S. HRG. 107–79

TECHNOLOGY AND PRESCRIPTION DRUG SAFETY

HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

WASHINGTON, DC

MAY 3, 2001

Serial No. 107–4

Printed for the use of the Special Committee on Aging

U.S. GOVERNMENT PRINTING OFFICE
73–598 PS WASHINGTON : 2001

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC. 20402

SPECIAL COMMITTEE ON AGING

LARRY CRAIG, Idaho, *Chairman*

JAMES M. JEFFORDS, Vermont
CONRAD BURNS, Montana
RICHARD SHELBY, Alabama
RICK SANTORUM, Pennsylvania
SUSAN COLLINS, Maine
MIKE ENZI, Wyoming
TIM HUTCHINSON, Arkansas
PETER G. FITZGERALD, Illinois
JOHN ENSIGN, Nevada

JOHN B. BREAUX, Louisiana
HARRY REID, Nevada
HERB KOHL, Wisconsin
RUSSELL D. FEINGOLD, Wisconsin
RON WYDEN, Oregon
EVAN BAYH, Indiana
BLANCHE L. LINCOLN, Arkansas
THOMAS R. CARPER, Delaware
DEBBIE STABENOW, Michigan
JEAN CARNAHAN, Missouri

LUPE WISSEL, *Staff Director*
MICHELLE EASTON, *Minority Staff Director*

CONTENTS

TECHNOLOGY AND PRESCRIPTION DRUG SAFETY

THURSDAY, MAY 3, 2001

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The committee met, pursuant to notice, at 2:30 p.m., in room SD–608, Dirksen Senate Office Building, Hon. Larry E. Craig, (chairman of the committee) presiding.

Present: Senators Craig, Breaux, Wyden, and Stabenow.

OPENING STATEMENT OF SENATOR LARRY E. CRAIG, CHAIRMAN

The CHAIRMAN. The committee will be in order.

Good afternoon, everyone, and thank you for joining us here today at the Special Committee on Aging, as we examine the critical issue of technology and prescription drug safety.

It is alarming to find that every year between 44,000 and 98,000 people are injured or die due to medical errors. In fact, just last month, the American Pharmaceutical Association estimated that medication misuse cost the economy over $177 billion per year.

As Chairman of the Special Committee on Aging, this issue is of particular concern to me. Senior citizens often must rely on multiple medications to control the many conditions associated with aging, conditions like high blood pressure, diabetes and arthritis. Each time a patient takes medication, they risk an adverse drug event. Since seniors take several different kinds of medications each day, they face the additional risk of experiencing a drug-to-drug interaction. Therefore, it is imperative for us to identify and develop new strategies to reduce medication errors.

The private sector has been working hard to resolve the dangerous problems associated with prescribing and dispensing errors, and I commend them for their innovative ideas. As Congress considers legislation to add a prescription drug benefit to the Medicare program, it is important to examine the medical technology available to reduce medication errors.

The witnesses today include Dr. Janet Corrigan, the Director of the Board on Health Care Services at the Institute of Medicine; Dr. Harold H. Allen, Jr., M.D., an orthopedic surgeon and founder of Picos; Peter Klein, the Vice President of En-Vision America; Neil Reed, the director of pharmacy at the Eastern Idaho Regional Medical Center in Idaho Falls, ID.; Dr. David Bates, Division of General Internal Medicine at Brigham Women's Hospital, America; and Marty McKay, President of the Louisiana Pharmacists Association.

Because of the table configuration, we have broken these into two panels today, and we will proceed accordingly. I want to thank all of you for agreeing to testify before the Aging Committee this afternoon. We certainly do appreciate your participation and look forward to your testimony.

Now let me ask Dr. Corrigan to proceed. Thank you for being with us.

STATEMENT OF JANET M. CORRIGAN, PH.D. DIRECTOR, BOARD ON HEALTH CARE SERVICES, INSTITUTE OF MEDICINE, THE NATIONAL ACADEMIES

Ms. CORRIGAN. Thank you.

Good afternoon, Mr. Chairman. I am the director of the Institute of Medicine's Board on Health Care Services, which is responsible for IOM's work in the area of health care delivery, coverage, access and quality. For the last 3 years, I have also directed the IOM's Quality of Health Care in America Project, and I am here today representing the IOM Committee which in late 1999 released the report, "*To Err is Human.*" It most recently released a second report, called "*Crossing the Quality Chasm: A New Health System for the 21st Century.*"

In its first report, the IOM committee concluded that as many as 44,000 to 98,000 people die in a given year as a result of medical errors, more than the number who die from motor vehicle accidents, breast cancer, or AIDS. These numbers reflect only patients who died in hospitals, and only deaths for which there was adequate documentation in the medical record for two reviewers to concur that the death was attributable to error.

Medication errors are one of the most common types of errors. The Harvard Medical Practice Study, which looked at more than 30,000 discharges from 51 hospitals in New York State, found that adverse events, manifest by prolonged hospitalization or disability, occurred in almost 4 percent of hospitalizations, and about one-half of these adverse events were judged to have been preventable. Drug complications were the most common type of adverse event, about 19 percent, one in five, followed by wound infections and technical complications.

Medication errors occur frequently in hospitals. For example, an analysis of near 300,000 medication orders written during a 1-year period estimated the overall error rate to be a little over three errors for each 1,000 orders written. The rate of significant errors, those that result in adverse clinical consequences, was almost two per 1,000 orders. These estimates of the incidence of medication errors are undoubtedly low because many errors go undocumented and unreported, and some errors go undetected in the absence of computerized surveillance systems.

An estimated 770,000 people are injured or die each year in hospitals from adverse drug events. Not all, but many, if not most, of these adverse drug events are preventable.

In hospital environments, most medication errors can be classified into one of five categories: a dose error, a known allergy, wrong drug/wrong patient, route error, or error in frequency. Over 50 percent of errors occur at the time of physician ordering or nurse administration. Two studies attribute a sizable proportion of adverse

drug events, about half, to excessive drug dosage for the patient's age, weight, underlying condition, and renal function. The potential for medication related error increases as the average number of drugs administered increases.

Most studies of medication error have focused on hospitalized patients. We know very little about errors that occur outside the hospital. In 1998, nearly 2.5 billion prescriptions were dispensed in U.S. pharmacies. Errors undoubtedly occur in the prescribing of drugs in physician office practices, the dispensing of drugs by pharmacists, and the administration of drugs by patients and their families.

I want to emphasize that errors are seldom due to carelessness or lack of trying hard enough on the part of health care professionals. More commonly, errors are caused by faulty systems, processes and conditions that lead people to make mistakes, or fail to prevent them. Errors can be prevented by designing systems that make it hard for people to do something wrong and easy to do it right.

Other industries, safe industries, such as aviation, chemical manufacturing and nuclear power, they learned this lesson long ago. While insisting on training and high standards of performance, they recognize these are insufficient to ensure safety. They also pay attention to factors that affect performance, such as work hours, work conditions, information technology, team relationships. Health care must do likewise.

The good news is that much of the knowledge and technology needed to prevent most errors already exists. The key to reducing many types of medication errors is the wise use of computerized systems. Several evaluations conducted by the Agency for Health Care Research and Quality, have shown that various types of computer monitoring systems are very promising. Anywhere from 28 to 95 percent of adverse drug events can be prevented.

As important as medication errors are, they are only the tip of the iceberg. In its most recent report, "*Crossing the Quality Chasm*", the IOM committee concluded that safety reflects only a small part of the unfolding story of quality in American health care.

Other defects are even more widespread. As medical knowledge, science and technology have advanced at an extraordinary pace in recent years, the health care delivery system has floundered. We fall far short in our ability to translate knowledge into practice and to apply new technology safely and appropriately.

The challenges of applying information technology to health care should not be underestimated. This is a very complex sector of the economy. With huge numbers of transactions, sizable capital investments are required, and large numbers of providers whose behavior has to be influenced.

In the absence of a national commitment and financial support to build a national health information infrastructure, progress on quality and safety improvement will be painfully slow. The topic today is a critical one, and a first step in the right direction.

Thank you for this opportunity to testify, and I would be happy to answer any questions you have.

[The prepared statement of Ms. Corrigan follows:]

Statement of Janet M. Corrigan, Ph.D.
Director, Board on Health Care Services
Institute of Medicine
The National Academies

Concerning Patient Safety and Medication Errors

Before the
Senate Special Committee on Aging

May 3, 2001

Good morning, Mr. Chairman and Senator Breaux, and members of the Committee. My name is Janet Corrigan. I am the Director of the Institute of Medicine's Board on Health Care Services, which is responsible for IOM work in the areas of health care delivery, financing, benefits coverage, access and quality of care. For the last three years I have also directed the IOM's Quality of Health Care in America Project, and I am here today representing the IOM Committee which in late 1999 released the report *To Err is Human: Building a Safer Health System*, and most recently, the report *Crossing the Quality Chasm: A New Health System for the 21st Century*.

In its first report, the IOM Committee on the Quality of Health Care in America concluded that as many as 44,000 to 98,000 people die in a given year as a result of medical errors, more than the number who die from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516). These numbers reflect only patients who died in hospitals, and only deaths for which there was adequate documentation in the medical record to concur that the death was attributable to error.

Medication errors are one of the most common types of errors. The Harvard Medical Practice Study, a study of more than 30,000 discharges from 51 hospitals in New York State, found that adverse events, manifest by prolonged hospitalization or disability at the time of discharge or both, occurred in 3.7 percent of hospitalizations, and about one-half of these adverse events were judged to have been preventable.[1] Drug complications were the most common type of adverse event (19 percent), followed by wound infections (14 percent) and technical complications (13 percent).

Medication errors occur frequently in hospitals. For example, an analysis of nearly 300,000 medication orders written during one year in a tertiary-care teaching hospital, estimated the overall error rate to be 3.13 errors for each 1,000 orders written and the rate of significant errors (those likely to result in adverse clinical consequences) to be 1.81 per 1,000 orders.[2] These estimates of the incidence of medication errors are undoubtedly low because many errors go undocumented and unreported, and some errors go undetected in the absence of computerized surveillance systems.[3]

An estimated 770,000 people are injured or die each year in hospitals from adverse drug events (ADEs),[4] defined as an injury resulting from medical intervention related to a drug. Not all, but many, if not most, of these adverse drug events are preventable.

In hospital environments, most medication errors can be classified into one of five categories: dose error, known allergy, wrong drug/wrong patient, route error or

error in frequency.[5] Over 50 percent of errors occur at the time of physician ordering or nursing administration. Two studies attribute a sizable proportion of ADEs (42 to 60 percent) to excessive drug dosage for the patient's age, weight, underlying condition, and renal function.[6] The potential for medication-related error increases as the average number of drugs administered increases.[7]

Most studies of medication error have focused on hospitalized patients. We know very little about errors that occur outside the hospital. In 1998, nearly 2.5 billion prescriptions were dispensed in U.S. pharmacies at an estimated cost of about $92 billion.[8] Errors undoubtedly occur in the prescribing of drugs in physician office practices, the dispensing of drugs by pharmacists, and the administration of drugs by patients and their families.

I want to emphasize that errors are seldom due to carelessness or lack of trying hard enough on the part of health care professionals. 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.

The good news is that much of the knowledge and technology needed to prevent most errors already exists. The key to reducing many types of medication errors is the wise use of computerized systems. Since the mid-90s, the Agency for Healthcare Research and Quality has funded numerous evaluations of computer monitoring systems that prevent and detect ADEs. The results of these evaluations are very promising--anywhere from 28 to 95 percent of ADEs can be prevented.[9,10,11,12,13]

Many leading health care organizations devoted to improving patient safety have called for the implementation of computerized medication order entry systems. These include the National Patient Safety Partnership, the Massachusetts Coalition for the Prevention of Medical Errors, the Institute for Healthcare Improvement, the National Coordinating Council for Medication Error Reporting and Prevention, and the American Society of Health-System Pharmacists.[14] The time has come for all health care organizations and clinicians to act on these recommendations.

As important as medication errors are, they are only "the tip of the iceberg." In its most recent report, *Crossing the Quality Chasm: A New Health System for the 21st Century,* the IOM Committee concluded that safety reflects only a small part of

the unfolding story of quality in American health care. Other defects are even more widespread. A synthesis of the literature conducted by The RAND Corporation, found over 70 major publications in leading peer reviewed journals since 1987 documenting serious and extensive quality problems throughout the U.S. health care system.[15]

As medical science and technology have advanced at an extraordinary pace, the health care delivery system has floundered. We fall far short in our ability to translate knowledge into practice, and to apply new technology safely and appropriately. As currently structured, the health care enterprise, does not make the best use of its resources.

Chronic conditions affect almost half of the U.S. population and account for the majority of health care expenditures. Yet there remains a dearth of clinical programs with the infrastructure required to provide the full complement of services needed by people with even the most common conditions, such as asthma, heart disease, and diabetes. Physician groups, hospitals and other health care organizations operate as silos, often providing care without the benefit of complete information about the patient's condition, medical history, services provided in other settings, or medications prescribed by other clinicians.

Health care delivery has been relatively untouched by the revolution in information technology that has been transforming nearly every other aspect of society. The IOM Committee believes that information technology must play a central role in the redesign of the health care system if a substantial improvement in quality and safety is to be achieved over the coming decade. The Internet has enormous potential to transform health care and to improve quality, safety, access and efficiency. Central to many information technology applications related to care delivery, is the automation of patient-specific clinical information.

The challenges of applying information technology to health care should not be underestimated. Health care is undoubtedly one of the most, if not the most, complex sector of the economy. The number of different types of transactions (i.e., patient needs, interactions, and services) is very large. Sizable capital investments and multiyear commitments to building systems will be required. Widespread adoption of many information technology applications will require behavioral adaptations on the part of large numbers of patients, clinicians, and organizations.

In the absence of a national commitment and financial support to build a national health information infrastructure, progress on quality and safety improvement will be painfully slow.

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

[1] Brennan, Troyen A.; Leape, Lucian L.; Laird, Nan M., et al. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical practice Study I. N Engl J Med. 324:370-376, 1991. See also: Leape, Lucian L.; Brennan, Troyen A.; Laird, Nan M., et al. The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II. N Engl J Med. 324(6): 377-384, 1991.

[2] Lesar, Timothy S.; Briceland, Laurie, et al. Medication Prescribing Errors in a Teaching Hospital. JAMA 263(17): 2329-2334, 1990.

[3] Classen, David C. et al., Computerized Surveillance of Adverse Drug Events in Hospital Patients. JAMA 266(20):2847-2851, 1998.

[4] Agency for Healthcare Research and Quality, Research in Action, Issue #1, March 2001. See also, Classen DC, Pestotnik SL, Evans RS, et al. Adverse drug events in hospitalized patients. JAMA 1997; 277(4):301-6; Cullen DJ, Sweitzer BJ, Bates DW, et al. Preventable adverse drug events in hospitalized patients: A comparative study of intensive care and general care units. Crit.Care Med 1997; 25(8):1289-97.; Cullen DJ, Bates DW, Small SD, et al. The incident reporting system does not detect adverse drug events: A problem for quality improvement. Journal on Quality Improvement 1995;21(10):541-8.

[5] Agency for Healthcare Research and Quality, Research in Action, Issue #1, March 2001.

[6] Classen DC, Pestrotnik SL, Evans RS, et al. Adverse drug events in hospitalized patients. JAMA 1997; 277(4):301-6; and Evans RS, Pestotnik SL, Classen DC et al. Prevention of adverse drug events through computerized surveillance. Proc Annu Symp Comput Appl Med Care 1992; p 437-41.

[7] Cullen, David J., Sweitzer, Bobbie Jean; Bates, David W., et al. Preventable Adverse Drug Events in Hospitalized patient: A Comparative Study of Intensive Care and General Care Units. Crit Care Med 25(8):1289-1297,1997.

[8] National Wholesale Druggists' Association. Industry Profile and Healthcare Factbook. Reston, VA. 1998.

[9] Cullen DJ, Bates DW, Small SD, et al. The incident reporting system does not detect adverse drug events: A problem for quality improvement. Journal on Quality Improvement 1995;21(10):541-8.

[10] Bates DW, Spell N, Cullen DJ, et al. The costs of adverse drug events in hospitalized patients. JAMA 1997; 277(4):307-11.

[11] Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events. JAMA 1995;274(1):29-34.

[12] Bates DW, Miller EB, Cullen DJ, et al. Patient risk factors for adverse drug events in hospitalized patients. Arch Intern Med 1999; 159(21):2553-60.

[13] Evans RS, Pestotnik SL, Classen DC, et al. Preventing adverse drug events in hospitalized patients. Ann Pharmacother 1994;28(4):523-7.

[14] IOM. To Err is Human: Building a Safer Health System. National Academy Press, 1999.

[15] IOM. Crossing the Quality Chasm: A New Health System for the 21st Century. National Academy Press, 2001. See Appendix A: Schuster, MA. et al., The Quality of Health Care in the United States: A Review of Articles Since 1987.

The CHAIRMAN. Doctor, thank you very much.

Now let us turn to Dr. Harold Allen, a practicing physician from Loudoun County, right here next door in Virginia, I understand.

Dr. ALLEN. Not too far out.

STATEMENT OF HAROLD H. ALLEN, M.D., PRACTICING ORTHOPEDIC SURGEON, LOUDOUN COUNTY, VA, AND PRESIDENT OF PICOS, INC.

Dr. ALLEN. Good afternoon, Mr. Chairman, Mr. Ranking Member, and distinguished members of the committee and assembled guests.

