient safety. Further, with the support of the AHRQ, the NPSF is cataloging patient safety research projects that will document the extent of patient safety research as well as identify gaps in existing knowledge.

Congress can further assist with these private sector efforts to reduce health system errors and adverse outcomes by providing funding to private sector organizations to analyze available data on errors, deaths, and other adverse outcomes. This will help identify their root causes and potential solutions.

Although the IOM has recommended a nationwide mandatory reporting system for deaths or serious adverse outcomes, we fail to see any linkage between the mandatory reporting systems established to date and real improvements in patient safety and quality of care. The IOM Report states, for example, that at least one-third of states already have adverse event reporting systems, and the IOM interviewed 13 of these states. However, **there is no data to indicate that patients accessing the health care systems of states with mandatory reporting systems are any safer than those in states without reporting systems.** Indeed, the IOM Report makes no such claim.

The AMA strongly supports the IOM recommendation for Congress to provide the funds and technical support necessary to analyze the information obtained from current error reporting systems and conduct follow-up action as needed. A focus group that the IOM conducted with 20 states identified a clear need for resources, tools, methods, and protocols to allow them to constructively address this issue. In addition to the states and the FDA, private sector organizations such as JCAHO, NCQA, U.S, Pharmacopeia, as well as private health insurance companies, have a wealth of data that has yet to be mined for information that could be used to improve patient safety.

The IOM Report does not describe how a nationwide mandatory reporting system—or even the state reporting systems that are in place right now—would lead to elimination of errors and improvements in patient safety and quality. The appropriate way to target the nation's scarce resources to improvements in health system safety is to fund research in the private sector to determine how best to utilize data to improve quality of care. What data elements are useful? How should these data be analyzed, tabulated, and evaluated to identify root causes, system problems, and safety problems? How can they be used to identify solutions and prevent future errors? How can such information be integrated into educational curriculums, practice guidelines, accreditation programs, and performance measurement? These are some of the questions upon which we must focus.

As the IOM Report notes, the sheer volume of reports to a system does not determine the success of that system. To the contrary, obtaining data on all deaths or adverse outcomes in a national mandatory reporting system would represent an unnecessary and inefficient allocation of resources. Programs that collect larger numbers of error reports are unlikely to yield much new information beyond what can be learned from a comprehensive analysis of a limited sample of error reports.

To date, the approaches that have been most successful in health services research provide government funding for targeted studies and demonstration projects conducted in the private sector or with private sector partners. Extramural research programs such as the Multipurpose Arthritis and Muskuloskeletal Disease Centers funded by the National Institutes of Health, the Veterans Administration's Health Services Research and Development Field Programs, and the Evidence-based Practice Centers (EPC) funded by the AHRQ are excellent examples. Similar extramural research centers could be established with AHRQ grants to focus on research in patient safety. As an alternative to establishing a Center for Patient Safety within the AHRQ, the EPC model could be used with AHRQ administering a program of grants for research and pilot projects to be conducted in several different patient safety centers. The nation's leading health systems, for example, could be funded to establish their own internal reporting systems and conduct research on patient safety problems and solutions using their own data. In addition, the activities of non-profit organizations, such as the NPSF, could be advanced considerably with new government funding.

Conclusion

The AMA believes that true reform must include all components of the health care system and not focus only on individual components. Hospitals, physicians, nurses, pharmacists, drug and device manufacturers, nursing homes, and others must all work together and be encouraged to work together to identify,

study, and solve system-wide problems that could cause errors or adverse outcomes. Our common goal must be to detect errors and system barriers to make corrections before a patient is harmed.

Simply adding more regulation and more mandates are not the answer to improve patient safety and quality. The AMA strongly urges Congress to advance with the same caution and deliberation as the medical community in its efforts to create a culture of safety for patients in all health care settings. Congress must understand the efforts already being implemented in both the public and private health care delivery systems before passing legislation. When and if legislation is enacted, we must all be certain that it will support and enhance the initiatives already underway, and not set back these efforts. As stated in the IOM Report, a system must be designed to detect, prevent, and minimize health care system hazards to reduce errors. This can be achieved best by first acknowledging that the vast majority of health care system errors are not intentional and must be distinguished from truly negligent behavior. The focus must remain on reforming the system, not punishing the individual. We must collectively focus our efforts on identifying solutions that benefit patients.

Nationwide dissemination of the identified solutions would do a great deal more to improve the safety of the nation's health care system than would a nationwide mandatory reporting system. As it has done with dissemination of practice guidelines, Congress should direct the AHQR to disseminate current information on patient safety and prevention of adverse events, and provide grants to research currently available data.

The AMA is committed to continuing and redoubling our efforts to work with Congress and our partners in the medical care system to achieve a health system in which patients are assured of safe, quality health care. We appreciate having the opportunity to be here today to support the IOM's efforts to reduce health system errors. Thank you.

Mr. THOMAS. Thank you, Doctor, and I am sure your handwriting is legible as well.

[Laughter.]

Mr. THOMAS. We are going to recess until 12:15.

[Recess.]

Mr. MCCRERY. [presiding] The committee will come to order. Mr. Thomas has been unavoidably detained for a few minutes and he has asked me to reconvene the hearing, which I am pleased to do.

Dr. Reardon, let me begin with you, if I may. As you know, I am very interested in this topic of liability. The AMA and members of Congress have talked for years about the liability system in this country and the flaws in the liability system, and we have tried mightily to correct some of those flaws through medical malpractice reform here at the national level, but not successfully. So we have depended on the States to go forward, and many have, with very reasonable reforms to their medical liability systems.

I noticed in your testimony that you talked about the failure or the culture of blame and punishment. You were speaking a little fast, which we appreciated, but it sounded as if you were saying that this culture of blame and punishment was producing bad results. That it inhibited the discovery of errors, omissions, that could be corrected or addressed. Was that the implication of those remarks?

Dr. REARDON. Yes, it was. Let me expand, if I may, just a moment. I think what I was talking about is that we need to change to a system of openness where we have open discussions and feel free that the information is not going to be discoverable, for instance, for medical malpractice.

For instance, I made a statement that we do have a system of accountability which is the court system, and if there is a medical error for instance and there is a lawsuit on one side, at the same time we need to be able to have an open discussion and what went on with that medical error, what happened, why it happened, and what we can put into place so it will not happen again. Those discussions we would like to see protected. They could be peer review discussions of a medical error. But we would like to have those confidential and protected so that they could not be discovered and used against the physician in a lawsuit.

We think if we do not have that, as was pointed out I think for the anesthesiologists when they first started their system, they sometimes put off the discussion of the medical error for three or four years until the suit was settled. I think you lose an opportunity there to talk about it when it is immediate and fresh and the information is fresh in everybody's mind and you can, I think, do a much better job.

Mr. MCCRERY. Does the liability system itself and this culture of fear or blame and punishment account at all for the fact that very few doctors around the country have been brought up before voluntary licensing groups around the country? I have got some data here that says that in a typical year the number of physicians who are brought before State boards of medicine is less than 5,000 around the country. Whereas, the report that we got recently from the IOM estimates that between 44,000 and 98,000 patients die a year from medical errors. I know that it not all doctors, but there does seem to be a disparity there.

Is that culture of blame and punishment and the liability system partly to blame for the lack of enforcement in your licensing boards?

Dr. REARDON. I think there are two issues here. First of all, many of the medical errors we are talking about are system errors, oftentimes not attributable to any particular individual but a fault in the system. The other issue I think, Congressman, is that a malpractice suit does not mean you are a bad doctor. You can provide the best care, do the best that you can and have an adverse outcome. So that the best doctors can get sued over the course of a lifetime.

So this does not ordinarily come to the attention of a State licensing board unless there are a series of errors on an individual doctor, and then a licensing board may feel inclined to step in and review that particular physician. So I think there are two different issues there.

Mr. MCCRERY. Yes, they are two different issues but why—let me just ask you. Why are there so few doctors brought before licensing boards for discipline? I mean, I am concluding that it is few. It seems to me to be a few. Maybe you disagree and you can explain why. But it seems to me to be a few in comparison to the number of physicians we have and the number of instances of medical delivery.

Dr. REARDON. I think the most common reason a physician is brought up before the licensing board is substance abuse, either alcohol or drugs. Probably the other issues can be sexual involvement with patients, sexual abuse, if there is a pattern of egregious med-

ical practices, and those issues do come up. Now I think it also depends on the individual State. I come from the State of Oregon, which I think we have a very active board. There are probably 80 to 100 physicians on probation at any one time, being monitored by the State board.

But also the State board of medical examiners are limited by two things. One is the powers invested in them by the State legislatures through the medical practice acts; and two, their funding. So I think those are the two issues that we look at, as we have criticism of boards and some boards are more active than others, they have some limitations based on what the legislature invests.

I cannot really comment whether 5,000 is a lot or not a lot, but I can tell you what the most common investigations are.

Mr. MCCRERY. If in fact most of the investigations are not related to the delivery of health care but rather with personal problems with the physician, that underscores to me the need to at least question whether the licensing procedures and the disciplinary procedures that are in place are effective.

Again, I want to try to relate it to this culture of blame and punishment. Is it in fact part of the culture among physicians not to expose fellow physicians that they know may be guilty of errors, omissions in their practice because they do not want someone to put the finger on them in this liability system that we have for fear of being punished?

Dr. REARDON. I can only comment on my own experience, and that is that I think it behooves all of us if we see a pattern with a physician of aberrant practice, of poor quality, to report that, and I think that is reported from time to time. But the fact of a medical error does not mean that he is a bad physician. We are taught in medical school to try and be perfect, to do everything right. And yet, because it is a complex system, patients are not—are different. You sometimes treat the same condition differently in different patients. So there is a lot of variation in that care.

But an adverse outcome or a malpractice suit does not mean that is a bad doctor. I think there needs to be a pattern of behavior.

Mr. MCCRERY. I agree, and I certainly do not mean to imply that every doctor who is guilty of some error or omission is a bad doctor. We all make mistakes, and unfortunately doctors are human too and they do make mistakes. But again, I think that we need to examine all the systems that we have put in place to try to exact quality care and reexamine those in light of the data that has come to light in the last few months. Certainly the disciplinary procedures that are in place are one of those systems that we need to look at.

I am a lawyer. We have the same kind of similar disciplinary boards and so forth as the medical profession and ours probably does not work very well either, to tell you the truth. So maybe we should take a look at that, among other systems that we have in place.

Now our chairman is back, and I am pleased to turn it back over to the chairman since I have to go to another function across the way. Mr. Chairman, I am going to return it to you. And before that, Mr. Stark, are you prepared to inquire of the witnesses?

Mr. STARK. I am not really prepared, but I am ready.

[Laughter.]

Mr. STARK. I guess I would ask both Dr. Langberg and Dr. Reardon, my sense is that you both—I do not know whether you object to running a reporting system and improvement system through the PROs (Peer Review Organizations) or prefer to do it through the AMA or the AHA. But I think that is a basic theme that I am getting, that somehow you want to do it yourself—I mean, the organizations you represent—and not do it through an independent agency.

But I think both of your constituencies have worked with PROs for 18, 20 years now, and the information I think is confidential, and I think the incentives are right. The AMA does not have half the doctors in the country. The AHA probably has all the hospitals or 90 percent of them. So if the AMA does it, we are not dealing with half the doctors, and that seems ineffective. The AHA would be investigating the people who pay their salaries, and that does not seem very productive.

So what would be wrong with having the PROs run a system of supervising and setting up error reduction plans and dealing with it? Dr. Langberg? Dr. Reardon?

Dr. LANGBERG. I think the fundamental question to any reporting system is what is the purpose of reporting and—

Mr. STARK. We have talked about that this morning. We are all trying to reduce errors.

Dr. LANGBERG. And in that light, the question is whether reporting to a PRO and having the PRO be responsible for improving errors within hospitals is the best way to get errors to be reduced. Working to improve care at my facility and watching the way in which people come together to address difficult, complex clinical circumstances and move forward.

Mr. STARK. Doctor, you are missing the point. Cedars has a good plan. Let us stipulate to that. But there are some hospitals—the San Leandro Hospital that is owned by Columbia in San Leandro, California is not worth poop. They do not have a good plan. Now how are we going to get them to have as good a plan as you have? And what is wrong with having PROs say, "look, you have got to have a plan"? Then go ahead and let them review and report back. That is what I am getting at.

I mean, what you are talking about is the plan in your hospital. Let us stipulate that that is excellent. Now how do we get the—you are suggesting the AHA is going to get other hospitals to do it? Well, I do not know. I think that the PRO groups would do it more efficiently and not be captive to the people who pay their salaries, which is the problem with the AHA.

Dr. LANGBERG. I thank you for the stipulation about the quality of my institution's program. What I want to try to describe is that in our experience and in the hospitals' experience generally there already exists organizations to whom we report in one form or another our programs and plans to improve care around these kinds of issues.

As you know, Congressman Stark, in California the accreditation process for hospitals involves a tripartite review of the California Medical Association, the State Department of Health, and the Joint Commission. They do a very thorough review not only of our out-

comes, but of our internal processes and systems which identify and improve errors.

Having recently gone through that experience in the last six months, it is a highly detailed, exhaustive experience. Our obligation is to respond to recommendations and improve any deficits that were found by that review within specific timeframes we face financial consequences if the recommended improvements aren't implemented and adhered to.

So I guess the response I am making is, firstly, that I believe there already are in place organizations that can be engaged to assist hospitals in developing those programs if they do not already exist.

Secondly, if I can make a couple comments about PROs. I agree with all the comments you made regarding our experience with them. My colleague, Dr. Golden, will be testifying later. I have a great deal of respect for the PRO. However, the PROs are generally viewed by practitioners as governmental agencies. I know they are technically not, but they are viewed as governmental agencies.

Mr. STARK. Okay, that answers that. Let us try this, Doctor. We have had 500 reports of workers mixing up two similar sounding medications, and before you get around to saying it it becomes obvious, we need to label it.

Each year we have 800,000 accidental needle sticks to health workers, some of which lead to death from AIDS and hepatitis. So it would seem that we need to reengineer needles for the safety of the workers, and in California, which you mentioned—I happen to be from there—we have legislated that that be necessary. Yet the AHA is still resisting doing that nationwide. Tell me how you are helping us there.

Dr. LANGBERG. The AHA is working with OSHA—

Mr. STARK. No, they are resisting it, not working with. Let us get that straight.

Dr. LANGBERG. As I understand it, the AHA is at least in dialogue with OSHA about ways in which to look at this nationwide. I hesitate to go back to my own experience in my hospital, however, at this point needles will not go away, and sharp things will not go away. I do not mean—

Mr. STARK. Okay, Doctor, thank you.

Dr. Reardon, what does the AMA say about working with PROs to accomplish some kind of review and collection of data and a system for helping to reduce errors?

Dr. REARDON. Mr. Stark, I think in my testimony I mentioned that we were supportive of the Agency for Health Research and Quality as being an agency potentially for doing that, with patient safety centers across the country for gathering data. Quite frankly, the answer I think from the physicians' point of view is that PROs, which are under HCFA, I think, are looked at by many as governmental and somewhat punitive in the past, and this I think would bother the physician community that they have been punitive. We would like to do this as an open process, to change the culture to one of safety away from punitive and punishment.

Mr. STARK. Can you give me an example of punitive actions that PROs have taken against physicians?

Dr. REARDON. I am not sure I can give you—I can give you in general terms——

Mr. STARK. No, no, I would challenge that.

Dr. REARDON. I cannot give you a specific example, I am sorry.

Mr. STARK. I think what you are both saying then is, you have both said you do not want Government to do this, you want to do it yourselves basically, or through some voluntary means—which is what we have had for the past 20 years or more and you have not done it. The docs have resisted, the AMA has resisted recertification. The hospital association has resisted safe needle requirements.

The indication is that the professional organizations are not willing to really do much on their own unless there is some requirement. Now I would be perfectly willing to let the courts do it, but then you want to be absolved from any chance that anybody will sue you.

So in the absence of anybody being able to sue you, and the absence of anybody being able to require you to do it except the guys paying their dues where you are all in the same club, I am just a little worried that it will not get done without a little more incentive. It does not have to be Government, as long as it is independent. It is my understanding the PROs are independent. We happen to pay them.

But the problem with JCAHO, which is a lousy organization, is that you guys pay them in the hospital community, so they cave in to you. And about every five years we have to threaten to fire them, and then they get tough and go look at some hospitals. But the rest of the time they just go out and have lunch with the hospital administrators and do not do poop.

Well, we are back to the same-old, same-old, Mr. Chairman. I mean, if we do not have laws, then I do not think we will get anything done. But these guys do. Thank you, gentlemen.

Chairman THOMAS [presiding]. Thank the gentleman.

Someone who has highlighted particular areas in medicine in a rather dramatic way is a doctor who also happens to be a fairly successful author by the name of Robin Cook. He has a penchant for one-word titles: Fever, Brain, Toxin. I read one called Coma, which was I guess, for wont of a better word, a diatribe against managed care, and that there was in essence at this one hospital a criminal conspiracy to kill people. You can imagine my reaction after having read that novel and looking at the IOM report, that those people who were consciously doing it are pikers.

Now I anxiously await a novel by Robin Cook, and I would even be so bold as to suggest a title: Oops. But I do not think he is going to write one, because I think when you have a centristic view of the universe and that all planets orbit around you, it is extremely difficult to address the fact that problems may, in fact a majority of problems may initiate with you. Part of the gentleman from California's frustration is the fact that if we are going to do something in this area, the same-old, same-old is probably not going to be acceptable.

Now I am willing to go along with you, and I would like to ask you a series of questions so that you can increase my comfort level that what you are advocating will in fact produce results. Dr.

Langberg, in your testimony in fact you said that the American Hospital Association is working with several organizations—I think it was three, as a matter of fact—to help improve patient safety and reduce medical errors. Have you got any specific data to show that medical errors have been reduced?

Dr. LANGBERG. The AHA's partnership with the Institute for Safe Medication Practices was announced in December, so I do not have any information in the last six weeks.

Chairman THOMAS. Do you know when we might get some evidence that the structure that you have initiated that you wish us to allow to self-nurture will produce changed behavior; i.e., fewer medical errors?

Dr. LANGBERG. I can, Mr. Chairman, give you the timeframe for the program the AHA has created afterwards.

Chairman THOMAS. Okay. And you oppose mandatory reporting? Or are there conditions under which you would accept mandatory reporting?

Dr. LANGBERG. Keeping in mind that the purpose of reporting is to improve care, I know from my own direct experience that virtually every meeting of physicians and other caregivers, every peer review meeting, every root cause analysis meeting generally starts off with a discussion about confidentiality, non-disclosability. In California we have an evidence code that goes by the number 1157 that allows for peer review to take place without fear of civil litigation, and that has been an extraordinary aid to open up discussions in our institution.

My fear about mandatory reporting is along the lines of chilling what in my experience has been dramatically productive discussions among colleagues, inclusive but not only with physicians, as we try to improve things.

Chairman THOMAS. You mentioned California, and obviously Cedars-Sinai is in California, and California has a mandatory reporting law on particular events. I am reading from the back of the IOM book which is invaluable to give me a State by State analysis. Do you believe that the mandatory reporting structure in California has had an ongoing chilling effect in the collection of data and the correction of medical errors since it has been in place since like 1972?

Dr. LANGBERG. No, I do not believe it has had a chilling effect.

Mr. THOMAS. So if we use a model kind of like California has then it would be okay?

Dr. LANGBERG. I think the practice in California and the kind of things that have to be reported, to the best of my recollection, tend to be move of catastrophic in nature, epidemic kinds of issues that may be occurring in a hospital, in contrast to the output of individual peer review root cause analysis looking at what may have gone wrong or close calls in a given case.

Chairman THOMAS. It has as a list of reportable events, disappearance or loss of a patient. I assume that means not having them expire, but you simply lose track of them. So lost patients are critical to this reporting structure, but not patients who have been terminated by medical errors. Do you know of the California law and why maybe it would not include that as a reportable event? And would you then be adamantly opposed to the California law

if it were amended to include that kind of an item as a reportable event?

