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IMPLEMENTING BEST PATIENT CARE PRACTICES

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

ON

EXAMINING IMPLEMENTING BEST PATIENT CARE PRACTICES

FEBRUARY 5, 2009

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IMPLEMENTING BEST PATIENT CARE PRACTICES

THURSDAY, FEBRUARY 5, 2009

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 10:14 a.m., in Room SD–430, Dirksen Senate Office Building, Hon. Barbara Mikulski, presiding.

Present: Senators Mikulski, Bingaman, Brown, Casey and Hagan.

OPENING STATEMENT OF SENATOR MIKULSKI

Senator MIKULSKI. Working group on quality for the Health, Education, Labor, and Pensions Committee will come to order. I apologize to my colleagues and to the panel. It's called traffic tardiness.

I commute everyday from Baltimore and traffic and I don't always gel. So I apologize for being late. I had a meeting.

We're going to hold a pretty extraordinary hearing this morning. The hearing will focus on best practices on quality. We have a distinguished panel. I'm going to say a few remarks. Then we'll go to the panel and go directly to questions because we might be having votes this morning.

The goal of today's hearing is to learn from a panel of innovators. What we want to hear is how the adoption of best patient practices has the potential to save lives and save money. We want to use this information to shape our thinking on public and private sectors in how they can do a better job of implementing best patient practices so that we can have better care for the patient and also more efficient care for either the taxpayer or the private payer.

We truly believe that providing quality means that we can also be a path to controlling cost. There's tremendous potential for the U.S. health system to improve quality, reduce cost and increase the value of health care spending. Our health care system underperforms.

We have a 20 percent higher per capita spending than Europe. We rank poorly on many key indicators including infant mortality and life expectancy. People don't get the care they need.

Some say only half of U.S. patients get the recommended services delivered by their doctor and some get services that they don't need. We also know that more service doesn't always mean better outcomes. So that's why we want to hear from you today. We in

the public sector must work with the private sector to make sure that the U.S. health care system does the right thing.

Now my staff wrote this phrase and I had an argument with them. So I'm going to give it to you. Then I'm going to tell you what I said to them. You'll know what I mean. We had a good conversation about it.

They said our goal is to make sure the U.S. health system is getting the right care to the right patient at the right time for the right price. Yeah, team. I said, "Oh, how old paradigm." This presumes that if you give the right technique or the right test or perform the right procedure to the right patient and not cut off the wrong leg or pierce the wrong ear or something, it's all OK.

My approach is that that is all so, but unless you really have patient-centered health care, doing the right test or procedure doesn't tell you the story. So you could do the most perfect amputation. But if the patient is a diabetic who drinks two Coca Colas every day for lunch and drinks two beers every night for dinner, you're just going to have one more amputation in the future.

So my view is to say, "yes" to this, but this is like the fourth paragraph that where we have to look at the totality of care. Also if you don't wash your hands while you're doing that amputation, that's a whole other thing. So sure, we want the right care to the right patient at the right time. But right care isn't always the perfect test, the most dramatic procedure and so on.

With that maybe we can have two beers and talk about this. My view is to have patient-centered health care where we look at the totality that we do with prevention, intervention where you need to and then the case management from the appropriate follow through so that an illness is either treated and cured or if it's chronic, it does not escalate to an even more serious situation. And even argue back with me. I really welcome that as well.

We know that some of our tools will be health information technology. But I'm a firm believer that technology—we can't just survive on techno case management. It takes human beings as well.

You can probably see that I'm a social worker. So I'm a big believer in case management. But I'm a big believer in what you do.

What a great panel of witnesses. I'm really excited about today. I know my colleagues will be as well.

We have Dr. Peter Pronovost from Johns Hopkins University. My neighbor. He's identified low-tech ideas, that famous checklist that results in high value results. Many call him the Father of the Medical Checklist. He will discuss how the adoption of best practices can provide pretty astounding results but also the barriers to implement the current system.

Our second witness will be Dr. Steve Pearson from the Institute for Clinical and Economic Review. Dr. Pearson's work focuses on clinical effectiveness which goes to some of the things we've been talking about. The cost effectiveness in medical innovations compares effectiveness to treatment value and informs patients how to reimburse and cover innovative therapies. We're interested in his views on the topic, very timely today, and even in the stimulus—comparative effectiveness research and what is it that we get out of it.

We also will hear from actually somebody who's got to pay the bills, Dr. Donald Fischer from the very eminent, Highmark Blue Cross and Blue Shield. Dr. Fischer, as the Chief Medical Officer, and by the way, it's in Pennsylvania, Senator Casey. His job is to determine which practices have the best potential for patient success and then how to devise those carrots and sticks to incentivize his network of patients and providers to adopt these standards.

On the new frontier of thinking, will be our witness, Dr. Jeff Gulcher from deCODE genetics. From him when we had the biopharmical industries perspective having development in adoption of best patient care practices and also looking at genetic predisposition, a way of really focusing on our testing. If we look, not at genetic determinism, but genetic, I believe predispositions that if you have one, say to diabetes, you would focus a lot more early on in testing. So we want to hear from you Dr. Gulcher.

So having said that we're going to turn right to our panel. I want to acknowledge here Senator Sherrod Brown, Senator Casey and Senator Kay Hagan for their participation. I'm going to turn to our colleagues on the other side. Will Senator Enzi be joining us?

You know, it's a pretty busy day. I'm going to acknowledge the very active role of Senator Casey. Because you see no Republicans, do not think that they're boycotting. It means that they're participating in other hearings that range from confirmation to oversight.

Any questions that they might have or statements we will submit those for the record.

I'm going to ask unanimous consent that all opening statements by my colleagues be included in the record.

[The prepared statement of Senator Kennedy follows:]

PREPARED STATEMENT OF SENATOR KENNEDY

Less than half of all medical care in the Nation today is supported by adequate evidence of its effectiveness. In other words, more than half of all medical care is not supported by adequate evidence about its effectiveness.

The question that has been ignored for too long is: What are the best practices in health care? Part of the answer involves using modern health information technology—it will help to coordinate team-based care, reduce overuse utilization and duplication of procedures, and improve patient safety. Comparative effectiveness research will help identify what works and what we still need to find out. Knowledge gained from this research must also be made more widely available.

Best practices obviously include knowing the prescribed course of therapy and continued management for a given disease. They include the policies and procedures that govern the day-to-day workings of a medical organization and how things get done.

They must also measure outcomes. In fact, we should start with outcomes, work backward to revise procedures to strengthen patient safety and satisfaction, improve efficiency and eliminate waste. We've already seen remarkable reductions in hospital acquired infections using this approach.

Another effective approach has become standard in private sector initiatives to improve quality, and has been taken up by some public sector initiatives as well. It involves changes that coordinate the

subject matter of experts and quality improvement facilitators to improve the procedures and outcomes for programs and services.

Another way to make sure that the right thing gets done is to have uniform "to do" lists for various procedures. It's simple, and it's a low-tech, standard way, to achieve consistent and safe procedures.

We can't afford any longer to have hospitals and practitioners "winging it," when patient safety is at stake, and health costs continue to spin out of control.

I look forward to working with President Obama and our Senate colleagues on the HELP and Finance Committees to expand access to the best possible care. I especially commend Senator Mikulski for her continued leadership on quality and delivery reform, and I look forward to learning more from each of our witnesses today about implementing these best practices.

Senator MIKULSKI. I ask unanimous consent that all of our witnesses complete content-rich statements be included in the record.

Senator BROWN. Madam Chair, could I have 30 seconds to say something about the panel, if I could?

Senator MIKULSKI. Sure.

SENATOR BROWN

Senator BROWN. Thank you, Madame Chair.

This panel is made up of very impressive thinkers. People who have influenced the thinking of many others in the health care system. I shouldn't single out, but I do, Dr. Pronovost and in the work he's done with his checklist and the increased quality of this huge cost savings.

The ideas that all four of you have had and have begun to make a difference. We know what's happened to health care.

We spend so much money. Our quality is not what it should be and our outcomes are not what it should be and our cost is too high. The little you four have done have contributed to beginning to change that.

So, thank you.

Thanks, Madame Chair.

Senator MIKULSKI. Thank you, Senator Brown. Senator Casey, you're the guy from Pennsylvania. Did you want to say something about our witness from Pennsylvania?

SENATOR CASEY

Senator CASEY. I'll just reiterate the gratitude of this committee for the testimony you're going to give today and the scholarship. I'll leave the kudos for the Pennsylvania fellow when my turn comes up.

Thank you, Madame Chair.

Senator MIKULSKI. Well I guess Senator Hagan I'm not going to let the two guys speak without you.

[Laughter.]

SENATOR HAGAN

Senator HAGAN. Madame Chairman, I'm just looking forward to hearing the testimony of these very distinguished individuals. Thank you.

Senator MIKULSKI. Very good. Dr. Pronovost, why don't you lead us off and give us more on the checklist.

STATEMENT OF PETER J. PRONOVOST, M.D., Ph.D., MEDICAL DIRECTOR, CENTER FOR INNOVATIONS IN QUALITY PATIENT CARE, JOHNS HOPKINS UNIVERSITY, BALTIMORE, MD

Dr. PRONOVOST. Thank you, Senator Mikulski and other members of the HELP Committee. I appreciate your commitment to address this topic of patient safety. Quality of care is by far the biggest opportunity to improve the health of U.S. citizens.

A few years ago an 18-month-old girl died from prevention mistakes at one of the world's best hospitals, at my hospital, Johns Hopkins. On the 4-year anniversary of that girl's death her mother, Sorrel, came back to the hospital and looked me in the eye and said, "Peter, could you tell me that she's less likely to die today than 4 years ago. Are you safer?"

The sad reality is I couldn't answer her. No hospital in my State could. The United States can't give her an answer. And fundamentally she deserves one.

The National Health Care Quality Report, rather alarmingly said that for most areas of quality and safety we don't even know how we're performing. Now I ask you to contrast that with the remarkable success in biomedical science over the last decade. AIDS has become a chronic disease. We cure most childhood cancers. We sequenced the human genome, all 300, or 3.2 billion letters with 99.99 percent accuracy. How could we perform so differently?

I think, Senators, the reason is that we haven't viewed the delivery of health care as a science. It's been solely the art. We've underinvested in it. We invest a dollar in discovering new knowledge and new genes for every penny we spend on improving quality of care.

So, we have this enormous gap between what we know and what we do. It has to be bridged. We've been trying to bridge that with some science, very practical science that I'd like to share with you.

We tackled the problem of catheter-related bloodstream infections. A type of infection that kills between 30,000 and 62,000 people a year. We approached it much like you would drug development.

In phase 1, we summarized evidence into a checklist, developed measures and identified barriers to using those evidence. Much of those barriers were team work and culture things. We then pilot tested a program at Johns Hopkins and virtually eliminated those infections there.

In phase 2, with funding from AHRQ, we implemented this program in the entire State of Michigan, 103 intensive care units. Within 3 months their rates of infections went from three per thousand catheter days to zero, a median rate of zero, a 66 percent reduction. That has sustained for 4 years.

We estimate that that intervention per year saved approximately 2,000 lives and $200 million. The investment from ARHQ was about $750,000 for 2 years. I wish my retirement had that kind of return on investment.

In phase 3 now we're working with AHRQ to put this around the country. We have some funding to do 10 more States. We have philanthropic support to add about 10 more. But that still leaves 32 States out of the picture from this life saving intervention.

Now there's many ills set before our health care system. These infections are but one. We need to develop a model to try to improve upon how we deliver care.

We think this is a model that has strong, strong legs that finds the right balance between centralized approach or regulatory approach and a free-market approach. We've tried to centralize what works, the evidence and the measures. And then work with local leaders to implement that.

Committee, I would ask you to consider investing in the science of health care delivery. Imagine what could happen if AHRQ's funding were a quarter for every dollar rather than a penny. We ask you to create an Institute for Health Systems Research. An institute that brings together patients and payers, consumers and providers, and scientists to make sure as you said Senator Mikulski, that we do what's right for the patients, that we take a systematic view of this.

We design programs. We see if they work. And what works, we continue.

We invest in building capacity. At my institution and around the country there's hundreds of people who you can find who study genetics, who teach physiology. You're rare if you can find anyone who can teach patient safety. It's just not being taught because there's no capacity.

Finally, I would ask you to support completing this CLABSI, this blood stream project throughout the country and support a pipeline to develop one for MRSA.

President Obama told us that he's going to restore science to its rightful place. Indeed we need to do that if we're going to improve quality and reduce the cost of care. I think we have a model. What we haven't had is courageous leadership, which is clarity of what the task is at hand and a commitment to make resources available.

I hope that this committee has that courage to bridge the gap between what we know and what we do so that I can look Sorrel in the eye and tell her, now indeed Josie is less likely to die throughout this great country of ours. I thank you.

[The prepared statement of Dr. Pronovost follows:]

PREPARED STATEMENT OF PETER J. PRONOVOST, M.D., PH.D.

EXECUTIVE SUMMARY

A few years ago, 18-month-old Josie King died from preventable mistakes at one of the world's best hospitals: my hospital, Johns Hopkins. On the 4-year anniversary of her daughter's death, her mother looked me in the eye and asked: "If Josie was admitted to Johns Hopkins today, would she be less likely to die than she was 4 years ago?"

We cannot tell Sorrel that Josie is less likely to die. In the 10 years since the IOM report *To Err is Human* raised healthcare quality and patient safety to the level of national priority, we have made only minimal progress, and for most areas, we

do not even measure performance. Yet at the same time, advances in biomedical sciences have been astounding. In just 13 years, an international collaboration between governments, scientists and private industries sequenced the entire human genome, all 3.2 billion letters with 99.99 percent accuracy.

This dichotomy between the success of biomedical science and the failure of patient care is because we have failed to view the delivery of healthcare as a science.

My research team applied a scientific approach to reduce catheter-related blood stream infections—a type of infection that kills between 30,000 and 62,000 people a year and results in nearly $3 billion in excess costs. Within 3 months of implementing the interventions in Michigan, the median rate of infection in the 103 participating ICUs plummeted to 0, and has stayed at 0 for 4 years.

Our national failure to view the delivery of healthcare as a science is also a significant factor in our limited success in learning from mistakes that do occur.

Though it took over 9 years, we are now close to having a voluntary mechanism for reporting healthcare errors at a national level. Yet we do not have an infrastructure or standardized approach to learn from the errors that will be reported.

There is something we can do to change this: to we can save lives and dollars, we can provide Sorrel an answer; are the Josie's in the world less likely to die?

Specific suggestions for Improving Healthcare Quality and Patient Safety:

1. Advance and invest in the science of health care delivery.
2. Create an Institute for Healthcare Delivery.
3. Coordinate public and private efforts to improve quality of care.
4. Invest in Healthcare information technology (HIT).
5. Build capacity.
6. Support completion and rigorous evaluation of the national program to eliminate central line-associated blood stream infections (CLABSI).
7. Support a new Program to reduce MRSA infections.

Paraphrasing our President, those of us who provide healthcare, and those who manage the public's dollars need to spend wisely, reform bad habits, and do business in the light of day. Courageous leadership must hold all stakeholders accountable for results. My hope and expectation is that together we find this courage.

Senator Mikulski and members of the HELP Committee, thank you for the opportunity to talk to you about this important topic.

A few years ago, 18-month-old Josie King died from preventable mistakes at one of the world's best hospitals: my hospital, Johns Hopkins. On the 4-year anniversary of her daughter's death, her mother, Sorrel, looked me in the eye and asked: If Josie was admitted to Johns Hopkins today, would she be less likely to die today than she was 4 years ago?"

I started telling her about our commitment to safety, listing all the quality and patient safety projects we were doing. She abruptly and appropriately cut me off. She did not care what we were doing. She wanted to know if care was safer. She wanted science. Unfortunately, at the time, we could not give her an answer.

We know precious little about healthcare quality and patient safety. We *do know* healthcare is increasingly expensive; we can give you detailed cost reports, because we have standardized measures and regulated practices for reporting financial performance. We cannot tell Sorrel that Josie is less likely to die. The national report on healthcare quality is less informative. In the 10 years since the IOM report *To Err is Human* raised healthcare quality and patient safety to the level of national priority, we have made only minimal progress, and for most areas, we do not even measure performance.

Yet at the same time, advances in biomedical sciences have been astounding. Thanks to recent science, AIDS is now a chronic disease and we have cured many childhood cancers. In just 13 years, an international collaboration between governments, scientists and private industries sequenced the entire human genome, all 3.2 billion letters with 99.99 percent accuracy. The results are publicly available so that scientists around the world can use the information to develop new therapies.

How do we explain this dichotomy between the success of biomedical science and the failure of patient care? It is because we have failed to view the delivery of healthcare as a science.

For every dollar of Federal health care research funding that goes towards learning how to better treat and understand disease, only one penny goes towards learning how to better care for patients. While it is essential that we continue to enhance funding for basic and clinical research, we need a more balanced research portfolio—

a portfolio in which we view quality and safety research as *essential to*, rather than separate from, basic and clinical research. We need to eliminate the gap that exists between what we learn in a lab and what actually reaches the patient. We must have a method to create standards and to measure and track our progress with measures that are meaningful and valid to those providing care, to those receiving care and to those paying for care, for resources are too scarce and patient safety is too precious to ignore.

Five years ago, wrong-site surgery—one of the most visible and troubling errors—was incorporated into the National Quality Forum "Never Events" list. Reducing these errors became a national patient safety goal, and hospital accreditation standards were established to guide local hospital efforts. Yet these standards were developed based on common sense, not science, without evidence of their benefit or costs, and without a valid method to monitor their effectiveness. Since the standards were put in place, reports of wrong site surgery have increased yearly. We do not know if this is due to better reporting, if the interventions do not work, or if they are not used correctly. However, the results are not encouraging, and the public, the payers of healthcare and the providers of care deserve better.

We need to approach patient safety the same way we approach curing a disease, through rigorous scientific research that produces hard data with clear measurable results. We need to summarize evidence into clear standards, develop measures and monitor performance with valid, reliable data, and work to improve teamwork and communication so evidence can be implemented.

We applied the model to tackle catheter-related blood stream infections—a type of infection that kills between 30,000 and 62,000 people a year and results in nearly 3 billion in excess costs. Prior to our study, little was known regarding how many of these infections were preventable.

We approached the problem scientifically. In phase 1, we reviewed existing data and selected five key procedures that would most likely prevent these infections. We compiled these procedures into an easy to follow checklist. We identified potential barriers to using the checklist and developed tactics to overcome those barriers so we could optimize compliance. We then pilot tested the intervention at Johns Hopkins and measured performance. The result, we nearly eliminated these infections.

In phase 2, AHRQ provided a matching grant to help us pilot test the program in the State of Michigan. Within 3 months of implementing the interventions, the median rate of infection in the 103 participating ICUs plummeted to 0, and has stayed at 0 for 4 years. These infections were reduced by 66 percent. The work was not easy; it required hospital leaders, doctors and nurses to implement interventions, improve teamwork, and monitor performance. But the results were well worth the investment. In just 1 year, the reduction in infections were estimated to have saved the hospital system millions of dollars and thousands of lives.

In phase 3, we are trying to implement this program across the United States, State by State, hospital by hospital. Thanks to funding from AHRQ we partnered with the American Hospital Association to implement this life saving program in 10 hospital systems in 10 States. Additional philanthropic support donated to my research team at Hopkins will permit us to reach another group of States. Most Sates are trying to reduce these infections, but they need support in order to be efficient, and to rigorously measure and improve performance.