My name is Dr. Harold Allen, and I have practiced orthopedic medicine for about 12 years. I currently am practicing in Loudoun County, VA and serve as an orthopedic surgeon at Loudoun Hospital Center, which is located in Loudoun County, VA. I am also the President of Picos, Inc., a software firm also based in Loudoun County.

I want to thank Chairman Craig, Senator Breaux, and members of the Senate Special Committee on Aging for allowing me to testify on how technology can be used to ensure the safe and efficient distribution of prescription drugs.

As the latest U.S. Census figures show, America is a growing nation. As the latest figures also show, America is becoming an older nation as well. More and more Americans than ever before will need health care in the coming decade. We owe it to them, as physicians, and as leaders, working together, to see that these patients get effective health care in as safe and as efficient a manner as possible, regardless of whether these patients live in a big city like Philadelphia or New Orleans, or in a smaller community like Shoup, ID, Evansville, IN, or Cape Girardeua, MO.

Simply put, it is essential that efforts are made to modernize the way doctors, hospitals and health care providers keep accurate patient medical histories and medical records. It is now more important than ever that this system be modernized. With the proliferation of new treatments and medicines available, and with Congress perhaps on the verge of approving a prescription drug benefit that will make helpful drugs become even more readily available, the risk of mistakes being made in the dissemination of medicines to patients will also increase. It is a simple math problem. More people having more access to drugs means yes, more benefits, but also more risks if those drugs aren't being properly prescribed and distributed.

These risks include, but are not limited to, giving the wrong drug to the wrong person, prescribing one drug that causes adverse and possibly fatal effects when combined with another, or perhaps distributing to a patient the wrong amount of a drug, which would also, of course, cause problems.

Medicines save lives and also improve our quality of life, so, naturally, we want as many people as possible to have access to the medicines they need. But the mismanagement of medicines can do more than just hurt people. It can kill. So the question is, how do we prevent these mistakes from happening?

Well, no doubt some mistakes are caused by human error, bad judgment calls, inexperience and oversight. That can be best pre-

vented by ensuring that all medical personnel are properly trained, certified, and supervised. But another major concern, as far as I'm concerned, is the system of medical recordkeeping in America's hospitals and private practices.

I can speak to this from personal experience as a physician. I can tell you, I have sometimes read prescription forms and patient medical records that I couldn't really read. I could barely read them or tell what the dosages were on any part of the medical record at all. Furthermore, I have encountered situations where a patient's medical records were incomplete. Vital information was missing. As a physician, let me reaffirm your common sense when I assure you, this is not a good thing.

If a patient has had an allergic reaction to a certain medicine in the past, as a doctor, I need to know that before I prescribe medication. Information like that absolutely has to be documented, and it has to be easily available to me as a doctor. We cannot always rely on patients to remember this information, especially elderly patients who may be forgetful. I also need to know if a drug has worked for a patient in the past. Not only does this save a patient time, it can also save a patient some money, as well as a whole lot of discomfort and pain, if I can quickly give that patient something we both know works best of them, from their own experience, as opposed to playing a game of trial and error with their treatment.

Now, keep in mind, I have practiced medicine largely in metropolitan areas for hospitals that tend to be relatively sophisticated. I shutter to think what the situation is in rural hospitals and medical offices, and in hospitals and offices located in low-income areas. Certainly, medical practices located in these areas tend to have a poorer medical infrastructure.

So, as an orthopedic surgeon, I asked myself the question, how can I better keep track of my patients' records, and then integrate all of this information into an easy-to-use, easy-to-find and affordable system. So I founded Picos, Inc. to develop what we call the Total Practice Manager, or TPM, software. Using this TPM software, I can access and update my patients' medical information as necessary, allowing the medicinal treatments I prescribe to be as accurate and as safe as possible. The Picos TPM software has an automated prescription feature that reduces written and transcribed errors with pharmacies by providing a typewritten prescription, such as the examples you see on the stand there.

Picos TPM software is HIPAA sensitive and it is secure, as you would expect medical records to be. Obviously, we want to protect a patient's privacy and ensure that their information is kept confidential. TPM allows doctors the access they need to a patient's information to keep them safe, but TPM also keeps that information as secure as possible. All of the information that a physician enters into his or her handheld computer remains within the physician's practice computer system.

Best of all, TPM software is affordable, which means hospitals and medical practices in rural and low-income areas that might not have the financial resources of larger hospitals in urban areas can have access to it and make use of it.

I would urge the members of this committee and Congress to seriously consider how technology such as TPM software can be used

to improve the accuracy of medical recordkeeping. America's senior citizens and, indeed, all Americans, rely on doctors and health care professionals to provide them with effective and safe treatment, regardless of where they live. Safe dissemination of prescription drugs is an issue that affects every American in every State who rely on their doctors to follow that simple creed of the Hippocratic oath: "First, do no harm." I thank the committee for its time.

[The prepared statement of Dr. Allen follows:]

Testimony of Harold H. Allen, MD
Before the U.S. Senate Special Committee on Aging
Hearing on Technology and Prescription Drug Safety
May 3, 2001

MR. CHAIRMAN, MR. RANKING MEMBER, distinguished Members of the Committee and assembled guests:

My name is Dr. Harold H. Allen, and I have practiced orthopedic medicine for over twelve years. Currently, I am practicing in Loudoun County, Virginia and serve as an orthopedic surgeon at Loudoun Hospital Center, located in Loudoun County, Virginia. I am also the President of Picos, Inc., a software firm also based in Loudoun County. I want to thank Chairman Craig, Senator Breaux and Members of the Senate Select Committee on Aging for allowing me to testify on how technology can be used to ensure the safe and efficient distribution of prescription drugs.

As the latest U.S. Census figures show, America is a growing nation. As the latest figures also show, America is becoming an older nation as well. More and more Americans than ever before will need health care in the coming decade. We owe it to them, as physicians and as leaders, working together, to see that these patients get effective health care in as safe and as efficient a manner as possible – regardless of whether these patients live in a big city like Philadelphia or New Orleans, or in smaller communities like Shoup, Idaho; Evansville, Indiana or Cape Girardeau, Missouri.

Simply put, it is essential that efforts are made to modernize the way doctors, hospitals and health care providers keep accurate patient medical histories and medical records. It is now more important than ever that this system be modernized. With the proliferation of new treatments and medicines available – and with Congress perhaps on the verge of approving a prescription drug benefit that will make helpful drugs become even more readily available – the risk of mistakes being made in the dissemination of medicines to

patients will only increase. It's a simple math problem. More people having more access to drugs means yes, more benefits, but also, more risks if those drugs aren't being properly prescribed and distributed.

These risks include, but are not limited to, giving the wrong drug to the wrong person, prescribing one drug that causes adverse and possibly fatal effects when combined with another, or perhaps distributing to a patient the wrong amount of a drug, which would also, of course, cause problems.

Medicines save lives and also improve our quality of life. So naturally, we want as many people as possible to have access to the medicines they need. But the mismanagement of medicines can do more than just hurt people. It can kill. So the question is, how do we prevent these mistakes from happening? Well, no doubt, some mistakes are caused by flat out human error – bad judgement calls, inexperience and oversight. That can be best prevented by ensuring that all medical personnel are properly trained, certified and supervised. But another major concern, as far as I am concerned, is the system of medical record keeping in America's hospitals and private practices.

I can speak to this from personal experience as a physician. I can tell you, I have sometimes read prescription forms and patient medical records that were nearly illegible. I could barely read them, if at all. Furthermore, I have encountered situations where a patient's medical records were incomplete. Vital information was missing. As a physician, let me reaffirm your common sense when I assure you, this is not a good thing.

If a patient has had an allergic reaction to a certain medicine in the past, as a doctor, I need to know that before I prescribe a drug. Information like that absolutely has to be documented, and it has to be easily available to me as a doctor. We cannot always rely on patients to remember this information, especially elderly patients who may be forgetful. I also need to know if a drug has worked for a patient in the past. Not only does this save a patient time, it can also save a patient some money, as well as a whole lot of discomfort and pain, if I can quickly give that patient something we both know works

best for them, from their own experience, as opposed to playing a game of trial and error with their treatment.

Now keep in mind, I have practiced medicine largely in metropolitan areas, for hospitals that tend to be relatively sophisticated. I shutter to think what the situation is in rural hospitals and medical offices, and in hospitals and offices located in low-income areas. Certainly, medical practices located in these areas tend to have poorer medical infrastructure.

And so as an orthopedic surgeon, I asked myself the question, how can I better keep track of my patients' records, and then integrate all of this information into an easy-to-use, easy-to-find and affordable system? And so I founded Picos Inc. to develop what we call the Total Practice Manager, or "TPM" software. Using this TPM software, I can access and update my patients' medical information as necessary, allowing the medicinal treatments I prescribe to be as accurate and as safe as possible. The Picos TPM software has an automated prescription feature that reduces written and transcribed errors with Pharmacies, by providing a typewritten prescription.
Please turn your attention to the screen, which shows two screen shots of the TPM Rx feature. (Here Dr. Allen demos with the handheld and can have the Senator do the same). Picos' TPM software is HIPAA sensitive and it is secure, as you would expect medical records to be. Obviously, we want to protect a patient's privacy, and ensure that their information is kept confidential. TPM allows doctors the access they need to a patient's information, to keep them safe, but TPM also keeps that information as secure as possible. All of the information that a physician enters into his or her handheld computer remains within the physician's practice computer system.

Best of all, TPM software is affordable, which means hospitals and medical practices in rural and low-income areas, that might not have the financial resources of larger hospitals in urban areas, can have access to it and make use of it.

I would urge Members of this Committee and Congress to seriously consider how technology such as TPM software can be used to improve the accuracy of medical record keeping. America's senior citizens, and indeed, all Americans, rely on doctors and health care professionals to provide them with effective and safe treatment, regardless of whether they live in Detroit or Little Rock, Birmingham or Bangor, or Portland or Laramie. Safe dissemination of prescription drugs is an issue that affects every American in every state who rely on their doctors to follow that simple creed of the Hippocratic oath: "First, do no harm."

I thank the Committee for its time.

The CHAIRMAN. Before I go to the next witness, Doctor, could you explain the two different displays we have in front of us here?

Dr. ALLEN. I select prescription, select the drug, and it brings up that form there that I can edit if necessary——

The CHAIRMAN. That's the one that says "my prescription pad."

Dr. ALLEN. Yes that allows the information you have entered in the computer under a list will pop up, so that if you entered it right, and the people who put it in the computer have entered it right—which we can check all the time—it will pop up automatically dosage correct. Then, when you print it, after you have looked at it and see if it's the number you want to prescribe, and the dosage also, then when you print it, it prints out on a small printer, thermal printer, like this. That's the prescription that the patient takes with them.

The CHAIRMAN. OK, and the patient leaves your clinic or office with the blue copy to go to the pharmacy?

Dr. ALLEN. Yes, sir.

The CHAIRMAN. OK. Thank you.

Let's now turn to Peter Klein, pharmacist and Vice President of Business Development for En-Vision America.

STATEMENT OF PETER A. KLEIN, R.PH., PHARMACIST AND VICE PRESIDENT OF BUSINESS DEVELOPMENT FOR EN-VISION AMERICA

Mr. KLEIN. Thank you. Good afternoon.

Thank you for the opportunity to speak with you this afternoon regarding technology and prescription drug safety. I am Peter Klein. I'm a pharmacist and Vice President of Business Development for En-Vision America.

En-Vision America is a privately held company that was founded in 1996 to develop and market technologies aimed at assisting the visually impaired to live a more independent lifestyle. Our most recent invention has been developed into a commercially available product known as the ScripTalk talking prescription label system. The ScripTalk system is a cost effective method that promises to enhance the safety of millions of senior citizens as well as a staggering number of Americans afflicted by other conditions or situations that prevent them from reading or understanding the directions that appear on their prescription labels.

Currently, there are over 120 million Americans who have difficulty reading or understanding the instructions of their prescription medications. In many cases, even identifying the contents of the prescription package is impossible. The small print and look-alike packaging of medicine vials can lead to confusion, noncompliance, and ingestion errors. The repercussions of such adverse events are immense and increase health care costs through additional hospitalizations, doctor office visits, and changes to or additions of drug therapies.

En-Vision America set out to develop a technology that would allow the visually impaired to safely manage their own medication regimen. The result is the ScripTalk, which combines radio frequency identification technology with advanced voice synthesizer capability to deliver a cost-effective solution for those unable to read or understand their prescription instructions.

Medication errors have been in the forefront of the news lately. The seriousness of this issue has been articulated today by Dr. Corrigan, and also through Institute of Medicine reports, that state up to two million people are hospitalized from side effects or reactions to prescription drugs. The IOM survey, however, does not consider statistics related to poor therapeutic outcomes as a result of noncompliance. A noncompliant patient does not achieve the expected benefit of their drug therapies and their conditions may not improve, or even worsen, because they did not take enough medication, or they did not take it at the proper interval, or, worse yet, they have over-medicated themselves.

Compliance cannot occur for up to 42 percent of United States citizens due to their inability to read, translate, or comprehend the instructions and warnings that appear on their prescription containers. The ScripTalk prescription label system eliminates this barrier to compliance by actually reading the text of a prescription label aloud to the user.

The United States Census Bureau reports that at least 18 percent of Americans over the age of 65 have a functional limitation seeing words and letters, or are unable to see words or letters. There are currently more than 35 million Americans over the age of 65, and approximately 6.3 million may not be able to safely read the directions that appear on their prescription labels.

I refer to Exhibit 1, which not only depicts the year 2000 statistics, but overlays it and projects through the year 2030.

According to several prescription utilization reporting agencies, seniors over the age of 65 consume, on average, 36 filled prescriptions annually. Therefore, in the year 2000, seniors experiencing a visual impairment consumed over 227 million prescriptions, which is depicted in Exhibit 2. This means that 7 percent of the prescriptions dispensed in the United States were for only 2 percent of the population, who may not have been able to read the instructions or warnings on the label. This alarming statistic illustrates the need for technology that enables this population to self-medicate.

If I could refer to Exhibit 3. Seniors with visual impairment are not the only group who could benefit from the use of the ScripTalk system. Exhibit 3 illustrates other segments of the population who could also benefit from this technology. You can see that the seniors with severe visual impairments represent the smallest group that could benefit from this technology.

Studies sponsored by the AMA have concluded that 90 million people in the United States have difficulty comprehending medical information, which limits their ability to care for their own medical problems. Of this group, 40–44 million people are functionally illiterate, which is reading at or below a fifth grade level, while an additional 50 million adults are only marginally literate and have difficulty with reading comprehension and/or computational skills.

These Americans are unable to read and/or understand prescription medication labels and auxiliary warning labels. Low health literacy skills cost the U.S. health care system approximately $73 billion annually in unnecessary doctor visits, hospitalizations, and longer hospital stays. Low health literacy is particularly common among the older population and low-income people. Some studies indicate that 66 percent of U.S. citizens over the age of 60 have ei-

ther inadequate or marginal literacy skills, and about 45 percent of all functionally illiterate adults live in poverty.

There are roughly 8.8 million people in the United States, and 80 million people worldwide, that have visual disabilities and are categorized as "legally blind." Only a small percentage of this population can actually read Braille, which renders Braille prescription labeling useless for the majority of that population.

It is estimated that approximately 11 million are severely affected by dyslexia, and 10 percent of the population may show some sign of dyslexia.

When a patient using a ScripTalk prescription read submits a prescription, the pharmacy software prints and programs a talking label using a dedicated, small-footprint printer. The label stores textual prescription information in an electronic format on a microchip embedded in the label. I am holding in my hand an insert, which is actually the micro-chip.

The pharmacist or technician then places the talking label on the prescription container. In the home, the patient uses a handheld ScripTalk reader that decodes the label information using speech synthesis technology. The patient then hears all of the information that is printed on the label. If I may demonstrate this technology.

[Voice Synthesizer: "Patient, Max Lieber. Drug name, Lanoxin, 500 milligram capsules. Instructions. Take one capsule three times daily for 2 weeks. Prescription date, March 5, 2001. Refills remaining: zero. Warning. Important. Finish all this medication unless otherwise directed by prescriber."]

So all the pertinent information that appears on the label is translated into audible speech for the patient to hear.

The CHAIRMAN. What did the handheld read, a bar graph?

Mr. KLEIN. No, Senator. There is actually a micro-chip that's embedded in the label.

The CHAIRMAN. Oh, all right.

Mr. KLEIN. And the handheld reader translates the information that was stored on that label through radio frequency technology.

A clinical trial of the ScripTalk system was conducted at the Veterans Administration hospital in Hines, IL. The study began in September of 2000, and concluded March 15, 2001.

Based on information provided to En-Vision America during a meeting in early April, we anticipate that a favorable report outlining the benefits of ScripTalk will be presented to the appropriate Veterans Administration officials. It is our understanding that the VA will then determine how the product may be made available to visually impaired veterans. The Hines VA pharmacy chief who was involved in the study has indicated his interest in planning another study to determine the usefulness of the product for marginally literate veterans.

We at En-Vision America are confident that this technology will be of great benefit to the elderly, visually impaired, and functionally illiterate users. We are working diligently to create opportunities to make this technology available to as many Americans as possible. We appreciate the support of the Veterans Administration who recognized the need for such a technology within that health system. Their support has been vital in helping us develop and refine the ScripTalk functionality.

Thank you so much for providing the opportunity to present information on our technology to the Special Committee.

[The prepared statement of Mr. Klein follows:]

Testimony Before the Senate Special Committee on Aging
Hearing on Technology and Prescription Drug Safety
Peter A. Klein, R.Ph.