Dr. LANGBERG. I confess ignorance on the legislative intent of the California law, having been in place as you point out for a couple decades. The question of reporting a death due to medical error is obviously a complex one, and my earlier comments went back to the effect of having to report, and what in which settings that would hamper our ability to surface concerns about a case and the detailed analysis required to get the answers.

Again from my direct experience, Mr. Chairman, the causality in any case of unexpected outcome is always complex. I have yet to be involved in an analysis of a case——

Chairman. THOMAS. As is the case of an airplane crash. As is the case in many other instances. Let me try to explain the situation we are in. I am trying to let you make your case. I want to turn to the gentleman from California on my left and say, I have a high comfort level that your push to get a mandatory structure is not one that I can support, and you guys have got to help me.

The question is this, if we could show that mandatory reporting reduced deaths due to medical errors, is not the ultimate thing to make sure that people do not die through medical errors? And if a mandatory structure could show that would you be in favor of a mandatory structure? Or are you just philosophically opposed to the idea of mandatory? That is what I am trying to understand here.

Dr. LANGBERG. For me it is not a matter of philosophy. For me it is a matter of direct experience with people going through this.

Chairman THOMAS. So I cannot create a comfort zone, change the liability laws, utilize that FAA total confidentiality structure? I have got a clean sheet of paper. What is it that you believe you need in place to have a minimal comfort level with a mandatory reporting system? Is there no list that we can write that would create a comfort level for you on a mandatory reporting system?

Dr. LANGBERG. Given the context of a mandatory reporting system——

Chairman THOMAS. No, we write the context.

Dr. LANGBERG. Right. No, given the question, which is given a mandatory reporting system, what would be required to make me more comfortable with that. That is the question.

Chairman THOMAS. Make you minimally acceptable of it.

Dr. LANGBERG. Right. Even though, as I know you know already, our position is to support a voluntary system. But in the context of a mandatory system, our biggest, first concern would have to be on the protections of peer review and its discoverability, disclosability in any kind of public and legal setting.

The ability to extend what are perhaps best practices in States and other locations that provide confidentiality protections resulting in full dialogue. These kinds of things I think ought to be identified and perhaps replicated on a national basis. They exist already in some locations. So that would be the first issue that I would want to put before you.

Chairman THOMAS. If we could come to an agreement over the next month on that, Dr. Reardon, if the conference on patient protection had not concluded and we were able to present that as an

additional item, which after all on patient protection if you are going to reduce the number of patients that are being killed that would seem to be a useful location and a very timely vehicle. Would the American Medical Association consider that a poison pill?

Dr. REARDON. Mandatory reporting are you asking me, Mr. Chairman?

Chairman THOMAS. No, all of the criteria that you folks write that you need to have acceptable mandatory reporting. Or better yet, your vision of voluntary reporting. If we offered that in the conference so that it could move through the House and the Senate expeditiously and be put in place, because I am quite sure the President would not veto something that would reduce medical errors and therefore accidental deaths; would that be a poison pill to you?

Dr. REARDON. May I respond, Mr. Chairman, about my concerns about mandatory reporting?

Chairman THOMAS. No, I asked voluntary. We will do voluntary.

Dr. REARDON. We would certainly be willing to look at a voluntary system and work with you on that.

Chairman THOMAS. Do you know how high a comfort level that is? Zero. You write it and give it to me, and then I put it in. Would you call that a poison pill in the patient protection bill?

Dr. REARDON. I am sorry, sir, you are asking me that we would write it and give it to you?

Chairman THOMAS. Sure. I will put in what you write. Would that be a poison pill?

Dr. REARDON. I would not look at that as a poison pill, no.

Chairman THOMAS. You would not.

Dr. REARDON. No.

Chairman THOMAS. Okay, that is a starting point. Now we will work on it.

Dr. Langberg, in your testimony you briefly mention JCAHO, the Joint Commission on the Accreditation of Hospitals. The commission has an external sentinel event reporting system in which hospitals participate. I believe that was started in 1996. Was there general acceptance and willingness to go with that system when it was first put in place or did hospitals resist it?

Dr. LANGBERG. There are two components to the sentinel event system and I actually would like to go on record as acknowledging the Joint Commission for coming up with this, and Dr. O'Leary personally for his role in advocating this.

Chairman THOMAS. And that was the basic position of virtually all hospitals, going on record, thanking, supporting, and willing to go forward?

Dr. LANGBERG. I do not know what the former positions were in previous testimony. The two components had to do with the creation of a sentinel event system. The second component had to do with the reporting of the outcome of those systems.

In my institution we have taken that direction to heart and have created, I think, an outstanding sentinel event—we call it significant adverse event system that tries to capture what might be sentinel events as defined by the Joint Commission as well as near misses, and encouraging all kinds of people in the institution from volunteers, nurses, transporters, to physicians, and administrators,

to report anything they might see through a process that leads to a rapid root cause analysis and an identification of problems and attempts to fix them. That has been a great boon to our process to improve care.

The question of reporting got a lot of evaluation at the hospital level, and from my recollection there were two primary considerations. The first consideration was that the protections under our State's non-disclosability law would only be valid if the discussions were taking place between designated peer review bodies within the State. So going to an out-of-State reporting peer review, according to legal evaluation, punch holes through the very protection in peer review that we were hoping to maintain.

The second issue had to do with issues around liability and malpractice considerations, if again this information was reported out of State. Those two considerations, not the reporting concept but the concept of chilling the atmosphere where the good work was in fact able to be done, was what the general objections were about.

Chairman THOMAS. I will just tell you that my guess is that there is probably not a comfort level that the only response that we would make would be three five-year demonstration projects under HCFA as our only response to this problem. There will be a contest as to the question of mandatory versus voluntary, and I believe you people will have a significant role to play in whether or not someone such as myself look seriously at mandatory reporting.

To the degree you are forthcoming, to the degree we actually set up a structure which does what we believe needs to be done, to the degree you minimize the arguments which I believe to have less merit than you attempt to present, since time I think they do not have merit, then we can try to put a fairly hefty voluntary structure. I still do not know that there may not need to be some mandatory.

I will tell you that there is no question in my mind that there has to be an absolute guarantee of the privileged nature of the information, the confidentiality. And I am more than willing, since I have tried to offer six times in the past and I did on this bill which the AMA called medical malpractice reform a poison pill on the patient protection legislation, an opportunity to change the liability question.

But somewhere in this matrix, looking a bit at the VA because they do, I believe, have a liability issue and I want to talk to them about that. Looking at what has occurred in aviation, notwithstanding all the differences that are involved in these two areas, there is, in my opinion, something that is going to be done.

To the degree it is something that you would rather live with than not live with is basically up to your folks in your willingness to have positive input in the process. By positive, that is not to continue a dialogue of great concern, upset by, unwilling to. Otherwise we will just write it without your input.

I would value your input in a constructive way in setting up a procedure which significantly—I would love to say 50 percent in five years—which significantly reduces medical errors for which I can see no conceivable reason for continuing. You people are eminent professionals, both in the institutional area and in the per-

sonal practice area. And you cannot sit here and tell me your professions on their own, pledging a professional commitment to do no harm, have produced a significant shift.

If you believe things are better than 10 years ago, show me. If you believe the things that you have done in the last three years are showing concrete results and we should wait for them to show more concrete results, show me.

But if you cannot, then we are going to move. It is absolutely unacceptable, especially given the beginning of every statement by every medical person, our pledge is to do no harm. You are. Through errors and failures to set up a systematic procedure of examining why things went wrong. We have got a lot of what. If we do not get to the why we will never change the what.

I want to thank you very much. I look forward to working with you. Apparently the conference on patient protection is going to extend longer than we thought. I have got a nice little slot available for a number of what I believe to be appropriate items that we could fit in there and expeditiously move them to the signature of the President. I would hope that you would examine your medicine chest and carefully reevaluate, Dr. Reardon, what you think is or is not a poison pill.

Thank you very much.

The gentleman from California.

Mr. STARK. I just want to say that thus far I think you and I can work together on this. Whether there will be a conference to get it into or not is a question. I suppose it depends on the health of the Democrats at this point.

But I am struck also by the Chair's interest in changing the way, for instance, the way we reimburse teaching hospitals. Now I have never heard any complaints from the American Hospital Association when we spend all that money to help them run their teaching hospitals. They like Government then, do you not, Dr. Langberg?

Dr. LANGBERG. I think the teaching hospitals—

Mr. STARK. It is kind of helpful, is it not?

Dr. LANGBERG.—appreciate the reimbursement that is given them.

Chairman THOMAS. Like the recent readjustment which gave a couple of bucks to California, versus New York.

Mr. STARK. They love us when we are paying them money. But when we suggest that maybe we get quality results and pass a law, then they do not want Government interfering.

Chairman THOMAS. Excuse me. Is the gentleman suggesting that they are in the human condition?

Mr. STARK. I may be. I just want to remind you that the next time you come in to ask for money, that you were here today saying do not get in our way, in terms of passing laws that would require higher quality. We would just make a note of that, because we will remind you of that again the next time the AHA wants to come and ask for help.

Chairman THOMAS. Again, thank you and I look forward to working with you. We do have some opportunities here and I believe it is incumbent upon us to do what we can as much as we can, not just in the current framework but moving forward. Thank you very much.

Now, thanking them for their indulgence, I would like to ask the last panel to come forward. There obviously was a reason why we did the panels in the order that we did, because I was anxious to have some interactive comment from some individuals who I think are actively involved in trying to make it happen in reflection of those to whom it is happening to.

Our panel consists of Dr. James P. Bagian, Director, National Council for Patient Safety, Veterans Health Administration, U.S. Department of Veteran Affairs; Dr. Kenneth Kizer, recently from that environment, now President and Chief Executive Officer, National Quality Forum for Healthcare Measurement and Reporting; Dr. Dennis S. O'Leary, President on the Joint Commission on Accreditation of Health Care Organizations; and Dr. William Golden, President, American Health Quality Association.

Thank you all. Your written testimony will be made a part of the record and, in the time that you have, you can address us in any way you see fit.

Why do we not start with you, Dr. Bagian, and then move across the panel.

STATEMENT OF JAMES P. BAGIAN, M.D., PE, DIRECTOR, NATIONAL CENTER FOR PATIENT SAFETY, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERAN AFFAIRS

Dr. BAGIAN. Thank you, Chairman.

It is a pleasure to have been asked to come here today. You already have my record, as you mentioned. I will not talk directly about that, but try to address some of the issues you brought up earlier in the morning, because I think we have a number of things we can concretely point to that might be a source of discussion.

To start out with one thing I would like to point out, and I know when Ms. Connell was up here she referred to it as well, about aviation. The problem in aviation was not much different from medicine 50 years ago. In fact, my father was a fighter pilot during World War II and stories he would tell me as a boy, it did not seem much different.

He would talk about in the afternoon, at training command, you could look around the horizon on any given afternoon and see a pillar of smoke somewhere from a crash. In fact, if you look at the statistics during World War II, more planes were lost in training and non-combat than in combat. That is no longer the case. It is because aviation looked at it in a different way. They could not just keep doing the same thing, they had to do it differently.

I think medicine is at the same point now, too, and that can refer to the comments that were made before, what has changed? I think things do need to change.

In the VA, we think reporting is important. The purpose for reporting, as has been mentioned, is not just to report. I think you were the ones that mentioned about the qualitative versus quantitative. Just counting does not do it. If Linda Connell was here, she would tell you, or Charlie Billings, her predecessor, that it is not about counting. It is about identifying vulnerabilities and then what you do about them.

To just know that they are there and do nothing serves no purpose. It might keep somebody employed, but that is not the point.

The point is what do you do to make it better, and how do you test that.

Along those lines, the VA looked at this system, and we have several systems. One of the ones I will talk about is an internal mandatory reporting system. When we say mandatory, I think there has been a lot of talk about mandatory and voluntary——

Chairman THOMAS. Dr. Bagian, as a backdrop, and if you are going to get to it then I apologize, but I have not been able to research it enough. If you would just give a brief overview, not necessary to come out of your time, about the legal difference, if there is any, of a physician or a medical employee of the VA versus the private sector. Because I do think you have some kind of a liability shield that we would have to take into consideration, while you describe your system, and that we would have to do something in the private sector if we like some of the things that you were doing. Is that true?

Dr. BAGIAN. There is a difference, yes. The difference is, you might look at ours as enterprise liability. If a physician or caregiver is acting within their scope of practice, what they are privileged and supposed to do, then any error or anything that would result in a malpractice claim, the Government is responsible. The individual is not financially responsible.

They still can sue the Government. In fact, there are pension benefits as well as tort redress they can take. So while you cannot come against the individual, it is not that much different. It might play a factor. I do not think it is the largest role. In fact, I will talk about that, if you will allow me. That is a good point.

With the mandatory and voluntary reporting, one thing I would point out is it is not just a difference between mandatory reporting and voluntary. You also have to look at what is the purpose, accountability or to learn? And then you have to look at issues of is it going to be confidential once it is reported, whether it is mandatory or voluntary, or not?

You could have mandatory systems that are confidential that you can get reporting to, whereas if it was mandatory and not confidential, it would be quite different. I think that is important. It is like a matrix. It is not just mandatory or voluntary, it is a little bit more complex than that.

With ours, we have a mandatory internal system that we use and we first started it back in 1997 and we have revised it most recently at the end of last year, and we have started to roll out that change beginning in November in VISN 8, our Network 8 in Florida, South Georgia, Puerto Rico. And we started last week in Southern California, Nevada. We tried to learn as we went along, because we are kind of in uncharted waters, if you will.

One of the things we found was that you have to make it very clear what people are reporting and why, so there is no ambiguity about whether they are sticking their head in the lion's mouth and not knowing. Because if people's perception is that it is a gotcha game, if they get surprised, they are not going to come back and talk to you again.

So we made it very clear. The way we made the distinction, and we did this in conjunction with the Office of Medical Inspector, with the Office of Health Inspection which is kind of like our IG,

with legal, and with the unions as well, and in our professional groups. We said look, we think what the whole point is here if someone reports an event, and I will not go into definitions of that, but an event and it is not thought to be the result of an intentionally unsafe act—and we define that as something that appears to be intentionally unsafe—substance abuse on the part of the physician, which you heard about earlier; a criminal act, a frankly criminal act; or alleged patient abuse, then we think that goes in the safety system. And then it gets a confidentiality shield, if you will.

We use it internally. We know what we need to do, but it will not result in individual discipline.

However, if it falls in one of those other categories, the intentional acts if you will, then it goes the administrative route where we still want to find out what happened, why did it happen, how do we prevent it, but we know there is an inkling there could be discipline required here, that it was not just stuff happened. And then we take whatever appropriate action is required.

By doing that, it appears that it has relieved some of the anxiety on the part of reporters to report, because they say we understand that. Everyone came forward and the various groups said that no one had a problem with intentionally unsafe acts getting more severe or a blame type of thing. So we have gone that way.

I know my light is up, may I go on if that is okay, sir?

Chairman THOMAS. I used some of your time, so you can keep going.

Dr. BAGIAN. Thank you.

When we put ours in place, we realized that the point was protecting confidentiality, accepting reports from all comers. Not just physicians, not just nurses. I mean, if a patient turns a report in, we look at it. It is not like we say oh, that is not the right status. We look at all information as good. We do not want to censor it. It is for us to then look at it and decide what we do.

Then we put a whole system, a very comprehensive system together, where we put teams together that will investigate whatever the particular event is and they not only say what happened, why did it happen, but then they come forward and also say what is the corrective action? What is the plan for implementing it? When will you check to make sure it worked?

I mean, we can have great ideas about how to make things better but without testing them, we do not know that they work.

And then we have one final thing, to have this accountability piece, if you will, that the facility director has to concur on not concur at each individual corrective action. If they non-concur, and they may. There may be a suggestion that is fiscally not possible or there are a number of things, they might have to make a risk-benefit analysis and then might say no, I do not think that is the right thing to do, we will do this. There has to be final concurrence before it is signed off.

But that is part of the official record. It does not get buried somewhere. It is not like a year from now we wonder how did that happen? We know how it happened. We think that is important. It keeps it all in the bright light of day, people know how it hap-

pened, it is not like it is some secret thing, we do that. And we concentrate on system solutions.

Another thing I will point out is, and it was mentioned I think by Mr. Stark and yourself in the last panel, is some of the tools we have had in the past in medicine, they have been available to others and that we just did not know were there or maybe were not generally appreciated. There are things about human factors, about things you have to look at. It is not enough to tell somebody, with the look-alike medications, to tell them to be more careful.

I cannot tell you how many reports we have seen historically that say "tell the nurse to be more careful." So does that mean they were not careful before? Oh, be careful, this is a new policy. Well no, that does not work. You have to do something different in systems.

One of those things, when you mentioned about the rental car thing earlier today, actually in 1994 one of the nurses at Topeka came back from being on a trip and she says how come—just what you said—they have this thing where a guy has a computer on his leg or whatever, and he does this.

They actually went ahead and developed a prototype of bar code reading and everything else, which we are now in the process of rolling out. And they showed in their studies that they reduced medication administration error by about 67 percent through using that. And now the VA is in the process of rolling that out nationwide in all of our facilities, and every one of our facilities should have that in place by June of this year, if not before.

So we absolutely agree that there are uses for technology to design the system to make it harder to make an error. You want to recognize that people can make errors, people are people, and make them fault tolerant.

From my previous life as an astronaut, we talked about fault tolerance all the time. We knew that errors can occur, whether it is equipment failures or personal failures. So you kind of have belt and suspenders. You do not just go out single string and take your chances.

We think medicine has to think more proactively about that, and we think we are doing that.

We have a number of other things. You mentioned about the black box. We actually have a medical simulator. In fact, at Palo Alto, Dr. Dave Gava is one of the pioneers in this area. We have a full operating room simulator with a mannequin that does everything like a real person. It changes the kind of gas it expires, CO2, O2 and the anesthetic agent. You actually can put a regular blood pressure cuff on its arm and you can change the blood pressure or anything you want. We run very sophisticated simulations to train people. We video them and use them for training.

It helps not only in the evaluative process, but also as a learning process. And the interaction, somebody talked about the arrogance and why people do not work in teams. Many of the exercises are set up just to demonstrate that. That if you do not all get along together and realize that the OR tech might have the key, and not just the surgeon, that you are missing the boat. You are not using your people correctly.

Aviation realized that, in the mid–1980s, and instituted it on a widespread basis. We are doing the same thing. In fact, at the center in Palo Alto, people come from around the country and the world, literally, to come train and learn how to do it. We are very aggressive in that area.

You talk about other changes, KCL, potassium chloride was a problem. We realized it was a systems thing. I was heartened by what you said earlier about even if it is 40 or 50 deaths a year, that is too many. We agree. We do not think you have to count the numbers. We know we do not want to have a death. And if we identify a vulnerability and see a systems way, or any way, to correct it then we want to do it. We do not say oh, let us wait until we have 50 more deaths and then it is time. We do not need to do that.

We did not do that with KCL, and we took that off the shelves. Dr. Kizer can say for sure, I think it was in the middle of 1998 we put out the—it was before I joined the VA. It was put out as a directive that KCL would not be kept in a concentrated manner on the floor, to take away this thing about telling the nurses to be careful. That old practice was foolish. That is not the way to do it.

So anyway, that is just the highlights of some of the things we have done, and I would be happy to entertain questions.

[The prepared statement follows:]

Statement of James P. Bagian, M.D., PE, Director, National Center for Patient Safety, Veterans Health Administration, U.S. Department of Veterans Affairs

Mr. Chairman and Members of the Committee,

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 (see Attachment 1). 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 mem-

bers, 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 Partnerships 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. (See Attachment 2) 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. (Attachments 3–6)

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. (Attachment 7)

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.

[Attachments are being retained in the Committee files.]

Mr. THOMAS. I appreciate it and we will have some questions. Dr. Kizer?

STATEMENT OF KENNETH W. KIZER, M.D., M.P.H., PRESIDENT AND CHIEF EXECUTIVE OFFICER, NATIONAL QUALITY FORUM FOR HEALTH CARE MEASUREMENT AND REPORTING

Dr. KIZER. Thank you and good afternoon, Mr. Chairman, Mr. Stark. It is a pleasure to be here. I am Dr. Kenneth W. Kizer. I am currently the President and CEO of the National Quality Forum. This is a new private, non-profit organization whose mission is to improve the quality of U.S. health care by improving the mechanisms and technology of measuring and reporting of quality.

