E-HEALTH AND CONSUMER EMPOWERMENT: HOW CONSUMERS CAN USE TECHNOLOGY TODAY AND IN THE FUTURE TO IMPROVE THEIR HEALTH

HEARING

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C O N T E N T S

E-HEALTH AND CONSUMER EMPOWERMENT: HOW CONSUMERS CAN USE TECHNOLOGY TODAY AND IN THE FUTURE TO IMPROVE THEIR HEALTH

MONDAY, JULY 23, 2001

U.S. SENATE,
SUBCOMMITTEE ON SCIENCE, TECHNOLOGY, & SPACE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Subcommittee met, pursuant to notice, at 1:05 p.m., in room SR–253, Russell Senate Office Building, Hon. Ron Wyden, Chairman of the Subcommittee, presiding.

OPENING STATEMENT OF HON. RON WYDEN, U.S. SENATOR FROM OREGON

Senator WYDEN. The Subcommittee will come to order, and I will have a short opening statement before I begin. I want to take this opportunity to say publicly how much I am looking forward to serving with Senator Allen on this Subcommittee. He has already shown, in a very short period of time, that he is going to make special efforts to address important technology issues.

In a sense, our States are similarly situated. Both Virginia and Oregon are very rural States where agriculture is, and will always be, extraordinarily important. In both States, there is a tremendous interest in technology. I think that our previously demonstrated interest in working together on other issues gives us an opportunity for a special alliance, and I very much look forward to the opportunity to serve with you, Senator Allen. I am going to make a short opening statement to begin with, but I especially want to welcome you and tell you how much I look forward to serving with you.

Senator ALLEN. Thank you, Senator Wyden. I appreciate it.

Senator WYDEN. When I served as codirector of the Oregon Gray Panthers, senior citizens often talked to me about their hope that our health care system could be made more user-friendly, convenient, and lower in cost. Even then, there was discussion about various exciting-sounding technology, such as smart cards, electronic medical records, and what seniors, the Gray Panthers described as, in their words, those "fancy gadgets". It seemed the day when seniors and other Americans would have great access to empowering technologies were just ahead.

Today's technologies offer an unprecedented opportunity to re-shape American health care, but in some respects the path to en-

hanced new health looks a little bit like a steeple chase. There are a fair number of obstacles in front of us. This Subcommittee is going to work aggressively, and on a bipartisan basis, to lower the hurdles that limit the expanded use of e-health in our health care system.

At the outset, I want to note that I believe that several of the problems blocking the increased use of e-health care are similar to the legal, regulatory, and cultural problems that challenge our health care system as a whole. That is why this Subcommittee has asked Dr. John Kenagy to testify here today. His work, based on the theory that disruptive innovation, which has formed so many other fields of our economy, ought to be extended to health care, looks like just the sort of jolt that is needed to secure the changes that seniors described to me in my Gray Panther days.

I believe that the vast majority of the obstacles to increased utilization of e-health can be achieved without enacting an avalanche of additional federal laws, but in some areas new legislation may, in fact, be needed to move this country forward.

One area that I believe ought to be examined is a requirement that all medical claims in the United States be submitted, captured, adjudicated, and paid using secure Internet technologies within 15 days. If it cannot be done within that time, the payer must notify the patient and the provider with a reason why.

Experts that I have consulted, such as medical economists and health information technology authority J.D. Kleinke suggest that such a requirement ought to be in place, certainly within 2 years, and that such a rule would make handling a claim fairly similar to ordering a book on Amazon.com.

I would like to note the Health Care Financing Administration, has made this a special priority and we are very pleased that the Director, Tom Scully, is here. The Health Care Financing Administration—known by its new name as the Centers for Medicare & Medicaid Services—has already begun to make significant headway in changing and improving the system for paying claims in this country.

American health care, which now chokes on administrative paperwork and redundancy, lags behind most other industries in electronic payment efficiencies and claims payment reform could significantly benefit the entire health care system. Certainly patients and doctors would be happier. The reform would improve data reporting, and, thereby, improve the quality of health care by saving time and money and reducing medical errors.

Broader efficiencies could be achieved from the technical standardization that electronic submission would necessitate and would allow us to build on the Health Insurance Portability and Accountability Act. Most significantly, if all the payers were required to modernize their payment systems to utilize the Internet at the same time, our Government would be removing the current competitive economic disadvantage that innovative programs now face.

Incredibly, today's health system perversely penalizes the innovative that use technology to pay claims faster and more efficiently than their competitors. Innovators find themselves with reduced investment income and less profit to show for their good deeds.

There are going to be a number of other issues that this Subcommittee will examine in connection with the e-health area. We will look at the development of a private sector-led program to monitor and even certify e-health information on public web sites, how hospitals and physicians could share a web site for patient admission and procedure scheduling without violating federal antireferral and antikick-back laws, and health care e-mail and reimbursement questions. In addition, the Subcommittee intends to explore how e-health can assist in responding to the health workforce shortage.

We are very pleased that Tom Scully is with us today. He has made it clear in previous public statements that he recognizes the web's potential for empowering patients and their families. He would also like outcomes and price information, currently in the possession of the Federal Government, made widely available. We are pleased that his tenure is going to be an activist one, and that he is back in public service. This Subcommittee intends to work with him often.

I also want to welcome our other panelists. In addition to Mr. Scully and Dr. Kenagy, we will have Dr. Sherrilynne Fuller from the University of Washington School of Medicine, Dr. Willie May of the National Institute of Standards and Technology, and Mr. Albert Patterson, of Premier, Incorporated.

We have asked all our witnesses to limit their statements so there will be time for questions. Their full written testimony will be made a part of the record, but first, I want to hear from Senator Allen.

STATEMENT OF HON. GEORGE ALLEN, U.S. SENATOR FROM VIRGINIA

Senator ALLEN. Thank you, Mr. Chairman, and I want to thank you for calling this hearing today. I think this is a great way for you to start the chairmanship of this Subcommittee, by having hearings on issues that are pertinent, relevant, and educating, not just to yourself as a leader and myself as a Senator, but to our other Senators, of the information and insight we glean from the Subcommittee hearings, so that we can hopefully improve the lives of our constituents, whether they are in Oregon, or Virginia, or anywhere else in the United States.

And since the United States is respected as having the best health care system in the world, although it is the most expensive. We so often have been the leaders in technology, and we might as well also be the leader in the adaptation and utilization of technology to improve health care.

So I very much commend you, Mr. Chairman, and do look forward to working with you. I am sorry I missed the meeting last Monday on cyber terrorism and cyber crime issues, but I am sure we will have a chance to revisit those issues in the future.

I, too, would like to welcome all of our guests here today. I look forward to hearing your testimony, and your testimony will certainly serve as the insight we need into any legislative initiatives that might come from the comments and the testimony here today.

As our Chairman, Senator Wyden well knows, technology is involved in everything in our lives, and it is improving, IT—we talk

about technology generally, IT more specifically—is improving all sectors of our economy. It is making our manufacturers more efficient, with better quality and also fewer pollutants. It is improving services. It is improving agribusiness. It is improving education and communications, and it is very logical, naturally, that the health care provisions would also get improved by using technology, in addition to obviously the life sciences and medical sciences research.

We do not have to look very far, Mr. Chairman, to see the conditions of our health care industry. It is the largest industry or economic sector in our country. It is comprised of hundreds of thousands of physicians and other health care professionals, thousands of hospitals, and in 1998 expenditures of over $1 billion.

Now, the expenditures in the provision of health care clearly will be increasing, because our population is increasing in age, and so there is clearly going to be an increase.

Now, the escalating cost of health care has caused many companies and consumer groups and the Federal Government to put pressure on the health care service providers to reduce cost through cost-efficient methods of servicing a growing number of health care consumers. Now, fortunately, Mr. Chairman we are going to hear about some of these ideas, but there are some innovative tools that can help, and the tools are information technologies. These technologies offer the possibilities to make significant reductions in administrative and clinical transactions.

There will be, as you say, and I agree with you, there will be fewer medical errors, because there will be better analysis of the actual patient's condition. There will be less paperwork. Sure, maybe somebody will have to print out something, because you are not going to have a terminal at every single, or a screen at every single spot, but nevertheless, it is going to reduce paperwork.

There will be more allocation of dollars, and most importantly, the time and attention of the nurse or the other health care professionals to be spending time not worrying about paperwork and duplicative and triplicative entries of data, but mainly paying attention and spending time with that patient.

I think the allocation of more time to patient care rather than paperwork and bureaucracy procedures would be desirable. To the extent any of our witnesses can elucidate on that, it would be great.

Now, according to ITAA, which is Information Technology Association of America, a leading trade association serving the information technology industry, an industry-wide investment in information technology of about $18 billion would yield a gross savings of more than $120 billion over a 6-year period. That is a 6-to-1 return on investment, which sounds like a great idea.

I do think that you have to look at the cost-benefit analysis, and when it is done, and hopefully some of the witnesses here will lead us that way, and make sure most importantly that the deployment of new technologies is done in a smooth way, always caring first and foremost about patient care, but I do not doubt that in an established older industry, changing standing procedures and practices can be a challenging situation.

But I think our Subcommittee here and, indeed, our Full Committee, what we are doing is seeking to identify ways in which we may assist, or, as Chairman Wyden says, "Knock down those hurdles"—those hurdles that prevent or may prevent this opportunity and technology to go forward, and so I am pleased we are seeking the advice of those who are considered to be the experts, our witnesses today. So again I thank you, Mr. Chairman, for holding this very important hearing, and I look forward to listening and learning from our witnesses.

Thank you, Mr. Chairman.

Senator WYDEN. I thank my colleague for an excellent statement, and you are absolutely right, this is going to be an exercise in knocking down barriers, and I look forward to doing it together.

Mr. Scully, welcome. We are excited to have you, and looking out I can see that you have got a chance to demonstrate for senior citizens and the people that your agency serves a little bit of how the new world is going to work, and you hold forth in any way that you find helpful.

STATEMENT OF TOM SCULLY, ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES; ACCOMPANIED BY CAPTAIN CYNTHIA WARK

Mr. SCULLY. Mr. Chairman, thank you for having me, and Senator Allen, first off, I would like to say, Senator, Chairman Wyden has been a friend of mine for over 13 years, since the first day in the first Bush administration where I did a lot of the White House health care, but he is an old friend, and he has been committed to finding new and creative ways to improving health care for a long time, so I look forward to working with you again and Senator Allen.

And Senator Allen, as Senator Wyden knows, I have long been an active Republican in the State of Virginia, so I am happy you are here, and as a not-quite-so-illustrious graduate of the University of Virginia—he was a very good quarterback. I was not—I am also happy to look forward to working with you.

Also, I would like to thank Captain Cynthia Wark of the Public Health Service for coming to help me out. I do not want you to think she had to come help me because I am incompetent on the Internet, but really she helped put together a lot of our web site and a lot of things we are going to talk about today, Dialysis Compare, and so she is going to very ably assist me today.

E-health issues are so big and so broad, and the impact on what we are going to do in health care in the next decade or so is so broad, I do not know where to start, but what I thought I would do today is talk a little about where we are and some of the things that we have that are underutilized, and one of the things that I found out when I did take this job 7 weeks ago—in my 7 weeks this has probably become my major hot button, that is what we are going to do on e-health, and how we are going to improve the use of the resources we already have.

CMS—that is one of my other goals, is to get Chairman Wyden to start using our new name, the Centers for Medicare-Medicaid Services. When he starts using them, I will know I have won. But CMS is the world's largest health insurer. We cover, through Medi-

care and Medicaid, more than 70 million Americans, and we will pay out $476 billion in benefits this year between the two programs, which is a pretty stunning number.

Thirty-one percent of seniors now have access to the Internet. That is up from about 7 percent 5 years ago, and when I came in here and I looked at our web site, which I have to say as a former health care lawyer and hospital person I had never actually looked at Medicare's web site, which tells me a lot of other people have not, either, and most seniors have not.

There is an enormous amount of information on there already, and we are going to strive to push more on there every day. We have already announced a few weeks ago a $35 million education campaign this fall, and that $35 million is a big number.

In fact, I am spending the rest of the day picking ad firms, and I can tell you, the reason I picked $35 million is, that is what a Presidential ad campaign spends in 2 months, and that level of impact we are looking to have this fall to educate seniors is the same kind of very broad-based, massive education effort to get seniors to start asking more questions about their program, to check the web site, to call 1-800-MEDICARE.

But we found that the tools already on there to educate seniors, they do not use. We are going to go through these in a few minutes, but when I went out and checked where I live in Alexandria, Virginia, on Dialysis Compare, and found out the information that was on there, there was no way in the world that anyone in Alexandria, Virginia that is on kidney dialysis should ever pick a dialysis center without looking at our web site.

When I went through to look at the nursing homes, which you are going to do in a minute, I found there was a ton of information in Alexandria, Virginia and every town in America on the nursing homes that you could pick for your parents, and when you look at the information we have, and we are going to continue to add in the next couple of years, it is an enormous educational tool for all seniors and for the families and for their kids.

So we have lots of goals, and I will talk about some others with HIPAA and other health issues in a moment. The first thing I want to do is get people to start using our web site more, and we have a lot more information up there. Starting in about a month, and one of my goals in the next 4 years is to educate, educate, educate seniors, and I think this is a very good place to start.

So what I want to do briefly is run through a couple of them. I picked, surprise, surprise, two different groups from Oregon and one from Virginia. I do not know why we did that, just a wild guess, but I think we are going to start off with just going through basically what is on our web site for Dialysis Compare in Portland—unfortunately, one of the things Medicare does not cover is reading glasses, so I cannot quite read this as well as you probably can, but——

Senator ALLEN. From this angle, we need binoculars.

Mr. SCULLY. What it does is, if you click up there a little bit and click through Dialysis Compare, maybe you can click through the ones that are in there. There is a lot of information in there about dialysis centers. I do not know if you are familiar with kidney dialysis. It is probably one of the sickest and lowest income groups

we have in Medicare. That is $14 billion a year in the Medicare program, a very low income, very sick population, and they tend to go—with all due respect to the nephrologists, they tend to go where the nephrologists suggest that They go, and there is a wide choice of dialysis centers, and my interest is in educating people on kidney dialysis about where to go, and when you look through these dialysis centers in Portland, you will find actually the ones in Portland—I looked through this last night—are actually pretty good. You are lucky.

If you look at the national rate of hemodialysis, which I think is the key Dialysis Compare standard, you will see the national rate is 83 percent, the State rate is 84 percent, and fortunately for Senator Wyden, the three major ones in the Portland area are all significantly above the national average, but I can tell you if you look in Alexandria there are a couple that are way below the national average, and if you look in Baltimore, where I looked for one last week, there was one hospital that had a 17 percent hemodialysis rate, so there is an enormous difference, and if you are on kidney dialysis that is the key rate, as to whether you are better than expected, worse than expected, and what the rates are, and kidney dialysis is essentially universal coverage.

There is a certain amount of deductible for the first certain number of days that you are on dialysis, but eventually all people—the only universal coverage we have in this country is for people on dialysis, so Medicare is effectively eventually paying all the bills. We pay, I think, 86 percent of all dialysis bills, because of the deductibles, but it is basically a federalized program, regardless of age.

So we are paying the bills. Seniors should have the information—everyone on dialysis is not a senior. These are people of all ages—they should have the information to pick the right dialysis center. They do not have it. They should be more aware of this.

Very few people use this, and this is, again, for people of all ages, and I am determined to go out as part of this fall education campaign to get dialysis patients on the web and find out where dialysis centers are, ask the doctors where they should be going, make choices based on their best health care outcomes, actually Captain Wark has spent a lot of time on this herself and helped to put this together.

This has been around. This is a model for what we are going to do in Medicare dialysis, that we have terrific outcomes, we have terrific information. There is no reason why any dialysis patient in the country should not ask these questions. This information is readily available, and we want to make sure every dialysis patient is aware of it and looks at it, and this is a model I have for going on with nursing homes and hospitals down the road.

This is the type of information we should have on patient outcomes for everybody, all through the health care systems, and I think the Dialysis Compare system is terrific, probably better than our other patient information right now. We are going to try to give every corner of health care this type of comparative information.

The second one I think is Health Care Compare, which I think—in this example I'm showing you on the screen—is also in Portland, Oregon, and again we have had a big problem with managed care

plans dropping out of Medicare Plus Choice. Another major initiative of mine is to get them hopefully, with the Senate's help, get more of them to stay in and convince them this is a good partnership with the Federal Government to stay in the Medicare Plus Choice program.

Senator WYDEN. I will not use this opportunity to try to put you on the spot to a higher AAPCC rate, or anything like that. That will help us. I am going to spare you that one.

Mr. SCULLY. I would love to work with the Senate to make the AAPCC work better, but I know, Senator Wyden, and fortunately in Oregon you have a broader base of Medicare Plus Choice than other places have. In Northern Virginia there is basically one, Kaiser. It is the only choice you have. In many other metropolitan areas, there are multiple ones, but again, if you look on here, these are the various plans that are available in Portland.

It goes through great levels of detail. There are actually hundreds of pages of comparisons behind here, comparing quality cost, copayments, drug coverage. If you are not looking on our web site and you are picking a private health care plan in Portland, you are probably making the wrong decision.

Just from the number of hits we get, most seniors are not aware of this, but we are going to try to get the seniors and their kids and their families to say, look, this is a resource, we are going to use it, and this is a big part of our education campaign this fall, because there are a lot of benefits out there for seniors that are worried about prescription drugs.

Hopefully on a bipartisan basis we will get a Medicare reform and prescription drug bill done this year, but until then, Medicare Plus Choice is a terrific place to have the option to get prescription drugs and a lot of plans, and a lot of them are not aware of that, so we want to educate them as to their options out there.

But if you look through the plans here in Oregon, there are enormous levels of information. I mean, if you went through here, I believe it would take you 45 minutes just to go through the available information and read it, on the health plans in Oregon, in Portland, and it is very, very helpful if you are trying to pick the right health plan for your parent, or for a family member, or for yourself.

The last one I wanted to show, and this is a little more controversial, is the Nursing Home Compare web site, and the reason it is controversial is, it basically lists—I put the one in here for Alexandria, Virginia. One of the nursing homes in here is actually two doors down from my house, so I am particularly familiar with it.

But again, if you are picking a nursing home any place, not to go on our web site and find out what the history of these are—I happen to live next to the Woodbine Rehab Facility in Alexandria. When you look down here and you flip through these facilities, there is a lot of very good comparative data.

Now, the nursing home industry would tell you this is not objective data, because it is based on State survey and certification rules, but I am currently working very closely with the nursing homes to put together a new health care quality measurement for the whole nursing home industry that we hope will be up and run-

ning in the next, certainly the next few months. We are not quite there yet, but we are working on it.

And I think that you will find that basically one of the most sensitive things people do in their lives is finding a nursing home or long-term care facility for a loved one or parent, and there is a lot of information people do not use, and again I have been in the health care industry for 20 years. I was totally unaware of this until I took this job, and my guess is most seniors are not as well, so our goal basically is to take this type of material, collect a lot more of it, put it out on the Internet, and advertise heavily to seniors and their families, this is available, get them to call.

If they do not have access to the Internet, and a lot of them do not, call 1-800-MEDICARE and ask questions, and our operators by November 1 will have all this information in front of them. They will be on our web site. They will be able to give you localized information about Portland or Philadelphia, or Alexandria, or wherever else you want to go, which ones not exist right now, and our goal is to basically get every senior in the country to be—and in the case of dialysis centers, it is nonseniors as well—aware of the coverage that is available to them, aware of the options available to them, get them to ask questions, and get good, quick answers from the Medicare system.

Seniors like Medicare. Congressmen all dislike HCFA. Hopefully they will like CMS better, but we are working on that one, but seniors do like Medicare, and it is a popular program, but our polling and our focus groups tell us that they really do not know much about it. They have very little understanding of the different coverages available to them, the choices available to them, and their opportunities in Medicare in their towns and cities and counties, and we want to make sure that is considerably better.

Anyway, there is a lot more in my written testimony, but I will just jump to one other thing I think is important that Senator Wyden alluded to. One of our personal goals is to collect data on quality and start in a cooperative way with the industry involvement to collect and disseminate it. We have done a very intensive analysis of the industry, and the dialysis folks like it. They like being compared. They like having their outcomes known. It has worked extremely well.

As I said, we are working on some other industries going forward but I think one of the other major benefits of the improvements in technology is, we have enormous capabilities to collect quality data and put it out there. Chairman Wyden is a giant believer in markets, and markets only work if people have information, and one of my other goals is to collect as much information as we possibly can on the health care system and put it out there for consumers, who I believe, in health care are starved for information, so we have made hopefully a good start in that direction.

We look forward to working with this committee and the Senate to push these goals forward as quickly as possible, and I hope the one thing you will see most tangibly this fall is, I think you are going to be in a very dark cave to miss our advertising campaign. Our information tells us about 97 percent of seniors will be aware of it by the time we are finished, before Christmas, and we hope

that will be a very, very positive step forward to getting all seniors to understand what their benefits are.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Scully follows:]

PREPARED STATEMENT OF TOM SCULLY, ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES

Chairman Wyden, Senator Allen, other distinguished members of the Subcommittee, thank you for inviting me to discuss the potential of new electronic technologies to help Medicare beneficiaries. This is an important issue, and I appreciate your interest and your efforts to ensure Medicare is well positioned to take full advantage of the opportunities that emerging electronic technologies present. I will also discuss some of the steps we are taking now to harness this power to improve Medicare services and the way we do business. I look forward to working with you on these initial steps.

As you know, we live in an age where technological advancements are improving almost every aspect of our lives—from developing artificial hearts to improving our ability to communicate, and from deciphering the genetic code to performing cross-continental surgery using electronic data transfer. Today we can perform many tasks faster and cheaper than ever before. As the world's largest health insurer, it is critical for the Centers for Medicare & Medicaid Services (CMS) to embrace technological advancements to expand our interaction with Medicare providers and ultimately improve the care and service that Medicare and Medicaid beneficiaries receive.

I am dedicated to ensuring that we seek opportunities to take advantage of all of the advancements that can help the people involved with Medicare, including health plans, physicians and providers, and the beneficiaries who depend on them. Medicare is a highly automated and fast payer in the health insurance industry

BACKGROUND

CMS is the world's largest health insurer, providing coverage to more than 70 million Americans. This year the Medicare, Medicaid, and SCHIP programs will pay an estimated $476 billion in benefits, Approximately $375 of which are Federal costs. Each year Medicare alone processes nearly one billion claims from over one million physicians and other health care providers who care for the nearly 40 million Medicare beneficiaries. This is a tremendous undertaking. Moreover, Medicare is complex and physicians, providers, and beneficiaries alike have complained that it is confusing and cumbersome to work with. We have a responsibility to employ every appropriate means to improve the way we do business and the care our beneficiaries receive. We recognize these challenges, and we know that electronic technologies present new opportunities to help address them.

We have begun to take advantage of electronic technologies in many ways in the Medicare program. We are taking steps to use technology in other ways to improve our programs. For instance, we are using Internet-based tools to educate Medicare beneficiaries about their health care options, to help them understand the alternatives available to them and how their choices might impact them. Additionally, we are implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA) provisions, which mandated a broad array of administrative simplifications for electronic transactions in the entire health care industry, including Medicare and Medicaid. Once fully implemented, these improvements will make it easier and more efficient for physicians, providers, and insurers to exchange health- and claims-related data, enhancing their ability to provide high-quality care for patients. And we are using technology to make Medicare as simple and understandable for physicians and other health care providers as possible so they can spend more time with their patients and less time on paperwork.

These initiatives are important, and they represent strong steps in the right direction. However, I recognize that there is more that we can do—other ways to take advantage of the opportunities that new technologies present to help Medicare beneficiaries. I look forward to continuing to work with you as we consider and investigate other ways that Medicare can take advantage of all that electronic technology has to offer.

BENEFICIARY EDUCATION

Secretary Thompson and I have placed a high priority on using Internet-based technologies to help beneficiaries better understand their Medicare options. More

and more, people with Medicare and those who will soon be eligible for Medicare use the Internet. In fact, Internet access among people with Medicare has increased dramatically from 1997 to 1999. Findings from the CMS-sponsored *Medicare Current Beneficiary Survey* indicate that the percentage of Medicare beneficiaries reporting access to the Internet climbed from 6.8 percent in 1997 to 21.3 percent in 1999. And, according to *Jupiter Communications*, older adults (people 50 and older) spend more hours online each week than any other age group, including college students and teenagers. In fact, senior citizens are the fastest growing sector of the on-line audience, exploding from a meager 600,000 in 1995 to an estimated 13 million in 1998, according to *SeniorNet*. Last year, *eMarketer* released an *eRetail Report* that supports this trend: in 1999, almost 10 million seniors, or 17 percent of all Americans aged 55 and older were active Internet users.

With Medicare beneficiaries using the Internet more and more every day, we have a tremendous opportunity to use this technology to help inform them about their Medicare options. Medicare beneficiaries and everyone involved in helping them with their health care decisions can use the wealth of information available on our award-winning beneficiary Internet site, *www.medicare.gov*, which is uniquely designed to provide customized comparative information on various Medicare-related topics.

For example, as of October 1, 2001, we will activate a *Medicare Personal Plan Finder* to assist beneficiaries in narrowing down and comparing their health plan choices based on the characteristics that are most important to them. The *Medicare Personal Plan Finder* will give users the ability to compare out-of-pocket costs among their health insurance options, and explore more detailed information for the plans on which they choose to focus. This tool will pull data from existing Medicare databases and web applications, and bring multiple search results together in a more useable and personalized manner. And for those beneficiaries who still prefer more traditional modes of communication, the *Medicare Personal Plan Finder* also will facilitate the 1-800-MEDICARE Help Line customer service representatives to more effectively help callers identify the health insurance options that are most appropriate for them. In addition to assistance via the telephone, the customer service representatives also will be able to provide a "print-on-demand" package of materials to send to the beneficiary for further review at a later time. This will be a good way to give more beneficiaries access to information, while introducing some of the ways the power of technology can work for them.

In addition to the *Medicare Personal Plan Finder*, there are a number of other interactive databases accessible on *www.medicare.gov* that allow visitors to search for information.

• *Prescription Drug Assistance Programs* provides information on programs that offer discounts or free medication to individuals in need. Beneficiaries can search for these programs by state, or by drug manufacturers. It also has a frequently asked questions section that includes information on prescription drug coverage and the President's Medicare prescription drug discount card program.

• *Dialysis Facility Compare* gives detailed information about Medicare approved dialysis facilities. This includes dialysis facility characteristics like the address and telephone number of the facility, whether the facility has shifts starting at 5:00 pm or later, the number of treatment stations, and the types of dialysis offered. Dialysis Facility Compare also contains quality measures and a glossary of terms used on the site.

• *Nursing Home Compare* is one of many efforts included in CMS' initiative to increase information about the quality of care in nursing homes. The primary purpose of this database is to provide information about the performance of approximately 17,000 Medicare- and Medicaid-certified nursing homes across the country. The database has detailed information gathered from the States that conduct surveys and certify the facilities, including whether any quality deficiencies were found, and how severe they were. Furthermore, it has characteristics of the nursing home residents, including the percentage of residents with pressure sores, percentage of residents with urinary incontinence, and more. And it has information about the number of beds, type of ownership, and whether or not the nursing home participates in Medicare, Medicaid, or both.

• *Medigap Compare* enables users to search for private health insurance plans that they can purchase to supplement original fee-for-service Medicare. The database includes basic information about each reporting insurance company, including which of the 10 Medigap plans they offer, to whom they are offered, and rating method. It also provides information on how to contact Medigap insurance companies in each state.

• *Medicare Health Plan Compare* was the first interactive database on www.medicare.gov, and provides detailed information on Medicare's health plan op-

tions, including the Original Medicare Plan, Medicare+Choice plan, and private-fee-for-service plans. *Medicare Health Plan Compare* also contains benefits and services offered by each Medicare+Choice plan, including: detailed information on premiums, co-pays and benefits, and more. And it has quality information about health plans such as health plan performance measures. The database also includes information about the number of plan members who have disenrolled from their Medicare managed care plans.

• *Helpful Contacts* provides state-specific contact information and phone numbers for agencies that can assist people with Medicare. Also included are websites that can provide assistance on a variety of topics of interest to people with Medicare such as: understanding their Medicare bill, Medicare rights and benefits, dealing with complaints and appeals, and managed care. Users can search this site by topic or by type of organization.

• *Local Medicare Events* allows visitors to search for upcoming activities in their area, including health fairs or presentations covering a range of Medicare topics. Visitors can search by state, month, event type, and topic to get information on events.

These database resources distill tremendous amounts of information for our beneficiaries and their families, presenting appropriate data so that the public can get their arms around the information they need and really use it to make decisions. This is a good start, and we know there is more that we can do to inform beneficiaries. We need to continue to offer other information electronically. Some of the additional information *www.medicare.gov* currently offers includes:

• *A Variety of Medicare Publications* for visitors to view, print, or order, including the *Medicare & You* handbook, which we mail every year to 34 million Medicare households, as well as the *Guide to Health Insurance for People with Medicare*. Many publications are available in Spanish and Chinese.

• *The Medicare Basics* section, which enables visitors to get answers to their questions about Medicare including eligibility requirements, how to enroll, coverage, billing, premium amounts for the Original Medicare Plan, how to read a Medicare Summary Notice, and a copy of materials in the beneficiary Initial Enrollment Package. There also are links to various Medicare publications that have information on Medicare benefits and places to find assistance for beneficiaries to pay health care costs.

• *Fraud and Abuse Information* that describes common Medicare fraud, how to report suspected fraud, and ongoing fraud campaigns. Website visitors also can obtain tips for spotting and stopping waste, fraud and abuse, and an online brochure for beneficiaries to guide their efforts to protect themselves and the Medicare program.

• *Health Information* about Medicare preventive benefits, references to publications, and websites with information that can help beneficiaries stay healthy. Current references and websites fall under the following disease-specific areas: cervical cancer, colorectal cancer, depression, diabetes, dialysis and kidneys, flu and pneumonia, mammography, and osteoporosis.

• *A Screen Reader Version* that allows people who are blind or visually impaired and who use screen readers for Internet communications to access the site.

• *Spanish and Chinese Sections* that consolidates all of the information currently available in these languages. This includes publications, fact sheets, and information on how to order publications. *Medicare Health Plan Compare* is completely available in Spanish, as well as inspection results for nursing homes. An increasing number of our Medicare publications are available in Chinese.

• *Frequently Asked Questions section* that has been redesigned to allow users to find the information they need quickly and efficiently. We have added a new search tool that allows users to search by category or phrase to find answers to their questions. Visitors can provide feedback using a rating scale on how satisfied they were with the answer. If visitors are unable to find answers, they can submit a question to us. Prior to submitting a question, the tool uses a knowledge base to provide customers with suggested answers to their questions. Also included is a subscription service that allows users to receive an update notification when questions are updated.