Good afternoon. Mr. Chairman and Members of the Special Committee on Aging, thank you for the opportunity to speak with you this afternoon regarding technology and prescription drug safety. I am Peter A. Klein, a pharmacist and Vice President of Business Development for En-Vision America. En-Vision America is a privately held company that was founded in 1996 to develop and market technologies aimed at assisting the Visually Impaired to live a more independent lifestyle. Our most recent invention has been developed into a commercially available product known as the ScripTalk™ Talking Prescription Label System. The ScripTalk™ System is a cost effective method that promises to enhance the Safety of millions of Senior Citizens as well as a staggering number of Americans afflicted by other conditions or situations that prevent them from reading or understanding the directions that appear on their prescription labels.

Currently, there are over **120 million** Americans who have difficulty reading or understanding the instructions of their prescription medications. In many cases, even identifying the contents of the prescription package is impossible. The small print and look-alike packaging of medicine vials can lead to confusion, non-compliance, and ingestion errors. The repercussions of such adverse events are immense and increase healthcare costs through additional hospitalizations, doctor office visits and changes to or addition of drug therapies.

En-Vision America set out to develop a technology that would allow the visually impaired to safely manage their own medication regimen. The result is the ScripTalk™ Talking Prescription Label System, which combines radio frequency identification technology with advanced voice synthesizer capability to deliver a cost effective solution for those unable to read or understand their prescription instructions.

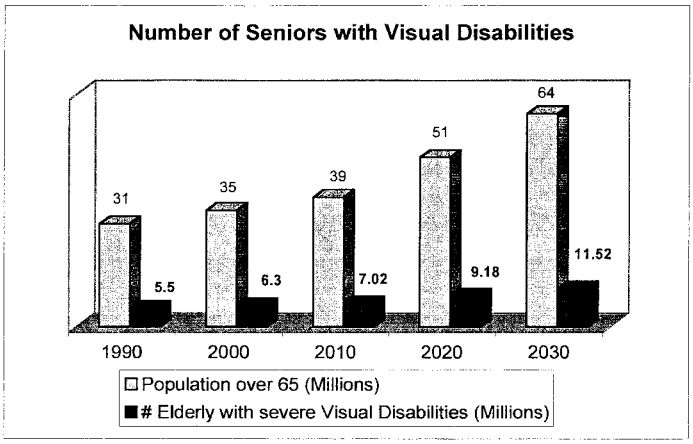
Medication errors have been in the forefront of the news lately. The seriousness of this issue has been articulated by Institute of Medicine (IOM) reports that state up to 2 million people are hospitalized from side effects or reactions to prescription drugs. The IOM survey, however, does not consider statistics related to poor therapeutic outcomes as a result of ***non-compliance***. A non-compliant patient does not achieve the expected benefit of their drug therapies, and their conditions may not improve or even worsen because they did not take enough medication or they did not take it at the proper interval, or worse yet, they overmedicated themselves.

Compliance cannot occur for up to 42% of United States Citizens due to their inability to read, translate, or comprehend the instructions and warnings that appear on their prescription containers. The ScripTalk™ Talking Prescription Label System eliminates this barrier to compliance by actually reading the text of a prescription label aloud to the user.

Seniors with Severe Visual Impairment

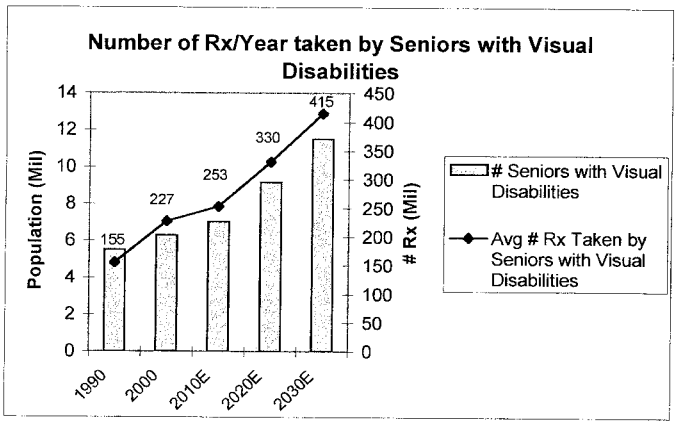
The United States Census Bureau reports that at least 18% of Americans over the age of 65 have a functional limitation seeing words and letters or are unable to see words or letters. There are currently more than 35 million Americans over the age of 65, and approximately 6.3 million may not be able to safely read the directions that appear on their prescription labels.

Exhibit 1 demonstrates the current population, along with well-known projections that depict "The Graying of America".



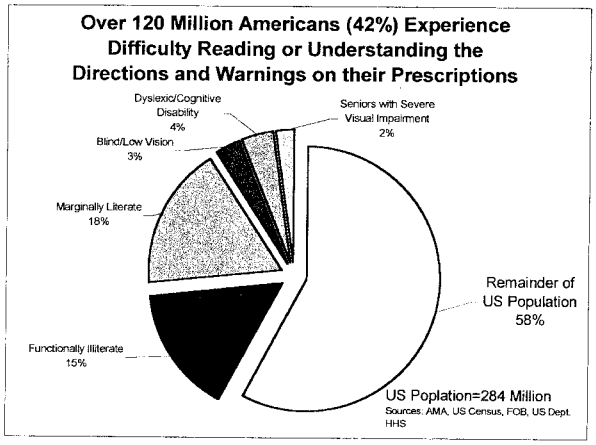
According to several Prescription utilization reporting agencies, Seniors over the age of 65 consume, on the average, 36 filled prescriptions annually. Therefore, in the year 2000, Seniors experiencing a visual impairment consumed over 227 million prescriptions. (See *Exhibit 2)* This means that 7% of the prescriptions dispensed in the US were for only 2% of the population, who may not have been able to read the instructions or warnings on the label. This alarming statistic illustrates the need for technology that enables this population to self-medicate.

Exhibit 2 examines the total number of Prescriptions taken by this Visually Disabled Senior population, based on recently reported statistics.



Others who would benefit from ScripTalk™

Seniors with visual impairment are not the only group who could benefit from the use of the ScripTalk™ System. **Exhibit 3** Illustrates other Segments of the population who would also benefit from ScripTalk™.



Health Illiteracy in the U.S.

Studies sponsored by the AMA have concluded that 90 million people in the U.S. have difficulty comprehending medical information, which limits their ability to care for their own medical problems. Of this group, 21% (40 million to 44 million people) are functionally illiterate (reading at or below a fifth grade level), while an additional 27% of adults (50 million people) are only marginally literate (having difficulty with reading comprehension and/or computational skills). These Americans are unable to read and/or understand prescription medication labels and auxiliary warning labels. Low health literacy skills cost the US health care system approximately $73 billion annually in unnecessary doctor visits, hospitalizations, and longer hospital stays. Low health literacy is particularly common among the older population and low-income people. Some studies indicate that 66% of US adults age 60 and over have either inadequate or marginal literacy skills; about 45% of all functionally illiterate adults live in poverty.

The Blind

There are roughly 8.8 million people in the U.S. and 80+ Million people worldwide that have visual disabilities and are categorized as "legally blind". Only a small percentage (less than 1%) of this population can actually read Braille, which renders Braille prescription labeling useless for the majority of the population.

Reading and Comprehension Difficulties

It is estimated that approximately 11 million people (4% of the US population) are severely affected by dyslexia (10% of the population "show some sign" of dyslexia).

How ScripTalk Works

When a patient using a ScripTalk™ reader submits a prescription, the pharmacy software prints and programs a Talking Label using a dedicated, small-footprint Talking Label printer. The Talking Label stores textual prescription information in an electronic format onto a microchip embedded in the label. The pharmacist or technician then places the Talking Label on the prescription container. In the home, the patient uses a hand-held ScripTalk™ Reader that decodes the label information using speech synthesis technology. The patient then *hears* all of the information that is printed on the label.

By simply moving the prescription within an inch of the ScripTalk™ reader, pertinent information such as, the name of the patient; the name of the drug; the dosage; general instructions; warnings; prescription (Rx) Number; along with the doctor's name and phone number are converted into speech.

A clinical trial of the ScripTalk™ system was conducted at the Veterans Administration Hospital in Hines, IL. The study began in September 2000 and concluded March 15, 2001.

Based on information provided to En-Vision America during a meeting in early April, we anticipate that a favorable report outlining the benefits of ScripTalk™ will be presented to the appropriate Veterans Administration officials. It is our understanding that the VA will then determine how the product may be made available to visually impaired Veterans. The Hines VA Pharmacy Chief who was involved in the initial Study has indicated his

interest in planning another Study to determine the usefulness of the product for marginally literate Veterans.

We at En-Vision America are confident that this technology will be of great benefit to the Elderly, visually impaired and functionally illiterate users. We are working diligently to create opportunities to make this technology available to as many Americans as possible. We appreciate the support of the Veterans Administration who recognized the need for such a technology within that Health System. Their support has been vital in helping us develop and refine the ScripTalk™ functionality.

Thank you so much for providing the opportunity to present information on our technology to the Special Committee.

Talking Prescriptions

A Cost Effective Solution to Enhance Patient Safety.

ScripTalk™

What is . . .

ScripTalk™ ?

ScripTalk allows individuals that have difficulty reading or understanding their prescription labels a better way to manage their own medication regimen.

Who benefits from ScripTalk?:

- Visually Impaired (Blind & Low Vision)
- Elderly with cognitive disabilities
- Reading Difficulties: Dyslexic/Illiterate
- Foreign Language Speaking Customers

ScripTalk also alleviates fears of part-time caregivers concerned with their patients' ability to self-medicate in their absence.

How it works . . .

- A Talking Label™ is printed and programmed in the Pharmacy
- Pharmacy dispenses Rx in standard vials or pre-packaging
- Talking Label™ placed on prescription container

At home, when the patient moves the prescription within an inch of the ScripTalk™ reader, the reader recites information such as:

- Patient Name
- Drug Name and Dosage
- Instructions for use
- Warnings/Cautions
- Pharmacy Name & Phone
- Doctor Name & Phone
- Pharmacy Rx#

About Talking Labels™. . .

Inexpensive

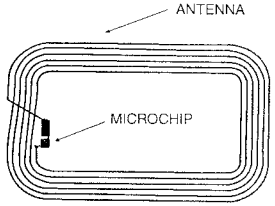
Serve as the primary label or can be placed under your standard pharmacy label.

Non-Volatile Memory - Prescription information cannot be erased.

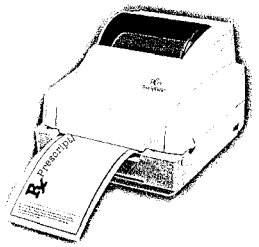
Data retention > 10 years

Information can be read over and over.

Label Operating Temperature Range: (-40°C to +85°C; -40°F to +185°F)



En-Vision AMERICA



The ScripTalk Printer

Thermal Transfer with an RFID programmer
Programs & prints simultaneously
Error Detection
Small Footprint
High output

Printer fits easily into existing fulfillment processes used by a retail or mail order pharmacy.

Contact Us
For Pricing & Distribution Information.

Benefits of ScripTalk:

- ☐ Attracts/Retains Customers
- ☐ Reduces medication error
- ☐ Increases compliance
- ☐ Makes re-ordering easier
- ☐ Creates tremendous good-will
- ☐ Can be tailored to meet your pharmacy labeling and marketing needs.
- ☐ Available in multilingual versions.

En-Vision AMERICA

Since 1995, En-Vision America has been dedicated to providing medical and non-medical related solutions for visually impaired individuals. The company's other products include it's well known "i.d.mate", a talking bar code identification system.

1013 Porter Lane
Normal, Illinois 61761

Phone: 309-452-3088
Fax: 309-452-3643
www.envisionamerica.com

The CHAIRMAN. Mr. Klein, thank you very much.

Before we go to Mr. Reed, we have been joined by two of our colleagues who are members of this committee. Let me turn to them to see if they have any opening comments before we proceed.

Senator Stabenow.

STATEMENT OF SENATOR DEBBIE STABENOW

Senator STABENOW. Thank you very much, Mr. Chairman.

I very much appreciate your holding this hearing on a very important and interesting topic that directly affects people's lives every day.

I would like to say that I know many of the errors in hospitals and other institutions involve prescription drugs, and that the inaccurate dosages and unknown drug allergies are just two of what I'm sure are many types of preventable mistakes that are occurring in the hospitals that the report from the Institute of Medicine outlined. I appreciate all of you being here today to talk about ways that we can address that with new technologies.

It is very exciting to see innovative new technologies that are being used and that need to be expanded on in order to be able to address medical errors.

I did want to share a couple of things happening in Michigan with you, that I discussed as we called around on this topic, that I think indicate the direction that many of our hospitals are going in. I also wanted, though, to state that, whenever I get the opportunity when we're talking about prescription drugs, to say that one of the ways, in addition to what's being talked about today, that people are making errors themselves relates to self-regulating of their medications because seniors are unable to afford their prescriptions. I hear from doctors all the time about seniors cutting their pills in half or taking them every other day or every other week because of the inability to afford a full prescription. So I think as we're talking about this topic today, it is very important to also address the fact that we have seniors who are self-medicating because Medicare doesn't cover prescription drugs and that that's a critical issue facing all of us.

Just for a moment, let me just say that the University of Michigan health system has initiated a number of programs to alleviate prescription error. These programs are system-wide. They involve many hospital divisions. The hospital pharmacy was one of the first in the Nation to use a robot system based on bar codes to prepare prescription refills. Because of the bar codes, there is less chance of dispensing the wrong prescription, as you know.

In addition, the hospital uses automated medical dispensers and they will soon connect those dispensers to the pharmacy patients' data base, which will allow them to prevent even more errors.

Recently, the system was using easier to read and more informative labels for intravenous drugs, and it also implemented a new policy requiring doctors to double check dose calculations for chemotherapy and install the standardized medical administration record that helps nurses and doctors track medication doses more efficiently.

I would submit for the record, Mr. Chairman, a more extensive description of those things.

The CHAIRMAN. Certainly.
[The information referred to follows:]

Opening Statement
Senator Debbie Stabenow
Aging Committee Hearing
On
Prescription Technology
May 3, 2001

Chairman Craig and Senator Breaux, I would like to thank you for convening today's hearing on the important topic of prescription drug technology. Since the publication of the Institute of Medicine Report on medical errors, this issue has received increased attention. Many of the errors in hospitals and in other institutions involve prescription drugs. Inaccurate dosages and unknown drug allergies are just two of the many types of preventable mistakes that are occurring in our hospitals that the report uncovered. I think this committee is doing a great service today by highlighting innovative ways that technology has been used around the country to prevent mistakes and increase patient safety.

Before I discuss more technical issues, I would like to mention another important patient prescription drug safety issue that is of great concern to me. Many preventable medical problems arise from the fact that Medicare does not offer a prescription drug benefit for seniors and individuals with disabilities. Physicians have shared with me that seniors are putting their lives in danger when the make risky choices about their healthcare because they cannot afford the medications they need. Seniors who

cannot afford their prescriptions may try to take their pills every other day or try to cut their pills in half. This can lead to serious problems and is a very important kind of medical mistake that I think we should not overlook. There is a way to prevent these health tragedies and that is to provide a real Medicare prescription drug benefit, so that seniors can have the medications they need.

There are many prescription technology innovations taking place in Michigan that I would like to share with the committee.

University of Michigan Health Systems

The University of Michigan Health System has initiated many programs to alleviate prescription errors. These programs are system-wide and involve many hospital divisions.

The hospital pharmacy was one of the first in the nation to use a robot system, based on bar codes, to prepare prescription refills. Because of the bar codes, there is less chance of dispensing the wrong prescription. In addition, the hospital uses automated medication dispensers. The System will soon connect those dispensers to the pharmacy's patient database, which will prevent even more errors.

Recently, the System is using easier to read and more informative labels for intravenous drugs. It has also implemented a new policy requiring doctors to double-

check dose calculations for chemotherapy and installed a standardized Medication Administration Record that helps nurses and doctors track medication doses more efficiently.

The System is currently working on installing new programs and innovations that include even more hospital divisions and would further reduce the risk of prescription drug errors

In the Operating Room, the UofM Health System has one of the first electronic information systems in the country called MorCARE. This system gives their surgeons and Anesthesiologists an up-to-date, complete picture of each patient, including patient histories, test results and most important, the medications they take and any adverse reactions they have had in the past.

Because the information is instant, lab test results, medical images and other crucial information reaches the surgeons more quickly than paper forms. This reduces the chances for medical errors. Further, the information is connected to the operating room equipment, so there is less chance for adverse drug interactions or incorrect anesthesia doses.

Detroit Medical Center

The Detroit Medical Center has invested in a paperless, seamless record system that tracks vital information about patients such as drug allergies and medical history. Physicians are connected to the system through remote

access so that they can check on their patients from their home offices.

In a few months, the Detroit Medical Center will implement a computerized physician order system that will be linked to the pharmacy. The system will check for drug interactions, will verify appropriate dosages based on patient specifications such as weight and size. A special alert will warn the physician immediately if she is ordering something inappropriate. Computers are currently located at nurse's stations and will be outside all patient rooms. Eventually, hand-held technology will also be available to make the technology more mobile. This prescription technology effort is just one component of a comprehensive safety effort underway at Detroit Medical Center.

Henry Ford Hospital Systems

Henry Ford Hospital is working on incorporating new technologies into their pharmacy and medication dispensary systems. Information technology now available to hospitals will allow them to reduce prescription error and deliver prescriptions to their patients in a timely manner.

Henry Ford is working toward installing a system that uses databases, bar code systems, and remote computer devices so that several different departments throughout the hospital can interact. It is key that the pharmacy, the clinicians who order the medications, and the nurses who administer the medications all have access to the same

information in order to reduce the risk of prescription errors.