Similarly, the National Association of Childrens Hospitals and Related Institutions is developing efforts to bring this same program to pediatric centers in the United States. Indeed, my wife, Marlene Miller, is leading these efforts. They used the same model, developed pediatric specific standards and have impressive results in reducing infections in pediatric ICU's. Just as with our adult program, they struggle to fund, organize, implement and measure improvement.

There are many ills that befall the U.S. healthcare system; CLABSI is but one. The fragmented approach to reducing these infections points to a deep problem with our healthcare system; vague or non-existent performance standards, poor or absent and often invisible measures of performance, misaligned financial incentives, fragmented and under resourced labors all cripple efforts to improve quality, reduce costs and implement health information technology.

Our ability to produce measured and sustained reductions in infections and costs, point to a possible way forward.

Reducing these infections could be a polio campaign for the 21st century—and we need one. These infections are common, costly, and often lethal. We know how to reduce them, yet support for this improvement has been left to a haphazard patchwork of local, regional and national efforts involving clinical, operational and policy levers. No one could argue that whatever the clinical effectiveness of such efforts, the inefficiency is glaring. A coordinated national effort to eradicate these infections should be an immediate priority.

Beyond these infections, however, I believe a closer look at our model offers tremendous potential for use on a broad scale. In the model, we centralize development of evidence-based standards, measures and data collection standards for a nationally relevant set of patient safety goals. We hold healthcare organizations accountable for improving quality, and we advance the science needed to improve healthcare delivery, so that learning does not need to take place one patient, one physician, one hospital at a time. In this model, payers, consumers, insurers, administrators, clinicians and regulators, work together to solve the problem. Now that we have a proven system that can measure and prevent harm we should align payment policies to support safe care.

Our national failure to view the delivery of healthcare as a science is also a significant factor in our limited success in learning from mistakes that do occur.

Though it took over 9 years, we are now close to having a voluntary mechanism for reporting healthcare errors at a national level. Yet we do not know how to learn from the errors that will be reported. There is no national infrastructure to learn from common, costly and lethal mistakes that are beyond the capacity of any single health system to fix. For example, in all of the 6,000 U.S. hospitals, patients sometimes get epidural pain medicine connected to an intravenous catheter, a potentially lethal error. The intervention to prevent this error is to encourage doctors and nurses to be more careful, to re-educate staff. Assume this education takes 1 hour: imagine the costs of re-educating all the doctors and nurses in the country and now imagine the probability that the education will work. Current methods for learning from this type of mistake are form over substance. They waste time, money, energy and the good will of caregivers who know they are human and will likely make the mistake again.

There is a better way. We learned it from aviation. In aviation they recognized that it is foolish to have individual airlines investigate and learn from mistakes in isolation. They formed a public private partnership called The CAST (The Commercial Aviation Safety Team). The industry works together to prioritize the greatest risks, investigate them thoroughly and implement interventions that work. Most of the interventions are product redesign. We need cast in healthcare. We need to get the manufacturers to design the catheters so that the epidural and intravenous catheters do not fit together. We need to eliminate the possibility of making this mistake rather than hoping that re-education will work. Yet there is no mechanism to bring administrators, clinicians, regulators, and device makers together in healthcare to accomplish this. We have a small planning grant from the Robert Wood Johnson Foundation (RWJF) to pilot this concept. All parties are eager to participate. Yet we need Federal leadership. We need your wisdom, your expertise and your support.

Through our work, we have learned that we can improve quality and reduce costs. Current efforts are too isolated, too weak on science, and too limited in focus. This will not get us where we need to go. There is something we can do to change this: to we can save lives and dollars, we can provide Sorrel an answer: Are the Josie's in the world less likely to die?

Specific suggestions for Improving Healthcare Quality and Patient Safety:

1. **Advance and invest in the science of health care delivery.**—Fund research under AHRQ so that rather than investing a penny in quality for every dollar in basic and clinical research we have a more balanced portfolio. Imagine the gains in quality and reduced costs if we increased the ratio to a quarter for every dollar.

2. **Create an Institute for Healthcare Delivery.**—This institute, similar to the human genome project, should link provider organizations, insurers, payers, and regulators to design, implement, and evaluate interventions to improve quality, reduce costs of care, and implement Health Information Technology. The products from this group can inform payment policies.

3. **Coordinate public and private efforts to improve quality of care.**—A "supra agency" should be established to facilitate and monitor integration of interagency activities to address deficits in the quality of U.S. healthcare. The agency should report directly to the Secretary of HHS.

4. **Invest in Healthcare information technology (HIT).**—HIT is essential for monitoring and improving quality and reducing costs of care. Efforts to improve HIT need to be linked with efforts to improve quality and reduce cost; to date they have not. Such efforts should provide, at a minimum:

a. A database of evidence-based standards.

b. A database to monitor and report performance measures to the public, clinicians, healthcare leaders and government officials.

c. Decision support tools to ensure patients receive the correct therapies.
d. Tools to help educate patients, families, and clinicians.

5. **Build capacity.**—Support training in quality improvement methods for physicians, nurses and other clinicians and administrators in order to improve the delivery of healthcare across the United States. At most academic medical centers, there are hundreds of faculty who can teach genetics, hundreds who can teach physiology, yet a precious few, if any, who can teach safety. This needs to change if we are to make and sustain progress.

6. **Support completion and rigorous evaluation of the national program to eliminate central line associated blood stream infections (CLABSI) and Support a new Program for MRSA.**—Patients in all States ought to have access to safe ICU care and reduced CLABSI. MRSA has become the most common pathogen causing hospital-acquired infections (HAIs) in healthcare facilities in the United States and throughout the world. Researchers at the Centers for Disease Control and Prevention examined MRSA data from more than 1,200 intensive care units (ICUs) from 1992 to 2003. They found that in 1992, 36 percent of *S. aureus* isolates were drug-resistant; but in 2003, 64 percent of isolates were MRSA, an increase of about 3 percentage points per year.

President Obama suggested the new administration would restore science to its rightful place . . . raise health care's quality . . . and lower its costs. To achieve this goal, programs that work—such as the model to reduce blood stream infections—should be expanded, and those that do not work should end. Paraphrasing our President, those of us who provide healthcare, and those who manage the public's dollars need to spend wisely, reform bad habits, and do business in the light of day.

Substantial improvements in healthcare quality and costs are possible. For too long we have lacked clarity of purpose and the commitment to invest the necessary resources to make this vision a reality. Courageous leadership must hold all stakeholders accountable for results. My hope and expectation is that together we find this courage.

Senator MIKULSKI. That was excellent. Dr. Pearson, we'll just go right on down and conclude with you, Dr. Gulcher.

STATEMENT OF STEVEN D. PEARSON, M.D., MSC, FRCP, PRESIDENT, INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW (ICER), BOSTON, MA

Dr. PEARSON. Thank you, Senator Mikulski and members of the committee for the invitation to testify today.

My name is Steve Pearson. I'm the founder and president of the Institute for Clinical and Economic Review or ICER. ICER is a research group in the Institute for Technology Assessment at the Massachusetts General Hospital. We work with patients, clinicians, manufacturers and health insurers to evaluate the comparative effectiveness of medical tests and treatments.

In my oral testimony today I want to cover two questions.

First, what is the connection between comparative effectiveness and best practices?

And second, what are the mechanisms and the requirements for effective implementation of comparative effectiveness findings?

The term best practice is usually meant to refer to systems for delivering care, systems, such as Dr. Pronovost's fabulous surgical checklist that produced optimum patient outcomes. Comparative effectiveness on the other hand is a newer term that is generally referred not to research on systems of care, but to evaluations of specific treatment options. For example trying to determine which patients with coronary artery disease do better with medication and which do better with cardiac stents.

So best practices and comparative effectiveness can be viewed as feeding into different approaches to improve the quality and value of care, but they can also be quite complementary. Comparative ef-

fectiveness helps figure out what the right care is. Best practices research helps us learn how to get that right care delivery as safely, effectively and efficiently as possible.

What are the mechanisms by which the results of comparative effectiveness research can be implemented? The ideal framework is for the findings to be able to support tools and policies that can be used by different stakeholders and that all reinforce each other. Implementation strategies include the following, some of which, but not all, are also options for the implementation of best practices.

First, patient information; Clinical guidelines; Physician group compensation incentives; Tiered benefit designs in which patients would pay different amounts out-of-pocket depending on the evidence of benefit and value; and last value-based coverage and reimbursement policies.

Now there are two key points I want to make about this list.

First, insurance coverage decisions are not the sole nor even the primary mechanism for implementing comparative effectiveness results. Sometimes concerns are raised that comparative effectiveness will only be translated into all or nothing, one-size-fits-all, coverage decisions. In fact comparative effectiveness assessments are expressly designed to hunt out any evidence that specific types of patients may benefit more or less from certain treatment options. These findings can then be used to support benefiting coverage policies that are flexible enough to recognize these differences.

The second point I want to make about implementation is that in order for assessment results to be truly useful to patients and clinicians and for the results to be linked in a transparent way to coverage and reimbursement decisions, some kind of common language about the evidence is necessary. To meet this need at ICER we've developed a rating system that assigns a capital letter to grade the degree of clinical effectiveness of whatever it is we're evaluating and a separate lower case letter indicating our assessment of the comparative value. These ratings can be looked at in isolation or they can be put side by side to form an integrated evidence rating.

In a demonstration project in Massachusetts we are now working with a coalition of employers, health plans and provider groups to assess prostate cancer treatments. The ICER integrated evidence ratings arising from these assessments will then be used to generate patient materials and new medical policies. The goal is to give patients better evidence to use in shared decisionmaking and to align that process with coverage and reimbursement policies that can help shift patterns of care toward those higher value options.

In conclusion, I believe that comparative effectiveness research and efforts to implement best practices are truly complementary and mutually supportive efforts. Finding out what works best and getting it done right, the left and the right hand, will both be needed to help us achieve a high quality, affordable health care system. Thank you.

[The prepared statement of Dr. Pearson follows:]

PREPARED STATEMENT OF STEVEN D. PEARSON, M.D., MSC, FRCP*

EXECUTIVE SUMMARY

Health policy experts recognize "best practices" as referring primarily to systems for delivering care that lead to optimum patient outcomes. As for the concept of comparative effectiveness, the boundaries are still somewhat under construction, but in general the emphasis has been on studies that either assess existing evidence on the best treatment options for a condition, or that develop new evidence via clinical trials or registries. Therefore, one way to think of the relationship between "best practices" and comparative effectiveness is to view comparative effectiveness research as establishing which treatments are best for which kinds of patients, while "best practices" research helps us learn how to get that right care delivered as safely, effectively, and efficiently as possible.

What are the mechanisms by which the results of comparative effectiveness research can be implemented? The ideal framework is for the findings to be able to support different tools and policies that can be used by different stakeholders but that all re-inforce each other. Implementation strategies include the following:

1. Patient information;
2. Clinical guidelines;
3. Physician group compensation incentives;
4. Tiered benefit designs, in which patients would pay less out-of-pocket for more effective and/or higher value alternatives; and
5. Value-based coverage and reimbursement policies for emerging technologies, including the possibility of linking payment levels to an agreement to gather further evidence on clinical effectiveness.

In order for the results of comparative effectiveness assessments to be communicated effectively to patients and clinicians, and to be "tied" in a transparent way to coverage and reimbursement, some kind of common "language" is necessary. To meet this need at ICER we have developed a rating scheme that assigns a rating of comparative clinical effectiveness and an independent rating of comparative value, based largely on cost-effectiveness considerations. The purpose of these ratings is to transparently communicate ICER's overall judgment regarding the evidence on comparative effectiveness, and to provide a template for innovative patient-clinician decision support tools as well as value-based coverage and reimbursement policies.

In conclusion, comparative effectiveness research and efforts to implement "best practices" are mutually supporting and complementary efforts. Using evidence to change practice is often challenging, but it is exactly this challenge that we must address moving forward in order to achieve a high quality, affordable health care.

Thank you, Senator Mikulski, and members of the committee for the invitation to testify about the links between comparative effectiveness research and best patient care practices. My name is Steven Pearson. I am a general internist and the Founder and President of the Institute for Clinical and Economic Review, or ICER, at the Massachusetts General Hospital. ICER is an academic research group which works through a transparent process with patients, clinicians, manufacturers, and health insurers—with *all* stakeholders—to evaluate the comparative effectiveness of medical tests and treatments. ICER's approach is distinguished by our engagement with stakeholders, and by our commitment to provide decisionmakers with information on the cost-effectiveness as well as the clinical effectiveness of medical services. Perhaps most germane for today's hearing, ICER has developed a method for translating comparative effectiveness results into a reliable rating format to enable the evidence to have traction; so that it can get off dusty academic shelves and into policy and practice in ways that will drive improvements in the value of healthcare.

The backdrop to the interest and sense of urgency surrounding comparative effectiveness research is well known to you. Although technological innovation is essential to the advancement of health care, medical tests and treatments often become widely used while significant gaps in evidence regarding their effectiveness remain. The harmful effects of this evidence deficiency grow each year, with wide, unex-

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*Attachments to this statement: Assessing the Comparative Effectiveness of a Diagnostic Technology: CT Colonography may be found at *http://content.healthaffairs.org/cgi/content/full/27/6/1503*; and Final Appraisal Document—Brachytherapy & Proton Beam Therapy for Treatment of Clinically Localized, Low-Risk Prostate Cancer may be found at www.icer-review.org (look under Completed Appraisals and click on title).

plained variations in care patterns and escalating costs divorced from any indication that our health care resources are being wisely spent.

I know you've heard this general theme before, so I'll provide a concrete example from an ICER comparative effectiveness review on the treatment options for prostate cancer. Prostate cancer is the second leading cause of cancer deaths in men in the United States, with nearly 200,000 new cases found each year. Men with prostate cancer have many different options to consider, including several different forms of radiation therapy. Radiation can be delivered by the implantation of radioactive "seeds," by a form of external radiation therapy called IMRT, or by proton beam therapy. The ICER review of these options found that radioactive seed implantation and IMRT had virtually indistinguishable net health benefits for patients; for proton beam therapy, the newest option, there have been only a handful of studies, and yet what little evidence is available does not suggest that it is any better than the other options. Our review also looked at upfront costs to Medicare and we also used cost-effectiveness analysis to estimate the downstream patient outcomes and costs for patients managed with each of these three treatments. We found that Medicare pays approximately $50,000 for proton beam therapy, $20,000 for IMRT, and $10,000 for radioactive seed implantation. Again, without any evidence of improved clinical outcomes, for any patients, Medicare pays doctors and hospitals as much as five times more for some treatments than for others. Not surprisingly, surveys of radiation oncologists suggest that these price differentials have led to impressive shifts in what kinds of treatments patients receive, and, as a result, it has been estimated that, without any evidence we are doing better by our patients, Medicare is now paying more than a billion dollars more per year just due to the shift to more expensive radiation therapy options for prostate cancer treatment. This is just one isolated example of how we continue to pay the highest prices in the world for many health care tests and treatments of dubious comparative value. And as we do so we put just that much further out of reach our hopes of making health care affordable for all Americans.

Comparative effectiveness research is intended to help address this challenge. In my oral testimony, I want to try to cover two specific questions:

1. What is the overlap between the concepts of comparative effectiveness and "best practices?"
2. What are the mechanisms and the requirements for effective implementation of comparative effectiveness research findings?

The term "best practice" has been around longer, and I think it's fair to say that health policy experts recognize "best practices" as referring primarily to systems for delivering care that lead to optimum patient outcomes. Dr. Pronovost's surgical checklist procedure for reducing hospital-acquired infections is a classic, and wonderfully effective, example. As for the concept of comparative effectiveness, the boundaries are still somewhat under construction, but in general the emphasis has been on studies that either assess existing evidence on the best treatment options for a condition, or that develop new evidence via clinical trials or registries. There is no *a priori* reason that research to evaluate alternative care delivery processes couldn't be considered comparative effectiveness. Nonetheless, we have long had a term for that kind of research: health services research, and comparative effectiveness as a distinct term came into being to emphasize the need for new kinds of head-to-head trials and of systematic evidence assessments to help decisionmakers with decisions about specific tests or treatments. So one way to think of the relationship is to say that comparative effectiveness research helps establish what treatments are best for which kinds of patients, and "best practices" research helps us learn how to get that right care delivered as safely, effectively, and efficiently as possible.

What are the mechanisms by which the results of comparative effectiveness research can be implemented? The ideal framework is for the findings to be able to support different tools and policies that can be used by different stakeholders that all re-inforce each other. Implementation strategies include the following:

1. Patient information;
2. Clinical guidelines;
3. Physician group compensation incentives;
4. Tiered benefit designs, in which patients would pay less out-of-pocket for more effective and/or higher value alternatives; and
5. Value-based coverage and reimbursement policies for emerging technologies, including the possibility of linking payment levels to an agreement to gather further evidence on clinical effectiveness.

There are a couple key points I want to make about this list. First, whereas coverage determinations are included, they are not the sole, nor even the primary

mechanism. Sometimes concerns are raised that comparative effectiveness can only be implemented through all-or-nothing, one-size-fits-all coverage decisions. To the contrary, comparative effectiveness evaluations are expressly framed to hunt out any evidence that specific types of patients may benefit more or less from certain treatment options, and these findings can be woven into patient materials and clinical guidelines, with any linked benefit or coverage policy made flexible enough to recognize these differences.

In order for the results of comparative effectiveness assessments to be communicated effectively to patients and clinicians, and to be "tied" in a transparent way to coverage and reimbursement, some kind of common "language" is necessary. To meet this need at ICER we have developed a rating scheme that assigns a capital letter rating of comparative clinical effectiveness on a six-part scale, and a separate lower-case letter rating of comparative value, based largely on cost-effectiveness considerations, on a three-part scale. These ratings can be looked at in isolation, or they can be put side-by-side to form an integrated evidence rating. The purpose of these ratings is to transparently communicate ICER's overall judgment regarding the evidence on comparative effectiveness, and to provide a template for innovative patient-clinician decision support tools as well as value-based coverage and reimbursement policies. We are now working with a coalition of employers, health plans, and provider groups in Massachusetts to implement ICER reviews of prostate cancer treatments through patient materials and policies linked to the integrated evidence ratings. The goal is to design specific patient and clinician materials to fit with coverage and reimbursement policies so that, working together, all the stakeholders can use comparative effectiveness results to increase shared decisionmaking and shift patterns of care to higher value alternatives.

In conclusion, I believe that comparative effectiveness research and efforts to implement "best practices" are mutually supporting and complementary efforts. Using evidence to change practice is often challenging, but it is exactly this challenge that we must address moving forward; and using evidence more effectively is exactly the right way for us to achieve a high quality, affordable health care. Thank you.

Senator MIKULSKI. Dr. Fischer, let's hear from you.

STATEMENT OF DONALD R. FISCHER, M.D., MBA, SENIOR VICE PRESIDENT, INTEGRATED CLINICAL SERVICES AND CHIEF MEDICAL OFFICER, HIGHMARK BLUE CROSS BLUE SHIELD, PITTSBURGH, PA

Dr. FISCHER. Senator Mikulski and other members of the committee, I'm Dr. Don Fischer, Senior Vice President and Chief Medical Officer at Highmark Blue Cross Blue Shield. I'm truly honored to have this opportunity to share with you what we are doing as a health plan to improve quality and affordability by helping to spread best-patient care practices. You're obviously aware that a quality chasm exists in the U.S. health care system.

