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THE RIGHT CARE AT THE RIGHT TIME: LEVERAGING INNOVATION TO IMPROVE HEALTH CARE QUALITY FOR ALL AMERICANS

HEARING

BEFORE THE

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THE RIGHT CARE AT THE RIGHT TIME: LEVERAGING INNOVATION TO IMPROVE HEALTH CARE QUALITY FOR ALL AMERICANS

THURSDAY, JULY 17, 2008

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:08 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Max Baucus (chairman of the committee) presiding.

Present: Senators Rockefeller, Wyden, Stabenow, Salazar, Grassley, Snowe, and Roberts.

Also present: Democratic Staff: Bill Dauster, Deputy Staff Director and General Counsel; Elizabeth Fowler, Senior Counsel to the Chairman and Chief Health Counsel; Billy Wynne, Health Counsel; Shawn Bishop, Professional Staff Member; and Mollie Lane, Law Clerk. Republican Staff: Mark Hayes, Republican Health Policy Director and Chief Health Counsel; Rodney Whitlock, Republican Health Policy Advisor; and Lyndsey Arnold, Intern.

OPENING STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM MONTANA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The hearing will come to order.

President Eisenhower's Treasury Secretary George Humphrey once said, "It's a terribly hard job to spend a billion dollars and get your money's worth." So imagine what Secretary Humphrey would have said about $2 trillion. America spends more than that on health care every day, and it is by no means clear that we are getting our money's worth. America spends more per person on health care than any other industrialized country. America's health care spending per person is well over double the average of OECD countries.

Health spending varies widely throughout America. Some States like Utah and Colorado spend no more per person than other countries; other States like Florida and Louisiana spend twice as much. But others with high spending do not get better results for better health outcomes. The geographic variation in health spending cannot be explained by prices, by illness, by patient preference, or evidence-based medicine. The system is just wasting money, and the problem is getting worse.

Over-use of services is a striking problem. In high spending areas, observers find what Elliott Fisher and others call supply-sensitive services. Those are services like imaging and discre-

tionary surgeries that are used more in places that have more doctors who perform them. These areas often have high ratios of specialists to primary care doctors.

We define ways to identify and encourage more efficient patterns of care. One recent study found that, if we could reduce spending in medium- and high-cost regions to the levels of low-cost regions, then Medicare spending would fall by a full 29 percent. Let me repeat that: one recent study found that, if we could reduce spending in medium- and high-cost regions to the levels in low-cost regions, then Medicare spending would fall by 29 percent.

Today we will explore the causes of geographic variation in health care spending. We will also look at two potential solutions: health information technology—or health IT—and comparative effectiveness research.

Many observers believe that widespread use of IT would improve health care quality and efficiency. Unfortunately, health care has been slow to adopt IT. Barriers such as cost, the lack of a return on investment, and the difficulty of successful implementation have slowed adoption. Many argue that the government needs to do more.

More health IT would support health care delivery. Think of what happens when a patient receives treatment: doctors, nurses, and other professionals must gather, sort, and evaluate information from multiple sources. Sources include patients, their families, laboratories, primary care doctors, consulting doctors, hospitals, and other providers.

Currently, most health care providers collect and transmit information on paper, over the phone, and via fax machines. More advanced information technology could streamline the process of collecting and analyzing the data.

Now, experts disagree about the benefits of health IT. They differ especially about its ability to generate savings in the health care system. But health IT adoption is likely to be a key component of health care reform, and, if that is so, we need to know what we are getting and we need to know how quickly we will be able to reap its benefits.

One of the key drivers of health cost growth is new technology. Medical advances give providers and patients more complex testing and treatment options. The problem is, we do not know enough about whether the newest and most expensive interventions actually work better, and we know even less about whether they improve patient care or outcomes.

The geographic variation in health care spending may be partly due to information. Providers and patients simply do not have enough unbiased information about treatments. As a result, treatment decisions have a greater chance of being determined by local norms and attitudes than by science or by evidence.

Comparative effectiveness research can build a better evidence base for medicine. Comparative effectiveness research compares the clinical effectiveness of one medical treatment to another. For pharmaceuticals and devices, this type of research differs from the reviews now conducted by the Food and Drug Administration. When approving a new drug or device, the FDA compares it to a placebo to ensure that it registers a clinical effect that is safe. In other

words, the FDA determines whether the benefits outweigh the risks.

Comparative effectiveness research compares one treatment to another rather than to a placebo. Results can provide better evidence concerning the best treatment, results can help with the prevention and management of diseases, and results can allow patients, providers, and insurers to choose services that provide the most value.

Health IT can facilitate comparative effectiveness research. By making clinical data easier to collect and analyze, health information technology systems could support rigorous studies of the effectiveness of different treatments. Health IT could aid in implementing changes in the kinds of care provided, and health IT could help track progress in carrying out the changes.

But who should conduct comparative effectiveness research? Who should pay for it, and what about the idea of a national research institute governed by public and private entities? Geographic variation in health care spending is a symptom of the inefficiency in our health care system. Today we can learn more about the issue. We can explore strategies for reducing the variation that will pave the way for a more efficient, high-quality system that delivers the right care at the right time.

It seems that it is not hard for the health care system to spend more than $2 trillion a year. Today we will look at geographic variations, health information technology, and comparative effectiveness research and we will see if we cannot find a way to get more of our money's worth.

Senator Grassley?

OPENING STATEMENT OF HON. CHUCK GRASSLEY, A U.S. SENATOR FROM IOWA

Senator GRASSLEY. Thank you, Senator Baucus.

At our Health Care Summit that we had a couple of weeks ago, I made the point that any reform we work for has to address three areas: increased access for the uninsured, the rate of increases in the cost of health care, and improving quality. Today's hearing focuses upon that quality aspect.

In April of 2008, Dartmouth published "Tracking Care of Patients With Severe Chronic Illness." Researchers made this statement: "In health care, it matters where you get your care." I think Senator Baucus has covered that issue, but I can add to what he said, because I have heard people from Minnesota and Iowa make these statements that, if medicine was practiced like it is in the Midwest, we would save that 29 percent. Now, maybe there are other parts of the country that can say exactly the same thing, but I have heard that claim over a long period of time in my State of Iowa.

In addition to that, there is widespread agreement on the potential of health information technology to improve quality, and when you improve quality, doing things right the first time, you control cost. If there was widespread adoption of that powerful tool, most everyone would be getting the right care at the right time. Health information technology will play a major role in moving the Nation towards being able to compare treatments.

If the Nation can wire every hospital and every physician's office, it will be that much easier to see what treatment works and what does not. It will also reduce duplicative testing and enable clinicians to share information. While it is clear that electronic patient records will improve efficiency of health care, the economics have not proven attractive to doctors. They say that the systems are expensive to install and that their practices suffer while they get used to having electronic systems.

Savings that result from increased efficiencies accrue to insurers or other payers and not to doctors, so we need to think about how to make adoption of electronic records more attractive to those who will use them. I had a conversation with Dr. Coburn yesterday, where he says it will be very inexpensive to get at least half of the doctors covered. So, I think we ought to have a conversation with him, Mr. Chairman, as well. He has studied this.

I will put the rest of my statement in the record. I think I want to put a full statement in the record.

The CHAIRMAN. Thank you, Senator, very, very much.

[The prepared statement of Senator Grassley appears in the appendix.]

The CHAIRMAN. Now we will turn to our witnesses. First, our regular panelist, Dr. Peter Orszag, Director of the Congressional Budget Office. Dr. Orszag, I want you to know we have agreed to provide you consistently a pitcher of ice for your Diet Coke whenever you want to come and testify.

Dr. ORSZAG. Thank you. Is that part of the benefits of the "Frequent Witness Program"?

The CHAIRMAN. That is one of the benefits of the "Regular Witness Program." [Laughter.]

Dr. ORSZAG. Regular witness. Okay.

The CHAIRMAN. It does not take much to become a regular witness. Then you get those services.

Next, Dr. Richard Hillestad, principal researcher and professor at the RAND Graduate School. Our third witness is Mr. George Halvorson, chairman and chief executive officer of the Kaiser Foundation Health Plan. Following Mr. Halvorson is Dr. Gail Wilensky, senior fellow for Project Hope. Dr. Wilensky is well known to this committee, having, among other things, been Administrator of the Health Care Financing Administration in the first President Bush's administration. We have a long association with you, Dr. Wilensky, and we admire your work very, very much.

Thank you all for coming here today. The usual rule is all your statements will be included in the record. We would ask you to confine your remarks to about 5 minutes.

Dr. Orszag?

STATEMENT OF DR. PETER R. ORSZAG, DIRECTOR, CONGRESSIONAL BUDGET OFFICE, WASHINGTON, DC

Dr. ORSZAG. Thank you very much, Senator Baucus, Senator Grassley, members of the committee. I will actually be brief because I think most of the points in my testimony have already been covered.

But let me just make a few points. First, if you applied that 29-percent factor which the Dartmouth researchers believe could be

applied to all of health care, not just to Medicare, the result is that we are spending $700 billion a year in health care services—MRIs, surgeries, and hospitalizations—that do not appear to improve health outcomes.

I cannot think of a single other sector of the economy that even comes close to having that magnitude of potential inefficiencies. The biggest opportunity that we face to put the Nation on a sounder fiscal footing is to try to capture that opportunity and improve the efficiency of our health system, and thereby also help to bend the curve on Medicare and Medicaid costs.

How do we do that? We have already touched upon it. I think basically you need to do a lot more research on what works and what does not. Too much of the health care delivered in the United States is not backed by specific evidence that it works better than anything else, and in order to do that you probably do need a much broader application of health information technology, which is therefore necessary, but not sufficient, to improving the efficiency of the health system.

So, if you had a broad system of health information technology, that could provide the data for a comparative effectiveness research effort and could also provide a platform for feeding information back down to medical professionals to effect the practice of medicine. But information by itself is not likely to be sufficient. You need to change financial incentives. We currently have a system, a payment methodology that pays for more care rather than better care. And guess what we get? We get more care. We need to change that if we want to improve the efficiency of the health system.

Third, I think we need to pay a lot more attention to behavioral norms, and frankly psychology, both for medical professionals and for beneficiaries. On the medical professional side, it does seem like medical practices are influenced by pure effects among doctors. Figuring out how those work and trying to influence them is crucial, and that includes how doctors are trained and how they are influenced by the people with whom they practice.

On the beneficiary side, we could be doing a lot more to help people live healthy lives, which is what they say they want to do, through improved exercise, diet, and what have you, making it easier for people to do what they say they want to do. We could return to that if you want.

But I want to end on a political economy point, which is, I think the key constraint at this point is impediments to political action. The question becomes, why is that? I think part of the reason is, frankly, that our political system does not deal well with gradual long-term problems, and rising health care costs are one of those problems.

Then the question becomes, how do you overcome that? I think it is going to require a combination of extreme passion among policymakers and the kind of leadership that we are seeing from this committee and others. It will possibly involve process changes, some of the things that you have discussed, Mr. Chairman, like a Federal health board. On that, I would note that the Congressional Budget Office has already started work on a report on that topic, laying out the sort of pros and cons and different options for organizing it.

Then, finally, and perhaps most importantly, I think it is going to require a change in the way Americans view their health system, making it more immediately salient that this system is imposing huge costs on State governments, where rising Medicaid costs are crowding out support for State higher education and thereby driving up public tuition, and at the Federal level, where our Medicare taxpayer dollars are financing huge variation, as you have already mentioned, in Medicare costs per beneficiary, including at our leading medical centers. We simply do not understand the benefits of the extra spending, and it is not clear we are getting any benefit from the more intensive approaches.

Then for American workers, employer contributions for health insurance are reducing take-home pay to a degree that I think is under-appreciated by the American public and unnecessarily large. I would just end by saying, I really do hope that we can overcome those various constraints so that we can move forward and tackle and try to capture that $700 billion opportunity. Thank you very much.

The CHAIRMAN. Thank you, Dr. Orszag, very, very much.

[The prepared statement of Dr. Orszag appears in the appendix.]

The CHAIRMAN. Dr. Hillestad?

STATEMENT OF RICHARD HILLESTAD, Ph.D., PRINCIPAL RESEARCHER AND PROFESSOR, RAND GRADUATE SCHOOL, SANTA MONICA, CA

Dr. HILLESTAD. Good morning, Chairman Baucus, Ranking Member Grassley, and members of the Committee on Finance. I am honored to testify about the potential benefits and costs of the adoption and effective use of health information technology, which I will refer to as HIT.

Simply put, the basic components of HIT are an electronic medical record that replaces the paper medical record and associated functions to enhance clinical decision-making and reduce errors. Interoperability to share this information digitally among providers is also a desired attribute. Although information technology has transformed much of what we do in other domains—travel, banking, and telecommunications, for example—health care is one of the largest information enterprises we know, and HIT adoption in the U.S. is low.

The health records for most people are still stored on paper and the physician-to-physician transfer of information about a patient, when done at all, is still most often accomplished by phone or fax. The important message I would like to leave with you is that HIT has a significant potential to help make health care more efficient and effective but, because of certain disincentives to its adoption in the U.S. health care system, there is an important role for government to play to make adoption happen.

Efficiency savings with HIT would derive from such things as reduced test duplication, lower-cost drug utilization, better scheduling, reduced paper record handling, and improved claims and billing administration. Care effectiveness would be enhanced by, for example, reducing errors such as handwriting-based errors, improved management of chronic illness, and improved continuity of care for those patients seeking care away from their primary pro-

vider, such as was needed, but generally not available, in the mass evacuation experienced after Hurricane Katrina.

But we are a long way from realizing these HIT benefits. Our own estimates of the adoption of HIT systems in the U.S. in 2005 indicated that about 20 to 25 percent of hospitals and 10 to 15 percent of physician offices had adopted systems that could perform at least some of the functions I just described.

The most recent estimates indicate improvements in hospital-based adoption, but the functionality of many of the adopted systems remains limited, and there has been relatively little change in physician adoption.

A major RAND study of HIT, begun in 2003 and published in 2005, made estimates of the potential benefits and costs of a much broader adoption and effective use of HIT systems. We developed models to extrapolate the limited event evidence available at that time, assuming 90-percent adoption, interoperability across providers, and related health care process changes.

Using our models, we estimated that the efficiency savings enabled by HIT could reach approximately $80 billion per year when adopted by 90 percent of hospitals and physicians. About 75 percent of these savings are associated with hospitals and 25 percent with physician offices. Potential effectiveness benefits include avoiding 2.2 million adverse drug events per year and their associated costs of $4 billion pear year.

We estimated the cost to achieve this 90-percent adoption in 15 years would average about $8 billion per year, or $120 billion total. Given these potential benefits relative to cost, why is HIT adoption in the U.S. so slow? The primary disincentive is that in most cases those who must purchase the systems—the hospitals and physicians—are not the same ones receiving most of the savings—the payers—or the health benefits—the patients. In fact, the physicians and hospitals could lose revenue.

Thus, there is little financial incentive for them to pay the cost and undergo the disruption of HIT implementation. There are a number of actions the government could take. An effective subsidy could encourage faster adoption and assist smaller offices and hospitals which have trouble affording the cost of implementation of HIT. An alternative is instituting a pay-for-performance program in which HIT is a necessary ingredient to measure the quality of care performance.

In closing, I would like to point out that the adoption of HIT should not be the end-all, but should be considered a necessary step toward real health care transformation. We do not know all the changes that should, or will, take place after widespread HIT adoption, but it seems clear that a lengthy and uneven adoption of an HIT system will only delay the opportunity to move closer to a transformed health care system. The government has an important stake in not letting this happen.

Thank you.

The CHAIRMAN. Thank you very much, Dr. Hillestad.

[The prepared statement of Dr. Hillestad appears in the appendix.]

The CHAIRMAN. Mr. Halvorson?

STATEMENT OF GEORGE C. HALVORSON, CHAIRMAN AND CEO, KAISER FOUNDATION HEALTH PLAN, INC., OAKLAND, CA

Mr. HALVORSON. Mr. Chairman and members of the committee, I thank you very much for the invitation to be here today to discuss the role of information technology in improving health outcomes.

I am George Halvorson. I am chairman and CEO of Kaiser Permanente. We are the Nation's largest private integrated health care system, and we provide comprehensive health care services and coverage to more than 8.7 million Americans.

As you pointed out, Mr. Chairman, caregivers in America today tend to operate in functional silos, unlinked and unconnected to one another in any systematic, patient-focused way. More than 75 percent of the health care costs in this country are attributed to patients with chronic conditions, and more than 80 percent of those costs come from patients with co-morbidities, patients who have more than one disease. Having more than one disease means having more than one doctor.

Those doctors tend not to be linked with each other. Most keep their medical information in separate paper medical records. Far too often, the physicians do not base important treatment decisions on consistent and current medical science or on a full set of information about each patient.

Major studies show huge inconsistencies in care delivery across the country. Diabetes consumes over 32 percent of the total cost of Medicare, and reliable studies show that the U.S. health infrastructure gets care right for diabetes less than 10 percent of the time. That level of inconsistency should be completely unacceptable. We are missing critical linkages between clinicians, and we are not guaranteeing that patients receive systematic, science-based, patient-focused care.

Now, the very best solution is to have vertically linked caregivers functioning in teams to deliver care supported by a secure and comprehensive electronic medical record that gives each caregiver all relevant information about each patient at the point in time of care. An electronic medical record by itself, however—and this is an important point—is not sufficient to provide optimal care. We also need special support systems that analyze data from the electronic medical record and give doctors and other caregivers reminders and prompts to support the delivery of consistent best care.

The very best approach is a complete medical record supported by an up-to-date, really well-designed care registry. That is the package that we need. For those Americans who will not have access to a complete electronic medical record in the near future, we need to use another computerized care support tool. We need to use a stand-alone care registry.

Care registries can focus on the 5 percent of the total population with chronic diseases that drives 55 percent of the care costs in this country, and make a huge difference in the outcome of their care. If we want consistent, better care for those patients, we should insist that all chronic care patients with serious co-morbidities have their care supported by electronic care registries, and we should adjust the payment system so that clinicians who choose not to use care registries and choose not to interact with them will be financially affected by that decision.

When care is fully supported by an electronic support tool, the outcome improvement can be huge. If we had fully computer-supported care, I believe we could set a national goal to decrease hospitalization rates for asthma patients by 50 percent, reduce congestive heart failures by 50 percent, and reduce kidney failures by 50 percent.

In one pilot program with Kaiser Permanente, by using electronic medical records supported by a focused care registry and running every single Kaiser Permanente heart patient through the program, in 2 years we cut the death rates from the two major forms of heart disease by more than 50 percent.

Keep in mind that the electronic medical record is essential, it is wonderful, but it does not do the work alone. The electronic medical record must be supported by panel management tools that scan the data and give advice to clinicians about needed care. It takes a package to get that whole job done, not just one tool.

So my advice for you today is this: as a Nation, we need to focus our care improvement agenda on those conditions that are driving the majority of health care costs in this country. We need a focused agenda, not an agenda that reaches across the entire spectrum of care. And we should put well-designed computer systems in place to significantly improve care for those patients, for the patients with chronic conditions and the co-morbidities.

So I thank you again for the opportunity to be here, and I look forward to your questions.

The CHAIRMAN. Thank you very much, Mr. Halvorson. Very, very much.

[The prepared statement of Mr. Halvorson appears in the appendix.]

The CHAIRMAN. Dr. Wilensky?

STATEMENT OF GAIL R. WILENSKY, Ph.D., SENIOR FELLOW, PROJECT HOPE, BETHESDA, MD

Dr. WILENSKY. Thank you, Mr. Chairman. It is a pleasure to be here this morning.

I hope you will note how much agreement there is in many of the areas that we are covering in this morning's hearing. I am particularly aware, as someone who has focused a great deal of attention over the last 2 years on trying to promote the notion of comparative clinical effectiveness, of how important it is to understand geographic variation, because it, along with information about high cost, will help provide important guidance as to where we should focus our first efforts in comparative effectiveness. And the development of health IT, as has already been suggested, will be important in order to be able to generate new information.