Taken together, this constitutes a huge volume of information presented in an easy-to-use format. Will every Medicare beneficiary need all of this information? Probably not—and we certainly hope they will not need it all at once. But it is available to them 24 hours a day, seven days a week, whenever they need it. And we continue to add more information that beneficiaries and their families might find useful. The Internet is a powerful tool, and we know we must continue working hard to ensure we use it to make life easier for our Medicare beneficiaries. In addi-

tion, this information will continue to be available through 1-800-MEDICARE and local community organizations.

ADMINISTRATIVE SIMPLIFICATION

In addition to the Internet, we are taking advantage of other electronic technologies to improve the way we do business. As I mentioned, in Medicare alone we process nearly one billion claims a year. Using electronic technology has made us a highly automated, efficient, and fast payer. Over 90 percent of Medicare claims are processed electronically, and we pay those claims an average 14.9 days after receipt. It costs us roughly $1 to $2 to process a claim. While we are proud of this efficiency, there are other ways that we, along with the entire health care industry can use electronic technology to improve the way we do business. To that end, the Administration has proposed user fees to encourage providers to submit claims electronically.

Congress recognized the opportunities that modern technological advancements present when it enacted the Administrative Simplification provisions in the Health Insurance Portability and Accountability Act of 1996 (HIPAA). These provisions require the Secretary of Health and Human Services, in coordination with standard setting organizations, to develop regulations standardizing electronic health care transactions. This includes data exchanged for payment of health care claims, determination of a person's eligibility for insurance coverage, and enrollment in or disenrollment from a health insurance plan. When Congress passed HIPAA, the health care industry had voluntary standards for data collection and electronic information transmission, but not everyone used them or applied them uniformly. This prevented the industry as a whole from moving to a single, efficient electronic transaction environment. Following Congress's leadership, as we move towards standardized transactions we should start to see tremendous administrative cost savings in both providing and paying for health care. Additionally, we anticipate that without the many different communication formats used previously, there will be much less confusion around the transmission of health and claims information for both patients and providers.

We know that standardizing these electronic transactions can improve the efficiency of health care by improving patient care, saving money, and limiting frustration. However, we also know that such an important shift requires big changes in many areas, and so has the potential of raising costs, at least in the short run. These changes will not be easy, nor will they be cheap. Every "covered entity" under HIPAA, which includes health plans, physicians, providers, and information clearinghouses, will have to refine its computer systems in order to implement the new standardized formats. Changes like this will help to make the health care industry more efficient, but the increased efficiency depends on the entire industry's significant up-front investment to standardize operations. We also need to take due care to ensure that the HIPAA standards are appropriate and remain up-to-date with rapidly progressing medical information capabilities.

At the same time we recognize that these changes could make it easier for unauthorized people to access health and insurance information. Because of this increased risk of inappropriate access to medical records, Congress wisely included privacy requirements in HIPAA. In April, Secretary Thompson announced that the two-year period would begin for the industry to implement privacy protections, as published in our privacy rule. These protections are intended to ensure that the privacy of health information is not inadvertently compromised by progress in technology. There is broad support in the health care industry for these uniform privacy standards, but implementing the standards also will require additional investment by the health care industry. While we all know that privacy of medical records is extremely important, I am concerned about the costliness of implementing the standards, and I am committed to working closely with the health care industry to implement these standards effectively.

In addition, we will be publishing final regulations for HIPAA security standards, which will provide guidance on how these privacy protections will be implemented. These protections will require even more education about the new regulations, for patients, physicians, providers, plans, and others impacted by the rule. It should also be recognized that sending individually identifiable information over the Internet must be accompanied by appropriate security protections. And so we are taking important steps to involve all components of the health care industry in the development and implementation of the HIPAA Administrative Simplification provisions, and to ease their transition into compliance with the law.

The new electronic transaction standards, which the industry must begin complying with on October 16, 2002, are not set in law, nor were they being established

unilaterally by the government. Rather, in accordance with HIPAA, we used a process that leaned heavily on private sector participation as well as substantial input from the full range of individuals and entities that will be affected by the changes. In this way we will develop a standard way of communicating electronically that will work best for all of the people who use the health system. We are working with standards setting organizations that specialize in developing national standards. These experts include representatives from the American National Standards Institute X12 standards organization, the National Uniform Claims Committee, the National Uniform Billing Committee, the American Dental Association, the Workgroup on Electronic Data Interchange, and the National Committee on Vital and Health Statistics. We continue to work with industry groups, holding numerous meetings and conference calls to elicit input from a broad array of providers and insurers. And we have solicited comments from impacted individuals and others in the public as the new rules have been proposed, and they have responded. In fact, we received about 17,000 comment letters when we proposed our rule on transaction and code sets, and more than 50,000 on the privacy rule.

PHYSICIAN AND PROVIDER EDUCATION

One of my top priorities as Administrator is to improve the responsiveness of CMS. Responsiveness is one of the standards by which we are—and should be—measured. In this spirit, we are taking several steps to communicate with providers through electronic as well as traditional avenues.

Secretary Thompson and I recently announced a multifaceted approach to improve our responsiveness to providers. This approach encourages us to listen, to learn, and then to administer our health care programs as effectively as possible. We are listening more to the public—the local seniors, providers, State workers, and the people who deal with Medicare and Medicaid in the real world. Some of the people who we hear from the most are the physicians and providers who are dealing with our rules every day. They are the ones caring for our beneficiaries, and they are the ones filling out many of the forms, trying to understand the rules, and working to do the things they spent years training to do—making people healthy. Under the first part of this approach, we will conduct public listening sessions across the country to hear directly from physicians and providers about how we can reduce regulatory burden and confusion in Medicare, while controlling costs and maintaining quality of care.

The second part will focus specifically on the collective expertise the industry groups who represent these physicians and providers. We will convene seven workgroups, with a senior CMS official as each group's principle contact, to suggest ways we can improve their interactions with the Medicare program. This type of input is good for our beneficiaries because regulatory reform will allow physicians and providers to spend more time caring for beneficiaries, and it will encourage physicians and providers to remain in the Medicare program.

In the third part of our plan, I am forming a group of in-house experts from the wide array of Medicare's program areas. I am asking them to think innovatively about new ways of doing business, reducing administrative burdens, and simplifying our rules and regulations in ways that control costs and continue to afford high quality care for beneficiaries. CMS staff have dealt with the system for years, and they have suggestions about how we can operate the Medicare program more simply and effectively.

While we are listening and learning, we also are teaching. We have long understood that when providers are well informed, it enables them to provide better care to our beneficiaries. And we know that we can use modern technology to help inform physicians and providers. Our new culture of responsiveness will help to build and improve education efforts through these emerging technologies. In response to increased health professional use of the Internet as a learning tool, we created a web-based Medicare education site. There are a variety of resources available on the Internet at our Medicare Learning Network, *www.hcfa.gov/medlearn*. This network provides timely, accurate, and relevant information about Medicare coverage and payment policies.

Among the featured tools on this site are quick reference guides to help users more easily access information resources on the CMS website, including resources that contain information about outpatient prospective payment systems (PPS), home health PPS, clinical trials, immunizations, and ambulance fee schedules. We also have available, free of charge, downloadable computer based training courses and manuals for physicians, providers, and suppliers on topics ranging from women's health to resident training to billing Medicare for services. Additionally, there is information about the satellite broadcast training sessions we offer for physicians and

providers on topics ranging from emerging health issues to our payment systems to fraud and abuse. And the site has downloadable booklets with information about the various health benefits that Medicare covers, including women's health, as well as information on other training programs that Medicare offers for physicians and providers. In addition to being web-based, these booklets are available in CD-ROM.

Our site also offers physicians and providers the ability to subscribe to listserves and mailing lists for topics like complex payment systems and clinical trials. Furthermore, to be as inclusive as possible, we maintain a current calendar on upcoming CMS town hall meetings, training sessions, and satellite broadcasts relevant to physicians and other providers. To help site visitors continue to expand their horizons, we also have links to other physician-oriented sites of interest.

We also have entered into an interagency agreement with the Centers of Disease Control and Prevention to promote our products to a more clinician-based target audience. We are placing products on their web page, collecting specific feedback information from users, and reviewing existing education videos and computer-based training modules to ensure that the modules qualify for continuing education credits. We also are converting the existing CD-ROM-based modules to web-based training modules, and assisting in the development of future web-based tools to ensure these valuable learning tools are distributed as widely as possible.

Although we have a great deal of valuable information available, we are not satisfied that we are reaching as many users as possible. So we will continue to upgrade this site. We plan to develop a national network of Medicare Learning Network faculty featuring nationally recognized experts on distance learning, professional education, and customer service. We are going to integrate clinical aspects of Medicare Learning Network products with the billing and payment education aspects to attract a wider audience of clinicians. And to ensure we are getting the best bang for our buck, we will establish processes to evaluate the effectiveness of Medicare Learning Network products and activities and venues to receive continuous feedback from the provider community. This is an ongoing process, and we will continue to work hard and solicit input from Congress and the physician and provider community on how we can use new technologies to improve Medicare.

CONCLUSION

I recognize the crucial role that technology plays now and will continue to play for health care in America as electronic and medical advancements are made. I cannot begin to imagine all of the fantastic improvements that technological progress will bring, but I know that Medicare's future depends on taking advantage of them. We have already started by using the Internet and other technologies to share tremendous amounts of information with beneficiaries and physicians and providers, while being sensitive to the privacy concerns surrounding the use of technology. However, there is much more that we can do. I appreciate your interest in Medicare's use of technology, and your support of our efforts to improve it in the future. Thank you for inviting me to discuss these issues with you today, and I am happy to answer your questions.

Senator WYDEN. Mr. Scully, that was an excellent statement. Does your colleague have anything she would like to add?

Captain WARK. No, just that I am pleased to be here to demonstrate some of our enhancements to the web site we have made.

Senator WYDEN. Senator Allen.

Senator ALLEN. Mr. Chairman, thank you.

Mr. Scully, I was listening closely. I have a few questions, some on your testimony, and also reading through your written statement. As far as the comparisons, and the poor consumers, you mentioned the nursing homes and the nursing home folks that you are working with obviously are going to be helping the CMS. It is not just a change in acronyms from HCFA, but actually an actual change that is meaningful and has some common sense.

You mentioned that they had a problem with some of the information, in that whatever the studies were as far as nursing homes are based off of State records, and I assume the logic of that, or the reason is because States administer it differently, or they have different criteria. What has been the response from the private sec-

tor on some of these ideas, and how can it be worked out in such a way that it does not end up being a costly nightmare with a bunch of data entry that ends up being changed every few years?

Mr. SCULLY. Well, it has to be done right, obviously, is the first answer. I think the dialysis was done before I got here, but the one thing I looked at when I first came in was the information on dialysis happened to be terrific and very positive, and on truth in advertising, I was on the board of directors of one of the bigger dialysis companies until a few months ago, and I asked them what they thought, because when I was nominated they said, it is great, they like it, it has been very helpful to get people educated as to what their options are.

Maybe somebody does not like it, but generally it has been supported by the industry as being good for seniors in helping to educate them as to what their options are.

I think the managed care world has also been very supportive. The nursing home complaint, which is probably a legitimate one, is the nursing home data on our web site now is all based on, under Medicaid, which is where most of the nursing home money is spent, and Medicare as well.

The States generally do the survey and certification of the nursing homes, so in Alexandria, Woodbine, for instance, the State of Virginia does the certification, so when you look on a web site you may find one nursing home in Alexandria, for instance, had 27 violations last year, and another one had 3, and the nursing homes would argue that is very subjective.

You may have one inspector that does not like them, who they had a bad history with, and it is not an objective measurement, it is a very subjective measurement, so they are nervous about that.

One of the things we are working on right now is to come up with basically some Nation-wide quality standards, and that is a project that is in development now. I do not want to prematurely announce it because it is not done, but we are working with them to address those concerns, and they have been very cooperative. The last 3 or 4 years have been kind of rough, as you probably know from the nursing home business.

One of the benefits I have had—I have never worked in the nursing home business, but I would say they are very anxious to work to rehabilitate—whether it is deserved or not, their image has not been particularly supersensitive, and in some ways I think that is good, because I think they seem to be much more willing to look at new ideas, to educate consumers than they might have been 3 or 4 years ago, but we are working with them.

People get very scared when they talk about hospitals. For instance, I was in the hospital business, and I was misquoted my fourth day on this job that I wanted to rank hospitals. That is not what we have in mind.

What we do have in mind, and Premier I notice is testifying after us today, again during my preconfirmation period I had a terrific briefing from Premier on the fact that they have, I think, 420 member hospitals, and they collected extremely good comparative quality information on about 20 different treatment categories in all 420 of their hospitals, so you have 420 participating hospitals, and they have a graph for each one.

Whether it is stroke treatment or heart treatment, pneumonia treatment, the top 20 treatments they have in their hospitals, they had all 420 of their hospitals compared on a graph as far as the quality, so they had measurements they could operate their own hospitals against.

So we are not interested in going out and ranking hospitals, or nursing homes, or dialysis centers. That is not what this is. What it basically does is show where people are better or worse, and where they can improve their performance, and I think that is vital if you have a market-driven and constantly improving health care system.

Senator ALLEN. Well, what pleased me about your answer, and it is not surprising, is you are working with those who are affected to make sure that they are in agreement with it, and then you can have, if you can get the whole industry, or the whole, say, the nursing home situation, not just get those in one State, but all the States to agree here are the standards, because if they are at a place in Southwest Virginia, or Northeast Tennessee, they may send their parents either side of the line, or here in the metro D.C. area they might want their parents to be in a place in Maryland, or Virginia, maybe even West Virginia for that matter, or Delaware, places that are all relatively close to this area.

So if you have a uniform standard, which all the nursing homes across the country, not just within a State, can utilize in developing it, I think that improves its credibility and also the compliance, and again they are going to be the ones having an input that data. Nursing homes are barely getting by as it is, with the reimbursement rates being as low as they are, and having the difficulty of hiring nurses, and obviously they want to bring in some qualified people from overseas as technology folks were a few years ago. The nursing home health care industry is looking the same way for immigrants.

Let me ask you another question, and this is off your written testimony, where you state, the Health Insurance Portability Accountability Act of 1996, HIPAA, requires the Secretary of Health and Human Resources, in coordination with standard-setting organizations, to develop standards for electronic health care transactions.

In that, two questions. One, do you have an estimate of how much cost savings will arise from these new standards when they are related, or how much savings, and do you have an estimate—and I know you have just gotten on the job—but are there any estimates of how much the private sector will have to spend to conform with these standards?

Mr. SCULLY. Well, I do not have any numbers, but I have heard a lot of talk, talked to a lot of people about it. My concerns—and it is a tough thing to balance. My goal is to try to have HIPAA regs, which are basically to have consistent data transaction information and codes out there Nation-wide by all users by, I think it is October 2002, and there is two tough things to balance here.

One is in the first Bush administration I remember sitting around having this exact discussion 12 years ago. We are all going to have standard measurements, standard coding, and we are going to make everybody streamline their reporting system so that everybody would be on e-commerce, and this was a big project of the

Deputy Secretary of HHS back then, and I remember spending a lot of time on this, and 12 years later you come back and nothing has changed.

So the one thing we want to do is keep the pressure on as much as you can to change. I mean, updating technology is important, but it is costly, and I have talked to a lot of Blue Cross plans who have said, look, if we are forced to do this in the next 18 months, our partners, they could be ready, but the hospitals are not, and I know that is true, a lot of hospitals will not be ready, and if you push us to come up with one standard data set, we are going to spend a ton of money, and it is just going to be mass confusion, and be careful that you do not blow up the whole system, also a very valid concern, but one of the things I have found is, if you take the pressure off, change will never happen.

So there is a delicate balance there between making sure we do not foolishly spend money and force a lot of the plans out there to spend money, which actually is coming out of all of our pockets, inevitably, while at the same time, if you do not push for change and streamlining of technology, it will never happen, and the people that push those changes, that is one of the roles of the Federal Government I think that is valuable, is standard setting for the Federal Government.

I am well aware of all the pressures. I have not heard from Trigon, but I have heard from a lot of others. Blue Cross said this is a big problem, and we are going to do our best to balance that.

Again, if we went out today and said, no, we are not going to do it, then I would be sitting here again in another decade saying, you know, we really ought to have one set of standard coding, so we are trying to balance that the best we can.

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

Senator WYDEN. Thank you, Senator.

Mr Scully, your agency is really a treasure trove of health care data concerning quality and price. The fact of the matter is that Americans can get good price information on just about everything else that they buy that is important to them, other than health care. I think what you are trying to do in terms of launching this quiet revolution, in terms of getting information that the Government now possesses out to people, is extraordinarily important.

I think you are on target in terms of making it clear that you are not going to rate anybody, but you are going to get this information out so that you empower people to make choices on their own.

Tell us, if you would, about how you see this evolving, particularly on the price issue, which is not out today. If you would, give us a timetable, or a process by which you are going to go about getting this done.

I want to make it clear, I am going to support you in every way possible, whether you are going to try to do this administratively, or come to the Hill and ask for support. But, I have to tell you, I was just flabbergasted at the fact that when you made common sense comments in a speech about getting quality and price information, it created such a thunderstorm that it arrived on the front page of the paper. I think it is an indication that this is something

of a revolution, a revolution for the consumer borne out of these technologies.

Tell us, if you would, how you see it going forward, particularly on the price issue, your timetable, the process, and know that you are going to have my full support on this.

Mr. SCULLY. Well, as you know, Senator, since you have known me, Mr. Chairman, for a long time, that was accidental. That was my fourth day on the job, and I feel very strong about those views, and that is the same talk I have been giving for years in the private sector about my views on getting more information on health care.

It just so happens, when it is your fourth day on the job, and you have not really—it was inadvertent that it got that much press for me to be announcing administrative initiatives, but I can tell you that the Secretary and everyone else in the White House feel equally strongly about getting market information out about what is going on in health care.

I think probably a few would have liked it if I had asked them first. That was my first couple of days after confirmation. But anyway, you live and learn. After you have been out of Government for 8 years you forget you can get a lot of attention with one little speech, but I feel very committed to it.

I do not know if there is a set timetable. I mean, I came out of the hospital sector, and I spent a lot of time working with my own former hospital members, many of whom are in both of your States, talking about this, and it is a little bit controversial, but as you know, philosophically I am a big supporter of the Medicare program, but the Medicare program is hard to put out relative prices because the Federal Government fixes the prices. Everybody pays the same amount.

So one of my views about the information is, the Federal Government is going to pay every hospital and every nursing home and every doctor the same amount of money. It is much more difficult for doctors, by the way, but if you are going to pay providers the same amount of money, you ought to know what the relative quality is the taxpayer is paying for, so if you are going to go out and have heart surgery at George Washington or Georgetown, or Sibley, or Alexandria Hospital, and the Government is paying the same price relatively for all of it, you ought to know what the quality is and what the outcomes are going to be.

I think we are a ways off from doing that. That is the kind of concept that scares a lot of people, depending on how it is done, and I probably scared a lot of people, even though I did not say it, saying we are going to rate hospitals, because I have no idea to do that.

But I do think the world is moving that way. Nursing homes are moving that way. Dialysis centers are moving that way. Health plans are moving that way. Everybody is, I think, there. The issue is, what is the fair measurement? I think everybody is willing to do that. The issue is, and it is a totally reasonable one, if you are a hospital the last thing you want to do is have somebody pumping out information that is not fair. The same thing with the nursing homes.

So the real issue, and the challenge to the Federal Government, is to come up with standards for measurement that are fair, because it is not fair to put out outcomes that mislead people, or that give you the impression that—you know, for instance, with nursing homes there is a lot of information out there. If you look at the nursing homes in Alexandria, for instance, which I am fairly familiar with, there are huge differences in levels of acuity for what those people try to treat.

If you have a very sick person in your family, you probably want to put them in one nursing home as opposed to the other. Some are kind of entry-level, lower acuity, more family-friendly, apartment-type situations, and others are high acuity, almost sub-acute hospitals, so giving people just flat-out information that all facilities are the same is not fair, so I think in all these sectors the key ingredient is not the people are afraid of information. In some cases that may scare some people, but the real issue is fairness, and I do not think we are going to put out any measurement until we are sure it is fair. That is what we are working on.

I think the dialysis information is fair. It has been well-received in that industry because it is fair, and the information on our web site is fair, and I think that is the struggle. If the Government is going to put out information that is going to move consumers to make different choices, which is what the goal is, it has got to be perceived to be fair or we are going to have a big problem on our hands, and a lot of people—I think 10, 12 years ago, someone you know, Bill Roper, who was then the HCFA administrator, who is a good friend of mine, put out mortality data in hospitals, and that maybe is not a fair measurement of what is going on in the hospital, and it caused an explosion, and so my goal is to put out information, but only when it is ready to be put out, so that it will be perceived to be fair.

Senator WYDEN. I think that is a thoughtful answer. You are talking about jump-starting these comprehensive changes, and clearly, it has to be tied to standardization, which, of course, is part of HIPAA. Do you see any reason why, after a relatively short period of time, you could not have, as I suggested, all of the claims in this country submitted, captured, adjudicated, and paid within a short period of time?

Mr. SCULLY. I do not think so. I think, as you know, Mr. Chairman, I also recently dropped off the board of a big managed care company, too, so I learned a fair amount about managed care claims, and I went through some ups and downs with Oxford, and I think it is possible to do that. I think the adjudication is much more difficult, but to get clean claims paid more quickly, that is obviously the goal of HIPAA.

If you have all hospitals and physicians and providers submitting the same claims data, there is no reason why, in Virginia, for instance, that Aetna and Trigon and Cigna and whoever else are paying claims in Richmond, the claims may be different, but the forms could be constant, and that is going to speed up the process for providers as well, so that is what the goal of HIPAA is, and I think that will be a step in the right direction.

But certainly it is technologically possible. I think the claims process in the appeals is a little more delicate.

Senator WYDEN. One of the reasons that I am interested in this is that I have been told that less than 50 percent of claims in the private sector are now being paid electronically. It seems to me that if you make those kinds of changes using Internet technology system-wide, you really do have a chance, as you are trying to do, to jump-start comprehensive reforms. I think it would solve a lot of problems. It puts everybody on the same footing so that you eliminate these perverse penalties against people who do pay claims promptly. However, I am willing, frankly, to say, let us make an exception to this if you notify a provider or a patient. It seems to me that in the Internet age you ought to be able to get through this process quickly, and that the exercise of getting claims paid should not be bureaucratic water torture, as it has been for so many years.

I have a couple of other questions for you. As you know, in effect, the contractors, the insurance companies really drive much of the work of the Medicare program, and for the last 20 years your predecessors then at HCFA and now, of course, CMS, have talked about contractor reform, and suffice it to say there has been an awful lot of resistance to contractor reform. How do you see the contractors figuring into your agenda for a broader role for e-health, and also getting more information out?

In the past you have talked about people like Visa and American Express running some of these functions, and I am willing to look at those kinds of approaches. I think you are talking about putting more competitive juices into the system, and I think that is appropriate. I would like to hear from you about contractors and the broader e-health agenda, and how it figures into getting information out.

Mr. SCULLY. Well, we would love your help on that. I think it is a big piece of the health agenda, because again, when I first got to OMB in 1978–1979, we had 71 contractors. We were going to reform contractors and get it down to 15. When I came back 12 years later, we still had 51, so not much has changed.

Part of it is an accident of history. When the program was invented in 1965, it was a compromise between the AMA and the AHA and hospital groups, and that is why we have part A and part B, and it was a delicately crafted balance, and it has worked pretty well.

Basically, what you had in most States until recent years was the Blue Cross plans with a couple of exceptions, Mutual of Omaha, basically, with the local contractors or carriers who were fiscal intermediaries. They have become somewhat less interested in being in the program, and for the purposes of us having greater efficiency, we want to get it down from 51 cooperatively over the next 4 or 5 years to about 18 to 20. We think that is about the right number, and so we are encouraging the people who do not want to be in the program to get out.

For years if you were a Blue Cross plan it was kind of a requirement, kind of emotionally almost to be the contractor in your State. More and more have dropped out. North Carolina Blue Cross dropped out about a month and a half ago. We are not necessarily discouraging that. We want to find people who want to be partners with the Federal Government running this program. We want to

consolidate the systems. We want to find the people that are best at running these programs and work with them, and we think 18 to 20 is the right number.

Every State has part A and part B contractors, which does not make much sense, in some cases the same Blue Cross plans, but even if you just combine part A and part B, you would end up with 30 contractors right now, so you want to start with that basic number and whittle them down.

One of the things that I think is completely inane about the Medicare contracting system is their cost-plus contracts, and I mean, cost contracts are in my opinion a joke. I have not found any place in the world where cost contracts work. We used to have cost-plus Medicare, and hospitals piled everything in the cost base.

Once we went to the DRG's, which is basically a capitated system, the system was much more efficient by all measures, and so one of our goals is to find the best contractors and give them a set of cost-plus contracts, give them basically an incentive to make a reasonable margin, become long-term, good, reliable Government contracting partners, and then make it a more stable Government contracting business.

So we really want to find people that we think are really good at this program, that are committed to it, that want to provide good services, that will make it a lot easier for us to come up with common systems to make the claims processing even more streamlined, and to give the patients better information, and that is our goal.

Senator WYDEN. Could you see using electronic efficiency as one of the measures to run one of these contracts in the future?

Mr. SCULLY. Yes. Right now we have a very limited ability We have no ability to move basically the prime contractor for part A is the national Blue Cross-Blue Shield Association. That is a very awkward relationship. They are great people. I work with them every day, and generally when we have a problem we can move it around, but it is a very artificial construct, and we are pushing to reform it, and the difference between the last 20 years and this year is that normally at least in my 4 years in the prior Bush administration this was usually about priority number 15 in OMB and about number 20 with the Secretary, and it never got the attention.

One of the good things about Secretary Thompson is, before he got confirmed, he spent a week with me up at the then HCFA in Baltimore, and the one thing that stunned him the most was our contracting system. This is very high up on his agenda, so he is going to push for it very hard. As you know, he talks about it all the time. He thinks the fact that the contracts are not—and I think the Blue Cross program is very cooperative.

Look, we do not want to throw anybody out of the program. We want to actually fund people who want to be in this program, work with you to get it down to the people who are going to look at this as a core business opportunity, and end up with a more efficient program in 4 or 5 years. We are not interested in publicly executing Blue Cross plans State by State. We want to work with them on a friendly basis, and so far the Blue Cross plans have been very receptive to that, and we want to find the people that want

to be partners in the long term and work with them to make it a good business opportunity for them.

Senator WYDEN. Let me ask you about a couple of other barriers. Obviously, the majority of medical encounters in this country, the vast bulk of instances where people come in contact with medical providers, are physician office-based. However, the most complicated and expensive of all of the encounters, bypass surgery, involves not just a physician's office, but the in-patient facility where the surgery occurs, out-patient rehab facility following the surgery, and the patient's community pharmacy. Information just flows on both ends of the system.

Unfortunately, there is not a coordination of the information systems, things like scheduling, and various other kinds of processes, because of the referral and kick-back laws. Do you think that that is an area that ought to be looked at in terms of the e-health agenda? Certainly it would be contentious, but in terms of sharing information so as to schedule and simplify the administrative processes, you have got to link these two, and you should not say every time you link the two, that it is a violation of the antireferral principles and the kick-back laws.

Mr. SCULLY. That is a pretty complex question, but I am glad that the Senator can ask that. I do not really want the Justice Department to visit my home tonight, so I am not sure I should answer that one. I am just kidding.

Senator WYDEN. Pete Stark will call first.

[Laughter.]

Mr. SCULLY. I think it is something we should look at, and clearly the information transfer, and one of the benefits, as you know, one of the reasons Medicare Plus Choice and Medicare capitated contracts are popular is because that kind of information flow can work back and forth.

One of my concerns about Medicare, one of three biggest flaws in Medicare, which I am going to hopefully try to get to some demonstration projects this fall is that Medicare Plus Choice really, right now, with the exception of one plan in Philadelphia, there is one PPO in Philadelphia, is a Medicare closed panel HMO option, so you either have the Government run a fee-for-service program, or you have got a closed panel HMO where you have a restricted network.

There is one PPO in the country that I am aware of, Sterling, which is a fee-for-service plan as well, but generally what is most popular, whether it is in Oregon or Virginia, are these point-of-service contracts and point-of-service plans which are hybrids, or closed networks if you want to save, if you want to have a low fee payment deductible, but if you have colon cancer and you want to get a specialist, you can go and pay a little more.

That is really what is exploding in the under-65 market, and that is what people want, and that choice does not exist in Medicare, and the benefit to that is, when you have that kind of information, you get a little bit of more—when you are in one network like that you do share more information. There is more information moving back and forth within contracted providers, but it also gives people the freedom to choose, which is what is lacking in Medicare, and one of the reasons why Medicare's private sector health plan

has not gone very well, because it lacks the flexibility that people are demanding in the under-65 market.

I think as you give them that direction, we get more Medicare point-of-service contracts and PPO's, you will get a little bit of that flexibility people want, but you will still have much more of the information-sharing and the ability to track patients, monitor what they are doing, and coordinate care a lot better.

Senator WYDEN. I understand both the VA and the Kaiser system have figured out a way of putting together an integrated electronic medical record system which has not gotten them afoul of the kick-back and the referral laws. I hope that you will look at that, because it is something that I have heard from a number of providers and scholars that have worked in the area.

One of the other areas I mentioned in my opening statement was the idea of a private sector-led e-health certification program, with the idea being that because there are so many web sites out there now, getting out so much information, suffice it to say some of it is not up to the kind of quality it ought to be.

If you all go forward with this initiative in terms of getting out information on quality and price, it seems to me that would dovetail very nicely with the kind of e-health certification program where you could cooperate with the private sector to help the sites ensure that people knew where they could get quality information. What would be your thoughts on that?

Mr. SCULLY. Well, I am always a little hesitant to get into regulating health care sites, but I do think——

Senator WYDEN. I am not talking about regulating sites at all. I am talking about the private sector going forward with an e-health certification program, and you all helping them in their work, because you are getting out information on outcomes and price.

Mr. SCULLY. To be honest with you, Mr. Chairman, I have not thought it through, but I do think the concept is obviously a good idea, and just looking through for today, I did not get into it, because I did not have enough time, but there are a lot of great web sites out there, and I have started asking the staff, most of the good managed care plans have web sites, or nurse call-in lines, where I deal with my kids. When my kids get sick, I check the web to find out, before I take them to the doctor, if there are any indications of what the problem is.

Now, not everybody is going to do that, but certainly information we have out there that something should be viable, we do not do it in Medicare, but Web MD has a basic site. The Navy has a terrific site for people in the Navy to check for kind of a quasi self-diagnosis, but there is a lot of great information out there, and I think finding a way to target what is best, the most useful for consumers, is a great idea.