I am pleased to appear before you this afternoon to discuss the urgent need to improve patient safety. I think for too long the topics of medical error, patient safety and therapeutic adverse events, if you will, have escaped public scrutiny.

At the outset, I think we should acknowledge, and indeed I am probably reiterating what has been said before by others today, that it really should not come as a surprise that health care has errors. In the latter part of the 20th century health care has become one of the most complex, if not the most complex, of all human activities. It involves hundreds or thousands of interactions among scores of caregivers and myriad complex technologies that can cause harm as well as help patients. If there ever were a high risk, high hazard activity, modern health care certainly qualifies as such.

While it should not be surprising that modern health care is a high risk, high hazard, and error-prone activity, I think what is perhaps surprising is that health care has lagged so far behind other high hazard industries in systematically implementing risk reduction and error reduction strategies.

In my written testimony, Mr. Chairman, I comment about the state of health care quality in the U.S. overall. I describe the genesis and the operation of the National Quality Forum, which I head. And I outline 10 areas of action which should be pursued to improve patient safety in the United States. In the interest of time, I am not going to repeat those things here. I would like to take the remaining three minutes or so that I have in these opening comments to stress at least a few of those points.

Despite the prevalence and the cost of medical errors, most health care executives, clinicians and consumers have largely been unaware of the magnitude of the problem, although aware that errors certainly occur. Many factors account for this lack of awareness, including especially the systematic underreporting of such events and the prevailing blame and punishment culture that discourages reporting and open discussion of errors, and that has been the focus of considerable comment already today at this hearing.

One of the most pressing needs in reducing medical errors is getting more complete data on the occurrence of such. Indeed, fundamental to any improvement effort is defining and measuring the extent of the problem. At present, medical errors are grossly underreported and there is very limited data about their occurrence.

The Institute of Medicine has recommended that a national reporting system be established that provides for the collection of standardized information about adverse events that result in death or serious harm to patients. They have also recommended that the National Quality Forum be tasked with promulgating and maintaining a core set of reporting standards.

The IOM further recommends that Congress pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected, analyzed, and used solely for the purposes of improving safety and quality.

I support those recommendations and I would strongly underscore the need for having a non-punitive approach to gaining these data.

I would also emphasize a second needed area of action, and that is of making patient safety a priority. Government health programs, health care organizations, and health care executives should make reducing medical errors and improving patient safety key strategic priorities. This should occur at all levels of Government and at all levels of health care organizations or institutions.

If patient safety is, indeed, to be a priority, it has to have a home within those health care organizations and within the relevant Government agencies and there must be individuals that are responsible for managing the data and the associated programs.

The National Quality Forum supports the Institute of Medicine's recommendation that there be a national center for patient safety, although we defer to the Congress and the Administration as to where such a center should be housed within the Government.

Finally, I would emphasize the need to implement medical error prevention best practices where such have been identified, and quite a few best practices have been identified and were referred to by others earlier today as the "low hanging fruit" that could be harvested quite readily. This is especially so in the area of medication safety practices, where a number of things have been identified and shown to be able to reduce errors in the short term.

In closing, Mr. Chairman, I would just note that too often Americans equate high technology health care with high quality health care. In many situations, this nexus is true. But in other cases, more sophisticated technology simply creates a delusion of higher quality and increases the risk of medical error.

With that, I will be happy to answer your questions.

[The prepared statement follows:]

Statement of Kenneth W. Kizer, M.D., P.H., President and Chief Executive Officer National Quality Forum for Health Care Measurement and Reporting

Mr. Chairman and Members of the Subcommittee, I am pleased to appear before you today to discuss the urgent need to improve patient safety in U.S. healthcare. For too long, the topics of medical error and therapeutic adverse events have escaped public scrutiny.

It should come as no surprise to anyone that errors occur in healthcare, for in the past fifty years healthcare has become one of the most complex of all human activities, typically involving hundreds or even thousands of interactions between people and technology during even "routine" treatment. Today, medical care is typically provided by teams of healthcare professionals, each of whom is responsible for a part of a patient's care; myriad diagnostic tests are routinely performed, many of which may be hazardous to the patient; and treatment often involves complicated invasive procedures that could injure a patient in multiple ways. If ever there were a high risk, high hazard activity, modern healthcare certainly qualifies as such.

Therefore, Mr. Chairman, I commend you and the Subcommittee for focusing on this important issue, and I welcome the chance to share with you some thoughts about policies and practices that might be employed to improve patient safety and, in turn, the quality of U.S. healthcare, as well as possible roles that the National Quality Forum might play in such efforts.

Healthcare Quality in the U.S.

The quality of healthcare in the United States presents a paradox. On the one hand, the generally high level of training of U.S. healthcare practitioners today, our extensive and highly sophisticated biomedical research program, the rapid dissemination of new medical knowledge, the extent of government funding for healthcare, and the widespread ready availability of state-of-the-art diagnostic and treatment technology have brought life-saving treatments to more Americans than ever before, and are the envy of much of the world. On the other hand, a number of studies in recent years have documented serious and widespread quality of care problems in

U.S. healthcare. Overuse, underuse and misuse of medical care occur too frequently in all types of healthcare delivery systems and with all types of healthcare financing.

While tens of millions of Americans reap the benefits of modern medicine each year, millions of others are exposed to unnecessary risks or are denied opportunities for improved health. Likewise, too many patients are injured, disabled or killed as a result of medical errors and treatment-related mishaps.

Quite simply, as good as American healthcare is, it could be markedly better!

Further, some experts believe that U.S. healthcare, which is by far the world's most expensive healthcare, could be significantly cheaper, if as much attention were focused on improving its quality, as was done in a number of other U.S. industries in the latter part of the 20th century. Higher quality healthcare may well cost less.

It is notable that interest in rigorously determining the quality of healthcare in America is only of relatively recent origin, arising largely in response to the managed care revolution and concern that the new healthcare organizational structures and reimbursement strategies brought by managed care might be creating incentives that were deleteriously affecting the quality of care. In evaluating this situation, however, the most striking finding is how little is really known about the quality of healthcare in America. (Not that it is known better any place else.) There is no mandatory national reporting or surveillance system, nor any regular systematic review of the state of healthcare quality to determine whether it is getting better or worse. Likewise, few healthcare systems or provider organizations even have rudimentary organized data systems that routinely inform them about the quality of care they provide.

Overall, it is highly ironic and quite remarkable that we know much more about the quality of airlines, automobiles, televisions and toasters in America than we do about healthcare, the nation's largest enterprise, accounting for more than $1 trillion in annual expenditures and some 15% of the gross national product.

In recognition of these problems and in response to growing consumer and purchaser demands for greater healthcare accountability, numerous efforts have been launched in the last 10 to 15 years to promote quality improvement in American healthcare. And while incremental progress has been made, in the aggregate, and despite the good work of many dedicated individuals and organizations, healthcare quality has not progressed to where it can and should be. There continues to be large gaps between the care people should receive and the care that they actually do receive.

This sentiment was clearly expressed in three independent reports published in 1998—i.e., reports by the National Academy of Sciences Institute of Medicine's National Roundtable on Health Care Quality, by investigators at RAND after an extensive review of the literature, and by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. Indeed, 1998 will probably come to be viewed as a watershed year for healthcare quality improvement because of these reports and actions they spawned.

The National Quality Forum

One of the sequels to the 1998 reports and one of the most notable of recent efforts to improve the quality of American healthcare has been the establishment of The National Forum for Health Care Quality Measurement and Reporting, a private, non-profit, membership organization proposed by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry.

The concept of the National Quality Forum arose in recognition of a strong American sentiment against government regulation and control of healthcare quality. Of note, the Commission proposed a public-private partnership involving two new organizations—a private-sector entity they referred to as the National Forum on Health Care Quality Measurement and Reporting (better known now as The National Quality Forum [NQF]) and a public entity they called the Advisory Council for Health Care Quality. The Commission's original vision was that the Advisory Council would identify national goals for quality improvement and provide oversight on the accomplishment of those goals, while the NQF would devise a national strategy for measuring and reporting healthcare quality that would advance the identified national aims for improvement. This paired public-private relationship seemed to reasonably balance concerns about the capacity of a private organization to meet important public needs against the prevailing negative sentiment towards vesting healthcare quality control with the government.

The NQF was birthed in the fall of 1999, following the work of the Quality Forum Planning Committee that had been launched in June 1998.

With in-kind support from the United Hospital Fund of New York, the Planning Committee drafted an initial mission statement for the NQF, proposed a governance structure and sought funding from selected foundations. Start-up funds were subsequently obtained from the Robert Wood Johnson, California HealthCare and Horace W. Goldsmith Foundations and the Commonwealth Fund. A president and chief executive officer was hired in the fall of 1999, and the NQF started to operate in late 1999.

Of note, no action has been taken, so far, to establish the proposed Advisory Council for Health Care Quality, and some of its envisioned functions are now being reviewed by the NQF for implementation.

The NQF sees its fundamental mission as being the improvement of healthcare quality—e.g., to promote delivery of care known to be effective; to achieve better health outcomes, greater patient functionality or a higher level of patient safety; or to make care easier to access or a more satisfying experience. The primary strategy the NQF will employ to accomplish its mission is to improve quality measurement and reporting mechanisms—i.e., to improve the technology for measuring and reporting quality. In doing so, however, the NQF does not envision itself developing quality indicators or measures *de novo.* There are myriad research, accreditation and oversight organizations and commercial interests already involved with developing measures.

The NQF has identified five key enabling objectives. These include:

(1) Developing a national strategy for measuring and reporting quality for the U.S. that is consistent with identified national goals for quality improvement;

(2) Standardizing the measures of and processes for reporting quality-related data so that data collection is consistent and less arduous for healthcare providers, and so that the data are of greater value;

(3) Promoting consumer choice by building consumer competence in using quality measures;

(4) Enlarging the healthcare system's capacity to evaluate and report on the quality of care; and

(5) Increasing the overall demand for healthcare quality data.

While there is much that needs to be done in each of these areas, the NQF sees a particularly acute need to reduce the burden and increase the value of quality reporting methods.

The NQF has convened a group of highly respected quality improvement, healthcare delivery and policy experts to help craft a strategic framework for healthcare quality measurement and reporting. This group is known as the Strategic Framework Board (SFB), and its essential mission is to determine the principles, intellectual framework and criteria for quality measurement and reporting.

In pursuing its mission, the NQF will seek to provide a clear, coordinated and coherent over-arching strategy and a set of guiding principles to inform the choice of measures that it will ultimately endorse. The NQF will strive to endorse measures that are compelling and causally related to better outcomes, and especially outcomes related to processes or activities that improve something that actually happens to patients. Indeed, the NQF believes that the true test of a quality indicator or measure is how well, and for what cost, the measure and its reporting actually helps improve care. The more ways that a measure promotes better outcomes, the better.

The NQF will also strive to ensure that its over-arching strategy has a sound theoretical framework that will inform and guide a strategic and proactive research agenda.

In approaching its work, the NQF will explore issues of quality across the entire spectrum of healthcare and will seek to coordinate quality measurement between and among the various levels or elements of the system—e.g., health plan, hospital, medical group, nursing home, individual practitioner, home care etc.

Likewise, the NQF believes that it must always ensure that the consumer's perspective is heard during the discussion of quality measures. In an effort to continuously actualize this, the NQF's Board of Directors is designed to have a majority of its members representing consumers and purchasers. This is an important structural precept that should facilitate keeping the consumer's perspective ever present.

Finally, in approaching its work, the NQF is committed to working constructively with the many other parties involved in the healthcare quality measurement and reporting area, including especially the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Committee for Quality Assurance (NCQA), to make certain that its work is not duplicative, but rather collaborative and helpful to the important work already begun by these entities. Improving healthcare quality is a matter of national importance that requires all of us to work together; there is neither time nor resources to pursue any strategy other than one of complete cooperation.

Medical Errors and Patient Safety

Recently, as a result of the Institute of Medicine's seminal report on the subject in November 1999,[1] considerable public attention has been focused on medical errors and other diagnostic or treatment-related mishaps that endanger patient safety—these will be further referred to here collectively as "therapeutic adverse events." The evidence is clear that therapeutic adverse events kill tens of thousands and injure or disable hundreds of thousands of Americans every year. They are a major public health problem that warrants immediate and decisive action, and the urgency for action is heightened by the fact that, for many problems, solutions to prevent their occurrence are known. In other cases there is a need for research to find the best practices that would prevent their occurrence.

Despite their prevalence and cost, most healthcare executives, clinicians and consumers are largely unaware of the burden of therapeutic adverse events. Many factors account for this lack of awareness, including especially the systematic underreporting of such events and the prevailing "name and blame" culture that discourages reporting and open discussion of the issue. This "name and blame" culture causes fear of punishment, fear of reprisal and/or fear of peer disapproval when an adverse event does occur; this has been particularly counter-productive in dealing with the issue in a forthright manner.

It is widely known that error is inherent to anything that humans beings do, and substantial evidence exists that errors are the result of poorly designed processes and systems that fail to account for the inherent limitations of human performance. Indeed, because medical errors typically involve problematic processes or systems rather than the incompetence or malice of individual practitioners improvement strategies that punish clinicians for reporting errors are misguided.

In my opinion, ten things, at a minimum, must be addressed if medical errors are to be reduced. These include the following:

1. Get more complete data on the occurrence of therapeutic adverse events.

Foundational to any improvement effort is defining and measuring the extent of the problem. At present, medical errors are grossly under-reported, and there is extremely limited data about their occurrence. Creating a data collection system is essential to the success of efforts to reduce their occurrence. Likewise, sharing information about errors with frontline clinicians is needed to further their understanding of the issues, as well as to promote collaboration and a sense of shared mission.

The Institute of Medicine recommended that a national mandatory reporting system be established that provides for the collection of standardized information about adverse events that result in death or serious harm to patients, and that the NQF be tasked with promulgating and maintaining a core set of reporting standards. The IOM further recommended that Congress pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected, analyzed and used solely for the purposes of improving safety and quality. I support those recommendations, and I would strongly underscore the need for having a nonpunitive approach to gaining this data.

In considering the data, it is important to remember that reporting such events is for both public accountability and quality improvement purposes, and not everything reported for quality improvement purposes warrants public reporting. There is a set of adverse events or untoward situations about which I believe we could obtain widespread consensus on the need for reporting for public accountability purposes (e.g., maternal death during childbirth, restraint-related strangulation, wrongsite surgery, to name a few), but there is a larger pool of events or circumstances that, at least at this time, should be maintained confidential for quality improvement purposes.

2. Make patient safety a priority.

Government health programs, healthcare organizations and healthcare executives should make reducing medical errors and improving patient safety key strategic priorities. This should occur at all levels of government and at all levels of healthcare organizations or institutions.

Patient safety work should be built into the schedule of managers and should be a defined executive responsibility. Patient safety issues should receive as much attention by healthcare facility governing boards as do issues like financial performance, market share and strategic planning. Healthcare facility management should

[1] Institute of Medicine. *To Err is Human: Building a Safer health System.* Washington, DC. National Academy Press. 1999.

be held accountable for patient safety performance just as they are held accountable for other performance.

3. Create a patient safety infrastructure.

If medical error data are to be collected and if patient safety is to be a priority, then it must have a "home" within healthcare facilities, healthcare organizations and relevant government agencies, and there must be individuals who are responsible for managing the data and associated programs. The NQF supports the notion of there being a national Center for Patient Safety, although we defer to the Congress and the Administration where such a center should be housed. Wherever it is located, though, it must be provided with adequate resources to accomplish its mission.

4. Create a culture of safety

Healthcare executives and managers should strive to create a culture of safety in their institutions or organizations.

A healthcare culture of safety can be defined as an integrated pattern of individual and organizational behavior, and the associated underlying philosophy and values, that continuously seeks to minimize hazards and harm to patients that may result from diagnosis and/or treatment-related processes. A culture of safety identifies safety as a priority and aligns organizational objectives and rewards accordingly.

A number of characteristics define a healthcare culture of safety. For example, in a culture of safety there is open acknowledgement that modern healthcare is a high risk activity and that everyone in healthcare has a responsibility for risk reduction and error prevention. Errors are recognized and valued as opportunities for improvement, and there is a non-punitive and safe environment in which errors can be learned from. There is honest and open communication about safety issues with well known mechanisms for reporting and learning from errors, and confidentiality of information. Likewise, in a culture of safety there are mechanisms for restitution and compensation for injuries that result from errors, and clear organizational commitment, structure and accountability for safety improvement.

5. Implement patient safety best practices.

Healthcare leaders and organizations should implement medical error "best practices" when such have been identified—e.g., such as those identified by the Massachusetts Hospital Association, National Patient Safety Partnership and Institute for Safe Medication Practices. This is especially so for medication safety practices, where a number of practices have been shown to definitely reduce errors.

6. Professional misconduct must be recognized and dealt with.

Gross negligence, malfeasance or unethical behavior should be recognized as a grave threat to patient safety and should be dealt with accordingly. Licensure, credentialing and privileging bodies should more aggressively discipline practitioners who have demonstrated impaired performance of this nature.

7. Healthcare regulators and accreditation organizations should embrace measures that enhance patient safety.

Regulations and guidelines should encourage root cause analysis and facilitate non-punitive reporting. Similarly, pharmaceutical and medical device manufacturers should be required to complete and disclose human factors testing of naming, packaging and labeling of medications and post-market surveillance of adverse events.

8. Patient safety self-assessments should be conducted.

All healthcare facilities should routinely conduct self-assessments for risk reduction and error prevention. When available, structured and standardized self-assessment instruments should be utilized—e.g., the self-assessment instrument developed by the Institute for Safe Medication Practices for medication safety practices.

9. Patient safety research should be funded and otherwise supported.

While a number of interventions are available that could improve patient safety in the short term, there is a need for additional research in the area of medical error reduction and patient safety. Research is needed in ways to make care processes safer, in how to make reporting systems optimally useful, and in ways of communicating information about healthcare hazards that do not unduly alarm patients, to name some fertile areas of research. Likewise, while basic research is needed in many areas, there is a need to investigate technology transfer and the application

of safety lessons from other industries to healthcare. A good model for the latter are the Veteran Health Administration's Patient Safety Centers of Inquiry.

10. Medical education should address patient safety.

Patient safety needs to be incorporated into the fabric of health professional training at all levels. Indeed, a significant part of the problem regarding the failure of physicians to report medical errors stems from attitudes and beliefs instilled during medical school. The fact that everyone makes mistakes, regardless of how well trained or how smart one is, and that modern healthcare is an inherently high risk, high hazard activity should be promoted throughout one's training, along with how mistakes should be managed.

Professional organizations and credentialing bodies should also give consideration to requiring continuing education specifically in patient safety, such as is required of practitioners in the veterans healthcare system.

CONCLUSION

In closing, Mr. Chairman, I would emphasize that even though improving patient safety in U.S. healthcare presents many challenges, improvement is eminently achievable, as has been demonstrated in the veterans healthcare system.

I would further note that too often Americans equate high technology healthcare with high quality healthcare. In some cases, this nexus is true, but in many other situations more sophisticated technology simply creates a delusion of higher quality, while actually increasing the risk of medical error. As healthcare becomes more and more reliant on complicated technology there will be increasing need for vigilance against errors. Many actions need to be taken to ensure that such vigilance is actualized and that healthcare in the 21st century becomes safer than it is today. The ten action areas described above would be a good beginning in this regard.

Again, thank you for the opportunity to testify before you this morning. I would be pleased to answer your questions.

Mr. THOMAS. Thank you very much. Tools of diagnosis do not replace diagnosis. Dr. O'Leary?

STATEMENT OF DENNIS S. O'LEARY, M.D., PRESIDENT, JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS

Dr. O'LEARY. Thank you, Mr. Chairman.