Let me reiterate the rationale for why I am so interested in developing a Center for Comparative Clinical Effectiveness. In a time in which there is a lot of dispute about how precisely to reform health care, there seems to be little disagreement that we need better information as to how to treat various medical conditions using various types of therapeutic interventions, so that we can learn to treat better and to spend smarter, both very urgent matters in a country where, as you have said, we have unsustainable spending

health growth rates, and we have unacceptable quality and clinical appropriateness.

Let me share with you something about the type of center and the role for the center that I am thinking about. The center that I have envisioned is one that provides an information function rather than being a decision-maker. Some countries use the latter. I do not think that is what we need here. We need to be able to provide objective, credible information so that clinicians and patients, as well as payers, can make better decisions.

It will require substantial funding for new research in addition to systematic research of existing data, and also disseminating what it is we know about the likely clinical result of different treatment options for various subgroups in the population, recognizing that it is the medical condition that we should be focusing on and not just merely on drugs and devices.

Data should be used from many sources, although it will be important to indicate how robust that data is, whether there are biases, whether there are limitations in terms of the methodologies that were used when it was collected. We need to also find ways to reduce the cost of doing prospective trials, because in some cases we will only know the answer about what works when, for whom, under what circumstances if we do new randomized prospective trials.

Several individuals who are known to you—Bryan Luce, Sean Tunis, and others—are trying to come up with strategies that will allow for these real-world clinical trials that do not take as long and cost as much as, historically, they have done.

There has been some discussion about where to place such a center. Let me say, first, I do not think there is a right answer. All of the choices have trade-offs. Most important is they have data that is regarded as credible, objective, and transparent, protecting it as much as possible from the political process and from interested parties. Some have argued to keep it in AHRQ. I would personally like a little distance from AHRQ. One of the strategies is to have a federally defined research and development——

The CHAIRMAN. Could you explain "AHRQ," please?

Dr. WILENSKY. Oh. Excuse me. AHRQ, the Agency for Healthcare Research and Quality. It is a part of the Public Health Service that is already doing small amounts of this type of research as a result of the Medicare Modernization Act.

A freestanding entity like a Federally Funded Research and Development Center could be attached to AHRQ. We use these in other places—Lawrence Livermore Labs, for example. There is an FFRDC, as they are called, that is attached to a part of government—or you could establish a new entity that is like the FTC or the Federal Reserve Board.

Governance will be very important. All of the stakeholders need to have a seat at the table, otherwise they will spend their money lobbing grenades inside the tent. Having staggered-year appointments so that no administration or no particular Congress will entirely dominate the governance of this type of center will also be important.

Let me talk a minute about funding. You could argue for direct appropriation, the way we fund the National Institutes of Health.

But having spent as much time in Washington as I have, I do not think that is a realistic way to have a significant amount of funding. So as an alternative, I would suggest a mix of a direct appropriation, a contribution from the Medicare trust fund, and a small assessment on all privately covered lives.

The reason I say that is that, while many groups will benefit, like clinicians and patients, the people who will benefit the most are the payers, in precisely the way we heard about health IT, public payers and private payers, but all the privately insured must be included.

A word about whether or not to include cost effectiveness or cost/benefit analysis. This is an area where I separate from some of my colleagues. I think these are important in setting reimbursement strategies, but they ought not to be a part of a Center for Comparative Clinical Effectiveness. They are too controversial. The methodologies are too controversial, and the politics are too great. We cannot start this process of learning how to spend smarter if we do not know more, and so anything that protects the development of comparative effectiveness research is very important.

But ultimately, information alone will not be enough. We need to change the reimbursement system so we realign financial incentives, rewarding the clinicians and institutions that do it right the first time, provide quality, and do it in an efficient way, and promote healthy lifestyles by individuals as well. But without more and better information, we will not be able to accomplish our goals either. So, I hope that this will be an area that you will remember as you go forward in your reform proposals.

[The prepared statement of Dr. Wilensky appears in the appendix.]

The CHAIRMAN. Well, thank you, Dr. Wilensky. I think, frankly, more than remember, it is something we are going to pursue. I think it is so important.

I would like to ask the other panelists, do the other panelists basically agree with Dr. Wilensky that we need some kind of semi-independent outfit to somehow look at the comparative effectiveness of drugs and treatment? Do the panelists agree or disagree? I will start down with Dr. Orszag. On the surface, does that make some sense or not?

Dr. ORSZAG. As CBO has said before, a significantly expanded comparative effectiveness effort, especially if it were combined with changes in financial incentives, holds substantial potential for reducing health care costs over the long term and improving the quality of our system.

The CHAIRMAN. Dr. Hillestad?

Dr. HILLESTAD. I think it is a good idea. I think that it is also another incentive for moving forward with the adoption of HIT so as to be able to provide this comparative effectiveness measure.

The CHAIRMAN. Mr. Halvorson?

Mr. HALVORSON. Yes. We are not using everything we know now as well as we could use it. We need this level of evaluation. We need to look at new things that are happening. We need to track things that have happened. We need to track the performance of treatments that are in place and technology in place. All of that needs to be done, and what we really need to do is create great con-

sistency in the application of it. So, we need both ends of that equation.

The CHAIRMAN. And Dr. Wilensky, how much, reasonably, is necessary to conduct this enterprise?

Dr. WILENSKY. I do not want to scare you, so I will try to slide into that answer.

The CHAIRMAN. All right. Slide in however you want.

Dr. WILENSKY. For the last 40 or 50 years we have had a huge amount of innovation that has been introduced, almost none of which has been subject to the kind of systematic evaluation that I am suggesting ought to be occurring. And the reason is, one of the two of you, I am not sure whether you, Chairman Baucus, or you, Senator Grassley, indicated that the FDA requires very different information, whether something is safe or effective relative to a placebo or a single state-of-the-art activity.

What I am suggesting is the need for questions looking at broad medical conditions, like the treatment of cardiovascular disease or the treatment of back pain, and the various strategies that are available and what we know about what works, when. That kind of information has not been generated because only payers would have the benefit, and they have not been willing to fund it, to date.

To start, I think you would probably need several hundred million dollars to get going at a level where you could begin to do systematic reviews of existing information. There was an Institute of Medicine study released in January, indicating a lot more difficulty in making use of existing information because there has not been agreement about what constitutes valid and reliable data, or how to summarize data that has been collected in various strategies.

Ultimately, I think we are talking about a center running at $4 or $5 billion on an annual basis, but that is at a steady state. It is a lot of money, but it is not a lot of money compared to $2 trillion, which is what we are spending on health care.

The CHAIRMAN. How much would that reduce the 29-percent gap that has been referred to here at this hearing?

Dr. WILENSKY. Well, it depends how aggressively you move on also trying to realign financial incentives. Right now, the most broken part, in my view, of Medicare is the physician fee schedule. It provides strong incentive to do more and more complex treatment, even if more conservative treatment would give you better results.

I was pleasantly surprised when CBO estimated that the presence of comparative effectiveness could provide a small savings over a 10-year period, but as Dr. Orszag has said, and I agree, if you also financially realign incentives, you could drive a big change. It will be hard, though, to get what you can in terms of spending smarter if we do not know more.

People honestly cannot know the best treatment for particular subsets of the population if nobody has looked at what you gain in terms of angioplasty versus bypass surgery or conservative medical treatment, or now, ablation therapy in cardiovascular disease for atrial fibrillation, versus conservative treatment by drugs.

There was an article about 6 months ago in the *New York Times* about how ablation therapy has become a very popular strategy to use in treating patients, with very little knowledge about what it actually means for these patients. And a more recent article about

CT angiography was on the front page of the *New York Times*. It just indicates how big an issue this is in terms of the impact on spending.

The CHAIRMAN. My time has expired. But in the next round I am going to ask you, Mr. Halvorson and Dr. Hillestad, just what are some of the barriers to IT, what practical barriers, and how we might overcome them. I will get to that in the next round of questions.

Senator Grassley?

Senator GRASSLEY. Dr. Orszag and Mr. Halvorson, we in Congress have not been very successful in tweaking Medicare's reimbursement system in our efforts to reduce geographic variation in medical practice. A question to Dr. Orszag, and then I am going to ask the question right away of Dr. Halvorson, so you know what I am going to ask you.

Dr. Orszag, do you think that the Medicare payment structure actually encourages geographical variation, and Dr. Halvorson, Kaiser uses salaried positions in an integrated care model. What lessons could Medicare learn from the way Kaiser reimburses?

Dr. ORSZAG. I would say that the Medicare reimbursement facilitates geographic variation, because we pay for basically whatever the doctor orders. Even if it is very low-value or zero-value care, we pay for it. Of course, that does encourage more of that kind of care.

Senator GRASSLEY. Mr. Halvorson?

Mr. HALVORSON. What we are doing within Kaiser Permanente is, we have put an electronic medical record in place for all of our doctors. We have created a single database about all patients, and we are now putting on top of that electronic medical record care support tools and panel support tools that help remind each doctor at the point of care what each patient needs. We are finding that to be a very powerful and effective tool that is very useful.

We are doing it a little bit differently from State to State to get a sense of what works best, for asthma patients, for example, with the goal of standardizing back to the best practices. One of the things that is true about medical science today is that not everything is known, so we need to do our own internal research on something like asthma care to identify the best possible treatment. But the goal is to do it consistently to track the results to know what happened, and then to embed those advisories into a computer support system so the doctor gets that information on the delivered care.

Senator GRASSLEY. Then could I follow up, because I think the key point I want to have you express is the difference that salary makes, paying doctors by salary.

Mr. HALVORSON. Paying doctors by salary removes all disincentives relative to doing unnecessary and inappropriate procedures. So the procedures that are done are done because they are medically appropriate, not because there is a financial consideration.

Senator GRASSLEY. All right.

Dr. Wilensky, some stakeholders suggest that by the time comparative effectiveness research would be completed, it would be outdated and a poor basis for clinical decision-making. Would you address the challenges of getting this comparative effectiveness re-

search from the journals to the bedside in a timely manner that minimizes the likelihood of it being outdated?

Dr. WILENSKY. Health IT. An obvious answer is, if you can access information quickly, that would cut down the time involved in the process. It needs to be understood that comparative clinical effectiveness research is not a one-time effort: make an investment, find out what is true as of that moment in time, and you are done forever. It is going to require continually updating research as appropriate, as goes on in biomedical research at the NIH.

But it is too important to say we do not have the time to understand better about what will work more effectively. Physicians have to make decisions when they need to make decisions. The rest of us need to help provide them with the best ongoing information and make it available to them as quickly as possible.

Senator GRASSLEY. A follow-up for Dr. Wilensky in a little different area. There will certainly be instances where a clinically accepted norm that is developed through comparative effectiveness will not work for specific patients in a specific instance. What do you think an exceptions process would look like that would allow providers to appeal the clinically accepted norm? If a provider's reimbursement is linked to providing the clinically accepted norm, how would we create a system that allows for exceptions?

Dr. WILENSKY. Let me back up and say that the center I am trying to get going is to provide the basic information that everybody will have available to them, public payers and private payers. How that information is used will probably differ by public payers and some private payers. Unless we force it otherwise, we need a common base of information about the best that is known in terms of likely clinical outcomes if you use a drug, device, or medical procedure in treating a particular medical condition.

Your question goes to the issue of, how do payers now decide whether or not they will reimburse for a particular medical condition? What does the standard of care suggest is appropriate? What clinical information can do is provide a better basis for making that decision, one that is much more open and transparent.

Senator GRASSLEY. Thank you.

The CHAIRMAN. Thank you very much, Senator Grassley.

Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman. Mr. Chairman, I want to start by commending you. You promised people at the Summit that we were going to stay at it and continue these hearings, and I think this is a great next round and a way to show that we are going to continue to prosecute this cause of fixing health care.

I want to start with you, Dr. Orszag, if I might. You once again highlighted the extraordinary inefficiencies in the health care system. I have come to the conclusion that the system is now so riddled with inefficiencies, I believe that the only way to bend the cost curve downward is to take two very concrete steps: (1) to demonstrate to our people directly how much the inefficiencies cost, for example, reduced take-home pay; and (2) to pass health reform legislation so that, in a more efficient, fairer system, our people have a new financial incentive to select health care carefully.

Would you agree with that?

Dr. ORSZAG. Yes. I like short answers.

Senator WYDEN. You have analyzed the Healthy Americans Act, and I believe we take those two steps, give people a real sense of what they lose in wages, and in effect make it possible for them to have financial incentives to choose plans carefully. Would you agree that the Healthy Americans Act, 16 Senators, takes those two steps?

Dr. ORSZAG. Yes, although there are also other ways of taking those steps. But, yes.

Senator WYDEN. That has really been my view, that now we have at least one way of getting there. I share your view that there are a lot of other ways, and that is what, under Senator Baucus's leadership and Senator Grassley's leadership, we are going to explore. But you have now identified, and it is good to have it on the record, that there is one way to actually bend the cost curve downward and squeeze out some of these inefficiencies, and I thank you for that.

My second question deals with you other three panel members who have done such great work in this field. When I get around the country and talk about innovation and quality, people say, by God, they are doing a great job at Kaiser, they are doing a great job at Inter-Mountain, they are doing a great job at Mayo.

But how do we take those lessons from those terrific programs and make them apply in small communities around the country where there is not that network of integrated kind of services? So for you three, how do we take some of these lessons from programs—I will start with you, Mr. Halvorson—and export them around the country or, say, to small towns in Oregon.

Mr. HALVORSON. I have a long history of small-town life, and I understand exactly what you are talking about. The issue for us is to prove that vertically integrated care can perform at a very high level in particular areas, and we are doing that. The key word there is "integrated." What we need for the rest of the country is vehicles and tools that accomplish that integration process.

Chronic care is a team sport. A team sport needs a captain. Somebody has to be the integrator. In the small towns, an integrator can be a computer system, it can be a care registry, it can be a local vertically integrated care system where different things can be used, but that function must exist. If the function does not exist, coordination will not happen. So the challenge going forward from a policy perspective is: how do you make sure that function happens every place in America where care is delivered so that there is a way of connecting the caregivers?

In my own view, when electronic medical records feed that system, it is an optimal system, but you can also feed them from a claims database, you can feed them from other databases that are locally available. But if you do not feed them from something and if there is not a coordination function in the middle, then it cannot happen in small-town America. So, we need to move in that direction.

Senator WYDEN. Dr. Wilensky, do you want to add to that?

Dr. WILENSKY. I thought that we were, as a country, moving more toward vertically integrated care in the 1990s, but I was wrong. Many people who have had an opportunity to do so, for

whatever reasons, do not seem to have chosen it; financial incentives may be wrong, et cetera. There also are not as many multispecialty physician groups that have organized outside of some of the very well-known ones, or at least they are not available everywhere in the country. Why that is the case is also not clear to me. So we need to begin to think about how we structure virtual systems that allow for people who do not have easy access to integrated groups to gain from what they can offer. There are some interesting areas that we can look to.

One of my experiences over the last 15 years is working as a trustee for the United Mine Workers' health and retirement funds. They are providing support to a frail, elderly population that is frequently not in areas where there is much of a medical infrastructure, and they have made use of geriatric case managers, very proactive involvement with poly-pharmacy management for people who are heavy users of pharmaceuticals to make sure that the care is integrated, along with other strategies to try to mimic some of what happens in an integrated system.

Doing virtual groups will be much easier if we can promote health IT. You have taken, now, a first step with the push for e-prescribing—a little step, but an important step—in the bill that was just passed. I think that may ultimately allow people to have better insight as to the gains they could have if they were part of an integrated system.

The CHAIRMAN. Thank you, Senator, very much. Appreciate it. Thank you, Dr. Wilensky.

Senator Roberts, you are next.

Senator ROBERTS. Thank you, Mr. Chairman. Let me say that you deserve some credit, along with the rest of the bipartisan group who passed the recent Medicare bill, because in that bill there is a push for e-prescribing by physicians under Medicare. But obviously we need to do a great deal more to get adoption of the electronic medical records.

Dr. Orszag, thank you for your comments and your frequent testimony. We actually have a company in Kansas that is doing great work in regards to this issue, and I am thinking about the Cerner Corporation. I recently visited their outfit and saw firsthand the great benefits of electronic medical records and how they are the future of the health care system. In remarks that I make, I compare the health IT challenge to our banking industry—perhaps not the banking industry right now in terms of the health of the banking industry.

But each of us, with our ATM cards, can go to any bank or any ATM in the world and access all of our financial information, but we are nowhere near that point in the health care industry. That is not an exact comparison, but it is one that I think that people understand. We have a situation where patients and providers still rely on paper, cannot easily share health care information, a patient's history, which leads to, as you have pointed out, unnecessary tests and drives up the cost of care.

I am a co-sponsor of legislation approved by the HELP Committee, championed by Senator Kennedy and Senator Enzi. It is called the Wired for Health Care Quality Act. It has a long list of bipartisan supporters. Under this office, which would be under

HHS, an American health information collaborative would be created to provide recommendations on developing this infrastructure, a public/private partnership known as the Partnership for Health Care Improvement. The bill also includes four separate grant programs. What we are trying to do here in this legislation is set standards. Now, standards are one thing if we could get that done, but what we need are incentives for the medical profession to latch onto this.

At any rate, I think that providing grants to institutions and others for the adoption of HIT would be very helpful. I am thinking of the small-town doctors and people who have practiced medicine for years, and people who are not that computer literate, still have sort of a fear of the computer, as opposed to the medical record hanging on the back of the bed, that we need some education there if we possibly could get that.

Now, you mentioned in your testimony the need for financial incentives. You have here the 2006 number: "Despite the potential gains from health IT, relatively few providers have adopted it, about 12 percent of physicians, 11 percent of hospitals." That is rather amazing, the testimony that has been provided, that that is where we are, so we obviously have a great challenge for the need for some kind of financial incentive.

Can you talk more about what those incentives might look like, especially in the rural areas? Senator Salazar and I have similar States. I am the co-chair of the Senate Rural Health Caucus, and the adoption of Health IT has been especially difficult for us because of the cost associated with adopting the technology and the perceived lack of benefit, even harm, to invest because of the limited return.

So how do we change this?

Dr. ORSZAG. All right. Well, there is either the carrot or the stick. The carrot is a subsidy to adopt health IT. The problem with especially small subsidies—and the subsidies tend to be small so that the budget cost does not become extraordinarily high—is that you are only sort of pushing over the line those providers or doctors who would have been close to adopting voluntarily anyway.

So, some doctors look at the current situation and say, it is in my interest to adopt and there is some net benefit, and I will do it. If you provide a small subsidy, the only people you are kind of kicking over the line are those who were pretty close to adopting anyway and you then made it in their interest to do so, and you are also buying out the base for everyone who would have adopted anyway. You are providing them the subsidy also.

The alternative is, and these could be done in combination, is to say after some period of time, and assuming that there are standards for interoperability, privacy, and what have you, that if you do not have a system in place you will not be reimbursed under Medicare. There is the stick. Part of my job is to say unpopular things. If you wanted to get to nearly——

Senator ROBERTS. Well, you have done that. [Laughter.]

Dr. ORSZAG. All right. I have succeeded.

But let me be clear: if you want to get to nearly universal health IT within the foreseeable future—and by that I mean the next 5 or 10 years—unless you are going to pay a very high subsidy cost

and buy out a massive amount of health IT adoption that would have occurred anyway, I really do not see an alternative to the stick.

The CHAIRMAN. Thank you very much.

Senator Rockefeller?

Senator ROBERTS. May I have just 1 minute?

The CHAIRMAN. You are over a minute already, but go ahead.

Senator ROBERTS. I will yield.

The CHAIRMAN. Go ahead.

Senator ROBERTS. We have just gone through an exercise in the Medicare reform bill to provide to health care providers, everybody, clinical labs, ambulance drivers, pharmacists, hospitals, home health care folks, and the doctors—God bless the doctors—10 percent. We are in a position now where, in order to bring the Medicare costs down, simply because of the lack of reimbursement, people are turning away from Medicare patients.