Some of these things we have actually talked about tying into our web site. We have not gotten there yet, but we have talked about what quality web sites would be good referrals for the Medicare.gov web site. That is a dicey thing to get into when you are sort of certifying products, but I have not really thought it through.

Obviously, there is a lot of information out there. The one thing we do want to make sure is, make sure the patients and consumers have access to it.

Senator WYDEN. One of the other concerns I hear from doctors is that it is hard to get understandable, straightforward information about Medicare and Medicare changes to them in a way that is usable. How do you see your e-health initiative, and your initiatives in terms of getting information out, helping to assist doctors, making it more convenient for them to learn about these issues?

Mr. SCULLY. One thing we have already done, and that is being a hospital person up until 7 weeks ago I was on the other side of this, is the perception—I do not think it is a fair one—that there was the strafing runs from CMS that we just pump out information in regs all the time.

We have already announced, the Secretary announced a month ago, right after I came in, that we basically are going to put out a quarterly compendium of all the regulations, so for instance, for the last quarter we put out a compendium that lists everything we put out as far as program notices and regulations, and if it is not out there as a compendium for the last quarter of the year, it is not going to come out, so you will see it coming, and then once a month on the same day, starting in the fourth quarter, we are going to put out regulations. Everything coming out of CMS is going to come out one day a month.

So the benefit of that, among many others, is that as a former lawyer—I would not even tell you how much they had to pay me an hour, but at Patton Boggs there are an awful lot of lawyers out there cruising through the Federal Register looking for new regulations and other things coming out of CMS, and out of the Government. I have been trying to tell our staff that, hey, look, have the information come out more regularly and more predictably, so that physicians, hospitals, nursing home administrators can know it is coming out. It is valuable to the outside world.

So we are going to start doing that in the fourth quarter, which is a quarterly compendium of everything coming out of the agency. You get it once a month, and if it does not come out on those days, it will not be coming.

Senator WYDEN. I have been asking you about what I think are some of the barriers to e-health, because this is what I have heard from practitioners in the field. If we reversed, where we are on the dias and at the witness table, what would you say are the biggest barriers at this point to e-health in this country? What would be, in your view, the biggest barriers to expanded use of e-health?

Mr. SCULLY. Well, first of all, that switch would be a very bad thing for the people in Oregon.

[Laughter.]

Mr. SCULLY. You know, I think the problem is, it is a great benefit for people and for patients. We have an incredibly diverse health care system with an unbelievably creative and diverse group of providers, but the problem is, like any other sector in the country it is so balkanized and so diverse it is hard to come up with standards, and obviously, every time you come up with a standard, as you said with HIPAA, it is going to cause problems for people. It is going to cost money, and so for instance, in Northern Virginia,

the biggest entity is Inova, but they still have many other market competitors.

I am not encouraging that much consolidation, but I am saying there are a lot of different entities that are not big corporations generally running health care, and the biggest of corporations have a fraction of the market share in health care.

You have got whatever, 75 different Blue Cross plans. The biggest hospital chain probably has 200 hospitals out of 6,000. It is just a very diversified provider network, which is terrific, but it leads to a lot of different standards, and it lends itself to a lot of creativity, but not so much as far as standardization.

Senator WYDEN. So you would put standardization as probably the single biggest barrier, as of today?

Mr. SCULLY. Yes, because I think change is difficult, and understandably. You can see the problems we have going on with HIPAA. When you change—I mean, I can just give you example of stuff. When people say we are ready for HIPAA, I went over and spent the day at Greater Southeast Hospital in Anacostia about 3 months ago, and they are doing a great job of trying to revitalize that hospital, but they have paper records everywhere, and you tell them to stop everything they are doing and turn that hospital around and go back to making sure they computerize all the paper records in the next 2 years, that is a number 1 fiscal priority for that hospital? Probably not.

I mean, it is a very low income neighborhood, and it is a very challenged hospital, and for them to go out and say, let us stop everything else and make sure we are HIPAA compliant—that is the balance you have. It is tough.

Senator WYDEN. What is striking about this, though, is that experts tell me that handling medical claims ought to be like using Amazon.com. There are likely more book titles on line now than there are medical procedures. I think what you are doing is extraordinarily important, and we are going to help you in any way, and, obviously, we are going to learn as we go.

I was working on this yesterday, and talked to some scholars in the field. They were arguing, and said as you get price information out to the public it actually might bid up the cost of health care, because everybody is going to want to go out and buy the very best. But I am on the side of markets, and I know Senator Allen is as well, and suffice it to say, the question of health care data and quality is not the most sensationalistic subject around. But I think it is of extraordinary importance, and I really want to wrap up this afternoon by commending you. I think this is an initiative that is going to pay very big dividends in the years ahead.

Anything you would like to add further?

Mr. SCULLY. Well, just one thing to note that I did not mention, which I forgot, you and I have discussed the President's drug discount card, and I do not want to get into the merits of that here, but the biggest behavioral driver of that is starting next year we are going to publish publicly the prices of all the participating PBM's, and people are starved for information.

When you find seniors who are very active in pursuing the best deals for their own health care costs, they are going to go on the web and see what the various prices of drugs are, that is going to

have a big impact in the world, and I think people are starved for information. There is no reason not to give it to them.

Senator WYDEN. Tell us how that would work. Let us take Coos Bay, Oregon, or Arlington, Virginia. If you are a senior who is 68-years old and paying $300 or $400 a month for your medicine, and you would like to lower the cost of your medicine, how would your initiative help that person in Coos Bay, Oregon, or Arlington, Virginia?

Mr. SCULLY. Well, first I would say we definitely do not want to oversell this. This is not the solution to every senior's drug problem There are many different forms of this proposal. Senator Hagel had a bill last year. This proposal actually has been sitting around HCFA for a long time. It is a staff proposal.

I would say the importance of this proposal is that every drug reform bill, whether it is Senator Graham's, Senator Daschle's, Congressman Thomas', this is a big component of all of them. Our actuaries tell us from 35 to 70 percent of the savings of every one of these drug proposals comes from consolidating market share, so our view is, why wait, because all of these bills, the subsidy value, whatever Congress decides to spend, you have got $300 billion in your budget resolution on a Medicare prescription drug subsidy. We can debate the subsidies. The administration cannot do that. You have to spend the money.

But the structure of giving seniors market power can be done now. The only people in the world to walk into an Alexandria, Virginia pharmacy and pay over-the-counter prices are seniors and the uninsured. Seniors pay retail drug prices, 14 million of them. 10 million do not have insurance coverage, and 4 million have Medigap, which includes—the two Medigap plans do not include any basic negotiation, so what we are trying to do, basically, is consolidate people into purchasing networks.

Right now, a lot of seniors get discount cards, but they generally have a wallet full of them. They'll have a Walgreen's one, and they will have an AARP one, and they will have five or six others, so none of them can really consolidate market power, because let us say you are the AARP, and you walk into Pfizer and say, I have got 3 million seniors signed up. I would like to negotiate a discount, and Pfizer says,well, you know what, those 3 million seniors all have nine discount cards each. There is no way to prove you have market power to move market share.

We believe by using the good name of Medicare, and we are going to use our 1-800 number where if you call up, starting this fall, in Coos Bay, and you say, I heard about the Medicare drug discount card, what can I do, the operator will say, there are four of them available in Coos Bay, which would you like, and we will transfer you to one, and you will be enrolled in that. You will only be able to get one. You will only be able to switch every 6 months.

Senator WYDEN. Let us stop right there, because this is helpful, and I want to walk exactly through it.

So the senior gets on the phone, on the 800 number, and they say, for example, there are four programs. Will the person tell the senior at that point what the various prices are for coverage?

Mr. SCULLY. Yes. The maximum is $25 one-time enrollment. We believe that it will quickly be zero, and we know of one company

that will immediately—Caremark has already told us that they will charge zero. Some of the companies that want to participate were concerned they could not get the startup cost if they did not have a one-time enrollment fee, so we allowed up to $25. It is very possible, and I believe if the senior calls up 1-800-Medicare, and they say one is $20 and another is zero, an awful lot of people are going to go for the zero.

Senator WYDEN. But the senior will not be able, at that point, to ask for a comparison on particular drugs. Say the person who paid $400 a month for their medicine, the biggest share of it, $250, was for extra. At that point, what they would be told is there are four programs that would get a discount that are part of the discount card, but they still have to shop around to see if they could get it for $400 or $325 or $280 or something.

Mr. SCULLY. The one thing is, no senior is worse off. After the end of the first year, the benefit of being on the web is the senior taking Lipitor, for instance, which I take, might say, look, Express Scrips have negotiated a great deal with Lipitor, I an going to sign up with them, or Caremark has negotiated a terrific deal with Prevacol. I will sign up with them. The goal is to move market share.

Right now, seniors just pay over-the-counter prices for everything. We do not believe this is going to solve all of their problems, but if you are paying $200 a month for a drug and you now are going to pay $160, that is a lot better than you have now. We do not want to oversell, because it is not like an insurance plan here you are walking in and paying $10 for a copayment. All it is going to do is give them the bulk purchasing power to lower their existing costs. It is not going to solve all the problems, but certainly it will save money quite a bit.

Senator WYDEN. How do we get to the day, because this is really what seniors have been asking me about for years, where they, in their particular town or State, can find out that Lipitor over here costs X amount, and Lipitor over here is $40 less, and Lipitor over here is $80 less? Is there any way that sometime soon we could put that online?

Mr. SCULLY. Our expectation is PBM's will have that online January 1, 2003. That is one of the goals of this program. If you look, there was an article in the Washington Post last week where they talked about somebody going to buy Lipitor at four different drug stores as a senior, and they had basically a 200-percent variation in price within a mile of each other, and that is the kind of thing that seniors have to deal with, and a lot of people do not.

In fact, I went through this discussion with some members of the Finance Committee the other day, and they said, "Well, we do not get discounts now." I asked them all to dig out their cards, and the FEHBP Blue Cross card, which I have on the bottom, says PCS.

They already have a negotiated drug discount. Every Member of Congress does. All federal employees do, almost everybody—I can tell you from Oxford almost everybody in a private health plan, almost every major health plan in the country already contracts with one of these people to negotiate bulk discounts on drugs Seniors do not get that, and they are really the only people in the country, outside the uninsured, who do not. It is crazy.

So the fundamental idea of this is to pool seniors in the purchasing groups to get those discounts now, and then we can go on to discuss in Congress hopefully about what are the appropriate levels of subsidy, and for whom, during the course of the fall.

Senator WYDEN. So in January of 2003, at least for the PBM's, or the big buyers in a community, it will be possible for seniors to comparison shop for individual medicines?

Mr. SCULLY. It is a requirement to participate in this program as of January 2003. We are actually going to publish discounts off the AWP, average wholesale price, this year, but as you know that is frequently a meaningless number. They are actually going to have to publish their real prices, starting in a year, and they have all said they will do that, and we expect a number of the drug store chains will probably have a plan. We hope that Epic, which is the small drug stores, will probably have a plan.

Senator WYDEN. I think the initiative will dovetail very well with the Snowe-Wyden and prescription drug legislation, the bipartisan prescription drug legislation.

Senator Allen, do you have any further questions?

Senator ALLEN. I have no further questions. I have enjoyed listening to yours and listening to your comments in answering the Chairman's questions.

As Ranking Member, I like to look at the folks that the President selected, and I will tell you, Mr. Scully, the President and Secretary Thompson have really picked a person who is great. Not only are you articulate, but best of all is your experience and your knowledge and your background in the private sector, and bringing those consumer-driven, market-oriented competitive juices from the private sector to your position now with CMS is great.

I would only suggest to you, remember, when you are implementing these standards, make sure the cost of putting in these standards and whatever these requirements are, make sure the costs are much less than the value to the customers, and for the actual service, and I am sure you will.

Thank you for coming back into service.

Senator WYDEN. What I think is helpful about the way you are approaching it, Mr. Scully, is that e-health can only work at its optimal level if you have the best and most current data. You, in effect, are making it clear that you want to get better data out to people, and that will be the fuel that is needed to run any health program that best serves the public. We look forward to working with you. Unless you have anything further you would like to add, we will excuse you at this time.

Mr. SCULLY. Thanks.

Senator WYDEN. Thank you.

Our next panel, Dr. Sherrilynne Fuller, Dr. John Kenagy, Dr. Willie May, and Mr. Albert Patterson, if you would come forward.

We are happy to welcome all of you. Why don't we begin with you, Dr. Fuller.

STATEMENT OF DR. SHERRILYNNE S. FULLER, HEAD, DIVISION OF BIOMEDICAL INFORMATICS, PROFESSOR, DEPARTMENT OF MEDICAL EDUCATION, UNIVERSITY OF WASHINGTON SCHOOL OF MEDICINE

Dr. FULLER. Good afternoon. I want to thank you, Chairman Wyden and Ranking Member Allen and the members of the Subcommittee, for inviting me to participate today. Improving quality and cost-effectiveness of health care for our Nation's 270 million citizens is one of the great challenges of our time, and I am very pleased to be able to participate in this discussion, particularly as a member of the Pacific Northwest contingent, and I want to first give a little background.

I am here as a representative of the President's Information Technology Advisory Committee, or PITAC, as it is familiarly known, and I am the cochair of the PITAC panel on transforming health care. You should all have copies of the report we issued in February of this year.

PITAC is a group of 24 information technology leaders in industry and academe. Our charge is to provide independent guidance to the President on maintaining U.S. leadership in high performance computing, networking, and information technology research and development.

In February 1999, PITAC issued a major report on the status of information technology research and development, and that is the maroon document we have provided to you. In that report, we describe 10 major areas of our national life, including health care, in which information technology can have a transforming effect to benefit all Americans.

As a followup to that report PITAC established a number of panels to conduct a more targeted analysis of the barriers and challenges in implementing information technology. My cochair on the panel was my friend and colleague, Dr. Ted Shortliffe, I know also a friend of Chairman Wyden's, professor and chair of the Department of Medical Informatics at the College of Physicians and Surgeons at Columbia University.

He has been very interested in the federal role in health information technology for years, as I have been. We have provided you with his recent paper from Health Affairs, in which he gives an historical context while identifying problems and some potential solutions.

Our panel reviewed the literature and consulted widely with federal and private sector experts in developing our findings and our report. Because the focus of the hearing today is information technology and how it can empower health care consumers, I want to read you a part of our panel's patient- and consumer-centric vision of better health care.

> "Telemedicine applications are commonplace. Specialists use videoconferencing and telesensing methods to interview and even to examine patients who may be hundreds of miles away. Patients are empowered in making decisions about their own care through new models of interaction with our physicians, and ever-increasing access to biomedical information via digital medical libraries and the Internet. New communications and monitoring technologies support treatment of patients comfortably in their own homes."

That is especially important with an aging population.

What must be done, then, to harness the enormous potential of information technology to empower health care consumers and maximize effectiveness of providers and services? Our panel concluded that we have a very long way to go. Critical long-term research, technology and policy issues stand between us and the consumer-centric health care that PITAC describes.

As a Nation, we simply do not have a broadly disseminated national vision of how information technology can enable improved healthcare and more cost-effective systems. Given the fragmented nature of our health care system, it is perhaps not surprising that provider organizations and others in the health care industry have not come together with a coordinated ensured model of what is required, and I think the previous hour's testimony documents that very, very clearly.

More surprising, however, is a lack of federal leadership, particularly health and human services, in bringing the community together, convening, guiding, educating, demonstrating, and ensuring the strategic role that information technology can play.

Currently, information technology is applied on a piecemeal basis in public health, medical research, and delivery of health care services throughout the United States and throughout the Federal Government. We have evidence, and this has been noted earlier, that computer-based records can substantially improve patient care outcomes and cost, but provider organizations lack information about the efficiency of IT solutions in terms of both cost and quality, so it is very difficult for them to make appropriate decisions about IT investments.

There is a real problem of incentives in this regard. We do not have a reimbursement strategy in place to encourage greater investment by health care organizations in advanced technologies, and an industry that is already financially stressed has difficulty justifying speculative technology investments in the absence of fiscal incentives and strong supporting data.

In medical research, information technology is typically viewed as a tool that researchers may use for very specific disease research process, but the result of that researcher-by-researcher approach, and using, by the way, often off-the-shelf software, is redundant effort and very slow adoption of cutting-edge technologies, plus a failure to recognize that the IT, in and of itself, is a vital and challenging area for biomedical research.

The human genome was decoded this year not by individual researchers working on desktop computers but by teams of researchers who have access to some of the world's fastest supercomputers capable of storing and analyzing vast data sets of genetic information. The researchers noted that advanced IT systems accelerated the decoding by as much as a decade.

That is a wonderful success story, and we continue to generate enormous amounts of raw data in clinical trials from bench research, but making sense of that raw data in the context of previously published research requires sophisticated information retrieval and management approaches not yet invented.

The recent death of a healthy volunteer in an asthma clinical trial, for instance, can be traced to inadequate review of the historical literature regarding documented fatal reactions to a drug. In

spite of the impressive data bases from the National Library of Medicine, vital information is still not at our finger tips. We need better user interfaces, more reliable software and systems, and more accessible high quality knowledge repositories for use in patient care.

Human life maybe at risk if, for example, information sent to medical monitoring or dosage equipment is corrupted, or if electronic mail records cannot be accessed in a timely, reliable fashion. We need to develop integrated decision support systems that can proactively foster best practices in clinical decisionmaking. Such systems require advanced information technology methods and tools that do not exist today.

A couple of examples. Automated reminders to clinicians and patients. I currently get regular reminders to follow up with my dog and my cat's care, immunization and checkups. I do not get them on myself or my daughter. A second example, rapid alerts to clinicians and patients regarding abnormal lab findings can speed up treatments, but the software to deliver that functionality is not available in most hospitals today.

I should note here that our PITAC health care report points to a significant workforce issue, limiting the research progress toward a more consumer-focused health care system through information technology. Only a tiny group of practitioners and researchers today can operate at the nexus of medicine and IT. We urgently need to expand the cadre of professionals who have expertise in both fields, and who can develop, deploy, and manage the technologies needed by the health care sector.

So looking at these problems, and what should we do about them, overall our report argues that the Nation must invest in research and development focused on realizing the potential of information technology to support 21st Century patient-centered health care. Just as we currently focus on research findings in medicine to help us prevent, treat, and cure human diseases, we recommend that the Department of Health and Human Services take the lead in this effort. We recommend that enabling technology centers be established, and large-scale research programs to study and develop practical uses of information technology in health care systems and biomedical research.

Instead of jumping to solutions, we need to be sure we have the facts and the research findings to provide the evidence that this, indeed, is a correct solution to the problem. That funding is currently not available. We currently have a patchwork and piecemeal approach to implementing technology, most of which was not designed for the life and death issues of patient care, or the scale and demands of complex information systems.

Enabling technology centers could build on the very good program models of the National Institutes of Health's National Library of Medicine, the integrated academic systems and telemedicine grant programs, both of which the States represented by Senators Wyden and Allen have benefited from, as has my own State of Washington and many others. But right now those kinds of broad, large-scale, long-term programs are simply not being funded. It is very much a project-oriented approach to funding, if funding is even available for IT research in health care.

We believe these enabling technology centers would provide a resource for developing the dual-trained workforce I mentioned earlier, and would also bring together researchers, clinicians, most importantly, patients, providers, industry, and Government stakeholders to solve these problems.

Some of the important unanswered questions, and some of these have been alluded to already today, involve the use of telemedicine for consultation. Studies, including studies I have been involved in, have repeatedly shown very high levels of satisfaction among rural patients, their primary care providers, and specialists. In spite of this positive response, the approach is not yet in general use.

Many limiting factors have been identified, including cost, rural connectivity, clinical efficacy, and regulatory issues. However, adequate funding of studies over long periods of time could permit the development of approaches to solving these and many other problems. Use of provider-patient e-mail is a potentially cost-effective approach, but is it clinically effective? Is it cost-effective? Does it reduce patient visits? Does it improve patient satisfaction? We simply do not have the research data on a large scale to respond to those kinds of questions.

We have heard a fair amount about the use of the Web to obtain health information. Increasingly, patients and providers look for information on the Web. We know that, but they encounter a bewildering quantity of information of variable quality. We need to study the types of questions patients and clinicians are seeking answers to, where they are looking, and develop strategies for helping them to find accurate answers.

A particular problem I might note based on my own work with Native American tribes that needs further study is that much of the available health information on the Web does not address the needs of minority populations. We need to look at how we can respond to those issues.

Use of IT to prevent medical errors. That seems like an obvious area in an approach to preventing medical errors, but there are many research issues involved in doing this, and we need to be able to answer questions about how to do this in a cost-effective way, in a way that benefits the health care team, and that does not slow down the processes of health care.

IT offers many solutions to these problems, but such solutions require not only organizational commitment and effective demonstrations, but fundamental research in biomedical computing, human cognition, and telecommunications. PITAC strongly believes that information technologies hold the potential to dramatically improve the U.S. health care system, but we need a national commitment to do the research. It will take to develop an array of 21st Century patient applications of information technologies.

Thank you very much for inviting my participation.

[The prepared statement of Dr. Fuller follows:]

PREPARED STATEMENT OF SHERRILYNNE S. FULLER, HEAD, DIVISION OF BIOMEDICAL INFORMATICS, PROFESSOR, DEPARTMENT OF MEDICAL EDUCATION, UNIVERSITY OF WASHINGTON SCHOOL OF MEDICINE

Good afternoon. I want to thank Chairman Wyden, Ranking Member Allen, and the members of the Subcommittee for the opportunity to be here today. Improving the quality and cost-effectiveness of health care for our Nation's more than 270 mil-

lion citizens is one of the great challenges of our time, so I am pleased to be able to join in this discussion.

BACKGROUND

I am here as a representative of the President's Information Technology Advisory Committee, or PITAC, and the co-chair of PITAC's Panel on Transforming Health Care. The PITAC is a group of 22 information technology leaders in industry, research, and academe whose charge is to provide independent guidance to the President on maintaining U.S. leadership in high performance computing, networking, and information technology research and development. In February 1999, PITAC issued "Information Technology Research: Investing in Our Future," a major report on the status of information technology research and development. In that report, we described 10 major areas of our national life—including health care—in which information technology could have a transforming impact that will benefit all Americans.

As a followup to that initial report, PITAC established a number of Committee panels to conduct more targeted analyses of the information technology barriers and opportunities in specific transformational challenge areas. To date, PITAC has issued panel reports on "Transforming Access to Government Through Information Technology" (September 2000); "Developing Open Source Software To Advance High End Computing" (October 2000); and "Digital Libraries: Universal Access to Human Knowledge"; "Using Information Technology To Transform the Way We Learn"; and "Transforming Health Care Through Information Technology" (all in February 2001). My co-chair on PITAC's Panel on Transforming Health Care was Dr. Ted Shortliffe, professor and chair of the Department of Medical Informatics at the College of Physicians and Surgeons, Columbia University, who has been particularly interested for several years in the Federal role in health care information technology. The Panel reviewed the current literature and consulted widely with Federal and private-sector experts over the course of a year in developing the findings and recommendations of our report.

PITAC TRANSFORMING HEALTH CARE REPORT

Our panel concluded that information technology offers the potential to expand access to health care significantly, to improve its quality, to reduce its costs, and to transform the conduct of biomedical research. The quality of U.S. health care and medical research are the envy of the world, but U.S. health care costs as a percentage of gross domestic product are among the highest in the world and are increasing despite recent changes in health care organization and financing. Further, a recent report from the Institute of Medicine (IOM), "To Err is Human," points out that despite our favorable reputation for especially complex care management, our health care system is not nearly as safe as it could be. The report argues that significant improvements in care would be possible if modern clinical information systems were widely implemented and a sound national health information infrastructure were in place.

Because the focus of this hearing is how information technology can empower health care consumers, I want to read you part of our Panel's patient- and consumer-centric vision of better health care enabled by information technology:

"Telemedicine applications are commonplace. Specialists use videoconferencing and telesensing methods to interview and even to examine patients who may be hundreds of miles away. . . . Patients are empowered in making decisions about their own care through new models of interaction with their physicians and ever-increasing access to biomedical information via digital medical libraries and the Internet. New communications and monitoring technologies support treatment of patients comfortably from their own homes."

The health sector will experience unprecedented change as it begins to take advantage of information technologies to increase productivity and to improve the quality of care in the ways the PITAC panel envisions. While new technologies can provide great opportunities for advances, key challenges exist to realizing the potential benefits to Americans' health and health care. The Panel made the following findings about these challenges:

1. The U.S. lacks a broadly disseminated and accepted national vision for information technology in health care.

Health care organizations are not well prepared to adopt information technology and applications effectively. Health care is largely a decentralized industry populated by diverse organizations with different motives, resources, and incentives. Fiscal constraints hinder the industry's ability to make major investments in information infrastructure and applications unless these investments can be shown to lead

to significant and low-risk returns. Provider organizations lack information about the efficiency of information technology solutions in terms of both cost and quality, making it difficult for them to make decisions about information technology investments. We now have sufficient evidence to state that computer-based patient records can substantially improve patient care, outcomes, and costs. Yet to date we do not have the national commitment to assure that Americans will reap the benefits of this technology.

2. Critical, long-term research, technology, and policy issues need to be addressed if we are to realize the potential of information technology to improve the practice of health care.

While significant advances in information technology have been achieved, many hard problems remain. For example, user interfaces that are easier to use and more easily integrated into the ergonomic patterns of health care can catalyze greater acceptance and use of innovative computer-based tools in medicine. Robotics and remote visualization methods supported by high-reliability and low-latency communications are needed to enable applications such as telepresence surgery. Reliability of systems and software is critical for many health care applications. Human life may be at risk if information sent to medical monitoring or dosage equipment is corrupted or degraded, or if electronic medical records cannot be accessed in a timely, reliable way.

Knowledge repositories are also an important research topic, including techniques for integrating data from multiple sources. Stronger forms of authentication are needed, both for persons accessing data and for assuring the integrity of the information. Methods are needed to protect patients' privacy while allowing valuable medical research and necessary reimbursement tasks to be performed. Better access-control methods would make it possible to partition and isolate the data elements as needed to protect patient privacy. Improvements in computational capability are therefore essential, including faster processing and more networked resources to meet the increased demands of modeling complex systems and performing information retrieval, data analysis, and automated inferencing.

From a policy perspective, perhaps the most significant problem is the lack of reimbursement for a range of applications that have demonstrated value, e.g., telemedicine, patient-provider interactions over the Internet, efforts to reduce medical errors, and initiatives that link a patient's data across provider organizations. We have sufficient evidence, for example, that computer-based patient records can substantially improve patient care, outcomes, and costs. But many provider organizations lack information about the efficiency of IT solutions in terms of both cost and quality, so it is difficult for them to make appropriate decisions about IT investments. (For a history and discussion of the health care community's role in networking, see Edward H. Shortliffe's article "Networking Health: Learning From Others, Taking the Lead," *Health Affairs*, November/December 2000, attached to this testimony.)

Further complicating matters is the fact that health care providers are currently licensed by individual states and are generally prohibited from providing care across state lines. This becomes a clear issue when a patient is in one state but the physician at the other end of a telemedicine link is in another. Liability claims are also handled at the state level, with considerable variation among states.

3. The introduction of integrated decision-support systems that can proactively foster best practices requires enhanced information technology methods and tools.

Decision-support tools can provide critical links between a current patient's condition and previous clinical studies. Existing systems largely focus on detecting errors at the source, through such methods as range checking, alerts, and reminders, or post-hoc quality monitoring and review. While these types of systems are vital components for improving quality of care, important information is often unavailable or inaccessible because it is spread across multiple information systems and/or organizations with differing systems. This can result in poor coordination of care and increased illness and mortality.

Scientists are generating enormous amounts of raw data from clinical trials as well as bench research. However, making sense of the raw data in the context of previously published research requires sophisticated information retrieval and management approaches not yet invented. For example, the recent death of a healthy volunteer in an asthma clinical trial can be traced to inadequate review of the historical literature regarding known, fatal reactions to a drug. In spite of the impressive National Library of Medicine databases, vital information is still not "at our fingertips." (See July 17, 2001, article from *The Baltimore Sun* attached to this testimony.)

Two examples of other technologies that could make a difference in patient care: automated reminders to clinicians and patients regarding treatments, followup vis-

its, and the like; and Rapid Alerts to clinicians and patients regarding abnormal lab findings. However, software that will deliver the power and functionality required for such time-critical communications is lacking in most hospitals today.

As a new report from the Robert Wood Johnson Foundation points out, "eHealth interventions have been shown to enhance social support and cognitive functioning; enhance learning efficiency; improve clinical decision-making and practice; reduce health services utilization; and lower health care costs among certain groups." However, the report goes on to note that "most assessments of eHealth interventions have been limited to small groups that may not be representative of the parent population, have not been randomized control trials, had limited follow-up periods or only assessed proprietary interventions that may or may not be replicable. . . . eHealth developers do not routinely conduct evaluations, especially post-market assessment for effectiveness. And when commercial companies and other private sector organizations DO conduct evaluations, the results are often not publicly available." (See Eng, T.R., "The eHealth Landscape: A Terrain Map of Emerging Information and Communication Technologies in Health and Health Care," The Robert Wood Johnson Foundation, 2001. Available at: www.rwjf.org.)

We cannot wait for industry to deliver solutions because we do not yet know all of the questions. What we need is a national commitment to do the research it will take to develop an array of 21st century patient-centric applications of information technology. The challenge of going beyond current methods to ones that proactively foster best practices will require a whole new generation of advanced technologies based on efforts in the following areas:
• Expanding the range and granularity of routinely captured data
• Standardizing terminology
• Developing robust techniques for incorporating new data types into existing clinical data repositories, e.g., images and patient genotype
• Organizing and collecting large-scale databases to determine best practices
• Developing guidelines based on such evidence
• Implementing guidelines so that they are usable effectively at the point of care, including embedded decision support that is continually updated as new evidence accumulates
• Reducing the cost and difficulty of integrating applications that reside on heterogeneous technologies

4. Achieving the potential of information technology to improve health care will be constrained until we develop a larger cadre of researchers and practitioners who operate at the nexus of health and computing/ communications.

In part, the missing national vision of information technology's key role in the U.S. health care system is due to a lack of critical investment by the biomedical community in computer infrastructure and enabling technologies. This issue becomes increasingly difficult to solve because the number of individuals who understand both the health care milieu and information technology is remarkably small. Yet, if we are to improve health care quality, increasing the number of trained professionals with biomedical information technology expertise is a critical need.

5. The biomedical community, including the Federal research agencies, has tended to rely on information technology innovations that are produced by investments in other parts of Government.