I am Dr. Dennis O'Leary, President of the Joint Commission on Accreditation of HealthCare Organizations. I am pleased to address you today concerning medical errors. This is perhaps the most pressing health care quality issue of our time.

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. This broad experience gives the Joint Commission a panoramic view of the strengths and weaknesses inherent in our health care delivery system.

My testimony will focus on the tasks that must be carried out to reduce errors nationwide. Dramatically reducing the numbers 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.

Medical error reduction is fundamentally an information problem. The solution to reducing errors resides in developing mechanisms for collecting, analyzing, and applying existing information. With this in mind, there are five critical information-based tasks that 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 get a handle on the epidemiology of medical errors, we must create a protected blame-free environment that will lead to an active understanding of 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 a serious adverse event.

The second task is the production and credible root cause analyses of serious adverse events. When a serious error occurs, there must be an intensive, no holds barred vetting of all of the causes of the underlying event. These root cause analyses, which we believe hold the critical answers to future error reduction, focus primarily on organizations, systems and processes.

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 the health care providers systems is akin to writing a plaintiffs' 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's 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 simply terminate with the report itself, or even an analysis of what went wrong. We view the monitoring of planned systems changes in organizations as a key element of public accountability.

The fourth task is the establishment of patient safety standards which health care organizations must meet. The Joint Commission has recently established explicit patient safety standards for health care organizations. These 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 last task is dissemination of experiential information to all organizations at risk for adverse events. To have a positive national impact on patient safety, information gleaned from the analyses of errors must be disseminated so that all organizations may reduce the likelihood of adverse events.

The Joint Commission does this through its series of sentinel event alerts. To date, we have issued alerts on medication errors, wrong site surgery, restraint related deaths, blood transfusion errors, inpatient suicides, infant abductions, and post-operative complications.

Finally, it must be understood that access to error related data and information underride and drive this overall system of accountability and oversight. Therefore, we believe that any national reporting program must ensure appropriate data sharing amongst all of the responsible oversight parties.

In conclusion, we believe that the work of the Joint Commission over the last four years provides significant lessons learned for policymakers 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. 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.

Thank you.

[The prepared statement follows:]

Statement of Dennis S. O'Leary, M.D., President, Joint Commission on Accreditation of Healthcare Organizations

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 House Ways and Means Subcommittee on Health regarding medical errors. The frequency and nature of medical errors is perhaps the most pressing quality of care issues we face in the health care today.

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 to 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 the health care providers have the tools and the commitment to sharply reduce their incidence.

My testimony will focus on the activities 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 policy making communities around this critical set of quality issues. Such synergy of purpose among stakeholders is a prerequisite for successfully addressing complex, multifactorial problems whose solutions depend upon information sharing among the parties. Dramatically reducing the numbers and types of errors will take a concerted effort by all who participant 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 simply, 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, particularly in the development and application of constructive information regarding medical errors. This coordinated approach must necessarily bridge the public and private sectors.

Medical error reduction is fundamentally an information problem.

The solution to reducing the number and types 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 what information we need to obtain, create, disseminate and apply to the problem. With this in mind, there are five critical, information-driven activities that must be supported in the overall system. In theory, a single organization could perform all of these functions, but in fact, multiple public and private sector organizations will have roles to play.

1. Creation of a blame-free environment to encourage the system 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. We believe that most medical errors never reach the leadership levels 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 the problem, we must create a climate that will led to an accurate understanding of its scope and nature.

An important feature of the Joint Commission's Sentinel Event Program (Attachment A) is the non-punitive reporting environment it seeks to create. Hoping to foster a positive culture that will 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 that eventually 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, our Sentinel Event Program has found it necessary to create procedureal 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 stop gap measures that we believe must be replaced by federal protections for error-related information.*

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 event*—including their nomenclature and taxonomy—that should be reported to the Joint Commission on a voluntary basis.

Our definition of a reportable event minimizes the external reporting burden for health care organizations while focusing on the most serious occurrences that have a high likelihood of being preventable. 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 collect information only on the "near misses."

2. Production of credible "root cause" analyses following the occurrence of serious adverse events.

When a serious error occurs, there must be a requirement for an intensive, no-hold-barred vetting of all of the causes underlying the event. We call these responses "root cause" analyses—a term borrowed from the engineering world's reliance on a systems approach to both solving problems and producing desired outcomes.

A root cause analysis focuses primarily on systems and processes, as opposed to individual performance. While an individual is invariably the proximal cause of error relate to systems failures distal to the error itself. For example, systems may fail to provide simple checks and balances; or they may be missing critical safeguards; or may have design flaws that actually promote the occurrence of errors.

These intensive analyses are rich learning processes that can elucidate multiple factors that ultimately contributed to the error. Many of these are not readily apparent until the root cause analysis is undertaken. Therefore, 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 investiga-

tions, 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, the majority of 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 many 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 unwarranted 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.*

3. Implementation of concrete, planned actions to reduce the likelihood of similar errors from happening in the future.

Monitoring is an critical element of the strategy for preventing errors, to ensure that the response to an error does not terminate simply with the report itself or a discussion 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 an independent review of the milestones associated with planned systems changes. We expect to see an organizational response that results in preventive actions.

We view the monitoring function as a key element of public accountability. The public must have confidence that there is an external body overseeing patient safety issues in the organization 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 national response to the IOM report must ensure appropriate data sharing among all of the responsible oversight bodies which perform any of the functions discussed in this testimony.* The health care quality oversight system involved a variety of private sector and public sector players today. Efforts should at least be made to better utilize existing structures through improved data sharing, and encourage the broad dissemination of what has been learned from medical mistakes. We do not want to end up with a fragmented, ineffective system where, for example, a single body is privy to reports of errors, yet organizations with public accountability for patient safety are not made aware of or do not have access to this information.

4. Establishment of patient safety standards which health care organizations must meet.

The Joint Commission has established developed explicit patient safety standards that became applicable to accredited organizations beginning in January 1999. These new standards were specifically created to establish patient safety as a high priority in provider 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.

We would like to see other accreditors and quality of care oversight bodies include meaningful 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 doing in terms of meeting these performance expectations.

5. Disseminating of experiential information learned from errors to all organizations at risk of similar 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. In 1997, the Joint Commission began to issue periodic **Sentinel Event Alerts 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 **Alert** have saved lives. Unfortunately, we cannot calculate real decreases in error rates with scientific certainty, because the full scope and frequency of serious adverse events is simply not known. 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 first **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 less benign substances. In analyzing the causes of KCl-related deaths, it became evident that accidental injection of KCl stored on hospital floors was an important cause of unanticipated deaths. The Joint Commission issued its **Alert** on the subject in February 1998. 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. The Sentinel Event Program has identified the critical information-based functions for solving the medical error problem. In carrying out these functions, the Joint Commission's efforts have assuredly prevented additional errors and saved lives.

But, the Sentinel Event program also illustrates the harsh realities of a 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 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.

We urge, therefore, that 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.

*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.

Mr. THOMAS. Thank you very much, Dr. O'Leary. Dr. Golden?

STATEMENT OF WILLIAM E. GOLDEN, M.D., FACP, PRESIDENT, AMERICAN HEALTH QUALITY ASSOCIATION

Dr. GOLDEN. Thank you, Mr. Chairman, and good afternoon.

As medical director for quality improvement at a Medicare peer review organization, I am pleased to be here today to talk about medical errors. I am also a professor of medicine at the University of Arkansas Medical School. The Arkansas PRO has extensive experience doing quality improvement, HEDIS measurement patient satisfaction surveys for Medicare as well as Medicaid.

Today I am here as President of the American Health Quality Association. This organization represents quality improvement organizations in this country which are private, community based, and work in all health care settings, hospitals, physicians offices, nursing homes, home health agencies in all 50 states, the District of Columbia, and U.S. territories.

Unifying our activities is the Medicare peer review contract. Over the last 10 years, the PRO system has evolved into a national network of quality improvement experts that systematically evaluate the delivery of health care in a region and institute projects to educate and alter the clinical behavior of institutions, health professionals, and patients. Today's PRO system is and can be a core element of a national system for improving patient safety.

We are already doing extensive work in this area to reduce errors. Our staffs have changed over the last 10 years to accomplish these goals. We currently have on staff clinical experts, nurses and physicians, who are trained in quality improvement techniques. We have data and statistical professionals on staff, medical record abstraction teams, an extensive infrastructure of community relationships to get change in the community structure and to communicate this information, as well as expertise in public relations and outreach strategies.

Indeed, in the major study on errors out of Colorado and Utah, the data collection was subcontracted to PROs by the teams out of Harvard to get the research performed.

The Institute of Medicine points out there are two kinds of errors, errors of omission and errors of commission. Much of the PRO system currently works to reduce errors of omission in prevention, diagnosis, and treatment. We are doing such things as increasing rates of mammography, increasing the use of pneumovax, pneumococcal vaccine, influenza vaccine. Appropriate drugs after the treatment of heart myocardial infarction improve the receipt of those drugs by appropriate patients. Timely administration of the correct antibiotics for the treatment of pneumonia. ACE inhibitors for

heart failure, making sure patients receive this medicine to improve function and survival. Better monitoring of potential diabetic complications.

We are even doing studies on errors of commission, such as the elimination of a dangerous drug in the treatment of stroke. I have a list of 22 performance measures attached to my testimony that goes into the areas we are currently working on to reduce errors.

The strengths of these activities reflects the fact that they affect a large number of older Americans. They have strong scientific support. And they are standardized, so we can compare treatments and progress across states, within regions, and also within our own program.

Given our experience over the last 10 years, we have seven recommendations to improve the system and improve patient safety. One is to expand the current performance monitoring system the PROs are using. We currently measure and improve medical errors. Our list of clinical topics could be expanded with new performance measures to improve care. Indeed, if we improve care for Medicare patients we often improve care for all patients, because once you have improvement for myocardial infarction, all patients with MI tend to benefit.

Many of these recommendations are consistent with what was in the Medicare Payment Advisory Commission report in June 1999 and was recommended by the Medicare Payment Advisory Commission.

We could work on things like adverse drug events, hospital acquired infections, post-operative hemorrhage, et cetera. We agree that the Agency for Healthcare Research and Quality, HCFA, and other stakeholders should get together and work on new performance measures to reduce errors.

It is important to note that this system would not increase burden to the hospitals because most of this could be done by using administrative databases, record abstraction, and does not require reporting. It can be done by data abstraction teams and rates of errors could be determined and improvements designed to improve safety.

We believe that there should be a mandatory reporting of some catastrophic errors. Much of this, as I said, can be done by abstraction, but there are some random events which break through safety systems in hospitals, and the reporting of those errors to a regional entity would allow for many institutions to learn from these rare events so that additional patients would not be harmed by recurrences at other settings.

We believe there needs to be accountability of this system and that this kind of activity should be handled by a qualified expert organization who can do root cause analysis, can communicate the information and can get behavior change.

The PRO program right now is under agreements with the Health Care Financing Administration to actually improve care in their areas and make it measurable.

We believe there needs to be confidential treatment of reported errors. It is very important that we do not punish people for reporting mistakes in their environment if it is under the rubric of improving patient safety. Right now the PROs have much of that con-

fidentiality in place, so we can go forward. That is much in keeping with the protections as outlined by the Institute of Medicine report.

We believe there also needs to be a mechanism for finding unreported errors. PROs, like Utah and Colorado did for their study, can do chart surveillance for either targeted errors or random errors, depending on the topics under review. That way, we can see whether there are additional events going on in the system that need to be addressed.

The system must promote best practices with good collaboration between institutions and the entity that is collecting the information, collect best practices and promote quality improvement in the communities.

And finally, we need to separate malpractice reform from error reduction programs. Malpractice is a very difficult topic and I believe we are here today to talk about how we can improve patient safety and reduce errors. That is our fundamental intent, and the malpractice reform, we will leave to other experts.

At this point, I will stop and welcome questions. Thank you very much for the time.

Chairman THOMAS. Thank you.

[The prepared statement follows:]

Statement of William E. Golden, MD, FACP, President, American Health Quality Association

Good morning, Mr. Chairman. Thank you for inviting me to testify today.

I am the Principal Clinical Coordinator for one of Medicare's Quality Improvement Organizations, or QIOs, called the Arkansas Foundation for Medical Care. I am also a Professor of Medicine and Director of General Internal Medicine at the University of Arkansas Medical School. My QIO has extensive experience in performance measurement and conducts quality improvement, HEDIS measurement, and patient satisfaction surveys for the state Medicaid program. We are also a recognized vendor for the Oryx Program of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). In fact, we created three of JCAHO's thirty performance measures in the proposed national core program.

I am here, today, as President of the American Health Quality Association (AHQA), a national membership association of organizations and individuals dedicated to health care quality improvement. Our member QIOs are private, community-based organizations that promote health care quality in all health care settings. QIOs work in all 50 states, the District of Columbia and the U.S. Territories.

The QIOs have several lines of business including work with state governments and private health plans. The work that unites them all, however, is their 3-year, competitively awarded contracts from HCFA to evaluate and improve the quality of care delivered to Medicare beneficiaries. For this work, our members are more commonly referred to as Medicare Peer Review Organizations, or PROs.

Congress established the PROs in 1983 to look for single case problems. During the 1990s, the PRO system evolved to become a national network of quality improvement experts that systematically evaluate the delivery of health care in a region and institute projects to educate and alter the clinical behavior of institutions, health professionals and patients. QIOs are staffed with clinical experts, communication experts, and data and statistical professionals who work together to analyze and collaborate with the health care system in their communities.

Today's PRO system is uniquely qualified to serve as the core of a new national system for improving patient safety. One of the greatest strengths of the PRO system is its extensive infrastructure of relationships in every region of the country. PROs work individually with hospital staffs and physicians offices. They are also increasingly engaged with home health care systems, nursing homes, academic health centers, and community groups such as heart associations and cancer coalitions.

In addition to technical expertise, they have developed public relations and outreach strategies with professional associations, public health authorities and state officials. This is critical for helping hospitals and other facilities implement improvement strategies as well as tailoring messages to the public about improving their

health (e.g. public awareness of receiving pneumococcal vaccinations or getting regular eye examinations to reduce the risk of diabetes-related blindness). This is also critically important for the effectiveness of the PROs' required projects with underserved and disadvantaged populations. These projects often require forms of outreach and communication that are culturally appropriate.

The Institute of Medicine (IOM) report released last November targets both medical errors of omission—care not provided that should have been—as well as errors of commission. In addition, the IOM Committee also states that errors occur and should be detected in all phases of medical care: prevention, diagnosis and treatment.

The Medicare PRO Program as a Model Error Reduction Program.

Medicare's national PRO system has been identifying, measuring and reducing error rates for several years. The PRO program is now embarking on an expanded three—year mission to identify and eliminate medical errors. The new program is focused largely on errors of omission—such as prescriptions that were not ordered for prevention of heart attack—and on errors in all three categories mentioned by the IOM. For example, in the prevention area, PROs are working to promote immunizations to prevent the most common fatal infection, pneumococcal disease. In the area of missed diagnoses, the PROs will be working to increase mammography screening and diabetic retinopathy testing. An example of PRO work to reduce treatment errors is that PROs will be emphasizing timely administration of antibiotics for newly hospitalized pneumonia patients.

I have attached a complete list of the 22 performance indicators in each of six clinical topic areas for which the PROs must reduce error rates. These PRO performance indicators serve as a useful model for a new medical error reduction system for several reasons. These clinical topics were carefully chosen because they affect a large percentage of older Americans and because the scientific basis for the desired therapy or action is well established. A national error reduction program should also focus on high priority problems and adopt a science-based approach.

In addition, the standardized national set of performance indicators assures national comparability of data within and between all states, which is critical to accurately measure improvement. We believe this is a sound model for a national system of identification and reduction of medical errors.

Recommendations.

Based on our experience working within a national system to identify quality problems and work collaboratively with providers to bring about improvement, here are our recommendations for a new system for improving patient safety.

1. Expand Monitoring System for Error Prevention.

Congress should expand the current system utilized by Medicare to monitor a targeted list of health care processes and patient conditions known to be associated with a disproportionate amount of medical errors. This system will identify many errors and adverse events, which have not yet resulted in dramatic or catastrophic patient outcomes. The published literature identifies some categories of preventable adverse events that are both relatively frequent and frequently preventable, and might be targeted by a national monitoring system. Some examples include adverse drug events, hospital acquired infections, deep venous thrombosis, postoperative hemorrhage. The Agency for Healthcare Research and Quality (AHRQ) and the Health Care Financing Administration (HCFA) should collaborate with representatives of our national network of Quality Improvement Organizations (QIOs), as well as professional and provider groups to define the highest priority areas of scrutiny for error-prone health care processes, and to develop a standardized system for measurement.

Congress will be asked to consider the burden of error reporting. The system of monitoring that I have described can be accomplished without imposing significant additional reporting burdens on hospitals or other providers. PROs can accomplish much of the data gathering necessary by expanding their current mechanisms for review of medical records and abstraction of key data for analysis. Quality improvements based on this kind of monitoring will probably continue to be the major method by which patient safety is enhanced. Because the PRO program has already established the relationships with hospitals necessary to perform this function, there is very little new work that hospitals must do to facilitate an expanded program to address errors in patient care planning and execution.

2. Mandatory Error Reporting.

We have recommended that Congress devote substantial resources to monitoring and educating providers about the adverse events that have strong potential to harm patients, rather than wait for patient harm to occur. But the smaller number of more dramatic events that result in patient harm must also be addressed by an error reduction system because the results of such errors are so often tragic and irreversible. This subset of adverse events often captures the attention of local health professionals and often results in demands for system changes to eliminate recurrence.

Health facilities should report the rare and seemingly random adverse events that result in patient harm to a regional entity to create a database. Monitoring and analysis of such a database can offer insight into better system design for all of our communities. The reporting of such errors allows for hindsight analysis to be available throughout the health system, so that more people can benefit from the analysis than just those in the local environment that witnessed the adverse event. The PROs are well qualified to manage and interpret such a database in each state, and have proven adept at educating providers and practitioners about ways to avoid errors in the future.

3. Ensure Accountability.

Congress should hold providers accountable for measurably reducing the incidence of errors. A qualified expert organization, completely independent of hospital providers, should analyze the incidence of errors and judge whether improvements are being made. The PRO program is already performing this function on a more limited scale. For the period 2000–2002, PROs will be accountable under their Federal contracts for measuring and reducing the frequency of missed prescriptions to prevent strokes and heart attacks, or missed lab tests to help control diabetes. If a PRO cannot accomplish sufficient measurable improvement, it may lose its Federal contract. In a new medical error system, Congress can rely on the QIOs to measure error rates and identify providers that have made no progress in eliminating errors. Providers that are making no progress on errors could be reported to a federal or state regulatory agency, or to the Joint Commission for Accreditation of Healthcare Organizations (JCAHO).

4. Assure Confidential Treatment of Reported Errors.

Reports identifying specific providers and individuals should generally not be disclosed. Part of the reason for this is that "naming names" tends to fix blame, even when this is inappropriate. The IOM report [page 45] noted, "Complex coincidences that cause systems to fail rarely have been foreseen by the people involved." This suggests that it is more important to understand system failures than to attempt to affix blame on one or more individuals involved in a system failure.

It is critically important to not to discourage, let alone punish, the active search for errors. Several studies demonstrate that errors are much more numerous than anyone can know without actively digging to find them. The IOM relied on two large studies of the prevalence of medical errors. PROs, in fact, did the medical record abstraction for the second study, based in Utah and Colorado. Both studies found a large number of preventable adverse events through careful review of the medical record. But these researchers also noted that many other errors could not be found in the medical record alone. When researchers at the LDS Hospital in Salt Lake City wanted to find out the true incidence of adverse drug events in their institution, they started by counting the incident reports filed by doctors, nurses, and pharmacists. They came up with about 20 reports a year. But after extensive mining of lab data, prescription records, and interviews with hospital personnel, they found the true incidence of adverse drug events was over 580 events a year. The hospital then tracked down the causes of these problems and reduced their true error rate below the original apparent rate.

The LDS project puts the idea of public reporting in context. If hospital personnel know that any error they find involving patient harm will be subject to public reporting, few will undertake the costly and difficult investigations that are necessary to discover errors. If public disclosure and punishment await those who dig effectively to find the true extent of errors, few errors will be found, and fewer still will be eliminated.