Two pharmacists in a small town I just recently visited, one did not, one did, serve Medicare. The guy who served Medicare ought to be a GS–16, because he has to tell everybody what to do with Medicare Part D. It is called triage. It is called rationing health care. It is not right. So, if we are going to use a stick to try to bring health care costs down to force some doctor who is 68 years old in Beloit, KS, America, or Dodge City, KS, America to do that, I would certainly prefer not to do that. We are really on the edge right now. So, I appreciate your straight-talk express. It must be the tea or the Coke that you are drinking. [Laughter.]

Dr. ORSZAG. I would say, I do not need to get elected either, so that is a luxury there.

Senator ROBERTS. All right. I just wanted to toss that in, because that was the main issue that we just faced in this Congress. Senator Grassley said "tweaking." We did not tweak, we saved an awful lot of people in regards to Medicare services.

The CHAIRMAN. Thank you, Senator, very much.

Senator Rockefeller?

Senator ROCKEFELLER. Dr. Orszag, I like you. I think you are good. One of the things that you have said that interests me is that, in 2006, only 12 percent of the physicians and 11 percent of providers took advantage of health information technology.

Dr. ORSZAG. Why?

Senator ROCKEFELLER. No, not why, unless you want to answer that. So this, to me—and I will say this with Senator Roberts in the room—I am almost tempted to make a comparison between the health care industry and the intelligence establishment, where you have these wild variations from the Mayo Clinic, which you talked about the last time and again this time, and very, very high expenses per person in West Virginia. Why, why, why, why? The answer is, you need to share information. That is HIT, in one sense.

The intelligence community declines to do that. They decline to do that because the people have been there a long time, because of habits, because of pride, because of ego, because of a fear they might be wrong, or whatever. What we did was, we put in something called the Director of National Intelligence, who has quite a lot of power but does not tell people how to run their organizations. It is beginning to have a very good effect, primarily because he is

a very good person and he observes behavior, comments on behavior, and has the power to adjust behavior as a result of that.

Now I switch back to health care. If you have so few people taking advantage of HIT in 2006, the idea that somehow, through carrots or sticks, you are going to really make a fundamental difference in what I think is a much more turf-conscious body, which is the health care industry—that is all the lobbyists, that is all the hospitals—they all have the best way of doing it. Doctors are very much that way.

I agree that some doctors in their 60s or 70s may not be very good on the computer, but I am going to suggest an idea to you, and you can shoot it down if you want.

If we are going to make progress on this, a health information and collaboration center which people can or cannot attach themselves to, based upon your 2006 analysis, has less interest to me. What has more interest to me is too radical to pass. But I would like your views on it, and any other members, too. That is, you say that as a precondition to taking Medicare, receiving Medicare, receiving Medicaid—that is, the institutions and the providers—children's health insurance, these kinds of things, that you do agree to participate in HIT, which is quite a massive behavior modification. Pride, diminution, anger, lots of things. But if you are going to have health care information, then people had better use it.

Dr. ORSZAG. Senator, let me just repeat what I said earlier, which is, if we were serious about getting to nearly universal health IT adoption, I frankly do not see a practical alternative unless you are willing to expend a lot of Federal resources for very deep subsidies for the adoption of the kinds of approaches that you were mentioning, painful though that is to say.

Senator ROCKEFELLER. You see no alternative, but just to pay people a great deal for doing the right thing?

Dr. ORSZAG. You could either pay people a great deal, and it will wind up being very expensive because you will have to buy out the base for people who would have been doing it anyway, and also provide a sufficiently rich incentive so that even people who do not want to do it will do it voluntarily, or you need to say, it is up to you. We will provide some subsidies for 2 or 3 years so that you adopt this, closer to what you did in electronic prescribing. We'll adopt some subsidies for some period of time, and you have 3 or 4 years to have a system in place, but thereafter, you will not get reimbursed under Medicare or Medicaid. That would get you nearly universal very fast.

Senator ROCKEFELLER. Thank you.

Others?

The CHAIRMAN. Very briefly. Your time has expired.

Dr. WILENSKY. The other change that would drive adoption very quickly is if you change how and what you reimburse for. So I agree with what Peter just said, but, if you change what you are rewarding, that is an even better strategy. You cannot keep doing what you are doing in terms of reimbursing physicians. You have to bundle what you pay for, what you are rewarding. That would make the adoption of health IT much more attractive, especially if you also provide some subsidies or low-cost loans to rural physi-

cians and small hospitals. The big guys, I don't think, need that kind of help.

The CHAIRMAN. Senator Snowe?

Senator SNOWE. Thank you, Mr. Chairman.

Dr. Wilensky and Dr. Orszag, on the issue of health information technology, Senator Stabenow and I have introduced legislation to do just that, to provide an integrated process here. I think that certainly Congress should take steps in that direction. I mean, that is certainly the wave of the future, and we ought to be adopting those efforts now to provide incentives.

I understand what you are saying, Dr. Orszag, about not being able to provide a large enough subsidy to individual practices. But in other words, do you not think we should begin this process, because certainly it would help, I think, to buttress what Dr. Wilensky is recommending in the Center for Effectiveness, being able to determine the performance and measure the savings from specific treatments, therapies, practices, or prescriptions.

So, do you not think we should take some steps in that direction? I mean, we provide grants and tax credits to help initiate that. I know a lot of physicians who want to adopt and integrate these systems. We should make them interoperable. It is certainly going to happen, and it is in our interests to do so, to make sure that Medicare and Medicaid can achieve the savings that can result from it.

Dr. ORSZAG. I think the more that we can spur health IT adoption, the better. The only question is, what will actually succeed in rapidly and dramatically expanding health information technology adoption.

The other thing, of course, as has already come up, is by itself, that is not enough. You need to have some system for using the data intelligently and for changing reimbursement so that we are steering care towards better care rather than more care.

Senator SNOWE. Dr. Wilensky, do you agree?

Dr. WILENSKY. Yes. It really is a combination of knowing what you are trying to incent, changing the reward rules so that you reward the physicians and institutions that are behaving the way you want them to, making money available to those groups that have a hard time accessing the capital market, which seem to be the smaller hospitals and the smaller physician practices, and making sure that the rest of the changes are encouraging that use.

Senator SNOWE. Would that be useful for the center?

Dr. WILENSKY. Oh, absolutely. Being able to have health IT will help generate information, help generate the data so that you will understand what appears to be working well through natural variation, although you might need to sometimes verify that with prospective trials in areas that are very important. It will also allow for rapid updates of information and dissemination. It will be much harder to have a robust Center for Comparative Clinical Effectiveness if we do not push forward on health IT.

Senator SNOWE. Mr. Halvorson, what can you recommend to us from your experience in all of this on how to proceed?

Mr. HALVORSON. My sense is, we should focus on what we really want the system to do, which is to take care of the people who really need coordinated care. The only way the care can be coordinated

is by having computer support, because individual doctors and individual officers with no other connectivity cannot coordinate care for patients. There has to be a linking tool. If we mandate that individual providers, in order to get paid by Medicare at a certain point in time, submit claims electronically, if we also mandate that, after a certain point in time for all of the patients with co-morbidities and chronic disease, that they interact with a care registry or an electronic medical record—if we mandate those two things and if we pay them a little bit for the connectivity, the combination of that, with the ingenuity of the American software world, will result in, I believe, a whole new series of products that will connect everyone.

But I think we need to start with the two mandates, start with electronic claim submission, start with the mandate to use the registry for the patients who need it the most, because 80 percent of the chronic care patients have co-morbidities. We could cut the number of kidney failures in half if we did a better job on their care. We need a computer tool to get there.

Senator SNOWE. That is helpful. Do you think we should take those steps immediately?

Mr. HALVORSON. I think we should set up that pathway immediately and then give the physicians and give the providers a couple of years to comply. I think it should be an immediate decision to move in that direction, yes.

Senator SNOWE. On the issue—and I think, Dr. Wilensky, your idea for a Center for Comparative Clinical Effectiveness is outstanding, frankly because I think we have to kick-start this process. We are just not going to be able to do it without something that is going to measure and evaluate these savings, and in terms of the methods that are used, and for the future, too, not only for existing practices, but also for the future.

I know that budget scoring is a problem, and it is up to us to make decisions with respect to, how do we change budget scoring under this scenario with a Center for Effectiveness? Do we do it for mandated studies or exception for scoring rules in order to examine these performances? What would you recommend, Dr. Orszag, or how do you see it? I mean, obviously it is up to us. We have to change the budget scoring rules.

Senator WYDEN. And if we could, briefly, because Senator Salazar has been waiting.

Senator SNOWE. Yes.

Dr. ORSZAG. Sure. Just very briefly, I would say I think there are potential changes that could be made to the budget scoring rules that have to be explored in consultation with the Budget Committees. I would just say, we are in the midst of putting together a whole series of options, hopefully many of which will generate budget savings, and we will have two significant volumes out at the end of the year that will provide options for you, including on regional variation.

I know we need to move on, but since Senator Salazar is one of these people too, I just noticed on this map that the two places that I am taking my children to this year, including Lake Sebegla in Maine, and Colorado, are very low-cost areas. [Laughter.] I do not know if that was on purpose or not, but there you have it.

Senator SNOWE. It is just gravitating. [Laughter.]

Thank you.

Senator WYDEN. Senator Salazar?

Senator SALAZAR. All we have to do is replicate what we are doing in western Colorado, and we will solve the problem, Mr. Chairman.

Let me just ask a question on the Center for Comparative Clinical Effectiveness. First of all, Dr. Wilensky, my own sense is that we have to find simpler ways of describing what it is that we are doing, because all the experts we are hearing, and maybe people on this committee, might be able to describe that. I think it is meaningless to the rest of the world. Frankly, the terminology that we use around the health care system, I think, is part of the problem and creates tremendous confusion.

But let me take that concept, and I want to ask for a response from each of you. I know that in your testimony, Dr. Orszag, you refer to the concept which Senator Baucus and Chairman Bernanke talked about with respect to a Federal Reserve Board lookalike that might help us in terms of setting out protocols for health care. I think that is what you are trying to get to in terms of your Center for Comparative Clinical Effectiveness, Dr. Wilensky, in some way.

I would like your sense of what it is that we would do with setting out those clinical guidelines or protocols. I want to be specific. My understanding is, 80 percent of the health care dollars are spent on a person in the last 2 years of life. How would a Federal health board, Center for Comparative Clinical Effectiveness, constitute that so that we have effectiveness in terms of how we are treating people in those last 2 years of life? Would you talk about a board that would have a regulatory authority, or is it simply some board that is giving advice?

Dr. Orszag, why don't we start with you and then just go down the row?

Dr. ORSZAG. Sure. Just very briefly. CBO is going to be putting forward a report that lays out the options, so I do not think any of this is kind of settled in whether it is integrated with the comparativeness effective entity or separate from that, or what have you. But conceptually, I think the question is, would it be beneficial to have a technical body that is politically insulated have a larger role in, for example, Medicare policy? We already have MedPAC, which is an advisory committee. One could imagine MedPAC's recommendations, instead of just being recommendations, being a set of policies that would be implemented unless the Congress overruled them as a package. That is for you all to decide.

Senator SALAZAR. How far away are you from that report?

Dr. ORSZAG. We will have it out before the end of this calendar year.

Senator SALAZAR. Before the end of the calendar year? All right. Thank you.

Dr. Hillestad?

Dr. HILLESTAD. First of all, that is not my area of expertise. I will not say much about it. But certainly——

Senator SALAZAR. Then that is fine. Mr. Halvorson?

Mr. HALVORSON. Generally, we as a country need to become a culture of continuous medical learning. We are not a continuously learning culture right now. We do not collect data, we do not compare data, we do not have good information about what works and what does not work, and we need to build that database to deliver optimal care. We figured out that Vioxx was causing a problem.

Senator SALAZAR. So would you support the concept of a protocol set by some Federal Reserve Board?

Mr. HALVORSON. I definitely do not think a protocol should be set by the Federal Reserve Board, because medicine changes all the time and people get smarter all of the time. So, no, I would not like a federally set protocol. But good, solid research on what works and what does not work, relative effectiveness is extremely important, and that information needs to be there, and it is not there now.

Senator SALAZAR. Dr. Wilensky?

Dr. WILENSKY. I am not envisioning a regulatory entity in what I am describing. First, we need to have better information available about what works, when, for whom, under what circumstances. The term "comparative effectiveness," without the middle clinical part, is fine if it makes it easier for people to understand. We need to get the information out there.

For Medicare, there could be a decision that either a separate body, MedPAC or somebody else, makes decisions about reimbursement based on the information that is available through this Comparative Clinical Effectiveness Center so that the strategies that look like they have a lot of clinical payoff get a high reimbursement or a low co-payment, or waive the co-payment, and others that are safe, FDA approved, but not as effective, can be provided at a higher cost.

Senator SALAZAR. All right. Let me say, I appreciate that, and I am very much looking forward to, Dr. Orszag, CBO's report on the board.

A question just on HIT, Dr. Orszag. You say carrots and sticks. So, if we do something like e-prescribing, carrots at the beginning, maybe mandatory for 3 years or 4 years on down the road. Do we have any concept of what the quantum of dollars are that we are talking about in terms of a program that would implement HIT nationwide?

Dr. ORSZAG. Do you mean the expenditures that would be required?

Senator SALAZAR. Cost. If we wanted to get to 90 percent like many of the European countries are now, what would it cost?

Dr. ORSZAG. It would likely involve tens of billions of dollars a year over many years. Who bears those costs is one of the questions.

Senator WYDEN. Let us go to Senator Stabenow, and then we will have a second round when the chairman returns.

Senator Stabenow?

Senator STABENOW. Thank you very much. Thank you to all of you. As many of you know, this is an area that I have been working on for some time, and I personally believe that this is at the heart of our ability to go forward on the quality side, and to be able to address costs, but particularly preventing deaths, saving lives, being able to do what we all want to do.

Just a quick story. A woman came into my office as part of a small business group, and we were talking about health IT—this was a few years ago—and she told me a story. She lived in northern Michigan, and her son was chronically ill. She took him to western Michigan, down a few hours, to drive to one doctor and over to the University of Michigan Children's Hospital for other treatments.

Because of her concern about the fact that they did not have complete information at all places, including X-rays and so on, she developed a filing cabinet in the trunk of her car. I would hope that, in America, we could do better than a filing cabinet in the trunk of a mom's car to be able to make sure all the information is available. That is really what electronic medical records are all about.

A question as it relates to comparing treatments and so on. There is an article in the *New York Times* today that says what many of us have known, which is that we are spending more than twice as much on each person for health care as most other industrialized countries. But to add insult to injury, we have fallen to last place among those countries in preventing deaths through use of timely and effective medical care. This is the Commonwealth Fund that did this research.

So my question is, and I guess I would start with Mr. Halvorson because you have an organization that has 9 million people together there, and is developing electronic medical record systems, which I think is terrific. But do you find with any of your systems that you are able to use the data that you have to compare different treatments and their effectiveness, both from a clinical standpoint as well as a cost standpoint?

Mr. HALVORSON. The answer is, yes, we do that. We look back. The Vioxx information that hit the public was the result of a study that we participated in, taking a look at the impact of Vioxx on our patients. We discovered that there was a higher death rate, and we announced that and triggered that whole series of dominoes. We did the same work on hormone replacement therapy, and we have done it in a number of other areas. So we used that database and worked backwards to figure out some important things.

One of the reasons that we are committed to a complete and full electronic medical record is, we want to have all of that information about all of the patients all the time so that we can track over years whether or not things that we thought worked initially—heart stents are a really good example—are actually good for patients in the long run. We are doing a lot of heart stents in this country. There is a lot of data showing a really good early impact. We do not know what the impact is over time.

Somebody needs to track that. We will definitely be tracking that, and we will be tracking it based on the variation of stents, as well as the diseases that people have, identifying whether or not diabetics have a different outcome in 5 years than people who are asthmatic or have other conditions. So it is really critically important to do that work and to have that kind of data, because without that work you do not know.

We just did a study on the type of glue to be used in hip implants and discovered that one type of glue had a failure rate three

times higher than any other glue. Because we had a large enough database to track that, we could know that. But no given hip surgeon has a couple of hundred patients that they can track over time and identify that there is a difference in outcomes. I mean, somebody has to do that work, and the work needs to be shared.

Senator STABENOW. We found in e-prescribing—and I am so pleased we have developed the first step in Medicare, both carrot and stick, because it does have a mandatory requirement a few years down the road. But in southeastern Michigan, since 2005, we have had about 2,500 physicians signed up through Blue Cross, the auto industry, and United Auto Workers, and so on.

I believe it is about 30 percent of the time when they have started to prescribe a medicine, the software, of course, shares the fact if there are medical interactions, allergies, and so on, and they have actually changed the prescription before sending it to the pharmacy, and as well, other data. So it is very clear that giving physicians more tools and more information, even starting with e-prescribing, makes a huge different in outcomes and people's treatment and people's lives.

Mr. HALVORSON. Yes.

Senator STABENOW. Thank you very much.

The CHAIRMAN. Thank you, Senator.

Mr. Halvorson, how did you get your health IT up and going? Did you just, by fiat, do it? What were the costs, and what is the return on investment, for example? Just some guidance here for us.

Mr. HALVORSON. Well, we are a vertically integrated care system, so we have hospitals, clinics, pharmacies, imaging centers, and we not only insure the care, we also provide every element of the care. It was obvious to us that we did not have all of the communication that we needed between caregivers, and we had caregivers in multi-specialty practice, with patients coming in and they would not understand all of the issues that the patient had, all of the prescriptions that had been written.

So we decided that a paper file, being carried from room to room, is not as good as an electronic record. So we decided to invest in an electronic system to have all of that information about all of our patients on the computer so the doctor can look at that information in real time at the point of care.

The CHAIRMAN. Right. But what is the return on investment then?

Mr. HALVORSON. We finished the entire roll-out. The last clinic was 6 weeks ago. But we have some clinics that have been in place for a couple of years. We phased it in across our system. The return has been extremely good in each of the places that we have full implementation.

But as I said earlier, we have to take the computer system, build the database, and then on top of that do an extract, and then figure out from the extract, for each doctor and their panel of patients, which patients need what follow-up care, and create the reminder system. That is how we managed to have over a 50-percent reduction in heart deaths in Colorado by doing the right follow-up on every patient.

The other thing we were creating was electronic visits. We have an ad that is going to come out pretty quickly that says, "Two mil-

lion visits, not one gallon of gas," because we had 2 million electronic visits last year with patients interacting with their doctor by computer. That creates an efficiency, it reduces costs, it makes a big difference in people's lives, because they do not have to drive to a clinic and sit in a waiting room.

So what we are trying to do is re-engineer the system using computer data at the core to deliver better care, and we are doing it because we think it is the right thing to do. But we also are doing it because we know that 1 percent of our patients is 35 percent of our costs. If we can intervene earlier in the progress of the disease for each of those patients, we are going to make a significant change in the cost outcome of care.

We know that, when we do the right intervention, on congestive heart failure patients, for example, we can cut the number of hospitalizations by over half, but we have to do it systematically. We have to identify them, we have to put them into the system, into the process, interact with the patients. A single doctor in a solo environment, without the connectivity, would have a very hard time getting that outcome and would have twice as many people.

The CHAIRMAN. And you developed the software to do all this, too?

Mr. HALVORSON. We actually purchased the core software for the medical record, and we have added on the care management tools.

The CHAIRMAN. But you also mentioned, in health IT, that it is also important to have the—I have forgotten how you phrased it—alert system, or some kind of——

Mr. HALVORSON. Yes.

The CHAIRMAN. And could you elaborate on that a little more, please?

Mr. HALVORSON. Well, when the physician has all of the data on a patient, that is a very good thing. It is an even better thing if the computer reminds the doctor that this particular patient has not had this test, that we need to do this kind of follow-up, that the patient has not had either a mammogram, or the patient has not had a current blood test.

What the system does is, it reminds the physician of what the next care steps should be. It also tells the physician that the patient did not refill their prescription, so they can have a conversation about why, if you need blood pressure control.

The CHAIRMAN. This all sounds too good. What is the down side?

Mr. HALVORSON. I do not see a down side to it. I think it is the future of health care.