Improving quality of care will drive improving patient outcomes and significant cost efficiencies by eliminating underuse errors, overuse errors and misuse errors. It is a myth that paying more buys you better care. Our goal at Highmark is to help ensure that the right care is delivered to the right member at the right time. That was already in my remarks before you discussed that.

Our quality improvement programs emphasize several guiding themes.

No. 1, we focus on measuring quality indicators that have been identified by national quality improvement organizations.

No. 2, we align financial incentives to improvements in those quality measures.

No. 3, we provide practice coaching and guidance to physicians and hospitals so they can be successful.

And No. 4, we provide education, coaching and incentives to members to improve their adherence to evidenced-based guidelines and their use of preventive care.

A key success factor has been the development of collaborative relationships with our network providers and our members rooted in mutually shared goals.

I'd like to give four examples of results of these programs starting with our work with hospitals.

First, our Quality BLUE hospital pay-for-performance program is focused on reducing the incidence of central line bloodstream infections in intensive care units. During 2008, hospitals in the program reported a significantly lower rate of central line infections compared to the national average, namely one infection per thousand line days compared to 2.7 infections per thousand line days nationally. That translates to an imputed savings just in our region of $21 million and saving between 69 and 142 lives.

Second we have a pay-for-performance program for primary care physicians. I'll give you one example of the program's impact. The percentage of generic drugs prescribed by our central Pennsylvania practices increased from 48 percent to 67 percent since the onset of the program in that region 2 years ago. Higher rates of generic prescribing not only results in financial savings to the member or to the employer, but also increases the likelihood that a patient will adhere to a treatment plan and that's better quality.

Third, let me talk about the consumer strategy. Highmark offers a program called Lifestyle Returns for our members designed to encourage wellness, increase use of preventive exams and shared decisionmaking. Since starting the program we've seen a striking increase in our own employees who've obtained preventive exams going from 9 percent each year to over 60 percent in the past year. That's over a 3-year period.

We've also shown that a comprehensive employee wellness program produced a $1.65 in cost savings for every dollar invested. That is in a short term. That material was published in the Journal of Occupational Environmental Medicine in February 2008.

Finally, we work with the Blue Cross Blue Shield Association spreading national programs like Blue Distinction Centers for specialty care. Capitalizing on the concept that those institutions that follow a standardized, systematic approach to management of complex conditions and do it frequently, achieve better outcomes at lower cost. That's a clear win for everyone.

In closing, you obviously see there's an imperative to improve the value equation in health care. We don't have all the answers, but we've seen trends that speak to some key success factors.

No. 1, collaboration among all stakeholders;

No. 2, better information sharing;

No. 3, a focus on process improvement;

No. 4, coaching for providers and members; and

No. 5, aligning financial incentives based on standardized quality metrics.

I would encourage you all to take bold action on this critical issue for our country. We are more than willing to help with solutions. Thank you for your attention.

[The prepared statement of Dr. Fischer follows:]

PREPARED STATEMENT OF DONALD R. FISCHER, M.D., MBA

EXECUTIVE SUMMARY

I am honored to be here today to share what Highmark and the Blue Cross Blue Shield Association (a national federation of 39 independent and locally operated Plans) are doing to improve quality and affordability by facilitating the implementation of best patient care practices for hospitals, primary care physicians, and members. There is ample evidence to show that a quality chasm exists in the U.S. health care system. Despite the highest per capita spending in the world, there is a widespread belief that we do not receive the value we should for our health expenditures. We believe that improving the quality of care will result in improved patient outcomes and significant cost efficiencies by eliminating underuse errors, overuse errors and misuse errors.

Our goal at Highmark is to help ensure that the right care is delivered to the right member at the right time. If we can achieve that goal, we believe we can bring substantial value to the health care dollar for our customers. We work every day with three key stakeholders—physicians, hospitals and our members—with a purpose of achieving documented improvements in quality and patient safety, while also addressing costs.

Highmark's quality improvement programs emphasize several guiding themes:

1. Focusing on measuring quality indicators that have been identified by national quality improvement organizations as areas of opportunity.
2. Aligning financial incentives to improvements in quality measures.
3. Providing practice coaching and guidance to support the hospitals and physicians who are Highmark's partners in improving quality.
4. Providing education, motivational coaching and incentives to members to improve adherence to preventive and chronic care evidence-based guidelines.

Highmark has used these approaches to address some of the most critical issues in health care today—with tangible results. Highmark's QualityBLUE hospital pay-for-performance program has focused on reducing the incidence of central line bloodstream-associated infections. Coaching and guidance combined with financial incentives have encouraged hospitals to follow best practices, and to standardize processes to avert these infections. During fiscal year 2008, hospitals in the program reported a significantly lower rate of central line infections compared to the national average, consistent with a savings of over $21 million and between 68 and 142 lives saved.

The company has helped moderate increases in prescription drug costs through efforts to encourage prescribing and dispensing of generic drugs when they are clinically appropriate. Elements of the program include a generic medication sampling program in physician offices and a generic prescribing measure as part of its QualityBLUE physician pay-for-performance program. As a result of these activities, Highmark has sharply increased its generic dispensing ratio, leading to a reduction in the rate of rise of pharmacy costs. Reduced pharmacy costs can play a significant role in improving patient outcomes because they generally result in increased patient adherence to prescribed medications.

Financial incentives and coaching are also important tools to help members make prudent health care choices. Using its own workforce as a testing ground, Highmark has demonstrated that health promotion and wellness programs can be cost-effective, and can reduce the underutilization of preventive care. According to a Highmark study published in the Journal of Occupational and Environmental Medicine, a comprehensive employee wellness program, including member financial incentives, produced $1.65 in cost savings for every dollar of program costs. We are now spreading these programs to other accounts.

INTRODUCTION

Madame Chairwoman and other distinguished members of the committee, my name is Dr. Donald Fischer, Senior Vice President and Chief Medical Officer of Highmark Blue Cross and Blue Shield of Pennsylvania. I am honored to have the opportunity to testify before you today on behalf of the Blue Cross Blue Shield Association on best practices to promote quality health care. BCBSA is a national federation of 39 independent, community-based, and locally operated Blue Cross and Blue Shield (BCBS) companies that collectively provide health care coverage to 102 million individuals—one in three Americans.

At Highmark, I have responsibility for overseeing the management of our clinical and non-clinical professionals who develop and deliver a comprehensive range of

programs, including case management, pharmacy management, condition management, and wellness and prevention. BCBSA and Highmark strongly believe that all Americans should have health care coverage, and that the care delivered should be of high quality. There is ample evidence to demonstrate that there remains a quality chasm in health care in this country; despite the highest per capita spending in the world, we do not receive the value that we should for our expenditures. It is estimated that as much as 30 percent of all health care spending is wasted, going toward ineffective, redundant or inappropriate health care. It is our firm belief that improving quality of care will result in significant cost efficiencies.

Highmark's efforts to improve the quality of care—and ultimately have an impact on costs—are built around trying to reduce the unwarranted variation in medical practice that cannot be explained by patient demographics or severity of illness. The variation can be due to the underuse of tests and treatment known to be effective, the overuse of tests and treatments that may not have significant clinical value, and the misuse of tests and treatments that contribute to medical errors. These are the significant factors that are preventing us from assuring patient safety. Our mutual goal with providers is to assure that the right care is provided to the right patient at the right time.

Most physicians and hospital staffs are well trained and well intentioned, but need to spend more time focusing on improving the processes by which care is delivered, and using systems to support decisionmaking that adheres to the scientific evidence that is available. This requires training in process improvement techniques, and a realignment of financial incentives. Our current system includes misaligned incentives that drive increased health care costs, without regard to quality of care or outcomes. I am often asked why I left academic medicine, where I truly found great satisfaction in helping children with congenital heart disease and their families.

My rationale is that I felt I could do much more to advance health in this country by having an opportunity to focus on championing patient safety and quality improvement for large populations of patients. My role at Highmark allows me to do that, and I believe we have demonstrated repeatedly that we bring value to our members and the caregivers in our network through our quality improvement programs.

BCBSA also believes that we must change processes and incentives in our current health care system to advance the best possible care, not just drive the use of more services. We believe that by helping providers implement best patient care practices, we can deliver better value and efficiency to members, ensuring access to affordable and high quality health coverage.

In my remarks today, I would like to focus on what Highmark is doing to improve quality and affordability by facilitating the adoption of best patient care practices for hospitals, primary care physicians, and members. Our main strategy with providers is to continue to raise the bar on quality through the use of pay-for-performance (P4P) programs that begin to align incentives through a program known as QualityBLUE. We also have pioneered an incentive program for members known as Lifestyle Returns, aimed at increasing adherence to preventive guidelines. These programs aim at aligning the incentives among the employer, the member, the physician, the hospital and the health plan. My testimony will emphasize four major lessons learned from these programs that are advancing best patient care practices:

- Focus on measuring quality indicators that have been identified by national quality improvement organizations as areas of opportunity.
- Tie significant financial incentives to improvements in these quality measures.
- Facilitate the improvement by providing practice coaching and guidance to support the hospitals and physicians who are our partners in improving quality.
- Provide education, motivational coaching and incentives to members to improve adherence to the evidenced-based guidelines for prevention and chronic care.

Our approach to implementing best patient care practices has yielded significant, measurable outcomes—not only saving dollars, but also saving lives. As I share these results with you, please keep in mind that Highmark has many other programs to improve quality, such as worksite wellness programs performed in conjunction with our employer accounts. In addition, we regularly work with other BCBS Plans and the Association to continue to raise the bar on quality. As Highmark's Chief Medical Officer, I meet quarterly with the other Blue Plan CMOs to spread best patient care practices. I also help my Plan take full advantage of Association-wide initiatives such as Blue Distinction, a program to identify the best hospitals and healthcare facilities for cardiac care, bariatric surgery, transplantation, and the treatment of complex and rare cancers.

IMPROVING QUALITY AND PATIENT SAFETY IN THE HOSPITAL SETTING

I would now like to discuss examples of how Highmark has applied these guiding principles into practice to address important clinical issues. When Highmark launched QualityBLUE, we decided to focus on evidence-based measures of clinical quality that are in accordance with nationally recognized guidelines, and to utilize measures that will drive the greatest proportional improvements in quality. We also sought input from the primary care physician community and our network hospitals to ensure that the measures were valid and actionable.

Our QualityBLUE program for hospitals focuses on the following major areas, with each hospital being mandated to participate in the first two, and electing to focus on two additional initiatives among the others:

- Reduction of Methicillin Resistant *Staphylococcus aureus* infections (MRSA).
- Reduction of Central Line Associated Bloodstream Infections (CLAB).
- Medical Technology Implementation.
- Reduction in Surgical Infections, using the Surgical Care Improvement Project (SCIP).
- Reduction of Deep Vein Thrombosis through use of SCIP venous thromboembolism project.
- Adoption of the American Heart Association's Get With The Guidelines (GWTG) programs for cardiac disease and stroke.
- Reduction of *Clostridium difficile* (CDAD) infections.
- Reduction of Catheter-Associated Urinary Tract Infections.

In addition, all hospitals are scored on their performance on the Centers for Medicare and Medicaid Services' Hospital Compare Process of Care Measure Set.

I would like to give examples of improvements related to the first two areas, because they represent among the greatest health threats to hospitalized patients.

Central Line Associated Bloodstream Infections (CLAB)

A central line is an invasive catheter device inserted in a patient and used to monitor hemodynamic status, provide nourishment, and administer medication. These types of devices place a patient at an increased risk for a bloodstream infection. Bacteria introduced through these lines can lead to life-threatening infections. Unfortunately, these catheter-related bloodstream infections are common, costly and potentially lethal. Each year in the United States, central venous catheters may cause an estimated 80,000 catheter-related bloodstream infections and, as a result, up to 28,000 deaths among patients in intensive care units. In 2007, the Centers for Disease Control National Healthcare Safety Network published a national average of 2.7 infections per 1,000 line days for intensive care unit patients. By comparison, the **average hospital-wide rate for hospitals in QualityBLUE for 2008 was only 1.0 infections per 1,000 line days.**

To attain this result, we coordinate with QualityBLUE hospital participants to implement procedures to reduce central line associated bloodstream infections hospital-wide, working toward a goal of zero. This includes following evidence-based practices for insertion, maintenance, and use of central lines. Removing central lines, when no longer necessary, has also shown to be an evidence-based practice to reduce CLAB infections. For this program year, we instructed hospitals to implement procedures to assess daily the necessity of continued line use and, when appropriate, to remove the line.

When comparing the baseline data (fiscal year 2007) to fiscal year 2008, many hospitals improved their CLAB rate from baseline: 23 hospitals reported a rate of less than 1.0 CLAB per 1,000 Central Line days, with four of 23 hospitals even reporting **zero** CLAB. The average reported CLAB rate for all hospitals at fiscal year 2007 baseline was 1.15 and for fiscal year 2008 was 1.02.

While there were still 341 CLAB infections at QualityBLUE hospitals in the past year, had CLAB infections occurred at the national average rate, there would have been a potential of 907 infections at these hospitals. At an estimated cost of $38,703 per case, that represents a potential savings to the health care system of more than $ 21.9 million compared to the cost had the network performed at the national average. More importantly, there was a reduction in mortality and morbidity compared to the national norm, with "mortality savings" estimated to be in the range of 68–142 lives saved.

MRSA

MRSA first emerged as a pathogen causing healthcare-associated infections (HAI) in hospitals throughout the United States in the late 1970s. Since that time, MRSA has spread to hospitals throughout the country and has become the most common pathogen causing HAI in healthcare facilities in the United States and throughout

the world. In 2004, MRSA accounted for up to 60 percent of the *Staphylococcus aureus* infections acquired in the intensive care units (ICU) of healthcare facilities that reported data through the National Nosocomial Infections Surveillance (NNIS) system.

Studies estimate the attributable medical costs associated with MRSA infections in U.S. hospitals average $35,367 per case. Additionally the Centers for Disease Control and Prevention (CDC) reported that approximately 120,000 persons were hospitalized in the year 2000 with an MRSA infection estimating an annual total cost of $3.2 billion to $4.2 billion for hospitals nationwide. For these reasons, and for the safety and welfare of our members, prevention and reduction of MRSA is an issue that we could not ignore.

A key component of the QualityBLUE MRSA indicator is to develop a system to identify the prevalence of MRSA entering the hospital from the community. By identifying patients as carriers of MRSA, upon admission, a previously unknown "reservoir" of MRSA is determined. Infection control procedures can be implemented for these patients that help prevent the transmission of MRSA from this patient population to other hospital patients. With fewer new patients becoming colonized with MRSA, future MRSA infection development is avoided.

Thus, to prevent and reduce the number of MRSA infections, QualityBLUE hospital participants implement active surveillance testing on their three highest risk units, and then take steps to minimize the likelihood of transmission of the MRSA to other patients. They screen hospital admissions to determine if a patient is a carrier of MRSA; when a carrier is identified, the hospital implements barrier precautions to reduce the likelihood of spreading the infection, uses dedicated equipment, adheres to strict hand hygiene practices, and requires staff to wear personal protective equipment at all times around the patient.

The QualityBLUE program measures the rates at which hospitals screen patients for MRSA on admission, and again at discharge, as well as determining the rates of transmission within the hospital setting. We require hospitals to monitor active surveillance testing compliance and set a goal of 90 percent compliance with obtaining cultures on patients admitted to one of the three units and at the time of transfer from the unit or discharge from the hospital.

For 1st quarter fiscal year 2008, the admission and discharge compliance with obtaining surveillance cultures for all QualityBLUE hospital participants was 92.0 percent and 81.5 percent respectively. By the end of the 3rd quarter of the program year, admission culture compliance improved by 4.5 percent over Qtr 1 (to 96.2 percent compliance) and discharge culture compliance increased by 11.8 percent over Qtr 1 (to 91.1 percent compliance). MRSA transmission rates ranged from 0.8 to 3.7 infections per 1,000 patient days, reflecting persistent unwarranted variation in practice among the participating facilities. That being said, it is only through measurement and awareness that these facilities can address the problem that was previously unquantified and unmanaged.

INCREASING THE QUALITY IN PRIMARY CARE PRACTICES

Our QualityBLUE program for primary care physicians (family practice, internal medicine, pediatrics) focuses on the following six areas of quality improvement:

1. Clinical Quality Indicators (focusing on eliminating underutilization of these evidenced base guidelines): Appropriate use of Acute Pharyngitis Testing; Appropriate Asthma Medications; Persistence of Beta Blocker Treatment; Breast Cancer Screening; Cervical Cancer Screening; Cholesterol Management for patients with Coronary Artery Disease; Comprehensive Diabetes Care; Adolescent Well-Care Visits; Varicella Vaccination Status; Well Child Visits for the First 15 Months; Mumps-Measles-Rubella Vaccination Status; Congestive Heart Failure Annual Care; and Well Child Visits—3 to 6 Years.
2. Increasing appropriate Generic Drug utilization.
3. Improving Accessibility for members, providing evening and weekend hours for visits.
4. Participating in a "Best Practice" process improvement project.
5. Adopting Electronic Prescribing tools.
6. Adopting Electronic Health Records.

All six measures drive overall improved quality care for our members, as well as encourage increased levels of care coordination. Care coordination at the primary care level is a critical component of improving outcomes for patients with chronic conditions, and we continue to seek strategies and practices to increase its practice.

As examples of success, the following are illustrative of the impact of the program during 2008.

Adoption of Electronic Health Records (EHR) and Electronic Prescribing tools

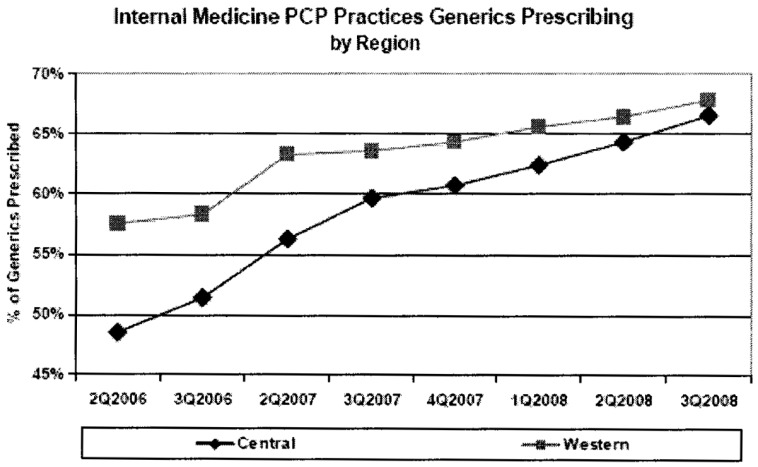
The implementation rate for EHR in 2008 increased by 50 percent, while the rate of use of electronic prescribing increased 52 percent, with 586 practices (40 percent of the total QualityBLUE practices) now using these electronic tools.

Generic Drugs

In early 2004, we implemented the Generic/Brand Prescribing indicator in the western region QualityBLUE physician program. In April 2006, the QualityBLUE physician program was implemented in the central region with the inclusion of the Generic and Brand drug measure.

Evidence of the impact pay-for-performance programs have on advancing practice change can be seen in the rapid growth in the Highmark central region's use of generic drugs. The central region incorporated the Generic/Brand indicator in the second quarter of 2006. At that time, there was nearly a 10 percent difference in generic prescribing rates for internists between the two regions. As of 3rd Quarter 2008, both regions essentially shared the same Internal Medicine network percentage of 68 percent (western) and 67 percent (central). This is a significant accomplishment for both western and central networks but most importantly demonstrates the rapid 40 percent increase in central region performance once physicians in that region had an incentive for generic prescribing (see Figure 1 below).