Congress has repeatedly recognized the importance of maintaining confidentiality for sensitive internal hospital quality improvement activities. For example, Federal law ensures that confidential data reported to PROs shall not be disclosed. Congress can ensure confidential treatment of this information by requiring that error reports be sent to the PRO in each state. The current PRO statute protects such informa-

tion from unauthorized disclosure. Public reporting of errors should be reserved for those institutions identified by the PRO that cannot or will not improve error rates.

At the state level, aggregate information without identifiers for individuals or institutions could be released to the general public. Data reported at the national level would first be encrypted for aggregate public reporting and would then be considered a publicly accessible dataset.

5. Establish a Mechanism to Find Unreported Errors.

Experience with other mandatory reporting systems for errors and health quality problems reveals that no mandatory reporting system will receive all appropriate reports. A separate mechanism to identify unreported errors is needed. One such system is already in place nationwide. Individual PROs periodically request records and analyze them for indicators of errors such as delayed administration of antibiotics in newly hospitalized pneumonia patients, and missed opportunities to prescribe medications to heart attack and heart failure patients. In addition, the national PRO program also utilizes clinical data abstraction centers (CDACs) to accomplish this task. These centers also observe strict confidentiality in managing the records, and have achieved a high degree of reliability in finding and reporting errors to PROs, which then work with the hospitals to prevent their recurrence. This system can be utilized to find many more types of errors.

Institutions should be required to provide information in response to a PRO request to actively identify or pursue information that may not be readily identifiable in standardized reports. This mechanism will help to ensure the integrity of the mandatory reporting system, as it may uncover reports that should have been filed with the PRO but were not.

6. Promote Best Practices.

Once errors are found, their causes must be understood, and solutions must be implemented. This is now accomplished through the national Medicare PRO program by collecting from each PRO their successful interventions to improve care, and then sharing it with all the rest. In this way, every PRO can approach local institutions with the benefit of the best knowledge of all the PROs and providers that have previously tried to solve a problem. By assisting hospital personnel in finding best practices, the PROs go far beyond merely holding hospitals accountable for their failures.

7. Separate Malpractice Reform from the Error Reduction Program.

Tort reform and facilitation or limitation of litigation is a matter for a separate set of public policy deliberations. All information should be reported to the PROs for the purpose of assuring that measurable quality improvement is accomplished. Neither regulatory remedies nor liability law need be affected by reports to the PRO or by the confidentiality protections afforded such reports.

AHQA believes these are the basic elements necessary for creating a systematic approach to reducing medical errors that will assure both medical professionals and patients that the problem is being addressed fairly and effectively. The key to a successful solution to this problem will be giving the medical community the opportunity to fully identify the possible extent of their errors and do the work necessary to systematically and measurably improve. Without this measurable improvement, the problem will continue to be discussed but never solved and consumers will never be assured that the quality of their medical care will become any better. The nation's QIOs can provide the accountability and results that the system will require.

Thank you again for the opportunity to share this information with Congress. I look forward to continued discussion as you work to improve the safety of patients across America.

National Health Quality Improvement Projects of Medicare PROs 1999–2002

Clinical Topic	Quality Indicators (proportion of beneficiaries receiving:)	Data Sources (Medicare FFS Only)	Expected Health Outcomes
Acute MI	• Early administration of aspirin on admission • Early administration of beta blockers on admission • Timely reperfusion • ACE inhibitors for low left ventricular ejection fraction. • Smoking cessation counseling during hospitalization • Aspirin at discharge • Beta blockers at discharge	• Hospital medical records for AMI patients.	• Inpatient mortality rates • Mortality rates at 30 days • Mortality rates at 1 year • Readmission rates with AMI CHF.
CHF	• Angiotensin-related drugs for left ventricular ejection fraction when appropriate.	• Hospital medical records for heart failure patients.	• Inpatient mortality rates • Mortality rates at 30 days • Mortality rates at 1 year • Readmission rates w/CHF.
Pneumonia	• State Influenza vaccination rate • State Pneumococcal vaccination rate • Inpatient Influenza vaccination (or screening) • Inpatient Pneumococcal vaccination (or screening) • Blood culture before antibiotics are administered • Appropriate initial empiric antibiotic selection • Initial antibiotic dose within 8 hours of hospital arrival.	• Flu and pneumonia immunizations—Claims or survey similar to CDC's BRFSS. • Other indicators: Hospital medical records for pneumonia patients.	• Hospital admission rates • Hospital readmission rates • Inpatient mortality rates • Mortality rates at 30 days • Readmission rates with Pneumonia.
Stroke/TIA and Atrial Fibrillation	• Discharged on warfarin, aspirin or other antiplatelet drug (stroke or TIA only). • Discharged on warfarin (chronic atrial fibrillation only). • Avoiding inappropriate use of sublingual nifedipine (stroke or TIA only).	• Hospital medical records for stroke, TIA, and chronic atrial fibrillation patients.	• Inpatient mortality rates • Mortality rates at 30 days • Readmission rates with stroke/TIA.
Diabetes	• Biennial retinal exam by an eye professional • Annual HbA1c testing • Biennial lipid profile	• Claims for all diabetic beneficiaries.	• Mortality rates at 1 year • Rate of development of diabetic retinopathy. • Rate of development of ESRD.
Breast Cancer	• Biennial mammography screening	• Claims for all female beneficiaries	• Percent of new cases of breast cancer detected at stage 1.

Chairman THOMAS. With all due respect, Dr. Golden, a major portion of your testimony sounded like a job interview.

Dr. GOLDEN. Sure.

Chairman THOMAS. You mentioned doing root cause analysis. Dr. O'Leary mentioned that they were engaged in root cause analysis. That sounds like a deep "why" probe is what it sounds like. Is that what it is?

Dr. O'LEARY. Why, yes.

Chairman THOMAS. Okay, a deep "why" probe, root cause analysis. Did you say, Dr. Golden, that you do it or that you need to have an agency that does it? Do you do root cause analysis?

Dr. GOLDEN. We facilitate it. As I said, most——

Chairman THOMAS. What does facilitate versus do it mean?

Dr. GOLDEN. As I said, we are doing data analysis to find rates of errors. We are suggesting improvement mechanisms to eliminate those errors. Some of these projects, we give to our collaborating institutions, and I will say right now that the average project we do attracts two-thirds of the hospitals in our State. We give them turnkey projects to effect fundamental system changes within those facilities.

Now, every now and then, you run into an institution—I will give you an example—which is an outlier that has a unique set of problems. We had one hospital that had a very high rate of bypass mortality. We—

Chairman THOMAS. You have lost me to a certain extent.

Dr. GOLDEN. Sorry.

Chairman THOMAS. My question was, do you do deep root analysis? Do PROs do deep root analysis?

Dr. GOLDEN. We do not do analysis of single-case events. We find experts to assist. What we do do is evaluate systematic reforms.

Chairman THOMAS. That is fine.

Dr. GOLDEN. So that is a different issue, different kind of errors.

Chairman THOMAS. I understand.

Dr. GOLDEN. Right.

Chairman THOMAS. You do a lot of other things, but one of the concerns I have is that there may be a drive to provide a one-basket approach, and my concern is that if, in fact, there is expertise out there in a number of different areas, one, I do not want to duplicate or reproduce it——

Dr. GOLDEN. Absolutely.

Chairman THOMAS.—and two, I want to make sure that we maximize the opportunity of the information flow so that those who are performing functions can continue to perform them.

Dr. O'Leary, you——

Dr. GOLDEN. We facilitate that deep root analysis and get the experts.

Chairman THOMAS. Right. I will not ask the obvious question. But Dr. O'Leary, the question I do want to ask is, did you find the hospitals as receptive as the statement that Dr. Langberg kind of intimated, that they had no problem at all accepting the sentinel reporting structure? Did you have any difficulty getting that sys-

tem up and running? Were the hospitals fully cooperative, in your opinion?

Dr. O'LEARY. Well, I do not think it is any secret that there were a broad base of concerns, that those concerns were driven primarily over the potential waiver of confidentiality if they shared that information with us, and in fairness, there are now some State laws that protect that sharing. But there had been very little testing of existing peer review statutes. I will tell you that there are a large number of organizations who said that they would be pleased to share with us the occurrences and the root cause analyses if such protections were in place, and I accept that on good faith.

Chairman THOMAS. Does it make sense to go ahead, as was indicated by several others, that we need to continue to have a State-based structure? I mean, it is going to remain, given the police powers of the State in terms of health and welfare, but would it not facilitate things if we provided a shield at the national level for the confidentiality, the collection of data, so that you would have a uniform structure nationwide, notwithstanding what may or may not be done in the State?

Dr. O'LEARY. I think that is absolutely crucial. The time it would take to pass——

Chairman THOMAS. Now, let me get this straight. You are a private sector operation?

Dr. O'LEARY. Yes.

Chairman THOMAS. And I am a Republican?

Dr. O'LEARY. Yes.

Chairman THOMAS. And we just both came to agreement on the idea of a national uniform structure?

Dr. O'LEARY. There are certain compelling needs, and this is one of them.

Chairman THOMAS. I think somebody is going to come to the conclusion that that is what should be driving this process. It is too important to get down into the gutter of politics or anything else, and we are going to do everything we can to do it as best we can.

I just have a lot of confusing information and I want to ask, Dr. Bagian, did I hear you say that you really have kind of like the FAA system, where it is kind of an all-comers reporting, that you accept voluntarily, although you do have the mandatory? Do you find that to be an information overload in your structure?

Dr. BAGIAN. No, sir, at least not yet. One of the things we have, we have a mandatory system. We also have a voluntary system that we are in the process of putting in place. It is not fully in place. If you would ask Linda, I mean, I have known Linda for 20 years and Charlie Billings back when I was at NASA, so I am familiar with their program. They sometimes see different things from the mandatory systems as opposed to the voluntary system. For example, there is mandatory reporting. And then there is the ASRS you heard about. They in certain cases can compare reports from the different systems; I mean, it is the same event. The stories are not always the same. It is the same incident we are talking about, but the story you tell the cops——

Chairman THOMAS. Between the mandatory and the voluntary?

Dr. BAGIAN. Yes, sir.

Chairman THOMAS. The coerced and the uncoerced?

Dr. BAGIAN. I do not know if that was the term I would use.

Chairman THOMAS. Okay.

Dr. BAGIAN. The one where you are more fearful than the other. Let us put it that way. At any rate——

Chairman THOMAS. That is better, yes.

Dr. BAGIAN. I think what they found, and you should ask Linda to tell you about that, the issue is that you get valuable things from both. That is not to say that the mandatory system, where you are in fear because it is disclosable, you do not get anything valuable. You do. But they are synergistic. You learn different things from both, and they both are essential.

One thing I might point out that I did not mention before is about close calls. You heard many comments about the need to get those severe, you know, the deaths, the severe thing. We think that misses the point by a lot.

Chairman THOMAS. Yes. You do not learn——

Dr. BAGIAN. That is right. I mean, if we have to stack up the bodies like cordwood to learn, that is kind of like the hard way to learn. That is not really very progressive. What you want to do is you want to look at close calls, the risk thereof, as they talk about in the Joint Commission's definition of single event, and we think that is very powerful, because several things have been shown in the aviation world. Often, you can learn as much or more from close calls, because people are more likely to be candid because it is kind of—this is not a word—not tortable, right, if there was no damage. But yet, people can talk about it more candidly——

Chairman THOMAS. There are more of them around to talk about it.

Dr. BAGIAN. And there are also more around to talk, that is correct. So we have emphasized very heavily to do the whole thing. The IOM report segregates it and says mandatory is just the real serious ones and voluntary is the other, and we disagree with that. We think you want to look at both, the whole thing, because you weave them together to learn even more than just saying that you want to look at one versus the other. We think that close calls are a very important thing not to lose sight of.

Chairman THOMAS. Okay, because that is one of the concerns. Now, have you had a breakdown of your system yet where information has been leaked, or have you been able to keep a lid on it?

Dr. BAGIAN. So far, no problem yet, and we emphasize it very clearly that that is an integrity violation and it will not be tolerated.

Chairman THOMAS. I mean, it is very difficult sitting here when one of the first arguments is that you cannot have everybody reporting, that humans always make mistakes, and that even if you go to a computerized structure, you are going to push the wrong button. At some point when you go through those explanations, they quit being explanations and they start becoming excuses. My concern is that I am already hearing what I consider to be some excuses as to why you cannot do a relatively broad-based approach.

Dr. Kizer, what I really liked in the ten points that you had in your written testimony was that you addressed what we have been alluding to and sometimes specifically referred to, and that is going back to the education structure and getting into the teaching hos-

pitals and into those support, both the professional and quasi-professional, and figuring out how to change the curriculum so that you can begin to do that systematically.

I find, interestingly, that the first thing I get out of most of these folk is we have to spend more money, we have to set up additional structures, and if, in fact, we are dealing with behavior and systems, there is a mental approach to behavior which allows the system to function that you do not necessarily have to spend a lot of money on, and that is basically behavioral alteration.

So if we have to write off today's current professionals, we ought to at least make sure that as we make these changes, we get down in there early, and I am not just anxious to set up a Federal agency to collect data to get the why and begin to do that. I am very anxious to get some help in exactly where there are people who are doing this.

Do you do any kind of, and notwithstanding the fact that you are no longer there, do you do any in-service training in the VA? Have you found that you have to set up a parallel program for those that are there to do training, to get people to understand, notwithstanding the fat that you put up a voluntary system and you can report? Even if it is voluntary, there are people who will be hesitant to do it because they have not been in that situation before. You have to create an environment of support, not just here is the environment.

Dr. KIZER. It goes beyond that. The VA actually put in place a requirement, a continuing education requirement for our existing practitioners, not the usual continuing medical education but a requirement specifically on quality improvement and patient safety that went beyond what is required, and as far as I know, that is unique in the nation.

But they also——

Chairman THOMAS. Now, was that an integral component of putting this plan in place or did you realize you had to have it as you were going along?

Dr. KIZER. It was one of the areas where we knew that we had to change the behavior of the existing cadre of folks. You also have to look at the next generation and put in place things to deal with them, so it requires a multi-faceted approach. Recognizing the culture and the barriers that exist, VA also has a financial rewards system where practitioners can actually get financially rewarded for identifying problems and solutions. But it is trying to change the dynamics from one of hiding the information to one were it is the norm that you come forward and you are as forthright and open as possible.

Chairman THOMAS. But can you not at least get into that aspect of this readjustment we need to make on a carrot and a stick basis? That is, you reward those institutions and other places that are doing those sorts of things, not the question of the transmission of the data itself, which has to be in a positive, supportive structure.

But it seems to me that one of the problems, and we have not really talked about it, is that we do not have the ability to collect the data, or we are beginning to get the ability, and even if we have it, we still do not have in place, except for maybe structures like yours that can impose it, kind of a best practices procedure so

that once you get the data, it can get out there and actually be converted into a workplace change.

In that sense, we ought to be able to reward and withhold, if not punish, for people who are picking up and making the changes that clearly have been indicated are the appropriate way to go. I think the medical culture causes problems there again, because now you are telling me how to practice the art of medicine for which I am my own best definer.

Dr. KIZER. There is no question that there is much that could be done in reimbursement strategies and how health care is compensated that could get at the issues that you are talking about.

Chairman THOMAS. I am actually going to be looking, and I know you folks do not have a lot coming out the other end of the pipe yet, but from what I have heard, it sounds to me like we have got a little bit of a microcosm here that has got a number of pieces in place. Now, obviously, the liability question is different and that is something we have to look at over in the other area.

But one of the things I hope people realize on this, and I hope in terms of the legislation, if we do move legislation this year or whenever we move legislation, is that it is not to do something simply to react to the publicity that occurred, and I am always concerned about that. But I do think there are some overdue at least first steps or positive steps about the control of information, the flow of information, the assisting in the collection of information, that certainly would lay a foundation for us to move forward, where governmental agencies or quasi-governmental agencies, although they may be thought of that way, and private commissions and agencies are going forward.

Now, I know that some people are going to be suspicious of the IOM report and its data and most of the beginning dates of a lot of activities and they seem awfully close to what is occurring now, and my assumption is that it is just the timeline of the awareness. As you indicated, maybe the aviation industry was in the 1970s, the 1980s, and the medical community's time period is in the 1990s and the first few years of 2000. If that is the case, we will accept the very interesting coincidence of the movement in this area.

My hope is that as much on a voluntary basis as we can, that we could move forward, but I am having a difficult time now accepting the belief that a totally voluntary structure will produce anywhere near 50 percent reduction in the time frame or a mandatory will create the climate which will allow us to build on what we are doing and move it forward as an ingrained culture rather than as another structure over which we are going to fight in terms of whether it helps or hurts.

The gentleman from California.

Dr. GOLDEN. Mr. Chairman, can I give you a piece of good news, at least?

Chairman THOMAS. Yes, Dr. Golden. I am looking for it.

Dr. GOLDEN. I know you had concerns when you had talked to Dr. Cassel about the physicians' attitude toward data and changing performance, and I have been giving physicians' data for seven years in my State and I can tell you that when they see clinically pertinent data, they do respond. I have gotten two unsigned hate letters in seven years, and I can tell you now I send data to——

Mr. STARK. Did they have a big red crayon?

Chairman THOMAS. Could you read the handwriting?

Dr. GOLDEN. No. Actually, one was from the east side of the State, one was from the West, but that was when we first started mailing to doctors' offices directly performances, and we get on average over 150 offices responding back to us now saying they were going to implement things in response to data on performance Statewide. So I think things are better than you think.

Chairman THOMAS. But also, in listening carefully to the aviation field structure, what was said if we were listening carefully was that when you are dealing with this data, they have pilots talk to pilots, air traffic controllers talk to air traffic controllers. They find a relationship in which there is a common understanding that you are in my business and we are all in this together, which is not always the case in the hierarchial structure of medicine. To the degree that we can learn from that, that also would be helpful.

The gentleman from California.

Mr. STARK. Thank you, Mr. Chairman, and I thank the panel. I guess, just quickly, Dr. Bagian, can you just very quickly give us some indication of whether on a dollars and cents basis, your program for quality in the Veterans Administration, has it saved you money, cost you money? What has been the result? Can you document that for us?

Dr. BAGIAN. That is one of the things we are looking at, to look for the business case, if you will. We do not have enough data to give you that answer, but we suspect for a whole host of reasons when we do the whole accounting, but we do not have any data to supply at this time.

Mr. STARK. If you save money, let us know. If you do not, shred it, okay?

Dr. BAGIAN. We certainly think that is important. We will look at it. But it is the right thing to do, too. We do not think you can do anything but do it. We think you cannot lose.

Mr. STARK. Dr. Kizer, your organization has got some, I guess, 29 standard performance measures that you have identified, maybe more now, I do not know, and my question, I guess to the panel, is does anybody feel that we should not try and develop and use standard performance measures for various aspects of quality control, that a single set of those performance measures should be used nationwide, and that the hospitals should be required to make public their progress in meeting these standard performance measures? Does anybody find anything wrong with that?

I mean, I think that is different from reporting serious errors, but some way to measure—I guess I do not know whether they do it with airlines. They do it with passenger complaints. I am not sure that is a very good standard.

Dr. Kizer, do you think that mandatory reporting has a place in this whole system? I mean, that is what IOM recommends. Do you want to comment?

Dr. KIZER. I believe there is a set of events we can define that that are important both from a quality improvement and a public accountability point of view; there are certain things that just should not occur in health care today and that the public has a right to know about them.

It is a fairly short list of things. I think some have alluded to them already, things like wrong-site surgery or perhaps medication error deaths or death during childbirth, things that just are not what one would expect today. I think that it would actually be quite possible to garner consensus among the health care professionals about that list of things that would be mandatorily reportable.

I think the list of things that one might want to maintain confidential is a much longer list, things involving judgment, particularly professional judgment, was it a premature death, was it unexpected, those type of things. But there is a set of information that really should be available for public accountability purposes.