Although the quality of U.S. health care is increasingly dependent on the effective use of new and emerging information technologies, Federal health agencies have played a limited role in supporting research and development in computer science. Unfortunately, the health care and biomedical research communities have generally viewed information technology as a tool to enable health care applications and support biomedical research, rather than a critical research field. The Department of Health and Human Services (DHHS) has heavily leveraged information technology research and development investments made by other Federal agencies such as the Defense Advanced Research Projects Agency (DARPA), the Department of Energy (DOE), the National Aeronautics and Space Administration (NASA), and the National Science Foundation (NSF). While DARPA, DOE, NASA, NSF, and other Federal agencies consistently make significant investments in fundamental information technology research and development, their primary mission is not health care and therefore their priorities do not necessarily match the critical needs of health care research and education.

DHHS has failed to make vital investments in fundamental information technology research and development and, as a result, health care lags behind other sectors. If DHHS does not begin to make substantial investments in information technology research and development, two serious problems will arise. First, the pace at which biomedicine benefits from information technology research will be adversely affected. Second, the needs of the biomedical community will not be reflected

in the priorities of the other Federal agencies unless the biomedical community itself is involved in information technology research. Similarly, the biomedical research agencies must collaborate on an equal footing with the other Federal research agencies that have dominated information technology research in the past.

6. The role and management of information technology in the Department of Health and Human Services has several limitations, which must be addressed if the health care community is to benefit from the promise of the information age.

DHHS does not have a clear, strategic vision of the benefit that the department and all of its agencies could receive from information technology research and use of information technology tools. It is evident that the decentralized management approach of DHHS has adversely affected both the development of a coherent information technology vision and the influence of departmental activities regarding information technology and its role in health care and biomedical research. It is important to change this practice and ensure that DHHS has the necessary leadership and budget and a coordinated information technology effort across all its agencies. In our discussions with DHHS agencies, it became clear that they do not have a mandate or budget to support information technology research, even though it is fundamental to their mission.

Although the Administration and Congress have placed a high level of confidence in information technology's benefit to this country, DHHS is not perceived as a significant player in Federal information technology research or policy development. It is clear, however, that state-of-the-art research advances in any field require state-of-the-art investments aimed at solving problems, developing the technology, and building the right infrastructure.

PITAC'S RECOMMENDATIONS

Over all, our report argues that the Nation must invest in research and development focused on realizing the potential of information technology to support 21st century patient-centered health care, just as we are focusing on the potential of research findings in microbiology to help treat and cure human diseases. We believe that we cannot get where we need to go within the current patchwork, piecemeal implementations of technologies, most of which were not designed for the life-and-death issues of patient care or the scale and demands of health information systems.

1. The Federal government should establish pilot projects, Enabling Technology Centers, and large-scale research programs to extend practical uses of information technology to patient care, health care systems, and biomedical research.

The Enabling Technology Centers could build on the very good program models of the National Library of Medicine's integrated academic systems and telemedicine grant programs, which have supported the development of applications linking distributed organizations via networks and prototyping technologies for specific health care uses. (For examples of NLM advanced networking applications projects, see list attached to this testimony.) These Centers would serve as a resource for developing the dual-trained workforce in biomedical information technologies that we believe is critical for the future, and would also bring together researchers, clinicians, patients, providers, industry, and government stakeholders to solve health care-specific problems.

With regard to large-scale research projects, the Nation is making significant investments in disease-oriented studies. But there is very little funding to support large scale, long-term studies of information technology interventions with large populations—across disease types. DHHS's Agency for Healthcare Research Quality and the National Library of Medicine of the National Institutes of Health have funded most of the health IT research to date. And NLM has also led in building medicine's vital resource databases, including the PubMED and genome databases. However, the funding is inadequate to meet the depth and breadth of the problems. For example:

Use of provider/patient email—Is it clinically effective? Cost effective? Does it reduce patient visits? Improve patient satisfaction?

Telemedicine for consultations—Studies have repeatedly shown high levels of satisfaction with this approach among rural patients, their primary care providers and specialists. In spite of this apparently positive response, the approach not yet in general use. Many limiting factors have been identified, including cost of rural connectivity and regulatory issues. However, adequate research funding of studies over longer periods of time could provide the answers needed to solve these problems.

Remote-care applications that integrate sensor technologies and/or remote instrumentation to monitor patients—For example, a significant number of people who reside in nursing homes are there more for health "security" reasons than for heath

care "needs." Many residents in extended-care facilities could be cared for at home at significantly reduced costs if the appropriate telemedicine tools were available to enable remote monitoring. Additionally, many of the home-health visits conducted today are based on the need to observe or monitor a patient's status, a function that could be accomplished through interactive video systems coupled with the appropriate instrumentation and a simple-to-use interface.

Using the Web to obtain health information—Increasingly, patients (and providers) seek medical information on the Web. But they encounter a bewildering quantity of information of variable quality. We need to study the types of questions patients are seeking answers to and where are they looking, and develop strategies for helping them find answers. A particular problem based on my own work with Native American tribes is that much of the available health information on the Web does not adequately address the needs of minority populations. (See "Health Information on the Internet: Accessibility, Quality, and Readability in English and Spanish," Berland, JAMA, Volume 285(20), 23/30 May 2001. This empirical study found issues in both health content and search engine efficiency.)

FEDERAL LEADERSHIP

The following recommendations of PITAC's report flow from the Health Care Panel's view that the Federal government's key health-care agency, DHHS, must develop a much more active and visible leadership role in articulating, developing, and modeling information technology methods and systems for improving U.S. health care. We also urge that NIH and other Federal science agencies collaborate on an advanced infrastructure for the biomedical research community. And we ask the Congress to enhance existing rules on information privacy. These proposals are needed to spearhead the broad changes we are describing across the decentralized and diversified landscape of the Nation's health care sector.

2. NIH, in close collaboration with NSF, DARPA, and DOE, should design and deploy a scalable national computing and information infrastructure to support the biomedical research community. This infrastructure should include an aggressive biomedical computing capability similar to that of the Department of Energy National Nuclear Security Administration's (DOE/NNSA) Accelerated Strategic Computing program.

Computational biology and other biomedical problems require the fastest computing cycles and information processing capabilities achievable today. And as we seek to improve our knowledge of the human body, these computing requirements will grow exponentially. There should be a biomedical equivalent of the DOE/NNSA program to provide multi-teraops/teraflops computing capability to high-end users and to fund the development of improved algorithms and enabling technologies for terascale systems. Facilities with mid-level computers also should be made available for researchers to develop and test software before moving to large systems. These mid-level systems can also be used for developing new algorithms and applications for biological problems.

To enable this distributed, scalable computing environment, investments are needed in software to support grid technologies to permit dynamic allocation of computing and information processing capability across geographically distributed locations as needed. Long-term information storage and management of biomedical databases are also important computing infrastructure requirements. DHHS should work with the community to decide which databases are to be maintained, for how long, and by whom. DHHS also should provide the necessary funding to support the infrastructure needed to maintain the databases over the long term.

3. Congress should enhance existing privacy rules by enacting legislation that assures sound practices for managing personally identifiable health information of any kind.

Protections are needed that deal with unauthorized access and disclosure and that allow for appropriate access and amendment by patients. Governing the stewardship of and access to medical information is an important issue. Legislation should identify the national standards by which information can be shared, should permit electronic authentication of information, and should include sanctions/penalties for violations. Despite the recent announcement of privacy regulations in response to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), uncertainties can be dealt with convincingly only by a clear legislative mandate.

4. Establish programs to increase the pool of biomedical research and health care professionals with training at the intersection of health and information technology.

The Panel applauds the efforts of the NIH's Biomedical Information Science and Technology Initiative to establish National Programs of Excellence in Biomedical Computing to support learning at the interfaces among biology, mathematics, and

computation. Such programs can play a significant role in educating biomedical-computation researchers. DHHS should identify and nurture similar programs to provide training at the intersection of information technology and health care professionals. For new applications of information technology to health care to be envisioned, developed, and implemented, it will be necessary to build teams of health care application experts, biomedical researchers, and computer scientists. Such teams can build bridges among near-, mid-, and long-term R&D to help ensure rapid adoption of new technologies in the health care system. DHHS should explore other educational opportunities, such as expanding health informatics training programs and curricula within the schools of health professions and computer science departments.

5. DHHS should outline its vision for using information technology to improve health care in this country and subsequently devote the necessary resources to do the basic information technology research critical to accomplishing these goals in the long term.

DHHS should develop an agenda to remove the policy barriers that currently inhibit the use of information technology in support of health care. This might, for example, include the development of an expanded agenda at the Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration) to evaluate the impact of such technologies on care quality and costs and to provide reimbursement (or other incentives) should the impact prove to be socially valuable.

The Department should also establish an aggressive research program in computer science that is motivated by health needs. It is important that the research program address long-term needs, rather than the application of existing information technology to biomedical problems. Some entities within DHHS, most notably NLM but also other elements of NIH and AHRQ, have invested in research in applications of computing and communications technologies. But much of this work has had short-term goals and DHHS itself has not made information technology research and development in health-related activities a priority. Financially stressed health care organizations will not increase their commitment to the use of information technology without strong leadership and demonstrations of value. (For examples of the types of research and development DHHS might encourage, see pages 14-15 of "Transforming Health Care Through Information Technology.")

6. DHHS should appoint a senior information technology leader to provide strategic leadership across DHHS and focus on the importance of information technology in addressing pressing problems in health care.

Information technology is of critical importance to the Nation and can be instrumental in providing the best possible health care to all of our citizens. At this time, information technology research and use are not viewed within DHHS as strategically as is necessary. We therefore recommend that DHHS create a high-level position designed to provide the necessary vision for the agency in its efforts to incorporate information technology in its agency mission and strategy. While we cannot best judge how this should be accomplished, we recommend that the position be at least at a level equivalent to the deputy undersecretary. This person should be an expert who operates at the nexus of health and computing/ communications. In addition, a budget should be provided to facilitate this person's coordinating and educational activities.

CONCLUSION

PITAC strongly believes that information technologies hold the potential to dramatically improve the U.S. health care system. The barriers are diverse, ranging as they do from basic technology questions that require fundamental research, to human, organizational, and social factors that complicate the application of technology in a complex setting such as health care. But in almost all such areas, there is a role for the Federal government to play. Our health care report has outlined those roles and we hope that you and your colleagues will find our suggestions engaging and persuasive. The Nation has much to gain if IT is more effectively applied to prevent disease, to reduce errors and expense, and to improve the overall quality of health care for our citizens.

The PITAC will be happy to provide the subcommittee with additional information and to work with members pursuing these significant aspects of U.S. health care quality.

Thank you.

NETWORKING HEALTH: LEARNING FROM OTHERS, TAKING THE LEAD

(By Edward H. Shortliffe)*

The Internet was created without much help from biomedical researchers or HHS. The time for leadership has arrived.

Abstract: The Internet provides one of the most compelling examples of the way in which government research investments can, in time, lead to innovations of broad social and economic impact. This paper reviews the history of the Internet's evolution, emphasizing in particular its relationship to biomedical computing and to the nation's health care system. Here I summarize current national research programs, emphasizing the need for greater involvement by the medical research community and leadership from Federal health care agencies.

Complex issues have arisen regarding the Internet and its potential role in health and health care, and they have naturally gained popular attention. The questions and concerns rest, however, on a history of networking development that dates back at least to the 1960's. By the mid-1990's it appeared that a revolution was upon us, but the sudden attention to the Internet was actually the result of its newly developed and most influential application, the World Wide Web.[1] Our attempts to place the Internet in context as a health care and biomedical issue will benefit from consideration of its evolution and of the gradual way in which it has penetrated not only our culture but also our thinking about scientific research and health care delivery.

Medical researchers—especially those addressing problems in biomedical computation—were involved as network users and experimenters almost from the Internet's beginning, but their influence on the Internet's development was limited. Today's health care community needs to anticipate and influence the next generation of the Internet and to work to ensure its effective and suitable role as a critical element in the health care system. To do so, we need to understand our achievements to date as well as the missed opportunities and the nature of the barriers that still exist.

This paper summarizes the evolution of the Internet, emphasizing a biomedical perspective.[2] I also summarize recent organizational and logistical developments, propose some likely future directions, and offer my views on the role that the health care community could and should be playing as the technology evolves. Much of what follows reflects my personal recollection and opinion and my recent experiences in studying the state of the Internet and its current and potential role in health care and biomedicine.[3]

HISTORICAL PERSPECTIVE

The technology of packet-switched networking, on which the Internet is based, arose in the 1960's. In the latter half of that decade the U.S. Department of Defense, through its Advanced Research Projects Agency (ARPA), sought to use the technology to link a handful of computers that were involved with defense-related research.[4] Some of these machines were on university campuses, while others were at Federal sites or in the facilities of government contractors. This was the era of an unpopular war in Southeast Asia, and much suspicion lurked on college campuses about the motives behind this kind of technology and its potential military uses. Ironically, some of the most vocal protestors of that era are no doubt heavily invested in today's dot-com startup companies.

By the 1970's it became clear that the ARPANET, as this network became known, was a boon to collaborative research in computer science and in a variety of application domains. Although its initial emphasis had been on remote login to computers (Telnet) and file sharing among machines (file transfer protocol, or FTP), an early application known as electronic mail was an unexpected success. E-mail quickly penetrated the ARPANET research community and accounted for much of the traffic on the national network. In addition, by the late 1970's Ethernet technology had been introduced, and campuses and research organizations were implementing the first local area networks (LANs). These networks facilitated connectivity to the na-

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tional network from various locations. By 1982 the networking protocol known as transmission control protocol/Internet protocol (TCP/IP) had been introduced; it became the dominant standard for communications both on the national network and, in time, on local networks as well.

As more parties became connected to the ARPANET, the need arose for more robust addressing conventions. Several new naming systems were introduced before the domain system of today (with the familiar .edu, .org, .gov, .com, and .net suffixes) was eventually implemented. Network speeds increased, and an ARPANET culture began to emerge. There was a strong sense of community, of openness and free speech, and of the need to avoid commercial activities. As recently as the late 1980's there was still no consensus that commercial organizations other than government research contractors should be allowed to connect to the Internet. Organizations such as the Electronic Frontier Foundation were created to defend free speech and openness on the Net and to provide resources for persons who wished to learn more about privacy, copyright, and intellectual property issues in the new electronic environment.[5]

If the 1970's were the decade in which the computer science research community discovered and built upon the ARPANET, the 1980's were the time when this experience began to be generalized to other branches of science. Nobel laureate and geneticist Joshua Lederberg had pointed to this potential as early as 1978.[6] He was later instrumental in promoting the notion of network-based "collaboratories"—a concept that has begun to gain acceptance in scientific communities, including medical research.[7]

By the mid-1980's the generalization of the technology and its growing maturity led to the gradual transfer of its oversight from the Department of Defense to the National Science Foundation (NSF), where it was known as NSFnet. Parallel networking activities, such as CSnet for the non-ARPA-related computer science community and BITNET for academic institutions, eventually merged, and the resulting conglomeration adopted the Internet name.

Acceptance of the role of the Internet in science failed to spark much interest within the health care delivery community. Practitioners largely remained unaware of the Internet, and the only health centers that were connected to the national network were those affiliated with research universities, in which case their network connection was typically "borrowed" from their main campus.

Several Federal entities played major roles in the evolution of the Internet and the development of policies regarding its use in the late 1980's and early 1990's. Most prominent among these were the Department of Defense (in particular its research arm, ARPA), the Department of Energy (DOE), the NSF, and the National Aeronautics and Space Administration (NASA).[8] These entities, and others with networking interests, formed the Federal Networking Council (FNC), which in turn formed an advisory group from the private sector, known as the FNC Advisory Committee (FNCAC). The Department of Health and Human Services (HHS) has been represented on the FNC by the National Library of Medicine (NLM), the agency at the National Institutes of Health (NIH) that has been most closely associated with biomedical computing and communications, including research programs, since the 1960's, when Medline was first introduced there.

GROWTH IN THE 1990'S

In 1989 Federal legislators began to promote the notion of a new national research program that would push the technology of the Internet and bring it to a level of quality and sophistication that would attract an even larger segment of society. One of the leaders of this effort, Sen. Al Gore (D-TN), argued that such technologies could address major societal needs while promoting U.S. economic competitiveness. He and others built bipartisan support for legislation in the area, which was eventually signed into law as the High Performance Computing and Communications (HPCC) Act of 1991.[9]

The political process to gain support for the HPCC initiative from Congress required a substantial educational effort. One enduring tool has been an annual "blue book," which outlines several societal "grand challenges" and argues for the role of high-performance computing and communications in achieving those goals. Many of the examples in these books have been drawn from biomedical science. The annual reports are now placed on the Web for public review as well as being distributed in printed form.[10]

• **Health-sector involvement.** The need soon arose to create an office that would help to coordinate the cross-agency activities. The first director of the National Coordinating Office (NCO) for the HPCC initiative was Donald A.B. Lindberg. Already playing a key role in the medical community as director of the NLM,

Lindberg agreed to take on the additional responsibilities associated with the NCO directorship, and he established its first office on the NLM grounds in Bethesda, Maryland. Locating the office at the NLM helped to make clear the link between medicine and the new research programs, and some of the research dollars were appropriated for advanced networking programs and testbeds that were promoted by the NLM.[11]

• **Enter the Web.** By far the greatest change in the Internet environment of the 1990's was the introduction and rapid adoption of the WorldWide Web. The Web has had a remarkable impact on our global society in just a few short years.[12] Its penetration into our homes, schools, and workplaces has arguably exceeded the rate of adoption of earlier popular consumer technologies such as television.

By April 1995 the Internet had been fully "privatized" and was no longer dependent on Federal funding for any component of the backbone (that is, the major high-speed lines that criss-cross the country and to which the regional networks connect). Thus, the Internet is an important and impressive example of how, over time, a speculative government research program that would not have been undertaken in the private sector can lead to technologies and systems that are commercially viable on their own. The increasing use of national networking by society has resulted in projections that Internet traffic on commercial communications systems will soon exceed the traffic derived from traditional voice telephony.[13] With explosive growth in other communications technologies, ranging from highspeed modems and cable modems to wireless communication systems and satellites, the communications vendors of the future will deal with products and services that we have only begun to contemplate. The Telecommunications Act of 1996 was intended, in part, to deregulate the industry so that novel alliances and new methods of communication could be more effectively introduced.

INVOLVEMENT OF THE BIOMEDICAL COMMUNITY

In the early 1970's, when the ARPANET was still young, two medical computing groups were affiliated with computer science departments that were among the earliest users of the network. At Stanford University there was an active collaboration between artificial intelligence (AI) researchers from the Computer Science Department and scientists from the Departments of Chemistry, Genetics, and Internal Medicine. Working first on a system to infer organic structures from mass spectral data (the Dendral program), and later on clinical problems in diagnosis and therapy planning (the MYCIN system), they proposed the creation of a mainframe computing resource to be shared among a national community of researchers interested in AI applications in biomedicine.[14] The resource, known as SUMEX-AIM, was funded in 1973 by a grant from the NIH Division of Research Resources (DRR).With the help of the DRR, the SUMEX machine became the first non-Defense-funded machine connected to the ARPANET. This resource continued for almost 20 years and supported a wide variety of collaborative research activities that depended upon the ARPANET for access.[15]

Much of the network use by biomedical researchers was focused on remote logins, since the computers themselves were being made available to distant users who did not have similar resources on their own campuses. However, e-mail rapidly became a major element in the community building that occurred, leading to Lederberg's prescient observations in 1978 about the role of the network in support of scientific research activities.[16]

By the late 1970's other university-based biomedical computing resources began to join the ARPANET club, but the greater biomedical community did not begin to use the national network until the 1980's. The NIH (with the exception of the NLM) was slow to realize the importance of the Internet and came online much later than did most of the academic research institutions that it funded and with which its scientists and program officers were interacting.

In 1986 several planning panels were commissioned to help to develop a 10-year plan for the NLM. One panel proposed the role of electronic information in support of biomedical sciences.[17] This insight led in time to the creation of the NLM's National Center for Biotechnology Information (NCBI) and, arguably, to the emergence of bioinformatics as a distinct discipline.

A second panel was charged with providing advice in the field of medical informatics; one of its recommendations dealt specifically with electronic communications.[18] The panel noted that "only small segments of the biomedical research community have access to the integrated computing and network communications services that are essential to future medical information systems." They accordingly urged the NLM to work to ensure that "by the end of the next decade, there will be a national computer network for use by the entire biomedical community, both

clinical and research professionals. The network will have advanced electronic-mail features, as well as capabilities for large file transfer, remote computer log-in, and transmitted graphics protocols. It will either be part of a larger national network of scientists or will have gateways to other federally sponsored networks." [19] A decade later the biomedical community did have the WorldWide Web and much of what the committee had proposed, although it was achieved through the natural evolution of the Internet and not from that community's efforts.

By the late 1980's, frustrated by the slow movement of the biomedical community in areas related to wide area networking, I and others began to promote the notion that we needed more effective leadership from HHS. This was the theme of an unpublished talk that I gave at the Symposium on Computer Applications in Medical Care in 1989 as well as one I presented in 1990 at the annual meeting of the Society for Medical Decision Making.[20] My concern was that the health care community, fragmented as it is, has a special need for Federal guidance in understanding and suitably adopting a complex technology such as the Internet. Yet HHS showed no emphasis on networking policy and involvement like those in other "mission-oriented" agencies, such as NASA. It seemed clear to me that wide area networking was just as important to the present and future of health care as it was to defense, energy management, and space exploration. It seemed illogical that HHS was allowing the other agencies to dominate the evolution of networking technology and related national policy.

The biomedical research community rapidly adopted Internet technologies in the 1990's, especially after the introduction of the WorldWide Web. In addition, the public has shown its appetite for health information in its aggressive use of the Web to explore medically related sites. Nearly every Federal health agency has moved to develop online resources (with major efforts by the NLM, the NIH, and the Agency for Healthcare Research and Quality [AHRQ]). The NLM has offered a connections grant program to encourage hospitals to link to the Internet, but there has been no coordinated Federal effort to bring together health care organizations in areas related to the Internet and its potential clinical use.

RECENT DEVELOPMENTS

At the end of the HPCC initiative's first 5 years, the Clinton administration sought to define what the next phase should be in the evolution of Federal research and development (R&D) in this area. Many of the president's speeches pointed to the role of the Internet in education, for example, where he has expressed a strong commitment to wiring the nation's schools. On the research side, he proposed a new program that has been dubbed the Next Generation Internet (NGI). Recent Federal budgets have included approximately $100 million annually in incremental funding for NGI-related research, with those dollars distributed principally to four key entities (Defense, the NSF, Energy, and NASA). The NLM has received a small component (around $5 million).

There has been some confusion about the nature of the NGI program because some have seen it as simply the creation of a newer, faster Internet and have wanted to be sure that they (or their constituents) are included in any connections program. The approval of the program was delayed in 1997 partly because of concerns that the NGI would create a Nation of "haves" and "have-nots" in which rural areas, or universities other than the major research centers, would be left behind. The NCO and Federal agencies drafted an implementation plan to clarify the research goals of the program as well as the plans for spending the appropriated funds.[21]

As the Federal Government was proposing the NGI program, a consortium of research universities was forming to address issues of Internet support for academic research. Members of the consortium agreed to make major upgrades to their campus networks and then proposed to work together to ensure high-bandwidth connectivity among their campuses. As the "regular Internet" has become congested with routine, nonscientific use, there has been a growing sense of the need for a more protected or higher-quality network that could support research (as the original ARPANET did). The original consortium was called Internet2, which led to confusion in Congress about the relationship between Internet2 and the NGI. With the involvement of nearly 200 universities, the consortium has incorporated and is now formally known as the University Consortium for Advanced Internet Development (UCAID).[22]

The "alternate network" to which the Internet2 organization initially sought connectivity was an NSF-funded network, overseen by MCI WorldCom and known as the vBNS (very high speed Backbone Network System), created to connect NSF-funded supercomputers in Illinois and California. Subsequently, UCAID broadened its infrastructure options to include a new network called Abilene, developed jointly

with commercial partners (Cisco Systems, Nortel Networks, and Qwest Communications).

The HPCC legislation called for the creation of a private-sector Presidential advisory committee to assist the White House and its Office of Science and Technology Policy (OSTP) with planning and policy in national information technology research. Known as the Presidential Information Technology Advisory Committee (PITAC), this committee was created in 1997 and draws its members from industry and academe. The committee meets several times a year and has produced reports and recommendations that have informed recent information technology (IT) research-funding activities.[23]

• **The research agenda.** PITAC has identified several major areas in which research is needed relative to the future of the Internet and high-performance computing: (1) methods for scaling the Internet to meet the needs of a global society; (2) solutions to the problems of the "last mile" (the lower-speed connections between the nation's homes and offices and the Internet); (3) development of new applications that will drive our understanding of what technical challenges remain; (4) creation of the devices that will provide connectivity to the networked society; (5) new generations of software, an area in profound need of research investment; (6) supercomputing that will work in tandem with the national network; (7) economic models for the future networked society (and how resulting insights should affect Federal regulatory philosophy and approaches); and (8) social and ethical concerns (topics that are especially important for health and health care, of which data privacy and confidentiality are prominent examples).[24]

• **What lies ahead.** Given the bipartisan support for the NGI program in Congress, it seems likely that Federal research investment in the future of the Internet will continue. The research program undoubtedly will be accompanied by congressional efforts to ensure that traditionally underserved regions and schools are not left out as the Internet advances and improves.

The commercial sector will continue to invest heavily in the Internet, both as users of the technology and, for telecommunications companies, as service providers and innovators. The rapid rise of the Web has shown us, however, that it would be folly to try to anticipate the rate of change or the new technologies that may arise in the decade ahead. We should probably look to industry largely for incremental change and for efforts to make the technology more robust, while academe and science will continue to be the source for paradigm shifts (such as the Web or, on the horizon, wearable wireless devices) that will be adopted by the commercial world. Interactions with regulatory policy will be extremely important.

But what of research? What will be filling the pipeline for 20 to thirty years hence in the way that the networking investment by ARPA did in the 1960's and 1970's? The Nation must have a balanced IT research portfolio, supporting both short-term demonstrations and longer-term innovation and technology development. We are in an era when Congress has been much more focused on short-term benefits from research investment, and many observers believe that the historical evolution of the Internet is ample evidence of how shortsighted that view of research can be. Investment into research on medical computing must be similarly balanced between basic and more applied investigations. We will be lost if we demand short-term payoffs from all research activities.

Partnerships among industry, academe, and government have become an important way to define shared responsibilities in IT research. Universities are developing innovative technologies with government grant support and then working closely with industry as technology-transfer challenges become clear. Ample opportunities exist for these kinds of academic/industry partnerships in health-related Internet applications.

NEED FOR STRATEGIC LEADERSHIP

Issues of vision and leadership are often crucial determinants of a successful health care application of IT, including applications that depend on the Internet. Limited, focused applications may arise at a grassroots level in an organization and be successfully applied. However, when applications require complex interactions across the organization and beyond (as is generally the case for networking infrastructure and projects that build upon such infrastructure to link the organization to individuals outside it), the skills and talents of individual participants must be applied in the context of institutional leadership and a shared vision of what the organization is trying to accomplish. Yet health care organizations are often perceived as failing to use IT as effectively as it is used elsewhere. Some comparisons with the evolution of IT leadership in other industrial settings therefore may be illuminating.

• **The private sector.** Until the 1980's the lead information system managers for major corporations typically played a technical, service-oriented role. They brought technical computing and communications skills to the organization, plus management abilities. In recent years, however, the role of information systems has become more strategic as corporations plan for the future; identify new business opportunities; and implement new practices for communicating with clients, distributing products, and managing inventories as well as finance. As a result, the technology managers are increasingly identified as key strategic leaders. Their titles have generally evolved (today typically to chief information officer [CIO] or vice-president for information systems and technology) to reflect this central role. When their roles were considered technical rather than strategic, they often reported to the chief financial or administrative officer. Today they more typically report to the chief executive officer (CEO) and participate actively in high-level strategic planning, priority setting, and decisionmaking. In fact, Peter Drucker has suggested that the CEO of the future will be the CIO.[25]

Another important change has occurred during the past two decades. Originally IT leaders had little industry-specific expertise (for example, a drug company CIO would typically not have a medical or pharmacology background). Their responsibilities were largely confined to managing large-scale technical installations and implementations. It is now axiomatic in some industries that CIOs should have deep industry expertise. Ideally, they grow up in an industry and combine domain training or expertise with education in, or an inclination toward, information systems.

By analogy, it would be natural to expect the IT leaders of large health care organizations to play increasingly strategic roles and to have deep knowledge of health care delivery and the culture of clinical practice. In health care, however, the pre-1980 model still widely persists. This is true at all levels, from community-based hospitals to large biomedical research universities to HHS, and it may help to explain why the health community has had so much difficulty making optimal use of IT.

The reporting level and professional background of the "information strategy leader" in an organization inevitably influences the attention that information management receives. In addition, a health care professional who also serves as CIO for a hospital or health department might place a higher priority on the establishment of electronic medical records, responsive to the needs of clinicians, than would a technical specialist CIO who moved up from the IT development ranks. This is not to suggest that every information strategy leader in health care needs to be clinically trained as well. However, the CIO must function as a professional peer of the organization's senior leadership.

What will it take to influence the culture of IT management, and recognition of its strategic role, in health care organizations? Major educational issues exist, both to familiarize health care leaders with the fundamental role that IT should be playing in their organizations and to produce a larger cadre of future CIOs who have the combination of technical and management skills, plus knowledge of the complex medical environment. Effective implementation of the NGI for health care, and its use for highly leveraged applications and demonstration projects, will require an investment and commitment from medical organizations. It also will require visionary leadership that understands the strategic role of the technology and the return on investment that can be expected.

• **The Federal role.** If the previous points are valid for large health care systems and medical centers, they are equally important for government bodies that oversee health care policy, provide care, finance health insurance, or attend to public health. It is remarkable, thus, that HHS—a major insurer and provider of health care, as well as the principal organization responsible for the nation's public health—should have no strategic, cross-agency leadership in IT. Each agency within HHS is attempting to deal with IT issues within its own boundaries but without a departmentwide vision or effective coordinating mechanism.[26] Although the various agencies have very different functions and roles, experience in other segments of society has demonstrated consistently that IT, properly managed and designed, can provide a coordinated infrastructure on which diverse needs can be built. Current IT leadership for HHS is focused largely on internal service computing and networking issues, without a broad mandate to plan and coordinate across all agencies. There is similarly no individual charged with convening public/private bodies in the area, with educating the health community about key IT issues that affect health care, with providing departmentwide strategic leadership in the area, or with attempting to evolve the IT culture of the health care system, both within government and in the private sector. In effect, the country needs a "health care CIO," for many of the same reasons that have led to the evolution of such positions in industry over the

past two decades. Imagine the impact on the health care community, for example, if Internet-based submission of Medicare claims were made mandatory.

CONCLUDING COMMENTS

In health care we have learned that creating useful information technologies is not enough. Effective implementation of new information technologies in complex environments like the U.S. health care system requires vision, commitment, and leadership at the highest levels, a well-funded research agenda, and a grassroots community of capable participants. The issues are emotionally and politically charged. Resolving them will require the concerted effort of many public- and private-sector organizations. Without deliberate, sustained action, the fundamental conflicts represented in these policy areas will keep the Internet from fulfilling its promise in health care.