The new system will ensure that when a doctor orders medications, the system screens the order to make sure there are no possibilities of allergic reactions or adverse drug interactions for that patient. Further the system will also improve the efficiency and accuracy of processing medication orders.

Henry Ford and other hospitals around the state – indeed around the country – face the challenge of balancing the costs of these new technologies with the need make these vital improvements for prescription drug accuracy.

Again, I would like to thank the committee for holding today's hearing on such an important topic. I look forward to hearing testimony from the witnesses.

Senator STABENOW. I would just say also the Detroit Medical Center has been investing in new technologies, as has the Henry Ford health systems, which is working on incorporating new technologies as well. Those are just three of the systems in Michigan, that I found, as a result of your calling this hearing. I appreciated the opportunity to speak with some of the health care systems in Michigan and ask them what they were doing, and I'm anxious to take back the information that we are uncovering today to be able to share with them about more that they can be doing.

I thank you.

The CHAIRMAN. Well, thank you very much. In fact, in just a few moments, we're going to hear from Neil Reed, who I think will talk about his robot and how it applies.

Now, it's interesting—and, Senator Wyden, you will also appreciate this, and for those of you in the audience, eat your heart out. This is a packet full of——

Mr. REED. Unit doses.

The CHAIRMAN [continuing.] Unit doses that we'll be hearing about in a moment. It just so happens that our unit doses are candy. Somebody is trying to steal our heart, or our taste buds. Anyway, let me turn to Senator Wyden of Oregon for any comment he would like to make.

STATEMENT OF SENATOR RON WYDEN

Senator WYDEN. Thank you, Mr. Chairman. I very much commend you for holding this important hearing. I'm glad to see the Northwest controlling the Aging Committee at this point, and also——

Senator STABENOW. I object. [Laughter.]

Senator WYDEN. That was fast.

The CHAIRMAN. Objection not recorded. [Laughter.]

Senator WYDEN. I was just going to register how pleased I was that the Senator from Michigan was on the committee, because she has already made it clear that seniors and their needs are going to be a special priority for her. So we are very glad she's here.

I will be very brief, Mr. Chairman. As I said, I'm glad you're holding this hearing. It's very clear, in my judgment, that government health programs, in particular Medicare and Medicaid, are simply behind the technological revolution. If you look at those programs, in many respects they really aren't any different than they were 15 or 20 years ago. So it is critical that, as we look at the next round of health care, particularly for prescription drugs, uninsured and the like, that we have this extraordinary opportunity for technology to both help in the delivery of quality health care and also to save time and money.

What I'm struck with is the number of doctors who tell us that if they had nothing else but access to up-to-date handheld devices, a dramatic difference could be made. For example, with a handheld device, a Palm or a similar kind of device, by making a couple of clicks, it would be possible to find out about drug interactions, it would be possible to get up-to-date information, and about therapeutic equivalents. This would eliminate the problem of physicians scribbling out prescriptions and then various people, be their own staff or pharmacies, not being able to read it. So, in my view, there

is the opportunity here to do a world of good by incorporating technology like this.

Again and again, this committee has shown that we can work on a bipartisan basis to really ensure that we are keeping up with the times as it relates to gerontology issues. So it's an exciting development and I look forward to working with you and our friend from Michigan.

The CHAIRMAN. Senator Wyden, thank you.

Oh, by the way. Happy birthday.

Thank you. I'm moving into my "golden" years. [Laughter.]

Now we will get back to our panelists. Let me introduce to the committee Neil Reed, pharmacist, Director of Pharmacy at the Eastern Idaho Regional Medical Center in Idaho Falls. Neil, welcome before the committee, and thank you for the candy. These individually wrapped items certainly provide a great visual demonstration of the manner that pills are packaged and labeled by your hospitals Robot Rx.

STATEMENT OF NEIL REED, PHARMACIST, DIRECTOR OF PHARMACY AT EASTERN IDAHO REGIONAL MEDICAL CENTER, IDAHO FALLS, ID

Mr. REED. Thank you, Mr. Chairman. My name is Neil Reed, and it is my pleasure to testify before you today about the potential of pharmacy technology and how to make patients even safer with regard to their medications.

The hospital I work at, Eastern Idaho Regional Medical Center, is a 350-bed community tertiary hospital, and it's part of HCA, the health care company which is based in Nashville, TN. We provide primary, trauma and long-term care for 2,500 square miles, serving the residents of Eastern Idaho, Wyoming, and Yellowstone National Park.

Our pharmacy department handles anywhere between 80,000 to 90,000 drug items each month, which translates to 14 to 16 items per day per patient.

I want to point out that hospital pharmacies, even those without robots, are impressively accurate. National statistics show that 99.9 percent of all medications are administered correctly. Yet, within health care, safety and well-being of our patients are at stake, and we consider even one mistake an unacceptable number.

In 1999, our hospital embarked on a comprehensive exploration of the benefits of automating part of our medication process. We were able to make this technology leap toward automation because we enjoy the support of our parent company, HCA. And automation is only part of HCA's extensive program to improve medication best practices. Other corporate initiatives which are included for every facility include adoption of a medication plan, establishing a medication safety team which monitors all medication throughout the facility, developing a list of high-risk medications for dispensing and administration, and education of the staff and physicians to heighten awareness of the cause and prevention of medication errors.

Common features of an automated system include bar code technology. In our instance, we have to package all medications onsite

because there is currently no manufacturers' standardization of bar codes being put on products.

Automation also includes robotic, and then, finally, the point-of-care which ties together the automation of bar coding, the risk span on the patient, which is bar code, the person administering the drug, all these three things come together for the proper administration of the drug.

At our facility we have Robot-Rx, which is located in the main pharmacy, and then computerized cabinets located throughout each nursing area which store and dispense drugs based on the patient's electronic medication profile. This is all hooked to and driven by the pharmacy information system.

We believe that automated technologies improve the medication delivery process in the following ways: it reduces errors, it reduces missed doses, and it frees pharmacists for more direct involvement with the patient and doctors.

For both our patients and health care providers, the benefits of automation have been real, measurable, and significant.

All medication picked by Robot-Rx has been 100 percent accurate. What that means is that the robot has not made one mistake since the implementation of the program. Before Acudose-Rx and Robot-Rx were implemented, the pharmacy department, on a daily basis, spent 8 hours, and now that task translates to an hour-and-a-half. With the extra time, we are able to spend more time with the patient and with physicians. We are doing more clinical pharmacy and less pill counting, and I believe this leads to better patient care.

In addition, and harder to measure, are the undeniably significant economic benefits. Also included is reduced liabilities which result from greater accuracy. Only 4½ percent of all hospitals and systems nationwide can be designated as fully automated. Particularly, this is due to the initial expense of automation which creates barriers for many, even those who see and appreciate the technology's potential.

I would like to recommend four things to improve the delivery and administration process of medications.

No. 1, standardization of bar code technology. Currently, there is no standard or requirement for manufacturers to place bar coding on unit dose packaged medications. Leaders in pharmacy and drug manufacturing must agree on standardization, which should include the national drug code, the product expiration, and even lot number. With standardization in place, even smaller facilities could reap the benefits of the technology safety net at the bedside, with the patient match technology, even if they lack a robot, again bringing together the patient, the person administering the drug, and the drug itself.

Second, I would like to recommend computerized physician order entry of the drug orders. And then financial incentives for institutions demonstrating improved medication safety, and then, last, incentives to increase the number of allied health professionals. Currently, there is an extensive shortage of all health professionals and all disciplines affected by the shortage, from nursing, pharmacy, lab and beyond. The promise of automation will not be fully

realized without trained, qualified personnel to provide clinical decisionmaking and ultimately deliver the product.

Mr. Chairman, I know that our focus today is about our aging population and their medication profile. The medication profile of this population typically remains constant throughout their length of treatment. This would afford a great application of automation by removing the human component of drug dispensing via bar code technology, followed by verification at the patient bedside, which would greatly decrease medication errors.

I appreciate the opportunity to testify before you today, and would be happy to answer any questions.

I would like again to bring attention to the packets that have examples of how the medication is packaged in our facility and distributed to the patient bedside.

Thank you.

[The prepared statement of Mr. Reed follows:]

Benefits of Automation in Medication Delivery: A Community Hospital's Experience

Neil Reed, RPH, MHSA

Personal Introduction and Statement of the Issue

My name is Neil Reed, and it is my pleasure and privilege to testify before you today about the potential of new pharmacy technologies to make patients even safer with regard to their medications.

I hold both a bachelor's of science and a master's degree in my profession, and have worked as a pharmacist since 1983, not only in my current position as director of pharmacy at Eastern Idaho Regional Medical Center in Idaho Falls, but also as a staff hospital pharmacist. I have therefore seen the hospital medication delivery process inside and out, from a variety of different vantage points.

The hospital where I work, Eastern Idaho Regional Medical Center, is a 350 bed community, tertiary hospital and is part of Healthcare Corporation of America (HCA) based in Nashville, Tennessee. We provide primary, trauma, acute and long term care for the residents of Eastern Idaho, Wyoming and Yellowstone National Park.

Our pharmacy department handles between 80,000 and 90,000 drug items each month. That translates to an average of 14 to 16 drug items per patient per day.[1] Those sound like very large numbers - and they are. But that volume isn't unique to our facility. A staggeringly large number of drug items are handled each and every day in hospital pharmacies throughout the United States. - with many steps, people and handoffs along the way before the meds finally reach the patients.

I was asked to speak to you today about the benefits our hospital has seen as a result of automating the way we give medicine to our patients – and we believe those benefits are considerable. But before I do, there's a point which is crucial to your understanding of the issue, and one that I fear may become lost in the recent rhetoric about patient medication errors.

That point is: hospital pharmacies, even those without robots, are already impressively accurate. National statistics show that over 99.9% of all medication ordered by doctors for patients gets there, gets there on time, gets there in the right amount, and gets there to the right patients.

Having said that, it is equally true that hospitals exist for the sake of patients. With the health, safety and well-being of patients at stake, we as hospital professionals view even one medication mistake as an unacceptable number. The crux of the issue is therefore not to "fix a broken system," but to create conditions within an existing system of high standards and an excellent track record for even higher levels of patient care.

The inescapable truth is that administering medicine in American hospitals is an endeavor of human beings. And because it is, there is potential for error. Our goal is to reduce that potential.

To pursue the goal, in early 1999, my hospital embarked on a comprehensive exploration of the benefits of automating our medication processes. For more than a year, we analyzed costs, benefits and other impacts of automating.

What would it mean for our patients? For our pharmacy department? For our nursing units? For our physicians? For our facility as a whole? The answers to all of those questions were very encouraging.

Why We Took the Plunge and Automated

We learned that we **could** tap technology to aid us in doing an even better job for our patients. And we learned that the best way to make the biggest impact on errors was to eliminate redundant processes in which human beings could incorrectly select, dispense and administer drug items. The "cart fill" process – the manual daily routine of getting scheduled medication to the patient – was quickly identified as the "step" in the chain where automation could make the biggest difference, so that is where we focused our early implementation efforts.

It also must be said that another reason we were able to make the technology leap toward automation is that we enjoy the support of our corporate parent, HCA. As part of its extensive program to improve medication best practices throughout all affiliate hospitals and facilities, HCA agreed to adopt the new approach at several hospitals with an eye toward improving medication safety. Not all facilities are similarly blessed, but I'm proud to be part of an organization with such foresight and initiative. Other corporate initiatives by HCA at each of its member facilities include: adoption of plans for medication safety; establishing a Medication Safety Team; developing a list of "high risk" medications for dispensing and/or administration; and education for staff and physicians to heighten awareness of cause and prevention of medication errors. These medication safety initiatives, combined with automation at our facility, improve the assessment, delivery, storage and administration of medication at all levels.

Common features in automated medication systems include:

- bar-code technology;
- robotics; and
- point-of-care drug administration

The automated systems chosen by our hospital have two main components: a robot located in our pharmacy (Robot-Rx^{R}) and computerized cabinets located in each nursing unit which store and dispense drugs based on the patient's electronic medication profile from the pharmacy information system (Acudose-Rx^{R}).[2] Both systems are manufactured and distributed by McKesson Automated Healthcare. These two separate and integrated products form the backbone for our automated system at EIRMC.

Automated technologies improve the medication delivery process in the following ways:

- they reduce medication errors
- they reduce missed doses
- they create significant cost savings
- they free pharmacists for more direct involvement with patients and doctors (instead of pill-counting and sorting, pharmacists can spend more time sharing their expertise with patients and doctors)
- they reduce billing errors related to medication

The Results: Benefits of Automation at Eastern Idaho Regional Medical Center

For those of you who are interested, I have included in your packets a simple depiction of how the robot and carts work and the steps involved in the process. You'll find that in your materials as Appendix 1.

Of more importance to you than "how it works," however, is, "Does it work?" And with six months experience behind us, I can tell you that it does.

For both patients and healthcare providers, the benefits of automation have been real, measurable and significant.

Accuracy: Housewide, our accuracy has improved since the inception of Robot-Rx^{R} and Acudose-Rx^{R}. Errors overall[3] have fallen from 0.021% to 0.0193% (comparing first of 2000 and 2001, respectively). And **all** medication picked by Robot-Rx^{R} has been 100% accurate. In other words, with medications picked by the robot, we have not had a single mistake since we installed the system.

Efficiency: Before Robot-Rx^{R} and Acudose-Rx^{R}, we spent up to 8 hours in our hospital pharmacy performing tasks that now take us just 1½ hours. What do we do with the time we're saving? We spend it with patients and with doctors. Pharmacists are the professionals on the cutting edge of what's new and what's promising for patients, pharmaceutically speaking. For patients to reap the benefits of new medicines, their doctors have to know the new medicines exist. We now have more time to teach them. We're also spending more time at the bedside, talking to patients about side effects they may experience, and helping coordinate their care. In short, we're doing more clinical pharmacy and less pill-counting, and clinical pharmacy leads to better patient care.

Savings: Having pharmacists available to use the meds the right way has also facilitated cost-capture. Harder to measure but undeniably significant economic benefits also include the reduced liabilities which results from greater accuracy.

We are so pleased with automation at EIRMC that we plan to take additional steps to fully optimize our system by adding "nurse-servers" and "point of care" drug administration tools at the bedside.[4] Essentially this means nurses will be able to quickly and directly confirm the accuracy of the medication and the "match" with the patient at the bedside, thereby decreasing the potential for mistakes. We also continue to add more Acudose-Rx^{R} cabinets throughout the facility to provide added security, improved access and documentation of narcotic and PRN (as needed) medication items.

Automation, Bar-Code Technology, and the Aging.

How does our experience at EIRMC apply to the aging, the group with which your subcommittee is concerned? Patients in long-term care facilities would benefit greatly from automation and bar-code technology[5] - in the same ways and for the same reasons as patients in our hospital have benefited.

The medication profile of elderly patients typically remains constant throughout their length of treatment, affording an efficient application of automation. Removing the human component of drug dispensing via bar-code technology followed by verification at patient bedside will greatly decrease medication errors.

What Lies Ahead

Automation in the hospital and long term care industry has advanced considerably over the past fifteen years. Even with all our progress, challenges remain.

Only 4.5% of all hospitals[6] and systems can be designated as fully automated. Lack of automation also factors into the large percentage of time (73%) that centralized pharmacists spent on monotonous, manual, repetitive, distributive functions, all of which decrease the time available for clinical services.

Hospitals and health systems need to capitalize on the advances of automation. Doing so will enable pharmacy and nursing to provide clinical care that improves both the medication safety, patient outcomes and the overall patient experience. However, the initial expense of automating creates barriers for many, even those who see and appreciate the technology's potential. In general, larger hospitals and health systems are much more likely to use new technology than smaller institutions[5] because they are better equipped to capitalize the upfront costs of providing an automated infrastructure.

Recommendations

As a pharmacy healthcare professional, I would like recommend four things to improve medication delivery and administration:

1. *Standardization of bar-code technology to the packaging medications:* Currently there is no standard or requirement for drug manufactures to place bar-coding on unit dosed packaged medications. Leaders in pharmacy and drug manufacture must agree on standardization which includes the national drug code (NDC) and product expiration. With standardization in place, even smaller players could reap the benefits of the technology "safety net" at the bedside, with the patient "match" technology - even if they lack a robot.
2. *Computerized physician order entry:* Physicians should be required to place patient medication orders electronically to assure clarity and accuracy of medication orders and avoid mistakes from illegible handwriting. This is a critical step in "closing the loop" to prevent errors.
3. *Financial incentives for institutions demonstrating improved medication safety:* Premium credit should be extended to those institutions demonstrating improved medication safety through installation of automation, bar-coding, point of care drug administration and institution of physician order entry of medication orders.
4. *Increase the number of allied health professionals:* Currently there is an extensive shortage of all healthcare professionals. All disciplines are affected by the shortage, from nursing to pharmacy to laboratory and beyond. The promise of automation will not be fully realized without trained, qualified personnel to provide clinical decision-making and ultimately deliver the product.

---

[1] Eastern Idaho Regional Medical Center average patient census 190 per day, and 30 day month.

[2] Jacque MB, Rascati KL & Rascati B, Effect of an automated, nursing unit-based drug dispensing device on medication errors, *Am J Hosp Pharm*, 1995; 52;1875-79.

[3] Medication error rate = Number of errors observed divided by the number of opportunity for errors x 100.

[4] Fitzpatrick K. Robotic automation of medication-use management. *Physician Assistant*, November 1993.

[5] Barker KN, Ensuring safety in the use of automated medication dispensing systems. *Am J Health-Syst Pharm*. 1995; 52:2445-47.