Mr. STARK. Dr. Golden, I suggested earlier to the Hospital Association and the AMA that they might like to use PROs as the group that would oversee any kind of a reporting system, and I got the sense that they dismissed the PROs as merely another bureaucratic governmental agency. It is my understanding that your funding comes as a government contractor, but do you want to differentiate yourself from Lockheed or other government contractors?

Dr. GOLDEN. All the PROs are independent corporations, if you will. Some of them have different structures. But we have a contract with HCFA to perform tasks in our environment.

As a member of the AMA House of Delegates off and on for 20 years, I know that the approach, the quality improvement approach of PROs over the last seven years, has been very positively reviewed, and, in fact, the AMA House with their reports have said so. They have found the educational approach to be very much to the liking of the organization and its members.

I think that they get nervous about government, but there is no question that in terms of relationships locally between PROs and physicians and hospitals, we have seen a great improvement over the last several years and it is a very collaborative and constructive relationship at this point.

Mr. STARK. JCAHO, Dr. O'Leary, was set up in 1965 to create the oversight of quality in the hospital structure, was it not?

Dr. O'LEARY. Yes, sir. The Joint Commission was established in 1951. The Medicare Act created the deeming relationship in 1965.

Mr. STARK. Why did it take you until 1999, according to your testimony, January of 1999, to develop explicit patient safety standards?

Dr. O'LEARY. Well, let me clarify.

Mr. STARK. That was 35 years, if you do not count going back to 1951, which even makes it longer. What was the problem? What were you doing all that time?

Dr. O'LEARY. Let me clarify that a large number of Joint Commission standards are patient safety standards in the sense that they reduce the risk of untoward occurrences, whether we are talking about credentialing and privileging standards or environmental safety standards or patient assessment standards. The particular standards that we referred to are standards specific to error identification or reporting inside organizations, where we now require organizations to set up processes or a plan, in line with your previous question.

Mr. STARK. What was the problem in getting that done? What took you so long?

Dr. O'LEARY. I think it was the realization that the problem that we were experiencing had probably less to do with organizations not reporting errors to us than the fact that they were not—errors inside organizations were not made known to the leaders within organizations and it dawned on us that we had not really created a requirement that organizations create systems to identify serious adverse events and require internal reporting and internal root cause analyses and the development and implementation of action plans.

So those specific standards to which that refers are those standards. You are requiring an internal plan, which was the question you asked earlier, inside organizations to surface these events and deal with them.

Mr. STARK. So it took you 35 years to figure that out?

Dr. O'LEARY. At least that, yes.

Mr. STARK. Thank you, Mr. Chairman.

Chairman THOMAS. Thank you. I do not remember whose testimony it was off the top of my head when I read it, but it may have been on this panel. It was an example of the Salt Lake City hospital situation, where there were 20 reported, and then when you went back and did an analysis inside the structure, there are actually 582. And by going back and doing it in a more systematic way, they actually wound up reducing it below the original 20 that were reported.

That, to me, in a nutshell, is kind of where we want to go, and that is we have got to set up a structure that allows us to systematically address what is really there because we can make the corrections. It has been proven over and over again. It is just that cracking this nut of the culture of medicine and truly putting in place structures which provide a comfort level for all, in my opinion, to report and then deep root analysis so that you can make the kinds of changes.

But what scares me the most is, and I guess it is the phrase low-hanging fruit, that low-hanging fruit has been hanging there for a long time and maybe this publicity will allow some folks to pick it. But my fear is, picking the fruit makes it look like movement has been made. There has been no systemic change, and we will have lost the opportunity to get in, and I am very, very nervous about that. That is why I want to make sure that we put at least some structure in place fairly quickly on, for want of a better term, an exoskeletal aspect of it, which would be liability or data collection that will allow the forces that seem now to be working to work in an environment in which they can actually perform better.

I do not know that I want to put in place a total structural approach which will do government mandatory, deep root, and the rest of it, but I do think we have to, I think sometime this year, create an environment which is nurturing and supportive of clearly, whether it started in 1999 or not, the willingness apparently to go forward. We have got to give you some of those tools.

I want to thank you folks. We are going to be back to you. Do not want for me. If you have got any additional information or direction or if you are alarmed by some of the legislation that is mov-

ing, I would appreciate a candid analysis of what is out there as legislation forms in terms of whether or not it is actually a help or a hindrance or if there are pieces of it that are better than not. We desperately need your help, your expertise, and your experience.

The gentleman from California.

Mr. STARK. I agree, and just a couple of anecdotes that may be helpful—just this last week, we heard about a report in Charlotte, North Carolina, where they found 28 questionable deaths in JCAHO-accredited mental health facilities, and yet JCAHO only knew about two of them. Now, that may not be their fault, but it indicates that it does not sound like people are stepping right up to report.

Then in our own State, we must have at least twice the New York State population, both of our States have mandatory reporting, New York and California, yet we reported in 1998 4,337 reports of serious events, and New York had some 15,000 to 20,000 reports. Now, we have to come to some kind of closure on what is different and why this huge difference in reporting.

Chairman THOMAS. It may very well be the definition of a serious event.

Mr. STARK. Yes, there may be a lot to it, but I think that is the problem.

Chairman THOMAS. But the point is, we have got to get to the bottom of it.

Mr. STARK. Somehow, we need to find a way that we are collecting these data and then we can act on it, I think, or the institutions can act on it. So I look forward to working with you.

Chairman THOMAS. Based upon the statement you just made, I do not think I have to make the following statement, and that is what we heard, if we did not hear anything, was not to set up a system which is punitive, accusatory, but rather open, voluntary, looking for professionals to be able to operate. Stating any kind of evidence based upon the current lay of the land, to me, is relatively less useful than to begin to figure out how to set up a structure in which we can move forward.

Personally, I am not interested in jettisoning anybody off of this vehicle of trying to reduce the staggering number of medical errors that produce deaths greater than what occur on the highway from cancer or from AIDS. I am enlisting everybody in both a voluntary and a mandatory effort to turn this around.

Thank you all. The subcommittee stands adjourned.

[Whereupon, at 2:06 p.m., the hearing was adjourned.]

[Submissions for the record follow:]

Statement of the American Academy of Orthopaedic Surgeons, and 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 Thomas' initiative in holding this 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 towards 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 Chairman Thomas and other members of the 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 the Subcommittee and other Members of Congress as you assess the need for legislation to address medical error reporting.

Statement of 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

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 strat-

egies 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.

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% 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 Committee 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.

Statement of American Osteopathic Association, and American Osteopathic Healthcare Association

This statement is presented on behalf of the American Osteopathic Association (AOA) and the American Osteopathic Healthcare Association (AOHA). The AOA represents the 44,000 osteopathic physicians throughout the United States who practice

medicine and are committed to ensuring the highest standards of patient care. The AOA is the national professional organization for osteopathic physicians, and is the recognized accrediting authority for colleges of osteopathic medicine, osteopathic postdoctoral training programs and osteopathic continuing medical education. The AOHA represents the nation's hospitals and health systems that deliver osteopathic healthcare or osteopathic graduate medical education. Through a for-profit subsidiary, the AOHA provides its members with access to risk management assistance, among other products and services.

Osteopathic medicine is one of two distinct branches of medical practice in the United States. While allopathic physicians (MDs) comprise the majority of the nation's physician workforce, osteopathic physicians (DOs) comprise more than five percent of the physicians who practice in the United States. Significantly, D.O.s represent more than 15 percent of the physicians practicing in communities of less than 10,000 and 18 percent of physicians serving communities of 2,500 or less.

The AOA and the AOHA are deeply concerned about the frequency of adverse events cited by the Institute of Medicine in its recent study, "To Err is Human." The Institute reported that between 44,000 and 98,000 patients died or were injured in 1984 and 1992 as a result of these adverse events.

The members of the osteopathic medical profession have long supported efforts to improve patient care by drastically reducing medical errors. In 1945, the AOA's Healthcare Facilities Accreditation Program (HFAP) was established. The HFAP is authorized by the Health Care Financing Administration (HCFA) to accredit osteopathic and allopathic hospitals and healthcare systems for Medicare purposes. The HFAP assists hospitals and their staffs in reducing or eliminating medical errors by developing Quality Monitoring and Improvement programs that monitor patient safety. On January 27, the AOHA held its first seminar on improving patient safety and reducing medical errors. Additional seminars are planned for March 24, and will be held throughout the year.

The AOA and AOHA generally support the IOM's recommendations to bolster nationwide efforts to improve patient safety. We support forums that explore ways in which healthcare organizations can participate in the effort to reduce medical errors. The healthcare community can, and should, expand current activities to identify and address system failures that lead to medical errors.

The osteopathic medical community will continue its efforts to strengthen existing quality improvement activities at every level, including the education and training of medical professionals and administrative personnel. We do not believe that the way to improve healthcare is to increase federal mandates, regulation, and administrative burdens, which could suppress reporting and inhibit open discussion of adverse events and medical errors.

The AOA and the AOHA agree with the IOM that it is important to have reliable information about adverse events that healthcare professionals can use to assess, analyze and correct systemic and other failures that lead to such events. There is potential for such information to enhance the understanding of medical errors, while preventing future errors. Unfortunately, there is scant proof among the approximately 20 states currently reporting such data that the healthcare systems are any safer in those states than in states that do not have such reporting.

We do believe, however, that state medical error reporting programs already in place may offer models for a federal effort to compile similar data. These should be closely reviewed and considered before federal action is taken. For instance, the data now being collected should be analyzed to determine whether or not the data used in the IOM study is reflective of the current state of affairs. Additionally, consideration ought to be given to the development of pilot projects designed to collect adverse event data. Finally, federal agencies should use the data compiled by states with mandatory reporting programs to determine whether their data is comparable with the IOM's data, which may be outdated.

Outdated data may have distorted the IOM's conclusions about the alleged epidemic of medical errors. Accurate data could help federal agencies determine which areas of healthcare experience the most errors and are most in need of restructuring. Accordingly, the AOA and AOHA would recommend a revised study using more current data than 1984 or 1992 as reported by the IOM.

Mandatory reporting of adverse events presents a number of serious problems. Healthcare facilities may be reluctant to cooperate with mandatory (or even voluntary) data reporting if they perceive that they will be disciplined. It will be difficult to learn from errors and to improve systems if facilities and individuals fear that the information will be used against them. Only after the IOM study and its supporting data have been analyzed fully and pilot projects established, should policymakers consider the establishment of a national database, with either voluntary or mandatory reporting.

If a national effort to gather and analyze adverse event data goes forward, the information should not be solely available to federal healthcare agencies. Stripped of its identifiers, it also must be available to healthcare facilities, researchers, accreditation organizations, and other healthcare entities that, in turn, could use the data to benchmark and monitor changes in the occurrence of medical errors. In this way, the database would serve as a tool to promote higher standards of patient care. Healthcare facilities and providers who report and assess medical errors can attempt to rectify particular problems by monitoring their data and comparing it with federal, state and local trends. Identifiable data is not necessary for this function to be met.

Identifiable data should not be available to the public because to do so would inhibit reporting due to a natural fear of punishment and litigation. Healthcare professions continuously work to correct medical errors. The AOA and the AOHA believe that the American healthcare system operates well on the whole. Public confidence in that system should not be undermined while healthcare providers seek to increase patient safety.

Another reason that the AOA and the AOHA recommend national data remain confidential and secure is that such data could be used as background information for litigation. Any national data that is gathered should be considered information only for peer review. Since peer review protections vary greatly from state to state, at a minimum, any federal data gathering initiative must provide protection from discoverability and use in malpractice litigation. The data must be used only for the purpose of improving the safety standards of American healthcare.

The AOA and the AOHA stand ready to support the IOM in improving patient safety in the United States. We welcome the opportunity to work with this committee and others dedicated to patient safety. Our members and staff are available to assist in the development of legislation that would lead to the continued improvement of the American healthcare system.

Statement of Association of Women's Health, Obstetric and Neonatal Nurses

AWHONN is a membership organization of 22,000 nurses who manage the complex health needs of women and newborns. Our membership includes registered and advance practice nurses who work in a variety of settings including clinical, research and academic.

AWHONN's Commitment

As the IOM report indicates, the scope of the problem is massive, and AWHONN is committed to working with other health care provider organizations to develop solutions to help nurses combat the problem of medical errors. As an initial expression of our concern with the issue of medical errors, AWHONN has signed on to the following statement circulated by the American Nurses Association:

The Institute of Medicine report, To Err is Human: Building a Safer Health System, shines a bright light on a significant problem within the U.S. health system. The patient care environment—across all health settings—is NOT conducive to the delivery of safe, quality nursing care despite the best efforts of dedicated nursing professionals. **It is time to shine that same bright light on those qualities which create an environment that promotes the highest standard in patient care and excellence in nursing services.** Qualities like sufficient nurse staffing, adequate support services; an appropriate skill mix of qualified providers that reflects patient acuity and needs; and dedicated nursing leadership in administration. Enhancing these qualities will result in better patient outcomes, fewer errors, and a stronger nursing profession emboldened to speak out on behalf of our patents.

Over the years, AWHONN has been committed to promoting excellence in nursing practice to improve the health of women and newborns. Nurses can play a critical role in the prevention of medical errors, as they are often the first and last level of communication with the patient. Because of their comprehensive education and experiences, registered nurses are capable of providing both highly skilled technical care and complex emotional care. Furthermore, professional registered nurses are able to effectively implement patient management strategies for both low-risk and high-risk patients.

Support of System Solutions

We strongly agree with the report's overall goal to look beyond using individual culpability as a means of correcting the significant problem of medical errors. Instead, the report places a great deal of weight on problem-solving across disciplines and developing various mechanisms to reduce the number of medical errors. Research has shown that because we are humans, we will commit errors...we are not perfect. Unfortunately, we cannot eliminate all medical errors, but we can strategize on ways to dramatically reduce them. We have learned that even the experts can commit errors—it is not simply a matter of lack of knowledge.

AWHONN agrees with many of the study's recommendations, including the creation of a center for patient safety within the Agency for Healthcare Research and Quality that would set national safety goals, track the progress and report to the President and Congress on the achievement of those goals, and research methods for identifying and preventing errors. It is important to create one central location where information can be shared on findings and trials.

Need to Address Nursing Shortage

While we support many of the recommendations of the report, we believe one critical component was not addressed. The report ignores the issue of inadequate and inappropriate nurse staffing, which increases the likelihood of medical errors, regardless of competency. In the managed care era, we have seen hospitals replacing highly qualified and educated nurses with less qualified technicians. AWHONN is greatly concerned with the growing nursing shortage and we challenge healthcare facilities to continuously evaluate the impact of patient-to-nurse ratios on patient outcomes, patient satisfaction, resource utilization and overall operating expenses.

Approximately 80% of our members provide bedside maternal/child care on maternity floors and neonatal units. Hospital admissions for infant births account for more than twice the admissions for any other medical condition or procedure.[1] We view the childbirth experience as an intensely physical and emotional event with lifelong implications. Only the registered nurse combines formal nursing education and clinical patient management skills with experience in providing emotional and psychological support and physical comfort measures to laboring women.

AWHONN supports evaluation models that would measure the impact that a registered professional nurse has on indirect cost savings, such as savings resulting from lower cesarean section rates, shorter labors and fewer technologic interventions. With fewer qualified nurses available, it will be more difficult to ensure that quality patient care is being delivered. Knowing that this shortage will gradually increase and peak around 2010, we must be prepared to address their impact on patient safety.

Recertification is Not the Answer

While we agree with the report's recommendation for health professional licensing bodies to work with certifying and credentialing organizations to develop more effective methods to identify unsafe providers and take action, we are concerned with the recommendation to require licensing bodies to implement periodic re-examinations and re-licensing of doctors, nurses, and other key providers, based on competence and knowledge of safe practices. Research has not proven that this intervention is any more effective than current strategies employed by the profession. The nursing profession is committed to ensuring competent practitioners through proven methods, such as appropriate education and competency validation. By including the re-examination component, the report contradicts its concept of not focusing on individual competency. Before determining a strategy, AWHONN urges true research to develop an evidence-based approach to professional certification.

Commitment to Providing Resources for AHWONN Members

AWHONN has a long history of providing resources to our members to support them in expanding their knowledge in order to deliver quality nursing care. AWHONN recognizes that delivery of safe patient care is directly associated with appropriate education and competency validation, creation of evidence based policies and procedures and proper equipment management. AWHONN also promotes safe patient care practices through its journals, practice reference service, research-based practice projects and legislative activities.

In providing quality of care to pregnant women and newborns we know that:

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[1] Agency for Health Care Policy and Research. (1999). *Most Common Diagnoses and Procedures in U.S. Community Hospitals, 1996 Health Care Cost and Utilization Project, Research Note.* (AHCPR Publication No. 99–0046). Rockville, MD: Author.

• **Proper fetal assessment is vital to the care of obstetric patients.** AWHONN therefore addresses this area through its Fetal Monitoring Workshops, *Fetal Heart Monitoring Principles & Practices book, videos, CD ROM, Antepartum and Intrapartum Fetal Heart Rate Monitoring Clinical Competencies and Education Guide and Fetal Heart Rate Auscultation symposia.*

• **Appropriate and timely patient assessment can elicit important information about potential risks. Proper assessments and subsequent interventions can promote positive patient outcomes.** AWHONN resources which enhance nursing assessment skills include a presentation package targeting domestic violence, a compendium of postpartum care, tapes on mother-baby postpartum assessments, videos on critical-care obstetrics, cross training and compromised neonates.

• **Safe medication administration contributes to safe clinical practice.** AWHONN's Perinatal Medication Administration *Competence Assessment Tool* tests staff's current medication administration knowledge and critical thinking skills.

• Once training has been completed validation of competence is imperative. AWHONN resources which address competency validation include a reference book entitled *Competence Validation for Perinatal Care Providers* as well as numerous clinical competencies and education guides on such topics as perinatal education, home care and limited ultrasound examination. *AWHONN's Assessment of Fetal Well-Being Competence Assessment Tool* is designed to measure nurses' knowledge and application of perinatal facts and principles.

• **Effective patient care guidelines, policies and procedures can guide quality patient care.** AWHONN resources to assist our membership in this include the AWHONN handbook entitled *Achieving Consistent Quality Care: Using Evidence to Guide Practice, AWHONN's Standards & Guidelines* (*5th Edition*) and the AWHONN publications *High Risk & Critical Care Intrapartum Nursing and Perinatal Nursing* both of which contain actual guidelines and/or care paths.

• **Equipment malfunction and misuse contributes to medical errors.** AWHONN includes a section in its *Fetal Heart Monitoring Principles & Practices* book on instrumentation troubleshooting. The video series on OB/GYN limited ultrasound includes an orientation to the machine's instrumentation and controls. In AWHONN's *Liability Issues in Perinatal Nursing,* a section is devoted to the appropriate use of technology and equipment.

Summary

AWHONN believes that nurses have the education and experience to deliver quality health care services, while monitoring the care their patient receives over the entire health care system. Nurses have long been known as strong patient advocates, working to ensure their patients receive access to the most appropriate care in a timely fashion. We would urge Congress to consider that the health care community needs to evaluate solutions that help address the issue of medical errors across the health care system.

AWHONN appreciates the opportunity to offer our comments on this very important issue. We will continue to work with the members of AWHONN to ensure that they have the resources available to them to make decisions about the care their patients receive and we look forward to working with Congress on developing possible solutions to this problem.

For further questions, please contact Melinda Mercer Ray, RN, MSN, Director, Health Policy/Legislative Affairs at 202–261–2405 or Kristen LaRose, Senior Legislative Specialist at 202–261–2402.

Statement of Health Care Liability Alliance

The Health Care Liability Alliance (HCLA) is a coalition of more than 30 organizations committed to reform of the health care litigation system to enhance its fairness, timeliness, and cost-effectiveness. HCLA's members are organizations and associations of physicians, hospitals, blood banks, health device manufacturers, health care insurers, pharmaceutical manufacturers, and biotechnology companies.

HCLA applauds the Chairman's timely leadership in connection with the issue of patient safety. We appreciate the opportunity to submit our views regarding the report of the Institute of Medicine (IOM) entitled "To Err is Human: Building a Safer Health System." We look forward to working with the Chairman, members of the Committee, and their staff as Congress debates this important issue.