Top-level IT leadership is required at HHS. The department should follow the example of successful health care delivery organizations and identify a senior strategic leader to oversee the coordination and integration of health IT initiatives throughout HHS. Not only should this person assume responsibility for coordinating the IT activities of all HHS agencies, but he or she also should create mechanisms that allow agencies to coordinate their support for fundamental IT research and development in health disciplines. Similarly, this person should work with health professionals, the health information systems community, and vendors to begin to address more effectively the significant coordinating issues and cultural changes that will be needed for IT to realize its potential in health care. The National Committee on Vital and Health Statistics (NCVHS), which already has a record of accomplishment in the area of IT coordination, might be an appropriate mechanism upon which to build, but a committee alone cannot do the work. Instead, the NCVHS could play an advisory role in supporting the work of the Federal leader for health care IT strategy.

HHS needs to take more seriously the need for its aggressive involvement in the area of national networking.[27] The NLM cannot be expected to handle these issues for the entire department. Core biomedical science agencies need to understand that health care applications can help to drive the underlying science of computing and communications and that IT investment is an important area for NIH support. To make the argument, biomedical computing researchers must continue to do the kind of work that will show the national IT research community that both basic and applied IT research efforts in biomedicine have important generic contributions to make.

The health care community could be doing much more with networking than it has to date, but it must recognize (1) the forces that are preventing optimal cooperation among our organizations, given an inherently distributed, competitive environment; (2) the logistical barriers to systems integration, largely in the area of standards development for data exchange and terminology; and (3) the difficulty in justifying institutional investment by demonstrating cost effectiveness in an environment where intuition is not enough but formal experiments are often flawed or impossible to perform.

Despite these problems, the future of wide area networking for the health care community is exciting.[28] The biomedical community has every reason to support the NGI effort and to contribute to it aggressively.

ENDNOTES

1. "The Year of the Internet," *Time,* 25 December 1995, 21.

2. Portions of this paper are adapted from a presentation given by the author at the Annual Fall Symposium of the American Medical Informatics Association, Orlando, Florida, November 1998.

3. National Research Council, *Network Health: Prescriptions for the Internet* (Washington: National Academy Press, 2000).

4. R. Kahn, "The Role of Government in the Evolution of the Internet," *Communications of the ACM* 37, no. 8 (1994): 15.

5. R. Gelman and S. McCandlish, *Protecting Yourself Online: The Definitive Resource on Safety, Freedom, and Privacy in Cyberspace* (San Francisco: Harper Edge, 1998).

6. J. Lederberg, "Digital Communications and the Conduct of Science: The New Literacy," *Proceedings of the IEEE* 66, no. 1 (1978): 1314.

7. V. Cerf and the Committee on a National Collaboratory, Computer Science and Telecommunications Board, National Research Council, *National Collaboratories: Applying Information Technology for Scientific Research* (Washington: National Academy Press, 1993); R. Kouzes, J. Myers, and W. Wulf, "Collaboratories: Doing

Science on the Internet," *IEEE Computer* (August 1996): 40; and E. Shortliffe et al., "A Study of Collaboration among Medical Informatics Research Laboratories," *Artificial Intelligence in Medicine* 12, no. 2 (1998): 97.

8. The name of ARPA has switched between DARPA and ARPA several times, depending on whether the administration has wanted the word "Defense" associated with the agency's title.

9. When Al Gore's father was a U.S. senator in the 1950's, he was instrumental in passing legislation that led to the creation of the interstate highway system. This analogy led some observers to dub the Internet Gore's "information superhighway," a nickname that became heavily used in the first part of the 1990's.

10. "About the National Coordinating Office," August 2000, <www. ccic.gov/about> (4 September 2000).

11. D. Lindberg and B. Humphreys, "The High-Performance Computing and Communications Program, the National Information Infrastructure, and Health Care," *Journal of the American Medical Informatics Association* 2, no. 3 (1995): 156. In time, it became clear that the NCO directorship was a major responsibility and that it required a full-time commitment. With Lindberg's resignation and the appointment of new leadership, the NCO moved to the offices of the NSF in Arlington, Virginia. The responsibilities of the NCO are much broader than networking alone. Coordination among agencies is promoted not only in large-scale networking (LSN) but also in high-end computing and communications (HECC); high-confidence systems (HCS); human-centered systems (HuCS); and education, training, and human resources (ETHR). Coordinated working groups in all of these areas involve agency representatives from several of the participating government organizations. The NCO provides support to the Committee on Computing, Information, and Communications (CCIC), the overall oversight group for such topics within the president's Office of Science and Technology Policy (OSTP). For information about the National Coordinating Office, its mission, and its relationship to other government organizations, see the NCO's home page, <www.ccic.gov>.

12. "The Year of the Internet"; and "The Internet," *Economist* (1 July 1995): S1.

13. Vint Cerf, WorldCom Communications, personal communication, June 1997.

14. B. Buchanan and E. Feigenbaum, "DENDRAL and Meta-DENDRAL: Their Applications Dimension," *Artificial Intelligence* 11, no. 1–2 (1978): 5; and B. Buchanan and E. Shortliffe, eds., *Rule-Based Expert Systems: The MYCIN Experiments of the Stanford Heuristic Programming Project* (Reading, Mass.: Addison-Wesley, 1984).

15. A sister AI-in-Medicine (AIM) machine was funded by the DRR a few years later at Rutgers University. The Rutgers Resource similarly supported collaborative research and featured a connection to the ARPANET.

16. Lederberg, "Digital Communications."

17. Planning Panel Number 3, *Long Range Plan on Obtaining Factual Information from Data Bases* (Bethesda, Md.: National Library of Medicine, 1986).

18. Planning Panel Number 4, *Long Range Plan on Medical Informatics* (Bethesda, Md.: NLM, 1986).

19. Ibid., 65.

20. E. Shortliffe, "Medical Informatics and Clinical Decision Making: The Science and the Pragmatics," *Medical Decision Making* 11, no. 4 (1991): S2.

21. See "NGI Implementation Plan," February 1998, <www.ccic.gov/ngi/implementation> (4 September 2000).

22. See the Internet2 home page, <www.ucaid.org> (4 September 2000).

23. The details of the advisory committee's activities can be found at the NCO's Web site, <www.ccic.gov/ac>. Its 1999 report to the president is available on the site as well: "PITAC—Report to the President," 24 February 1999, <www. ccic.gov/ac/report> (4 September 2000).

24. National Research Council, *For the Record: Protecting Electronic Health Information* (Washington: National Academy Press, 1997).

25. P. Drucker, *Management Challenges for the Twenty-first Century* (New York: Harper Business Press, 1999).

26. An HHS data council comprises representatives from all of the major agencies, but it suffers from the problems of all committees that lack a coordinated reporting mechanism to a central authority charged with giving direction and heeding advice.

27. NRC, *Networking Health*.

28. E. Shortliffe, "Health Care and the Next Generation Internet" (editorial), *Annals of Internal Medicine* (15 July 1998): 138.

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HOPKINS FAULTS SAFETY LAPSES—PANEL SAYS VOLUNTEER LIKELY DIED FROM
DRUG USED IN ASTHMA STUDY; BOARD, RESEARCHER BLAMED

(By Jonathan Bor and Tom Pelton)[1]

A Johns Hopkins panel investigating the death of a 24-year-old woman in an asthma experiment has concluded that she most likely died from a drug given to her in the test, and it faulted both the lead researcher and an internal oversight board for safety lapses.

The panel said the Institutional Review Board at Hopkins' Bayview campus should never have approved the study because the scientist did not present sufficient evidence that the drug used in the experiment was safe.

The consent form signed by volunteers was "misleading" and "inadequate," the panel said, because it failed to disclose that the drug, hexamethonium, was no longer used clinically, lacked approval by the U.S. Food and Drug Administration and could cause severe side effects, even death.

Additionally, Dr. Alkis Togias, the physician who ran the study at the Johns Hopkins Asthma and Allergy Center, should have suspended it after an earlier subject developed a cough that persisted for 9 days.

At that point, Togias should have performed more research on the drug's potential toxicity before giving it to other people, the panel said.

Ellen Roche of Reisterstown, who was healthy before participating in the experiment, died June 2 at Bayview of lung damage and multiple organ failure. A lab technician at the asthma center, she was the third volunteer who inhaled the drug in the study.

The experiment was to have included 10 subjects, but Hopkins halted it when Roche was hospitalized with a cough and fever.

Several medical journal articles in the 1950's and 1960's linked hexamethonium to rare cases of fatal lung disease. But Togias did not find these articles until after Roche became ill, according to Hopkins officials.

Her death is being investigated by the FDA and the Federal Office of Human Research Protection. A preliminary FDA report 2 weeks ago faulted Togias for failing to follow safety procedures.

The report prepared by the Hopkins panel was released yesterday at a news briefing on the Hopkins medical campus in East Baltimore.

"I am the father of a 25-year-old daughter and I can imagine what the family is going through," said Dr. Edward D. Miller, Hopkins medical dean and chief executive officer. "We accept full institutional responsibility for her death." The seven-member panel, all Hopkins professors, was chaired by Dr. Lewis C. Becker, a cardiologist. The committee included an ethicist and specialists in various medical disciplines. Two outside consultants also advised the panel.

"This was a horrible tragedy to have befallen any healthy volunteer," said Becker. "But Ellen gave her life in a truly noble cause, to try to understand asthma and to try to help people who suffer from this condition."

Roche died from adult respiratory distress syndrome, a condition in which small air passages of the lungs break down and lose the ability to supply the blood with oxygen.

The reason this happened might never be known, Becker said, but he said the condition was most likely a reaction to the drug. Tests have shown no evidence that Roche caught an infection in the experiment, though she later developed a secondary infection while being treated at the Bayview medical center.

Hopkins has taken several steps to ensure that further tragedies are avoided in medical experiments, said Dr. Chi Dang, vice dean for research.

These include the creation of a third Institutional Review Board—in addition to Bayview, another board currently operates at the main campus—to monitor the large volume of experiments. Random inspections of studies under way will also be increased, he said.

Dang said the university has suspended 10 additional experiments under the direction of Togias. It has also halted 16 other studies involving the use of drugs not approved by the FDA. The Hopkins investigating panel faulted the Institutional Review Board for not requiring Togias to ask the FDA whether its approval for the experiment was needed.

Reactions to the Hopkins report varied yesterday, with some praising the institution for a thorough review and others criticizing it for approving the experiment in the first place.

[1] Sun Staff, Originally published July 17, 2001.

Sheldon Krimsky, a science policy analyst at Tufts University, said: "It sounds like the university has not issued a whitewash. It sounds like they are doing some real soul-searching and that they admitted wrongs."

Dr. Frederick Wolff, a professor emeritus at the George Washington School of Medicine, said he found it "foolish" and "lazy" that Togias and the Hopkins review board failed to look up the 1950's medical journal articles warning of lung damage caused by hexamethonium.

"Anyone trained in academic medicine knows how to do this research," Wolff said. "This is just laziness. What happened is not just an indictment of one researcher, but of a system in which people don't bother to research the literature anymore."

Togias had searched an electronic medical data base, called PubMed, which lists articles back to about 1960. And he had consulted contemporary edition medical textbooks, but none of them mentioned the 1950's-era reports on hexamethonium's toxicity, according to Hopkins officials.

The Hopkins committee acknowledged, however, that a routine search using two popular Internet search engines, Yahoo and Google, would have produced a French medical school's Web site that listed the past studies.

While the panel believed the researcher made a "good faith effort" to learn of the drug's effects, some members said Togias should have found the articles.

Craig Schoenfeld, a lawyer representing Roche's parents, said the family had no immediate comment. Dr. Gary Briefel, chairman of the Bayview Institutional Review Board, which approved Togias' experiment, also declined to comment, according to a university spokeswoman.

In the fatal experiment, Togias and other doctors were attempting to discover the neurological mechanism—or reflex—that protects the lungs of healthy people against asthma attacks. They administered hexamethonium to see whether it would block the reflex.

Hexamethonium was used as a high blood pressure medication during the 1950's and '60's, but it was taken off the market in 1972 after the FDA ruled that it was ineffective.

Togias designed the study and submitted it to the Bayview review board, which approved it.

According to the investigatory panel, the review board should never have approved the study because Togias did not present enough data demonstrating the safety of hexamethonium. While he did present four studies showing that inhaled hexamethonium produced only temporary problems—such as dizziness—the studies included only 20 patients.

"Small clinical trials give uncertain estimates for even frequent adverse events, and may miss even relatively common toxicity," the report said.

Togias did not have a response yesterday to the Hopkins report, said his attorney, Daniel Kracov.

However, some of Togias' thoughts about Roche's death can be found in a letter that Kracov sent yesterday to the FDA.

On June 28, an FDA investigator faulted Togias for failing to obtain necessary FDA approval, neglecting to warn his subjects of the risks of inhaling a non-approved drug, and failing to report that the first volunteer in his study coughed for 9 days after inhaling hexamethonium.

"It is important to note that while Dr. Togias takes issue with a number of the FDA's regulatory findings, our response is not intended to suggest any diminution in Dr. Togias' deep concern and sorrow regarding the death that occurred," Kracov wrote.

Togias believes it would be "unfair" to point the finger of blame only at him, according to the letter. Togias relied upon the Hopkins review board to guide him on whether to seek FDA approval, and the board did not tell him to consult the Federal agency, the letter says.

He did not report the first volunteer's cough because he thought it was caused by a cold, his lawyer said.

According to the Hopkins panel, Roche received two doses of hexamethonium May 4. The drug was administered with a nebulizer, a device that turns a liquid substance into an aerosol.

On May 7, she reported that she had been sick for 2 days. Her symptoms began with a cough and progressed to a fever. Two days later, on Togias' advice, Roche returned to the asthma center for tests, which revealed a lung inflammation and a 101-degree fever. She was admitted to Bayview.

Within days, her condition worsened, and she was transferred to the intensive care unit. Tests revealed a "ground glass" appearance to her lungs, evidence that they were injured and that tissues were breaking down, the panel said.

A week into her hospital stay, the young woman was placed on a respirator. Later, she developed kidney failure and her blood pressure dropped dangerously low.

"Given her worsening condition and unsupportable oxygenation, the family elected to withdraw [life] support and Ms. Roche died," the report said.

Although Roche worked at the asthma center, she did not report directly to the scientists conducting the experiment. She had participated in several other research studies before enrolling in Togias' project. For that experiment, a doctor drew her name from a registry of past volunteers and called to ask whether she wanted to take part.

Two likely reasons Roche volunteered were an "altruistic desire to help people with asthma" and compensation of $365, the panel said.

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EXAMPLES OF NIH ADVANCED NETWORKING APPLICATIONS PROJECTS

BIOMEDICAL TELE-IMMERSION

By combining teleconferencing, telepresence, and virtual reality, Tele-Immersion enables teachers and students to interact with three-dimensional models, point, gesture, converse, and see each other.

Contact: Jonathan C. Silverstein, MD, University of Illinois at Chicago, School of Biomedical and Health Information Services, 1919 W. Taylor, Chicago, IL 60612-7249; Phone 312-996-5112; Fax: 312-996-8342.

CONNECTIVITY, SECURITY, AND PERFORMANCE OF AN NGI TESTBED FOR MEDICAL IMAGING APPLICATIONS

This project implements an NGI testbed in Northern California's San Francisco Bay Area for medical imaging applications. The clinical applications include: impact of telemammography consultation service in a regional environment compared with a local level; and how real-time interactive teaching in breast imaging would improve the confidence level of general practice radiologists.

Contact: H.K. Huang, D.Sc., University of California, San Francisco, Department of Radiology, 530 Parnassus Avenue, Rm. CL-158, San Francisco, CA 94143-0628; Phone: 415-476-6044.

INDIANAPOLIS TESTBED NETWORK FOR NGI APPLICATIONS TO TELEMEDICINE

The Indianapolis Network for Patient Care (INPC) provides a testbed of NGI technologies including IP security (IPsec), Quality of Service (QoS) in televideo applications at a nursing home, and IP roaming capabilities with a portable wireless workstation. (Clement J. MacDonald, M.D.)

A MULTICENTER CLINICAL TRIAL USING NGI TECHNOLOGY

This project provides the infrastructure of a multicenter clinical trial of new therapies for adrenoleukodystrophy (ALD), a fatal neurologic genetic disorder. It enables the formation of a worldwide imaging network of clinical institutions to evaluate ALD therapies. Three centers collaborate on this project. The Imaging Science and Information Systems (ISIS) Center at Georgetown University Medical Center, the Kennedy Krieger Institute and the Department of Radiology at Johns Hopkins University. NGI technology will be used to speed the transmission and evaluation of high quality MRI images. The project provides procedures to ensure medical data privacy and security.

Contact: Hugo W. Moser, M.D., Kennedy Krieger Research Institute, Inc., 707 North Broadway, Baltimore, MD 21205; Phone: 410-502-9405; Fax: 410-502-9839.

HUMAN EMBRYOLOGY DIGITAL LIBRARY AND COLLABORATORY SUPPORT TOOLS

This application enables collaboration between multiple, distributed researchers and advances clinical and educational goals. It integrates existing data capture and analysis procedures at the National Museum of Health and Medicine (NMHM) into a high performance testbed network that includes a petabyte archive and analysis capability.

Contact: J. Mark Pullen, Ph.D., George Mason University, Computer Science MS 4A5, 4400 University Drive, Fairfax, VA 22030; Phone: 703-993-1538; Fax: 703-993-1710.

MEDICAL NOMADIC COMPUTING APPLICATIONS FOR PATIENT TRANSPORT

This project provides real-time transmission of multimedia patient data from an incident scene and during transport to a receiving center enabling diagnostic and treatment opportunities prior to arrival. It includes acute ischemic stroke and trauma scene response—to define a range of Quality of Service (QoS) requirements for multiple critical care applications.

Contact: David M. Gagliano, TRW, Inc., One Federal Systems Park Drive, Fairfax, VA 22033; Phone: 703-345-7497.

NEXT GENERATION INTERNET (NGI) IMPLEMENTATION TO SERVE
VISIBLE HUMAN DATASETS

This project develops a production system to serve visible human datasets. These include a comprehensive set of interactive 2-D and 3-D browsers with arbitrary 2D cutting and 3-D visualizations. An interactive Web navigation engine is deployed to create and visualize anatomic fly-through, under haptic control of the user.

Contact: Brian D. Athey, Ph.D., University of Michigan School of Medicine, Ann Arbor, Michigan 48109-0616; Phone: 734-763-6150; Fax: 734-763-1166.

Senator WYDEN. Dr. Fuller, thank you for an excellent statement.

Dr. Kenagy, we welcome you. I want to note that when "Forbes Magazine" last year described you as the man who would save health care, I thought that was a fairly sweeping kind of statement. I would not like to have an article state that Ron Wyden is the man who could save Government. I think that would be a little pressure to try to handle. We welcome you and note you do have roots in Oregon, so please proceed.

STATEMENT OF JOHN W. KENAGY, MD, MPA, HARVARD BUSINESS SCHOOL

Dr. KENAGY. Thank you, Senator, Chairman Wyden. I appreciate your support and interest in this. This is not the standard way we approach things. That is what makes disruptive innovation so challenging but also so powerful, and your leadership in bringing these views to the committee, to the Senate, should be noted, because it is not the standard, and I certainly appreciated it.

I appreciate this opportunity to speak. This is a very important subject. I speak from the point of view of a physician. Health care is very troubled. A few examples. We must improve our systems for patient safety and quality. Indigent care and 40 million uninsured remain unresolved puzzles. Finally, health care costs appear to be rising, and at double digit rates, while our economy slows, placing an increasing competitive burden on our major employers and governmental resources.

Chairman Wyden, Senator allen, these problems have existed in one form or another the entire 30 years I have been a physician, and we are no closer to solving them now than the day I received my medical degree. This is what makes the concept of disruptive innovation so timely.

Developed by Harvard Business School Professor Clayton Christensen, the core of the strategy is that paradoxically the capabilities of our successful organizations and institutions and the advice of our best industry experts become our disabilities when faced with developing more reliable, low-cost disruptive solutions.

Trapped by the business models that led to our success, we miss opportunities to develop new products and services based on simpler, less complex ideas, and technologies that are promising but

initially do not have great functionality. The established organizations and industry experts cannot see it.

Why consider telephones, when telegraph is doing quite nicely? Why give up profitable mainframe and minicomputers for those dinky personal computers? Why bother with discount merchandising when our big downtown department store has it all? Why build low-cost or accessible ambulatory or diagnostic centers when our hospital has all those full-service operating rooms and laboratories? Why should I change my practice? It has worked great for years?

That is the innovator's dilemma. Doing well what we do best causes us to overshoot the needs of many of our patients and miss simple opportunities to create more reliable, accessible, low-cost health care, and history suggests these opportunities are great.

Whenever an industry makes a dramatic transformation, whenever someone rewrites the script it is almost always through disruptive change. Many of our economy's most powerful and successful companies had their origins in disruptive innovation. AT&T, Microsoft, Intel, Cisco, Toyota, Sony, Merrill Lynch, Charles Schwab, Sears, Wal Mart, and in health care the Mayo Clinic, Blue Cross, Brigham and Women's Hospital, Kaiser Permanente, and many others all had their origins in simple, less costly ideas that improved underneath the leaders and then supplanted them.

So disruptive innovation is a strategy tool, a new lens through which to view opportunity.

So what are the disruptive issues today? It is not the pace of present innovation. We have lots of innovation. What is important are the opportunities presented by innovations that are not happening. The first innovator's dilemma: established organizations innovate based on their present business models. We call that sustaining innovation, but cannot initiate disruptive change because the processes and values that led to their success also trap them.

Their capabilities, great though they may be, become their innovative disabilities. What are we investing in now in health care? New technology to do better what is profitable, high-tech medicine, big silver bullet technological solutions to our problems, cardiopulmonary disease, cancer, more procedures, sicker patients, but where is the bulk of health care? The other 95 percent, which we tend to ignore, try to avoid, or exit because they represent unattractive tiers of the market, but that is exactly the place where disruptive ideas begin and develop.

The second innovator's dilemma: the developers of new technology must sell to their best customers, the established institutions. This means that investment pours into sustaining innovation, improving functionality of present products and services. Internet connectivity may be a new enabling technology for transformation and health care, but at present, we treat it as a technical challenge to adapt to our present business needs. Disruptive innovation suggests that if e-health initiatives transform health care, they will come from outside and under, not through present systems.

A final innovator's dilemma: regulation tends to pour concrete around the status quo. In all industries, established institutions commonly use regulation to stave off disruptive challenges. In addi-

tion, well-intentioned regulation can kill disruption simply by sapping the innovative energy out of an organization as it tries to negotiate regulatory barriers and avoid political land mines.

Health care is troubled, Senators. At present, the solutions appear inadequate. This is truly a time for leadership. Government and health care industry leaders need to step forward, not to regulate the existing system, but to coordinate the removal of barriers that prevent disruptive innovation from happening.

Leadership must specifically create the environment that will allow insurers, regulators, managed care organizations, hospitals, and health care providers, professionals, to create together the new partnerships, organizations, and institutions, the new capabilities that will lead health care into the 21st Century. Then our patients can realize the benefits that will come with disruption because it is the fundamental mechanism through which we will build a higher quality, more convenient, lower cost health care system.

If leaders with such a vision do, indeed, step forward we will all have access to more health are not less, no trade-offs. Wise men have said, it is insanity to repeat the same behaviors and expect different results. That was Mr. Anonymous. You cannot solve the problems of the present with the solutions that have produced them. That was Einstein. Anonymous and Einstein, two classic disruptive thinkers.

Thank you.

[The prepared statement of Dr. Kenagy follows:]

PREPARED STATEMENT OF JOHN W. KENAGY, MD, MPA, HARVARD BUSINESS SCHOOL

DISRUPTIVE INNOVATION IN HEALTH CARE—NO TRADEOFFS

Tradeoffs.—Throughout history there have been tradeoffs for suppliers and customers. Higher quality products cost more and customers paid a higher price. For traditional U.S. automobiles through 1970's, if you wanted higher quality, you bought a Cadillac, the tradeoff for customer's—a higher price. More convenience often meant a product with less functionality. If suppliers wanted to decrease delivery times, they faced the tradeoff of increased inventory.

No Tradeoffs.—But historically the tradeoffs have been broken. You can now buy high quality cars that are convenient and low cost. Computer technology is another example—continued higher quality, greater convenience and lower cost. And whenever the tradeoffs have been broken, it has been through Disruptive Innovation.

Disruptive Innovation.—In any industry, a disruptive innovation sneaks in from below. While the dominant players are focused on improving their present products or services, they miss less complex, more convenient, less costly innovations initially designed for simpler, less demanding needs. Starting with *worse* functionality, the disruptions improve over time—improve so much they meet needs of the mainstream with higher quality, more reliable and convenient, lower cost products and services. There are many examples of disruptive innovation occurring in healthcare in the past. No tradeoffs.

The Dilemma.—Historically, the leading institutions never lead a disruptive innovation. While they continue to reap benefits out of the top end of the market (sustaining innovation), they miss the opportunity to create new products and services based on ideas and technologies that are promising, but initially do not have great functionality and are based in simpler, less costly business models. "Why worry about those crummy Japanese cars? Americans want big cars with fins." "Why give up profitable mainframes and minicomputers for those dinky new personal computers?" "Why bother with discount merchandising when our big downtown department store prospers?" "Why build an ambulatory surgery center when we have all these empty, full service operating rooms?" "Why change the way I practice? It's worked great for years."

The Opportunity.—Find a new view of our options through Disruptive Innovation. Develop a new common language for change. Create the environments that allow

disruptive innovations to grow and proper. Present policy initiatives in healthcare offer us some form of the following:

- Decrease available health care;
- Wring more cost out of the system;
- Increase governmental and private subsidy.

A policy initiative based on disruptive innovation offers the opportunity for industry transformation. When the tradeoffs are broken, we have the opportunity for more, much more, for less. We can do the same for healthcare—more, much more for our patients, more reliably, more conveniently *and* for lower cost.

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A BRIEF COMMENTARY ON DISRUPTIVE INNOVATION IN HEALTHCARE

THE PROBLEMS

We face many problems in healthcare today. A few examples:

- We must improve our systems for patient safety and quality improvement.
- We face severe man (and women) power shortages, particularly in nursing.
- Major healthcare institutions across the country incur losses in the multi-million dollar range.
- Indigent care and 40 million uninsured remain unresolved puzzles.
- Most clinicians find their practice environment has deteriorated significantly.
- Health care costs appear to be rising at a double-digit rate while our economy slows, placing an increasing competitive burden on our major employers and government.

THE PRESENT SOLUTIONS

Despite these well-recognized problems, intense effort and investment, present policy and strategy seem limited to five, well-worn, "no-win" solutions.

- Control costs by decreasing available healthcare.
- Wring more cost out of the system.
- Find a technological "silver bullet" solution.
- Increase organizational market power to leverage higher reimbursements.
- Increase governmental and private subsidies.

It seems as if we have heard this story before.
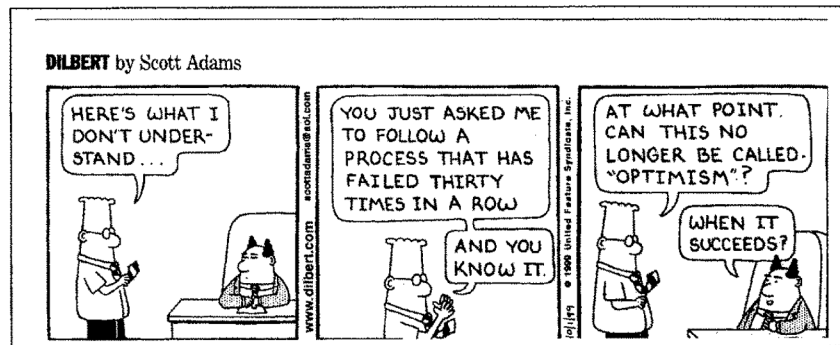
THE ISSUE

Large numbers of dedicated, intelligent people have spent a great deal of time, effort and money on solving our healthcare problems and yet they are unresolved and the solutions proposed appear inadequate. Are there other examples when the Best Leadership with the Most Resources doing all the Right Things failed? Is there a way to take a different view, find a new common language, discover another way to frame our problems and there solutions?

A "DISRUPTIVE VIEW" OF THE PROBLEM

Being surrounded by difficult problems and inadequate, conventional wisdom solutions is what makes the notion of Disruptive Innovation such a timely idea. Coined by Harvard Business School professor Clay Christensen, it is at the heart of his book "The Innovator's Dilemma." The core of his argument is that success handcuffs organizations. Paradoxically, the very act of successfully serving their

best customers well makes them vulnerable. While they continue to improve and reap maximum benefits out of the top end of the market (sustaining innovation), they miss the opportunity to create new products and services based on ideas and technologies that are promising, but initially do not have great functionality, and most importantly are based in simpler, less costly business models. The established organizations scoff: why worry about telephones when telegrams are doing quite nicely? Why give up profitable mainframes and minicomputers for those dinky new personal computers? Why bother with discount merchandising when our big downtown department store prospers? Why build an ambulatory surgery center when we have all these empty, full service operating rooms? Why change the way I practice. . . . it's worked great for years?

The more successful you are the worse it gets. Companies with the best technologies, the most effective products, the best services and particularly the most prosperous businesses always work on improving what they do best, sustaining innovation—they don't (in fact they usually cannot) work on the technologically simple, but poorly functioning ideas that eventually grow to dominate the market. That's the "innovator's dilemma" doing what you do best, will cause you to overshoot the needs of many of your customers and miss great but simpler opportunities that can serve those you have left behind. And those simpler opportunities can grow to meet mainstream needs.

WHAT IS THE OPPORTUNITY OF DISRUPTIVE INNOVATION?

History suggests the opportunity is great. Whenever an industry makes a dramatic change, whenever somebody rewrites the script, it is almost always through disruptive innovation. And the disruption is never led by the established leadership.

Success has been great; many of our economies most powerful and successful companies had their origins in disruptive innovation, AT&T, Microsoft, Cisco, Intel, Toyota, Sony, Merrill Lynch, Charles Schwab, Sears, Barnes and Noble, and many others had their origin in simple, poorly functional, less costly ideas that improved underneath the leaders and eventually supplanted them. Finally, it is the customer who benefits the most as disruptive innovation has always brought more—better quality products and services at lower and lower cost.

So disruptive Innovation is a strategy tool. A new way to see success and failure, a new common language for success and a different lens through which to view our ideas and the environment in which our ideas live, to better tailor them for growth and expansion.