[6] Percentage of Hospitals and Systems with Centralized Inpatient Pharmacy Distribution Systems and Degree of Automation

	Centralized Inpatient Pharmacy Distribution System			Automation		
Characteristic	n	%	n	% Not Automated	% Partially Automated	% Full Automated
Occupied beds						
All hospitals	535	74.8	530	77.4	18.1	4.5
<50	189	91.0	190	90.0	10.0	...
50-99	115	82.6	115	80.9	19.1	...
100-199	122	68.0	119	74.8	18.5	6.7
200-299	50	50.0	49	61.2	32.7	6.1
300-399	26	46.2	25	52.0	24.0	24.0
≥ 400	33	39.4	32	43.8	34.4	21.9
Metropolitan. Statistical Area (MSA)						
All hospitals	536	74.8	531	77.2	18.3	4.5
Within an MSA	334	66.8	330	69.4	23.6	7.0
Outside an MSA	202	88.1	201	90.0	9.5	0.5
Medical School Affiliation						
All hospitals	535	74.8	531	77.2	18.3	4.5
Yes	158	59.5	155	60.6	29.0	10.3
No	377	81.2	375	84.3	13.6	2.1

Ringold DJ, Santell JP, Scheider PJ ASHP national survey of pharmacy practice in acute care settings: Dispensing and administration—1999. Am J Health-Syst Pharm. 2000; 75:1759-75

The Rx for even better patient care at your hospital? EIRMC's new pharmacy robot!

New-fangled technology means more old-fashioned patient care. Instead of counting pills, EIRMC's new Robot-Rx frees our pharmacy experts to do what they do best: **help patients.** The robot gives pharmacists more one-on-one, face-to-face time to spend with patients and physicians. This lets them share their knowledge about the newest, most promising medicines and answer questions abut drug interactions and side effects.

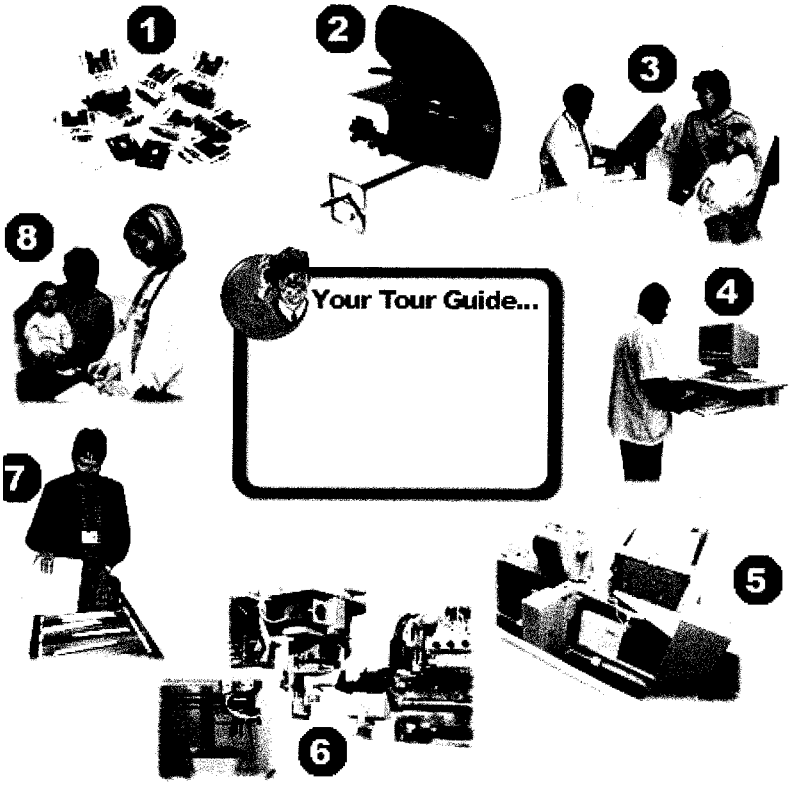
Dispensing medicine just got faster and more accurate. Where your care is concerned, we're leaving no room for error. The manufacturer of Robot-Rx says the system is completely accurate. The robot is fast, too; it can process more than 10,000 unit doses per day!

When we see a way to take even better care of you, count on EIRMC to lead the way. EIRMC's state-of-the-art pharmacy robot is the first of its kind in Idaho, and one of just 200 used in hospitals nationwide.

So, how does it work? Take a look!

Pharmacy Robot Tour

Move your mouse over each step and the "tour guide" will tell you what's happening.



Tour Guide points:

1. Medications are packaged, bar coded, and checked for accuracy
2. Robot sorts prepared medications and stores them inside its octagonal cell
3. Physician examines patient and writes prescription
4. Pharmacist enters prescription into computer
5. Robot's envelope system labels patient's medication envelope and waits for robot to fill prescription
6. Robot's arm picks up prescribed medication and drops it through chute into envelope
7. Pharmacy staff pick up patient prescriptions and deliver to various floors in hospital
8. Nurse gives medication to patient

NEIL H. REED
3765 Spring Creek Dr.
Idaho Falls, ID 83404
(208) 542-0799

OBJECTIVE: *Director of Pharmacy with full management responsibility over pharmacy staff, budget, medication procurement, distribution and clinical initiatives and programs.*

EDUCATION: *M.H.S.A., College of Health Related Professions*
Medical University of South Carolina, 1992
G.P.A. 3.9/4.0

B.S., College of Pharmacy
University of Wyoming, 1983
G.P.A. 2.9/4.0

EXPERIENCE: *EASTERN IDAHO REGIONAL MEDICAL CENTER, IDAHO FALLS, IDAHO*

JULY 1998 – PRESENT

Director of pharmacy for 350 bed community hospital. Pharmacy staff includes seventeen pharmacists (1-Clinical Coordinator, 1-Assistant Director of Pharmacy,14-staff pharmacists) fifteen technicians (8-full time pharmacy technicians, 7-parttime pharmacy students). Facility provides primary, trauma and acute care for residents of eastern Idaho, western Wyoming and Yellowstone National Park. Projects and programs have included; routine assessment of manpower, managing day-to-day operations, budget preparation, attendance of various inter-disciplinary teams. Instituted, with collaboration of OR nursing, anesthesiologists, OR pharmacy satellite. Successfully installed and implemented cabinet based dispensing units, new narcotic admission forms. Institution of Robot-Rx, state of the art barcode drug delivery system. Participated in house wide Administrative Review Committee, reviewing all policies for interdisciplinary Patient Care Manual.. Developed medication handbook for nursing, revised policy and procedure manual, new employee training and competency notebook. Currently monitor and attending construction meetings as EIRMC expands, which includes new and expanded pharmacy department.

NOVEMBER 1997- JUNE 1998

LAKE MEAD HOSPITAL MEDICAL CENTER, LAS VEGAS, NEVADA.

Director of pharmacy for 200 bed community hospital. Pharmacy staff includes six pharmacists, clinical manager and eight technicians. Pharmacy had undergone extensive amount of transition. Stabilized staff and improved working relationships with hospital management and between departments. Initiated and received approval for pharmacy remodel. Participated in hospital wide chart audit team to decrease billing errors. Oversaw maintenance and relocation of pharmacy automation Meditrol cabinets. Prepared pharmacy for successful JCAHO review.

SEPTEMBER 1994 - OCTOBER 1997

WESTERN MISSOURI MEDICAL CENTER, WARRENSBURG, MISSOURI.

Director of pharmacy. Successfully managed hospital pharmacy with staff consisting of three pharmacists and four technicians. Responsibilities included preparation of financial and management reports in a timely fashion. Setting priorities for completion of successful Joint Commission review. Negotiated contract renewal. Effectively implemented Meditech computer module, resulting in no loss of patient charges. Led multi discipline medication use team. Initiated and oversaw expansion of IV fluid preparation room and storage area. Initiated bi-monthly newsletter for medical staff. Completed several off-site special projects for Regional Director and Interim Resources.

AUGUST 1993 - AUGUST 1994 — ***DIRECTOR IN TRAINING, COMMUNITY HOSPITAL, GRAND JUNCTION, COLORADO.***

Completed Director in Training program through Owen Healthcare. Requirements for progran included introduction to director of pharmacy management functions and quality assurance. Participated in and completed Hospital Pharmacist Management Training Program sponsored by Burroughs Wellcome Company fall 1994, Raleigh/Durham North Carolina.

JANUARY 1985 - AUGUST 1993 — ***GREENVILLE HOSPITAL SYSTEM, GREENVILLE MEMORIAL MEDICAL CENTER, GREENVILLE, SOUTH CAROLINA.***

PHARMACIST IN CHARGE, July 1991 to August 1993
Successfully managed Cancer Treatment Center pharmacy with responsibility for dispensing 9,000,000+ dollars of oncology products yearly. Duties included coordinating investigational drug therapy with physicians and nursing staff; performing patient counseling and providing drug information to oncology staff.

PHARMACIST IN CHARGE, January 1989 to July 1991
Managed Home Health and Pain Therapy Center pharmacy with complete responsibility for dispensing IV products and oral medications. Additional duties included streamlining billing procedures for Medicare, Medicaid, indigent and self pay patients; supervision and coordination of IV products and CADD pumps; and performed clinical evaluation of patient medication use. Initiated and created the Greenville Hospital System's first pharmacy newsletter, The Pharmacy Network. Undertook entire responsibility of organization, editing, layout, printing, public relations and writing.

STAFF PHARMACIST, January 1985 to January 1989
Performed various pharmacy duties characteristic of large medical institution. This included compounding extemporaneous medications and outpatient dispensing; preparation of large volume IV, hyperalimentation and piggy-back fluids; aided in streamlining medication procurement for the emergency department; and performed all aspects of order entry.

APRIL 1984 - OCTOBER 1984 — ***REGISTERED PHARMACIST, REED DRUG, BIG PINEY, WYOMING.***

Successfully managed family-owned retail drug store, which included complete pharmacy responsibility for dispensing, ordering and patient medication counseling; and supervision of all financial and general business operations.

JANUARY 1984 - APRIL 1984 — ***INTERN PHARMACIST, DESOTO GENERAL HOSPITAL, MANSFIELD, LOUISIANA.***

Performed all duties required for small hospital pharmacy which included IV preparation, unit dose dispensing, ordering, and patient counseling.

PHARMACY LICENSE: *Idaho, Wyoming, Colorado, Nevada*

PERSONAL:
Age 42
Married
U.S. Citizen
Excellent Health

REFERENCES: *Excellent business and personal references furnished upon request.*

The CHAIRMAN. Thank you very much. I appreciate all of your testimony. Let me ask you a couple of questions, and I'm sure Senator Stabenow will have some, also.

Dr. Corrigan, in your opinion, why is the health care delivery system falling behind other leading service industries in the use of innovative technologies?

Ms. CORRIGAN. You have asked, Senator, probably the most difficult question to answer. Our committee has grappled with that for about 3 years. It's complex, and let me just identify a few factors that we think contribute to the state of affairs.

We are convinced that health care is way behind the curve, in terms of its adoption of useful information technology. I think one of the first reasons I would like to cite is just that there has been a lack of awareness of how serious the quality of care and safety problems are.

We have had a steady flow of literature for over 10 years now on this issue. We have over 80 publications just in the last decade in leading journals on quality of care problems. They all point in the same direction. We know we have a very sizable quality gap. We do not deliver care safely and effectively. We're not using our knowledge base in technology, but the American public hasn't known that until very recently. Our leaders in the policy world, like yourselves, have not known that, either, I don't think. It has tended to be in research journals.

Another reason is that health care is a highly decentralized, almost cottage industry. The majority of providers still practice in small group settings. As to the investment in technology, they may lack access to the necessary capital, as well as the skilled personnel that are needed to be able to make the investment in an information technology infrastructure.

Third, we are not sure that we know how to infuse capital into the industry effectively. Many not-for-profit organizations lack the same degree of access to capital as perhaps some of the for-profit organizations. So capital probably is an issue, and it's probably a particular issue at the level of physician groups, small practices. That's the primary mode of organizations still.

Fourth, we lack standards, clinical standards, data collection standards, data transmission standards, data exchange standards. Until very recently, we lacked standards for confidentiality and protection of personally identifiable information. We are behind the curve on creating a national health information infrastructure. There is a very real need for a national policy in these areas, to facilitate what we want to have happen at the delivery system level.

Fifth, we lack a business case in many instances. If one hospital invests significant amounts in improving safety, improving outcomes, better quality, it's not clear that they really benefit because it isn't recognized in the marketplace. It may not be recognized by oversight or regulatory agencies. We don't measure it. It isn't immediately apparent to everyone.

I think last, but not least, there are some major cultural issues. Our physicians are typically trained to rely on their own memory and ability to deliver care, almost in an isolated fashion. We have grossly underestimated how complex and complicated it is to pro-

vide quality health care in this day and age. It requires interdisciplinary teams, it requires information support systems, and a much different environment than the one we're currently training them in.

The CHAIRMAN. Thank you very much for that.

Dr. Allen, obviously you have sensed the need and you have become directly involved in developing systems and software that respond to your concerns and the concerns that this committee is focusing on.

What measures does your system take to safeguard a patient's most sensitive medical information from computer "hackers", those that might gain access to that information pool?

Dr. ALLEN. Well, the biggest sort of way we use secure measures is that it's all inner-office. They really don't have the ability to "hack" in from outside. We are not on line as yet, and that prevents that from happening.

As far as people "hacking" from inside, it is password protected, and also each individual employee has a password and has certain areas they can access. The medical side can access the chart and some of the others that need to use it for billing information can access the chart. It's all integrated.

So each person doesn't necessarily have the ability to get into the part that shows sensitive information, except the ones that need to know.

The CHAIRMAN. But it's an in-house system?

Dr. ALLEN. Yes, an in-house system.

The CHAIRMAN. You're not on line yet, nor do these patients patch to a national system with their medical records?

Dr. ALLEN. That's correct.

The CHAIRMAN. My time is up. Let me turn to Senator Stabenow.

Senator STABENOW. Thank you, Mr. Chairman.

Just to follow up for a moment on the question Senator Craig asked, I think it's important to look at the issues of privacy. We are talking about very patient-specific information that is being placed into these systems.

I'm wondering if there are issues that we need to be addressing or that you see need to be addressed as it relates to the gathering of specific information, patient-specific information, and how that can be used, because certainly people are very concerned right now about their privacy, their health privacy, and we always have a challenge as we're developing these new technologies to make sure that, in fact, the information is used appropriately, that patients are aware of sharing of information and that there are systems in place for making sure it's not shared inappropriately.

Dr. ALLEN. For me?

Senator STABENOW. Yes. I would be happy to have anyone respond to that.

Dr. ALLEN. One of the issues it comes down to—I mean, charts are accessible by lots of people, more so than some of the higher tech ways of charting. Just as we can break into a computer, they can break into an office and steal charts maybe even easier.

We want to be absolutely private, but people can get access to it through a lot of different ways now without trying too hard, through people selling prescription lists, for people selling claims

lists from insurance companies, people's names and other things. So when we're in an electronic record, we can protect it pretty well via the password accessibility, and if we went on line, encryption would help a whole lot and hacking that is pretty difficult.

I think the protection of that information through technology is happening as we go along, but we have had those issues in the past anyway, so I think we can address it with technological breakthroughs and we can have protected charts and protected information just as easy now with higher tech ways of charting than we had with the charts.

Senator STABENOW. Would anyone else like to respond? Yes.

Mr. REED. If I could comment. HCA, as far as the house system, provides to each of its facilities what I consider to be a very sophisticated system, where the pharmacy and every department is connected together. We have a very strict zero tolerance, of course, on the inappropriate use of accessing medical information, to the extent that, for myself, I looked up my own medication record and I was called in and given a warning, which seems silly. But that's how important it is. I do know we have those safeguards in place right now.

The CHAIRMAN. When you called up your own record, Neil, what triggered the event of you calling it up?

Mr. REED. On a daily basis, our information systems monitor—probably what happened for me was my access was access to a similar name, so that was a trigger, and then the trigger goes off when it compares my name against maybe other people with the last name "Reed". I can't even access my own wife's record without her signoff. So there is a lot of privacy that goes on. It's very secure, very secure.

The CHAIRMAN. Excuse me for interrupting.

Senator STABENOW. Yes, go ahead.

Ms. CORRIGAN. I think you ask a very important question, Senator. We really are going to struggle over the next few years to move toward a balanced policy for protecting the confidentiality of information. We know it's critical, from studies we've seen again and again, and surveys of consumers, we know that if a patient is concerned that their information will not be protected and kept private, they don't share it. You just can't deliver good health care. So we have to find a way to make sure that people are confident and comfortable that their information will be handled very carefully. At the same time, I think my colleagues are correct, that many different types of technology currently exist to put in place some very strong safeguards.

What we have to do over the coming years, as we especially move into implementing the most recent regulations that have been promulgated in this area, is to monitor whether we've got the right balance, because the tighter we make it in terms of restrictions on access and sign-offs, the more expensive it is to implement these systems, and the more barriers we put up to using the information technology. So the American public needs to know that they pay a price if the protections are too stringent or too costly, because, in turn, the information doesn't get automated and these tools aren't used, which really are critical to providing good quality and safe care.

Senator STABENOW. Thank you.

The CHAIRMAN. Mr. Klein, the device you showed us, how much does that device cost? How expensive are these computerized labels and will the costs of these products add to the overall price of medication?

Mr. KLEIN. Well, first of all, Senator, as with any electronic device, with mass adoption and mass distribution, price obviously decreases. Right now, the label technology, which basically consists of this circuitry which is embedded in the label, will cost somewhere around one dollar. The reader itself, right now, costs around $200 to manufacture, but again, we anticipate that that cost would drop significantly through mass adoption.