Because of its concern for the effect the tort system has on the quality of care, HCLA welcomes the IOM Report. The Report makes a significant contribution by recognizing that the tort system is a major barrier to improving the quality of care. That underlying conclusion provides the basis for meaningful tort reforms.

INTRODUCTION

The tort system as it now operates in this country increases health care costs by forcing providers to practice defensive medicine and by imposing inordinate litigation costs on the health care system. These costs are borne by patients, people with insurance, people who are trying to buy insurance, people who need care, and taxpayers—through higher health care costs, higher insurance premiums, higher taxes, and reduced access to care.

The tort system does not provide benefits that justify these costs. It does not carry out its intended functions. It does not establish a rational standard of care. Findings of liability, made in court with hindsight and with the benefit of leisurely contemplation that rarely are possible in the actual delivery of care, often do not provide an accurate standard of medical conduct. As one expert on the tort system has summarized this situation, "The fundamental problem of tort liability, especially in the areas of products liability and medical malpractice, stems from the unpredictability of its imposition." [1]

This retroactive, case-by-case, and arbitrary standard making has caused doctors to practice defensive medicine—to order medical procedures out of a perceived need to have a defense available if there should be an adverse event. Cesarean delivery rates provide one example. Because juries awarded large recoveries for birth injuries where obstetricians did not perform a Cesarean section, doctors have performed them more often than they otherwise would have. Cesarean rates rose from 4.5 per 100 births in 1965 to 24.1 in 1986.[2]

The essentially unlimited power of juries to award non-economic damages results in verdicts that are not just and that when publicized whet the appetite of trial lawyers and traumatize providers. In many cases, (enough to engender disdain for the litigation system and fear on the part of the provider), there is no logical or medical connection between the provider's action and liability or between the injury and the amount of damages awarded.

The Harvard Study of hospital care in New York itself demonstrated that the filing of claims was not correlated to negligence.[3] In a follow-on study of claims of malpractice filed by patients in the Study, several of the authors concluded that "the severity of the patient's disability, not the occurrence of an adverse event or an adverse event due to negligence, was predictive of payment to the plaintiff." [4] In other words, the amount patients recovered through the tort system was a function of their health condition, not any negligence by the health care system. The authors concluded more generally, therefore, that "the standard of medical negligence performs poorly in malpractice litigation." [5]

The tort system thus presents a provider with the random risk of catastrophic financial injury. This causes some providers to quit practice and others to limit their practice, reducing patients' access to care, particularly in inner-city and rural areas. Most of those who continue to practice are forced to engage in defensive medicine. This results in more medical interventions for patients, as the increased rate of Cesarean deliveries demonstrates, thereby adding costs and putting patients at greater risk. It is estimated that defensive medicine costs at least $50 billion per year.[6]

At the same time, the litigation system does not provide fair and timely compensation for injured patients. They must wait on average 3½ years for resolution of their claims by the litigation system. If they prevail, they typically must give 33–60% of any recovery to their lawyers in contingency fees. Only 28 percent of the amount spent to provide insurance coverage actually goes to victims; the rest is spent in transaction costs and in operating the tort litigation system.[7] The tort system imposes a 72% tax on patients and providers.

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[1] Jeffrey O'Connell, "Two-Tier Tort Law: Neo No-Fault & Quasi-Criminal Liability," 27 Wake Forest Law Review 871 (1992).

[2] Richard E. Anderson, "Billions for Defense," Archives of Internal Medicine. 1999; 159: 2401

[3] Paul Weiler et al., A Measure of Malpractice. Cambridge: Harvard University Press; 1993.

[4] Troyen A. Brennan et al, "Relation Between Negligent Adverse Events and the Outcomes of Medical-Malpractice Litigation," N Engl J Med 1996; 335:1963–7.

[5] Ibid.

[6] David Kessler and Mark McClellan, "Do Doctors Practice Defensive Medicine," QJ Econ. 1996; 111: 353–390.

[7] Jeffrey O'Connell and C. Brian Kelly, The Blame Game. Lexington Books; 1987:127.

Because of the threatening and contentious climate it creates, the litigation system, rather than protecting patients, is actually impeding efforts to improve the quality of care. It makes it difficult for providers to acknowledge mistakes. It deters open discussion of possible errors. And it discourages providers from filing reports, seeking assistance, and collaborating with other providers and experts to improve quality.

The money spent on defensive medicine and litigation expenses could be better used to improve the quality of care and access to it. The energy and focus that the present system channels into litigation-related and litigation-induced actions should be redirected into developing better quality control systems and innovative ways of delivering care.

INSTITUTE OF MEDICINE REPORT

With one exception, the IOM Report avoids inflated rhetoric. The exception is its statement that as many as 98,000 people may die annually because of medical error. This figure is extrapolated in ways that are not explained from 71 deaths that the Harvard Study of the medical records of 31,429 patients discharged from 51 New York hospitals in 1984 said were attributable to negligence.[8] This extrapolation has no scientific basis, as the authors of the Study themselves have recognized.[9]

The Harvard Study, moreover, suffered from methodological flaws, and its results have not been duplicated. The reviewers who determined which records reflected negligence agreed in only 10% of the cases. In an effort to confirm findings that rest on this shaky foundation, a second set of reviewers examined a subset of 318 of the records. Apparently they did not reach the same conclusions on individual records that were attributed to the primary set of reviewers.[10]

The authors of the Harvard Study also applied their methodology to patients in Colorado and Utah hospitals in 1992. Extrapolating the results of this study, the authors concluded that 44,000 deaths were caused nationwide by medical error. The IOM Report finds this, and the unexplained figure of 98,000 deaths, to represent a range.[11] The more recent study, however, could equally be seen as an indication that health care improved in the 8 years after the New York study, that better care is provided in Colorado and Utah, or, since the results of the Harvard Study could not be duplicated, that the parameters of the Study are vague and the methodology is flawed.

It is not our purpose here to discuss the weaknesses of the Harvard Study or the exaggerated extrapolations that have been made from it. Patient safety and quality care should not be a numbers game. We should, as a health care system and as a society, endeavor to eliminate avoidable injuries. In doing so we must remember, as the Harvard Study reminds us,[12] medical intervention is inherently risky and is provided by people. People are only human, and the title chosen for the IOM report reflects the reality this presents; "To Err is Human." Because we are dealing with medical intervention by human beings, we must focus on what we can do together to reduce the number of unnecessary injuries suffered during the delivery of health care services.

The IOM Report makes a vital contribution to this effort by its recognition and discussion of the three interrelated factors that now impede efforts to improve patient safety.

First, it emphasizes that the problem is not "bad apples,"[13] although there are some "bad people" and they must be weeded out. Mistakes are often caused, or are not prevented, by system (both technical and organizational) failures. As the Report suggests, because providers are only human, they need systems to help them avoid mistakes; but we cannot let reliance on systems dull the special intelligence that humans posses or lull them into lethargic complacency.

The focus must be on developing systems that avoid future mistakes and not on attempting to pin blame for past conduct on an individual. This important observation leads the Report to balance public policy in favor of error prevention and away from faultfinding: "When an error occurs, blaming an individual does little to make

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[8] Berkeley Rice, "Do doctors kill 80,000 patients a year?" Medical Economics. November 21, 1994; 1(discussing extrapolation to 80,000 deaths).

[9] Troyen Brennan et al., "Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study," N Eng. J Med 1991; 324: 370–6.

[10] "Billions for Defense" at 2400. The second set of reviewers found the same incidence of adverse events and adverse events due to negligence, but not in the same charts. Rather than confirming the reliability of the methodology used, this provides further demonstration of the uncertainty of what is an adverse event and what is negligence.

[11] "To Err is Human" at 1, 22.

[12] A Measure of Malpractice at 138.

[13] "To Err is Human" at 42.

the system safer and prevent someone else from committing the same error." [14] "Although a punitive response may be appropriate in some cases (e.g., deliberate malfeasance), it is not an effective way to prevent recurrence." [15]

Secondly, the Report emphasizes the need to report information about adverse events or potential adverse events in order to identify patterns of conduct that threaten safety and to assess the success of corrective actions. It correctly recognizes that reporting is essential to the primary goal of prevention. The Report provides a comprehensive summary of the numerous and varied reporting systems that are currently in effect.

Thirdly, and most importantly, the Report recognizes that there is a critical and common element or impediment that prevents all the reporting systems, regardless of how they are structured, from collecting the information they need. That impediment is the tort system.

Participants and witnesses to an adverse event are reluctant to report it (even if required by law to do so) out of fear that doing so will trigger or support a tort claim. The irrationality of the litigation system and the randomness of its results trigger a defensive reaction. Fear of being enmeshed in that system, even if one is ultimately found not to be liable, deters reporting.

As the Report concludes, "Patient safety is also 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." [16]

As a result, it finds "All reporting systems, whether mandatory or voluntary, are perceived to suffer from underreporting. Indeed, some experts assert that all reporting is fundamentally voluntary since even mandated reporting can be avoided. . ..The volume of reporting is influenced by more factors than simply whether reporting is mandatory or voluntary. . ..One factor is related to confidentiality." [17] "Thus," the Report concludes, "the prominence of litigation can be a substantial deterrent to the development and maintenance of the reporting systems discussed in this report." [18]

It is refreshing that the IOM Report recognizes this problem. It is important to the debate that it does so. The tort system impedes efforts to improve health care by deterring the reporting of data needed to make improvements in the health care system. Recognition of this fact by The IOM should provide the needed impetus for addressing this basic problem.

As the Report recognizes, the tort system deters reporting even where confidentiality is promised. There is concern that confidential data will leak. There is also fear that what is confidential today may not be protected tomorrow. The Report cites the powerful example of the continuing political pressure to "open up" the National Practitioner Data Bank.[19] Providers are concerned that the constant political pressure eventually will be successful, leading to a breach not only of a particular data source but also inserting the opening wedge for a more general release.

Confidentiality of adverse event reports, therefore, is necessary to develop an effective reporting system that will permit identification of safety problems and permit assessment of remedial actions. But there is on-going concern that even confidential reports will be fed into the litigation system—by leaks or by surrender to political pressure to remove the confidentiality protection. Confidentiality of reports is necessary to improve reporting, but it is not sufficient. The tort system also must be reformed.

Two reforms that are needed

The findings of the IOM Report, therefore, confirm the need for a combination of two reforms: confidential protection for adverse event reports and a reformed tort system.

Confidential reporting

It is important that Congress act on the findings of the Report by protecting the confidentiality of reports made of adverse events or of problems that could lead to adverse events.

The Report in several places emphasizes the need for reporting to be confidential. It appears, in fact, to call for Federal legislation to protect confidentiality of all re-

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[14] Id. at 4.
[15] Id. at 47.
[16] Id. at 37.
[17] Id. at 85.
[18] Id. at 94.
[19] Id. at 105.

ports although it also makes an inconsistent recommendation that would deny confidentiality to reports of adverse events leading to serious injury. The Report recommends Federal 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."[20]

As the Report's discussion of peer review protection reflects, the nature and the scope of the current protection varies widely from state to state.[21] Not only does the scope of the protection afforded by each state differ greatly, but in some instances the sharing of peer review materials with third parties engaged in health care quality efforts, such as The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), has been held to waive any confidentiality protection.[22] Moreover, the efficacy of these state protections is further undermined by uncertainty surrounding the application of the peer review privilege should the parties be drawn into federal court. This occurs, for instance, in actions brought under a Federal statute with related medical malpractice claims under state law (i.e., pendent state claims).

As the Report recognizes, health care providers must have confidence that the peer review privilege will be applied with consistency and predictability if they are to come forward with information regarding medical errors.[23] The discussion in the Report focuses on immunity and protection of peer review materials and deliberations from discovery. In urging that the protection be expanded, the Report at a minimum recommends that quality and safety information derived from reports or from investigation (the main areas now protected in different ways by peer review statutes) be protected from use in litigation and from public dissemination. The information derived through the peer review process may involve the "most serious adverse events"; thus this recommendation calls for the appropriate confidential treatment of such information.

However, the Report also says that such information should be available for public consumption and that only reports of events other than the "most serious adverse events" should have confidentiality protection.[24] We discuss this misplaced, and internally inconsistent, position below. The important fact is that the Report finds that confidentiality is necessary for effective reporting and patient safety improvements and recommends in, at least one place, across-the-board confidentiality.

Tort reform

Even where confidentiality would be provided, but particularly where it would not, reporting and improvements in the health care system quality can best be advanced by reforming the tort system to protect providers from random and excessive judgments. HCLA urges Congress to enact the tort reforms embodied in its proposed legislation which is modeled on the MICRA reforms enacted in California in 1975.

These reforms would preserve the ability of injured patients to obtain compensation for their economic injury and to recover reasonable non-economic damages. They would: 1) encourage non-judicial resolution of claims and ensure that plantiffs' lawyers did not capture an excessive contingency fee from their clients; 2) prevent plaintiffs from obtaining double recovery (collateral source rule); 3) limit non-economic damages to a reasonable amount ($250,000); 4) require plaintiffs to bring any action in a reasonable time after the injury occurs or is recognized (statute of limitations and statute of repose); 5) protect any particular defendant from paying a larger percentage of any recovery than is warranted by his/her conduct (joint and several liability).

Passage of these measures will restore a measure of balance to the tort system, give providers more faith in the system, and therefore facilitate reporting—which ultimately will result in greater patient safety.

As the IOM Report recognizes, patient safety is not adequately served by the present system. If the tort system in its current state were adequately protecting patient safety, the Report would not have been necessary. The tort system is not only not the answer; it is the barrier to the enhanced quality systems that the Report correctly finds are the best way to improve safety. The underlying, if

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[20] Id. at 9.
[21] Id. at 103–104.
[22] As the Report recognizes, "One legal fear is that disclosure of internal quality data to outside reviewers not under a peer review statute will lead to discovery from JCAHO in lawsuits; indeed, many fear that disclosure to JCAHO would invalidate even the nondiscoverability protections each hospital enjoys for its own data under its state peer review statute." Id. at 108.
[23] Id. at 96.
[24] Id. at 9.

unarticulated, theme of the Report, therefore, is that tort reform is necessary to improve the quality of health care in this country.

Actions that should not be taken

The Report correctly concludes that the barrier to systems improvements in health care is not the lack of reporting mechanisms but the tort-induced reluctance of participants to provide data through the existing avenues. There is no indication that there are not enough reporting requirements. The Report describes them comprehensively. The need is to make the changes necessary to encourage more reporting, and for the agencies and institutions to which reports are made to analyze the information and act on them more vigorously.

HCLA questions, therefore, whether any purpose would be served by adding new reporting requirements or creating new agencies to collect or coordinate reports. In fact, adding new reporting requirements would only distract attention from the need to make the essential tort changes to support the existing reporting requirements.

No new reporting requirements without confidentiality

While recognizing that the barrier to existing reporting requirements is a lack of confidentiality and fear of the tort system, the Report does not address this barrier, except in its recommendation that peer review protections be expanded.

Instead it recommends that mandatory reporting of serious adverse events be expanded by federal statute, without corresponding confidentiality protection. Indeed, while it offers a gesture toward the states' role, it would make mandatory reporting a federal requirement in any state that did not on its own come to the conclusion that mandatory reporting is needed.[25] Although The Report recognizes that the absence of confidentiality is impeding compliance with existing reporting requirements, it would make mandatory reporting a national requirement while providing no confidentiality protection.

The Report would permit confidentiality protection only for voluntary reporting of events that are not serious—where it is least useful. If an event results in little or no harm, there may be less concern about tort litigation. The Report offers confidentiality protection here, where it is worth less, but would deny it in the serious cases, where it is important to elicit reporting. Recommending confidentiality for voluntary reports is not a sufficient response to the problem identified by the Report itself—that lack of confidentiality deters reporting.

Drawing a line, moreover, on when reporting is required and when it is confidential on the basis of whether the action resulted in "serious" harm will bog down the health care system in line-drawing and hair-splitting. What is serious harm? Who defines it? Suppose the event could have had a serious harm if it had not been caught? How long is serious? Is an extra day in a hospital serious? Is a false positive that leads to patient concern serious? Suppose the patient was not able to understand the test result; is a false positive serious in that case?[26]

Rather than trying to impose reporting by regulation and mandates, and varying the protection for different types of reports, Congress should provide protection for all safety and quality reports, and for consideration of them. This is the best way to advance patient safety efforts.

No centralization of safety efforts

It would be both unnecessary and harmful to create the new Federal Center proposed in the IOM Report. The Report envisages various roles for this new Center. HCLA believes these are unnecessary and would actually detract from efforts to improve patient safety.

The Report sees a need for the Center to establish a "national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety."[27] The premise that only the creation of a government Center can create a national focus and provide leadership is disturbing.

As the Report indicates, efforts to enhance patient safety are being undertaken in different ways by a variety of individuals and institutions: insurers, manufacturers, providers, academic institutions, trade associations, etc. It may look messy and confused, but the pursuit of knowledge often is, particularly in an area as complex

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[25] Id. at 8.

[26] Unintentionally demonstrating the problem, the Report also refers to the kinds of acts that would fall under the voluntary (and confidential) reporting scheme as ones that resulted in "no harm...(near misses) or very minimal patient harm." (p. 74) What is supposed to be done with respect to injuries that fall between serious and minimal?

[27] "To Err is Human" at 5.

and varied as the design and manufacture of health care products and the delivery of health care.

Commissions, meetings, and public awareness can all contribute to a national focus. So can efforts by political leaders, if conducted without demagogy and finger pointing. A new Center is not necessary to do this. This proposal is really symbolic; concern would be demonstrated by creating a new Center and spending more money.

An approach based on centrally developing and collecting safety-related data could in fact impair safety research and promotion of safety activities. A centralized agency for safety research could well become hitched to a particular view or approach, subordinating all others. It is more effective for different people to try different approaches.

Creating a "highly visible [governmental] center" is likely not only to diminish the diversity of research and views but to politicize patient safety. Once there is a "highly visible" government agency tasked to provide leadership and develop research and recommendations, every interest group will descend on it in an effort to gets its agenda adopted. Congress will inevitably be drawn in. It would be far more effective, if more research is needed, to provide funding to a variety of researchers on a scientific, non-political basis.

The Report also has another role in mind for the new Federal safety Center. It would not be limited to research. It would receive and analyze reports (from the states)—apparently the mandatory reports of "serious adverse events" discussed above. The Center would become a national data bank for at least some kinds of reports. But it is unclear how the information would be used and who would have access to it. The Center apparently would "identify persistent safety issues that require more intensive analysis and/or a broader-based response."[28] In other words, it would use the data to do more studying. But would the agency act on the information? To whom would it give its findings?

What is needed is not central collection of information, nor more analysis and dissemination. Needed information should be given to those in a position, and with the most powerful incentive, to use it to improve patient safety. Instead of funneling data through a centralized, and possibly politicized, government agency, the focus should be on doing what is necessary to get the information to those who will actually use it to improve patient safety.

Hospitals need more information about errors that are made there. Licensing boards need more information about their licensees. It is far simpler, and more effective, to inform a device manufacturer that the labeling is confusing than to report this to Washington. With this information, manufacturers, providers, and insurers would have the greatest incentive and the best ability to use it to improve safety.

Instead of creating a centralized, nation-wide, government-led reporting system, we should focus on doing what is necessary to get more information to the people on the front lines of health care quality.

Compliance will be enhanced if reporters know they are reporting to an entity that will use the information effectively. A nurse is far more likely to report an error to her nursing supervisor or to report a problem with a device to its manufacturer than to file a form destined for a distant Federal bureaucracy. Health care providers are the people who are most concerned with quality of care and patient safety. They are more personally and directly concerned than is a distant government bureau. They strongly want to avoid adverse events. They want to provide good care.

There is another practical factor that must be considered. Providers function under conditions of considerable stress. They are quite astute in distinguishing between what is real and what is more government make-work. They are more likely to report when they believe it will do good (particularly if they have protections of confidentiality) than where they are told to fill out another government-imposed form that seems to bear little or no relation to their real world—patient care.