Figure 1.



During 2008, the generic prescribing rate for Highmark's book of business increased by 3.8 percent, resulting in cost savings for our accounts of approximately $137 million, and direct savings to our members of over $24 million. These savings are also associated with increased adherence of our members to their medication regimens, a clear quality benefit related to the increased affordability of generic medications.

Survey data from 2007 showed a 4 percent increase across all Blue plans in generic fill rates due to system-wide implementation of such strategies. That increase translates into an estimated $3.3 billion in health care cost savings in 2007 due to increased generic drug use. A recently-released CMS report supports these findings, noting that reduced growth in the United States in 2007 of retail prescription drug spending (only 4.9 percent, as compared to 8.6 percent growth in 2006) was due in large part to sustained growth in the generic dispensing rate.

ALIGNING FINANCIAL INCENTIVES TO QUALITY IMPROVEMENTS

Our QualityBLUE programs for both hospitals and physicians have achieved clear successes in raising the bar on quality. One key driver behind this success has been a thoughtful restructuring of our reimbursement system to reward best practices that achieve good outcomes.

Hospitals

Hospitals in the Highmark network are offered an opportunity to participate in QualityBLUE via their contract negotiation. The QualityBLUE Hospital program provides program participants a negotiated program reimbursement based on the attainment of identified performance objectives and targets throughout a contract year. The hospital places at risk a portion of their negotiated reimbursement based on the achievement of agreed upon clinical quality improvements targets, approximating from 1 to 3 percent of total hospital reimbursement. The earned reimbursement is paid to the hospital either via a lump sum payment at the conclusion of the program year or the reimbursement is integrated into the hospitals rates for the subsequent year (earn in 1 year, paid in the next). In the fiscal year 2008 QualityBLUE program, Highmark paid more than $42 million in earned performance-based reimbursement. In this setting, quality departments of these hospitals are no longer simply tolerated as a requirement of JCAHO, but they become revenue centers bringing real value to their patients and to the hospitals' bottom lines.

Physicians

Physicians participating in QualityBLUE receive quality scores based on the measures described earlier, up to a maximum of 115.

Quality Measure	Description	Possible Quality Score
Clinical Quality	Expected Quality Guidelines	65
Generic/Brand Rx	Prescribing Patterns	20
Member Access	Weekly office traditional and non-traditional hours	5
Best Practice	Clinical Practice Improvement Activity	15
Electronic Health Record	Uses evidence of implementation progress	5
Electronic Prescribing	Uses evidence of purchase and functionality	5
Total		115

Physicians are scored on a quarterly basis, and receive incentive payments for each evaluation and management claim filed during the subsequent quarter, based on their total score. Those who score less than 65 points do not receive incentive payments. Those scoring between 65 and 89 receive $3 per filed claim; between 90 to 100 receive $6 per filed claim; and more than 100 points receive $9 per filed claim. These incentive payments are highly significant, comprising up to 15 percent of a practice's total reimbursement. Our experience is that only incentive opportunities of this magnitude have the potential to motivate changes in practice. In 2008, 60 percent of the 1,297 physician practices participating in QualityBLUE earned bonuses. A total of $14 million was paid in incentive payments to primary care physicians in fiscal year 2008.

PROVIDING COACHING AND GUIDANCE

Significant incentives are necessary to raise performance on key measures, but they are not sufficient without additional coaching and management support. That is why Highmark feels it is paramount to cultivate on-going relationships with its provider community by providing information and establishing forums to obtain feedback and share best practices, through newsletters, Lunch and Learns, and Best Practice Forums, and through the dedication of consultative resources that provide on-site program guidance.

Hospitals

To support QualityBLUE hospital partners throughout the performance year, Highmark has developed engagement strategies designed to provide quality of care information to healthcare staff, facilitate inter-facility communication, provide consultative support and encourage implementation of best practices. We have formed Highmark QualityBLUE teams of professionals that include medical technology experts, Registered Nurses, Certified Infection Control Professional, Speech Pathologists, Registered Health Information Administrators, and Certified Professional Healthcare Quality experts, including Medical Directors.

The teams have established and led the following types of activities:

Partners in Quality Newsletter: The Highmark QualityBLUE team developed the Partners in Quality Newsletter, a quarterly publication, as a tool to communicate

with QualityBLUE hospital partners regarding program highlights. Topics of interest related to the program, as well as interviews with physician champions, submission of articles by QualityBLUE hospital participants and information on upcoming "important dates" related to the QualityBLUE program are included.

Best Practice Forum: Annually, Highmark hosts the QualityBLUE program "Best Practice Forum" inviting QualityBLUE participants to share their positive clinical improvements identified through participation in the program. The day-long event includes poster presentations, clinical break-out sessions, nationally renowned speakers, and presentations by clinicians recognized as experts in a wide range of clinical topics. In November 2008, more than 250 hospital staff attended this event.

Program Orientation and Ongoing Clinical Consulting: Highmark QualityBLUE staff members are available to answer questions regarding the program throughout the year. As new hospitals consider entering the program, QualityBLUE staff members meet with healthcare facilities and discuss the QualityBLUE program with the hospital Quality teams. For new participants, orientation to the program is conducted early in the program year and prior to the mid-year evaluation. The QualityBLUE team provides consultative support throughout the program year. Currently, the hospitals are visited as part of the program requirements at mid-year and year-end to facilitate quality improvement activities and to assess alignment to the current QualityBLUE program year.

Physician Support

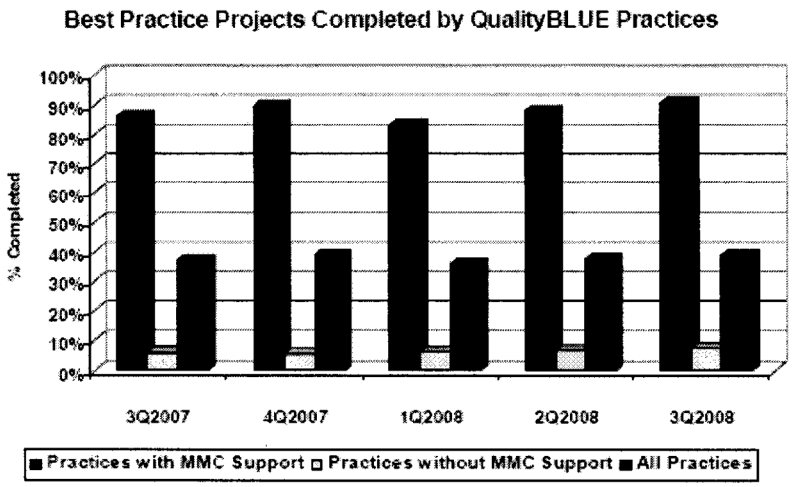
To support physicians in their quality improvement efforts, Highmark formed the Medical Management Consultant (MMC) Team over 10 years ago. The team is comprised of 15 staff members, one Medical Director, and two Clinical Pharmacy Consultants. This experienced and dedicated staff provides consultative quality improvement support, education and training to more than 3,221 physicians. They have developed long term relationships with these physician groups, and have become trusted partners in bringing value to the delivery of healthcare in their practices.

Specifically, MMC teams help physician practices by:

- Assessing where the practice's current performance is against quality performance criteria—the Quality Improvement Roadmap to Success.
- Evaluating the practice office operations to determine process improvement opportunities.
- Meeting with the physicians and staff to provide feedback and recommend a course of action to improve clinical quality and office operations.
- Collaborating with the physicians and staff to create a work plan that defines the problem; establishes baseline measures; specifies action steps; designates responsible team members; establishes a timeline for expected outcomes; and incorporates a control mechanism to ensure the operations don't falter.
- Scheduling meetings to monitor and report on the practice's performance against their clinical quality and process improvement activities, helping to assure they succeed in their efforts and maximize their incentive opportunity.

We have demonstrated that practices which have the benefits of a Medical Management Consultant are more successful with every aspect of the QualityBLUE program. It is quite evident in Figure 2 that the practices with this resource were far more successful in implementing Best Practice projects leading to measurable quality improvement in their offices.

Figure 2.



ENGAGING MEMBERS IN QUALITY IMPROVEMENT

In addition to health plans, hospitals and physicians, our members play an important role in helping to improve quality and manage costs. For many years, the challenge for health plans has been to consistently engage consumers in wellness and healthy lifestyle improvement programs. Our experience, using our own employee workforce as a testing ground, shows that financial incentives make a big difference.

Since 2005, Highmark has encouraged our employees to participate in a program known as Lifestyle Returns, designed to improve adherence to preventive care guidelines, and encouraging use of personalized online programs that focus on weight management, stress reduction, smoking cessation and healthy eating habits. Employees receive financial incentives if they set and meet targeted health goals. Prior to 2005, a maximum of 9 percent of Highmark employees obtained a preventive health exam during the year. During 2008, over 60 percent of employees obtained all preventive exams and screenings recommended for their age and gender. We have also provided on-site fitness facilities and have encouraged employees and their managers to encourage regular use of these resources. In addition, all employees are able to access health coaches for management of chronic conditions, targeted health conditions, and wellness training.

The results show that health promotion and wellness programs are cost-effective. Our study showed that employee participation in the program produced an estimated savings of $1.65 in avoided health care expenses for every dollar spent on the comprehensive employee wellness program, including the payment for the employee incentive. The study's findings were published in the February 2008 Journal of Occupational and Environmental Medicine. Equally important, empowering individuals to lead healthier lifestyles has an immeasurable positive impact—higher quality of life, increased productivity, reduced time off work, and stronger communities of healthier people.

We are now spreading these member programs to our Plan accounts, and seeing similar health and productivity gains.

FOSTERING QUALITY IMPROVEMENT ON A NATIONAL SCALE

As I mentioned at the beginning of my testimony, Highmark has implemented a number of other important strategies, some unique to Highmark, some established by the Blue Cross and Blue Shield Association. To give you an idea of other approaches to implementing best patient care practices, I would like to focus on one Highmark initiative and one Association initiative. BCBSA has designated nearly 800 Blue Distinction Centers (BDC) across 43 States. This national program designates facilities that have demonstrated expertise in delivering quality healthcare in the challenging specialty areas of Transplantation, Bariatric Surgery, Cardiac

Care, and Complex and Rare Cancers. To receive this designation, facilities within participating Blue Plans service areas must meet stringent quality criteria, as established by experts in the specialty field. To meet these BCBSA requirements, the Centers must demonstrate better outcomes and consistency of care, which provide greater value for Blue Plan members. Facilities that have the BDC designation are subject to periodic evaluations as criteria continue to evolve. At this time Highmark's 49-county service area has facilities with Bariatric Surgery, Cardiac Care and Complex and Rare Cancer designations.

Cardiac Care

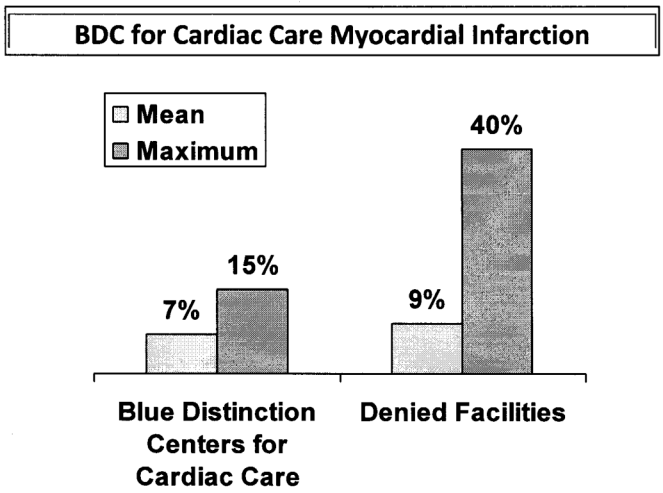
The early results for the Cardiac Care BDCs are especially encouraging. Currently there are more than 410 Blue Distinction Centers for Cardiac Care across the country, including those in Highmark's network. The stringent clinical criteria that facilities met were developed in collaboration with the American College of Cardiology (ACC), the Society of Thoracic Surgeons (STS), and with the input from a panel of leading clinicians.

For example, a study by HealthCore, Inc., found that readmission rates for certain procedures performed at Blue Distinction Centers for Cardiac Care® were lower than at other hospitals. The study found:

- 26 percent lower re-admission rates for bypass surgery and 37 percent lower for outpatient angioplasty, based on 30-day cardiac-related re-admission rates.
- 21 percent lower re-admission rates for bypass surgery and 32 percent lower for outpatient angioplasty based on 90-day cardiac-related re-admission rates.
- Lower costs, 5 percent less for bypass procedures and 12 percent less for outpatient angioplasty, with a 90-day episode of care.

Similarly, there is a significant difference in the inpatient mortality of patients admitted to BDC facilities as opposed to those facilities that were denied the designation. Figure 3 demonstrates the difference in mean and maximum mortality levels between these two groups, findings which further support the value of the program.

Figure 3. Inpatient Mortality Rates for Myocardial Infarction at Blue Distinction Centers for Cardiac Care compared to Facilities denied the designation.



And in a striking confirmation that improved quality leads to better affordability, allowed charges for CABGs were $45,215 in BDCs, $2,260 less than in non-BDC hospitals. Keep in mind that economic criteria were not used to designate facilities as BDCs—it just turned out that facilities that offered better care were associated with better clinical outcomes and generated more affordable care, an important insight for national policy. Quality pays.

CONCLUSION

The best care is that which assures that the right care is provided to the right patient in the right setting at the right time. Providers should be rewarded for delivering high quality healthcare with financial incentives to have full information about their patient at the point of care, coordinate their care with other caregivers, and use a systems approach to adhere to evidence-based guidelines to assure appropriateness. This is especially true for the increasing number of individuals with chronic conditions. Properly aligned incentives can reinforce the adoption of evidence-based practice standards and are a necessity to providing transparent quality information for consumers to make informed choices about their care. Raising the bar on quality—which will lead towards elimination of wasteful spending—will result in better outcomes and more prudent use of valuable resources.

As leaders in the health care community for over 80 years, BCBSA and the entire Blues system looks forward to working with the new Administration, Congress, and all stakeholders to enact healthcare reforms that improve the quality of care delivered to all Americans.

ATTACHMENT.—PROVIDER OPERATIONS QUALITY PERFORMANCE MANAGEMENT (ACHIEVEMENTS FY 2008)

I. INTRODUCTION—WHY IT MATTERS

2008 Provider Quality Improvement Program Results

Highmark's strategy to improve the quality of care provided to our members is to continue to raise the bar on provider quality through the use of pay-for-performance programs and provider engagement. This strategy allows Highmark to differentiate payment among providers based upon their performance on key quality and clinical measures. The commitment to develop and enhance quality programs that promote clinical care and safety improvements is central to this strategy. The following pay-for-performance programs are currently being administered by Highmark:

Physician Specific Programs	Hospital Specific Program
QualityBLUE Physician Pay-for-Performance Program ..... Provider Quality Performance Management Department—Medical Management Consultant Supported Practices..	QualityBLUE Hospital Pay-for-Performance Program

These programs support and advance the corporation's commitment to helping members receive the right care at the right time and are aligned with national quality organizations and philosophies in an effort to ensure the consistency and relevance of quality topics.

It is important to Highmark that providers participating in these programs achieve the highest levels of performance possible. Highmark feels that its strategy to maintain collaborative, supportive and productive relationships with providers is paramount to the success of not only quality programming, but the company as a whole. Since providers are the front line of care delivery, Highmark works diligently to cultivate on-going relationships with its provider community by providing information and establishing forums to obtain feedback and share best practices (newsletters and conferences) through the dedication of consultative resources that provide on-site program guidance.

Highmark is committed to providing consumers with cost-effective, high-quality health care. By continuing to seek innovative approaches to quality improvement, staying engaged with the provider community to drive high levels of performance, being an advocate and providing programs that serve the community, Highmark remains committed to its mission to "*provide access to affordable, quality health care enabling individuals to live longer healthier lives*."

The contents of this report include 2008 program achievements for our QualityBLUE Hospital Pay for Performance Program, QualityBLUE Physician Pay for Performance Program, achievements derived from our Provider Quality Performance Management Department's provider engagement efforts and our designated Blue Distinction Centers.

I am pleased to present the results of our provider quality improvement efforts.

LINDA WEILAND,
Vice President, Provider Operations.

Senator MIKULSKI. That was excellent, all of it's excellent.
Dr. Gulcher.

STATEMENT OF JEFF GULCHER, M.D., Ph.D., CHIEF SCIENTIFIC OFFICER, DECODE, CHICAGO, IL

Dr. GULCHER. Thank you, Senator Mikulski, members of the committee and staff. I trained and worked as a neurologist at Harvard Medical School for several years. Twelve years ago I co-founded deCODE genetics with Kari Stefansson and now serve as the Chief Scientific Officer. Our company is a member of the Personalized Medical Coalition, a group that works to advance the understanding and adoption of personalized medicine and have attached our white paper on improving health care to my written testimony.

I'm here to tell you that personalized medicine probably saved my life. The traditional risk factors that were used for predicting some of the most common diseases like heart attack, stroke and cancer are not very effective. For example, most patients with prostate cancer or breast cancer have none of the risk factors. Furthermore these are not smoking related cancers. The better we can predict risk for common diseases, the more we can target higher risk patients with prevention strategies and with more intensive screening for early detection.

We've recruited most of the Icelandic population to participate in industrial scale genetic studies. We've been fortunate to discover some of the most important genetic risk markers for common diseases. We've worked with numerous U.S. institutions as well including the University of Pennsylvania to confirm and validate those findings. And have already launched several genetic risk tests to make them clinically available for diseases such as stroke, heart attack, breast cancer and prostate cancer. These tests measure genetic risk even if the patient doesn't know their family history or even if they have a family history of that disease.

I personally have already benefited from one of these tests. Last spring I received the results from my prostate cancer test, risk test. This is a test that measures eight genetic changes in your genome. It can define which 10 percent of the population has two-fold risk, higher risk for prostate cancer. And I fit that category.

I was only 48 years old at the time. So best patient practices actually dictate that you wait for prostate cancer screening until you're in your fifties unless you have some other risk factor. Given my higher genetic risk factor with this novel test, my primary care physician ordered a PSA test, a blood test, to see if I might have prostate cancer.

That came back in an upper normal range, still within normal range. But he was concerned enough to refer me to a urologist, Bill Catalona at Northwestern University in Chicago. He was concerned enough to recommend, instead of watching and waiting, to actually do a biopsy of my prostate.

It came back with I had high grade prostate cancer on both sides of my prostate. Of course, it was a shock to me that I was diagnosed with prostate cancer at such a young age, relatively young age. But I took his advice that I should have it removed surgically given that I have two young daughters, three and five, and that was successful.

My PSA level has now gone down to 0.0 after I had my surgery 6 months ago. Had I waited until my fifties, according to the standard recommendations to get my first PSA or screen for prostate cancer, there's a good chance that this high grade tumor would have spread by that time. Unfortunately for prostate cancer, we don't have any chemotherapy that works once the tumor has spread beyond the prostate into your bones. Inevitably you have a long, painful and very costly to the health care system, course then eventual death.