The CHAIRMAN. What are some of the problems you have run up against that you had to deal with? Maybe doctor resistance——

Mr. HALVORSON. I actually received some minor care last night from one of our doctors in Washington, DC, and she told me that she would kill anybody who tried to take that system out. She said she absolutely loved it.

The CHAIRMAN. That is pretty serious. [Laughter.]

Mr. HALVORSON. Well, I think she might have meant damage or something. [Laughter.] But she basically said, when she first heard that we were doing that, there was some reluctance on her part. Now that she has all of the information about the patients and she

has it immediately, she could interact with me in a fully informed way.

The CHAIRMAN. But again, there must be some problems you run up against.

Mr. HALVORSON. Initially, we learned that we had to make sure that we had the computers available all the time. You have a different standard of availability if you have patient information on the computer. We have worked on that, and it is coming along quite nicely, Senator.

The CHAIRMAN. I understand the benefits. But what resistance do you think you would run up against the more we encourage this?

Mr. HALVORSON. I think there is a timing issue to any major change. I think, when I change from one cell phone to another, I go through a period of adjustment.

The CHAIRMAN. And Dr. Hillestad, your take on this?

Dr. HILLESTAD. Well, the biggest barrier is clearly financial. I mean, that is borne out by surveys and by the pattern of the——

The CHAIRMAN. So how do we solve that one?

Dr. HILLESTAD. Well, there are several——

The CHAIRMAN. Dr. Orszag says that it is a whole lot of money, just sock it to them.

Dr. HILLESTAD. There are incentives. You could do it part of the way with incentives. I would not give up on the idea of some form of subsidy incentive that you could get at significant levels.

The CHAIRMAN. Yes. But, Mr. Halvorson, would you not be upset if Congress gave a big subsidy to all those who have not yet provided health IT, and you have already done it?

Mr. HALVORSON. No.

The CHAIRMAN. You would not?

Mr. HALVORSON. I would strongly encourage it, and would welcome that. If Congress decided they wanted to pay us something additional for doing it, we would take that. [Laughter.] But I would not feel bad about it.

The CHAIRMAN. All right.

Senator Grassley?

Senator GRASSLEY. Dr. Orszag, you mentioned in your opening statement that we are spending $700 billion that is wasted on not improving outcomes. Now, if we instituted policies that would reduce that, would CBO score that favorably for those policies?

Dr. ORSZAG. So, for example, the $700-billion number is coming from regional variation calculations and others, and we are exploring and putting together options to try to capture some of that money, and you will see those in December. So, the short answer is yes. But obviously, how much of that you capture—first of all, that number is not just Federal Government savings, it is overall savings.

Senator GRASSLEY. Yes, I know.

Dr. ORSZAG. And second, how much of it you capture depends directly on how aggressive you are in attacking this problem.

Senator GRASSLEY. Do you have any idea what some of those proposals might be?

Dr. ORSZAG. Yes. [Laughter.]

Senator GRASSLEY. Just a couple examples.

Dr. ORSZAG. Well, there are a couple of different strategies. One is that you can go the route of comparative effectiveness research and reimbursement rate changes, which I think will drive some decline in the regional variation. The variation is most severe where we have the least idea of what works and what does not, so, where there is most ambiguity about appropriate care, there is more variation.

But beyond that, you could imagine, for example, introducing some variation in the reimbursement rate under Medicare in order to try to offset some of this variation, so that, in regions where there are services that are delivered more intensely, you try to ratchet back a little bit on the financial incentives that providers in that area face. That is one hypothetical example.

Senator GRASSLEY. All right.

Mr. Halvorson, what was your experience in dealing with geographic variations between those States, and how did you overcome those differences? I have to assume in my question that when you put together a system that covers so many different States from one end of the country to the other, you found great differences.

Mr. HALVORSON. We have had variation in our care delivery from State to State. It has not been in sync with the local State variation. There are some cost differences because nurses in some communities are much more expensive than nurses in others, and you get those kinds of differences.

But in terms of patterns of care, we have not found that our practices directly reflect the community practice, because we are a closed system. We work with ourselves, and our physicians are organized as a multi-specialty group practice. There are no fee-for-service incentives in our system, so we do not make more money by doing unnecessary things.

Senator GRASSLEY. All right. So I think I interpret what you are saying as, you have narrowed differences but you have not eliminated them geographically.

Mr. HALVORSON. Right. We have not eliminated differences. In some areas, we do not want to eliminate differences because medical science is not perfect. So we have one program for taking care of heart patients in northern California that has had a really good result; we have another one in Colorado that has had a spectacular result. They are slightly different. We want to learn from both of them and then incorporate into the computer support tools the best features of both.

So we do not think medicine is at the point of science when it makes sense to say there is one perfect way of doing things, but we think we need to do it in a consistent way, we need to track it, we need to support it, we need to compare it, and we do internal comparisons so we know the difference in our system of various approaches.

Internally, our commitment is to be an organization that learns from itself, shares that, and transplants the learning. But right now, science and medicine are not at a point where we could say there is only one right way of doing any single thing. We know there are some very wrong ways of doing things, but there are various pathways to getting it right.

So, the congestive heart failure model: in some States it works extremely well, heavily dependent on nurse interaction with patients; in other States, it might be a primary care doctor who has the patient interaction. The key is to have the interaction to anticipate when the patient is beginning to go into crisis and do an intervention to educate the patient. There are key steps that need to be done, but different people can do them and you can do them in a slightly different order.

Senator GRASSLEY. Thank you, sir.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman.

On the comparative effectiveness issue and the health information technology issue, I do not think it is by design, but most of the discussion always seems to focus upon insurance companies, payers, providers. It seems that, very often, the patient and their family are almost an after-thought. I would be interested in changing that, particularly now, since we are going to be talking about the architecture.

Chairman Baucus and Senator Grassley are going to be leading our efforts here. We are going to be talking about the architecture of how to pull the patients and their families into this discussion about comparative effectiveness and health IT. We are, frankly, looking for ideas. For example, in the Healthy Americans Act we put in a requirement that there should be online information about providers that is searchable by zip code so that you could easily find a way to locate people who offer good-quality, affordable services in your geographic area.

As with all of this, I am not saying this is the last word, but I would be interested, and I think it tracks the chairman's question, in getting a sense of what we can look at, again in a bipartisan sort of way, to shore up the architecture of health information technology and comparative effectiveness in a way that boosts the patient and the patient's family. Why do we not just go down the row? I think I have time to start with Dr. Orszag, and I know Mr. Halvorson and Dr. Wilensky have thought a lot about it, and RAND, too. Go ahead.

Dr. ORSZAG. Let me just say, as a patient myself, that I have encountered situations in which I have felt like the medical information that would be necessary to make a good decision is simply not available. And so this effort at comparative effectiveness research, regardless of your grand vision for the health system—whether it is a consumer-directed health system in which consumers need that information, or a single payer system in which the single payer needs the information, or something in between—the information is necessary, and beneficiaries—otherwise known as people—do need that information. In the absence of that, we are sort of flying blind to a degree that is quite unfortunate.

Dr. HILLESTAD. One of the important benefits of HIT should be the connectivity, not just between providers, but with the providers and the patients. That becomes particularly important as you move into chronic illness, where you really have to involve the patient as a member of the care team and monitor them, keep them heavily

involved in what they are doing. So I think the HIT provides a conduit that should improve health care and should improve communication between provider and patient.

Senator WYDEN. Mr. Halvorson?

Mr. HALVORSON. I would agree. We need data for patients. Patients need to know about comparative data about their caregivers, and they need to know comparative information about the care options they have in front of them. That data is typically not available. If somebody was diagnosed right now with cancer and there are two or three alternative treatment modes for that cancer, the patient should know what the average 3-year survival rate is for each alternative.

Right now, none of that data is fully understood, so people are making really important decisions about their own life and death in a very uninformed way, and we should not allow that to happen. We should have that data, we should track that data, we should compare that data, and we should make that data available to individual patients so patients can make informed decisions about their own care.

Senator WYDEN. Dr. Wilensky?

Dr. WILENSKY. One of the problems we have now is that there is a lot of information that is available on the Internet, but there are no quality screens. So, if you want to go find out about various ways to treat your cancer or other illness, you need to know the source and how reliable the source is, and then you can try to figure it out.

If there was a place people could go to look that had good, reliable information—I talked about it as a tool for payers, but clinicians and patients are clearly the ones who would benefit in terms of having available the best that is known. The question is, how do you get going on this strategy?

It may be to try to help people understand that there is information they can get now that is available in making health care decisions. Medicare has Hospital Compare, and the nursing home deficiency information, getting people used to the notion that they can search out information and maybe push the physicians and health plans to make more information available, and make more frequent use of electronic exchange of information.

This notion that people do not always feel comfortable asking, that it is their data, their medical record, and they ought to be able to get access to it, is part of the other efforts that are needed to develop standards and to promote health information technology. People need to be comfortable that that is an easy way to get information. But they seem to do it at Kaiser, so presumably, if it were available, large numbers of people would indeed go access it.

Senator WYDEN. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

I would just like your general reaction, panelists. It seems to me that one of the explanations of geographic variation, partly, is it is just nice to live where the sun shines. I mean, there are a lot of doctors in these areas that have very high utilization, which is not directly related to outcomes. Whereas, the States that are more efficient, like mine and Minnesota, it is at times a little colder—and Oregon.

So, if we were to pursue this—and I think we should, health IT and comparative effectiveness, et cetera—it seems to me that, logically, doctors all over the country would provide services and procedures based on the right quality of care, the right outcomes and so forth, which necessarily means that a lot of doctors living in Miami or whatnot would not get the same reimbursement that they are currently getting. They will not like that.

I am just trying to figure out how we can kind of realign the reimbursement system based on quality, outcomes and so forth that addresses that. I suspect that it is going to be very difficult to cut back on their payments. You heard Senator Roberts say we cannot use sticks, although I think some kind of a reduction in some areas, in some places, probably does make some sense, depending on how you do it. I apologize for rambling here.

But what ideas do you have for how we deal with those parts of the country where there is over-utilization, where there are an awful lot of doctors, an awful lot of procedures and so forth, and solve it in a way that is certainly fair to States where utilization is not quite as high and it is also fair to those States where it is very high. Any thoughts that you might have on how to begin to tackle that one? Dr. Orszag, I will start with you.

Dr. ORSZAG. I guess I would say that I agree with you, that the changes that will be necessary are going to be difficult to do, which may be one of the motivations for the kind of idea that you have floated for a Federal health board or some other decision-making possibility.

The CHAIRMAN. Right.

Dr. ORSZAG. But we cannot continue the existing system and perpetuating these inefficiencies. So I do not have the magic bullet for avoiding any pain or avoiding any political economy difficulties in the kinds of adjustments that gradually would be necessary, but I also do not see an alternative, which is the problem that we face.

The CHAIRMAN. I think you are right.

Dr. Hillestad?

Dr. HILLESTAD. Well, one thing that is potentially possible that tries to deal with both the quality issue and with the adoption issue, is a pay-for-performance type of incentive that pays physicians for measured performance. But that performance has to be measured with an electronic medical record system so that there is an incentive to adopt in order to get this pay-for-performance, and there is an incentive to do the right kind of performance to get the payment. That is another kind of incentive that I would suggest as an option.

The CHAIRMAN. All right.

Mr. Halvorson?

Mr. HALVORSON. I think there are two major spending streams in American health care: chronic care and acute care. Chronic care is about 75 percent of the cost. It needs to be a team sport. I think we should put in place care protocols, best practices, and tools that link the doctors with one another, and there should be a payment mechanism involved that includes either a penalty or a reward, either one, or a combination, for not using the linking mechanism.

I think on the acute care side, the 25 percent of the cost, we need to start putting out scorecards for patients and we need to start

building the database so that we know on knee surgery what the outcomes are, we know on cancer treatment what the survival rates are so patients can make informed choices. I think we need two pathways.

The CHAIRMAN. Are your efforts similar to those that I hear, like at Mayo, Cleveland, or other systems or not?

Mr. HALVORSON. Quite similar. Mayo and the Cleveland Clinic, Geisinger Clinic, quite a few clinics—almost all of the major multispecialty practices in the country are doing electronic medical records and are trying to coordinate the care for all of the patients that they have. Some of those clinics are focused on specialty care, and so we differ on this focus. But certainly we are doing very similar things and sharing information with each other.

The CHAIRMAN. All right.

Dr. Wilensky?

Dr. WILENSKY. It is easier for the people who are part of multispecialty clinics or full integrated groups like Kaiser. You need to worry about the vast majority of people who go to physicians that are part of small groups. You need to change physician reimbursement, to bundle payments so that physicians get paid for the care of diabetes, of another chronic disease, or multiple chronic diseases, an amount that will cover the cost of caring for the patient for the year.

You need to think about putting together all the costs associated with high-cost interventions like bypass surgery—either all of the physicians who take care of that patient get a single payment, or even extend it to the hospital to including the cost of it as well. You need to recognize that, if you effectively slow the rate of growth in spending, which we must do, the people who have been used to having a high growth in spending—physicians, industry, hospitals—are not going to like it.

The CHAIRMAN. Yes.

Senator Wyden?

Senator WYDEN. Mr. Chairman, do we have time for one additional question?

The CHAIRMAN. We certainly do, for you.

Senator WYDEN. You are great. Thank you very much.

I want to explore this question that Senator Baucus raised about the idea of a board. It also touches on what Dr. Orszag talked about with respect to political economy. I am not convinced that using a base-closing model will work for health care. Part of this discussion with respect to recommendations in the health care area almost seems to touch on that as the example for the way to go.

The reason I think it is different is that, in the base-closing kind of area, you got the sense that those were judgments that were really locally driven. People cared passionately about their base and they were going to fight like crazy for it, and they would be heard and the decision would be made.

The issues that we are talking about here are national in scope. Chairman Baucus just raised one of the most important ones, which is, how do we figure out a way to wring more efficiency out of the payment system and do it in a fashion that is going to be acceptable politically?

So, to get your sense, perhaps, Dr. Wilensky, because you have been in an administration—lots of us ask you for your advice from all political philosophies—how would you draw the line with respect to what, say, independent experts ought to be doing in terms of making recommendations to the Congress, and then what elected officials ought to be doing? Because I am trying to find a role that is satisfactory that incorporates both of those. I think Chairman Baucus's last question really touches on it. We have to figure out how to sort those two roles out.

Dr. Wilensky?

Dr. WILENSKY. The notion of an entity that would make decisions about clinical protocols that would have the force of law for either all public programs or for public and private programs, does not seem consistent with my view of what the American population will accept.

Getting information out that is regarded as untainted, reliable, valid, credible, in a center like the NIH—in the sense that its biomedical research is not regarded as tainted—will be very important. Providing guidance to the Medicare program, which is a Federal responsibility, about using that information to reimburse smarter, differentiate the co-payments, use value-based insurance, makes a lot of sense to me. That is a power that Medicare does not now have.

This means there are areas when it comes to public programs where information that is available to all payers, patients, and clinicians could be used to change reimbursement and, therefore, the incentives that now exist in addition to these broader changes.

There is so much that is unknown, and the "art" is still part of medicine. To have declaratory judgments made that affect the way medicine is provided outside of public programs, if that is the kind of regulatory function you are considering—which may be an extreme interpretation, more like Senator Salazar was thinking about—that to me is not the right function.

Having coordinated, integrated information so everybody does not have to re-learn what we know about clinical effectiveness and how it translates into clinical protocols, getting the colleges like ACC and STS involved, and other various experts, that is very important and that needs to be organized in a way so that it is not repeated by the public and private sector.

Senator WYDEN. Dr. Orszag, did you want to add anything to that?

Dr. ORSZAG. I am going to come back to what I said in my opening statement, which is that I think the key issues here are not just technical, but ones of a political economy. I mean, imagine the world that we heard about from Kaiser in which electronic health records are widely available and you can have electronic visits. I mean, who among us is not annoyed that we have to fill out those forms every time we go to a different doctor? I mean, personally, I am. I would love a system in which we did not have to do that, let alone the more advanced benefits that come from electronic visits and what-have-you.

So the question then becomes, we are stuck, and how do we jump? I do not have the answer to that, but I think we need to be very carefully thinking through ways in which we can get to where

we need to be, again underscoring that continuing on the same path is not a viable option because you will create a fiscal crisis at some point.

Senator WYDEN. Mr. Chairman, thank you.

The CHAIRMAN. Thank you all very much. This has been one of the more thoughtful, productive hearings we have had, and I deeply appreciate the time and attention that you all have devoted to the subject. Eventually we are going to be revisiting this, all of us together, many, many times. But thank you very, very much.

The hearing is adjourned.

[Whereupon, at 11:56 a.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

United States Senate — *Sen. Chuck Grassley · Iowa*
Committee on Finance — *Ranking Member*

http://finance.senate.gov
Press_Office@finance-rep.senate.gov

Opening Statement of Sen. Chuck Grassley
Committee Hearing: Right Care at the Right Time
Thursday, July 17, 2008

At our health care summit, I made the point that any reform we work on must address three areas. We must increase access for the uninsured. We must address the rate of increases in cost in health care. And we must improve the quality of care we provide. Today's hearing will allow us to focus on the challenge of improving the quality of care we provide in America.

In the April 2008 Dartmouth publication, *Tracking the Care of Patients with Severe Chronic Illness*, the researchers lead with a very stark statement: "In health care, it matters where you get your care." Their report found wide geographic variation in the frequency of primary care visits, visits to specialists and hospitalizations.

If you have a chronic condition, where you live has a significant bearing on the quality of care you receive. That shouldn't be the case. We have the tools to ensure that all Americans get the highest quality of care available. Two of the potential tools we will be discussing today are health information technology and comparative effectiveness. There is widespread agreement on the potential of health information technology to improve quality and control costs. If there was widespread adoption of this powerful tool, then most everyone would be getting the right care and the right time.

Health information technology will play a major role in moving the nation toward being able to compare treatments. If the nation can wire every hospital and every physician's office, it will be that much easier to see what treatments work and what do not work. It will also reduce duplicative testing and enable clinicians to share information about patients. While it is clear that electronic patient records will improve efficiency of health care delivery, the economics have not proven attractive to doctors.

They say that the systems are expensive to install, and that their practices suffer while they get used to having the electronic systems. Savings that result from increased efficiencies accrue to insurers and other payers, not to doctors. So we need to think about how to make adoption of electronic records more attractive to those who will use them.

The other tool we should more fully develop is the use of comparative effectiveness. When a provider makes a diagnosis, what treatment is the most effective? Doctors should not have to

operate in an information vacuum. Comparative effectiveness might also encourage those designing new drugs, devices, and treatments to come up with ones that improve care, and are not just "me too" products. I know there are concerns about comparative effectiveness studies being biased, or addressing the wrong populations. For example, what if a drug only worked on a certain type of people? And what if the study comparing its effectiveness didn't narrow it down to that group? Would the drug be determined to be less effective than another treatment?

Others suggest that by the time studies are done, a given drug or device might be outdated and replaced with something else. But there must be a way to account for these types of concerns in the design of an organization. It stretches belief to think that patients in the United States should continue to get health care without anyone really knowing what treatments work better than other treatments. We can do more to supply providers with updated research and information so they can provide the best care possible. Ultimately, I think that before we will see widespread adoption of electronic health records we will need to reform our payment structures to reward providing high quality care. Today's system merely rewards providers for more care, not better care. Until quality care is explicitly built into the business model and made part of the bottom line, then quality care will continue to get a lot of lip service but not as much action as it really needs. Of course, I'm talking about value-based purchasing, and I am looking forward to a future hearing on delivery system reform where we will explore the issue further.

Testimony of
George C. Halvorson
Chairman and Chief Executive Officer
Kaiser Foundation Health Plan and Kaiser Foundation Hospitals
Before the
Senate Finance Committee
U.S. Senate
July 17, 2008

Thank you for the invitation to be here today to discuss the role of health information technology in improving health outcomes. I am George C. Halvorson, Chairman and CEO of Kaiser Foundation Health Plan ("Health Plan") and Kaiser Foundation Hospitals ("Hospitals"). Health Plan and Hospitals, together with the contracting Permanente Medical Groups, constitute the Kaiser Permanente Medical Care Program. Kaiser Permanente is the nation's largest private integrated health care delivery system, providing comprehensive health care services to more than 8.7 million members in nine states (California, Colorado, Georgia, Hawaii, Maryland, Ohio, Oregon, Virginia, Washington) and the District of Columbia.