Providers, manufactures, suppliers, employers who sponsor health plans, and insurers, deal with each other and with various licensing and quality institutions on an on-going basis. They should be encouraged to report potential or existing problems and discuss improvements among themselves. This can best be achieved by protection of confidentiality for reports and discussions, and by reform of the tort system. Requirements that they file reports with a state agency for forwarding to Washington, D.C., will not encourage reporting or enhance collaborative efforts to improve the quality of care.

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[28] Id. at 76.

CONCLUSION

The IOM Report documents the obstacles to greater patient safety efforts: the difficulties in securing more reporting that result from the lack of confidentiality and the shadow cast by the litigation system. But rather than addressing these problems, it recommends more reporting (but without confidentiality) and centralizing the reporting system.

The problem, however, is not a lack of centralized reporting; it is the barriers to reporting and to safety-improvement measures posed by the tort system.

The problem is not a lack of reporting mechanisms, but a lack of assured confidentiality and fear on the part of the people who would report that they will be enmeshed in the litigation system.

The primary need is not more data and more studies; it is for those in the field attempting to improve patient safety to have confidence that cooperating in safety-improvement measures will not result in involvement in burdensome tort litigation.

The fears induced by the tort system cannot be resolved by expanding the already unsuccessful requirements to report. The problems of the tort system itself must be addressed.

The solution should not be centralized or governmental; it should be private and dispersed. Medical errors, when they occur, happen at the local level, and local solutions are best crafted to solve local problems.

The quality of health care, consequently, can best be improved by reforming the tort system to: 1) reduce the number of lawsuits, 2) make the system more fair and efficient, and 3) reduce its costs. Reforms in this direction would lessen the pressures to practice defensive medicine, lower health care costs, and increase access to care. At the same time, a fairer and less random tort system, and assurances of confidentiality, would reduce the barriers to reporting and enhance the ability of the field to identify problems and to make corrections.

Statement of Healthcare Compliance Packaging Council, Falls Church, VA

Falls Church, Virginia, February 10, 2000—The Healthcare Compliance Packaging Council, a not-for-profit trade association established in 1990 to promote the many benefits of superior pharmaceutical packaging, today commended the Health Subcommittee of the House Committee on Ways and Means for holding a hearing on the important national issue of medical errors. "We are especially encouraged," noted Peter G. Mayberry, HCPC Executive Director, "by the attention that is being paid to medication errors that take place in hospitals and other in-patient settings. Hopefully, these hearings will serve as a catalyst for change." Considering that, on average, an estimated seven percent of all hospitalized patients—some 2 million people—experience an adverse drug event each year, the HCPC believes that inquiry by the Health Subcommittee is critical and timely. Moreover, in light of the fact that proven, cost-effective steps have already been identified to address the problem, the HCPC is hopeful that attention to the problem by the Health Subcommittee will lead to adoption of in-patient pharmaceutical distribution systems that can reduce adverse drug event incidents by fifty percent or more. "One element of such systems," Mr. Mayberry noted, "is the adoption of unit dose pharmaceutical packaging by drug manufacturers, hospitals, and other inpatient facilities throughout the country."

Most people are familiar with unit dose formats, or blister packs and strips, through over-the-counter medications and prescription birth control pills. With solid oral dosages such as pills or tablets, these formats separate each dosage unit in its own compartment or blister cavity. As Mr. Mayberry explained, "What many people may not know, is that unit dose formats can be combined with bar code technology such that no medication could be dispensed unless the doctor's prescription, the patient's medical chart, and the drug itself all match up correctly. These dispensing systems are already available, and are considered state-of-the-art when it comes to ensuring that the right drugs are given to the right patients at the right time."

"As far as we know," Mr. Mayberry continued, "every group that has examined the problem of in-patient adverse drug events has recommended the use of unit dose formats as a solution."

Indeed, in its list of recommendations released on May 12, 1999, the National Patient Safety Partnership urged hospitals to "Use unit dose drug distribution systems for inpatient care; also use such systems for outpatient care, where appropriate." Similarly, in its November 1999 report, *To Err is Human: Building a Safer Health System,* the Institute of Medicine (IoM) recommended that "If medications are not

packaged in single doses by the manufacturer, they should be prepared in unit doses by the central pharmacy." (page 166). The IoM report further stated that "Unit dosing can reduce errors by eliminating the need for calculation, measurement, preparation, and handling on the nursing unit and by providing a fully labeled package that stays with the medication up to its point of use." The IoM report also noted that unit dosing has been recommended by the American Society of Health-System Pharmacists, the Joint Commission on the Accreditation of Health Care Organizations, the National Patient Safety Foundation of the AMA, and the Massachusetts Hospital Association as a means of reducing adverse drug events.

Lucian L. Leape, M.D., Adjunct Professor of Health Policy at the Harvard School of Public Health, is also a proponent of unit dose packaging as a means of reducing adverse drug events. As Dr. Leape—who testified before the Senate Health Committee on January 26, 2000—told the FDA on January 8, 1998 during its workshop entitled "Minimizing Medical Errors: A Systems Approach," distribution of drugs in unit dose formats is the "right thing" for pharmaceutical manufacturers to do.

Despite this widespread support, however, certain hospitals and other inpatient facilities have been directed to abandon unit dose formats in an effort to reduce pharmacy expenses. As the IoM explained in *To Err is Human: Building a Safer Health System,* "As a cost-cutting measure, unfortunately some hospitals have recently returned to bulk dosing, which means that an increase in dosing errors is bound to occur." (page 167). This is a penny wise/pound foolish approach that, as the IoM predicts, will surely lead to even greater numbers of adverse drug events. It is primarily for this reason that the HCPC lauds efforts by the Health Subcommittee to focus on such an important healthcare issue. Hopefully, by conducting this inquiry, the Health Subcommittee will help to underscore the importance of unit dose packaging, along with other recommended practices, as a systematic approach that can be immediately adopted to prevent adverse drug events.

Mr. Mayberry may be contacted in care of the Healthcare Compliance Packaging Council at 7799 Leesburg Pike, Suite 900N, Falls Church, Virginia, 22043.

Statement of Annette Guarisco, Honeywell

We appreciate the opportunity to present the views of Honeywell on the important issue of medical errors in the health care system.

As policymakers consider ways to reduce medical and medication errors, such as adverse drug effects, modernize the Medicare system and promote safety for children and adults, the promotion of unit dose/unit of use (known as blister packs) should be considered:

- Blister packs are inherently child resistant
- Blister packs are tamper-resistant and tamper-evident
- Drugs packaged in unit dose formats are protected against cross-contamination
- Efficacy of the drug is maintained for a longer period of time without being compromised when unit dose formats are used
- Special labeling, color coding, is available to designate when and if the drug has been taken when unit dose formats are used
- Blister packaging provides for greater individual product barrier protection against moisture, light and oxygen
- The rate of compliance with unit dose packaging is significantly higher, resulting is fewer and less serious adverse health consequences:

Contraception—92% compliance rate, vs. 70% for anticoagulants, 82% for organ transplant rejections drugs, 60% for hypertension medication, 80% for asthma, 50–70% for epilepsy, 50–60% for diabetes and 53% for estrogen deficiency drugs

- It was estimated in 1990 that nearly 10% of hospital admissions were the result of pharmaceutical non-compliance and up to 23% of nursing home admissions were primarily due to an inability to manage medications at home.
- When drug regimens are not taken as prescribed, taxpayer dollars are wasted on drugs paid by Medicare, Medicaid, and VA programs, and unnecessary and longer hospital and nursing home stays.
- Unit dose packaging takes less pharmacist time to prepare and reduces the chance for errors, leaving them more time to consult with patients on the proper use of medications.

The recent Institute of Medicine Report, *To Err is Human: Building a Safer Health System,* called for implementing unit dosing:

If medications are not packaged in single doses by the manufacturer, they should be prepared in unit doses by the central pharmacy. Unit dosing—the preparation

of each dose of each medication by the pharmacy—reduces handling as well as the chance of calculation and mixing errors. Unit dosing can reduce errors by eliminating the need for calculation, measurement, preparation, and handling on the nursing unit and by providing a fully labeled package that stays with the medication up to its point of use.

Unit dosing was a major systems change that significantly reduced dosing errors when it was introduced nearly 20 years ago. Unit dosing has been recommended by the American Society of Health-System Pharmacists, JCAHO, NPSF, and the MHA in their "Best Practices Recommendations." As a cost-cutting measure, unfortunately some hospitals have recently returned to bulk dosing, which means that an increase in dosing errors is bound to occur. Page 166–167.

Honeywell urges the Committee to consider ways to encourage drug manufacturers, hospitals, nursing homes, and other inpatient facilities to utilize unit dose formats, and to promote unit dosing in the Medicare and Medicaid systems as well as in the federal employee health benefit system.

We appreciate the Committee's consideration of these recommendations and applaud the Committee for deliberating on the important subject of reducing medical errors.

ANNETTE GUARISCO
Corporate Director, Public Policy and Government Relations, Honeywell (202) 662–2644

Statement of New Medical Concepts, Inc., Fort Lauderdale, FL

SAFE MEDICATION USE IN THE OUTPATIENT SETTING: THE PROBLEM OF MEDICATION NON-COMPLIANCE

New Medical Concepts, Inc. (NMC), a telecommunications and healthcare information company headquartered in Fort Lauderdale, FL is pleased to present this statement for the hearing record to the House Committee on Ways and Means Subcommittee on Health it examines medical errors. We believe the Institute of Medicine's Report *To Err Is Human: Building A Safer Health System* and the report to Congress issued last week by the General Accounting Office on *Adverse Drug Errors* provide a strong basis for Congressional action on one of the most serious problems in our healthcare system: the need to improve patient safety.

Our comments focus on problems associated with one of the most significant aspects of this problem in terms of impairment of quality of care and unnecessary costs: the need to assure safe prescription drug use by patients in the outpatient setting.

New Medical Concepts, Inc.

NMC was founded in 1997 by a group of business, healthcare and telecommunications professionals with recognized expertise in innovative technology, medicine, pharmacy and healthcare operations. The firm has developed **RxAlerts,gT1 a unique voice and text messaging alert system, using automated, personalized wireless and wired communications, which has the potential for dramatically reducing patient medication non-compliance and fostering more effective communications between healthcare providers and their patients.**

Most would acknowledge that drug therapy is often the most effective and cost-efficient way to achieve desired therapeutic outcomes in the treatment of patients. But drugs cannot work if they are not taken or are taken improperly. All drugs have side effects; some known, some unknown; some serious, some not. Because of the potential for harm and the increased significance of drug therapy as a treatment modality, safe medication use must be a priority objective in today's healthcare system. The problem of medication non-compliance is very real and demands practical solutions, the kind that foster integrated communication between patient and provider and which our company has developed.

Adverse Drug Events

An adverse drug event (ADE) would typically be defined as any undesired effect associated with drug therapy such as harmful reactions (adverse drug reactions or ADRs), treatment failure, medication errors, overdoses and non-compliance. Consequences range from ineffective treatment to injuries, at times resulting in death. The population that is most at risk because of these events are the chronically ill patients of all ages and the elderly. With an aging population, the use of prescrip-

tion drugs will rise and likewise, the risk of medication misuse and ADEs will also increase.

Medication Non-compliance

We wish to emphasize to the Committee that the problems associated with medical errors and adverse drug events are just as significant (and probably more prevalent) in the outpatient setting as in the institutional setting. Certainly the overwhelming percentage of the several billion medications dispensed per year are to patients who are not in hospitals, nursing homes or other institutional settings, but who receive their drugs from community pharmacies. Safe medication use and the associated problem of medication non-compliance by patients in the ambulatory setting deserve this Committee's serious attention.

Indeed, the General Accounting Office report on "Adverse Drug Events" released last week identified patient non-compliance in the ambulatory setting as a major source of adverse drug events. The report also described medication non-compliance as a major source of emergency room and hospital admissions. For example, the GAO cites a report finding that 58 percent of adverse drug events in patients visiting an emergency room were caused by medication non-compliance. Another study it cites found that 11 percent of all elderly admissions to a hospital were related to medication non-compliance. Among the proposals the GAO makes for reducing adverse drug events is improving communication between patients and physicians about the risks and benefits of medication.

Definition, Reasons, Those Most Seriously Affected

Medication non-compliance, or not taking a medicine as it was prescribed, is a worldwide health issue. Non-compliance includes taking too much medication, taking medication not prescribed, not taking medication prescribed, altering the prescribed dosage, or altering the time between doses. The reasons for non-compliance vary and may include forgetfulness, confusion over generic and brand names, unclear information about how to take or how much to take of a medication, disappearing symptoms of an illness, no perceived improvement in a patient's condition or well-being and, for those with low income, the difficult choice of having to select food or heat over drug expenditures. As with ADEs generally, the elderly and the chronically ill are particularly susceptible to the problem of medication non-compliance. They usually take multiple prescriptions, and they are more susceptible to memory problems and confusion.

Relevant Statistics

- Thirty years ago (1970) only 650 medications were available; today the number approaches 10,000
- Over 2.7 billion retail prescriptions were dispensed in the U.S. in 1998.
- 30–50 percent of all prescriptions are not taken correctly. (U.S. Food & Drug Administration)
- More than a billion prescriptions are taken incorrectly each year. (U.S. Chamber of Commerce)
- The estimated annual cost of medication non-compliance exceeds $100 billion. (National Pharmaceutical Council)
- Non-compliance kills 125,000 Americans each year. (National Pharmaceutical Council)

Social and Economic Consequences

Non-compliance with the taking of medication has significant implications not only in terms of poor health outcomes for the patient but for the healthcare system itself. Its full effect on morbidity, mortality, and the associated healthcare costs are only beginning to be recognized. One national study (Johnson, Jeffrey A. and J. Lyle Bootman. "Drug-Related Morbidity and Mortality: A Cost-of-Illness Model," Archives of Internal Medicine 155:1949–56, Oct. 6, 1995) revealed more than $75 billion in direct annual costs (with variable assumptions, the range was from $31 to $137 billion) as a result of medication use problems in the United States. It based its findings on preventable treatment associated with increased admissions to hospitals and nursing homes and increased visits to physician offices and hospital emergency rooms which resulted from medication non-compliance.

The costs estimated in this study related only to the direct cost of first time events and did not address consequential adverse health events (i.e., new medical problems resulting from the primary illness) or the indirect cost of lost employee productivity/absenteeism and turnover. When indirect costs due to non-compliance are added to the direct cost figures, total economic costs exceed $150 billion. (John-

son, Jeffrey A. and J. Lyle Bootman. "Drug-Related Morbidity and Mortality: A Cost-of-Illness Model," Archives of Internal Medicine 155:1949–56, Oct. 6, 1995) Drug-related morbidity and mortality costs are in the same range as diabetes, cardiovascular disease and obesity—leading some experts to suggest that drug-related problems should be considered a major category of disease.

Failure to Address the Problem

Medication non-compliance has reached the forefront of the medical community's awareness, but efforts to focus on safe medication use and the problem of medication non-compliance have been limited. While there have been major efforts made in developing technologies to detect and minimize adverse drug reactions, essentially sophisticated computer systems utilized by pharmacies and hospitals, these innovations do not address the more complex and subtle causal factors associated with non-compliance, notably communications between patient and healthcare professionals. Patient counseling requirements, consumer information sheets that accompany prescriptions, public service announcements, educational brochures and the specialized educational programs that are part of "disease management" programs are all positive developments, but have not proven sufficient to assure appropriate and safe medication use by patients. There have been few efforts made, technological or otherwise, to develop programs or products to assist health professionals and individual patients in dealing comprehensively with the problem.

Conclusion: Innovation That Addresses Medication Non-Compliance Must Be Encouraged

The inescapable conclusion is that if patients are non-compliant with medication therapy, desired outcomes (whether it be a cure, relief of symptoms or improved quality of life) are impaired. Indeed, it is clear that many emergency room and physician office visits and hospital and nursing home admissions could be prevented with interventions targeted at improving medication compliance. There can be little doubt that non-compliance is a significant health and economic burden on the healthcare system; that interventions directed at improving compliance will result in improved health outcomes; and that a significant cost savings will be realized through interventions directed at improving compliance.

NMC believes our product **RxAlerts** is an effective and practical tool which will assist the healthcare system in addressing the problem of medication non-compliance. **RxAlerts** is a comprehensive medication compliance and support product/program which uses sophisticated state-of-the-art software, utilizing proprietary computer time-clocking engines, to provide personal, customized health-related information to patients from their health providers through wired and wireless communication media—alphanumeric and voice paging, facsimile transmission, cellular telephony, the internet, wired telephones and television (pending). The product applications have two-way communications capability and are encrypted to assure patient confidentiality. NMC is initially focusing on disease states like HIV, asthma, diabetes, post-organ transplants and certain pulmonary and heart conditions where medicine regimens are difficult, where there is a criticality of maintaining consistent medicine levels, where there is a need to modify or enhance behavior and where there is an overall need to communicate with patients on a regular basis.

New Medical Concepts is encouraged that the Committee is examining the issue of medical errors, and we pledge to work with Congress, federal and state health agencies and the healthcare community in finding real world "Patient Connectivity" solutions which will foster safe medication use and improve the quality of care patients receive.

Statement of J. Richard Gaintner, Shands Healthcare, Gainesville, FL,

Dear Mr. Chairman, Members of the Committee:

I am writing as CEO of Shands HealthCare, with its mission of providing excellent patient care, improving community health, and supporting education and research for the State of Florida. Shands HealthCare is an integrated clinical delivery system, which offers the most comprehensive range of services in North Central Florida. The not-for-profit enterprise encompasses six acute care hospitals, two specialty hospitals, a home care company, and manages the University of Florida clinic operations as well as an extensive physician network. Shands at the University of Florida, the system's flagship hospital, is the academic medical center for the University of Florida Health Science Center and is recognized as one of the Southeast's

leading tertiary care centers, and as such receives the majority of its patients from every county of Florida and Southeast Georgia. Shands at the University of Florida is closely linked with the College of Medicine at the University of Florida resulting in the development and delivery of cutting edge technology for the delivery of patient care.

In addition, Shands HealthCare, the University of Florida, and University and Methodist Medical Centers have joined forces to form Shands Jacksonville, of which I am the Chairman of the Board of Directors.

I also have the honor of serving as Chairman of the Council of Teaching Hospitals (COTH), a PO Box 100326 Gainesville, FL 32610–0326 352.395.0421 352.395.0177 fax gaintjr@shands.ufl.edudivision of the Association of American Medical Colleges (AAMC), representing over 400 teaching hospitals across the nation. In addition, I serve on the Boards of the American Hospital Association and the Florida Hospital Association, and was recently elected Chair of the Florida Statutory Teaching Hospital Council. As a member of the Board of the National Committee for Quality Health Care, I have been directly involved in the promotion of quality for health care teams.

We believe that we have a fundamental responsibility to continually improve the quality of care and services provided to our patients. As part of their mission, teaching hospitals provide a disproportionate share of the most complex health care services. This translates to patients entering the health system who are sicker and more complicated, yielding health needs greater than those traditionally seen elsewhere.

Hospitals have long recognized their role in improving the care provided to patients. Initiatives already in place at teaching hospitals include, but are not limited to: leadership commitment to improving the care provided; internal reporting of incidents for the identification of possible opportunities for improvement; teaching conferences where cases are subjected to detailed review; use of external benchmarking; proactive attention to improving processes through the use of quality improvement tools and techniques; and, sharing of information related to trends and successes.

Shands HealthCare participates in each of these, as well as required external reporting to the State of Florida for specified serious incidents. These reporting processes have only been successful because of the protections put in place by the Florida Legislature to maintain the confidentiality of the information reported. This is a crucial step to ensure that the process remains non-punitive and successful.

One of the keys to success has been the focus of the Quality Committee of the Board of Directors on quality improvement, of which reducing errors is but one component. Reporting of issues and involvement of the Board has reinforced the commitment at all levels of the organization to improving and maintaining the health of people in the State of Florida and the Southeastern United States.

Thank you for your consideration and response to our desire to work closely with Congress as it pursues ways to continue to improve the quality of health care services.

Sincerely,

J. RICHARD GAINTNER, MD