So I firmly believe that these genetic markers that we discovered and developed in a test were at least useful in my case to prompt me to have early detection and early treatment for my prostate cancer. I expect that others may benefit from this approach of targeting higher risk patients who have high risk for common diseases, targeting prevention and early detection strategies. If, for example we, for every prostate cancer or breast cancer that is detected in the early stage as opposed to late stage, saves the health care system hundreds of thousands of dollars in terms of treatment, palliative care and complications.

For every stroke that you prevent, you save the health care system $65,000. So I think personalized medicine has an opportunity of making our health care system much more affordable for all. Thank you.

[The prepared statement of Dr. Gulcher follows:]

PREPARED STATEMENT OF JEFF GULCHER, M.D., PH.D.

EXECUTIVE SUMMARY

The U.S. taxpayer funded the bulk of the human genome project creating the draft sequence of 3 billion letters of our genome. Combining this knowledge with more cost-effective ways of measuring DNA variation in very large patient collections in Iceland, United States, and Europe, we have discovered and validated the strongest genetic risk markers for prostate cancer, breast cancer, heart attack, and stroke. These markers are not determinative as are the genes associated with rare genetic diseases like Huntington's disease; rather, they are used to define patients who are at higher risk than the general population. Genetic risk tests using these markers are clinically available now and may be implemented into best patient care practices to target patients at highest risk for these common diseases for prevention and early detection. This may lead to more cost-effective allocation of established diagnostic and prevention strategies to higher risk patients, resulting in saving of money and lives.

While some advocate waiting until we have shown through large randomized clinical trials that these markers ultimately change outcomes over a 10-year period, such trials would cost billions of dollars and ultimately delay the benefits that come from measuring and targeting risk *today*. In contrast to new drugs with unknown safety profiles which do indeed require clinical trials to determine risk and benefit, the benefit of defining and targeting risk with diagnostic tools has been well-validated for these common diseases—the genetic risk tests only provide a more complete targeting of higher risk patients when added to traditional factors. Therefore, they can complement already established best patient care practices today. The approach that emphasizes early detection and prevention will transform the healthcare from a reactive system to a proactive preventive system with more efficient use of resources.

The costs of genetic testing have also greatly decreased, especially when testing for 25 of the most common diseases in parallel. DNA fingerprinting using a million markers allows for future updates without incurring additional testing charges.

For example, targeting patients with higher genetic risk for breast and prostate cancer for earlier screening or more sensitive screening with established diagnostic tests will lead to earlier diagnosis of cancer in many who otherwise would be diagnosed with late cancer. For every late case of cancer moved forward to early cancer, saves the health care systems hundreds of thousands of dollars in treatment, com-

plications, and palliative care. My own case of prostate cancer was diagnosed and treated in my forties after genetic testing revealed that I was at two-fold risk.

Cardiovascular disease remains the No. 1 cost driver and cause of death despite improvements due to LDL-cholesterol treatment. Stroke rates continue to climb every year. Genetic risk markers for heart attack allow for more accurate assessment of risk and more aggressive prevention strategies for those at higher risk than originally thought based on conventional risk factors. Genetic risk markers for stroke show that the health care system is misdiagnosing the cause of almost 100,000 stroke patients each year—instead these patients likely had a stroke related to atrial fibrillation. Patients who have atrial fibrillation as their cause for stroke do not benefit from aspirin or Plavix used for other types of strokes. If instead these patients are more accurately diagnosed, their stroke rate would be cut by at least 60 percent through warfarin treatment. By targeting patients with higher genetic risk for this common type of stroke for extra outpatient cardiac monitoring, tens of thousands of strokes could be prevented with billions of dollars in savings by CMS.

The U.S. taxpayer funded the bulk of the human genome project creating the draft sequence of 3 billion letters of our genome. Congress also supported the HapMap project which catalogued the bulk of common genetic variation across several populations. Combining this knowledge with more cost-effective ways of measuring DNA variation in very large patient collections in Iceland, United States, and Europe, we have discovered and validated the strongest genetic risk markers for prostate cancer, breast cancer, heart attack, and stroke. These markers are not determinative as are the genes associated with rare genetic diseases like Huntington's disease; rather, they are used to define patients who are at higher risk than the general population. Genetic risk tests using these markers are clinically available now and may be implemented into best patient care practices to target patients at highest risk for these common diseases for prevention and early detection. This may lead to more cost-effective allocation of established diagnostic and prevention strategies to higher risk patients, resulting in saving of money and lives.

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While some advocate waiting until we have shown through large randomized clinical trials that these markers ultimately change outcomes over a 10-year period, such trials would cost billions of dollars and ultimately delay the benefits that come from measuring and targeting risk *today*. In contrast to new drugs with unknown safety profiles which do indeed require clinical trials to determine risk and benefit, the benefit of defining and targeting risk with diagnostic tools has been well validated for these common diseases—the genetic risk tests only provide a more complete targeting of higher risk patients when added to traditional factors. Therefore, they serve to complement and enhance the established best patient care practices of today. The approach that emphasizes early detection and prevention will transform the healthcare from a reactive system to a proactive preventive system with more efficient use of resources.

I. EARLY CANCER DETECTION SAVES MONEY AND LIVES—RESOURCES NEED TO BE SHIFTED FROM EXPENSIVE TREATMENTS TO SMARTER SCREENING STRATEGIES

Avastin is thought by many providers to be a wonder drug for late-stage breast cancer. It chokes off the blood supply to tumors and can save the lives of women with late stage cancer. However, it is an expensive drug to manufacture and costs up to $100,000 for just the drug—accessory costs and palliative care for those who do not respond pile on to explode the price tag. Clearly our healthcare system cannot sustain such great but expensive technology. For every woman, driven by her genes and environment to develop breast cancer, whose cancer is diagnosed early instead of late, the health care system saves hundreds of thousands of dollars. Like breast cancer, the most common cancer in women, prostate cancer is the most common cancer in men. Both cancers are the second leading cause of death for their respective sexes and major sinkholes of medical costs. These two cancers cannot be blamed on lifestyle ills like smoking—so that claiming we can solve this problem just by convincing citizens to lead a healthy life is not the answer.

To save our healthcare system from fiduciary collapse, we need to move as many women and men from the late cancer category to the early category. How do we do that? Only 5 percent of the health care dollar is used to diagnose diseases while 95 percent is devoted to treatment of disease after it is diagnosed, early or late. If we

can somehow allocate a little more of the budget to early detection and prevention in patients diagnosed as high risk, we could substantially decrease the huge treatment side of the healthcare budget. However, until now, we did not have the diagnostic risk tools to measure intrinsic risk for future common diseases. The explosion in genetic studies of common diseases such as breast and prostate cancers after the sequencing of the human genome has led to the discovery of widely replicated genetic variants that we are born with that confer risk to common diseases—that is, we have found a small number of key differences in the 3 billion letter genetic code that are more common in patients with a disease than in normal individuals and can be used to determine who is most at risk. These markers are also independent of whether the patient has a family history of cancer and so can be useful to define genetic risk in individuals without known family history of these cancers, which includes 85 to 95 percent of us.

Genetic screening for prostate cancer can identify the 15 percent of the population accounting for 30 percent of cases.

For example, the only conventional risk factor for prostate cancer in white males is family history of early prostate cancer in the father or brother—this doubles the risk for prostate cancer from 16 percent to 32 percent lifetime risk. Fewer than 5 percent of males have this risk factor—therefore, 95 percent of white males are considered average risk and are told to wait until age 50 to begin screening for prostate cancer by a yearly rectal examination to feel for hard nodules of cancer in prostate and yearly blood test measurement of prostate specific antigen (PSA). The higher risk patients are encouraged to begin screening by age 40 or 45.

Through our large genetic studies using over 10,000 patients and 30,000 controls in Iceland, United States, and Europe we recently found eight genetic differences which together define 10 percent of the male population with a two-fold risk for future prostate cancer. This is the same level of higher risk contributed by a family history of early prostate cancer. These markers have been confirmed by our laboratory and others in tens of thousands of patients and controls and published in the leading scientific journals. About 1 percent of the male population has a three-fold risk or almost 50 percent chance of developing prostate cancer in their lifetime. These genetic risks are independent of family history—so about 15 percent of white males either have a family history of early prostate cancer or are higher risk based on our genetic test—these 15 percent of men account for 30 percent of all prostate cancer. Some of these markers also further increase risk for African-American males who already have a higher baseline risk for prostate cancer than white males. Just imagine if we can direct extra resources to identifying these higher risk patients and then follow them closely and earlier using the existing diagnostic methods including yearly examination and blood sampling for PSA, and then ultrasound with biopsy as indicated. Higher risk patients who have a more subtle rise in PSA may benefit from earlier biopsy as recommended by some professional societies. Early detection of prostate cancer when the tumor is still restricted to the walnut size prostate gland usually results in a cure by surgery or local radiation. In fact, no one should die of prostate cancer and the healthcare system should not be saddled with the costly treatments of late stage cancer, if most patients can be targeted for earlier diagnosis.

Targeting women at higher genetic risk for the common forms of breast cancer even if they do not have a family history.

Breast cancer may also benefit from focusing on higher risk women even if they do not have a family history of breast cancer. Our validated test of seven genetic markers can define the 5 percent of women who have about a two-fold risk and about 1 percent with a three-fold risk of the common forms of breast cancer. This test does not predict risk for women who have the rare form of breast cancer with a strong family history of early cancer, covered already by BRCA1 and BRCA2 testing. Instead the test covers risk for the common forms of breast cancer which account for 95 percent of breast cancer. The test defines another 5 to 15 percent of women who may be higher risk despite the lack of family history and who therefore may benefit from earlier mammography or breast MRI, which is more successful than mammography alone in picking up early breast cancer. Higher risk women may also benefit the most from chemoprevention with tamoxifen and raloxifene.

My own case study of how measuring my genetic risk for prostate cancer led to successful early detection and treatment of high grade cancer.

I have already benefited from these new genetic risk tests for common diseases. Last spring I received the results of deCODEme, our comprehensive genetic test which measures 1 million markers and annotates the genetic risk of 25 common dis-

eases; it also includes our prostate cancer test. I found through my online genetic profile that my risk for prostate cancer was about twice that of the general population. As I was 48 years old at the time, the best patient care practice guidelines recommended that I wait until my fifties to be screened for prostate cancer by rectal examination and the blood test, PSA. However, given my higher risk, my primary care physician ordered a PSA, which came back in the high normal range as 2.0 (conventional normal range is 0.0 to 4.0 but some have lowered the bar to improve the sensitivity of the test). Because the PSA test is not highly accurate, patients will normally have repeat measurements of PSA over an 18- to 24-month period to see if the PSA is rising, indicating that a tumor is growing. However, I was referred to a urologist who agreed that I should be more aggressively screened for cancer than other men with average risk. The urologist biopsied my prostate and found high grade cancer on both sides of my prostate which was surgically removed for presumed cure. Had I waited a few years before getting screened for prostate cancer, there was a good chance that the tumor would have spread beyond the prostate. As there is no useful chemotherapy for prostate cancer, spread beyond the gland often leads to a long painful and expensive course and eventual death. I think it is likely that the genes that we discovered and developed into a genetic risk test saved my life and will be useful to prioritize resources to early detection in other higher risk patients.

II. TARGETING MORE AGGRESSIVE PREVENTION THERAPY FOR PATIENTS AT HIGHER GENETIC RISK FOR HEART ATTACK AND STROKE

A common genetic risk factor for heart attack can target some patients who have higher risk than thought based on conventional risk factors.

Cardiovascular disease is still the No. 1 killer and health care expense despite the demonstrated benefit of LDL-cholesterol reduction by statin therapy. The number of heart attacks and death rate from heart attacks have decreased over the last decade showing the benefit of screening for higher risk patients using traditional risk factors like blood pressure, cholesterol, diabetes, and smoking, and treating each risk factor. Best patient care practice guidelines also recommend compensating for overall risk by further reducing LDL-cholesterol levels below normal in higher risk patients. However, we do not yet know all risk factors for cardiovascular disease and further improvement can be made by more accurately measuring cardiovascular risk once we do. We and others discovered a new major risk factor for heart attacks that is based on a common genetic factor that 20 percent of the general population has. This genetic marker has been replicated in tens of thousands of patients and controls in the United States, Europe, and Asia and is very easy to measure in a blood sample or inner cheek swab. It is clinically available from our regulated reference laboratory. It is as important as LDL-cholesterol in terms of its magnitude of risk. Prospective studies have shown that the genetic marker significantly improves the accuracy of MI prediction—it reclassifies some who are thought to be of average risk into a higher risk category. Best patient care practice guidelines would suggest that those patients would benefit from a lower LDL cholesterol target level to compensate for their higher risk.

The strongest genetic risk factor for strokes can help diagnose and treat a hundred thousand patients, annually, who have undiagnosed atrial fibrillation as their cause for a stroke.

Despite the successes in reducing the number of heart attacks using risk measurement and targeted statin therapy, the annual rate of strokes continues to rise—this year there will be an estimated 800,000 strokes and 300,000 ministrokes (TIAs) in the United States. Soon strokes will surpass heart attacks as the most frequent cardiovascular event. Much of the increased stroke rate is due to the aging of the population stemming in part from reduction of death rates due to heart attacks. However, statins are not as effective in prevention of strokes as they are for heart attacks, probably because the causes of strokes are not all tied to atherosclerosis (hardening of the arteries).

We discovered and validated genetic markers that doubles a patient's risk for atrial fibrillation, a common cause of heart rhythm disturbance. Atrial fibrillation (AF) is known to cause about 15 percent of strokes (causing a blood clot to form in the heart and to move to the blood vessels to the brain). However, we have shown and confirmed in numerous populations that the genetic markers for AF are the strongest genetic risk factors for strokes in general. Our work showed that AF is a much more common cause of a stroke than originally thought. As many as a third of patients diagnosed with carotid strokes or with strokes of unknown cause, instead have AF that is not originally detected while they were hospitalized for their stroke.

We estimate that at least 100,000 patients each year are misdiagnosed as having carotid stroke or a stroke of an unknown cause instead of having AF as their cause for stroke. This means that AF strokes are twice as frequent as currently thought. This is a large problem because prevention of an AF stroke is different than prevention of other types of strokes. Anti-platelet drugs like aspirin and Plavix reduce carotid and small-vessel stroke risk, but they have little or no effect on AF-related strokes. Instead, warfarin is the drug of choice for AF strokes and reduces the stroke rate by 60 percent to 70 percent. AF-related strokes are the worst strokes to have since they cause greater disability and higher death rates than other types of strokes. The recurrence rate of an AF-related stroke is higher as well—12 percent to 19 percent of AF stroke patients will have another stroke within the first year.

Defining patients at highest risk for AF using genetic markers and other risk factors may lead to more targeted outpatient cardiac monitoring, resulting to better primary and secondary prevention of AF strokes. Because each stroke prevented saves the health care system an average of $65,000 over 4 years, the ramifications of targeted prevention are immense in terms of saving of costs and lives. For example, successful prevention of just half of the 100,000 AF strokes per year could save CMS billions of dollars. Because African-Americans have a higher risk for a stroke than whites, this approach may have an even greater benefit to address this healthcare disparity.

ATTACHMENT.—PERSONALIZED MEDICINE COALITION (PMC)

PERSONALIZED MEDICINE AND HEALTHCARE REFORM: POLICY THAT PROTECTS INNOVATION WHILE IMPROVING VALUE AND QUALITY

Policies intended to bring about healthcare reform could have significant implications for the adoption of personalized medicine. The Personalized Medicine Coalition (PMC) has developed a set of policy recommendations to ensure that the potential for personalized medicine to improve healthcare quality and affordability is appropriately reflected in policies that may emerge as a result of the healthcare reform debate.

The PMC represents a broad spectrum of academic, industrial, patient, provider, and payer communities, and it supports healthcare reforms that improve quality and affordability while fostering continued medical progress. PMC believes meaningful healthcare reform must encourage continued advancements in personalized medicine and that, to help achieve the goals of high-quality, affordable care for all Americans, health reform should:

- Support and incentivize medical research in the public and private sectors;
- Establish a national initiative to advance collaboration in support of personalized healthcare across Federal health agencies;
- Encourage adoption of a national health information infrastructure;
- Research and identify care delivery and management models that encourage effective, evidence-based disease prevention and care coordination;
- Develop and apply research findings in ways that empower providers and patients by reflecting differences in individual needs; and
- Ensure that relevant provider performance measures and incentives support the adoption of new personalized medicine interventions.

Reform of our national healthcare system has gained fresh prominence as a topline issue for Americans and will be high on the agenda of the new Congress and presidential administration. Covering the uninsured, improving healthcare quality, and controlling rising healthcare costs all will be central themes in this debate.

The renewed discussion of healthcare reform coincides with a time when significant and rapid advancements in genomics and other relevant areas of science and technology are accelerating the emergence of personalized medicine. Personalized medicine uses new methods of molecular analysis to better manage a patient's disease or to assess that patient's pre-disposition toward a disease. The field includes genetic tests and other types of diagnostics, as well as targeted therapies. It helps providers and patients achieve optimal health outcomes by preventing or intervening early in the onset of disease and by identifying the approaches to treatment and care that are best for each individual.

Medical advances arising through the science of personalized medicine, particularly when combined with health information technology, hold great promise for improving the quality and value of healthcare. In turn, healthcare reform holds significant implications for personalized medicine. In particular, policy measures designed to control costs and expand access—but that fail to encourage continued develop-

ment and adoption of personalized medicine—could substantially delay or diminish opportunities for meaningful, measurable improvements in healthcare value and quality.

THINKING DIFFERENTLY ABOUT HEALTHCARE

There is no question that the U.S. healthcare system needs reform. Almost 46 million Americans are uninsured.[1] Nearly $2 trillion is spent annually on healthcare in the United States, and national health spending as a percentage of gross domestic product is projected to hit 20 percent by 2016.[2]

When considering the growing burden healthcare costs place on our national economy, our healthcare and research infrastructure, and on our individual finances, policymakers may be tempted to focus on seemingly expedient fixes, such as aggressive government price controls and access restrictions, applying rigid evidence standards to achieve short-term cost-containment goals, or by cutting back on covered benefits.

While such solutions may provide some short-term relief in healthcare spending (likely accompanied by a sacrifice in quality and health outcomes), they would ultimately raise system-wide costs, stifle valuable opportunities for improvements in care and outcomes, and undermine the continued development and adoption of personalized medicine as the model for effective, state-of-the-art healthcare delivery in the United States. For example:

- Proposals that seek to contain costs by promoting the least expensive treatment on average, rather than the best care for the individual, will discourage the development and adoption of gene-based diagnostic tests and targeted therapies, which can have a higher up-front cost but will offer substantial clinical and economic benefits over the long-term;
- Cost containment proposals that impose access restrictions based on average, population-wide study results will overlook the different needs of individual patients and discourage adoption of personalized tests and therapies based on these differences;
- "Pay for performance" programs focused on short-term provider efficiency could discourage physicians from using gene-based tests and targeted therapies to optimize care for the individual; and
- A focus on cutting costs in narrow healthcare sectors will fail to optimize patient care and improve care coordination across care settings, which is essential to achieving the promise of personalized medicine.

Alternative approaches are available that support medical progress in areas like personalized medicine while improving healthcare quality and affordability. An overview of such approaches is provided below.