DISRUPTIVE INNOVATION IN HEALTHCARE

But what about healthcare? When I help a healthcare audience discover disruptive innovation, I come to a slide that lists many of the great companies who started as disrupters and I can see the audience mentally saying "no, not us." Where is the healthcare on the list?

In fact, many of our great institutions began with simple ideas in a corner of the market the leaders did not care about. For example, The Mayo Clinic started when two frontier Minnesota surgeons had the still disruptive idea that there is "no place for individualism in healthcare." Baylor University Hospital's Depression Era innovation of guaranteeing Dallas school teachers 21 days of hospital care for $6 per year became Blue Cross. The inability to obtain healthcare for WWII shipyard workers and the technologically simple innovations of capitation and salaried physicians led to Kaiser Permanente, the largest healthcare organization in America. Surgery and anesthesia similarly began as disruptive innovations, derided by the established institutions, just as more recent changes such as out-patient surgery centers, angioplasty and non-MD clinicians.

WHAT DOES A DISRUPTIVE INNOVATION LOOK LIKE?

How can you identify an innovation as disruptive? Look for the five cardinal characteristics of Disruptive Innovation listed below.

1. Technological simplicity, initially "worse" functionality.

2. Fundamentally simpler, less costly business model starting in market tiers that are overlooked or financially unattractive to the leaders.

3. Takes root in markets where institutional and regulatory barriers can be minimized.

4. Customers do not have to change their ways as incremental improvement moves the disruption to more sophisticated users.

5. The innovation eventually allows many more accessible, appropriately skilled people to do the work formerly done by centralized, expensive specialists. No tradeoffs; more for less.

WHAT ARE THE "DISRUPTIVE" ISSUES TODAY?

It is not the pace of present innovation that is important, but rather the opportunities presented by innovations that are *not occurring*.

Disruptive innovation has been the source for great change in many industries and has worked in healthcare in the past. Why not now? What is happening? It's another part of the lesson; put on your disruptive lens and take another view.

First, present leadership never leads disruptive change because the business models that led to their success also trap them; *their capabilities are their innovative disabilities*. They continue to improve functionality but that only overshoots the needs of more and more patients and aggravates the problem. We will use hospitals as an example but the same is true for physicians and other institutions. What are your hospitals investing in now? All the places they can make a profit, cardiac-pulmonary, orthopedics, more procedures, sicker and sicker patients, but where is the bulk of healthcare—it is in the other 95 percent. Because hospitals are saddled with the high cost business models that led to their success in the 60's and 70's they exit unprofitable tiers of the market to move upstream. We overshoot the needs of most of our patients and everyone starts to crowd into the upper end of the market—a space where there is little room and no air to breath.

Second, the developers of new technology must meet the needs of their best customers. This means more investment poured into sustaining innovation improving the functionality of present products and services based in traditional business models. Internet connectivity may be a new enabling technology but established institutions treat it as a technical problem to be adapted to present needs. Disruptive innovation suggests that if e-health initiatives transform healthcare, they will come from "outside and under," not the present established organizations and institutions.

Third, as the established institutions overshoot the needs of more patients, *the basis of competition changes* from increasing functionality to new parameters for success—reliability, access, customization, convenience and low cost. Poorly equipped to compete on this basis, the leaders turn to market power, subsidy and regulation for support. When present business models fail, particularly when they involve entrenched and highly valued institutions, the pressure for increasing subsidies and protective regulation becomes almost overwhelming.

Finally, regulation pours concrete around the status quo. Attempts to use regulation to stave off disruptive attacks are quite common. U.S. automakers, for example, relied on import quotas as long as they could to keep disruptive Toyota and Honda at bay. The links between healthcare institutions, Federal and State regulators, and insurance companies are strong and wielded to preserve the status quo. In addition, because healthcare is so complex and dynamic, well-meaning regulatory institutions such as the JCOHA, HCFA or the FDA, can kill disruptions simply by sapping the innovative energy out of an organization as it tries to negotiate regulatory barriers or defuse bureaucratic land-mines.

These are not simple issues; regulators are not bogey men and everyone else victims, but, a remember #3 in "What's a Disruptive Innovation Look Like" above. *Disruptive innovations take root (and grow) in markets where organizational and regulatory barriers are minimized.*

THE NEED FOR LEADERSHIP

Once an industry is in crisis, individual leaders become paralyzed. They're incapable of embracing disruptive approaches because the profitability of the institutions they lead has been so eroded. Typically, not only do they ignore the potential disruptions, they work to actively discredit and oppose them. Thus far, this pattern has held true in the healthcare industry as well.

Successful disruptive transformation of this system will unfold more quickly, and far less painfully for everyone, if leaders at regional and national levels work together—not to regulate the existing system but to coordinate the removal of barriers that have prevented disruptions from happening.

Government and health care industry leaders need to step forward—to help insurers, regulators, managed care organizations, hospitals, and health professionals work together to facilitate disruption instead of uniting to prevent it. Then patients can realize the opportunities that come with disruption—because it is the fundamental mechanism through which we will build a higher quality, more convenient, lower cost healthcare system. If the leaders with such a vision do indeed step forward, we will all have access to more healthcare, not less. No tradeoffs.

Wise men have said:

• "Insanity is repeating the same behaviors and expecting different results"— *Anonymous.*[1]

• "You cannot solve the problems of the present with the solutions that produced them."— *Einstein.*[1]

Senator WYDEN. Thank you. We will have some questions in just a moment.

Dr. May.

STATEMENT OF WILLIE E. MAY, CHIEF, ANALYTICAL CHEMISTRY DIVISION, CHEMICAL SCIENCE AND TECHNOLOGY LABORATORY, NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY (NIST)

Dr. MAY. Good afternoon. My name is Willie Eugene May. I am Chief of the Analytical Chemistry Division at the National Institute of Standards and Technology in Gaithersburg, Maryland, and I would like to thank you, Mr. Chairman and members of this Subcommittee for the invitation to testify today on the measurement standards needed to improve the efficiency of health care delivery, and to comment on the role of reliable data in e-health.

I will now briefly summarize my written statement that was provided earlier for the record. Information technology will play an increasingly important role in the management and interchange of health care data. Improved efficiency at a significant reduction in cost should result since a considerable portion of health care cost roughly 20 percent is associated with processing information.

However, additional savings would result from accuracy-based clinical measurements that are traceable to national and/or international standards. This will be the focus of my testimony today.

Clinical measurements that are reliable and comparable over both time and space are essential for optimal patient care, most efficient use of available health care funds, and full utilization of the potential of new information technology tools. The accuracy and traceability of data from medical tests are becoming increasingly important. Typically, medical guidelines are derived from clinical studies where medical outcomes are correlated with medical test results.

Such data are often collected from many different laboratories and instruments in different parts of the world and at different times. However, effective use of such data will require that any differences observed be attributable to clinical parameters being measured, and not the measurement processes.

Valid decisionmaking requires that a medical test result from an individual patient, from a different laboratory at a later time, be correlated to the clinical study data for the broader population. This can be best accomplished if all measurements are of known quality, linked to a common truth. NIST can provide the measurement quality assurance tools needed to improve measurement accuracy and reliability.

In my written statement, I have provided quite a bit of information regarding the magnitude and scope of the health care measurement problem. To summarize here, measurements are responsible for 10 to 15 percent of the $1.3 trillion annual cost of health care in the United States, a significant portion, 25 to 30 percent

[1] Anonymous and Einstein, two classic disruptive thinkers.

of health care related measurements are performed for nondiagnostic reasons—retests, error prevention and/or detection.

To illustrate the need for measurement data of increased accuracy and reliability, I focused on two clinical diagnostic markers related to heart disease, the number 1 cause of death in the United States, accounting for roughly one-third of all deaths annually. One of the markers discussed, blood cholesterol, is a risk factor for coronary heart disease. Dr. George D. Klee of the Mayo Clinic has used frequency distributions for cholesterol values for 20,000 patients to mathematically model the wide variations in medical diagnoses that small measurement biases or errors can produce.

In this group, 249 patients per 1,000 had cholesterol levels higher than the 240 milligram per deciliter level where current guidelines call for further testing and/or possible need for medication. Even a plus 3 percent error in the test would result in an additional 51 persons per 1,000 being incorrectly reported to need medical intervention. In this false positive case, patients could require retesting, and/or be subjected to prescribed medical intervention, both entailing unnecessary costs.

Conversely, this model shows that if there were a minus 3 percent bias, 46 people would be missed, and thereby have treatments delayed or omitted altogether, both leading to potentially dire circumstances.

The General Accounting Office report of December 1994 on cholesterol measurement test accuracy and factors that influence cholesterol levels states that the variability of cholesterol in blood measurements decreased from 18 percent in 1969 to 5 percent in 1994. NIST (with its definitive methods and standard reference materials), in cooperation with the Centers for Disease Control (with its reference methods and reference laboratory system), and the College of American Pathologists (responsible for proficiency testing most of the clinical laboratories in the United States), maintain this reference system that was largely responsible for improvements that represent a potential savings of $100 million per year in treatment costs for misdiagnosed patients, in addition to lives saved through timely and accurate diagnoses.

The measurement variability has improved further since 1994, and is now roughly 3 percent. We think that our provision, that is, NIST's provision of a new standard reference material for lipids and protein serum in 1997 to address computability problems experienced with some of the clinical analyzers contributed significantly to this improvement. However, Dr. Klee's data showed that additional cost and patient benefits would result from reducing this variability still further.

A second marker discussed, Cardiac Troponin-I, is a heart muscle protein that is released into the blood stream following acute myocardial infarction. In controlled studies, Troponin-I has been shown to be a highly specific diagnostic marker for heart attack. However, at this time, data from tests for Troponin-I can only be used in a very restricted manner. Medical decision points for this test are manufacturer specific, and therefore, decisions cannot be made based on norms established for broader population groups.

Each of the three assays cited in my written statement measures different isoforms of this complex protein. Efforts are underway in-

volving NIST, the medical professional community, and IVD manufacturers to identify the specific form to be measured. While the range of reported results for Troponin-I represents one of the more extreme situations, medically significant differences exist for many other important clinical diagnostic markers.

In addition to reliability and cost concerns, another important measurement and standards-related commerce and competitiveness issue has recently emerged, the European Directive on *in vitro* diagnostic medical devices. By December 2003 manufacturers must declare that any IVD products to be sold within the European Union complies with all essential requirements of this directive.

One of these requirements is that IVD products be traceable to standards of the higher order—whatever that means. Our interpretation is nationally and/or internationally recognized reference methods and/or certified reference materials. At present, IVD devices are used in clinical laboratories to measure more than 300 different chemical or biochemical species. Reference methods and/or materials exist for about 30 of these. Approximately 60 percent of the IVD products currently on the European market are imported from the United States.

As we look to the future, "and the future is now," in many ways—Senator Allen, I thought you might appreciate that.

Senator ALLEN. I have heard that.

[Laughter.]

Dr. MAY. We realize that home diagnostics is a rapidly growing field that will eventually encompass many devices and technologies, ranging from single-use test strips such as for glucose— that my mother uses—to sophisticated multianalyte monitors, or sensors.

As such point-of-care-testing devices migrate from the clinical laboratory to the home environment, there are concerns that the accuracy of these measurements might suffer, and further reduce the comparability of data from which medical decisions are made. Today, it is not uncommon for diabetic patients to discover that they get different blood glucose readings from devices from different manufacturers. Accuracy-based point-of-care testing standards will become increasingly important for assuring U.S. dominance of the worldwide IVD market, and to foster better and more affordable health care, both at home and abroad.

In conclusion, I was asked to focus my testimony on the measurement standards needed to improve efficiency and health care delivery, and to comment on the role of reliable data in e-health. Unreliable and inconsistent measurement data contribute to waste and inefficiency in health care delivery. Accuracy based reference methods and reference materials that NIST can provide will help to increase the reliability of health care measurement data from which medical decisions are made, and facilitate continued access to the EU market for U.S. manufacturers of IVD products.

Certainly, information technology will play an increasingly important role in that management and interchange of health care data. Improved efficiency and a significant reduction in cost should result. However, further savings will result from a more effective linkage between clinical measurement results and medical decisionmaking. Health care measurements of improved quality are

necessary as input data to fully realize the benefits that information technology can provide.

This completes my statement.

[The prepared statement of Dr. May follows:]

PREPARED STATEMENT OF WILLIE E. MAY, CHIEF, ANALYTICAL CHEMISTRY DIVISION, CHEMICAL SCIENCE AND TECHNOLOGY LABORATORY, NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY (NIST)

Mr. Chairman and Members of the Subcommittee, thank you for the invitation to testify today. My name is Willie E. May. I am Chief of the Analytical Chemistry Division, Chemical Science and Technology Laboratory, National Institute of Standards and Technology (NIST). I am pleased to be offered the opportunity to add to this discussion regarding ways and means for increasing the effectiveness of our health care system. I will focus on the role that national measurement standards can play in increasing the accuracy and reliability of health care measurements that should lead to better medical decisionmaking and more efficient use of available health care resources.

OVERVIEW

Chemical and physical measurements provide information that is extremely important for the prevention, diagnosis, and treatment of disease. Clinical measurement results used by medical and other health care decisionmakers that are reliable and comparable over both space and time are essential for optimal patient care, most efficient use of available health care funds, and full utilization of the potential of new information technology tools. The accuracy and traceability of the data from medical tests are becoming increasingly important. Typically, medical guidelines are derived from clinical studies where medical outcomes are correlated with medical test results. Such data are often collected using many different laboratories and instruments, in different parts of the world, and at different times. However, effective use of such data will require that any differences observed be attributable to the clinical parameter(s) being measured and *not* to the measurement processes. Valid decisionmaking requires that a medical test result for an individual patient—from a different laboratory at a later time—be correlated to the clinical study data for the broader population. This can be only accomplished if all measurement results are of known quality. NIST can contribute to increased efficiency in health care delivery by providing the measurement quality assurance tools—reference measurement methods, certified reference materials and calibrations—needed to improve measurement accuracy and reliability.

MEASUREMENT RELIABILITY AND COST ISSUES

A 1999 study by the National Academy of Sciences Institute of Medicine discussed the impact of medical errors on health care costs within the United States. While the majority of medical errors are not due to inaccurate measurements, improved measurement accuracy could save lives, a significant amount of time and money, and improve our quality of life. Health care costs are estimated to exceed $1.3T in 2001 and currently represent over 14 percent of the U.S. GDP. Estimates of the portion of these costs that are measurement related vary by which activities are included, but typically range from 10 percent—15 percent. The *Washington Post* and *Medical Laboratory Observer* have reported that 25 percent—30 percent of health-related measurements are performed for non-diagnostic reasons (re-test, error prevention and detection). While not providing an explicit number for the cost of non-diagnostic measurements, the Committee on Quality of Health Care in America, in a 1999 Report, "To Err Is Human: Building a Safer Health System (*http:// books.nap.edu/html/to—err—is—human/exec—summ.html*), stated that "Dollars spent on having to repeat diagnostic tests . . . are dollars not available for other purposes. Purchasers and patients pay for errors when insurance costs and copayments are inflated by services that would not have been necessary had proper care been provided. It is impossible for the Nation to achieve the greatest value possible from the billions of dollars spent on medical care if the care contains errors." The "German Health Report of 1998" (*www.gbe-bund.de*) states explicitly that "the costs of repeat measurement amounts to $1.5 B U.S. per year in Germany." If normalized to the U.S. GDP for that year, these costs would be $7.4 B. Even modest improvements in measurement accuracy and quality assurance will result in multi-billion dollar savings in health care costs.

Considerable data exist to demonstrate the effectiveness of NIST's measurement, standards and calibration activities in the areas of clinical chemistry, radiation therapy, and medical imaging. The accuracy of all 26 million mammograms and 600,000 cancer patients treated with radiation (per year) trace to physical measurement standards at NIST. A flat panel display metrology standard has been developed in our Electronics and Electrical Engineering Laboratory that has allowed the Mayo Clinic, Scottsdale, AZ, to upgrade its diagnostic capabilities by moving from traditional x-ray photo images viewed on light panels to video flat panel displays. Converting from radiographs to digital images viewed on flat panel displays eliminated the need for an estimated one million radiographs per year (estimated at about $1.50 per radiograph.). The NIST Advanced Technology Program (ATP) has awarded several grants to companies seeking to improve the flow of information between health care providers. For example, VitalWorks of Waltham, MA, used ATP support to adapt an existing computer note-writing system so that it could capture clinical data automatically through a pleasing user interface. This new technology makes it easy and productive for physicians to enter patient data directly into computers, an advance that overcomes a major obstacle to the conversion from paper to electronic medical records. NIST also develops and disseminates organizational performance metrics for health care through its Baldrige National Quality Program.

As you can see, NIST has many activities that contribute to improving the effectiveness of health care delivery; however, I'll talk in detail only about the area that I'm most familiar with—measurement methods and standards for clinical diagnostic markers. For more than 20 years, NIST has developed, maintained and refined "Definitive Methods" for health status markers to support the national reference system for clinical measurements, including but not limited to calcium, chloride, cholesterol, creatinine, glucose, lithium, magnesium, potassium, sodium, triglycerides, urea, and uric acid. NIST methods for these health status indicators have been used to value-assign Standard Reference Materials that NIST sells to the public and reference serum pools used by the Centers for Disease Control and Prevention (CDC) as the anchor point for its reference methods and by the College American Pathologists (CAP) as its benchmark for proficiency testing more than 15,000 U.S. clinical laboratories. Improved accuracy facilitated by this program has led to better diagnosis, treatment and reduced health care costs. The provision of these accuracy-based anchor points for the clinical measurement community also facilitates the development and critical evaluation of new measurement technologies for providing cheaper and faster test results.

Results of Measurements of Troponin-I from Same Sample Pool Using Immunoassay Kits from Three Different Manufacturers

Assay Manufacturer	Troponin-I Concentration ng/mL	#labs reporting
A	19.9	115
B	6.7	489
C	0.85	7

From G.S. Bodor, Denver Health and Hospitals personal communication 1997.

A new generation of health status markers, now emerging, shows great promise from the clinical diagnostic perspective, but offers new and more difficult challenges for measurements and standardization. Many of the new markers are proteins, peptides, or other large biomolecules, usually present at very low concentrations. Because of the vast market for tests for these new markers, many different approaches have been developed that often provide different answers. For example, Cardiac Troponin-I is a protein that is found in heart muscle that is released into the blood following acute myocardial infarction (AMI). In controlled studies, it has been shown to be a highly specific diagnostic marker for heart attack. Currently, data from tests for Cardiac Troponin-I can be used only in a very restricted manner. Medical decision points are manufacturer-specific, and therefore, decisions cannot be made based on norms established from broad population groups. While the range of results reported in the Table provided here are a bit extreme, this lack of comparability exists for many other very important clinical diagnostic markers, whose utility are therefore not being fully realized. This lack of comparability among Cardiac Troponin-I assays is very significant since heart disease is the No. 1 cause of death in the United States—accounting for ⅓ of all deaths. Acute myocardial infarction is responsible for 30 percent of these deaths. Approximately 6 million people visit Emergency Rooms (ERs) annually for chest pain and approximately 3 million

of these are admitted for possible AMI. Of these, 2 million are not diagnosed as having AMI [false positive result that potentially lead to unnecessary medical costs]. Of those not admitted, 2 percent–8 percent actually had an AMI [false negative result that might cause delayed treatment which could result in severe medical consequences].

Recently, Dr. George G. Klee of the Mayo Clinic in Rochester, MN, has shared information with us regarding the effect of measurement bias on medical decision-making. He used the frequency distributions of cholesterol values from 20,000 patients to mathematically model the wide variations in medical diagnoses that small measurement biases/errors can produce. As an example, in this group, 249 patients per 1000, had cholesterol levels higher than 240 mg/dL—the level at which current guidelines call for further testing and the possible need for medication. A +3 percent error in the test would result in an additional 51 persons per 1000, being incorrectly reported to need this medical intervention. In this false positive case, patients could either get retested or be subjected to the prescribed medical intervention, both entailing unnecessary costs. His work showed that if conversely, there were a −3 percent bias, 46 people would be missed and thereby have treatment delayed or omitted altogether, both potentially leading to dire consequences.

In 1969, the variability of cholesterol in blood measurements was reported to be 18 percent in College of American Pathologists Proficiency Testing Surveys. Over the next 25 years, NIST (definitive measurement methods and Standard Reference Materials) in cooperation with the CAP (proficiency testing) and the CDC (reference methods and reference laboratory network) established and maintains a reference system for cholesterol measurements that has contributed to a steady decrease in the measurement variability to the ? 5 percent level in 1994 [Cholesterol Measurement Test Accuracy and Factors that Influence Cholesterol Levels, General Accounting Office Report GAO/PEMD–95–8, December 1994]. These improvements represent potential savings of over $100M per year in treatment costs for misdiagnosed patients, in addition to the lives saved through timely and accurate diagnosis.

Driven by the availability of new sensor-based measurement technologies, more and more clinical testing is being done outside the traditional clinical laboratory. The annual U.S. market alone for this new form of clinical measurements, called point-of-care testing (POCT), is currently estimated at a billion dollars and is estimated to be growing at an annual rate of 10 percent. POCT is expected to be used extensively in the home as a part of a self-care trend, which is also experiencing rapid growth. Some studies have indicated that POCT can provide nearly the same level of diagnostic value as centralized testing, but at half the cost. Therefore the standards infrastructure that has supported clinical chemistry for the past three decades must adapt to support POCT. New techniques and non-biohazard standards based on biomimetic materials are needed to assure the accuracy of POCT. NIST leadership in developing accurate and internationally recognized and accepted POCT standards will help assure continued U.S. dominance of the worldwide *in vitro* diagnostics (IVD) market and foster better and more affordable health care both at home and abroad.

NEW MEASUREMENT AND STANDARDS-RELATED COMMERCE AND COMPETITIVENESS ISSUES

In addition to the reliability and related cost issues that we have discussed up to now, another important measurement-related driver has recently emerged. On December 7, 1998, the European Directive 98/79/EC on *in vitro* diagnostic medical devices was published in the Official Journal of the European Communities, marking the start of a transition period of 5 years. An *in vitro* diagnostic device is any medical device intended for use in the testing of samples derived from the human body. The stated purposes of the directive are to eliminate trade barriers within Europe by ensuring access to the entire European Union (EU) market with one single product approval (CE marking), and at the same time to maintain or improve the level of health protection attained in the EU Member States. By December 2003 all new IVD products that are placed on the EU market must be labeled with the CE mark. In order to apply the CE mark, the manufacturer must declare that his product complies with all the "essential requirements" of the Directive. One of the major components of this directive is a requirement that products be traceable to "standards of the highest order", e.g., nationally/internationally recognized certified reference materials (CRMs). At present, neither CRMs nor reference methods are available for most of the several hundred analytes that are measured in medical laboratories. Excluding home diagnostics, the overall worldwide *in-vitro* diagnostic market is approximately $20 billion. The total IVD market in Europe was about

$5.6 billion in 1998. Approximately 60 percent of the IVD products on the European market are imported from the USA.

In November 2000, NIST convened a Workshop on "Measurement Traceability for Clinical Laboratory and *in Vitro* Diagnostic Testing Systems". There were over 150 participants in attendance, with representatives from the IVD industry, regulatory agencies, international standards laboratories, commercial providers of clinical reference materials and proficiency testing services, and professionals involved in standardization of laboratory methods. The consensus of the group was for the establishment of global reference systems composed of reference laboratories, reference methods, reference materials (issued by National Measurements and Standards Institutes), and a mechanism for demonstrating measurement equivalence among national standards. The participants agreed that internationally recognized measurement and standards laboratories should be the initial nodes in this reference network, and that this system should expand rapidly to include nodes distributed around the world. There was concurrence that when properly implemented, measurement traceability—to national and/or internationally recognized standards—is a value-added component that will improve patient care, testing accuracy, reliability and availability, market access, and, in the long run, reduce costs. They all agreed that NIST should continue to provide leadership in the establishment of this reference system.

WHY NIST SHOULD BE INVOLVED

As stated earlier, NIST has many activities that contribute to improving the effectiveness of health care delivery and has a long history of excellence in the development of unbiased and authoritative measurement methods, reference materials, calibrations, and evaluated data bases. These, coupled with new innovative preventive, diagnostic and treatment technologies, can play a key role in enhancing the quality of life in the U.S. and throughout the world. According to the Advanced Medical Technology Association (formerly, Health Industry Manufacturers Association), "the lack of organized measurement-related research can be best addressed by the coordinated efforts of NIST working together with industry". Standards-related research and measurement services, and the development and transfer of new measurement technologies are part of NIST's congressionally mandated mission and can help to facilitate the reduction of the overall cost of health care in the U.S. Close working relationships are already established with industry, the public sector and international organizations concerned with public health to assure that new measurement and technology needs are understood and properly addressed.

There are a number of technical, regulatory, and economic needs for traceability to national measurement standards: instrumentation used in the area of health care diagnostics and therapy requires accurate calibration; regulatory agencies such as the FDA and NRC require NIST traceability for medical devices and radiation therapy instrumentation; one-third of U.S. hospital patients' treatment involves radiopharmaceuticals with dosages traceable to NIST; and proliferation of foreign requirements for quality systems documentation (such as European Directive 98/79/EC on *in vitro* diagnostic medical devices) will greatly expand the need for NIST traceability for export of U.S. health care technology. The NIST role in health care is complementary to the role of the National Institutes of Health (NIH). NIH relies on NIST and CDC to facilitate clinical measurement accuracy and on the College of American Pathologists for proficiency testing of hospital and clinical laboratories in the U.S. For 15 years, the CAP maintained a Reference Laboratory at NIST for the development of advanced clinical methods and reference materials.

SUMMARY

I was asked to focus my testimony on the measurement standards needed to improve efficiency in health care delivery and to comment on the role of reliable data in e-health. I hope that I have provided you with useful information regarding the waste and inefficiency caused by unreliable and inconsistent health care measurement data as well as the benefits of nationally and internationally traceable measurements and standards in addressing increasing needs for measurement quality systems documentation.

In addition to NIST's chemical and physical measurement standards activities, expertise resides in our Information Technology Laboratory to work with the health care community to overcome barriers to the effective integration of information technologies into the administrative and clinical measurement sectors of the health care industry. It is estimated that as much as 20 percent of health care costs is associated with processing information. The implementation of standards to support elec-

tronic interchange of information could result in tremendous savings—some estimates are as high as $9B per year.

Additional savings would result from more effective linkage of measurement results with medical decisionmaking. However, to fully realize the benefits that information technology can provide to health care delivery, we need health care measurements of improved quality as input data.

In closing, I have tried to demonstrate that NIST can make significant contributions to increasing the efficiency of health care delivery.

Thank you Mr. Chairman. This completes my statement and I will be happy to entertain questions.

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CURRENT STATE AND ISSUES REGARDING POINT-OF-CARE-TESTING

SUMMARY

Driven by the availability of new sensor-based measurement technologies, more and more clinical testing is being done outside the traditional clinical laboratory. The annual U.S. market alone for this new form of clinical measurements, called point-of-care testing (POCT), is currently estimated at a billion dollars and is estimated to grow at an annual rate of 10 percent. POCT is expected to be used extensively in the home as part of a self-care trend, which is currently experiencing a 70 percent growth rate. Published studies have concluded that POCT provides at least the same level of diagnostic value as centralized testing, but at half the cost. The standards infrastructure that has supported clinical chemistry for the past two decades must adapt to support POCT. Collaborative efforts will be needed among National Standards Laboratories, in-vitro diagnostic device (IVD) manufacturers, and others in the medical professional community to develop appropriate technologies and non-biohazardous standards to facilitate the provision of data used in medical decisionmaking that are accurate and traceable to national/international standards. NIST participation in developing traceable POCT standards will help to assure continued U.S. dominance of the worldwide IVD market and to foster more affordable healthcare both at home and abroad.

PROBLEM MAGNITUDE AND SCOPE

As we look to the future, we realize that home diagnostics is a rapidly growing field that will eventually encompass many devices and technologies ranging from single-use test strips (such as for blood glucose testing) to sophisticated multi-analyte monitors. As such point-of-care-testing (POCT) devices migrate from the clinical laboratory to the home environment, there are concerns that the accuracy of the measurements made by such devices will suffer, further reducing comparability of data from which medical decisions are made.

The most widely used home testing devices are for glucose. Diabetes affects more than 10 million Americans and its prevalence rose from—5 percent to 7 percent during the 1990's (1–2). Acute and chronic complications of diabetes include hypoglycemia, diabetic ketoacidosis, impaired immunity, cardiovascular disease, kidney disease, and nerve disease (3). The cost of diabetes is extraordinary, accounting for 1 of every 8 health care dollars spent in the United States of America (3). Diabetes is characterized by excess glucose in the blood and treatment of diabetes focuses on reducing the excess glucose and normalizing other associated metabolic abnormalities (4). Current regimens to treat diabetes are imperfect and individuals with diabetes rely on the results of blood glucose monitoring systems for therapeutic adjustments to minimize low and high excursions of blood glucose. Today, it is not uncommon for diabetic patients to discover that they get different blood glucose readings from devices made by different manufacturers.

Self-monitoring blood glucose (SMBG) devices are unique among medical devices in the high volume of use (daily use by many of the nation's 16 million diabetics) for critical decisionmaking and for the unusual setting (patient homes) in which this testing occurs. Although home blood glucose monitoring has clearly revolutionized diabetic care and changed both the therapy and outcome for this disease, use of these testing systems remains problematic. In 1993, Devreese and Leroux-Roels (5) published a laboratory assessment of five blood glucose monitoring systems. For the five systems, results of the same low and normal samples ranged from 1.35 to 3.5 mmol/L (24–63 mg/dL) and 4.0 to 6.4 mmol/L (79.3–115 mg/dL), respectively. Since the publication of this study, technology of blood glucose monitoring systems has advanced. Furthermore, it should be noted that this study deviated from the way consumers use these systems. Each of the investigators in this study used venous blood treated with an anticoagulant (lithium heparin). Home-based systems use fresh

whole blood and measure glucose using systems based on either electrochemical or photometric principles in which electric current or light intensity is actually measured and then related to blood glucose levels.

Most units require blood from a finger prick to be deposited on a test strip or cartridge that has been impregnated with one of a variety of glucose-specific enzymes. In addition to the variability that may result from the use of different types of impregnated test strips or cartridges, they also exhibit lot-to-lot variability. Each manufacturer uses its own in-house method to calibrate its systems. Many manufacturers do offer quality controls to consumers to verify proper function of the selected system, but these materials are specific for each system. There is no "higher order" measurement traceability for these systems at this time. The lack of common ground for comparison of the SMBG device performance in home—use settings is a problem that needs to be solved. According to the CDC, "The evolution of blood glucose monitoring systems, without traceability to higher order standards (reference methods or certified reference materials), may result in high analytical variation."