When you ask the question of who will pay for it, or how will it be paid for, one thing I would ask you to consider is that this is a new technology and there has never been a technology delivered to assist people with their compliance in this manner. So we have had a very positive response from prescription outlets, major chains, major mail order pharmacies. The AMA gave us a very positive response, the National Federation of the Blind, blind organizations. So we're convinced there is a need and a demand and somehow, in getting grassroots support, we will be able to figure who will pay for the device as time passes on.

The CHAIRMAN. With the experience you have had with it, how durable is your device?

Mr. KLEIN. Well, it's been engineered to withstand a three foot drop on its corner, on to a hard surface. That was one of the criteria. So it is very durable and its useful life extends well beyond 5 years. So there is really no durability issue with it.

From a user perspective, these are tactile push buttons and self-help descriptions are on board. Basically, anybody can pick one up and start using it.

The CHAIRMAN. It's fascinating technology. I have seen a variety of labels that have chips built into them which can be read, and that's a fascinating approach.

Before I turn to you, Mr. Reed, we have just been joined by the ranking member of the committee, Senator Breaux. Do you wish to make any comments before we proceed? Senator Breaux.

STATEMENT OF SENATOR JOHN BREAUX

Senator BREAUX. Thank you, Mr. Chairman. Just very briefly. We've been in some other Commerce Committee hearings, and it is kind of a busy time, as you well know. Right now we're trying to put the budget to bed and trying to do it by the weekend, so it has been very difficult.

This is a very important hearing, to have people who are experts, to have their suggestions before the Congress about how we can reduce medical errors through modern technology. It is very important that we in the Congress, through the work that we do with Medicare and Medicaid and government-run health programs, to try and encourage and create a climate that allows for the greatest use of technology for the greatest number of benefits.

I am fascinated by the technological aspects about what we can do to eliminate errors of humans. You're holding up your device, and I was showing the Chairman that I got my new "smart tele-

phone", which is a telephone that you just flip open and it's a Palm Pilot. It's a combination. These are things that are happening so fast.

The point I would make is that if someone like me can understand this, it's amazing what others, I'm sure, will be able to do with it. I didn't invent this, as we've heard some Democrats say before—— [Laughter.]

The technology is something that we should not be fearful of, not be scared of. We should embrace it, understand it, and utilize it. These people have taken the lead in this area and I'm delighted they have taken the time to be with us.

[The prepared statement of Senator Breaux follows:]

PREPARED STATEMENT OF SENATOR JOHN BREAUX

I thank the Chairman for calling this timely and interesting hearing on "Technology and Prescription Drug Safety" and I thank our witnesses for being here today.

Almost two years ago the Institute of Medicine released their report, *To Err is Human,* which caught the nation off-guard when it stated that up to 98,000 deaths occur each year due to medical errors. I was further alarmed to learn that close to 20,000 of these deaths are caused by preventable medication errors. During the course of today's hearing we will learn about the innovative ways that physicians, pharmacists and consumers are working to improve the efficiency of prescription drug delivery while reducing needless errors that cost both dollars and human lives.

Health care in the United States continues to make impressive progress even though Congress has thus far been unable to modernize the Medicare program. As we continue to consider reforming our national health insurance program we must work to develop a health care system that is flexible enough to incorporate cutting-edge technologies without over-burdening it with reams of regulations and micro-management.

I look forward to hearing from our witnesses today because our country's health care delivery system continues to be plagued by medical errors. Every year 770,000 people are injured or die in hospitals due to an adverse drug event—and that figure is for hospitals alone. As we will hear from Mr. Marty McKay, the president of the Louisiana Pharmacy Association, long-term care facilities are also rife with prescription errors and the number of adverse drug events that occur in the outpatient setting remains unknown, but is presumed significant.

Today we will hear that these problems have not gone unanswered. I look forward to hearing from our physician, pharmacist and consumer-oriented witnesses about the new technology that has begun to address this serious problem of prescribing errors. Thank you.

The CHAIRMAN. Thank you very much, John.

Neil, talk to us a bit about the robot and it's 100 percent accuracy. That is obviously a marvelous and important statement. But what is the risk of cross-contamination if drugs are dispensed through a single chamber, or how are they dispensed and ultimately arrive in this form?

Mr. REED. The very initial step is packaging. First let me lead you through the process of what takes place during the initial step of packaging the medication. We have two machines the overwrap machine and the bulk packager, medications that aren't bar coded from the drug manufacturer, we have to either place these in this type of envelope, called the overwrap, and they're easily opened by nursing. You just open them and then you have access to the medication.

Cross-contamination is very unlikely. During the packaging process the technician pulls up the drug on a data base that has the NDC number for every drug, matches that, packages it, and at that point quality standards per McKesson Automated Healthcare. I

might pull up a hundred tablets of Lanoxin, package those, and the tray that it sits on is cleaned, then I package the next item. There is very little possibility of cross-contamination.

After those are packaged with the bar code, they are placed into the robot. Currently the robot we have stores about 4,500 medications, about the top 350 items we use in the pharmacy. The process begins driven by the pharmacist putting the medication order in. That electronically is fed over to the robot.

The robot we have is eight-sided. It has a stationary mechanical arm with a bar code reader. Of course, in the data base, it has memorized the position of every item inside the octagon cell. Then it goes to each rod where these are stored. You can see the little hole there. These hang on a rod. The mechanical bar code reader comes out, reads the bar code three times, or scans it three times.

So what the robot actually does, pick the bar code. It doesn't pick the med. Again, the error could take place if we, as the humans on either the setup side or the side to the patient, are incorrect. But the robot has not picked anything wrong. Every day we do a 5-percent quality check, just to ensure that.

The CHAIRMAN. You mentioned in your testimony the need for standardization of bar code technology. Would current software programs be capable or compatible for this use? Or are you talking about national pharmaceutical companies not bar coding?

Mr. REED. All of us know you can bar code a small package, but many medications that are unit dosed, are not bar coded. Having bar coding placed on medications would allow facilities that don't necessarily have a robot to pick the med by bar code to still utilize the bar code technology this would allow a safety check right before it's administered to the patient.

Right before I came out, I looked at our refrigerator and the medications are stored in there. About every other medication had a bar code on it. A lot of them don't have any. There just needs to be an effort put forward to drug manufacturers and pharmaceutical representatives, such as myself, to somehow come up with standardization on a unit dose package for bar coding.

Senator BREAUX. Are you talking about bar coding it on the medication itself, on the package of medication?

Mr. REED. Typically in pharmacies, everything is unit dose. So one medication is in its own package. Right now, a lot of those don't have bar codes on it. Everything we use, we have to package onsite and bar code it ourselves.

The CHAIRMAN. So that the robot, for purposes of——

Mr. REED. Can read that.

The CHAIRMAN. It's for the robot's access in reading that?

Mr. REED. That's correct.

The CHAIRMAN. Thank you all very much for your testimony this afternoon. We appreciate your presence and your willingness to come and provide us with your expertise.

Mr. REED. Thank you.

The CHAIRMAN. Thank you all.

Let me call up our second panel. Dr. Bates, we understand your presence here is time-sensitive?

Dr. Bates. That's correct.

The CHAIRMAN. All right.

Dr. Bates. But we're doing fine.

The CHAIRMAN. Let me introduce to the committee Dr. David Bates, Chief of the Division of General Internal Medicine at Brigham & Women's Hospital; Medical Director of Clinical and Quality Analysis, Partners HealthCare System; and Associate Professor of Medicine, Harvard Medical School.

Dr. Bates, welcome to the committee.

STATEMENT OF DAVID W. BATES, M.D., CHIEF, DIVISION OF GENERAL INTERNAL MEDICINE, BRIGHAM & WOMEN'S HOSPITAL; MEDICAL DIRECTOR OF CLINICAL AND QUALITY ANALYSIS, PARTNERS HEALTHCARE SYSTEM; AND ASSOCIATE PROFESSOR OF MEDICINE, HARVARD MEDICAL SCHOOL; APPEARING ON BEHALF OF THE AMERICAN INFORMATICS ASSOCIATION

Dr. BATES. Thank you very much for the invitation to speak with you today, and thanks in particular to Chairman Craig and Senator Breaux and members of the committee.

I have been asked to discuss the role of handheld devices in improving the safety of prescription drug prescribing. I am speaking on behalf of the American Medical Informatics Association. I am an elected member of the American College of Medical Informatics.

I have spent much of the last 7 years doing research on the magnitude of the problem of prescribing errors and on the impact of computerization of prescribing to prevent those errors and the associated injuries. Much of this research has been sponsored by the Agency for Healthcare Research and Quality, or AHRQ. I am also a member of the board of the Institute for Safe Medication Practices, which has prepared a white paper on this topic, and I have brought that with me today. I have left copies outside.

Errors in prescribing are a major health care problem and can often result in injuries and even death. This is a particularly important problem in older patients, who take more drugs, have more illnesses, and are thus more likely to experience problems with their medications than younger patients. In an AHRQ-sponsored study we did in hospitalized patients, there were 6.5 adverse drug events for every 100 admissions, among which 28 percent were preventable. Prescribing errors caused most preventable ADEs.

Computerization of prescribing has major benefits. In one study, we found that computerizing prescribing on desktop computers with even simple decision support reduced the serious medication error rate by 55 percent. In another study, we found that computerization of prescribing on desktops with more advanced technology reduced the overall medication error rate by more than 80 percent.

As several people have pointed out, compared to data about inpatients, we have much less information about the frequency of medication errors and adverse drug events outside hospitals, where handheld devices are likely to see their greatest use, at least at first. However, the available data suggest that such problems are frequent in this setting as well.

Computerization of outpatient prescribing can occur via handhelds or desktop technology. The desktop approach is now more prevalent, although this may change, and many companies

now are building applications that will allow electronic prescribing via multiple platforms.

Handheld devices represent an exciting development in information technology and health care. Because of their small size, they can be taken anywhere, and providers are using them enthusiastically. I have mine with me today. One way that they can be used is to hold information—for example, information about drugs. However, stand-alone applications are limited. To have a major impact on errors, it is essential to computerize the entire prescribing system, and handhelds can make this possible. A number of companies have developed applications that allow physicians to write prescriptions electronically using handheld devices.

This approach eliminates the problem of handwriting, which has accounted for about 10 percent of errors in inpatient studies. The devices can display ranges of doses and require that all prescriptions include a dose, route and frequency. No published studies to date that I'm aware of address the impact of prescribing using a handheld on medication errors or adverse drug events.

However, based on inpatient experiences, such devices will have a much greater impact on prescribing errors if patient-specific information, such as the patient's age, allergies, other medications, insurer and medical conditions, are available to the device. Handheld devices can use wireless, infrared or direct electronic links to communicate with the health care organization's applications. Electronic prescriptions can also be transmitted to pharmacies.

This is technically possible today, though it must clearly be done in ways that protect consumers' privacy and confidentiality. If patient-specific information is available, the device can improve safety by doing things such as suggesting a dose appropriate for the patient's age and kidney function, and checking for allergies. Drug costs can also be substantially reduced because the prescriptions can be compared to the formulary of the patient's insurer. Most of the applications available today provide some but not all of these features. It is challenging to do all the computing that's required on a handheld device.

In the long run, I think handheld devices will represent an extremely valuable adjunct to information systems, but their potential will depend on having effective links to key data. In the short run, handheld devices represent one option for computerizing prescribing and are especially attractive for physicians who are using only paper prescriptions, which are the vast majority of physicians in America.

My guess, based on the inpatient experience with computerization of prescribing, is that devices that have minimal patient information will reduce medication error rates by up to 50 percent, but they will have only a small impact on the adverse drug event or injury rate. To affect the injury rate, wireless or other types of links which bring patient information to the point of care are essential.

To summarize, computerization of prescribing is a very important goal. However, computerization is going to be most beneficial only if sophisticated decision support is provided. This will happen faster if health care organizations have financial incentives to

adopt these technologies, like those proposed in legislation announced today by Senators Graham and Snowe.

More research on the actual impact of these devices is needed. If computerization of prescribing can be accomplished, patients will be safer, and our health care costs will be substantially reduced.

Once again, thank you very much for having me here today, and I would be happy to take questions.

[The prepared statement of Dr. Bates follows:]

Senate Aging Committee Testimony
David W. Bates, MD, MSc
Chief, Division of General Internal Medicine
Brigham & Women's Hospital
Medical Director of Clinical and Quality Analysis, Partners HealthCare System
Associate Professor of Medicine, Harvard Medical School

Thank you very much for the invitation to speak with you this morning. I have been asked to discuss the role of handheld devices in improving the safety of prescription drug prescribing. I am speaking on behalf of the American Medical Informatics Association; I am an elected member of the American College of Medical Informatics. I have spent much of the last 7 years doing research on the magnitude of the problem of prescribing errors and on the impact of computerization of prescribing to prevent those errors and the associated injuries. Much of this research has been sponsored by the Agency for Healthcare Research and Quality, or AHRQ. I am also a member of the board of the Institute for Safe Medication Practices, which has prepared a white paper on this topic, which I have brought with me today.

Errors in prescribing are a major healthcare problem, and can often result in injuries and even death. This is a particularly important problem in older patients, who take more drugs, have more illnesses, and are thus more likely to experience problems with their medications than younger patients. In an AHRQ sponsored study we did in hospitalized patients, there were 6.5 adverse drug events or injuries due to drugs per 100 admissions, among which 28% were preventable. Prescribing errors caused most preventable ADEs.

Computerization of prescribing has major benefits. In one study, we found that that computerizing prescribing on desktop computers with even simple decision support reduced the serious medication error rate by 55%. In another, we found that computerization of prescribing on desktops with more advanced technology reduced the overall medication error rate by more than 80%.

Compared to data about inpatients, we have much less information about the frequency of medication errors and adverse drug events outside hospitals, where handheld devices are likely to see their greatest use, at least at first. However, the available data suggest that such problems are frequent in this setting as well.

Computerization of outpatient prescribing can occur via handhelds or desktop technology. The desktop approach is now more prevalent, although this may change, and many companies now are building applications that will allow electronic prescribing via multiple platforms.

Handheld devices represent an exciting development in information technology and healthcare. Because of their small size, they can be taken anywhere and providers are using them enthusiastically. One way that they can be used is to hold information, for example information about drugs.

However, stand-alone applications are limited: to have a major impact on errors it is essential to computerize the entire prescribing process, and handhelds can make this possible. A number of

companies have developed applications that allow physicians to write prescriptions electronically using handheld devices.

This approach eliminates the problem of hand-writing, which has accounted for about 10% of errors in inpatient studies. The devices can display ranges of doses, and require that all prescriptions include a dose, route and frequency. No published studies to date that I am aware of address the impact of prescribing using a handheld on medication errors or adverse drug events.

However, based on inpatient experiences, such devices will have a much greater impact on prescribing errors if patient-specific information such as the patient's age, allergies, other medications, insurer and medical conditions are available to the device. Hand-held devices can use wireless, infrared or direct electronic links to communicate with the health care organization's applications. Electronic prescriptions can also be transmitted to pharmacies.

This is technically possible today, though it must clearly be done in ways that protect consumers' privacy and confidentiality. If patient-specific information is available, the device can improve safety by doing things such as suggesting a dose appropriate for the patient's age and kidney function, and checking for allergies. Drug costs can also be substantially reduced because the prescription can be compared to the formulary of the patient's insurer. Most of the applications available today provide some but not all of these features; it is challenging to do all the computing required on a handheld device.

In the long run, I think hand-held devices will represent an extremely valuable adjunct to information systems, but their potential will depend on having effective links to key data. In the short run, hand-held devices represent one option for computerizing prescribing and are especially attractive for physicians who are currently only using paper prescriptions, which are the vast majority of physicians in America. My guess based on the inpatient experience with computerizing of prescribing is that devices that have minimal patient information will reduce medication error rates by up to 50%, but will have only a small impact on the adverse drug event or injury rate. To affect the injury rate, wireless or other types of links, which bring patient information to the point of care, are essential.

To summarize, computerization of prescribing is a very important goal. However, computerization will be most beneficial only if sophisticated decision support is provided. More research on the actual impact of these devices is needed. If computerization of prescribing can be accomplished, patients will be safer, and our healthcare costs will also be substantially reduced.

Once again, thanks very much for inviting me here today.

Additional Testimony (written only):

Based in part on the data I presented regarding inpatients, a coalition of employers called the Leapfrog Group sponsored by the Business Roundtable and including GM and GE and representing 24 million Americans, has identified computerization of prescribing in hospitalized patients as one of the three changes in care that would most improve the quality of healthcare in America. They estimate that this would prevent 522,000 serious medication errors in hospitals per year, and have challenged healthcare organizations to adopt computerized prescribing in hospitals. In addition, California has enacted a law mandating computerization of prescribing or other error reduction technology in all non-rural hospitals by 2005.

In one outpatient study, 31.5% of patients recently discharged from a hospital had an adverse drug event, and in another they occurred in 5% of all patients per year.

One of several popular stand-alone drug databases is called qRx, made by ePocrates, which can be downloaded free from the Web. In a survey we did of 870 users, 60% reported using it more than twice daily, 90% said they could find the information they needed in less than a minute, it answered more than three quarters of their questions for 88% of users, and 46% said it changed more than 3 drug decisions per week.

Most devices use standard technology such as Casio's Casseiopeia, the Hewlett-Packard Jornada, or 3Com's Palm Pilot. The typical operating system is Windows CE or Palm OS. The devices are easy to use and can be mastered in about a half-hour.

Electronic prescribing will also be most attractive to physicians when prescriptions can be electronically communicated to pharmacies because it will reduce their workload; for this to occur, legislative reform is needed in many states.