THE POLICY AGENDA: DELIVERING ON THE PROMISE OF PERSONALIZED MEDICINE

Reforms to achieve care that is preventive, coordinated, evidence-based, and personalized hold the greatest promise for improving healthcare quality and affordability. To support continued progress in personalized medicine, policymakers should support healthcare proposals that:

1. Invest in the science and practice of personalized healthcare by:

(a) Supporting basic research in the public and private sectors by creating new incentives for private sector research and expanding funding for the National Institutes of Health and public-private initiatives to accelerate the science of personalized medicine. Of particular importance is the growth of Federal investment and resources for educating and training the next generation of research scientists, especially those focused on genomics and personalized medicine.

(b) Support Federal research and policy to identify and support timely adoption of the medical interventions and health system tools needed to support the emergence of personalized medicine through a national "Personalized Medicine Advisory Commission" (PMAC). The advisory commission would oversee and provide input on Federal activities to conduct and synthesize outcomes research in support of evidence-based, personalized health care decisions by physicians, other providers and patients. Commission activities would include: recommending research prior-

[1] "Household Income Rises, Poverty Rate Unchanged, Number of Uninsured Down." U.S. Census Bureau. *http://www.census.gov/PressRelease/www/releases/archives/income_wealth/012528.htm/*. August 28, 2008.

[2] Poisal JA, ET al. Health Spending Projections Through 2016: Modest Changes Obscure Part D's Impact. *Health Affairs.* 21 February 2007:W242–253. Via "Health Insurance Costs." National Coalition on Health Care. *http://www.nchc.org/facts/cost.shtml.* Accessed October 21, 2008.

ities on the range of medical and health system interventions (such as diagnostic tests, therapies, and approaches to organizing and managing care) that are important to the advancement of personalized medicine; supporting development of methods for conducting and communicating research in ways that enable or enhance the delivery of personalized medicine; and recommending policy approaches that support delivery of personalized medicine.

2. Support for research to identify what works in healthcare (comparative effectiveness research) that:

(a) Encompasses all of the elements of care relevant to high-quality, personalized healthcare, including research on diagnostic tests and therapies, processes of care, chronic care prevention and management programs, and approaches to healthcare delivery and benefit design.

(b) Generates and communicates evidence in ways that support personalized medicine by accounting for differences in treatment response and preferences among individuals and sub-groups.

(c) Applies evidence in ways that support personalized medicine by ensuring that emerging health information technology platforms and performance measurement initiatives support the physician's ability to optimize individual care based on the range of treatment options.

3. Support coverage for preventive services that are facilitated through emerging personalized medicine advances. The science of personalized medicine promises new tools—like genetic predisposition testing—that enhance the ability of individuals and caregivers to engage in early disease prevention and preemption. Steps should be taken to identify and support evidence-based screening, predisposition, and risk-assessment tools that can help predict an individual's risk for future disease. Additionally, as described above, health reform proposals should include provisions to identify approaches to care delivery and coordination and benefit design that support adoption of predictive and preventive care for these patients.

4. Adopt Federal health information technology (HIT) and e-prescribing standards that inform treatment decisionmaking based on the range of treatment options—taking individual genetic characteristics and other factors into consideration.

Adoption of HIT is an important building block to support preventive, predictive medicine and early disease intervention and to enable higher quality, more efficient healthcare. According to the RAND Corporation, HIT adoption could save and improve many patients' lives, as well as cut up to $81 billion a year in health costs.[3]

HIT and e-prescribing standards adopted by the Federal Government should provide for transmitting and communicating information on personalized healthcare technologies. HIT decision-support platforms, including e-prescribing, should facilitate communication of information in ways that enable physicians and patients to consider risk and benefit trade-offs of a range of treatment options and to understand how these trade-offs may vary depending on an individual's genetic profile. Tools that obscure these differences by applying overly simplistic population-based comparative evidence or narrow cost-cutting targets will discourage the evolution of personalized healthcare.

To give patients and providers all of the information that they need to deliver personalized care, e-prescribing platforms should be integrated with the individual's electronic medical record (so that information on diagnostic test results, comorbidities, etc. can be used for optimal treatment decisionmaking). HIT and e-prescribing standards also should enable rapid appeals and prior authorization decisions based on results of molecular diagnostics and other personalized medical information.

5. Adopt performance measures/incentives that facilitate healthcare interventions based on personalized healthcare technologies. Healthcare performance measures adopted by Federal agencies should help physicians tailor interventions (including tests, treatments, and care management approaches) based on personalized healthcare technologies. Healthcare measures that cover a broad "episode of care" and longer-term outcomes, rather than point-in-time interventions and short-term outcomes, may be one step that supports this approach.

Provider incentives based on performance measures should allow for exceptions based on individual genetic variations. This allowance will ensure that physicians

[3] "RAND Study Says Computerizing Medical Records Could Save $81 Billion Annually and Improve the Quality of Medical Care." RAND Corporation. *http://www.rand.org/news/press.05/09.14.html.* September 14, 2005.

are not penalized for delivering optimal care for patients who differ from the "average" patient population.

Performance measures that define economic outcomes should account for differences in treatment cost that may arise as the result of delivering optimal, personalized care based on genetic test results and other information.

6. Improve care coordination. Health policies that shift the focus to disease prevention and care coordination will support the adoption of personalized medicine and also offer a key solution for healthcare quality and affordability. Ultimately, through policies that help move us toward consistent delivery of the right treatment for the right patient at the right time, the entire system will benefit from higher quality, more affordable, personalized care.

Developing chronic care management tools that make use of the science of personalized medicine, for example, can help the more than 133 million Americans who suffer from one or more chronic conditions.[4] They also can make healthcare more affordable: By making basic improvements in preventing and managing chronic disease, the United States could save $1.1 trillion in 2023, including $218 billion in savings from direct treatment costs.[5]

PERSONALIZED MEDICINE: A CRITICAL ELEMENT OF HEALTHCARE REFORM

Advances in personalized medicine exemplify the opportunity for meaningful improvement and greater value in the healthcare system—central objectives of healthcare reform. As a result of targeted therapies and other advances in cancer care, for example, survival times of metastatic breast cancer increased by 30 percent during the 1990s.[6] New, biomarker-based treatments are dramatically enhancing diagnosis and increasing effectiveness and safety of medical interventions, which in turn can help contain overall healthcare costs by avoiding expense from complications that might otherwise result from the wrong diagnosis or treatment, improving patient adherence to therapy, and helping to prevent disease before it emerges.

In contrast, health reform approaches that seek to contain costs by restricting access to and delaying the adoption of medical innovation will hamper the continued development of personalized medicine and ultimately perpetuate outdated approaches and inadequacies that continue to drive system-wide costs up.

Based on our growing understanding of human genomics and related fields, personalized medicine can give us an unprecedented ability to address unmet health needs in ways that:

- Prevent disease by identifying an individual's likelihood of developing it in the future and by enabling individualized approaches to address key risk factors;
- Detect the onset of disease at the earliest stages based on new biological markers and changes at the molecular level to pre-empt disease progression; and
- Tailor treatments to each patient based on genetic and other factors, so each individual receives the safest, most effective care available for them.

Advances in personalized medicine can help bring about a new era in which medicine is pre-emptive, predictive, and patient-centered. Policies crafted with personalized medicine in mind will empower clinicians with the tools and information they need to deliver the right treatment to the right patient at the right time (the *first* time)—and ultimately benefit patients by significantly enhancing the quality, value, and safety of the treatment and care that they receive.

CONCLUSION

America stands on the cusp of significant scientific advances that promise to usher in a new era of personalized medicine. We also stand at the threshold of a new debate about how to address challenges with healthcare access, quality, and cost.

A supportive policy framework is needed to foster and help sustain research, development, and adoption of personalized medicine-based technologies and treatments. The Personalized Medicine Coalition supports healthcare reforms that improve quality and affordability while fostering continued medical progress, and it commits to advancing patient care through development and adoption of evidence-

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[4] "The Growing Crisis of Chronic Disease In the United States." Partnership to Fight Chronic Disease. *http://www.fightchronicdisease.org/pdfs/ChronicDiseaseFactSheet.pdf.* Accessed October 21, 2008.

[5] "An Unhealthy American: Economic Burden of Chronic Disease—Charting a New Course to Save Lives and Increase Productivity and Economic Growth." The Milken Institute. *http://www.chronicdiseaseimpact.com/* and *http://www.milkeninstitute.org/*. October 2007.

[6] Chia SK, ET al. The impact of new chemotherapeutic and hormone agents on survival in a population-based cohort of women with metastatic breast cancer. *Cancer.* 2007;110(5):973–979.

based, personalized medical technologies and care delivery models. By incorporating the elements described above, healthcare reform can facilitate the advancement and adoption of new personalized medicine technologies while meeting the challenge of improving access, quality, and affordability.

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Senator MIKULSKI. Well, first of all thanks to the panel. I'm going to go by the 5-minute rule so we all get a chance to ask our questions. Then if there's the opportunity we'll go back for even a second round.

I'm going to jump right in and target, focus, not target, focus my first area of questions to Dr. Fischer.

Dr. Fischer, you're the author of the right care at the right time, to the right patient at the right time.

Dr. FISCHER. No, I would not take authorship on that. It's a common patient safety.

Senator MIKULSKI. That's exactly right. And it seems good. Yet when I look at your four points I think you also embrace the concept that I raised, which is during the amputation for the diabetic who's drinking two beers and two Coca Colas everyday in preventing infection using Dr. Pronovost then goes to what I'm talking about.

What I note in your four points that are your guiding things, in addition you talk about providing practice coaching and guidance to support the hospitals and physicians who are your partners and also provide education, motivational coaching and incentives to members to adhere to that which has been prescribed to them which then of course goes to having the medical home, health IT and so on. Could you elaborate on your three points about what ex-

actly does it mean in terms of quality and how did you provide or pay for incentives in, for example, this coaching?

You know the word coaching has just been bandied about. There are people who like, kind of resent coaches. Then you have a nurse practitioner or a physician's assistant or a diabetic educator who's a coach. Highly educated, credentialed, certified, you know, meeting their own quality standards to be a "coach." Could you elaborate?

First of all, do you agree that we need the continuum? Obviously you do. Then how did you achieve that? How did you have the financial payments to accomplish it?

Dr. FISCHER. Well thank you for the question. First of all, right care. I would include in the concept of right care, prevention and appropriate ownership by an individual of behavioral lifestyles that impact ultimate health.

So that's embedded in there. We firmly believe that prevention and then wellness programs have benefit. We need to focus more on that aspect.

If you look at our incentive program for physicians, the clinical quality indicators, which I did not speak to and is in my written documentation, accounts for well over 50 percent of the bonus opportunity. Many of those had to do with preventive screenings and preventive exams. So well child care visits for instance at the appropriate ages.

Senator MIKULSKI. Can you give me a case example about how it all works?

Dr. FISCHER. In 3 more minutes?

Senator MIKULSKI. Yes, go ahead.

Each one of these has an area. But it comes down to most of our private payers come through, I think, Blue Cross or a variation of a high level health care provider. And we use words like coaching but nobody knows what it means.

Dr. FISCHER. OK.

Senator MIKULSKI. We don't know how to do the legislation. Then we leave it to the Finance Committee to talk about financial incentive. We have to have health insurance reform, not health care financial reform.

Dr. FISCHER. Let me talk about coaching then. What we have done for about 10 years now is we have a stable of about 15 medical management consultants along with medical directors and two pharmacy staff who go out to practices and help them do process improvement.

Look at the data that we provide them, much of which is close to real time. Look at a given indicator and help them find who is the denominator that's not in the numerator.

How do we work to increase the rate at which, say, you get preventive exams for the 3- to 6-year-old population and set up a system? It may be that although they have an electronic system that can help accommodate that, but first they need to understand systematic approaches.

It may be a paper system. But by doing that learning process improvements, spending the time it takes to improve, they can get better results. They have found that these medical management consultants and medical directors bring value to their practice.

Initially there was resistance. Who are you as a health plan to come tell us what to do? Trust me. We do the right thing.

Senator MIKULSKI. And looking over your shoulder because we don't want to create a nanny State here.

Dr. FISCHER. But we develop relationships over time. So they have the same individual coming to the practice working with them. They see their bonus opportunity increase. They see that their results are better. They see improved satisfaction, frankly, among their patients.

I think it does take a concerted effort working over time to be able to get that kind of result and that kind of trust. We're not adversaries. We're there with a common goal.

Now these medical management consultants, many of them are advanced practice nurses. Some of them are people who've spent time in prevention. If I'd look at our member coaching which is telephonic, the wellness coaching, some of that is done by exercise physiologists, by dietitians. But we try to get the right skill set to the right person to meet their needs.

Senator MIKULSKI. So you actually do two types of coaching? One is to those who actually are the providers, the clinicians.

Dr. FISCHER. Yes.

Senator MIKULSKI. And help them organize their practice and these are one set of professionals to another set of professionals.

Dr. FISCHER. Correct.

Senator MIKULSKI. Is it voluntary?

Dr. FISCHER. It is voluntary. We asked physician groups to sign up for this program a number of years ago saying you have an increased opportunity for bonuses if you work with us. The benefit is you get data and you get assistance with practice improvement and a better payout.

Senator MIKULSKI. But you incentivized also for them to invite you in to look at what's going on.

Dr. FISCHER. Right. So we provide claims data that may show that there's a care gap or that they're not doing as well on an indicator. The usual response was, "No, you're wrong. Your data is wrong."

We might have said, "Well 60 percent of your patients got a retinal eye exam for diabetes." And they said, "You're wrong." Well then we would say, "OK."

Let us help you pull charts and let's really look through the charts. The real number would turn out to be 61 percent. And we would say, "Well guess what, it really doesn't matter, but 60 percent, 65 percent." There's an opportunity here. People aren't getting the care they need.

It's almost a death and dying process for many physicians to recognize there is a quality problem, that you've got to recognize it. You grieve a little bit. You move on. How do we fix it? The fact that we've had relationships using people with skills that can help them, they've shown value.

Now with the member we're doing telephonic coaching to help educate, help motivate, and help them to adhere better to what the physician has asked them to do.

Senator MIKULSKI. Then would you escalate? Escalate is not the right term. But elevate it?

Let's take the case I gave you of the diabetic. That person got a call. But say they're A1C was still in the danger zone, obviously when I just described to you their lifestyle and so on, would you then escalate that to counseling, to family counseling?

What would you do in a situation where someone—first of all would anybody actually ask what is it that you eat and drink every day?

Dr. FISCHER. Yes.

Senator MIKULSKI. I mean a practical question like that. The next question is, why are you doing that to yourself? Not quite as directly as I'm presenting it to you, but that's pretty heavy duty because of what the man said to his wife.

See I heard this through the wife after all the man eventually died, was that's what they invented insulin for.

Dr. FISCHER. I think that takes some education. It takes behavioral change tactics. What we do is we use our claims data. We use a variety of data.

Senator MIKULSKI. What would happen with this type of patient in your system? How would the problems be identified? A dangerously elevated A1C, what would that trigger, because both the primary care and the specialist in diabetic endocrinology would be aware of this.

Would contact be made by telephone? Would they call the patient every day and say don't drink your Coca Cola. I mean what would happen here?

Dr. FISCHER. Two ways it could be identified, either the practice calls and says we have a patient that we're just having terrible problems with. Will you spend the time and have your health coach call, reach out to them and spend the time? Get them in a program that will be helpful. We have a variety of programs that can be done in person, online or telephonically.

The other way is through claims. That we would be able to find people who are at the highest risk, who had the greatest number of care gaps, who are not doing well and reach out to them as a cold call. But once they're engaged, be able to have a one on one relationship with a health coach to be able to get them to understand, get them to comply better.

If, in fact, there's a crisis, contact the physician's office and say, you know, we've got this patient we're working on with you who's really an issue. Here's what we think may help. We could say, "How can we help?"

Senator MIKULSKI. Well I'm going to now turn to my colleagues. But this is where health IT, that was standard and interoperable, would work because you would all have the data. There would be flashing yellow lights from the individual patient.

Well, thank you.

Dr. FISCHER. Well, I would just say that you need to have interoperability among the health plan data, among the physicians, the hospitals. All of it needs to talk together. We shouldn't have a strategic advantage over information. We need to have information shared. It should be health plan neutral.

Senator MIKULSKI. Great. That's great.

Senator BROWN. Thank you, Madame Chair. Dr. Pronovost, your comments about seeing health care delivery as a science are just

exactly right. By your illustration of a penny on the dollar, the incredible advances we've made in science are far and away the best ever in human history, obviously. The best of any place in the world in the way we deliver is such a huge gap.

Thank you for that and for your suggestion that there should be an institute which I think might be something that we'll look at. I mean, I would like to seriously consider an institute. I think we might look at locating those—an institute like that somewhere outside of Washington and outside of—I should not say that with the Chair sitting here, but perhaps outside of the campus of NIH and in the heartland and several places that would be closer to the real delivery. But that's an issue perhaps for another day.

I want to talk for a moment, Dr. Pronovost, with you about the checklist and Dr. Fischer with you about antibiotic resistance and something else. But I will start with Dr. Pronovost.

The catheter line infection issue, the checklist and I know you've worked the checklist to prevent other kinds of hospital infections and other kinds of medical mistakes. I've been working with the Ohio Hospital Association and many of them are very interested in figuring out how we bring this life saving mechanism and cost cutting mechanism to my State. The system is so fragmented, obviously, that's it's difficult State by State or any other way.

How do we do this? Do we only do this through NIH? I mean, obviously setting up an institute is one way. I mean is it through HHS? Obviously setting up an institute makes a lot of sense.

But in terms of the practicality of beginning to do the things that you've done in Michigan that have happened in Rhode Island. I want to bring to Ohio. Talk that through how prescriptively we should do that.

Dr. PRONOVOST. Sure. Thank you for the question, Senator Brown. Senator Mikulski very carefully crafted these witnesses and if you arranged our order, you would have the whole spectrum of biomedical research at this table, what's called the translation superhighway.

So you would have the genetics basic discovery that we need. You would have the comparative effectiveness finding out what works. You would have learning the science of how to put into practice, not just telling that diabetic not to drink Coke. But finding out the science of what leads to behavior change. What do we actually do?

Then you would have management and financial incentives putting that science into practice. Right now that flow of knowledge is discontinuous. There are no gaps in this.

The tail that I'm on is virtually nonexistent. It's not funded. Comparative effectiveness isn't much better. There needs to be this continuum of knowledge.

How does it work? Well I think we have to find out programs. One of the things we learned, Senator Brown, is that it is neither efficient nor effective for every hospital to reinvent the wheel. Developing measures takes scholarship and thousands of hours. Summarizing evidence is a science and takes hours.

Once we find that, we in this country need a distribution channel to put that evidence into practice, and we don't have one. In our model right now, we believe a state-by-state model is a distribution channel. The reason is, there's infrastructure at the States.

People care about the care that their citizens receive. I think that model works. In this case we've been partnering with the insurers, with the consumers to say let's put this in. The efforts have been coordinated by the State Hospital Associations.

One of the reasons why we do that is the science clearly shows that social support in these efforts are very effective. That people get motivated when they say, you know, I'm just not improving the care at the Cleveland Clinic. But I have a commitment to say the citizens of Ohio deserve safe care.

We're going to make sure that no matter where they go, we're not competing on safety or high quality of care that a health system that spends $2 trillion should guarantee safe care to our citizens. In this case to the citizens of Ohio that wherever they choose care that it will be safe. Someone has to coordinate what I call the technical components. How you're going to measure that? What is the evidence summary?