The ability of the FDA to regulate these devices and to provide guidance to manufacturers has been hampered by inadequate data regarding the performance of glucose meters used in home settings. The FDA has recognized that improving the accuracy and performance of SMBG devices is an urgent task. NIST and FDA have had discussions regarding the need for a study to determine how SMBG devices perform in the hands of actual users—How accurate are the results? (6). The CDC is also planning a study to investigate the degree of analytical variation between several leading (in terms of use) systems used for measuring glucose in the home (7).

On a more personal note, a respected scientist and former NIST employee has developed adult-onset diabetes, and uses a personal monitoring device for pin-prick glucose monitoring measurements. He ordered a new model, which operated on a slightly different principle, and was to return the old one to the manufacturer. Accordingly, he unpacked the new model and took a blood glucose reading that was totally incompatible with the last reading from the old model. Being a scientist, he unpacked the old one and took comparable, back-to-back readings to confirm the incompatibility. The results from the two were considerably different. He immediately called NIST and asked us to think about developing standards for these instruments!!

HOW NIST CAN HELP

In the short term, NIST can help by assisting CDC and FDA in their investigations of the performance of glucose monitors. We have been asked to provide the reference method and whole blood reference materials to support these studies. In the longer term, additional activities would be required. For the past two decades, NIST (and other standards producers such as USP, CAP, etc.) have tailored clinical standards for use in the largely solution-based clinical laboratory. These reference materials are not appropriate for use with the new surface-based technologies being developed for POCT. Current laboratory approaches rely mainly on fixed instrumentation and bulk solutions that can be calibrated and then utilized to make a number of determinations before the next calibration cycle. On the other hand, POCT technology comes in both reusable and single-use-disposable formats. POCT vendors have developed QC/QA tests for use with their devices during manufacture and use, and since such devices are subject to regulatory approval by the FDA, the vendors have done extensive testing to demonstrate their devices' efficacies. However, the vendor-developed testing is often as proprietary as the devices themselves, and according to a professor of clinical pathology at a large university hospital "the lack of adequate independent test standards is a major impediment for both hospital and POCT that will grow more significant as POCT expands into the personal care market." Recent international trade regulations on IVD devices further exacerbate the need for traceable standards. The EU IVD directive mandates that new IVD devices, calibrators, and control devices be traceable to "standards of the highest order" by 2003.

Currently, serum or blood-based materials are used to calibrate many POCT devices to mimic closely the conditions of the actual assay. These materials are costly and difficult to prepare, risky to use because of possible contamination by HIV or hepatitis viruses, require controlled storage and disposal conditions, and may be subject to degradation in a few weeks. The use of blood-based calibrants is feasible for hospital and some settings where the constraints can be managed, but such approaches are not reasonable for less controlled environments such as home care.

A new generation of clinical standards is needed based on biomimetic materials, synthetic substances with properties similar to physiological materials. These mate-

rials will have a tremendous impact on clinical analyses by simplifying the preparation, handling, storage, and use of calibration samples. Over the past 20 years, there has been a large research effort to develop artificial blood components that might be used for formulating low biohazard, long-shelf-life POCT standards. One of the biggest challenges in POCT measurement standardization is in the determination of "blood gases" such as oxygen and carbon dioxide. For example with biomimetic blood gas standards, oxygen is the most difficult because of its reactivity (on storage), its difficulty in delivery (interference from perfluorocarbons with some membrane sensors), the need for intermediate level (<100 percent saturated) calibrants, and the need for buffer capacity (because of changes in concentration that can occur on exposure to air or from diffusion through plastic tubing in the instrument).

Another class of biomimetic materials is based on liposomes—macrochemical structures comprised of a phospholipid bilayer membrane surrounding an aqueous cavity. Because of their composition, they are often treated as model cells in research. The aqueous interior of a liposome can be used to hold a wide variety of hydrophilic materials such as electrolytes (ions), enzymes, sugars, etc. or can be filled with detectable bio-markers. Liposomes can be synthesized so that they have excellent stability when stored at room temperature for over a year, and furthermore, they tend to stabilize the materials encapsulated within their structure. These characteristics make them excellent candidates for the cellular components of biomimetic fluid standards. But even in the protected environment of a liposome interior, the transitory nature and reactivity of physiological materials will make it challenging to create standards.

We expect that the research on the use of biomimetics as surrogates for physiological materials will only be a portion of the effort required to exploit these materials as POCT standards. A significant effort will be required to develop packaging to make such standards clinically useful and to ensure their viability over time. As non-invasive optical sensing technologies are developed and come to market, still other types of standards will be needed to link the increasing number of home-based measurements to universal truths.

Senator WYDEN. Doctor, thank you.

Mr. Patterson, welcome.

STATEMENT OF ALBERT PATTERSON, VICE PRESIDENT FOR CONTRACTING, PREMIER, INC.

Mr. PATTERSON. Mr. Chairman, Senator Allen, I would first like to thank you for the opportunity to present to you. My name is Bert Patterson. I am vice president of contracting for Premier Strategic Alliance of more than 1,800 not-for-profit health systems in the United States. I am also a clinician, a pharmacist who has practiced in organized health care for well over 30 years.

For health care providers, purchasers, and suppliers across the country, tapping the vast potential of the Internet has become an integral component of strategic thinking and planning. Health industry observers herald the potential value of the Internet to promote quality-of-care improvement and cost efficiency through both private sector initiatives and public policy action.

While enumerable e-health issues may be debated before this committee, I will focus my testimony on one specific initiative. This initiative is the adoption by the health care sector of an electronically readable, uniform industry data standard, namely the universal product number, UPN, that will be prominently displayed at every level of packaging and transmitted via bar code technology into hospital and vendor information systems. UPN implementation has vast potential for improving health care safety and quality, facilitating clinical product and service innovation and enhancing cost-efficiency at the supply chain level. The technology exists. It is used widely and with documented success in countless other industries, the retail sector perhaps being the most obvious example.

Within health care, implementation has been far less extensive, particularly at the unit-of-use level. It is important to point out that the failure of the health system to embrace this technology does not imply reticence on the part of hospitals. Hospitals, in fact, are eager to develop and deploy this kind of technology to improve the quality of care they provide and to achieve economic efficiencies.

In this regard, I wish to focus on three important areas where UPN as an essential health initiative can improve patient health and safety. UPN has great potential to, (1) facilitate sustain quality improvement and medical error reduction, (2) generate industry-wide cost-savings and efficiencies, and (3) enhance knowledge transfer and engender quality improvement through the use of comparative data.

Although the causes of medical errors and less than acceptable measures of care are complex and deeply rooted, the most immediate and far-reaching solutions lie in the implementation of technology. New and emerging technology such as computerized physician order entry, electronic medical records, automated pharmacy dispensing and bar code-enabled bedside verification, to name a few, harbor immeasurable promise for the safety and quality improvement of health care in America.

As numerous studies have documented, patient safety may be improved and reinforced through the industry-wide adoption of a standardized system of machine-readable codes on all medication packages and medical devices. In the patient-care setting, a bar code can help guarantee that the right drug in the right dose is administered in the right way to the right patient at the right time. Technological advances in the last few decades allow data of greater complexity to be embedded within a bar code. Making the coding of even the smallest packages possible. The technology is out there. It can be done.

The Coalition for Health Care E-Standards states that the adoption and promotion of uniform industry data standards, typified by UPN, would reduce cost and improve efficiencies across the industry and improve patient safety and quality of care, and just 2 weeks ago, the National Coordinating Council for Medication Error Reporting and Prevention, along with the pharmaceutical industry information system vendors and the standard organizations issued recommendations for health industry implementation of bar code technology.

It is clear that momentum for UPN adoption is growing. In addition to its potential for improving patient safety, UPN implementation can generate significant cost savings and efficiencies across the health industry. Unlike pharmaceuticals, to which unique national drug code numbers are assigned, the standardized identification of medical and surgical supplies has no such Government mandate. Clearly, this makes web-enabled linkage of information systems, even for purposes of comparisons alone, anything but seamless. Federal regulation of the identification of medical and surgical supplies would support industry compliance and facilitate the broad-based implementation of these technologies.

The 1996 Efficient Health Care Consumer Response, EHCR report, predicted UPN implementation would yield annual savings of

over $11.6 billion health care supply chain cost. These projected savings are based on the automation of transactions and the integration of a frictionless supply data stream from point of manufacture to point of use. EHCR projects that the standardized use of UPN across the supply chain would yield among the highest returns on investments in automated transactions.

Finally, UPN implementation holds great promise for knowledge transfer and quality improvement through the use of comparative data. Perspective, Premier's signature health care informatics product, is the most complete cost-based, test-level clinical and financial data warehouse in the country. In a nutshell, this enables us to provide an apples-to-apples comparison for a hospital's clinical experience.

Unfortunately, the absence of industry-wide standard product identification, such as UPN, creates a situation in which there is no reliable referable link between a product's facility-specific inventory number and references to the products used in health care. In other words, we are unable to compare product to product to choose the best product available, back to Mr. Scully's comments this morning about comparing apples to apples and choosing the best.

Let me briefly share with you an actual case study. In one of Premier's hospitals, Perspective's data revealed that the use of multiple orthopedic implant vendors was resulting in excessive cost. By comparing its performance in orthopedic implants in terms of cost, length of stay, and outcome, to that of the top quartile performance in this area, Premier was able to demonstrate to the hospital that improved vendor utilization would be more cost-effective.

If the implants had unique identification numbers accessible across the industry by bar coding systems, critical vendor-level data on cost and outcome would be accessible and ripe for analyses. In this case, the hospital was able to convince its physicians that streamlined utilization of selected implant vendors was significantly more cost-effective, and yielded comparable or higher quality outcomes, but only after exhaustive manual tabulation of vendor data.

Our ability to benchmark in the health care setting and to reap the benefits of quality improvement and cost efficiency is contingent on the standardized identification of all pharmaceuticals, medical and surgical products and supplies. UPN's unique identifiers offer such a tool.

In conclusion, Premier believes that adoption of a uniform industry standard is a critical e-health initiative with potential to yield significant progress in patient safety, quality improvement, and cost efficiencies. On behalf of Premier, its hospitals and their patients, I appreciate having the opportunity to attest to the vast, untapped potential of new and existing technology implementation in e-health in the health care industry.

Thank you.

[The prepared statement of Mr. Patterson follows:]

PREPARED STATEMENT OF ALBERT PATTERSON, VICE PRESIDENT
FOR CONTRACTING, PREMIER, INC.

Mr. Chairman, distinguished members of the Subcommittee. My name is Albert Patterson. I am vice president of contracting for Premier, a strategic alliance of more than 1,800 not-for-profit hospital and health systems in the United States. The

Premier family of companies provides an array of resources in support of health services delivery, with a focus on patient safety and quality improvement initiatives, including healthcare informatics, clinical technology/best-practice products and services, insurance consulting, and physician practice management. Premier, Inc. operates major facilities in San Diego, CA; Charlotte, NC; Chicago, IL, and Washington, DC.

For healthcare providers, purchasers, and suppliers across the country, tapping the vast potential of the Internet has become an integral, even requisite, component of strategic thinking and planning. Health industry observers herald the potential value of the Internet to promote quality-of-care improvement and cost efficiency through both private sector initiatives and public policy action. As Paul Starr, Princeton University professor and founder of the Electronic Policy network, observed, improved uses of greater information hold vast promise for health cost reduction, coverage expansion, and greater innovation. Patients, too, have come to appreciate this power. Not simply "opening up their email and saying 'ah'," as J.D. Kleinke, president of Health Strategies Network recently opined, consumers are using Web-based resources not only to inform, but also to *empower*, themselves and their families. In effect, the "system" is coming to the "people" as health plans and providers establish Web sites and open up on-line avenues of communication with patients and each other. A variety of healthcare businesses on the Web now provide customized health information, medical advice, and a widening array of services. Patients with chronic conditions, such as diabetes, are now able to offer their physicians daily updates of their conditions through Web-enabled reporting systems. Taken together with new e-commerce processes in which individual patients may order health supplies for delivery to their own homes, it's clear that the informational, networking and commercial opportunities for the healthcare industry are immense.

While innumerable e-health issues may be debated before this committee, I will focus my testimony on one specific initiative. *This initiative is the adoption by the health sector of an electronically readable, uniform industry data standard—namely, the Universal Product Number (UPN)—prominently displayed at every level of packaging and transmitted via bar code technology into hospital and vendor information systems.* UPN implementation has vast potential for improving healthcare safety and quality, facilitating clinical product and service innovation, and enhancing cost-efficiency at the supply chain level. The technology exists. It is used widely and with documented success in countless other industries—the retail sector, perhaps, being the most obvious example. Within healthcare, implementation has been far less extensive, particularly at the unit-of-use level. It's important to point out that the failure of the health system to embrace this technology does not imply reticence on the part of hospitals. Hospitals, in fact, are eager to develop and deploy this kind of technology to help them improve the quality of care they provide and to achieve additional economic efficiencies. In this regard, my testimony will focus on three issues:

• the potential of UPNs to facilitate sustained quality improvement and medical error reduction;
• the potential of UPNs to generate industry-wide cost savings and efficiencies;
• the potential of UPNs to enhance knowledge transfer and engender quality improvement through the use of comparative data.

SUSTAINED QUALITY IMPROVEMENT AND MEDICAL ERROR REDUCTION

From the Institute of Medicine (IOM), the Agency for Healthcare Research and Quality (AHRQ), the Quality Interagency Coordination Task Force (QuIC) and countless public, private, business, consumer, and healthcare organizations, the message is resounding and the mandate unmistakable.

Sustained quality improvement and medical error reduction in the American healthcare system can be significantly enhanced through hospitals' and other health providers' acquisition and implementation of new patient safety and information technologies.

The mounting significance of technology for the quality improvement of health care—a notion Premier has long championed—was underscored in the March 2001 IOM report, *Crossing the Quality Chasm: A New Health System for the 21st Century.* Recommending no less than a top-to-bottom system overhaul, the report called for the widest possible "utilization of information technologies to improve access to clinical information and support clinical decisionmaking." The committee concluded that the "automation and standardization of clinical, financial and administrative transactions are *essential* to improving quality, preventing medical errors, enhancing consumer confidence . . . and improving efficiency." It is extremely regrettable that, as

the IOM observes, "while medical science and technology have advanced at a rapid pace, the healthcare delivery system itself has foundered."

Although the causes of medical errors and less-than-acceptable measures of care quality are complex and deeply rooted, the most immediate and far-reaching solutions are imbedded in the sphere of technology implementation. New and emerging technologies—such as computerized physician order entry (CPOE), electronic medical records, automated pharmacy dispensing and bar code-enabled bedside verification, to name a few—harbor immeasurable promise for the safety and quality improvement of health care in America.

As has been documented in numerous inter-disciplinary studies, patient safety may be significantly improved upon and reinforced, beginning at the supply chain level, through the industry-wide adoption of a standardized system of machine-readable codes on all medication packages and containers and medical devices. In the patient care setting, a scannable bar code can help guarantee that the *right* drug in the *right* dose is administered in the *right* way to the *right* patient at the *right* time. Technological advances in the last few decades have been such that larger amounts of information, more comprehensive in nature, can be imbedded within a bar code, making the coding of even the smallest packages possible. The technology *is* out there. It *can* be done.

• A study published in the July 5, 1995 volume of the *Journal of the American Medical Association* (*Systems Analysis of Adverse Drug Events*) identified drug administration errors (i.e., wrong dose, wrong drug, missed dose, wrong time, wrong route, extra dose, etc.) as the cause of 58 percent of all adverse drug events (ADE). The vast majority of these errors, the study concluded, could have been prevented with the use of bedside medication verification technology.

An underlying requirement for any bedside technology—to ensure patient identification and the five medication 'rights' (right drug, right dose, right route, right time, and right frequency) is a "unique symbology identifier for both the patient and medication." Authors of the study go on to observe that this unique symbology can be accomplished with *current* bar code technology, allowing all drug dosage forms to be labeled with its unique identifier, the National Drug Code, or NDC. "Today's bar code reader technology would allow the accurate reading of over a dozen different bar code symbology formats," the authors observe, "yet only 60 percent of all drugs administered at the bedside are so (commercially) packaged." The study concludes that the simple addition of a "unique bar code identifier" on all medications used at the bedside could prevent nearly 60 percent of all medication errors.

• The Coalition for Healthcare e-Standards states that the adoption and promotion of uniform industry data standards, typified by UPN and other bar coding systems, would "reduce costs and improve efficiencies across the industry, and improve the safety and quality of care for all patients." In its mission statement, the Coalition cited the November 1999 IOM report, *To Err is Human: Building a Safer Health System*, which clearly identified the integration of bar coding technology as an effective tool in the prevention of medical errors and improvement of overall patient safety. The IOM report, itself, maintained that "patient safety programs ought to incorporate well understood principles, such as the standardization and simplification of equipment, supplies and processes." In addition, investigators emphasized the safe use of drugs in both pre- and post-marketing processes through the development of standards for drug packaging and labeling.

• Two weeks ago, the National Coordinating Council for Medication Error Reporting and Prevention, in collaboration with the pharmaceutical industry, information systems vendors, regulators, and electronic standards-setting organizations, issued recommendations relative to the industry implementation of bar coding technology. While honing in on the application of bar codes in institutional settings, the Council made clear that its recommendations have "broader applicability to other settings."

In summary, the Council recommended that the Food and Drug Administration and the U.S. Pharmacopeia (USP) collaborate with appropriate stakeholders to establish and implement uniform bar code standards for the immediate and intermediate packaging of all commercially available prescription and non-prescription medications. These standard bar codes would be featured on all unit-of-use packaging, including single and multiple unit and dosage. As you know, through the Federal Food Drug and Cosmetic Act, USP is responsible for establishing strength, quality, purity, packaging, and labeling standards for medicines. Regulatory requirements for bar coding would fall under the purview of FDA and its labeling standards for pharmaceuticals.

The Council recommends that the data elements of such a bar code be uniformly ordered, and include, at a minimum,

• the National Drug Code (NDC) number,
• the respective lot, batch or control number, and

• expiration date.

The NDC already enjoys regulatory standing with the FDA and is used by the pharmaceutical industry and numerous healthcare organizations for the automated tracking of drug products. The Council further envisions professional associations developing relevant standards of practice, including the repackaging and labeling of compounded preparations and the education of practitioners on optimal bar code use.

The Council characterizes its recommendations as the "first step to the ultimate use of bar codes in the medication-use process." As Council Chairman Jerry Phillips, associate director of medication error prevention for the FDA's office of post-marketing drug risk assessment, observed, "Once implemented, we believe this standardized approach to bar coding technology is a primary and important mechanism to improve patient safety in hospitals and other health care institutions." The Pharmaceutical Research and Manufacturers of America (PhRMA) and Generic Pharmaceutical Association (GPhA), both dominant process shareholders, agree that the implementation of standardized bar codes would be an effective way to improve pharmaceutical product, and ultimately, patient safety.

• As Premier urged in its formal comments to HHS with respect to the Medicare inpatient prospective payment system (PPS) proposed rule and the current outpatient prospective payment system (OPPS), all new medical devices qualifying as 'new technologies' (and therefore subject to special 'pass-through' payment) ought to be identified by the appropriate UPN, or universal product number—a unique numerical sequence identifying a specific healthcare device and its manufacturer.

Given that healthcare providers have agreed to accept either of two industry-standard data formats, we believe UPN could be readily incorporated into the Centers for Medicare and Medicaid Services' (CMS) existing coding system. By mitigating administrative and payment system complexity for both hospitals and CMS, and fostering wider application of a bar code that, recognized at all levels of the supply chain, can assist in ordering, tracking, and validating inventory, such implementation would go a long way toward improving safety in the patient care setting.

As I just described, the explicit identification of medical devices that qualify as 'new technologies' is but a single application of a standardized bar code system. While admittedly specific, the example is emblematic of this technology's inherent promise for wider integration in our health care delivery system.

COST, AFFORDABILITY, AND INNOVATION

One of the most significant developments to come out of the e-commerce revolution is the ability for businesses to link information systems seamlessly. Business-to-business ('b-to-b') e-commerce is defined as the direct sale of goods and services to other firms and government agencies. Health e-commerce b-to-b models, including medical and surgical supply Web sales and on-line auctions for refurbished equipment, are extensions of general business e-commerce. Unlike pharmaceuticals, to which unique government-mandated National Drug Code (NDC) numbers, recognized across the industry, are assigned, the standardized identification system for medical and surgical supplies has no such mandate. Clearly, this makes Web-enabled linkage of information systems—even for purposes of comparison alone—anything *but* seamless. Federal regulation of the identification of medical and surgical supplies would support industry compliance and facilitate the broad-based implementation of these technologies.

Application of existing bar coding technology to the healthcare supply chain harbors great potential for driving down management costs. The 1996 Efficient Healthcare Consumer Response (EHCR) report predicted such developments would yield annual savings of $11.6 billion in healthcare supply chain costs. These projected savings are largely based on the industry's implementation of a series of automated trading transactions, and integration of a frictionless supply data stream across the healthcare industry, from point-of-manufacture to point-of-use. EHCR projects that the standardized use of UPN across the supply chain would yield among the highest returns on investments in automated transactions. Most importantly, the study indicates that UPN implementation can result in significant efficiencies and cost savings for the healthcare supply chain, and ultimately, individual medical centers and health facilities.

We all have become accustomed to having our purchases scanned at the checkout line. We know the technology is there. We know efficiencies can be achieved through the technology. By positioning the supply chain to engage in new e-commerce capabilities, the health industry would be able to leverage investments in health information networks and reduce the cost of patient care. Such positioning would fuel

the momentum essential for the prompt introduction of new products, the reduction of administrative costs, and the dissemination of data across the supply chain.

OPPORTUNITIES FOR BETTER BENCHMARKING

Technological innovation makes higher-quality health products and services, as well as improvements in productivity and supply chain efficiency, possible. Comprehensive data on—and the ability to conduct rigorous comparisons of—existing and emerging health practices, products, and services is critical to decisionmaking in the clinical and business spheres. Across the health industry, from the supply chain to the inpatient setting, comparative data—and more pointedly, the ability to compare and qualify different sets of data—is essential for clinical process and resource utilization improvement.

Perspective, Premier's signature healthcare informatics product, is the most complete cost-based, test-level clinical and financial data warehouse in the country, permitting peer group comparisons at the resource consumption level. Hospitals track resource utilization and patient billing for products and services rendered through what is called a 'chargemaster,' unique to each institution. *Perspective* compiles these individual chargemasters, and translates or normalizes them to a standardized, 'master' chargemaster, if you will, enabling the ever-elusive 'apples to apples' comparison. Now, to appreciate how truly monumental in scope the implementation of a standardized bar coding system for product identification would be, consider the following:

• It is likely that every distributor and user of a specific product identifies it with a different 'inventory' or 'stock' number.

• Manufacturers' product identification numbers are not usable for ordering from a distributor.

• Often, distributors and recipients/users of products find different product number on packing slips and invoices.

The absence of standardized industry-wide product identification creates a situation in which there is no reliable, referable link between a product's facility-specific 'inventory' number and references to that product in the chargemaster. Utilization comparison at the facility or system level is rendered virtually impossible because providers are able to 'drill down' in the data only *so* far. General comparisons are permissible with respect to a product's general grouping or category—i.e. catheters or stents—(often variable, themselves, among facilities), but isolating product specifications, or even the manufacturer, can prove insurmountable. Standardized product identification through a universal bar coding system would vastly improve supply chain efficiency, and make richer, more valuable data comparisons possible. These comparisons would facilitate true clinical comparability, providing for greater cost and quality improvement.

The UPN would be especially valuable for high-cost, 'high technology' items, such as pacemakers, defibrillators, and orthopedic implants, as illustrated by the following case study.

CASE STUDY: ACHIEVING GREATER COST EFFICIENCIES IN ORTHOPEDIC TRANSPLANTS

An analysis of *Perspective* data revealed that the engagement of multiple orthopedic implant vendors by one of Premier's hospitals was resulting in needlessly excessive costs. By comparing its performance in orthopedic implants (hips, knees and related components) in terms of cost, length-of-stay and outcome, to that of the top-quartile performers in this area, Premier was able to demonstrate to the hospital that improved vendor utilization would be more cost-effective.

Because orthopedic implants and related components are not identifiable across the health industry in a consistent, standardized way, hospitals cannot provide vendor-level data in their chargemasters. As a result, this valuable vendor-level data cannot be compiled and analyzed by Premier's *Perspective* data base. Its absence, and more pointedly, its unavailability, required Premier to go back to their top-performing (with respect to orthopedic implants) hospitals, *one by one*, to gather data on the vendors they engage and costs they incur.

If the implants and related components had unique identification numbers, accessible across the industry by a standardized bar coding system, critical vendor-level data with respect to cost and outcome would be not only available, but ripe for analysis. In addition, standardized identification would make the data compiled vastly more accurate and reliable. The accuracy of data is absolutely critical, especially when comparative analyses reveal that changes in practice or behavior are warranted, from either clinical or business perspectives. In this case, the hospital was able to convince its physicians that streamlined utilization of selected orthopedic implant vendors was significantly more cost-effective. Had the vendor-level data nec-

essary to make such a determination been readily available, Premier's *Perspective* data base could have conducted the analysis in a more prompt and effective way.

In summation, if all medical and surgical products and supplies were identifiable by UPN, Premier would be able to:

• Identify cost, length-of-stay (LOS), and outcomes (re-admissions, mortality and complications) by vendor;

• Use that information to select which vendors would be better for standardization;

• Identify and quantify the value of product standardization; and

• Identify cost, LOS, and outcomes by vendor in hospital-to-hospital comparisons.

CONCLUSION

Comparative data is the building block upon which quality and safety improvements in the clinical setting are achieved. To date, with more than 520 reporting hospitals, Premier's experience in this arena has yielded critical success. The fact remains, however, that our ability to benchmark in the healthcare setting, and to reap the benefits of subsequent quality improvement and greater cost efficiency, is contingent on the standardized identification of all—pharmaceutical, medical, and surgical—products, devices and supplies. UPNs—as unique identifiers—offer such a tool.

On behalf of Premier, its hospitals and their patients, I deeply appreciate having had the opportunity to attest to the vast, untapped potential of new and existing technology implementation in e-health and the health care industry.

ABOUT PREMIER

Premier is totally owned by its not-for-profit healthcare systems, which operate or have affiliations with approximately 1,800 hospitals in all 50 states. The Premier family of companies provides these members an array of resources in support of health services delivery, with a focus on contributing to the improvement of clinical care quality, cost-effectiveness of health services, and patient and worker safety.

Premier's member services include group purchasing for pharmaceuticals, supplies, and equipment; healthcare informatics and comparative data bases that help hospitals benchmark and improve; clinical technology services supporting hospitals' acquisition, use, and maintenance of biomedical equipment; consulting expertise in support of performance improvement; management of member-owned insurance programs; and support services for physician office management. As reflected by its organization, products and services, Premier is grassroots-oriented, value-based, and guided by the interests of its community health system owners.

Senator WYDEN. Thank you.

Senator Allen.

Senator ALLEN. Thank you. I have a whole series of questions. I guess I will do it in the way that you all gave your testimony, although there may be a strain or a thread that goes through all of them.

Let me first start with Dr. Fuller. Your statement emphasized that the health care industry has difficulty justifying the expenditures for technology investments in the absence of any real fiscal incentive and strong supporting data that putting all this money into it is actually going to save them any money or do anything better.

Can you elaborate on that point in reports which seem to suggest that there are financial incentives, therefore investments, and what sort of supporting data, so that we understand what kind of supporting data do you think is needed to justify such investments?

Dr. FULLER. To respond to your question, my own experience is as a faculty member in an academic medical center which is composed of two large medical centers, affiliated hospitals, and a very complex environment that includes primary care clinics that are part of that organization, and I think the data issue and the primary issue has to do with the fact that you cannot implement just a piece of a solution and fix a single problem.

It is a very complex set of information systems and technologies and tools existing in every hospital today, and certainly in academic health centers, which are composed of numbers of hospitals and in health care plans, and right now, one of the critical pieces that is missing is that the vendor community and the software that is available to us to implement are simply not responsive to the complexity of the environment in which we live.

The idea of the enabling technology centers I referred to—which could provide a way of experimenting with an entire system, and not just a piece of the system—was that very point that you are making, which is to look at the data, look at the evidence, look at the way that it can be implemented so that it becomes a seamless system. Off-the-shelf solutions simply do not exist today to respond to the complexities that we have all been discussing on this panel and that we have heard about from Mr. Scully earlier.

Senator ALLEN. Let me follow up in this regard, then. You are saying that whatever adaptation software, and so forth, that they are off the shelf, just do not respond to the reality. They may be perfect for manufacturing automobiles, they may be perfect for something or another, but it is just not fit, and your response to the long-term research and development that is needed are dollars or money for these enabling technology centers.

Has there ever been an effort made, say, from the health care industry to get, say, with Oracle, where some of these folks will say they will work with universities, and will say here is what a university needs. I am not talking about the medical schools, but an Oracle or a Cisco or whomever it may be and say, "Here is what we want, can you develop it?"

It would seem to me that the private sector folks, who are going to be the ones eventually involved in this and competing for this business, would love to work with a confederation or association of health care providers and service providers. Has that ever been attempted?

Dr. FULLER. It actually has, and there are a number of examples that I could point to, a number of companies that have participated, but it requires an investment on the part of the organization. The vendor community will not come to the table with all of the money that is required to implement a very large-scale solution to a problem, and so therein lies the opportunity and, in fact, the solution.

One of the strategies that has worked with a vendor partnership with academic and other health sciences organizations, and with federal funding, is the integrated advanced information management system program that the National Library of Medicine has funded for the last 15 to 20 years.

A number of institutions have benefited from that and, in fact, in our own case at the University of Washington, and also, I believe, at the Oregon Health Sciences University, which benefited from that program, there was extensive vendor participation. I will say that we certainly leapfrogged ahead in terms of a development of a complete electronic medical record for our medical centers that includes retrospective data and is very comprehensive. It was very much a result of that federal funding that helped us to provide the incentives for the organization to look at itself comprehensively, to

attract the vendor community to work with us and so forth, but it does require an investment in research and development. It is not, again, a case of off-the-shelf software that will solve the problem.

Physician order entry has been mentioned, and that is one of the thorniest issues of all. We are just beginning to move in that direction, and I think the other panelists have alluded to solutions that are pieces of the answer to the problem of having true order entry that is responsive to the needs of health care teams.

Again, it is extraordinarily complex, when you are dealing with multiple hospitals, multiple primary care clinics, and trying to get a system that works seamlessly in support of health care teams. It is not a trivial situation, and we simply do not have the research evidence and the experiments have not been done that will provide us with the fuel to do this with as little pain as possible for the participating health care organizations.

Senator ALLEN. Well, you listened to Dr. Kenagy's principle of disruptive innovation, as far as helping revolutionize and change the health care industry. I thought I noted you nodding in agreement. Do you agree with that?