Major research needs in general in this area are support for studies on the impact of computerization of prescribing in general and on prescribing on handheld devices in particular on medication error rates, and on the general problem of medication errors and adverse drug events outside the hospital.

The CHAIRMAN. Thank you very much.

Now let me turn to my colleague, Senator Breaux, for the introduction of our next panelist.

Senator BREAUX. Thank you very much.

Just very briefly, I am delighted to have Marty McKay as our next witness, from LeCompte, LA. I think Marty wanted me to introduce him because the chairman wasn't sure how to pronounce LeCompte. [Laughter.]

The CHAIRMAN. I was struggling with it, yes. I ran it through a couple of times, John.

Senator BREAUX. But we are delighted he is here. He is a registered pharmacist who has been practicing in both retail and long-term areas of medical practice. He's been doing that for 27 years. He has worked in this area of pharmacy automation and we're delighted that he's going to present some things that I have been exposed to, about trying to simplify the way these prescriptions are handled and how medicine is distributed.

He serves also as Chief Pharmacist for Pearson Medical Technologies, which is a company in Louisiana that I have been fascinated about in what they have been able to do, which sort of coincides with everything else that's happening out there. Marty, we're glad to have you.

STATEMENT OF MARTY R. MCKAY, PARTNER/MANAGER OF PEARSON DRUGS; PRESIDENT OF THE LOUISIANA PHARMACIST ASSOCIATION; AND CHIEF PHARMACIST, PEARSON MEDICAL TECHNOLOGY, LeCOMPTE, LA

Mr. MCKAY. Thank you very much for this opportunity to speak with you today.

I would like to discuss the tremendous opportunities we have today for using technology to prevent medication errors and save lives, how the pharmacist should play a critical role in implementing that technology, and how Federal legislation and regulation should enable the use and the development of that technology and not restrict it.

In addition to being a member of the Louisiana State Board of Pharmacy and the current president of the Louisiana Pharmacists Association, I have been a practicing pharmacists for over 26 years, and I also have been involved over the last 15 years in research on using technology to prevent medication errors and enhance patient safety.

As you know, the IOM report released in November 1999 concluded that up to 98,000 people die each year in hospitals due to medical errors. This study estimates that the increased hospital cost alone of preventable adverse drug events in hospitals is over $2 billion per year. I believe that this study may only be the tip of the iceberg. A recent study estimates that drug misuse costs the economy more than $177 billion each year, and the estimated number of patient deaths due to drug misuse, both inside and outside hospitals, has increased from 198,000 in 1995 to 218,000 in the year 2000.

Senator BREAUX. If I may interrupt you, that's legal drug use, right, or is that total for illegal as well?

Mr. MCKAY. That may also be illegal drug use in that report. That's quite a substantial number when you look at it.

Senator BREAUX. Thank you.

Mr. MCKAY. In considering long-term care, there are about 1.6 million patients in more than 17,000 nursing homes and other long-term care facilities in the United States. A recent study concluded that about 350,000 adverse drug events occur in nursing homes annually, of which about 20,000 are fatal or life-threatening.

The major reason for these errors is that many hospitals and most nursing homes and other health care facilities use manual medication, prescribing and medical charting systems. Most medications are delivered without any automated verification technology, such as bar code readers. Once a prescription drug leaves a pharmacy, there is more sophisticated technology used to determine if you are charged the right price for a gallon of milk at a super-market than is typically used to make sure that a patient is getting the right dose of a potentially fatal drug.

Please look at Exhibit A, which is the one there nearest the front. You will see a typical patient medication administration record called an MAR. It is used by most nursing homes in the United States. The MAR shows the medications prescribed for the patient. Typically, on a routine med pass, the nurse must manually find these medications on a medication card holding the medications for 25 or more patients. The nurse must then pick out the right medication, administer these to a patient, manually chart this administration, and then move on to the next patient, all within a one to two hour window.

Changes to the MAR are typically handwritten by the nurse pursuant to the doctor's instructions and are communicated to the pharmacy by the nurse. Any discontinued medications are often then just destroyed. A 1994 study estimated that 6.7 percent of all medications dispensed in long-term care is destroyed.

I believe that one important way to help prevent adverse drug events is to create medication delivery systems and procedures that allow the pharmacist to do more than just count pills. A 1999 study reported that including the pharmacist on medical rounds with the physician reduced the errors related to medication ordering by 66 percent. The pharmacist should serve as the gatekeeper of a patient's entire drug regimen and, through technology and appropriate reimbursement mechanisms, be allowed to more actively participate in prescribing and monitoring a patient's drug therapy.

Now look at Exhibit B, which is the second one. This is an illustration of a computerized MAR which shows the same information as the handwritten MAR, but it is also available to the pharmacist electronically. This smart MAR shows the medication to be administered to the patient, which medications are due for a patient on any given med pass, and charts the administration. This information is kept in real time and can be electronically linked to an automated medication delivery device that uses bar coding or similar technology to verify that the right drug is given to the right patient, at the right time, and the right dose.

Comparing the two different medication delivery systems described in Exhibits A and B, think about which system you would want the nurse administering medication to your mother to use.

I strongly encourage you to enact legislation which would help prevent regulatory road blocks to implementing today's life-saving technology, and establish new and innovative reimbursement mechanisms that will promote investment in information technology and automated delivery systems. Federal regulations like HIPAA should not prevent or discourage the pharmacist's use of the new automated technology. An example of a progressive step is the Drug Enforcement Agency, which just released for comment its recommendation to allow controlled drugs to be stored and delivered from automated dispensing devices, located in long-term care facilities, but controlled by pharmacists.

Reimbursement policies and mechanisms should encourage investment in sophisticated automation and information technology. The States and Federal Government have the most to gain financially from decreasing medication errors in our medical institutions across the Nation. Reimbursement mechanisms should reflect these savings and help pay the up-front cost of implementing these systems to help save patients' lives and save the billions of dollars in unnecessary cost.

Thank you for this opportunity to testify, and I would be happy to answer any questions you might have.

[The prepared statement of Mr. McKay follows:]

Senate Special Committee on Aging

Hearing Date: May 3, 2001

Written Testimony Submitted by Marty R. McKay RPh

Partner/Manager Pearson Drugs, LeCompte, LA
President, Louisiana Pharmacist Association
Member, Louisiana Board of Pharmacy
Chief Pharmacist, Pearson Medical Technologies, LLC

Senate Special Committee on Aging
Hearing Date: May 3, 2001

Written Testimony Submitted by Marty R. McKay Rph
Chief Pharmacist, Pearson Drugs and Pearson Medical Technologies, LLC

Thank you very much for this opportunity to speak with you today. I would like to discuss the tremendous opportunity we have today for using technology to prevent medication errors and save lives, how the pharmacist should play a critical role in implementing that technology in our health care system, and how federal legislation and regulation can enable the development of that technology and not restrict it.

In addition to being a member of the Louisiana State Board of Pharmacy and the current President of the Louisiana Pharmacists Association, I have been a practicing pharmacist for over 26 years. I have also been involved over the last 15 years in research on using technology to prevent medication errors and enhance patient safety, especially in the nursing home setting. As a practicing pharmacist, primarily in the retail and nursing home areas, I see the deficiencies and dangers of current medication delivery systems on a daily basis. But I also see the opportunities that technology holds for preventing a large percentage of these errors.

Medication error is a huge problem in the United States today, causing patient deaths and injury and costing the United States billions of dollars each year.

As you know, the Institute of Medicine (IOM) released a report in November 1999, which concluded that anywhere from 44,000 to 98,000 deaths occur each year in hospitals due to medical errors. This study estimates that the increased hospital cost alone of preventable adverse drug events in hospitals is over $2 Billion per year. I believe that this study may only reveal the tip of the iceberg. This figure probably greatly underestimates the cost because it does not include indirect costs (such as loss of productivity of the patient, increased insurance costs, or long-term increased medical costs of the patient). Also, adverse drug events occur in places other than hospitals, such as nursing homes, retail pharmacies, home health care, prisons, outpatient clinics, and doctors' offices. A study released in the March/April Journal of the American Pharmaceutical Association estimates that drug misuse costs the economy more than $177 Billion each year and the estimated number of patient deaths due to drug misuse both in and outside hospitals has increased from 198,000 in 1995 to 218,000 in 2000.

To illustrate how the scope of this problem extends beyond hospitals, please consider nursing homes. There are about 1.6 million patients in the more than 17,000 nursing homes and other long-term care facilities in the United States. Patients in long-term care facilities routinely receive many doses of many different medications each day and nursing homes have fewer nurses per patient than do hospitals. Also, nursing homes are staffed with lesser-trained nurses than are hospitals. Just from these basic facts, you can see how the problem of medication errors in long-term care facilities could be significant.

Although there has been relatively little research on medication errors in nursing homes, a recent study (Gurwitz, et al) reported in the August 1, 2001 issue of the *American Journal of Medicine*, concluded that about 350,000 adverse drug events occur in nursing homes annually, of which 20,000 are fatal or life-threatening. Most of the preventable errors found in this study occurred in the ordering and monitoring stages of care. The pharmacist and technology can help prevent many of these errors in hospitals, nursing homes, and all other areas of patient care in a cost-effective manner.

A major reason for these errors is that many hospitals, and most nursing homes, and other in-patient and outpatient health care facilities use simple, pen-and-paper medication prescribing and medical charting systems. Most medications are manually delivered without any automated verification technology such as bar code readers. **Once a prescription drug leaves a pharmacy, there is more sophisticated technology used to determine if you are charged the right price for a gallon of milk at a supermarket than is typically used to make sure that a patient is getting the right dose of a potentially fatal drug.**

As an example of this manual system, please look at Exhibit A attached to my written materials. You will see a typical patient medication administration record (called a "MAR") used, in one form or another, by most nursing homes in the United States. Notice that although most of the medications to be given to this patient are printed out by a computer, the remainder of the chart is hand-written by the nurse. Typically, the nurse must manually find these medications which are stored on a medication cart along with the medications for anywhere from 25 to 50 patients. The nurse must then pick out the right number of doses of these medications, administer these drugs to the patient, manually chart this administration, and then move on to the next patient. The nurse must usually complete her med pass for 25 to 50 patients within a 1 to 2 hour window. Obviously there is great opportunity for an error to occur in this entirely manual and hand-written process.

Please also note that some medications have been discontinued and new medications have been added by hand written instructions. These changes occurred because the doctor changed the patent's medication. Such changes are typically hand-written by the nurse pursuant to the doctor's instruction and are telephoned to the pharmacy by the nurse. Not only are the discontinued medications often then destroyed (one 1994 study estimates that 6.7% of all medications dispensed to long-term care facilities are destroyed), this process is rife with the opportunity for error. Although all pharmacists use sophisticated computer software to check for drug interactions, drug allergies, and proper drug utilization, all that technology may be meaningless if the nurse sends the pharmacy the wrong information or if the pharmacist does not have access to critical patient information. Often, by the time the mistake is caught, it is too late and a patient has been harmed or even died. This problem will only worsen, as the shortage of nurses and pharmacists becomes more acute (it is estimated that the United States currently has a shortage of 12,000 pharmacists and 20% of nurses plan to leave the field within the next 5 years).

The Pharmacist should play a key role in preventing adverse drug events.

Probably the single most important way to help prevent adverse drug events is to create medication delivery systems and procedures that allow the pharmacist to do more than count and fill prescriptions. No other health care professional has the extensive training and knowledge about prescription drugs that a pharmacist has. In fact, a 1999 study reported that including the pharmacist on medical rounds with a physician reduced the errors related to medication ordering by 66% (IOM Fact Sheet, *Medication Errors: The Scope of the Problem*). However, the pharmacist is too often used just to fill a prescription and to provide limited counseling to a nurse, physician or a patient. A pharmacist should serve as the gatekeeper of a patent's entire drug regimen and, through technology and appropriate reimbursement mechanisms, be allowed to more actively participate in prescribing and monitoring a patent's drug therapy. The pharmacist, already the front-line of defense for preventing medication errors, should be allowed to expand his role through the use of more sophisticated information technologies and automation. So even though the pharmacist cannot make rounds with the physician, he can still help reduce medication errors just as if he did.

As an example, please refer to Exhibit B attached to my written statement. This is an illustration of a computerized MAR, which Pearson Medical Technologies has been developing over the last several years. This MAR shows the same information as the handwritten MAR, but it is also available to the pharmacist electronically. This MAR shows the medications to be administered to the patient, but the computer automatically "knows" which medications are due for any given med pass and the correct number of doses of each medication to be administered. As the nurse administers the medication, the software charts the administration. This information is kept in real-time and can be electronically linked to an automated medication delivery device. This software and the automated delivery device will use bar coding or similar technology to verify that the right drug is given to the right patient at the right time in the right dose. New medication orders are electronically entered by the physician and verified as appropriate for that patient by the pharmacist who has access to all pertinent patient information. This type of medication delivery system will assist the nurse, enhance patient safety and care, and help prevent medication errors. Although this particular software is about one (1) year away from being available on the market, there are numerous automated devices and computer software already developed for retail pharmacies, hospitals, nursing homes, home health care, and doctors offices and clinics that can help prevent errors.

Comparing the two different medication delivery systems described in Exhibits A and B, think about which system you would want the nurse administering medications to your mother to use.

Congress can help prevent roadblocks to implementing new error-preventing technology.

As this Congress considers adopting a prescription drug benefit plan, regardless of the size or scope of such a plan, I strongly encourage you to enact legislation which would (1) help prevent regulatory roadblocks to implementing today's life-saving technology and (2) establish new and innovative reimbursement mechanisms that will promote investment in information technology and automated delivery systems. This will save patient lives and save this country billions of dollars in unnecessary costs.

All states regulate the dispensing of prescription drugs by pharmacists. Some states rules and regulations have not been updated to allow a pharmacist to fully utilize the automation technology that is currently available. In Louisiana, the State Board of Pharmacy has recently completely revised its regulations to allow pharmacist-controlled medication delivery systems to be used outside the four walls of a traditional pharmacy provided adequate safeguards are in place. Some states have not revised their rules to allow the use of such technology. Federal regulations, like HIPAA, should not prevent or discourage states from enacting modern pharmacy automation regulations that enable the safe use of the new automation technology so a pharmacist can help prevent medication errors. An example of such progressive steps is the Drug Enforcement Agency, which just released for comment its recommendation to allow controlled drugs to be stored and delivered from automated dispensing devices located in long-term care facilities, but controlled by the pharmacist.

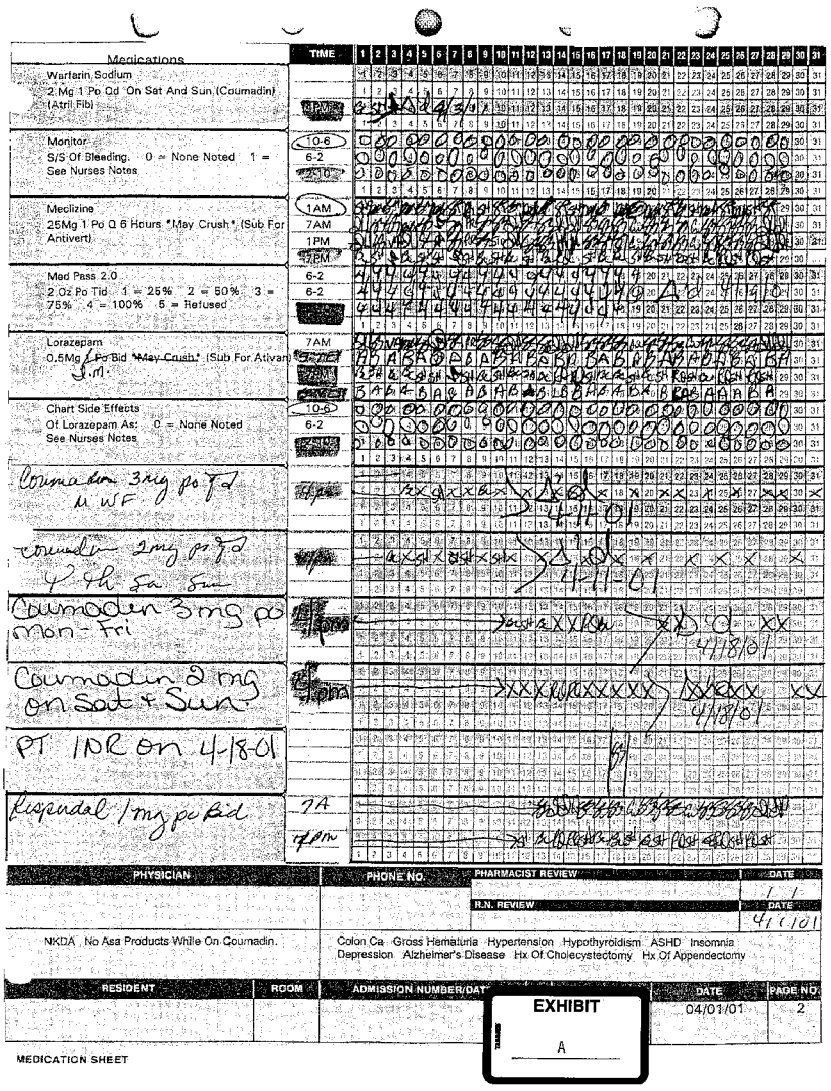
Just as important in preventing any regulatory roadblocks, reimbursement policies and mechanisms should encourage investment in sophisticated automation and information technology. The state and federal governments are the primary payors of the cost of health care in the United States through Medicaid, Medicare, VA, and military medical programs. As such, the federal and state governments have the most to gain financially from decreasing medication errors in our medical institutions across the nation. Preventing these medication errors would not only prevent patient injury and deaths, but would save billions of dollars in health care costs each year. Since the major benefactor of these savings would be state and federal governments, reimbursement mechanisms under Medicare and Medicaid should help pay the up front cost of implementing these systems to help save patient lives and save the billions of dollars in unnecessary costs caused by medication errors. The Veterans Administration has already begun this process in its facilities and implementation of such advanced technology has reduced the medication error in one facility by 70% according to a report by the Agency for Healthcare Research and Quality (IOM Fact Sheet, *Medication Errors: The Scope of the Problem*).