I am sad to say that health care in America is a disorganized, weakly coordinated, inadequately linked, $2.3 trillion care infrastructure[1] that is currently our country's fastest growing industry. It is an industry that will not be reformed without intervention by public policymakers and purchasers.

There is no incentive -- in fact, there is a disincentive -- for providers to adopt more coordinated and efficient approaches to care delivery.[2] Clinicians in America tend to operate in functional silos -- unlinked and unconnected to one another in any systematic, patient-focused way.

More than 75 percent of the health care costs in this country are attributable to patients with chronic conditions[3] -- and more than 80 percent of those costs come from patients with co-morbidities[4] -- patients who have more than one disease. Having more than one disease means having more than one doctor. Those doctors tend not to be linked with one another; most keep their medical information in separate paper

medical records systems. Too often they do not base important treatment decisions on consistent medical science.

Major studies show huge inconsistencies in care delivery across this country. For example, diabetics consume over 32 percent of the total costs of Medicare,[5] and reliable studies show that the U.S. health care infrastructure provides the right care for diabetics less than 10 percent of the time.[6]

What is missing? Why do we spend so much money for such inconsistent and inadequate results? We are missing critical linkages among clinicians and we are missing systematic, patient-focused care.

One key element of the solution is to have vertically linked clinicians functioning in teams to deliver care, supported by a secure electronic medical record (EMR) that gives each clinician the relevant information about each patient in real time at the point of care.

Another key element of the solution is to have special computer systems -- care registries -- that analyze data from the electronic medical record and give doctors and other clinicians reminders and prompts to recommend what the best scientific evidence and expert opinion would agree is necessary and optimal care for each patient.

Only a few places in this country will be able to achieve the full electronic medical record supported by an up-to-date care registry in the immediate future.[7] At Kaiser Permanente, we have made a significant investment in health information technology to provide the tools necessary for providers to deliver optimal care. In 2003, we began the KP HealthConnect™ project, the world's largest civilian deployment of an electronic health record. KP HealthConnect™ is a comprehensive health information system that includes one of the most advanced electronic health records available. It securely connects our 8.7 million members to their health care teams, their personal health information, and the latest medical knowledge, making possible the integrated approaches to health care available at Kaiser Permanente.

In April of this year, we completed implementation in every one of our 421 medical office buildings, ensuring that our 14,000 physicians and all other ambulatory caregivers have access to members' clinical information. In addition, we have completed the deployment of inpatient billing; admission, discharge, and transfer; and scheduling and pharmacy applications in each of our 32 hospitals. Now, we are in the midst of an aggressive deployment schedule of bedside documentation and computerized physician order entry (CPOE). As of today, we have 15 of our 32 hospitals fully deployed and will have 25 completed by the end of the year.

At Kaiser Permanente, we are already realizing the value of health IT. With secure 24/7 access to comprehensive health information, our care teams are able to coordinate care at every point of service - physician's office, laboratory, pharmacy, hospital, on the phone, and even online. Our early results demonstrate that health IT, as the Institute of

Medicine's *Crossing the Quality Chasm* report predicted, helps to make care safe, effective, patient-centered, timely, efficient, and equitable.[8]

To provide a few examples:

- Our use of IT and our comprehensive approach (partnership of primary care providers, cardiologists, nurses and pharmacists with accountability across the continuum of care - preventive, chronic, and acute) have significantly reduced emergency department visits and mortality.

- In Colorado, we've seen a 60 percent reduction in cardiac mortality versus historical KP data. Based on NCQA data as compared to the national HMO average, we prevent more than 280 cardiac events annually in Colorado and realize $2 million in hospital savings.[9]

- In Northern California, Kaiser Permanente patients have a 30 percent lower chance of dying of heart failure than members of the general population. The cost of heart disease and stroke in the United States is estimated at $450 billion in 2008, including direct medical costs and lost productivity from death and disability.[10] Improving the management of just this one chronic condition, we have the opportunity to make a real dent in quality, efficiency and overall spending.

- In Oregon and Washington, using KP HealthConnect™ in a new Regional Telephonic Medicine Center staffed with emergency room physicians and advice nurses, has led to an 11 percent reduction in the number of members who need to visit the emergency room between the hours of 12 noon and 10 p.m.

- In Southern California from 2004 to 2007, combining the power of our IT systems and our integrated delivery model, we were able to

increase mammography screening rates from 80 percent to nearly 90 percent in female members aged 50-69.

This last example was highlighted for me by a recent letter from a member that puts a human face on these statistics.

> Early last year, I came to your facility to have a foreign body removed from my eye. I visited your Ophthalmology Department and your competent staff dealt with this minor emergency.
>
> What made this visit so meaningful was my interaction with your nurse after my visit with the doctor. In addition to giving me some after visit instructions, she noticed in the computer that I needed a mammography exam. I had been reminded before but I tend to be too busy to take care of my own health. This time the nurse was very insistent. She even made me an appointment so I could walk in and get the exam within the hour. Since I did not have to wait too long, I had the exam done that day. Well, they found a mass in my right breast and it was cancer. I have gone through chemotherapy and radiation therapy and today I am cancer free.
>
> I am convinced that I am alive today because of your organization's focus on my total health. My interaction with your entire health care system has been nothing but positive. I am especially appreciative to the young nurse who took the time to convince a stubborn old lady to take responsibility for my health.
>
> Thank you for giving me many more years to thrive.

This letter describes a simple act by one of our nurses, but it was possible only because the nurse had access to that information, acted on it, and was part of an integrated health care system that encourages this series of events.

KP HealthConnect™ also allows us to share content across all of our regional facilities, providing the technical platform to provide drug formulary changes, best practice alerts and automated clinical guidelines to the entire enterprise. Our members can move through any facility within a given region and have their clinical and administrative information follow them.

As an example, during the 2007 wildfires in San Diego as Kaiser Permanente facilities within the fire lines were closed, members were contacted and directed to other open facilities. When they arrived, their new care teams had appropriate access to their records via KP HealthConnect™, ensuring continuity of care in the time of crisis.

What Kaiser Permanente and other multi-specialty groups such as Group Health Cooperative, Intermountain Healthcare and Geisinger can accomplish is to set the gold standard with a sophisticated electronic medical record and a fully integrated system. But the rest of the health care system is not vertically integrated and does not have appropriately aligned financial incentives. However, as a country, we can decide to move towards virtual integration and to create payment structures that reward good care, rather than the quantity of services delivered.

Most American patients will need another pathway to computer supported care. That second pathway is possible. We don't need algorithms for hundreds of diseases in order to transform care. We do need algorithms and support systems for the five chronic conditions (congestive heart failure, asthma, diabetes, coronary artery disease, and depression) and for the five percent of the total population who drive 50 percent of the care costs in this country.[11]

If we want care to get better for those patients, we need to insist that all chronic care patients with serious co-morbidities have their care supported by electronic care registries -- and that clinicians who choose not to interact with those registries should be financially affected by their decision.

What happens when care is fully supported by electronic panel support tools? The outcome improvements can be huge. We should set a national goal to decrease hospitalization for asthma patients by 50 percent. We should also reduce congestive heart failure crisis by 50 percent. We should reduce kidney failure by 50 percent.

The electronic medical record alone does not do the work. EMR is a great thing, but an EMR all by itself is not enough. The EMR must be supported by panel management tools that scan the data and give advice to clinicians about needed care.

At Kaiser Permanente, the results of combining those two support tools have exceeded our expectations. A year from now, as we continue to roll our pilot programs out more broadly, I will have another set of outcomes to share.

My advice for you today is this: Our nation's current non-system - depending on siloed and separate paper medical records and providing perverse financial incentives that directly reward sub-optimal care and discourage efficiency -- will never reform itself. It will also never magically become a "system."

We need to focus on the areas of the greatest potential - and we need to put computerized support systems in place as soon as that work can be done.

Thank you again for the opportunity to be here, and I look forward to your questions.

Endnotes

[1] Centers for Medicare and Medicaid. National Health Expenditure (NHE) "Amounts by Type of Expenditure and Source of Funds: Calendar Years 1965-2017." http://www.cms.hhs.gov/NationalHealthExpendData/25_NHE_Fact_Sheet

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[3] U.S Centers for Disease Control and Prevention. "Chronic Disease Overview," Nov. 2005. http://www.cdc.gov/nccdphp/overview.htm#2.

[4] Partnership for Solutions, "Chronic Conditions-Making the Case for Ongoing Care," September 2004 update, Johns Hopkins University. 2004

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TESTIMONY

The Potential Benefits and Costs of Increased Adoption of Health Information Technology

RICHARD HILLESTAD

CT-312

July 2008

Testimony presented before the Senate Finance Committee on July 17, 2008

Richard Hillestad, Ph.D.[1]
The RAND Corporation

The Potential Benefits and Costs of Increased Adoption of Health Information Technology[2]

Before the Committee on Finance
United States Senate

July 17, 2008

Chairman Baucus, Ranking Member Grassley, and members of the Committee on Finance, I am honored to have the opportunity to testify before you today about the potential benefits and costs of broader adoption and effective use of Health Information Technology (or HIT).

In this testimony, I will use HIT to include an electronic medical record that replaces the paper medical record and includes such associated functions as clinical decision support for facilitating evidence-based medicine, patient tracking and reminders for preventative services, computerized physician order entry to facilitate prescribing and other physician orders, and electronic connectivity of providers (and, in some cases, among providers and patients).

I applaud the committee for including HIT as a component of getting the right care at the right time. Better health care information at the point of care, evidence-based decision support, and continuity of care across providers in time and location are some of the important promises of HIT. IT has transformed much of what we do in other domains—travel, banking, and telecommunications, for example—but despite the fact that health care is one of the largest information-intensive enterprises we know, HIT adoption in the United States is low. The health records for most people are still stored on paper, and the provider-to-provider transfer of information about a patient is still most often done by phone or fax. The questions are, then, what are the potential benefits and costs of increasing the adoption of HIT and if such adoption is worth it on balance, what actions might improve the progress of adoption?

My testimony today covers three main areas: (1) how HIT might transform care and reduce costs; (2) our estimates of the potential savings and costs if HIT is widely adopted and done right; and (3) some of the important disincentives to achieving the benefits along with possible government actions to reduce such barriers. First, what is the possible role of HIT in improving health care?

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[1] The opinions and conclusions expressed in this testimony are the author's alone and should not be interpreted as representing those of RAND or any of the sponsors of its research. This product is part of the RAND Corporation testimony series. RAND testimonies record testimony presented by RAND associates to federal, state, or local legislative committees; government-appointed commissions and panels; and private review and oversight bodies. The RAND Corporation is a nonprofit research organization providing objective analysis and effective solutions that address the challenges facing the public and private sectors around the world. RAND's publications do not necessarily reflect the opinions of its research clients and sponsors.

[2] This testimony is available for free download at http://www.rand.org/pubs/testimonies/CT312/.

The Hope for Information Technology in Health Care—Efficient, Effective, and Consistent Health Care

The hope of many is that the broad adoption of HIT systems with the aforementioned functionality in the United States will transform health care in terms of making it more efficient and effective simultaneously. Efficiency would be enhanced by reduced test duplication, improved drug utilization, better scheduling, reduced paper record handling, and improved claims processing and billing. Effectiveness would be enhanced by reduced errors (reduced handwriting-based errors, for example), reminders to improve preventative care, decision support for better evidence-based practice, improved management of chronic illness, and improved continuity of care for those patients seeking care away from their primary provider (such as was needed to support the mass evacuation that occurred after Hurricane Katrina). Effectiveness would also be enhanced by the quality of care assessment such systems would make possible and by improvements in the evidence base for best practices derived from the analysis of large electronic medical record databases.

But we are a long way from the broad adoption of HIT. Our own estimates of the adoption of HIT systems in the United States in 2005 indicated that about 20–25 percent of hospitals and 10–15 percent of physician offices had adopted systems that could perform at least some of the functions I just described. More recent estimates indicate that hospital-based adoption has improved but that the functionality of many of the adopted systems remains limited and that there has been relatively little change in physician adoption of HIT. Most important, only about 4 percent of physicians have HIT systems with some of the supporting functions mentioned earlier.

The Potential Benefits and Costs of Broad Adoption of HIT in the United States

The RAND study of HIT[3] (begun in 2003 and published in 2005) estimated the potential benefits and costs of a much broader adoption and effective use of HIT systems. To deal with the limited evidence of savings and health benefits at that time, we developed models to extrapolate this evidence assuming 90 percent adoption, interoperability across providers, and related health care process changes, such as restructured hospital and physician office workflow, increased

[3]Richard Hillestad, J. Bigelow, A. Bower, F. Girosi, Robin Meili, Richard Scoville, and Roger Taylor, "Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Costs," *Health Affairs*, Volume 24, Number 5, September/October 2005; Anthony Bower, *The Diffusion and Value of Healthcare Information Technology*, MG-272-1-HLTH, Santa Monica, CA: RAND, 2004; James H, Bigelow et al., *Analysis of Healthcare Interventions That Change Patient Trajectories*, MG-408-HLTH, Santa Monica, CA: RAND, 2005; Katya Fonkych and Roger Taylor, *The State and Pattern of Health Information Technology Adoption*, MG-409-HLTH, Santa Monica, CA: RAND, 2005; Federico Girosi, Robin Meili, Richard Scoville, *Extrapolating Evidence of Health Information Technology Savings and Costs*, MG-410-HLTH, Santa Monica, CA: RAND, 2005.

preventative interventions, and aggressive team care for chronic disease. Our estimates were not best-case estimates because we used a range of evidence for each effect. However, they were also not worst-case estimates either because we did not include some negative effects. With respect to these negative effects, some papers reported some increased errors as a result of the introduction of computerized physician order entry. We assumed that these errors would decrease either because of improvements in the systems or because the systems that induced such errors would not proliferate.

Please bear in mind that our projections show the potential benefits and costs at a 90 percent adoption level and that this level might not be reached for 10–15 years based on the historical adoption rate of complex technology and the current adoption pattern of HIT. Also, the potential savings we calculate are spread among stakeholders—insurers or payers, providers, and individuals—so such savings are not necessarily savings the government might realize from programs to enhance the adoption of HIT.

Using our models, we estimated that the efficiency savings enabled by HIT could reach approximately $80 billion per year at the 90 percent adoption level for hospitals and physicians. In turn, we estimated the costs to achieve those efficiency savings in 15 years would average about $8 billion per year or $120 billion total. These costs include software licenses, hardware and its maintenance, planning, training and implementation, and the reduced revenue or increased provider costs during implementation. During the 15-year adoption period, the cumulative net savings would be about $510 billion or approximately $34 billion per year. To put these potential savings in perspective, $80 billion is 4 percent of the annual $2 trillion cost of health care in the United States.

About 75 percent of the potential efficiency savings are associated with hospitals and 25 percent are associated with physician offices. In hospitals, the major savings would come from improved scheduling and shorter patient stays, reduced nursing administrative time, savings in chart administration, and better laboratory and radiology utilization (reduction in duplicate tests, for example). In physician office settings, the savings would be in drug utilization, chart administration, more efficient patient scheduling, and better laboratory and radiology utilization. We did not estimate possible savings from billing and claims administration, but we would expect those to be substantial. Furthermore, we also did not estimate possible process improvements that might further improve quality and reduce costs and that have been typical consequences of IT introduction in other industries. (Just-in-Time inventory management and Toyota's quality improvement processes are examples.) Thus, while our estimates do indicate significant potential efficiency savings, we do not consider our estimates to be overly optimistic.

Turning to effectiveness, potential safety benefits include avoiding as many as 2.2 million adverse drug events per year and their associated costs of $4 billion per year. The improved safety derives from reduced errors from handwriting, better allergy warnings and warnings of drug-drug interaction because of the completeness and accessibility of the electronic medical record, and better dosage monitoring. Because most prescribing occurs in physician offices, the magnitude of this benefit depends heavily on physician adoption of HIT.

About 75 percent of the national health expenditure is on chronically ill patients. HIT should enable substantial improvements in managing chronic illness. What is needed in this case is better coordination and communication across providers dealing with the multiple health impacts of a chronic illness. It also involves substantial patient screening, monitoring, and involvement. Linked HIT provides a way to coordinate support, monitor patients, and involve the patient in an effective team of care. We simulated such improved chronic illness management for four chronic illnesses[4] and found the benefits from life style change, prevention, and better management of chronic illness could be 20 million fewer inpatient days, 5 million fewer emergency department visits, 9 million fewer office visits, and 20 million added workdays per year. We did not estimate cost savings from such healthier patients because it is not always true that reducing the incidence of a disease reduces health care costs—in fact, costs can go up or down depending on the effect on longevity and the occurrence of other diseases.

We estimated the costs to move hospitals and physician offices from their levels of adoption in 2005 to 90 percent adoption in 15 years to be about $120 billion—$100 billion for hospitals and $20 billion for physician offices. These costs were estimated using the actual real costs of systems being implemented for physicians and hospitals and include the costs of planning and implementation, practice disruption, software, maintenance, and training.

Barriers to HIT Adoption and the Possible Role of Government

Given the potential efficiency and effectiveness savings and benefits relative to costs, it may seem surprising that the health care system has been so slow to adopt HIT. However, there are a number of significant disincentives to adoption, the primary one being what can be called a "market failure": Those who must purchase the systems (the providers—hospitals and physicians) are not the same ones receiving most of the savings (the payers) or the health benefits (the patients). Our simulation of HIT-based chronic disease management is a good example. Better management led to fewer acute episodes of the illness, which, in turn, produced significantly fewer physician office and hospital emergency department visits. Doing this reduced payer costs and produced a

[4]Diabetes, asthma, congestive heart failure, and chronic obstructive pulmonary disease.

healthier patient, but it also reduced physician and hospital revenue for those patients and diseases. Looking at the other savings we estimated for HIT—reduced duplication of tests, reduced length of hospital stay, better drug utilization, etc.—we can see that most of the benefits are likely to go to the payers and that there is little financial incentive for the physicians and hospitals to pay the costs and undergo the disruption of HIT implementation. This market failure is a key indicator of the need for government intervention.

There is a second important issue about adoption. Current evidence is that the larger, better-endowed hospitals and physician practices are adopting HIT at a significantly higher rate than smaller, lesser-endowed hospitals and physician practices. The effect of this uneven adoption in the rate of adoption could be to increase disparities in health care. Those patients served by small offices or hospitals in rural areas or those patients seeking health care in disadvantaged urban regions might be less likely to receive the benefits of HIT-enabled health care, thus leading potentially to increases in regional health disparities as a result of this uneven adoption.

Overcoming these disincentives to adoption may require subsidies. This does not necessarily imply the outright purchase of the HIT systems for providers, but it could involve a pay-for-use incentive that compensates the physician or hospital on a per-encounter basis for the use of the HIT system. We modeled the effects of a time-limited subsidy for physicians—a per-encounter payment of $1.50 for three years—and found that under reasonable assumptions about price elasticity, if such a subsidy were done early enough, it could increase the adoption and dramatically leverage the subsidy dollar. In this case, the cost of the subsidy was about $2 billion over the three years and the value of the incentive over 15 years (based on the potential HIT savings previously described) would be about $16 billion.

There may be other ways to incentivize the adoption of HIT. The institution of a pay-for-performance process that requires an electronic medical record system to measure and report the provider performance on quality of care measures—such as the appropriate ordering of screening services or the ordering of needed treatments—would provide an indirect incentive and would also place more attention on the quality of care delivered. However, this approach may also require more advanced HIT systems to be adopted to capture all the appropriate contextual information to judge quality of care.

The payers who, as I have described earlier, reap most of the projected savings of the HIT systems might be the most appropriate parties to provide subsidies. Medicare, being the largest payer, could provide significant leadership for such actions. Subsidies might also be targeted to smaller offices and hospitals and to those serving disadvantaged populations to avoid exacerbating disparities in care because of uneven adoption of HIT.