Ideally as we're working now it could be Federal agencies. So the CDC has a way to measure these things. We ought to be partnering with those Federal agencies.

But ultimately it's the doctor and nurse at the bedside, individual hospitals. It's the managers creating financial incentives with insurers, with management. Without this whole spectrum we're going to lose our pre-eminent position in the world of health care.

We already don't have it on the outcomes. We still have it on the science. But they have to be coupled together.

Senator BROWN. Thank you. Let me shift fairly dramatically. Dr. Fischer, the whole issue of antibiotic resistance is obviously complex.

There's the use of antibiotics, of prophylactic use in animals as we pack the chickens or beef closer and closer together and feed them antibiotics partly for growth, partly for prophylactic purposes. The antibiotic resistance that might create the overprescribing from doctors on demands from patients. That even if I have a virus, if my young daughter has a virus I want an antibiotic because I think I want an antibiotic. The doctor certainly goes along. Then the lack of enough antibiotics in the research pipeline, all is conspiring for obviously a serious national health problem.

What do you do as an insurer? What makes the most sense in how we pursue physicians not over prescribing antibiotics?

Dr. FISCHER. Well there are two pieces to our program with paper performance for primary care that touch on that.

One is advocating for greater use of generic medications. Very often the first line medication for common bacterial infections has a generic alternative.

The second is through an indicator we call the pharyngitis indicator which is also a heatus indicator. We measure practices who have filed a claim for a patient with a diagnosis of pharyngitis where they ordered an antibiotic and did they in fact do a strep test to see if it is a bacterial infection? The logic there is that the only cause of pharyngitis that requires an antibiotic is strep throat.

Strep is a dumb germ. It's killed by penicillin still. OK. There are very few people, some people who are allergic. So there would be

a small percentage of people who you'd have to give something other than a generic penicillin or amoxicillin to for that diagnosis.

There are still many physicians out there who are looking in the throat and saying it looks like strep throat. You know, here's a prescription. Not going through the diagnostic process of saying is it strep. So you have people with viral sore throats who are getting an antibiotic and also often getting one that is a second line, third line antibiotic that is expensive and a brand name and fosters antibiotic resistance.

Senator BROWN. Well, I get the second part of your answer. The first part sounds more like cost containment, which is fine that it does dealing with antibiotic resistance because if you're just substituting generic you're still—the doctor if he/she wrongly prescribes is still contributing to perhaps antibiotic resistance, right? If you're only substituting generic, it seems to me that it's the second part of your answer.

Dr. FISCHER. Not if you're treating the correct diagnosis. So if you've gotten a diagnosis of strep you're not going to contribute to antibiotic resistance by prescribing penicillin.

Senator BROWN. Right. OK, OK, fair enough.

Dr. FISCHER. If you're giving the right drug for the right diagnosis, you're fine.

Senator BROWN. Well if I could add one real quick point, Dr. Fischer. This doesn't save you money except for later illnesses perhaps in the patient which does save you money. But is part of this making sure that the doctor spends the time with the patient to make sure the antibiotic is taken correctly? Is that contributing significantly to the problem of antibiotics? I mean I just go back to years ago before I ever thought about any of this if I had gum surgery or something and was taking penicillin or some other antibiotic I was supposed to take it for 10 days and after 7 days I felt OK.

Just like, particularly with tuberculosis we see that all the time. Particularly developing a role in other places where they quit taking it after they quit coughing. Is that part of your regimen to make sure it's taken through the whole course?

Dr. FISCHER. We do not take that on. That is, in fact, a real problem. Adherence to any medication regimen is a problem. And in the antibiotic world that leads to resistance.

We have focused on adherence to other kinds of medication that were supposed to be taken chronically. Whereas for instance we have seen marked increases in the rate at which beta blockers are prescribed to patients with acute myocardial infarction when they leave the hospital. That's something we really don't need to incent anymore.

But if you look at what's happened to those same patients 6 months later, it drops to about 30 percent of that patient population still taking the medication they're supposed to be on chronically. That's a problem. We now use that as an indicator. What's the persistence of adherence?

That is both a physician issue and a patient issue. Both need to be educated and incented to work on that.

Senator MIKULSKI. And a discharge planning issue.

Dr. FISCHER. Yes.

Senator MIKULSKI. We're going to turn to Senator Kay Hagan.

But if you watch people leave the hospital they usually get a bag of drugs. They get their bag of drugs, but nobody talks to them about what do they take, why are they taking it and when should they take it? Do they take all seven of them at one time in the morning? I think that goes to something else.

But it's Senator Kay Hagan's time.

Senator HAGAN. Thank you, Madame Chairman. This is a question for Dr. Pronovost. I appreciated your paper on the results oriented and the scientific approach, especially for the catheter-related blood stream infections.

But you also talked about how patients sometimes get an epidural pain medicine connected to an IV catheter which could then have lethal errors. Then you talked about how most of this could be solved through product design and intervention and if the manufacturers designed the catheters so that the epidural and IV catheters don't fit together you wouldn't have that kind of medical error. Since people are human and you talked about you'd educate, but at some point in time something is going to happen.

What would it take to have that small design take place? I think about just putting gasoline in my car. I mean, the diesel is not going to fit in the unleaded. The leaded is not going to fit in the unleaded. Basic, basic product design.

Dr. PRONOVOST. Thank you for picking that up Senator because I didn't have time to go about it. In our work to improve safety, we recognize that there are types of problems that are not putting evidence into practice that you've heard about. But there's another type of problem that we talk about—not learning from mistakes.

The epidural catheter is so striking. In our literature review, literally every one of the 6,000 hospitals in this country, we connect those two things—an epidural catheter to an IV that can kill someone. Our response is to re-educate. The probability that re-education works scientifically is close to zero.

Yet, if you think it's an hour to educate every doctor and nurse, that's an awful, awful expensive waste of money. What we learned from aviation was that they created a public/private partnership to find these design problems. Then work with the manufacturers to either require or say, "Hey, we're not going to buy this Boeing engine if this thing isn't fixed. But if it's fixed, we will. But we want it designed right."

That forum does not exist in health care. It's a shame because we've been working now for 9 years to get a national error reporting system. As you know we now have that with the Patient Safety Organizations. But there is no mechanism to create this forum.

We were fortunate enough to get a C grant from the Robert Wood Johnson Foundation to pilot test what would this system look like in health care, to plan it out. We were working with people from aviation, from the FAA to advise us. But that needs Federal leadership.

I mean, it shouldn't be a researcher at Johns Hopkins creating this. This public/private partnership ought to be created and funded because it's much more cost-effective to re-design equipment. I mean we did this same thing, Senator where we found that when patients had heart attacks in the hospital, 30 percent of the time

the doctors or nurses push the wrong button on the defibrillator or delayed pushing it because they couldn't figure out what to push. Right. And that we can tell them to be smarter, but that's a design problem. We have to design it so they don't happen to go and just—I love your example of the gasoline so they can't stick the wrong hose in.

We need a mechanism with Federal leadership to do that. We have the model. We're partnering with our colleagues around the country. But it does need Federal leadership to create it.

Senator HAGAN. Thank you.

Dr. Gulcher, you talked about the potential for the genetic testing for improving patient outcomes and obviously reducing costs to the system at some point. But what is the availability of genetic testing and the sort of predisposition of somebody to actually want to spend that money and go forward with that?

Dr. GULCHER. We've made several of these tests already clinically available through a federally regulated CLEA laboratory where we run the test and provide that. They're not FDA-approved, but they're under the CMS regulations for CLEA.

Each of the markers——

Senator HAGAN. Right, for what now?

Dr. GULCHER. For the genetic tests that we offer.

Senator MIKULSKI. She wants to know what CLEA is.

Dr. GULCHER. I'm sorry. These are the Federal regulations that cover laboratory derived tests. Tests that are performed just by one laboratory where the laboratory itself has to document that they are accurate and clinically validated.

These tests that we offer are for prostate cancer, breast cancer risk for the common form of breast cancer as distinguished from the highly familial form that Myriad runs their test for, BRAC-1, BRAC-2, also for stroke. We also have tests for myocardial infarction and Type II diabetes. But from those particular tests the way some physicians are using them today is to help identify patients who might best be screened earlier or more intensively for cancer, like prostate cancer or breast cancer. In some cases they change how they treat the patient in terms of prevention for heart disease based on the extra genetic risk factor that's independent of the conventional risk factors for heart disease. So they're already being used today.

In terms of evidence that it saves money in the long run, we don't have data like that. We certainly would like to work with payers and other organizations to actually demonstrate that as a demonstration project to do comparative effect and also look to see how it might save money. But I have to say that with your example about how one can change behavior of payers, the stakeholders, the payers, physicians and the patient.

Let's say in the context of Type II diabetes. We heard from Dr. Fischer they have a coaching staff, right? But they're going to have to make decisions on who gets coaching, perhaps or maybe there is more intensive coaching for those who are at highest risk.

So for those who let's say have pre-diabetes. They're already at risk for Type II diabetes. Some of our tests show that patients who have pre-diabetes are even at a higher risk for converting to Type II diabetes ultimately.

Here's an opportunity to help prevent Type II diabetes if they lose weight or if they're put on certain medications. So it's an opportunity to use the genetic test to maybe motivate the patient himself to lose weight or do something different with their diet. It will motivate the patient to call on the services of coaching, perhaps, to try to get the patient to change their behavior and more for the payer, to optimize their coaching resources to those at highest risk to begin with.

I mean, one size hopefully, you know, will eventually fit all. But we don't have the resources. We don't have the man power. We don't have the funding to do that. But maybe we can prioritize the highest risk patients first and demonstrate that those approaches work even better.

Senator MIKULSKI. Senator.

Senator HAGAN. Thank you, Madame Chairman.

Senator MIKULSKI. Those were excellent. I'm going to turn to Senator Bingaman who brings a lot to the table. He's also chairing one of the three working groups here on coverage and is also a member of the Finance Committee and has spent a great deal of time on this topic. We really welcome his participation today.

SENATOR BINGAMAN

Senator BINGAMAN. Well thank you very much. Thanks for having this hearing. Thank you all for testifying.

You know what occurs to me—and this may be something that was discussed before I arrived—this whole subject of how do you implement best patient care practices. It would seem to me that since the Federal Government is the largest purchaser of health care services in the world, I guess, there are some particular ways in which the Federal Government ought to be able to move the ball forward in this regard, the medical care system that the military has, the VA system, the Indian Health System.

To what extent are the kinds of clinical guidelines that ought to be put in place, in place in those settings? For example, I think Dr. Pronovost you've talked about the five procedures that you've implemented at Johns Hopkins with regard to the catheter-related blood stream infections. Are those procedures being followed in the government-funded health care systems that I referred to?

Dr. PRONOVOST. Thank you, Senator. Excellent question. One of the things that you brought up so importantly is evidence is exploding so much.

If you look at this geographic variation in the use of care, I'm sure you've seen how those regionally we overuse or underuse. There's some evidence that when you have more doctors, but what is much more important for that is uncertainty about what to do. When there's uncertainty, we either hedge our bets and as a group, as a region, you over treat or under treat.

Linking this stuff to health technology, as science grows. As we get genetic medicine, we're going to need checklists for individual patients that say, OK for Mrs. Smith and with this genetic variation this is what you need or you respond to this therapy.

It's one of my pleas that health technology, if it's not linked to quality measurement and cost reduction, it will simply be an expensive electronic charting system. Because what we care about is

answering that question, are we getting better value? And so that link has to be.

As to your question about the VA and the DOD, we've worked with Jim Bashin at the VA and the DOD to use this. So I believe they've taken it up.

But what I don't believe they can answer, Senator is what are the rates of infections? That, for me, is a fundamental question because when I talked to Sorrel King, she doesn't really care if I tell her I'm using a checklist. What she wants to know is am I likely to get infected in your hospital? I don't know that we're doing—I know Representative Waxman, after the GAO Report surveyed the country and only 11 States in his report actually were measuring these infections right now.

Senator BINGAMAN. As you understand it the VA doesn't measure them?

Dr. PRONOVOST. I don't think as a system that they are——

Senator BINGAMAN. And neither does our military health care system.

Dr. PRONOVOST. Yes, I don't. As I said, I know that we've met with them. They are interested in using it.

But when we had discussions about overall, you know like we can say for the State of Michigan for example the rate of infection in Michigan is x. I wish we could say it for the whole country. I don't know that we could.

Senator BINGAMAN. Well obviously at least it strikes me at first impression that we ought to be requiring that they do measure those types of issues.

Dr. PRONOVOST. Completely agree.

Senator BINGAMAN. We ought to be requiring that they do adopt these best practices where there's general agreement that these are best practices. If this guideline that you folks have put in place at Johns Hopkins with regard to these catheters is—these infections is generally agreed as the best practice for this particular aspect of medical care, I don't see why we shouldn't require that it be implemented in all federally-funded facilities.

Dr. PRONOVOST. Right. Right. Senator, I agree. What we've seen in the financial incentives is often that politics or the payments policy far exceed the science.

So we're designing payment systems to incentivize that we're not really sure how to measure or if we can prevent them. I think we have to flip it, the science has to drive. It's got to go back to its rightful place and drive the payment on.

In this case we know we can virtually eliminate these or dramatically reduce them. That is something we ought to have—really clear payment policies. I completely agree.

Senator BINGAMAN. That policy would be that the——

Dr. PRONOVOST. That the marginal cost of these infections are not paid for. That as CMS has done for this, but for other things on the list that we don't know yet how to do.

Senator BINGAMAN. In Medicare and in Medicaid.

Dr. PRONOVOST. Correct. I completely agree that we ought to require that States monitor and report these in a valid way, like the CDC has definitions. What I'm less sure about is do we legislate the use of this checklist because legislation is blunt and slow.

Science emerges. We may learn next week that there's a better thing on the checklist.

What we could require is that they participate in these quality improvement programs to reduce the infections. So we don't have to legislate that they actually do the items on the checklist. If there's a mechanism with the DOD or with States to get together to work to reduce these infections and that we're going to monitor their performance. They will be held to account how well we do for these.

Senator BINGAMAN. Thank you, Madame Chairman.

Senator MIKULSKI. We have time to go another round if members are interested.

Senator Bingaman, looking at our schedule, one of the things I'm contemplating is a hearing just on lessons learned from military medicine rather than having the VA do it. Do we actually invite them in from what we've been learning through both military medicine and VA?

They've done a lot of pioneering in this. We hope to be able to do that. Also, we hope to be able to go over to Hopkins one day.

But let me go to my question, first to Dr. Pronovost about the checklist and then a question about the implementation goes to Dr. Pearson and everybody.

You said in 32 States they don't use this. One of the questions that I asked was, Why doesn't everyone introduce a checklist? It's a piece of paper.

It's not find a new technology. It's not re-designing the catheter, interlocking gadget, you know, system with FDA and all of that. Then somebody said, "Well, no one's paying for it."

What is there to pay to implement the package? What is it that we need? Why do we need to pay people to implement a checklist?

And second, so that's a general related question. That's more abstract. But what are the barriers in the way of a new tech? A solution that could either be paper or digital?

I'm going to ask you that question. I'd like to zip down to anyone on the panel who'd like to jump in. And then I want to come back to we have a National Institutes of Health, but not a National Institutes of Quality which goes to your question—Dr. Pearson's really important contribution on the comparative research effectiveness issue.

So do you want to kick that off?

Dr. PRONOVOST. I absolutely will. Your experience as a social worker is clearly coming through in thinking of these barriers. Now let me be clear when the GAO Report, after they surveyed all the States, every one of the States said, "Oh, of course we're using it. But only 11 monitored infection rates."

The question, say is that good enough? To me, the answer is no. It's easy to say I'm doing something. But there has to be help to account for performance.

Now what are the barriers? Though the checklist was popularized and it's a simple concept. I think it's naïve to think that if we hand doctors or nurses a piece of paper with a checklist on it, it's going to be used because we have to create a culture and incentives where we're allowed to work together.

I'll give you a very concrete example. When I put this in Hopkins, I asked the nurses to use the checklist to make sure the doctors did these five things all the time. When I did that you would have thought I was causing World War III.

The nurses said my job is not to police the doctors. If I do, I get my head bit off. The doctors said, there is no way a nurse could second guess me in public. It makes me look like I don't know things.

Nobody debated the evidence. The checklist was clean. The evidence is sound. What was debated was the hierarchy and politics. So we pulled people together and said is it tenable that we harm people at Johns Hopkins. And everyone says no.

I said, "then nurses you will question the physicians and physicians you will listen. And if you give the nurses flack, nurses page me any time of day or night." And I had the backing of our CEO and Dean Ed Miller. It will be supported.

We've learned now that the barriers are some systems the supplies have to be available on the check—you have to be able to get the supplies. You need a culture of teamwork and collaboration that frankly doesn't exist in the U.S. health care system. So we've coupled these interventions and why they've been successful with efforts to improve culture and teamwork. It's a program called CUSP. It's what we're rolling out.

Once you have that teamwork you could then rotate whether you're doing these infections or MRSA or VRE or diabetes care. You have a collaborative network of people working together trying to solve problems. That's the fundamental fabric that we need to tackle and that these programs rather painstakingly have accomplished.

Senator MIKULSKI. But one, Hopkins has been listed as the No. 1 hospital for a decade now in U.S. News World Report. So it goes to part of what's been said here, a culture for quality. You also had a phrase earlier that we don't compete on quality. That should be a threshold. But we don't compete on safety. That was what you said, so that there is a threshold.

Even when you pick an airline, you shouldn't pick one based on who's got the safest pilot. It should be a national standard that's adhered to. Every day you get on the plane and when you have a stunning situation like what we recently had in the Hudson, all that comes through. So that's it.

But let's go down and say anybody who wants to comment when I said, "Why, what does it take to do this and why do we need to pay to do it?" I drew a picture. Dr. Fischer and then anybody else who'd want to jump in on this one.

Dr. FISCHER. I think if you look at the challenge that Hopkins has had being able to spread this kind of knowledge and changed behavior I would say that it is even more difficult as you move out into the periphery in the country. What you have at Hopkins and what you have the potential for even on a grander scale, say at the VA is an organized system. You have people where the physicians and the hospital are aligned about common goals.

But very often, having been the medical director of a children's hospital and an academic center, I know that trying to get things to change involves cajoling physicians to do something different

very often. Or cajoling the nurses to change what has been a pattern. If we focus on teamwork, if we focus on the common goal, and we get incentives aligned, it's much more likely to happen.

Right now many physicians, most physicians are smart. They're well-trained. They're well-intentioned.

But their system is saying, "I'm smart, I'll remember." That is not a system. Many of them say, "Trust me, I do it my way. It's always worked."

But they haven't done the chart review, the research to show, in fact, what their results are. They don't know what their results are. So being able to put systems in place and frankly starting where you have the greatest opportunity which is at programs like the VA where there is interoperability, there is a common attitude across the system as to what needs to happen.

There are also other integrated systems in the country who've made great progress. If you've not been exposed to it already, the Dartmouth Institute came out with a white paper on an approach to organized care. Much of it based on the work on Dr. Jack Wenberg.

But I think there is much good information there about how we can be transformational with spreading these kinds of systems to our advantage, to all our mutual advantage.

Senator MIKULSKI. Before I move on to another issue, that question about the National Institutes of Quality, Dr. Pearson, Dr. Gulcher, did you want to comment on this line of conversation?

Dr. PEARSON. I would. Just briefly to say that in some ways it's ironic because we're talking about the difficulty of implementing a checklist which as you said, it's so tangible. It seems so easy just to—and people can come and see it. They can see how it works. Sometimes the light just goes off.