I agree with the conclusions of the report of the Institute of Medicine (IOM) Committee on the Quality of Health Care in America, titled, *Crossing the Quality Chasm: A New Health System for the 21st Century*, which recommends that current payment methods be examined to remove barriers to innovation and quality, and to test options to better align payment methods with quality goals. For instance, a pharmacist who implements and is responsible for monitoring a patent's drug therapy using an information system and automated medication delivery system

should be compensated for his cognitive services, not just receive a fee for dispensing medications. This compensation could be a fee for service, a flat rate for each patient for which the pharmacist is responsible (capitation), an amount based on the estimated savings resulting from the prevention of medication errors, or a combination of those methods. Such new payment mechanisms would encourage the use of error-preventing automation and information technology, prevent thousands of needless patient deaths and injury, reduce direct medical costs for state and federal governments, and reduce indirect costs to the entire economy of this country.

Conclusion

The problem of medication errors in our health system today is huge. Patients are dying needlessly. The costs created by preventable patient injury and deaths, both direct unnecessary medical costs and indirect costs suffered by the nation as a whole are mind-boggling. A major cause of the preventable errors is the use of outdated systems for prescribing, charting and monitoring a patent's drug therapy. The pharmacists of this country are in the best position to help reduce medication errors and serve as the nation's gatekeeper of prescription drug utilization and monitoring. To fulfill this role, the pharmacist must utilize modern automation and information technology in new and innovative ways. To accomplish this, regulations must not limit a pharmacist to practicing his craft inside the four walls of his pharmacy, but enable him to use technology to apply his skills to prevent medication errors. New and innovative payment incentives must be adopted to encourage the development, implementation and use of this new technology.



Medications	TIME
Warfarin Sodium 2 Mg 1 Po Qd On Sat And Sun (Coumadin) (Atril Fib)	5 PM
Monitor S/S Of Bleeding. 0 = None Noted 1 = See Nurses Notes	10-6 / 6-2 / 2-10
Meclizine 25Mg 1 Po Q 6 Hours *May Crush* (Sub For Antivert)	1AM / 7AM / 1PM / 7PM
Med Pass 2.0 2 Oz Po Tid 1 = 25% 2 = 50% 3 = 75% 4 = 100% 5 = Refused	6-2 / 6-2 / [redacted]
Lorazepam 0.5Mg Po Bid ~~*May Crush*~~ (Sub For Ativan) S.L.	7AM / 7PM / [redacted]
Chart Side Effects Of Lorazepam As: 0 = None Noted See Nurses Notes	10-6 / 6-2 / 2-10
Coumadin 3mg po Tu Th Sa	5pm
Coumadin 2mg po M W F Su	5pm
Coumadin 3mg po Mon-Fri	5pm
Coumadin 2 mg on Sat + Sun	5pm
PT INR on 4-18-01	
Risperdal 1mg po Bid	7A / 7pm

PHYSICIAN	PHONE NO.	PHARMACIST REVIEW	DATE
			/ /
		R.N. REVIEW	DATE 4/1/01

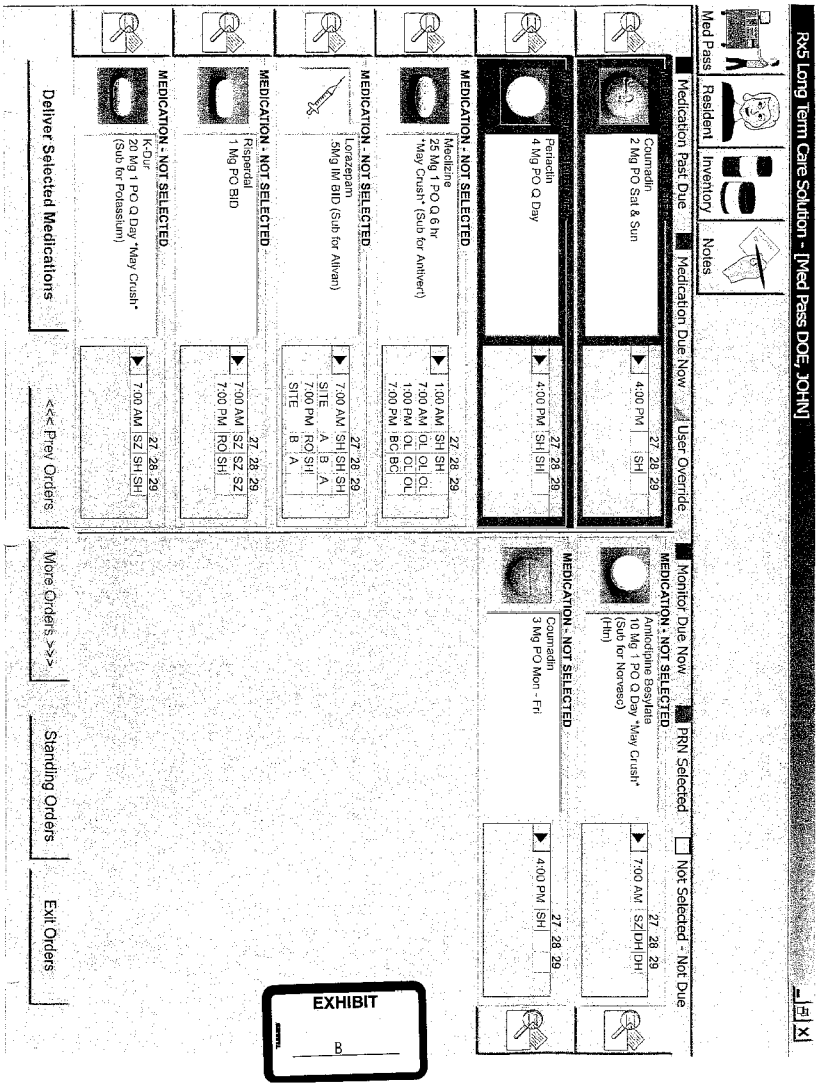
NKDA , No Asa Products While On Coumadin.

Colon Ca Gross Hematuria Hypertension Hypothyroidism ASHD Insomnia Depression Alzheimer's Disease Hx Of Cholecystectomy Hx Of Appendectomy

RESIDENT	ROOM	ADMISSION NUMBER/DAT	DATE	PAGE NO.
			04/01/01	2

EXHIBIT A

MEDICATION SHEET


Rx5 Long Term Care Solution - [Med Pass DOE, JOHN]
Med Pass
Resident
Inventory
Notes
Medication Past Due
Medication Due Now
User Override
Monitor Due Now
PRN Selected
Not Selected - Not Due
Coumadin
2 Mg PO Sat & Sun
4:00 PM
Periactin
4 Mg PO Q Day
MEDICATION - NOT SELECTED
Amlodipine Besylate
10 Mg 1 PO Q Day *May Crush*
(Sub for Norvasc)
7:00 AM
Coumadin
3 Mg PO Mon - Fri
MEDICATION - NOT SELECTED
Medizine
25 Mg 1 PO Q 6 hr
May Crush (Sub for Antivert)
1:00 AM
7:00 AM
1:00 PM
7:00 PM
MEDICATION - NOT SELECTED
Lorazepam
.5Mg IM BID (Sub for Ativan)
MEDICATION - NOT SELECTED
Risperdal
1 Mg PO BID
7:00 AM
7:00 PM
MEDICATION - NOT SELECTED
K-Dur
20 Mg 1 PO Q Day *May Crush*
(Sub for Potassium)
Deliver Selected Medications
<<< Prev Orders
More Orders >>>
Standing Orders
Exit Orders
EXHIBIT
B

MARTY R. McKAY, Rph
P.O. Box 369
LeCompte, Louisiana 71346
Phone: 318-776-5646
Fax: 318-776-9212
E-Mail: mmckay@pearsonmedical.com

BIOGRAPHICAL INFORMATION

MARTY is a Registered Pharmacist practicing primarily in retail and long-term pharmacy. He is Partner and Manager of Pearson Drugs, LeCompte, Louisiana, where he has practiced for 27 years.

MARTY graduated from University of Louisiana at Monroe with B.S. in Pharmacy in 1974. Marty was legislative chairman (1996-1997), and a member of the Board of Directors (1996-2000) and is currently President of the Louisiana Pharmacist Association (2000-2001). In addition he is a member of the Louisiana State Board of Pharmacy and Louisiana Medicaid Advisory Committee of the Louisiana Department of Health and Hospitals. He currently holds membership in the American Pharmaceutical Association and the American Society of Consultant Pharmacist. He is a member of the LeCompte Rotary Club and served as its President (1993-1994).

Marty has also worked with pharmacy automation and information system technology as Chief Pharmacist for Pearson Medical Technologies, LLC.

The CHAIRMAN. Thank you, Mr. McKay. I appreciate your testimony.

Dr. Bates, what do you mean by sophisticated support for computerization, and by whom?

Dr. BATES. What I mean is decisions support that is smart, that, for example, calculates the patient's kidney function. To do that involves knowing the patient's age, their gender, their last serum creatinine level, which tells you how good their kidney function is. If you do that, you can adjust the dose of a medication so that it's appropriate for patients. So that's an example of the sort of thing that I mean.

The computer can do all of that in the background, and then suggest to the clinician an appropriate dose. If that happens, we have shown that it is substantially more likely that the doctor will choose the right dose for that patient.

The CHAIRMAN. Are there software programs available today that do that kind of interfacing, with constant input of the patient's condition and, therefore, a reaction to the medication that is currently being delivered?

Dr. BATES. Yes, there are.

The CHAIRMAN. Do you know what percentage of physicians currently use a form of computerized prescribing?

Dr. BATES. Roughly 15 percent of hospitals have computerized prescribing applications in place. However, in most of those institutions, a minority of physicians actually use the applications. So it is hard to say exactly what the number is.

There are a relatively small number of institutions in which computerized prescribing is the rule. Our institution happens to be one of those.

On the outpatient side, it's been much harder to come up with good numbers. The best guesses are somewhere around the range of 5 percent.

The CHAIRMAN. Would you judge that, based on the current state of the technology, to be low?

Dr. BATES. Yes.

The CHAIRMAN. Mr. McKay, in your testimony you propose that new technology will free pharmacists to accompany physicians on medical rounds. In this time when the cost of health care continues to steadily rise, it is hard to financially justify paying pharmacists to accompany physicians on medical rounds.

What service can a pharmacist provide on medical rounds that some of the new technologies, such as the handheld device we heard talked about today, cannot? That would be one question. And does it justify the cost to the patient when using these new technologies to ensure safety would be far less expensive and, therefore, more accurate?

Mr. MCKAY. Well, I think what I wanted to point out with that 66 percent figure was the fact that having a pharmacist do that prevented these medication errors. Now, technology can also do that. But you have to remember that the only place that that technology has been used so far has been in the hospitals. Many of your prescriptions now come into a pharmacy, a retail pharmacy, where there may be multiple doctors seeing a patient, so one doctor may not know what the other is prescribing.

My point that I want to make is that if we have the technology available in the retail or in the long-term care, where we can see everything that is happening to that patient from their drug information, and have other tools and information from that patient's chart in there, we can make an informed decision. So that if something occurred that maybe this physician didn't know, in relation to the other physician, then we can be a gatekeeper of that and prevent those medical errors.

Dr. BATES. May I also just comment briefly?

The CHAIRMAN. Yes.

Dr. BATES. That was a study that we did. The cost of the pharmacist per year is around $50,000, and we have shown that the pharmacist saved between $450–500,000 in terms of suggestions that they made and the interventions that were implemented.

That is something that can be done today. That was in an intensive care unit, so it is one specific setting. I don't think we could do that in all other settings. But within the intensive care unit, I think that can be justified by health care institutions around the country.

The CHAIRMAN. Gentlemen, thank you.

Let me turn to my colleague, Senator Breaux.

Senator BREAUX. Thank you, Mr. Chairman, and I thank the panel members.

This is fascinating information. I was looking at this *Time article* of April 23, about the problems out there with medical errors. They talked about a report out last week—and maybe this has already been mentioned—by the Federal Agency for HealthCare Research and Quality, that electronic prescriptions and monitoring could help eliminate many of the medication errors and other adverse drug events that kill or injury 770,000 people in hospitals each year. Mr. McKay, you were talking about the number of deaths.

Also, the article pointed out something that I find really fascinating. Each year, pharmacies make 150 million calls to doctors, to clarify confusing prescriptions, and they only write about 1 percent of their prescriptions electronically today.

A hundred and fifty million phone calls to find out what your handwriting was supposed to instruct me to do is incredible.

Mr. MCKAY. It's even greater than that, when you look at how many times we call a physician back daily, and many times the problem is it puts the patient at harm, also, because it may be 6 or 7 hours before he can even get his prescription because the doctor may be at the hospital or we may be unable to locate him. But there are many reasons we call back other than just not being able to read the prescription. So electronic prescribing is going to be great for pharmacies and it will take a lot of the risk out of health care.

Senator BREAUX. I'm looking at the two charts that you have here. The chart on the left, as I understand it, is a typical nursing home chart that's used, where the nurse makes the rounds delivering medicine to patients?

Mr. MCKAY. Correct.

Senator BREAUX. And all of that is entered by hand, I take it, and changes are made by hand?

Mr. MCKAY. All the changes are made by hand. Typically, at the first of the month it is printed out as accurate as possible. They go through and make any changes. But as the month unfolds, every time the doctor writes a new order or there's a change in the condition of the patient, then it is recorded on that chart and she must go through this over and over each time.

If you look at this particular chart up here, one of the things you notice is that they had several changes on one drug. Sometimes there's as many as two and three on one page. It's confusing for the nurse because, when she goes through here, she can easily make a mistake by using the wrong line to record the drug on and have the wrong dose.

Senator BREAUX. It looks like a very bad eye chart.

Mr. MCKAY. It's much worse than that, I can assure you.

Senator BREAUX. I remember talking to Mr. Pearson about being able to save medicine that is currently discarded when the prescription is changed.

Mr. MCKAY. That's correct.

Senator BREAUX. Tell me a little bit more about how that would work.

Mr. MCKAY. Well, one of the pieces of technology that we've been working on is a medicated delivery system that uses an MAR like this, and also has a mobile cart that goes up and down the hallway with the nurse as she administers the medication. What this does, no drug is actually dispensed to that patient until the time of use. So you don't have drugs that are being sent to the nursing home and then the order is changed and that drug is destroyed.

If you look at——

Senator BREAUX. On that point, if a person in a nursing home is on a particular prescription and used maybe only 25 of it, if the doctor then changes that prescription, is the other 75 percent sometimes just discarded?

Mr. MCKAY. In most cases, that's what happens. That drug is destroyed.

Senator BREAUX. That's a huge cost.

Mr. MCKAY. It's a huge amount of money.

Senator BREAUX. Would this type of delivery system be able to help reduce that?

Mr. MCKAY. With this type of delivery system, you wouldn't have any of that type of destruction. The only reason is if the drug was dispensed to that patient one dose and the patient refused it, or for some reason that patient didn't get that dose, you wouldn't have these large amounts of drugs given out to the patient and then destroyed because the doctor changed the order.

Senator BREAUX. Because the change order would be plugged into the delivery device instantaneously?

Mr. MCKAY. Immediately. In real time, it would be plugged in.

Senator BREAUX. That's a huge savings.

Is there anything that prevents this technology from being used? I mean, we're listening to this as Members of Congress. Do we have to pass a law that says use modern technology? Why aren't we doing this already? That stuff on the left, that's hieroglyphics.

The CHAIRMAN. And Dr. Bates was said there is only 15 percent application of the use of the technology.

Dr. BATES. I think the biggest barrier is that hospitals are in such bad financial positions right now. Two-thirds of the hospitals lost money last year. If you have to invest in a new computerized MAR, you might be charged half-a-million dollars. Hospitals are finding it hard to justify doing that right now.

Senator BREAUX. It would seem that the ultimate outcome of this is some real serious financial savings, actually, in eliminating errors, which are very costly. I mean, if you give the wrong medicine to a person who is a senior citizen on Medicare in a hospital, the cost of that one mistake would pay for a dozen of these machines.

Mr. MCKAY. Absolutely. I think you're correct in that analysis.

But one of the problems we have run into, especially in pharmacy, with the reduced reimbursements by third parties, including Medicaid, it is very difficult for a pharmacist to go out and purchase this type of technology and use it. It may save money, and it will save money in the long run. There's no doubt about it. But it's going to be difficult to get it used unless you find some method of reimbursement that will allow him to go out and purchase the technology.

Senator BREAUX. We need to take a look at that, because I think in the long term we would end up saving money by helping to reimburse for modern technology, whether it's yours or somebody else's. I think it would make a lot of sense.

It has been fascinating. I thank you very much.

Mr. MCKAY. Thank you.

The CHAIRMAN. Gentlemen, thank you very much. We appreciate your input and your involvement. This is extremely valuable information.

As I mentioned in my opening statement, as we move towards a prescription drug program for this country, and certainly for the Medicare recipients of this country, it is going to be important that we investigate this more thoroughly as it relates to the application and the cost and cost savings that can come by effective unit doses and their application.

Thank you very much. The committee will stand adjourned.

[Whereupon, at 4 p.m., the committee was adjourned.]