The last issue I'd like to discuss is the difficulty of connecting the provider-based HIT systems into a network of interoperable systems supporting a patient's care wherever and whenever it is needed. Although the technology exists to do this and the national coordinator of HIT in the Department of Health and Human Services has taken important steps toward developing standards and making systems interoperable, there remain important barriers to achieving the desired interoperability. First, there is a market disincentive. The infrastructure to support interconnection includes managing master patient identification lists across providers, managing interfaces between systems, and administratively managing the network. Ideally, the funding for this would come from the users, but except for large health care systems that are under single ownership, there is little market incentive for users to share patient data with others in the network or to fund the network administration. Some early attempts to create interconnected health care networks, such as the Santa Barbara Care Data Exchange, have not succeeded once the original seed money from foundations or the government has been expended. We know there are demonstration experiments going on to understand possible financial models, but this is an area in which government action or subsidy may be needed.

Second, privacy is another concern and barrier to interconnection of HIT. This is a subject much bigger than what we can accommodate in this testimony, but we note that concern about the protection of the privacy of personal health care information is also a significant barrier to the seamless flow of patient information across the health care system. Current privacy and security protections appear to be inadequate for a national health information network and must be enhanced as the health care system becomes digitized and interconnected. An important government role will be to establish the privacy protocols that permit the networking of health information.

In closing, I have described in this testimony some of the important potential benefits of HIT in the current health care system and discussed some of the important barriers to adoption and interconnection of HIT systems. However, it is important to note that the broad adoption of HIT systems and connectivity should be considered necessary but not sufficient steps toward real health care transformation that delivers efficient and effective care at the right time. For example, the adoption of HIT systems in conjunction with comparative performance reporting could enable the development of value-based competition and quality improvement to drive transformation. We do not know what changes should or will take place after widespread HIT adoption, but it seems clear that a lengthy and uneven adoption of HIT systems that do not interoperate is likely to delay the opportunity to move closer to a transformed health care system. The government and other stakeholders have an important stake in not letting this happen. Thank you.

Congressional Budget Office

Testimony

Statement of
Peter R. Orszag
Director

The Overuse, Underuse, and Misuse of Health Care

before the
Committee on Finance
United States Senate

July 17, 2008

This document is embargoed until it is delivered at 10:00 a.m. (EDT) on Thursday, July 17, 2008. The contents may not be published, transmitted, or otherwise communicated by any print, broadcast, or electronic media before that time.

CONGRESSIONAL BUDGET OFFICE
SECOND AND D STREETS, S.W.
WASHINGTON, D.C. 20515

Mr. Chairman, Senator Grassley, and Members of the Committee, I appreciate the opportunity to appear before you to discuss the importance of getting the right health care to the right patient at the right time—and the existing evidence about how frequently that objective goes unrealized. The breadth and scope of those topics are such that they are not amenable to comprehensive analysis in a single testimony, so I would like to focus today's remarks on several key points:

- Rising health care costs represent the central fiscal challenge facing the country, exerting a larger influence on the long-term fiscal balance than other commonly cited concerns such as the aging of the population.

- Spending for health care varies substantially across the United States, mostly because of variation in the intensity of services provided, but Medicare enrollees in areas with higher spending do not appear to have better health outcomes on average than those in areas with lower spending. Those observations suggest that substantial opportunities exist to reduce costs without harming health overall, but capturing those opportunities will be technically challenging to bring about through changes in policy and may also prove to be controversial.

- Expanded use of health information technology (IT) has the potential to improve the quality and efficiency of the care that patients receive, but realizing that potential would require broader changes in the health care system (including, especially, changes in the financial incentives for doctors).

- One reason that the most appropriate care is not always provided is that, for many conditions, the evidence is limited about which treatments work best for which patients and whether the benefits of more expensive therapies warrant their additional costs. More information about the comparative effectiveness of medical treatments would help to address that problem, especially if the findings were linked to Medicare's payment rates or cost-sharing requirements.

- A growing body of research on behavioral economics suggests that, in addition to financial incentives, norms and default options can exert a strong influence on individuals' choices. Such findings could inform efforts to improve efficiency in the health sector.

- Given the importance of health care issues, the Congressional Budget Office (CBO) is devoting increasing resources to that topic. As part of its effort, CBO is in the process of analyzing a number of options that could improve the efficiency of health care delivery and possibly reduce geographic variation in Medicare spending—including greater bundling of payments and stronger incentives to provide effective care—and plans to release the results of its analysis by the end of the year.

Background on Health Care Spending and Inefficiency

The most important factor influencing the federal government's long-term fiscal balance is the rate of growth in health care costs. CBO projects that, without any changes in federal law, total spending on health care will rise from 16 percent of gross domestic product (GDP) in 2007 to 25 percent in 2025 and 49 percent in 2082; net federal spending on Medicare and Medicaid will rise from 4 percent of GDP to almost 20 percent over the same period.[1] Many of the other factors that will play a role in determining future fiscal conditions over the long term—including the actuarial deficit in Social Security and a decision about extending the 2001 and 2003 tax laws past their scheduled expiration in 2010—pale by comparison with the impact and challenges of containing growth in the cost of federal health insurance programs.

Concerns about the level and growth of health care costs in this country might be less prominent if it was clear that the spending was producing commensurate gains in health, but substantial evidence suggests that more expensive care does not always mean better care. Although many treatments undoubtedly save lives and improve patients' health—and the aggregate benefits from health care spending probably exceed the costs—evidence also indicates that much spending is not cost-effective and in many cases does not even improve health. Indeed, recent studies have highlighted three types of shortcomings in the quality of care that people receive, each of which may constitute a form of inefficiency:

- **Overuse.** Overuse occurs when a service is provided even though its risk of harm exceeds its likely benefit—that is, when it is not warranted on medical grounds. A more expansive definition would include cases in which the added costs of a more expensive service did not exceed the added benefits it was expected to provide. A number of studies have found, on the basis of after-the-fact reviews by independent panels of doctors, that a sizable share of certain surgeries were performed despite their being clinically inappropriate or of equivocal value; those findings held true under various types of insurance plans.[2]

- **Underuse.** At the same time that some services are overused, others do not get provided even though they would have been medically beneficial. One recent study found that Medicare enrollees frequently did not receive care that was recommended or deemed appropriate; another study, which examined a broader population, found that patients typically received about half of recommended services, whether for preventive care, treatment of acute conditions, or treatment of chronic conditions.[3]

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2. See Elizabeth A. McGlynn, "Assessing the Appropriateness of Care: How Much Is Too Much?" RAND Research Brief (Santa Monica, Calif.: RAND, 1998), available at www.rand.org/pubs/research_briefs/RB4522.

3. See Stephen F. Jencks, Edwin D. Huff, and Timothy Cuerdon, "Change in the Quality of Care Delivered to Medicare Beneficiaries, 1998–1999 to 2000–2001," *Journal of the American Medical Association,* vol. 289, no. 3 (January 15, 2003), pp. 305–312; and Elizabeth A. McGlynn and others, "The Quality of Health Care Delivered to Adults in the United States," *New England Journal of Medicine,* vol. 348, no. 26 (June 26, 2003), pp. 2635–2645.

- **Misuse.** That term includes incorrect diagnoses as well as medical errors and other sources of avoidable complications (such as infections that patients acquire during a hospital stay). Over the past decade, the Institute of Medicine has issued several reports documenting the extent of medical errors and their consequences. Recently, Medicare has stopped paying for what are termed "never events"—mistakes such as operating on the wrong body part. The range of avoidable errors is undoubtedly larger, but other types may be more difficult for an insurer to identify.

Geographic Variation in Spending for Health Care

Perhaps the most compelling evidence suggesting inefficiency in the health sector is that per capita health care spending varies widely within the Medicare program, and yet that variation is not correlated with measures of the quality of care or health outcomes overall. In 2004, for example, Medicare spending per beneficiary ranged from about $5,600 in South Dakota to about $8,700 in Louisiana. Yet a comparison of composite quality scores for medical centers and average Medicare spending per beneficiary shows that facilities in states with high average costs are no more likely to provide recommended care for some common health problems than are facilities in states with lower costs (see Figure 1); if anything, it would appear that the opposite might be true. (For the country generally, health care spending per capita also varies widely, ranging from roughly $4,000 in Utah to $6,700 in Massachusetts in 2004, but the connection between that variation and health outcomes has not been examined as closely. In addition, Medicaid spending per enrollee also varies considerably among states.)

The observed variations in Medicare spending per enrollee are even greater when examined by the region in which enrollees generally get their hospital care (see Figure 2)—but a link between higher spending and better health is still hard to discern. In 2005, average costs ranged from about $5,200 in the areas with the lowest spending to nearly $14,000 in the areas with the highest spending (those averages were adjusted to account for differences in the age, sex, and race of Medicare beneficiaries in the various areas). According to one study, higher-spending regions did not have lower mortality rates than lower-spending regions, even after adjustments were made to control for different rates of illness among patients and in various regions.[4] That study also found that higher spending did not slow the rate at which the elderly developed functional limitations (reflecting their difficulties in taking care of themselves).

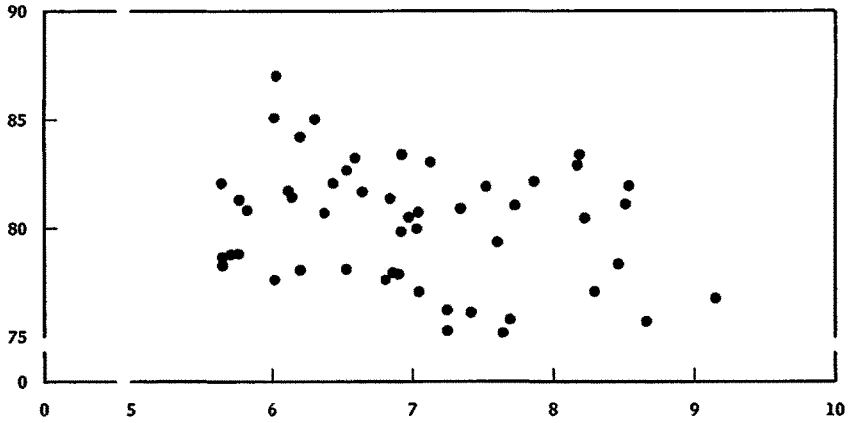
Other studies of spending variation reach somewhat different conclusions, even though they also suggest opportunities to improve the efficiency of the health sector. For example, some research suggests that health overall might not suffer in the process

4. Elliott S. Fisher and others, "The Implications of Regional Variations in Medicare Spending, Part 2: Health Outcomes and Satisfaction with Care," *Annals of Internal Medicine*, vol. 138, no. 4 (February 18, 2003), pp. 288–298.

Figure 1.

The Relationship Between Quality of Care and Medicare Spending, by State, 2004

(Composite measure of quality of care, 100 = maximum)



Source: Congressional Budget Office based on data from the Centers for Medicare and Medicaid Services and from Department of Health and Human Services, Agency for Healthcare Research and Quality, *National Healthcare Quality Report, 2005* (December 2005), Data Tables Appendix, available at www.ahrq.gov/qual/nhqr05/index.html.

Notes: The composite measure of the quality of care, based on Medicare beneficiaries in the fee-for-service program who were hospitalized in 2004, conveys the percentage who received recommended care for myocardial infarction, heart failure, or pneumonia.

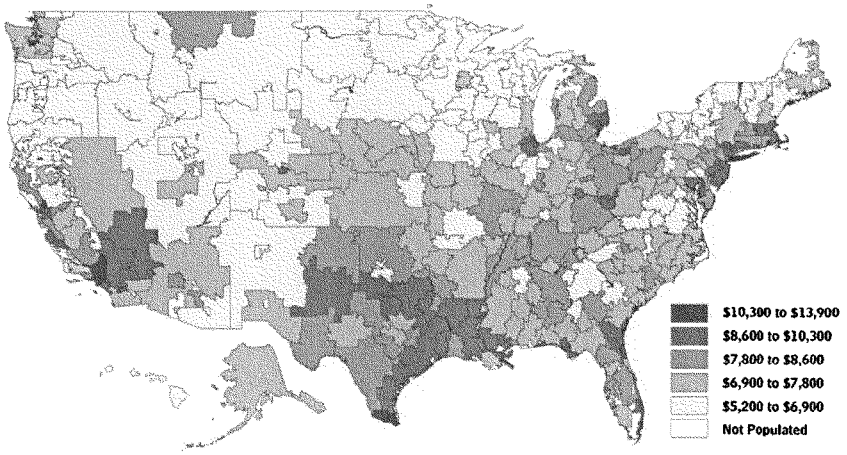
Spending figures convey average amounts by state.

of changing medical practice to match that of lower-cost regions but that patients who would benefit most from more expensive treatments might be made worse off as a result, while patients who would do better with less expensive treatments would gain.[5] Other, older studies of geographic variation indicate that there may be room to reduce spending without harming health in both high-use and low-use areas of the country, because, in both types of regions, a large share of certain surgeries were found to be clinically inappropriate or of equivocal value.

5. See Amitabh Chandra and Douglas Staiger, "Productivity Spillovers in Health Care: Evidence from the Treatment of Heart Attacks," *Journal of Political Economy*, vol. 115, no. 1 (2007), pp. 103–140; and Mary Beth Landrum and others, "Is Spending More Always Wasteful: The Appropriateness of Care and Outcomes Among Colorectal Cancer Patients," *Health Affairs*, vol. 27, no. 1 (January/February 2008), pp. 159–168.

Figure 2.

Medicare Spending per Beneficiary in the United States, by Hospital Referral Region, 2005



Source: Congressional Budget Office based on data from the Centers for Medicare and Medicaid Services.

Note: The data are for Medicare spending per beneficiary in the fee-for-service program, adjusted for age, sex, and race. The geographic unit is the hospital referral region, as defined by the Dartmouth Atlas of Health Care. Areas labeled "Not Populated" include places such as national parks, forests, lakes, and islands.

What factors contribute to geographic variation? Some of the differences in spending reflect varying rates of illness as well as differences in the prices that Medicare pays for the same service (which are adjusted on the basis of local costs for labor and equipment in the health sector). But according to researchers at Dartmouth, differences in illness rates account for less than 30 percent of the variation in spending among areas, and differences in prices can explain another 10 percent—indicating that more than 60 percent of the variation is due to other factors.[6] Differences in income or the preferences of individuals for specific types of care appear to explain little of the variation in spending. Unmeasured differences in the demand for care could be important, but some of the variation in medical practice probably is attributable to regional differences in the supply of medical resources (specialist physicians or health care facilities, for example) and the propensity to take advantage of the financial incentives provided by Medicare or other payers in developing and using those resources. Overall, patterns of treatment in high-spending areas tend to be more intensive than those in low-

6. See John E. Wennberg, Elliott S. Fisher, and Jonathan S. Skinner, "Geography and the Debate Over Medicare Reform," *Health Affairs*, Web Exclusive (February 13, 2002), pp. w96–w97.

spending areas. That is, in high-spending areas, a broader array of patients will receive costly treatments.[7]

How much could spending be reduced? Some analysts have estimated that if spending in high- and medium-cost areas was reduced to the level seen in the lowest-cost areas, Medicare spending would be reduced by as much as 30 percent.[8] Achieving such savings by eliminating only inappropriate and unnecessary care, however, presents substantial technical and policy challenges.

The Potential and Limitations of Health Information Technology

Health information technology has the potential to significantly increase the efficiency of the health sector by helping providers manage information. In particular, electronic health records—comprising electronic documentation of providers' medical notes, electronic viewing of laboratory and radiological results, electronic prescribing of medications, and an interoperable connection among providers of health care—could have a significant impact on medical practice. When used effectively, electronic health records could reduce the duplication of diagnostic tests; remind physicians about appropriate preventive care; identify harmful drug interactions or possible allergic reactions to prescribed medicines; and help physicians manage the care of patients with complex chronic conditions.

The most auspicious examples of health IT have tended to involve relatively integrated health care systems. Such systems typically involve a hospital network or a health plan that owns the hospitals that provide most care to enrollees, with doctors and other providers who work exclusively for the organization (either for a salary or under contract). In such systems, any savings that are generated by health IT at most points in the process of delivering care would be captured. A number of integrated delivery systems, including Kaiser Permanente, Intermountain Healthcare, Geisinger Health System, and Partners HealthCare, have implemented electronic health records either across their organizations or in some regions, and officials of those systems believe that the efficiency and quality of the care they provide have improved as a result.

For providers and hospitals that are not part of integrated systems, however, the benefits of health IT are not as easy to capture, and perhaps not coincidentally, those physicians and facilities have adopted electronic health records at a much slower rate. Office-based physicians in particular may see no benefit if they purchase such a product—and may even suffer financial harm. Even though the use of health IT could generate cost savings for the health system as a whole that might offset the start-up

7. For further discussion, see Congressional Budget Office, *Geographic Variation in Health Care Spending* (February 2008).

8. See Wennberg, Fisher, and Skinner, "Geography and the Debate Over Medicare Reform."

and operating costs involved, many physicians might not be able to reduce their own office expenses or increase their own revenue sufficiently to pay for it. Despite the potential gains from health IT, relatively few providers have adopted it—about 12 percent of physicians and 11 percent of hospitals as of 2006.

The bottom line is that research does indicate that, in certain settings, health IT appears to facilitate reductions in health spending if other steps in the broader health care system are also taken to alter incentives to promote savings. By itself, however, the adoption of more health IT is generally not sufficient to produce significant cost savings.[9]

Comparing the Effectiveness of Medical Treatments

Two potentially complementary approaches to reducing total spending on health care and increasing its efficiency involve generating more information about the relative effectiveness of medical treatments and changing the incentives for providers and consumers of health care. Those steps would address two shortcomings of the U.S. health care system. First, experts in the medical research community report that, for many serious medical conditions, there is surprisingly little hard scientific information about which treatments work best for which patients or whether the benefits of more expensive therapies warrant their additional costs. As a result, treatment choices often depend not only on the experience and judgment of the physicians involved but also on anecdotal evidence and local practice norms. At least in some cases, that method of making decisions does not yield the most effective treatment. Although estimates vary, some experts believe that less than half of all medical care provided in the United States is based on or supported by firm evidence of effectiveness.

Second, the financial incentives for both providers and patients tend to encourage the adoption of newer, more-costly services even in the absence of clear evidence establishing that those services are superior to cheaper, proven alternatives. For doctors and hospitals, those incentives stem largely from fee-for-service reimbursement, which encourages providers to deliver a given service efficiently but also creates an incentive to supply additional or more expensive services—as long as the payment exceeds the costs. Insured patients, for their part, generally pay only a portion of the costs of their care and, consequently, have only limited financial incentives to seek lower-cost treatments; that trade-off is inherent in insurance protection. Private health insurers have some incentive to limit the use of ineffective care but may lack information about which treatments work best for which patients and may be reluctant to be seen as limiting the treatment choices of physicians and patients. For its part, the Medicare program lacks clear legal authority to take costs into account in determining which services are covered and has made only limited use of the available data on relative effectiveness in setting payment amounts.

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9. For further discussion, see Congressional Budget Office, *Evidence on the Costs and Benefits of Health Information Technology* (May 2008).

Analysis of "comparative effectiveness" is simply a comparison of the impact of different options that are available for treating a given medical condition for a particular set of patients. Such studies may compare similar treatments, such as competing drugs, or they may analyze very different approaches, such as surgery and drug therapy. The analysis may focus only on the relative medical benefits and risks of each option, or it may go on to weigh both the costs and the benefits of those options. In some cases, a given treatment may be found more effective for all types of patients, but more commonly a key issue is determining which specific types would benefit most from it.

Such research can also be pursued in various ways, ranging from systematic reviews of previous findings to clinical trials—and one significant potential benefit of health IT that has thus far gone relatively unexamined involves its role in facilitating such research. Widespread use of health IT could make available large amounts of data on patients' care and health, which could be used for empirical studies that might not only improve the quality of health care but also help make the delivery of services more efficient. By making clinical data easier to collect and analyze, health IT systems could support rigorous studies to compare the clinical effectiveness and cost of different treatments for a given disease or condition—without having to incur the expense of full-scale clinical trials. Then, in response to the studies' findings, those systems could aid in implementing changes in the kinds of care provided and the way those services were delivered, and they could be used to track progress in carrying out the changes.