Much as there are other types of difficulties. When you try to do this outside of academic settings, most of the types of implementation of best practice or best evidence doesn't come in something as neat a package as a checklist. We do need, and this may verge into a response to the question about some kind of institute to help codify or come up with ways to help people do this.

It's just very hard for clinicians of any type and for systems of care to try to grasp how to implement ideas about changing practice unless it is put into a format that they can understand and that they can clearly see how it could fit into their system because we have all these different systems of care across the country. Some of them might actually think a checklist—they might put it up on the wall, others might hand it to the doctor. You know, they have to figure out how to do this.

Working at that level to translate best evidence into things like a checklist is something that, again, we really need more work on.

Senator MIKULSKI. Alright. Did you want to comment on that part?

Dr. GULCHER. I just want to comment on quality. But when it comes to trying to get physicians to go by even standard guidelines issued by NIH supported wards, for example like the National Cholesterol Educational Program. We found that as we're trying to educate physicians on how to use our genetic tests for heart attack that they aren't always going by the guidelines.

So what we do is we try to provide that information as a checklist of how they can catalog other risk factors and then how that fits into the genetic risk. So we've actually been implementing that aspect of it in the context of our test.

Senator MIKULSKI. Well, we've raised two points.

One which goes on in an acute care facility which is hierarchical centralized and you can give mandates.

Then that which goes into clinical practice and also that occurred in an academic center and an academic center of excellence by all standards of measurement.

So we see how tough that is. Then we need to go out to actual clinical practice. Most physicians' practices, as I understand it, are Wednesdays through Tuesdays. That's a lot to put on them, you know, those days of just going to the monthly medical society meeting is pretty dated.

Dr. Gulcher what you're talking about when you talk about genetic testing is the basic tool that a physician uses—the family history. They do a history when you come in. They say tell me about yourself, the presenting symptomotology.

Second, tell me about your family. Well my father, my grandfather and so on, all died of—and my mother da da da dum. Wouldn't that be the one that would then trigger the genetic testing because you would see in a family history propensity?

Dr. GULCHER. Yes, certainly.

Senator MIKULSKI. It's not a substitute but it says, "Oh wow." Every adult woman, every first child gets a whatever.

Dr. GULCHER. Right.

Senator MIKULSKI. So.

Dr. GULCHER. Yes. That's certainly a valuable technique. Certainly there are sites, the Surgeon General for example just put up a site that helps facilitate taking of some family histories for physicians. We certainly encourage that.

But one of the things one has to emphasize is that most common diseases tend to skip generations. So they won't be evident in your parents or even your siblings. Most of us don't know our family history of our cousins or maybe our great grandparents or maybe we don't know precisely what that is. And so we can't use that information.

So what the new genetic says for common diseases is these genetic variants tend to be common, ultimately common in population. It's what you're born with. But, for example, most patients with prostate cancer don't have a family history of prostate cancer.

But yet we can find genetic determinants that they actually have, genetic risk factors I should say that they have, that put them at higher risk even if they don't have a family history. If they do have a family history it complements that. But unfortunately 95 percent of men do not have a family history of early prostate cancer.

Senator MIKULSKI. Wow, that's interesting, so family history always has to be essential to providing good clinical care. But it wouldn't be the trigger.

Dr. GULCHER. But it's not enough. It's not enough. There's a benefit to also doing genetic testing for people who don't have a family history of whatever disease you're interested in or better yet to ac-

tually have a panel of genetic tests that actually allow the physician to survey, not just cancer, but also heart disease, glaucoma, macular degeneration, things that we could actually do things about if we detect it early.

By the time you are diagnosed with glaucoma many times you've already lost part of your vision. So here's a simple way of, once again, optimizing care to those who are at highest risk by actually scanning the entire genome. We know many genes for the 25 most common diseases. We already have genetic risk factors that have been well validated in tens of thousands of patients and tens of thousands of controls. So these are real risk factors. The question is how do they fit into the health care system and are they useful?

Senator MIKULSKI. Senator Hagan, do you have a question?

Senator HAGAN. Thank you, Madame Chairman. Listening to the testimony today it just re-emphasizes to me the need in this country for health care information technology across the broad spectrum of diseases and hospitals and best patient care from physicians and practices all over. Dr. Pearson, in some of your material you've described the waiting system that you've developed at the Institute for Clinical and Economic Review to translate the results of comparative effectiveness research into concrete results that can help improve patient care.

It seems to me that health information technology across the country would certainly be of great benefit. I know this is going to take years to put together. But I think it's something that you will see this Administration start working on very quickly.

But I was just wondering what do you see as the major challenges to developing this system for translating the results of comparative effectiveness research into actionable information? In the work that you've done so far have you found that most doctors and patients are comfortable with the system that you've developed?

Dr. PEARSON. Thank you. It's a wonderful question. The challenges to translating evidence come on different levels.

But I think the most important one is that any time you try to take a large body of evidence, let's say there have been 10 studies done to compare two different options for prostate cancer. All 10 of these studies are going to say slightly different things. They don't always say the exact same thing.

There were different types of patients enrolled in them. You have to make a judgment at a certain level about how to synthesize that information for patients and for clinicians. Anytime you synthesize and formulate it so that people can actually understand it and take action you run the risk of over simplifying. Maybe making people feel that you are creating a cookie cutter approach to medicine.

Now this always rings bells for physicians. They don't like the idea that there's one way to do something. Patients are always concerned, rightly concerned that the special aspects of their health history or their personal family factors, whatever it might be, are not being considered accurately.

So for me, as an evidence review group, I think our greatest challenge is to be able to communicate tangible findings that people can really do something with. Yet not lose the important nuances to look for the different types of patients who might have different kinds of reactions or benefits from certain treatments. We have to

be able to keep that nuance with our information as we pass it on to insurers, to physicians, to patients.

So the rating system is there to, in a sense, trigger an initial conversation about what we think are the balance of benefits and harms and the comparative aspects of that. But it's not meant to, in a sense, shut out those other aspects.

Senator HAGAN. Madame Chairman, if I could ask just one more question. There's such a propensity today for patients in hospitals to get the MRSA. I was just wondering if any of you at the panel today had any comments on sort of an update on what's going on and what may be the best practices is in that concern.

Dr. PRONOVOST. I can take a crack at that. I want to just end with your last question about health information technology because one of the things that it offers the potential for is if we go one disease at a time to make checklists, I'm going to be long dead before we simplify evidence. One of the great uses in information technology would be literally to create the program for a checklist maker that is openly available.

So no matter what area you're working in that's transparent for patients because these things democratize knowledge. So when you go to your doctor you can say, "Hey, this is the checklist that everyone says if I have diabetes this is what you ought to do for me." You could have a discussion about it.

But it's a very powerful tool. But we don't have the technology to make it out there and available. So no matter what disease you're talking about, it's there.

With MRSA that's actually the pipeline that we're working on. So there's a lot of evidence that says what we should do. There are some small stories of successes.

I think the biggest problem is we don't really have, yet, widely accepted ways to measure who we gave it to. That's a real barrier, because what docs want to know and what you want to know is not so much am I using the checklist? Did you infect me?

When I go to my hospital there's been a couple success stories. I think the Pittsburgh Regional Health Initiative has done some. But what I would put forth to you is picture this model that we've presented of drug development.

So Phase I, you get the experts to find out what the evidence is and how do you measure it accurately.

Phase II, pilot test it in a couple places to see if it works.

When it works Phase III, have an infrastructure to put it across this country.

That's the kind of pipeline we need if we're going to make substantial improvements in quality and reducing costs of health care.

Dr. FISCHER. We've been a partner with the Pittsburgh Regional Health Care Initiative for many years. And that work, PRHI was one of the first to say, zero is the goal for nosochomial infections. So MRSA transmittal in the hospitals, central line blood stream infections, zero is the right rate.

You know whereas I talked about we're down to one per thousand line days, that's not close to zero yet. But we had 4 hospitals out of 30 who were at zero. OK, so, we are making progress.

MRSA and central line blood stream infections are two mandatory indicators for all the hospitals and we have 30 now in our pay-

for-performance program for hospitals. And we have seen and the approach is screening on admission, screening on discharge, measure and isolating those who are positive, using full precautions for those patients so you'd lessen transmission. We have seen a marked decrement in transmission of MRSA in those 30 hospitals.

So we're having an impact. We're not at zero. But we're making progress.

Those are the kinds of things where the health plan is representing employers and the members or patients, the hospital, the physicians, everybody wins. Ultimately these programs are in place at the hospitals that are seeing CMS patients. So the government is winning by, you know, the private payer being out there doing these kinds of programs.

Just wanted to add one more thing that's about why pay for performance? We have to explain this to our accounts. They're saying this is the right thing to do why would you pay them to do what's supposed to be right.

Senator MIKULSKI. Right.

Dr. FISCHER. The problem is it takes time to do process improvement. You have to not see some patients or not do something else in order to get people around the table, be trained, understand there's a problem, put in place a system to fix it. So we're paying for the process improvement effort.

But the goal is you get performance to change. And so we call it pay-for-performance. But it's not. It's not blindly paying for a difference. It's paying for the effort it takes to do process improvement.

Senator HAGAN. Thank you.

Senator MIKULSKI. Thank you.

Senator Casey.

Senator CASEY. Senator Mikulski, thank you very much for calling yet another important hearing on health care. You've been so good to bring us together. You've labored in this vineyard a long time. And we've made progress already this year and I just appreciate your leadership on this issue.

I know I'm the last one. I know I've been in and out of here. I have to apologize, one of those days of juggling.

I want Senator Mikulski and our witnesses to know I have one question. It's broad. It would take a long time to answer but you guys only have a couple minutes. So you've got to be brief.

But it's really this, and it's not—by asking it I run the risk of being too brief, but also being a little redundant because you've covered this question in a lot of different ways. But it is basically this. It's the political reality question in a sense.

We've had tremendous success already, with a new Congress and new President. Senator Mikulski led the way to pass a Lilly Ledbetter Act, a tremendous achievement for those who are victims of discrimination.

President, former Senator Obama, President Obama signed into law the Children's Health Insurance Bill. Great achievement. That wasn't going to happen in the last Congress with the last Administration. But if we look at this realistically in calendar year 2009 I would love to be able to say that we're voting in calendar year

2009 on a major piece of health care legislation beyond children's health insurance.

Let's assume for purposes of this question, what if that does not happen? If there's one bill or initiative or action the U.S. Senate could take to give meaning and integrity to the quality initiatives that all of you have articulated and have put into practice. You've actually gotten results.

What is it, absent an overhaul our health care system? What's the one action that we could take to give meaning and integrity to what you've testified to and what you've worked so hard on? I do want to start with Dr. Fischer because he's a Pennsylvanian. I'll be in big trouble if I don't give it to you first.

Dr. FISCHER. Tough question to ask for one thing. I am clearly an advocate of the systematic approach to improving health care. Although you cannot computerize chaos, many practices especially in this cottage industry do not have systems in place that they could simply computerize.

I do believe that health IT is absolutely essential. Interoperable health IT is essential to making quantum leaps in patient safety and quality improvement. We have made strides in getting to nearly a tipping point where people are adopting tools. As you probably know, Highmark put $30 million out there for physicians in our network to adopt electronic prescribing tools and electronic health records.

We're at the point where nearly 40 percent of the practices in our program for paper performance is just primary care and have adopted some form of electronic tools. That being said, we're a long way from being able to capitalize on that kind of opportunity. But I think we do need to support health information technology. I don't believe that physicians will make the investment on their own without some help.

Senator CASEY. OK. Anyone else? We've got a little more than a minute. Sorry for the shortness.

Dr. GULCHER. We all talked about the wonderful discoveries that have been made, a lot of work has been done to look at some of the evidence for quality improvement. But there's not really a way of translating those discoveries or those better practices as efficiently. We have a very large budget within the NIH that's done a great job sequencing the human genome, making some of the discoveries, complementing the work of what some of us have done in private industry.

If the concern has been there's not been enough studies to actually show markers that have been well-validated and demonstrate risk for certain diseases whether or not they're clinically useful. There's been a call to actually do a large number of either ammonize clinical trials or other clinical utility studies to translate that information. The same thing in the case of Dr. Pronovost in terms of translating some of the quality data.

Why not force the NIH, whose mission really it is to help improve health care, force them to allocate 5 percent of their budget to nothing but clinical translation and clinical utility and safety practices as a way of fostering the discoveries that we're making into clinical practice that hopefully will improve and save health care costs in the long run.

Senator CASEY. Doctor, we're out of time. But with the Chair's indulgence you can have——

Dr. PRONOVOST. Yes, I agree. Health information technology is going to be important and it needs to blink to measures of quality. But I think what you could do is invest in the science of how we deliver care. Then with that science the market will align payment policies and the insurers will drive costs.

There's a hunger for new knowledge of works. I mean this checklist is one thing and it's gotten so much attention because it's the rare sample of a performance improvement program that worked. And that's a sad statement.

We need to have scores of these things that work. That's going to come with I think, wise investments in the science of health care delivery.

Senator CASEY. Thank you very much.

Senator MIKULSKI. Great question. Thank you. I'm going to wrap up with my one question. But Dr. Pronovost, I note behind you are two young ladies. Are they your children that came to provide support? You want to introduce them here, Dr. Pearson?

Dr. PEARSON. Absolutely. Thank you.

Senator MIKULSKI. Now I'm sorry Senator Hagan left. I mean this is what change looks like.

Dr. PEARSON. Well, thank you. We are residents of Maryland, by the way, so.

Senator MIKULSKI. Oh, and there's a young man behind you as well?

Dr. PEARSON. Yes, there is. This is my family. My wife, Kim, Dr. Pearson, also. My daughter, Deanna. My son, John. And my youngest daughter, Brett.

Senator MIKULSKI. Great.

Dr. PEARSON. Thank you for recognizing them.

Senator MIKULSKI. So you brought a choice of your backup team too.

Dr. PEARSON. Yes.

Senator MIKULSKI. I want to pick up on Senator Casey's question and what was said about the science of health care, also taking part of NIH's budget and getting it out into clinical practice. Also one of the topics we didn't even talk about here today was public health.

In addition to great federally-funded health delivery, whether it's VA or some of the others that were mentioned, we have something called CDC, FDA, and so on. And often missing from the conversation is public health, the safety of our drinking water, food supply, all of these other things.

While we've got a lot of agencies, what is needed to get out where there's the hands-on practice, whether it's from a physician, a diabetic educator, ET cetera.

We'll start with you, Dr. Pronovost and just go right on down the panel to give a response to Do we need a new agency? Do we need to take an agency that we have to get what we know out there and in a way, if you'll pardon the colloquialism, to get "news you can use" to the people who are actually involved with patients? That's what we're here to talk about.

Dr. PRONOVOST. Excellent question. I would love to see 5 percent of NIH's budget go for this. I don't think that's going to be sufficient.

I think we need, like the human genome was, a public/private partnership to advance the science that links, like the human genome did, some of the top research universities that are doing this. That links the community hospitals and doctors who are delivering it. That links insurers. That links Federal agencies. All with the common goal to say how can we combine our levers that we pull?

What do we learn about these financial incentives? How do we get that diabetic to stop drinking the Coke? And that those programs then become publicly available. So I think it's got to be bigger than just 5 percent.

I think if we're going to make substantial improvements this has to be invested. It's what I said about this institute of health system delivery. We need a learning lab to put a lens at what's working in all this mess including economic incentives and behavior change incentives and population health. Then share those lessons widely.

I think if it's just State—Federal agencies have to have part of it. I don't think they could own this because this lives in the community where health care is delivered.

Senator MIKULSKI. Dr. Pearson.

Dr. PEARSON. Again, it's an excellent question. It is a time when many of us are thinking of new things, new goals, ET cetera. It's always wise to think couldn't we just either increase investment in existing structures or tweak them a little bit.

Thinking about comparative effectiveness specifically, I actually think that we do need a new structure. I think that in order to help doctors and patients out there who wrestle everyday with so many questions in clinical practice for which they don't feel like they have adequate evidence. They don't feel like they have a trusted source that they can go to that has synthesized the evidence, tried to make some judgments, and is also launching new research to try to fill the evidence gaps.

I really think our health care system needs that. Other developed countries have similar institutes or agencies that have been viewed as very positive contributions to their overall health care system.

I do think that with that kind of structure, particularly of Senator Baucus' work in this area so far, but others as well, there's reason to think that with that structure it wouldn't take a huge amount of initial investment to start to drive the appreciation of what that brings in terms of return on the investment. Health plans have said that they're interested in supporting it. I do think that it would be a structure, outside of the existing agencies that we have, that could really make a difference.

Dr. FISCHER. I would emphasize that government can play a major leadership role in making this happen. But clearly you need collaboration from the other parties. What health plans do is population health. We look at the big picture. We're looking at populations of patients and how we can impact that population by what's known about public health.

What you need, I think, is the collaboration with the health plans. Certainly the Blue system is willing to partner. I'm sure the other health plans, the other major health plans would as well. But

I would also invite the large organized health systems who are more capable of making an impact quicker.

Senator MIKULSKI. Excellent.

Dr. GULCHER. Great. I just want to point out that it's been estimated that the NIH spends less than 0.1 percent on clinical utility or translation studies. So already that budget is quite, quite, quite small. The reason I mention them is because certainly they've been trying to push the bar when it comes to finding new biomarkers and risk markers, aren't they well positioned if they are encouraged to fund some more of the clinical utility studies?

You mentioned the CDC. They have a very small budget compared to the NIH, but certainly as you mentioned Muin Khoury who runs the genetics there at CDC has been trying to foster both public and private partnerships along with the NIH, along with some of the other stakeholders. But I think what everybody seems to recognize is there's a lack of support or funding to move that ball forward. I'm not sure where that money comes from, but certainly to move these rapid discoveries forward in a clinical practice is going to require some investment.

Senator MIKULSKI. Well, this was an excellent hearing. It was titled best practices, but I think we've gotten excellent thinking. On behalf of the committee I'm going to thank you for your participation, the time and effort that you put into this is very evidenced-based.

We would invite you to submit to us, after you've heard our questions upon further reflection, recommendations on concrete ways we can proceed as we move forward.

I do believe that we will be, for everything we've heard from our President, that we will be doing health care reform. That's different than health insurance reform. But it is the goal of this committee under Senator Kennedy's leadership, with the support of Senator Enzi to do health care reform that's on a very sound, fiscal footing.

That's why we're so committed to the quality debate. It's patient-centered because at the end of the day that's why we're all here and work so hard for this. Yet at the same time we have to be stewards of the taxpayer's money and also cognizant of those who have to pay for it whether it's the taxpayer or business or whatever.

Again we thank you for your participation. This committee stands in recess until February 23d when we will hold a hearing on integrative health care. We also want to advise our colleagues that the Institute of Medicine is holding a summit on the concept of integrative health care which goes to personalized health care, patient-centered, but goes to the continuum, Dr. Pronovost, that you talked about and I believe Dr. Fischer, you're trying to fund and Dr. Pearson, it goes to the heart of what you're working on.

We are looking forward to the IOM report. This committee is very influenced by the thinking that is going on at the Institute of Medicine, the Commonwealth Foundation and Robert Wood Johnson. But ultimately at the end of the day it's people like you who are actually out in the world working to make a difference. So thanks a lot.

[Whereupon, at 11:55 p.m. the hearing was adjourned.]