Dr. FULLER. That is exactly the idea that I think was driving our thinking about the enabling technology centers. We need a place to experiment and not put people's lives at risk, and experiments on the whole health care system across the United States are simply not feasible, but if you can create a system in which you can control the inputs and the outputs and what you are studying, I truly believe that you could engage in the kind of disruptive innovation that Dr. Kenagy points to, and that is why I was nodding. I said yes, that is precisely what we could do, but these have to be very large-scale experiments, and they have to happen over a period of time.

Much of federal funding for IT interventions is very short-term. I did a telemedicine project that was 2, 2½ years. It was extremely difficult, and the results were not what we had hoped for because we could not get the numbers of cases. We could not create a randomized control trial the way we wanted to. We could not move as quickly as that money—the clock was ticking, and trying to come up with a study, do the study, assess the results, and do the reports was not feasible in the amount of time we had.

So again, I believe that the solution is much more long-term research and development ways that we can do this over time, and really do what we do with medical research. We do not expect bench researchers to return findings—well, we may expect it, but we know that it is going to take years in the laboratory for some things to be discovered, the cures for diseases. We should expect the same kind of investment in tedious research to be done with the information technology solutions that we believe have incredible potential.

Senator ALLEN. That is good insight, and it is all understandable, and we want to make sure what we do is right, because this is not just a question of whether somebody has 5 percent or 4 percent of the market share. This is someone's health, and the capability of getting quality health care provided to them.

On the other hand, there does seem to be a need to start moving. Everyone recognizes there needs to be greater utilization of infor-

mation technology, and listening to our previous testimony from Mr Scully, his view was that if you did not put a date certain that you have to do this, it would dawdle, and generally I have seen in bureaucracies if there is no measurement, if there is no accountability, if there is no performance standards, everything will get dumbed down to the lowest common denominator, and no one will ever do anything, because the mind set is one in which if it has been done this way for the last 20 years, that is complete justification.

So that is the quandary I think we have here, is that inertia of bureaucracy, or people just liking to do things the same old way. There are plenty of jokes even in Virginia and in the U.S. Senate about things have been done this way. There is no electronic voting in the Senate. It is amazing to me. That is the way it is always done.

I am sure they talk about how great the old light bulb was when you have to change a burned out light bulb, but nevertheless, with all of the inertia, to stay the same, there needs to be change, but it has to be careful in how it is done.

I like, Dr. Kenagy, your concept. Now, you cite in your statement how current hospital investments are in areas—and I am writing these things down. They all focus where they can make the profit, supposedly in the cardiac-pulmonary, the orthopedics, the more procedures, and not in the bulk area of health care, the other 95 percent.

Now, why is this that mentality, when the other 95 percent offers opportunities to reduce costs which will obviously ultimately improve profitability? Why is it that they focus just on that 5 percent?

Dr. KENAGY. Because, Senator, they are good businessmen, and they have built organizations over the last 30 or 40 years to continually improve the functionality of health care, and we have done wonderful things.

When I became a physician, cardiac surgery was a rare and highly dangerous procedure, and now it is commonplace. It is routine, and that is wonderful, but it was developed in the context of a very high-cost business model to build that functionality.

We have reached a point in health care where we do not need to be so focused on improving the functionality of our products and services. Yes, we need to continue to push the edge. We need to continue to push and work on the sickest and sickest of patients, but now I believe the basis of competition has changed in health care. Instead of increasing functionality, we need systems that will be first of all reliable. We would just like to get the right medication to the right person at the right time in the right place, and we obviously have a tremendous difficulty in doing that.

After reliability could come access, customization, the ability to fine tune the health care system to the needs of specific individuals and people, and then finally lower cost. It is not that our present organization and our present leadership does not want to do that. They do. It is the characteristic of disruptive innovation that leaders do best what their processes and values have built them for, and they continue to work in that area.

They cannot do disruptive innovation. Clay Christensen has studied over 350 different industries and incidences of disruptive

change, where a whole organization or a whole industry changed, and leadership was never able to lead that change within the confines of their mainstream organizations, simply because the business models drove them into that far upper right-hand corner.

Senator ALLEN. How would you, Dr. Kenagy, handle with your disruptive innovation concept what Dr. Fuller was saying, which made a great deal of sense, that before we impose this on the whole industry, or even if you did it in the Southeast or the Northeast or the Midwest or Rocky Mountain West, or Pacific Coast, before you actually did something like that, how do you mesh that understandable view versus your desire for this change, and this change relatively quickly?

Dr. KENAGY. I agree completely with Dr. Fuller and her view, and how really IT changes will occur in health care. They will start with small, understandable pieces that have the opportunity to iteratively improve and get better. They will start in small places.

Senator ALLEN. So without standardization, then, because generally speaking I believe that whatever gets measured accurately gets better.

Dr. KENAGY. You are exactly right, Senator, and we need to measure at a much lower level. We suffer from a myth in health care that we can put together data. Like the instrument panel on a 747, and I will be able to just drive this hospital right down the runway.

It is much more complex than that, exactly to Dr. Fuller's points, and a major problem that I see working in health care in my interest is how do you get next to the patient, and build up systems from the patient and their needs? How do you buildup from the patient, matching patient needs, not a top-down solution but a bottom-up solution?

What we find is, software and hardware pour bad processes in concrete. It is a tremendous problem. It is extremely difficult to make changes in computer systems. In our studies, we find hospital health systems are chaotic. If we computerize chaotic systems we will get turbochaos, and that is a problem.

Senator ALLEN. All right. Now, what role can the Federal Government play, which is generally one of the things that the Chairman and I are trying to figure out? What role can the Federal Government play in promoting disruptive innovation? I am not sure if we would want to go out and run campaigns on, we want to be disruptive innovators of your health care system. You can do that as a doctor and an academic, but nevertheless, let us just say forward-thinking innovations, where can the Federal Government help move this process and this service along?

Dr. KENAGY. I believe this is a leadership issue, and I believe leadership within the Federal Government, understanding the concepts, if you can put on the lens of disruptive innovation, our present situation not only becomes more understandable, it becomes completely predictable, and creating opportunities for leadership to learn and understand the concept of disruptive innovation, and then to take a lead in that area I think is very important.

Harvard Business School and Harvard Medical School have combined together, I think for the first time ever—that is a disruptive innovation in and of itself—to offer to develop consortiums on dis-

ruptive innovation in health care. We have invited Senator Wyden and his staff to the first one in September, where we bring real companies and organizations who are actually trying to do disruptions together, five or six companies at a time, to try to understand how these ideas work and how they happen.

Most importantly, from the governmental point of view, disruptions do not take root and grow in areas where they face organizational and regulatory barriers. They do not grow in large, established organizations, because established organizations have their own barriers to disruptive growth, so you must separate those ideas within your organization. You have to create a safe place within your organization to do this, and we can help, it has been done. It has been done by many companies, IBM, Hewlett-Packard. We have good data on how that can happen.

From the regulatory point of view—and I do not know how this would happen, Senator, I would have to rely on your expertise. How can we create some safe havens, or some safe places to safely experiment? Dr. Fuller's point is much to the case. These disruptions do not just spring full-blown from the heads of a brilliant person. They develop iteratively, and improve through the system.

How can we do that safely, and avoid regulatory barriers? How can we create some safety within the regulatory system for disruption to happen, and interestingly, I believe the changes will come out of the uninsured and the indigent population. That is the unattractive market segment, and that, is a fascinating area to explore.

If you look at the history of disruptive innovation, they always grew out of unattractive, overlooked markets, to grow into the mainstream, and I think trying to develop disruptions in those areas would be exciting and interesting.

Senator ALLEN. Well, I know you love that concept, or that phraseology, and you are conversant with it, but regardless of what words are used, what I think would help the Chairman and myself and other members of the Senate is to give examples of where those regulations—currently, if somebody has an idea—and I do not know if you have any examples of where your concept of disruptive innovation has had a regulatory barrier, or there was a regulatory barrier the concept of disruptive innovation was put in. Do you have any examples of where this concept somehow faced a regulation, or this concept has been utilized, and we can say, "Well, this is an example," rather than just talking in general theory. Any real-life examples?

Dr. KENAGY. A few that I have just come across happenstantially in the course of doing this. A physician, actually in Virginia, a pediatrician who was very interested in developing home care products for patients, really an ultimate disruption. Disruptive innovations allow more accessible, appropriately skilled people to do things that were formerly done by expensive centralized specialists. His plan, and he started a business to do it, was to try to get more health products into the home, and teach families how to use them, and he had a great deal of difficulty involving other physicians in this product, because of the fear of the kick-back and referral laws, even though he carefully designed his endeavor to avoid those.

The general fear among physicians was, I just cannot get involved. I just do not want to get involved. There is too much risk. I cannot take that step. I cannot do something different.

I talked to a hospital administrator in Ronan, Montana, a little town, seeking to keep health care within his community, and developed a clinic associated with his hospital, followed every guideline perfectly, and ran into a gigantic hurdle from HCFA that it was very difficult for him to circumvent. It took a huge amount of time, effort, and money for him, even though they had really dotted the I's and crossed the T's completely, at least in his report to me.

So the examples are out there. The examples are small, and that is the important thing, because these ideas, they do not start with a gigantic wave from the top. They bubble up from the bottom.

Not all regulation is bad, certainly regulation is an essential part of our business, but it gets back to patient care. You do not have to regulate something that works, and we ourselves have to get this piece to work.

Mr. PATTERSON. Mr. Allen, if I may.

Senator ALLEN. I would think Mr. Scully would be one who, if you all came up with some probative ideas, whether it is in the Pacific Northwest or anywhere in the country, I think we would certainly want to allow you to do that, and it seems to me that Tom Scully would be very willing to do that as well. He just strikes me as someone who is innovative. He has not been in Government for the last 8 years. He has been in the private sector.

Go ahead, Mr. Patterson.

Mr. PATTERSON. I would like to bring up one example of where regulation has helped, and where the lack of it currently is hindering even the utility of what Dr. Fuller has talked about.

You go back to the regulation that mandated the use of the national drug codes on pharmaceuticals, and that the pharmacy profession then created a standardization around that allows the tracking of pharmaceuticals by class and the grouping of those, and then the complete lack of standardization on the medical device and medical product side, where you have over 400,000 items out there that cannot be characterized.

You cannot go into a library in this country looking for a mystery and not go to a catalogue telling you every mystery book they have and where to find it. You cannot do that with health care products, other than pharmaceuticals.

Senator ALLEN. Well, I guess one thing, Dr. May was talking about, besides stating the future, is now, which it is, and we wish it were sooner sometimes as well, but that is a good attitude that I think of a lot, but you stated, Dr. May, and this may get into the medical devices that, Mr. Patterson, I have some questions of you, too, following Dr. May's, but you stated in 1980—excuse me, 1998, the European directive on *in vitro* diagnostic medical devices, IVD's, should encourage greater NIST leadership in establishing a global reference system, and this just has to do with the United States and competitiveness.

What would be the cost to the United States if we do not become involved in this process, which almost follows perfectly?

Dr. MAY. I guess I have some numbers in my written statement and elsewhere, but I will say that 60 percent of the European market now is supplied by United States-based manufacturers.

Senator ALLEN. So in the event we are not involved, we are going to lose that. We potentially could lose that.

Dr. MAY. We could potentially lose that, and I guess the other concern that some IVD manufacturers have expressed is that, although, as stated, the EU directive should provide for an even playing field, and that it should provide for higher quality health care services for citizens of the European Union, they see the possibility of it being abused, and it being used as a technical barrier to trade, unless we in the United States are very aggressive and make sure those standards are in place.

Senator ALLEN. That was my followup question, was whether or not the EU directive, if we are not involved, would be another excuse for the EU to deny that market, or use it as a trade barrier.

Now, as far as these technological standards, do you think NIST should play a role in the adoption of those standards for the health care industry, such as Mr. Patterson's universal product number?

Dr. MAY. NIST is involved in information technology standards through its information technology laboratory and through the advanced technology program. There are also measurement standards on the chemistry side that we are involved in. Obviously, my very biased opinion would be that certainly NIST should be involved, but other folks around the world seem to share that opinion that, in fact, this cannot happen unless NIST takes a leadership role for many reasons that I will not enumerate here for lack of time.

Senator ALLEN. Let me go on to Mr. Patterson now. Thank you, Dr. May.

I like what Dr. Kenagy said as far as customization, and I think the uniform product number is fine, but I always like to look at the advancements in technology and in the customization aspect, and I think the UPN is fine. I do not mean to be criticizing, just so you understand. My main interest in all of this, is in an nterest in technology; in the monitoring and the gauging and the transmitting of information of a patient who is at home and not in a hospital.

Now, obviously, some people are going to have to be in a hospital with close monitoring, but I would like to see the day, and I do not think it is that far away, where you have a more customized—you are at home in a friendlier setting. They may have diabetes, or some allergy that is being tested or monitored accurately.

That information is being transmitted wirelessly, or over the Internet to the doctor, wherever he or she may be, and then there is a reaction to it, and in fact you may not even need the physician involved. The dosage and the medicine is customized. Let us not take one pill. Somebody might need 8/10ths of a pill, or .87 percent of a pill, and whatever the dosage is, is being monitored or given automatically, with the record going back to the physician who has the information that he or she needs to make sure everything is being monitored accurately, and the reaction is being accurately administered.

Now, Dr. May, discussed some of the potential benefits from measurement standards and the role of increasing the reliability and accuracy of health care measurements. We talked about the fi-

nancial benefits of management standards. Now, can we expect a similar type of return from the use of the UPN number, or uniform industry data standard? Would you see the same sort of returns?

Mr. PATTERSON. I believe we could, and I also believe that it is a mechanism to enable the consumer to be at home and get health care. Take an example of one of the highest cost diseases in this country to treat, diabetes. The diabetic definitely can be treated at home, but most diabetics who are out of sight of their clinicians are not doing what they are supposed to be doing, and therefore it costs the health care of this country more money.

Take a web site. We have some examples of one of our employees who has actually done this, and you plug in your information into that web site. It automatically goes to your doctor. If your insulin, if your syringes, if everything has a product number on it, you scan all of that in.

All of the information is there for the doctor to look and see if, in fact, you have the right insulin, and if, in fact, you are doing the right thing with your blood testing, and the fact that you are using the standards that Dr. May talked about, and the clinician can look at that, or can have some triggers in the system, in his home page, if you would, to have some triggers in the software that said, this patient just put in their blood sugar, they just indicated that they have product number XYZ, which is linked to insulin, they should have regular insulin, no wonder they are out of control, that could have tremendous applicability to enable the consumer to better track their health care progress, and the physician, and the clinicians.

Senator ALLEN. You actually applied the UPN in your customized approach. Thank you for making that—because the UPN's are great. It is great to have the bar codes and all of that, but thank you for fitting it into how it would work in a way that I would like to see technology benefiting the actual patients.

Now, do you see, and if you do see any private sector or Federal Government barriers, regulatory barriers to greater adoption of information technology such as UPN in the health care industry, if you see any, please let us know right now.

Mr. PATTERSON. I do not see any barriers, other than just essentially creating a tracking system for UPN, but you essentially already have it for NDC's. You already have a tracking system. I do not see any barriers at all to implementing something like this.

Senator ALLEN. Well, how do you see the Federal Government playing a greater role in the adoption of information technology for products, in particular, UPN?

Mr. PATTERSON. The Federal Government, in order for UPN to work, must get involved. The industry does not want UPN. My view of that is, because it allows the health care practitioners to, in fact, shop, if you would for the best value amongst products.

Senator ALLEN. By industry, who do you mean?

Mr. PATTERSON. Medical supply, medical device industry. They have the capability of using UPN right now. All the standards are there. They just have to implement them, and what that will do is enable all the purchasers of health care products in the country to do exactly what they do with pharmaceuticals today, and that is to

group them in classes and look at the best product for the application at that time.

You take an example of gauze sponges, or 4 x 4's, whatever you want to call them. There are 400 to 500 of those marketed today. There is no place you can go and look to see which ones are the same, which ones can you use, what is the best value for the customer, because there are no standard numbering systems that would allow a body, if you would, to create a cross-reference of those products.

Senator ALLEN. So, are you then suggesting there should be one mandated?

Mr. PATTERSON. Yes. What I am suggesting is that the use of a standard numbering system for medical products and medical devices should, in fact, be mandated.

Senator ALLEN. Thank you. I have no further questions, but I want to thank each and every one of you for your time and your expertise and your insight.

Thank you, Mr. Chairman.

Senator WYDEN. Well, I thank my colleague. Those are very good questions, and I have just a few in addition.

Dr. Kenagy, I think what Senator Allen was grappling with was along the lines of what you and I talked about on the phone. We are going to need real case studies of examples where the Federal Government impeded innovation.

That is why I asked the questions I did of Mr. Scully concerning the kick-back and referral statutes. To some extent those laws, which are clearly important in terms of blocking egregious conflicts, are chilling the sharing of information through electronic health programs. We would appreciate some examples—and by the way, just in the area that you are talking about, the uninsured, Senator Smith and I were able to get $28 billion in the budget in order to jump-start the effort for the uninsured, and so nothing could be more timely in that area.

I have noted, for example, some comments you and others have made about an expanded role for physician assistants, who would simply have at their hip what amounts to microprocessor control diagnostic tools, and high-speed data links. With this information, they could in effect keep people out of hospitals, and various other services. I am not sure the Federal Government is blocking that at this point. If it is, we need to have you walk us through that.

I wanted you to come to the U.S. Senate today, because I think what you are talking about is one of the most exciting things out there in the debate over health care in this country. If you could give us a handful of examples, especially in the area of the uninsured, because we are on the cusp of going for it in the Senate Finance Committee, trying to figure out how to utilize that $28 billion.

It is not something that is going to happen in 6 months. It may start next week, conceivably, and so that would be very helpful, and Senator Allen and I could work on that in a bipartisan way.

Dr. Fuller, I was struck by something you said at the beginning of your testimony which to some extent was something I raised earlier today. That is that many of the biggest challenges in front of e-health are not any different than the challenges in front of health

care as a whole. You mentioned the fact that you get notices about your pets' immunizations and you do not get them for yourself.

You do not need some fancy integrated e-health medical information program for that. That is something that could have taken place with a phone call, or putting something in snail mail and getting it to you that way. Why do you think we have gotten to the point where so many obvious solutions to better assist people have not been utilized? What is the lesson out of that so that we do not repeat it, as we look to design these e-health systems?

Dr. FULLER. Clearly, that is the crux of the issue, and I wish I had an easy answer to your question. I do not, but it does relate to the inertia in our current health care system where people in it—well-meaning people who work very hard to introduce improvements—are simply overwhelmed by the complexity they face in creating solutions that will scale, and by the way, I did not mention this at the beginning, but I am a librarian by background.

I was trained as a librarian, and I fell into bad company early on of computer scientists. People have said that about me, and that somehow very early on in my career I became a transformed person in terms of my interests, and the interest in information technology as a way of solving many of these kinds of problems.

How do we introduce solutions that overcome the inertia and the fact that people are so overwhelmed in our health care system today that they simply do not have additional minutes in the day to learn a new computer program, to learn a new software package, to look at data that is presented to them in not very good formats, I must say. But those are the kinds of questions that I think are conducive to research, and that we really can fine-tune and use the technology to save people's time, but that has not been the focus of much of the work we have done.

Instead, we have said, you are going to love this, and handed them a new computer program, or handed them an order entry system, and never asked them what they thought of order entry, of online order entry, or how is it really done today? Do we really know, in a complex health care system, how orders are entered today, who enters them?

It happens in many cases not to be the physician, and so we have some very difficult change management problems, and I guess my single tune has to be that if we do not know the questions, we cannot possibly come up with the right answers, and I do not think we even are asking the right questions, and so we are not coming up with the right answers to many of these issues.

Senator WYDEN. How much of the problem, in terms of really speeding up these innovations that are technology driven, stems from the fact that in many ways you get penalized for doing it?

Dr. FULLER. Yes, you do.

Senator WYDEN. Fifty percent of the problem, 75 percent of the problem?

Dr. FULLER. I think that the people who have attempted to be innovative in information systems have very often suffered as a result of those innovations, either personally or organizationally.

Senator WYDEN. So you would not disagree with the theory that I advanced earlier that if you told everybody to submit, capture,

adjudicate, and reimburse claims in a hurry, that would force some system-wide changes? It would not penalize people.

Dr. FULLER. Yes, I think that is true, but I think we have to separate innovations in the administrative aspect of health care which I think need to go on, and can be driven by edicts like that, from the fact that in health care the Federal Government has not invested in the basic IT research in support of health care. Instead, we have lived off of the inventions of the Department of Defense, the Department of Energy, the National Science Foundation and so forth, and those solutions, as good as they are for security, for networking, for other kinds of technical issues, the Internet itself, simply are not responsive to the kinds of problems we are talking about.

Senator WYDEN. Well, then let us ask about public investments. What should the Federal Government do in terms of investing in the next generation of supercomputers so that the information from the human genome can be quickly transformed into individualized drugs that assist people?

Dr. FULLER. I think the investments must be made in a way that includes health, biomedical informatics researchers as part of the research teams, and without a federal investment in computing that includes health care information technology researchers as part of the solution, we are not going to get the solutions that we need, and we may get them eventually, but we will not get them as quickly as we need to get them.

Most companies do invest in information technology development and research, and there are percentages that are quoted between 3 and 6 percent of the budgets of corporations. I believe that in the Federal Government's health care budget across the board, and I am speaking for myself, although we have made aa similar recommendation, but not a number, that some percentage, 3 percent, some percentage should come off the top and be used by all of the federal health care agencies to fund the kinds of innovations and research and development that will address the kinds of problems that we have been talking about this afternoon.

Senator WYDEN. Dr. May.

Dr. MAY. Just one comment regarding the human genome project. We are talking about ways of disseminating this information, and this is truly revolutionary information that will transform the way that we all live, but we also need to invest some resources in looking at the quality of that data.

Dr. FULLER. Absolutely.

Senator WYDEN. Dr. Kenagy.

Dr. KENAGY. I think along the same line, I mean, because it strikes home so true, and all the way across the board, for the genome to work and to—you know, before we invest in gigantic supercomputers, let us understand the processes of care. Let us understand how things really work.

The example of the veterinarian who can get information to the owner of the dog, and the fact that we cannot get that information to our patients, it is not a technical problem. We have got bucketloads of technology that can do that. Those are organizational issues, and until we confront those issues and deal with

them at the very point of care, we will continue to have these problems.

Senator WYDEN. Well, that has essentially been one of the key points that I have been trying to make over the last 3 hours. I think there are problems in the IT area, and the e-health care area, that are not very different than other problems that we face, and that is why I made the proposal I did today with respect to medical claims. I think we also ought to be dealing with the fact that innovators are being penalized. They are being penalized again and again.

The health system in the State of Oregon, Dr. Kenagy knows, went out and was in the vanguard of managed care and a variety of other innovations, brought competition, and the Federal Government said, "Good for you, we are going to send you smaller checks." Now it is going to be a lot tougher to attract the top-flight health care providers as a result of the fact that you did all this heavy lifting before everybody else. The message to the converse is that if you did not really care, and you really wanted to just keep jacking up costs, do not sweat it, because the Federal Government will just send you a bigger check for your labors. Those are good points.

Let me turn to you, if I might, Dr. May, and I was glad you mentioned the *in vitro* area. One of the issues that I follow over the years, I wrote the fertility clinic success rate statute a number of years ago, so I have been interested in this area, and I would be curious—you know, we have got national standards for 12 health status markers. Do you think that there is a need for standards for additional health status markers, and if so, what would they be?

Dr. MAY. Well, certainly, to set the record straight, I guess, we have national standards for a bit more than 12. We have 12 that are listed there, that are what we call definitive, but we have others that we have realized using other approaches, but certainly what about the other 300 minus whatever that X is that people measure every day, and there are medical decisions being made based on that data, and they are not all linked to any universal truth. This certainly has some implications on patient care.

But the IVD directive in Europe is saying that to the extent possible, all data used in the European Union will be truth-based, and certainly that is going to have a large impact on us in the United States, whether we like it or not, and the IVD industry has accepted that they are going to have to spend more money on this activity, and they have also identified a role for NIST.

Senator WYDEN. And you have a lot of work to do between now and December of 2003.

Dr. MAY. First of all, there is no way we can get all that done by that date, and it is going to require a sustained effort over time, and it is not only going to be the United States, and it is not only going to be NIST. It is going to require the involvement of standards laboratories around the world to get this done.

Senator WYDEN. Now, the manufacturers are also making products for home diagnostics market, and there is great interest in this. I think Senator Allen is absolutely right that this, of course, is something that the American public will want to see as more of these home diagnostic tests enter the marketplace. Are there going

to be measurement standards in place to ensure the accuracy of the tests?

Dr. MAY. The short answer is no. They are not in place, and one of the reasons they are not in place is that in many ways we will have to look at a new paradigm for delivering standards to address the point of care home-testing market.

Senator WYDEN. Before we go making new paradigms, the American people are going to want to know if they are at risk in certain areas. Are there areas where they are at risk at this point, as a result of these products?

Dr. MAY. I think appropriately used, many of these home care testing devices do not necessarily have to be accurate—they have to be precise—as long as there is a linkage between these very precise and reproducible measurements with truth at some point, perhaps back in the clinical laboratory.

For example, you can easily determine whether or not a medication is working by whether the value goes up or down, it does not necessarily have to be absolutely accurate, and you can also determine if there is some change in your physiological condition.

So I guess I am not saying that there is a great panic, but as these things proliferate there is the possibility that people will tend to self-medicate using these devices, without linking back to the physician. I guess one of the statements made here indicated that perhaps through appropriate use of IT, that will not happen.

I do not know whether I answered your question.

Senator WYDEN. Well, I think as part of your work you have got to be careful about not panicking people. I understand that, and there is a difference between accuracy and risk, but I would like to hold the record open and have you all get back to us with respect to whether or not there are some of these home diagnostic products at t his point here there is a significant risk to the public, OK?

Dr. MAY. Sure.

Senator WYDEN. The only other question I had for you, Dr. May, and my staff really kind of jumped on me as I was thinking about this is, you all obviously work with private industry in developing information technology standards. That is the central focus of your work.

But do you also do some work in conjunction with the Department of Health and Human Services, because clearly, as they go forward with their work in terms of outcomes and price, and getting all of this on the web, it is going to be important to have these linkages. How does your agency interact with Health and Human Services on this?

Dr. MAY. Well, we are trying to improve our interaction. We recently had a meeting with the science advisor at FDA to start talking about more effective collaborations. In the past, we have had a number of scientist-to-scientist interactions. We have not had the interactions at the highest levels that perhaps we should, and that is something we are fixing now.

Senator WYDEN. OK, very good. Let me just ask one other question for you, Mr. Patterson. You are in the unenviable position of calling for regulation, and my friend Senator Allen certainly raises legitimate questions there, and to some extent I am more sympa-

thetic to his position than one might normally think. This is Ron Wyden, director of the Gray Panthers, probably a vending machine for Government regulations. If there is a problem out there, put your quarter in and out spits a regulation.

I will tell you that if you can make the case that there is a role for Government that makes markets work better, then it seems to me, at least from my standpoint, that is what is most compelling, but I think Senator Allen makes a concern that I also share, that historically what happens with a lot of these regulations is, you freeze innovation, and you get a kind of one-size-fits-all kind of concoction, and you create as many problems as you solve, so I am not going to at this point grill you about the kind of regulation that you are interested in.

I think you have certainly raised the question appropriately that this could conceivably allow people to make choices more efficiently, make markets work better, but as you work with us on the Committee and in the Congress, keep in mind that there is some sympathy for what Senator Allen is talking about, even in unlikely quarters like mine, and I think probably some other Democrats as well.

All right. This has been an excellent panel, and you all have been hardy, waiting for 3 hours. Is there anything any of the four of you would like to add further at this time?

Dr. Fuller.

Dr. FULLER. I just would like to make a clarifying comment, because I am afraid that my remarks about investing in research and health care may have been interpreted as solely related to the technology and the software.

I am a firm advocate of research in the sociopolitical as well as technical issues, and understanding how health care teams work before you introduce information technology is vital to the kind of solutions we have all been talking about today, and that is a great unknown. There simply is not funding out there, with a few exceptions, particularly National Library of Medicine funding, that will support that kind of research.

So that was just a clarifying comment. Thank you very much.

Senator WYDEN. Fair enough. Any other clarifying comments?

[No response.]

Senator WYDEN. The Subcommittee is adjourned.

[Whereupon, at 3:50 p.m., the Subcommittee adjourned.]

APPENDIX

August 3, 2001.

Hon. RON WYDEN, *Chairman,*
Subcommittee on Science, Technology, and Space,
Senate Committee on Commerce, Science, and Transportation,
Washington, DC.

DEAR CHAIRMAN WYDEN: On behalf of Premier, Inc., an alliance of more than 1,800 of the nation's leading not-for-profit hospitals and health systems, I wish to thank you for having convened the July 23 Subcommittee hearing on e-health and consumer empowerment. As Bert Patterson, our vice president for contracting, maintained in his written and oral testimony, the uncharted e-health frontier holds vast potential for the sustained quality improvement of healthcare, itself, as well as its supply chain and delivery mechanisms. We deeply appreciate having had the opportunity to contribute to the hearing and assist the subcommittee as it explores the promise of e-health.

In this regard, I wish to clarify one of the issues Premier raised with respect to the widespread support for health industry adoption of an electronically readable, uniform industry data standard. We believe that such a standard is embodied in the Universal Product Number (UPN), and recommend that these unique identifiers be displayed at every level of packaging, for transmission via bar code technology into hospital vendor and information systems.

The adoption of this technology, as noted in our testimony, provides an e-health 'trifecta,' if you will——

• enhanced patient safety and reduced medical errors,
• improved healthcare efficiency and savings through better supply chain management,
• heightened knowledge transfer and clinical performance improvement through comparative data.

In this way, UPN represents a critical building block in the emerging e-health infrastructure.

As Premier noted, when a manufacturer of a specific pharmaceutical submits an application for approval with the Food and Drug Administration (FDA), the assignment of a National Drug Code (NDC) number is required. In fact, the NDC enjoys regulatory standing with the FDA, and is employed by the pharmaceutical industry and numerous healthcare organizations for automated tracking of products.

In contrast, there is *no* industry-wide, standardized identification system for medical and surgical supplies that receive FDA approval. The UPN is uniquely positioned to provide that standard. As Mr. Patterson noted in his statement before the committee, Premier believes a parallel system is in order—one in which FDA requires that medical and surgical supply manufacturers, in addition to pharmaceutical companies, obtain a UPN prior to submission for item approval.

As the Subcommittee moves forward with its review, and ultimately develops initiatives to bolster e-health adoption, we believe that the implementation of this critical building block—the assignment of a unique identifier for FDA-approved medical and surgical supplies—would set the stage for significant healthcare improvement.

Sincerely,

HERB KUHN,
Corporate Vice President, Advocacy.

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