To affect medical treatment and reduce health care spending, the results of comparative effectiveness analyses would ultimately have to change the behavior of doctors and patients—that is, to get them to use fewer services or less intensive and less expensive services than are currently projected. Bringing about those changes would probably require action by public and private insurers to incorporate the results into their coverage and payment policies in order to affect the incentives for doctors and patients. Making such changes to the Medicare program would require legislative authority; private insurers would not face the same constraint but might be reluctant to take such action if Medicare did not do so. Because those steps would probably be controversial, some proposals would establish an independent agency—sometimes referred to as a federal health board—that could be given authority to implement those decisions (see Box 1).

Although insurers could choose not to cover drugs, devices, or procedures that were found to be less effective or less cost-effective, they would have a number of additional options as well. They could adjust payments to doctors and hospitals to encourage the use of more-effective care. Alternatively, insurers could require enrollees to pay some or all of the additional costs of more expensive treatments that were shown to be less effective or less cost-effective (in which case enrollees would have to decide whether the added benefits were worth the added costs). Indeed, some recent proposals call for a "value-based" design of insurance, which encourages the use of services when the clinical benefits exceed the costs and likewise discourages the use of services when the

benefits do not justify the costs. Although insurance plans generally vary cost sharing by the type of service provided, that new approach would be tailored to the patient and the treatment.[10]

Behavioral Economics and Efficiency Improvements

What else could be done to improve the efficiency with which health care is delivered—and specifically to reduce the delivery of services with little or no value? In health care, the vast majority of decisions are heavily influenced by doctors and other medical professionals. Restraining cost growth will therefore primarily require changing their choices.

Like other people, doctors tend to follow professional norms of behavior. There are a number of reasons for that tendency—not following professional norms may be a more difficult and time-consuming way to practice and may be perceived to help defend against charges of malpractice. The problem is that the professional norms in different parts of the nation do not always follow evidence-based standards of best practice. Indeed, the regional pattern of health care delivery (apparent in Figure 2) probably reflects, at least in part, differences in norms of practice among doctors. Professional norms may differ by locality because colleagues in the area may have a disproportionate influence and because a tendency to favor the status quo may make norms slow to change in the face of new evidence.

How can norms be shifted? Anesthesiology provides one example of a success story in putting evidence-based standards into practice. In the mid-1980s, after analyzing the most common sources of errors, the American Society of Anesthesiologists promulgated standards of optimal practice (both in procedures and in equipment design).[11] Providers had an incentive to follow the standards because deviations from them made the imposition of malpractice liability more likely. After the standards were adopted, mortality rates fell to about 5 per million encounters, as compared with averages above 100 per million during earlier periods.[12] Thus, aggressively promulgated standards backed by some incentives can alter a long-standing and suboptimal status quo.

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10. For further discussion, see Congressional Budget Office, *Research on the Comparative Effectiveness of Medical Treatments: Issues and Options for an Expanded Federal Role* (December 2007).

11. See Jeffrey B. Cooper, "Getting Into Patient Safety: A Personal Story," *AHRQ WebM&M: Morbidity and Mortality Rounds on the Web* (Agency for Healthcare Research and Quality, August 2006), available at www.webmm.ahrq.gov/perspective.aspx?perspectiveID=29.

12. See David A. Hyman and Charles Silver, "You Get What You Pay For: Result-Based Compensation for Health Care," *Washington and Lee Law Review,* vol. 58, no. 4 (Fall 2001), pp. 1427–1490.

Box 1.

Considerations in Establishing a Federal Health Board

One proposal that has received attention recently would create some type of federal health board; for example, Senator Baucus and Federal Reserve Board Chairman Bernanke expressed interest in that idea during the Finance Committee's recent summit on health care reform.[1] The Congressional Budget Office is in the process of producing a report on options for structuring such a board.

The basic purpose of the board would be to serve as an expert, independent entity with the goals of containing costs and maximizing quality in federal health programs generally and in Medicare in particular.

One role could be to evaluate research on the comparative effectiveness of medical treatments. Such research could help to improve the efficiency of federal health care programs, but applying its results to Medicare's coverage or payment policies would require substantial technical knowledge and would be controversial—involving transition costs and trade-offs that could leave some stakeholders worse off.

The board could be structured in a number of ways. One often cited institutional analog is the Federal Reserve Board, which has substantial insulation from political pressures in setting U.S. monetary policy. Several important considerations would arise in designing the new entity:

- **Effect of Decisions.** The board could either be advisory—tasked with making recommendations to existing executive agencies or the Congress—or be delegated the regulatory authority to make binding decisions with the force of law (over, for example, coverage rules or payment rates). If the decisions were binding, the board's authority would be akin to the powers held by the Federal Reserve with respect to certain interest rates and the regulation of member banks. To the extent the board was advisory, its functions might largely duplicate those of existing entities such as the Medicare Payment Advisory Commission, and in an advisory capacity, the board might have difficulty achieving efficiencies in the many areas that could provoke controversy.

1. "Prepare for Launch: Health Reform Summit" (seminar sponsored by the Senate Finance Committee, Washington, D.C., June 16, 2008). See also the Federal Health Care Board Act of 2007, S. 2107, 110th Congress, 1st sess. (2007); and Tom Daschle, *Critical: What We Can Do About the Health-Care Crisis* (New York: St. Martin's Press, 2008).

Continued

Box 1. Continued

Considerations in Establishing a Federal Health Board

- **Extent of Legislative Guidance.** Policymakers would face a trade-off between allowing the board flexibility and, at the same time, providing guidance as to what was to be accomplished. For instance, in setting monetary policy, the Federal Reserve is tasked with the broad objectives of maximizing employment and minimizing inflation but is granted flexibility to make independent decisions about how to balance those often competing objectives.

- **Degree of Independence.** To the extent that policymakers wanted to insulate the board from political pressure, a variety of mechanisms would be available. For instance, board members could be given long terms of service—on the order of a decade or more—as are governors of the Federal Reserve system. Further, appointments could be such that members could be removed only "for cause," rather than serving at the will of the President (a feature that distinguishes independent agencies like the Federal Reserve Board and the Federal Trade Commission from other agencies of the executive branch). Legislation could also establish an independent source of funding for the board so that it was not subject to the annual appropriation process—as is done with the Federal Reserve system, whose operations are financed primarily by interest earned on its holdings of federal debt and by fees paid for the financial services it provides. Depending on the scope of the federal health board's decisionmaking authority, however, some policymakers and stakeholders might object to granting substantial authority to an agency with limited accountability.

CBO's Activities and Future Analyses of Options

Because future health care spending is the most important factor determining the nation's long-term fiscal condition, CBO is devoting increasing resources to assessing options for reducing such spending. The agency has expanded the number of full-time-equivalent staff analyzing health care issues from 30 at roughly this time last year to 45 now, with 3 more coming on board within the next three months. Last year, CBO established a panel of health advisers—consisting of experts from academia, industry, and independent research organizations—which meets periodically to examine frontier research in health policy and to advise the agency on its analyses of health care issues. As part of its work generally, CBO continually reviews research conducted both in and outside of government.

As part of its analysis of health care, CBO is examining options that could improve the efficiency of health care delivery and thereby might also reduce geographic variation in Medicare. The options could include the following approaches:

- Increasing the bundling of services in payments to providers (such as those that have been implemented in the Medicare program for payments to hospitals, for example), which could help to curb current incentives to provide increasingly intensive services that produce only modest or no improvement in health.

- Enhancing incentives to provide care consistent with accepted guidelines for low-cost, highly effective care, thus helping to change patterns of medical practice in places that now are characterized by lower-quality, higher-cost care.

Not all interventions that would reduce geographic variation in health care spending would necessarily improve the overall efficiency of medical practice. For example, reducing payments to high-spending areas while increasing payments to low-spending areas would reduce spending variation but could result in worse outcomes if the quality of care declined in the high-spending areas more than it improved in the low-spending ones. To the extent feasible, CBO will take those considerations into account in its analysis.

Late this year, the agency plans to release two significant reports on health policy: One will present budget estimates for numerous specific policy options, and the other will address critical topics related to proposals to make major changes in the health insurance and health care systems. CBO hopes that those efforts will be of significant value to the Congress in assessing ways to address these critical policy issues.

Comparative Clinical Effectiveness:

Leveraging Innovation to Improve Health Care Quality for All Americans

Presented to

Committee on Finance
United States Senate

By

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On

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Mr. Chairman and Members of the Finance Committee: Thank you for inviting me here to testify on how information on comparative clinical effectiveness can facilitate getting the right care delivered to the patient at the right time. My name is Gail Wilensky. I am currently a senior fellow at Project HOPE, an international health foundation that works to make health care available to people around the globe. I have previously directed the Medicare and Medicaid programs as the Administrator of the Health Care Financing Administration and also chaired the Medicare Payment Advisory Commission. The views I am presenting here reflect my training as an economist, my experience at HCFA and MedPac and also my membership on a committee established by AcademyHealth (the professional society for health services research) that considered the placement, structure and financing of comparative effectiveness research. My testimony reflects my personal views and not necessarily the views of Project HOPE, AcademyHealth or any other organization.

I am here today primarily to discuss ways to develop information on comparative clinical effectiveness (CCE) through the creation of a new Center for Comparative Clinical Effectiveness, but I also want to note how the use of information on geographic variation can help set priorities for research in such a center and how the development of health IT will greatly facilitate the generation of information needed for a center on CCE. All three of these issues are synergistic with the theme of this hearing: Leveraging Innovation to Improve Health Care Quality for All Americans.

My testimony is based on an article I wrote that was published on-line in *Health Affairs* in November of 2006 which laid out the fundamentals regarding the placement, financing and functions of such a center, modified by the evolution in my thinking that has occurred since the publication. This evolution reflects the result of the many conversations I have had about CCE over the last 20 months with potential stakeholders and funders, elected officials and policy analysts and supporters or opponents of CCE.

Rationale:

In a period when the country is still struggling about how and how much to reform American health care, there seems to be a developing consensus on the need for better information, particularly on comparative clinical effectiveness—that is, information on how various medical conditions respond to treatment using different therapeutic interventions. Driving this interest is the recognition that the current rate of spending growth in health care (a long-term average annual growth rate that is 2.5 percentage points faster than the growth rate in the economy) is simply not sustainable and that even with this spending growth, there are clear and persistent indications of problems with patient safety and with quality. As current and previous CBO testimony has also made clear, geographic variation in the rate of spending for treating individuals with similar medical conditions indicates the opportunities that are available to reduce spending without harming clinical outcomes. The existence of wide variations in Medicare spending per beneficiary has been known for many years but more recent studies by Elliot Fisher and his colleagues at Dartmouth has indicated that the high spending areas are neither associated with better health outcomes nor are they more consistent with patient preferences.

To be sure, better information will not by itself be enough to moderate spending (or not by very much) and maybe not even be enough to change physician behavior. Realigning financial incentives between patients, clinicians and institutions, encouraging healthy lifestyles by consumers, rewarding clinicians and institutions that provide efficiently-produced, high quality care, setting reimbursement rates to reflect comparative clinical effectiveness information along with cost data and many other changes will also be needed to significantly affect spending growth rates. On the other hand, without better information on what works when, for whom, and provided under what circumstances, it is hard to imagine how the U.S. will be able to develop strategies that will allow the country to learn to spend "smarter" and without this, it is hard to imagine how we will lower the longer-term "excess" spending growth rate.

Role of the Center:
The interest in comparative clinical effectiveness information is neither new nor is it limited to the U.S. Other countries, however, have tended to focus their analyses primarily on pharmaceuticals and devices and their assessments tend to be important or required elements in the coverage or reimbursement decisions of their national health systems. This is beginning to change as more and more countries realize that too much money is spent on medical procedures to keep their focus only on pharmaceuticals and devices.

I am advocating for a Center for Comparative Clinical Effectiveness that would have a different focus and purpose than those used in other countries: one that serves an **information function** rather than a decision-making function. Further, I believe that comparative effectiveness information should primarily be used to inform better clinical decision-making and to be available for use in the design of more appropriate reimbursement rather than being used to set new requirements for coverage. Current FDA coverage rules focusing on safety and efficacy seem quite sufficient to me.

The purpose of the Center on CCE is to fund new research as well as funding systematic reviews of existing research, and to disseminate and otherwise make available what is known about the likely clinical results of using different treatment options for different subgroups of the population. The focus therefore needs to be on medical conditions rather than on specific interventions or therapeutics and needs to include medical procedures rather than only be limited to pharmaceuticals and devices. The work of the center is based on the premise that technologies are rarely **always** effective or **never** effective (assuming that some kind of approval process is required such as the FDA) and that the role of the information made available by the center is to help inform decision-makers about the probability that a favorable outcome will occur. Thus, comparative clinical effectiveness not only provides information that is comparative across various interventions but also recognizes that the outcomes may differ substantially for various subgroups of the population. Because of the nature of the discovery process and incremental changes that occur over time, it is important to recognize that investment in CCE needs to be thought of as a dynamic process and not once-done, finished forever.

I had previously assumed that systematic reviews of what is already known about the likely outcomes of various therapeutic interventions would be a relatively straight-forward first step in determining what new research should be undertaken. An important report released by the Institute of Medicine in January of 2008 entitled "Knowing What Works in Health Care: A Roadmap For The Nation" indicates that much more work also needs to be done regarding the scientific synthesis and interpretation of existing evidence, particularly in terms of establishing rules of evidence and appropriate methodologies for use in the syntheses. Comparatively speaking, however, investments in learning how to make better use of existing data are likely to be far less than the investments that will be needed to collect and analyze new data.

There have been occasions where researchers have spoken as though only data reflecting the results of double-blinded randomized control trials should be regarded as an appropriate basis for decision-making. My views are the comparative effectiveness analyses need to include data from many sources although it will be important to make clear the robustness of the data collection strategies and methodologies used in the analyses and presumably the conclusions made from the data should also reflect the robustness of the data. All data have limitations and errors. Specifying these limitations and biases and correcting for them where possible is appropriate and should be expected of information made available through a CCE center. It will also be important to find ways to reduce the costs and time required for the collection of prospective data. Such efforts as those by Sean Tunis in his "real world" randomized trials or Bryan Luce in developing his PACE initiative (Pragmatic Approaches to Comparative Effectiveness) which makes use of Bayesian statistical approaches to establish shorter end points in certain types of clinical trials are examples of efforts in this vein.

Placement of the Center:
The question of where the center should be placed has prompted considerable discussion. I believe the placement of the center need to be determined by the defining characteristics of the center's information. To be more specific, the data made available by the center must be regarded as **objective, credible, and transparent**—protected from both the political process as well as the interests of affected parties. The information should also be timely, span the full range of data available and be understandable to the various parties who want to make use of the data but the most important characteristics are those associated with "trust". Without that, the center won't be able to serve its fundamental reason for existing.

Some have argued the merits of keeping the Center directly within government, with many choosing to house it in the Agency for Health, Research and Quality, AHRQ, the place where the Medicare Modernization Act directed a limited amount of comparative clinical effectiveness analysis to occur. Others have argued the merits of keeping it outside of a direct involvement with government. While any placement will have its advantages and disadvantages, on balance the two that are most appealing to me are the creation of a new free-standing entity, perhaps modeled after the Federal Trade Commission or the Federal Reserve Board or the use of a Federally Funded Research and Development Center, **FFRDC**, which is **attached to AHRQ**. FFRDC's are entities that

are primarily funded by government (minimum of 70%) and are sponsored by an executive-branch agency, which monitors its use of funds. There are several that have been around for many years. The Lawrence Livermore Labs is one of the larger, better known FFRDC's. This model best reflects the dictum of "close . . . but not too close to government" and also assures a close linkage with AHRQ, the lead agency for health services research which needs importantly to continue in that role. Starting the center is AHRQ while it remains small has the advantage of not needing to create a new bureaucracy but if that is the choice made, its appropriateness or desirability should be assessed after two or three years. I am concerned that if a CCE center were to reside permanently in AHRQ, it would overwhelm all other health services research. I am also concerned about past vulnerability shown by AHRQ's predecessor agency AHCPR to political pressure although I recognize that this could be a problem anywhere.

I also think the Center would be most effective if it had both **intramural** (in-house research) and **extramural** (contract research) functions as do both AHRQ and the NIH. The in-house researchers provide an important element of expertise and hands-on experience but my assumption is that much of the work would be contracted out to universities, free-standing research groups, etc.

Governance:
The governance of such a center is almost as important as its placement. Again, the key concepts are credibility, objectivity and transparency. This means a governing body that is reflective of all the major stakeholders (including both industry and patient advocates), with staggered year appointments by the executive branch (and maybe subject to Senate confirmation) so that no one administration has too much control. Specialized scientific advisory boards would presumably be created for advice on particular comparative effectiveness studies, particularly those involving new research. Full public disclosure of any conflicts or interest will be critical along with full public access to the meeting transactions.

Funding:
Like any new entity, a Center for Comparative Effectiveness would require several years to reach a "steady-state" which I have assumed would be several billions of dollars. My guess is that the center could reach a critical mass of activity with a few hundred million dollars on its way to reaching this steady state.

Because information is clearly a "public good" as the economist uses the term, it should be available to all users without attempting to introduce exclusionary measures. My preferred funding would be by direct appropriation, as is the funding for the NIH. That, however, may not be a realistic strategy. Another option is to combine funding sources that include monies from direct appropriations, a contribution from the Medicare trust fund and a small assessment on **all** privately covered lives. Putting an assessment only on those lives not covered by the ERISA pre-emption would be a serious mistake since the self insured will be able to benefit in much the same way as the other privately insured. Although all will benefit from the availability of such information, thus the

rationale for a direct appropriation, payers will be especially advantaged by having this information available.

The Role of Costs:
The most controversial issue to date has been whether or not to include cost-effectiveness or cost-benefit analysis directly in a center for Comparative Clinical Effectiveness. While I firmly believe the data made available by the Center should be used by payers in their cost-effectiveness and cost benefit analyses and that funding to CMS should be made explicitly for this purpose, along with the ability of the agency to use such elements in their reimbursement decisions, I believe it is best to keep these functions housed separately. Payers would be wise to have their C/E and C/B analyses subject to the same criteria of credibility and transparency that are so critical to the acceptance of comparative clinical effectiveness information. This will be critical to their acceptance and credibility. It is also my expectation that different payers would use the information differently in designing their reimbursement policies. While I don't minimize the controversies that are likely to continue regarding coverage and reimbursement decisions, at least the bases for making these decisions will start from a common data base.

My rationale for the separation is two fold. One reason is technical. Measurement issues and policy decisions involved with C/E and C/B analyses are more controversial and subject to dispute: where in the life cycle is the technology and how much does that affect costs, whose costs are being measured—Medicare, small purchasers, large purchasers, etc, what functions are or are not absorbed by the purchaser, i.e. is the purchaser wholesale or retail, etc. Because of these technical issues but also because of the more controversial nature of the implications of cost analyses, including the perceived threat regarding coverage or reimbursement that could result from these analyses, I believe combining the inclusion of cost analyses will increase the political vulnerability of a center for comparative clinical effectiveness. Since CCE information is the **most elemental building block** to learning how to spend smarter, it needs to be protected.

Priority Setting:
Even with the anticipated addition of substantial funding for CCE, setting appropriate priorities will become one of the most important functions of the governance structure. General guidance seems to me to be clear and obvious. Priority for new systematic reviews and also for the collection of new data from prospective trials should reflect those medical conditions for which the payers costs are substantial and where the geographic variations are also significant. In general, these are likely to be medical conditions for which there is substantial uncertainty about the proper diagnosis, given the symptoms and/or substantial uncertainty about the proper treatment, given the diagnosis.

To summarize: The center for Comparative Clinical Effectiveness would be an information center, not a decision-making center, providing credible information for clinicians, patients and payers to use to make better decisions. Priority-setting for new systemic reviews as well as the collection of new prospective data should be based in large part on the treatment of medical conditions that are both high cost and that exhibit substantial variation. Such information would have many important purposes including

the development of a reimbursement system in which co-payments could be tiered to what makes the most sense clinically and economically, with the treatments that are associated with the highest likelihood of success having the lowest copayments, all informed by credible, objective transparent data. Patients and clinicians that want more or want to choose different therapies should be able to do so but should need to pay more for their choices. Medicare does not currently have such authority in setting reimbursement rates and granting the agency this authority would be one of the many changes that would need to occur in learning to spend smarter under Medicare. As a small start to allowing Medicare to generate more evidence so that it can improve its national coverage decision-making, local carriers who grant coverage should be required to do so with some type of evidence development.

ABHC

Alliance for Better Health Care

ABHC Statement for the Record on
The Right Care at the Right Time: Leveraging Innovation to Improve Health Care Quality for All Americans
Submitted to the Senate Finance Committee
July 17, 2008

The ABHC Coalition thanks the Committee for holding this hearing on innovations that can improve the quality of care. We are a coalition of consumers, employers, unions, health care providers, pharmaceutical benefit managers, health plans, pharmacists, researchers, and other stakeholders who believe that high quality health care requires good evidence to support sound medical decision-making.

Independent, objective comparative effectiveness research (CER) has the potential to improve greatly health care quality and patient outcomes by helping to ensure that consumers receive the best care at the best value. With adequate funding, this research can aid in health care decision-making to ensure that the resources expended by patients and payers (including government health programs) result in the delivery of quality, evidence-based and high value healthcare that is appropriate for the individual patient. Well-designed comparative effectiveness research will seek to identify specific subpopulations of patients for whom one intervention might be more appropriate than another intervention. As a result, such studies often enable physicians to make better decisions based on specific patient characteristics, applying the scientific information elicited in evaluating various treatment options.

Currently, under authority granted by section 1013 of the Medicare Modernization Act (MMA), the Agency for Healthcare Research and Quality (AHRQ) conducts CER studies

examining the outcomes, comparative clinical effectiveness and appropriateness of different treatments, and the ways that those treatments can be provided in a more effective and efficient manner. From FY2005 to FY 2007, AHRQ received $15 million per year for CER, and received $30 million for this research in FY 2008. This modest initial investment has already produced valuable results. AHRQ has released thirteen reports on treatment options for a variety of conditions, including reports on breast cancer, gastroesophogeal reflux disease (GERD), cancer-related anemia, low-bone density, and depression.

We believe that the findings released by AHRQ have just begun to show the significant value of CER for patients, providers, and health care payers. However, we are also concerned that, under current levels of funding, AHRQ can only conduct a few CER studies each year, and the agency is limited in the types of studies it can conduct. Due to the lack of sufficient funding, AHRQ's research efforts have not reached their full potential, in terms of improving care and saving significant federal dollars. That potential can only be realized fully if Congress acts to increase its investment substantially.

As Congress moves forward in this debate, ABHC has developed the following principles for prioritizing, conducting, disseminating, and using CER:

- CER has the potential to benefit the health of all Americans and is a true public good.
- Significant and stable investment is needed in CER—in the development of research methods and researchers, the design and conduct of studies, the scientific review of research, and the dissemination and communication of results—for it to reach its full potential.
- The scope of CER should address the full spectrum of health care treatments, including pharmaceuticals, devices, medical and surgical procedures, and other interventions.
- Scientific integrity and independence are paramount.

- CER should be based on scientific evidence employing an array of appropriate methods, such as randomized clinical control trials, observational studies, meta-analyses, and systematic technology assessment reviews.
- The processes for identifying research priorities, conducting research, validating the science, and disseminating results should be transparent.
- Any entity that commissions or conducts CER should involve stakeholders in setting research priorities and disseminating research.
- Board governance should assure accountability in the conduct and dissemination of CER.

Comparative effectiveness research has the potential to improve health care delivery and ultimately benefit the health of all Americans by reducing inappropriate and ineffective care. A significant and stable investment is needed for this research to reach its full potential. We urge you to consider a long-term, fully-funded approach to comparative effectiveness research as an essential element of your examination of innovations to improve health care.

ABHC Coalition members include:

AARP • Academy of Managed Care Pharmacy • Aetna Inc. • AFL-CIO
Alliance of Community Health Plans • America's Health Insurance Plans
American Academy of Family Physicians • American Osteopathic Association
American Pharmacists Association • American Society of Health-System Pharmacists
Blue Cross Blue Shield Association • Blue Shield of California • Caterpillar, Inc.
Coalition for Health Services Research • CVS Caremark, Inc.
DaimlerChrysler Corporation • Ford Motor Company • Express Scripts, Inc. General Motors Corporation • Group Health Cooperative • Honeywell
Kaiser Permanente • Marshfield Clinic • Medco Health Solutions, Inc.
National Business Group on Health • National Partnership for Women and Families
Service Employees International Union • The Dow Chemical Company
The Joint Commission • UnitedHealth Group • WellPoint, Inc.

Joined by,

Consumers Union

For further information, please contact Anna Schwamlein Howard of AARP at 202-434-3770.

Blue Cross and Blue Shield Association (BCBSA)
Health Reform Starts With Research on What Works
Serota applauds Baucus, Grassley for holding hearing examining key issues
July 17, 2008

WASHINGTON – In response to today's hearing before the Senate Finance Committee on how best to improve quality in our nation's healthcare system, Blue Cross and Blue Shield Association (BCBSA) President and CEO Scott P. Serota issued the following statement:

"The nation's 39 Blue Cross and Blue Shield companies applaud Senate Finance Committee Chair Max Baucus and Ranking Member Charles Grassley for holding today's hearing examining how best to improve quality and expand access by changing payment incentives to providers, encouraging research on what works, and implementing health information technology.

"As today's new report from the Commonwealth Fund notes, the U.S. spends more on medical care than any other industrialized nation, yet all too often we are not realizing value for that spending. Other data shows that fully 30 percent of healthcare spending goes to care that is ineffective, inappropriate, or redundant.

"Blue Cross and Blue Shield companies are committed to improving the healthcare delivery system and have developed innovative models of payment for hospitals and doctors based on quality outcomes with demonstrated results.

"Regrettably, much more needs to be done. Our system is spending blindly on procedures, devices, and drugs without any real information about what works best and what is most effective. This approach is not sustainable and a system that is not embracing best practices today cannot be expected to provide optimal coverage to nearly 50 million more people.

"Consensus is emerging that an independent comparative effectiveness research institute would be an important step forward in bringing better information to patients and doctors so they may make more informed treatment decisions. BCBSA strongly supports the efforts of Senators Baucus, Conrad and others to advance legislation in this area.

"Changing provider incentives and putting more information quickly into the hands of consumers and providers could help bring about a sea change in delivering quality care."

The Blue Cross and Blue Shield Association is a national federation of 39 independent, community-based and locally operated Blue Cross and Blue Shield companies that collectively provide healthcare coverage for more than 100 million individuals – one-in-three Americans. For more information on the Blue Cross and Blue Shield Association and its member companies, please visit www.BCBS.com.

COALITION
FOR HEALTH SERVICES RESEARCH

THE RIGHT CARE AT THE RIGHT TIME: THE PROMISE OF COMPARATIVE EFFECTIVENESS RESEARCH

STATEMENT OF

THE COALITION FOR HEALTH SERVICES RESEARCH

TO THE

COMMITTEE ON FINANCE

UNITED STATES SENATE

JULY 17, 2008

Advancing Research, Policy and Practice

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The Coalition for Health Services Research (Coalition) is pleased to offer this statement for the record regarding the promise of comparative effectiveness research. The Coalition's mission is to support research that leads to accessible, affordable, high-quality health care. As the advocacy arm of AcademyHealth, the Coalition represents the interests of 3,500 researchers, scientists, and policy experts, as well as 130 organizations that produce and use health services research.

Health care in the United States has the potential to improve people's health dramatically, but often falls short and costs too much. Health services research is used throughout the health care field to understand how to better finance the costs of care, measure and improve the quality of care, and improve coverage and access to affordable services. As an emerging science in the broader field of health services research, comparative effective research—where pharmaceuticals, medical devices and medical procedures used to treat the same conditions are evaluated for their relative safety, effectiveness, and cost—has great potential to improve health care quality and patient outcomes while ensuring that consumers receive the best care at the best value. When optimally funded, comparative effectiveness research has the promise to inform health care decisions that are:

- **Patient-specific**, enabling doctors to make individualized treatment decisions according to patient characteristics (sex, age, and race/ethnicity).
- **Evidence-based**, providing patients and practitioners with the timely, scientific information they need to evaluate which treatment options will help them achieve better outcomes.
- **Value-driven**, empowering patients to make informed decisions in the face of rising health care costs and myriad treatment options.

There are increasing examples that demonstrate how comparative effectiveness research provides the scientific basis needed to make better decisions when it comes to the care we give and receive:

- The Agency for Healthcare Research and Quality (AHRQ) found that episiotomies—a preemptory incision intended to prevent pregnant women from tearing tissue during labor—has no positive benefit, and probably results in more complications and causes more pain than if no incision was made during childbirth.[i] The report will save millions of women from having to undergo this painful procedure, not to mention the costs saved by eliminating the routine use of this procedure.
- Another AHRQ study found that drugs can be as effective as surgery in management of gastroesophageal reflux disease (GERD)—where stomach acid enters the esophagus, causing heartburn and potential esophageal damage.[ii] GERD is one of the most common health conditions among older Americans and results in $10 billion

annually in direct health care costs. Knowing that, for the majority of patients, drugs can be as effective as surgery in relieving the symptoms could result in significant health care savings and improved quality of life.

- The National Institute of Mental Health (NIMH) found that, within a class of antipsychotic drugs, the older, less expensive drug (Perphenazine) was just as effective and caused no worse side effects than the three newer, more expensive drugs in treating patients with schizophrenia. One of the newer drugs (Zyprexa) was slightly more effective in controlling systems than the other drugs, but at the cost of serious side effects.[iii] This study enables greater flexibility in care and informs patients and providers about costs and quality of care.

- In a study of more than 2,200 patients funded mostly by the Veterans' Administration, researchers found that those who underwent non-emergency angioplasty—a procedure where a tiny wire-mesh tube called a stent is placed in an artery to hold it open—were no less likely to suffer a heart attack or die than those who took only aspirin and other medicines to lower blood pressure and cholesterol and prevent clots, along with adopting lifestyle changes.[iv] The procedure, often performed to relieve chest pain and to reduce the risk of having or dying from a heart attack, costs about $50,000 and has become one of the most common medical procedures in the United States.

As these examples suggest, comparative effectiveness research can contribute greatly to better health care at lower cost. It is a true public good, providing a basis for improvements in our health care system that benefit the general public. Americans overwhelmingly agree. According to a 2006 *Research!America* survey, 92 percent of Americans polled agree that it is important to invest in health services research.[v]

Despite the promise of, and general support for, comparative effectiveness research, this type of health services research by definition often results in "winners" and "losers," making the entity that commissions this research vulnerable and susceptible to attack. For example, if research based on post-marketing surveillance finds that device "A" has better outcomes and fewer risks than drug "B," one would expect the demand for device "A" to increase at the expense of drug "B." The manufacturer of drug "B" might then attempt to leverage the political process to discredit the research and, as has happened in the past, exert political pressure to substantially reduce the funding for, or even abolish the entity funding, the research.

Given the potentially controversial nature of comparativeness effectiveness research findings, in September 2005 AcademyHealth issued a report that provided guidance on the placement, structure, and funding of comparative effectiveness research (see appendix A). [vi] The AcademyHealth report recommended that comparative effectiveness research be established either within AHRQ or through the creation of a new entity that would, in varying degrees, be linked to the lead agency for health services research. As part of this

recommendation, the report recommended that the following five principles be used to guide policymakers' deliberations on comparative effectiveness research (see also Appendix B):

- Comparative effectiveness research is a subset of the broader field of health services research, so increased investments in comparative effectiveness research should not be at the expense of investments in a robust health services research portfolio.
- Given the potentially controversial nature of comparative effectiveness findings, this research must be based on scientific evidence and be kept separate from funding and coverage decisions.
- As a subset of the field of health services research, comparative effectiveness research must be closely linked to AHRQ—as the lead agency for health services research—to ensure that findings are consistent with the best available research, methods, and data.
- Since comparative effectiveness research as a public good requires significant federal investment and has the potential to affect the delivery and cost of health care for all Americans, the entity commissioning or conducting this research should be subject to congressional oversight.
- Stakeholders should be involved in developing the research agenda and ensuring the validity of the research produced. Ensuring transparency in the prioritization, conduct, and dissemination of research will promote public acceptance of the research findings and strengthen support for the program's mission.

The entity's overall funding and ability to recruit the expertise needed are critical factors that should inform the choice among these options — the best arrangement for a budget of $50 million might not be the best if $5 billion were to be made available for this function. It may also be desirable to have portions of this responsibility undertaken by a combination of entities. Under such a scenario, the lead agency for health services research might commission and undertake the research studies, an affiliated entity might do the assessments based on that research, and an independent quasi-governmental entity might develop consensus studies on the methods and data to be used for these studies and assessments.

Regardless of how this research program is structured and governed in the future, AcademyHealth and its Coalition recognize that comparative effectiveness research will require a significant investment to realize its potential. For example, some experts suggest that a robust comparative effectiveness program should be funded at a level of $4–$6 billion annually to meet the U.S. health system's demands. Comparatively, the federal government in 2006 spent nearly $33.2 billion on health research, of which only 4.5 percent—about $1.5 billion—was apportioned to health services research.[vii, viii] The

federal government's comprehensive investment in comparative effectiveness research across the various agencies conducting and funding this work is unknown, as comparative effectiveness research is not uniformly defined across research funders and such information is not systematically collected. However, we do know that AHRQ's comparative effectiveness program was appropriated $30 million in fiscal 2008 (and $15 million in each of the previous three fiscal years).[ix]

Congress should increase and expand the sources of funding for conducting and coordinating a wide spectrum of comparative effectiveness research, including systematic reviews of existing literature, analysis of administrative data and clinical registries, and pragmatic, prospective, head-to-head trials. Doing so would ultimately help patients, providers, payers, and policymakers make rational choices about new and existing health services, and assure that our investments in basic and clinical research are integrated into health care delivery. After all, increased spending on new medicines and equipment is wasted if the system does not adopt these new treatments in a safe and efficient manner.

In addition, we believe that increased investment in comparative effectiveness research must be coupled with greater investment in the research infrastructure—the data, methods, and researchers needed to conduct this work and ultimately generate meaningful research and knowledge. The field of health services research has experienced an erosion of investment in its methods, data, and particularly its researchers over the last several years. If left unchecked, these declining investments could threaten the field's capacity to address public and private sector research needs.

In conclusion, the best health care decisions are based on relevant data and scientific evidence. Increased investment in comparative effectiveness research and the health services research infrastructure will show returns in improved quality, accessibility, and affordability. At a time when America is spending over $2 trillion annually on health care, we need research—now more than ever—to help us spend our health care dollars more wisely.

The Coalition appreciates the opportunity to submit this testimony for the record and looks forward to working with the Committee as it continues to assess options for structuring and funding a robust comparative effectiveness research capability in the United States. If you have questions or comments about this testimony, please contact Emily Holubowich, Director of Government Relations at 202.292.6743 or e-mail at emily.holubowich@academyhealth.org.

Appendix A: Committee on Placement, Funding, and Coordination of Health Services Research within the Federal Government

(Affiliations at time of committee appointment)

Sheila Burke, Committee Chair, Deputy Secretary and Chief Operating Officer, Smithsonian Institution

Jeanne Lambrew, Ph.D., Vice Chair, Associate Professor, Department of Health Policy, George Washington University

David Abernethy, Senior Vice President, Operations, HIP Health Plans

Michael Chernew, Ph.D., Professor, Department of Health Management and Policy, School of Public Health, University of Michigan

Jordan Cohen, M.D., President, Association of American Medical Colleges

Judith Feder, Ph.D., Dean of Public Policy, Georgetown University

Harold S. Luft, Ph.D., Caldwell B. Esselstyn Professor and Director, Institute for Health Policy Studies, University of California, San Francisco

Nicole Lurie, M.D., Senior Natural Scientist and Alcoa Chair, RAND Corporation

Donald M. Steinwachs, Ph.D., Professor and Chair, Department of Health Policy and Management, Bloomberg School of Public Health, Johns Hopkins University

Gail Wilensky, Ph.D., Senior Fellow, Project HOPE

Appendix B: Five Principles to Guide Decisions for the Placement of Comparative Effectiveness Research

Principle 1: Overall funding for the field of health services research should continue to support a broad and comprehensive range of topics.	• Recognizes that while comparative effectiveness research is important, it is a subset of the broader field of health services research. • Regardless of where comparative effectiveness research is placed, this principle stresses the need to fund a broad health services research portfolio.
Principle 2: Assessments should be based on scientific evidence and kept separate from funding and coverage decisions.	• Given the controversial nature of comparativeness effectiveness findings, this principle stresses the need for a structure that ensures the scientific integrity of comparative effectiveness research. • This principle stresses the need to separate the entity that funds and conducts these studies from the entity directly responsible for making coverage decisions.
Principle 3: Entity commissioning or conducting comparative effectiveness research should maintain close linkage to the lead agency for health services research.	• Recognizes that comparative effectiveness research is a subset of the broader field of health services research. • As such, comparative effectiveness research must be closely linked to the lead agency in order to ensure that findings are consistent with the best available research, methods, and data.
Principle 4: Entity commissioning or conducting comparative effectiveness research should be subject to congressional oversight.	• Since comparative effectiveness research has the potential to affect the delivery and cost of health care for all Americans, this principle recognizes that the federal government is responsible for ensuring that decisions about what health services and products should be provided are based on sound scientific research. • Since this research requires substantial federal funding (and would not be funded adequately by the private sector alone), this principle recognizes the need for appropriate congressional oversight of public funding to ensure accountability.
Principle 5: Entity commissioning or conducting comparative effectiveness research should involve key stakeholders to assure transparency of the methods and process, promote public acceptance of research findings, and support for the entity's mission.	• Given the controversial nature of comparative effectiveness research, this principle recognizes the importance of involving key private sector representatives in developing the research agenda and ensuring the validity of the research produced, thereby increasing public support for the research findings and the entity's mission. • As such, comparative effectiveness research must be funded in an open process to ensure that no one group is perceived as dominating the process and/or skewing the results.

[i] Viswanathan, M., et. al. "The Use of Episiotomy in Obstetric Care: A Systemic Review," Agency for Healthcare Research and Quality (May 2004). Available on the Web at www.ahrq.gov/downloads/pub/evidence/pdf/episiotomy/episob.pdf

[ii] Ip, S., et. al. "Comparative Effectiveness of Management Strategies for Gastroesophageal Reflux Disease," Agency for Healthcare Research and Quality (Dec. 2005). Available on the Web at www.effectivehealthcare.ahrq.gov/reports/final.cfm

[iii] Lieberman, J.A., et. al. "Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia," *New England Journal of Medicine*, Vol. 353, No. 12, pp.1209-1223 (Sept. 22, 2005). Available on the Web at http://content.nejm.org/cgi/content/abstract/353/12/1209

[iv] Boden, W.E., et. al. "Optimal Medical Therapy with or without PCI for Stable Coronary Disease," *New England Journal of Medicine,* Vol. 356, No. 15, pp. 1503-1516 (April 12, 2007). Available on the Web at http://content.nejm.org/cgi/content/abstract/356/15/1503

[v] *America Speaks: Poll Data Summary, Vol. 8.* Research!America (Mar. 2007).

[vi] *Placement, Coordination, and Funding of Health Services Research within the Federal Government*, AcademyHealth (Sept. 2005). Available on the Web at http://www.chsr.org/placementreport.pdf

[vii] Catlin, A., et. al. "National Health Spending in 2006: A Year of Change for Prescription Drugs." *Health Affairs,* Vol. 27, No. 1 (Jan./Feb. 2008).

[viii] *Federal Funding for Health Services Research,* Coalition for Health Services Research (Feb. 2008). Available on the Web at http://www.chsr.org/CoalitionFundingReport08.pdf.

[ix] Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008 (H.R. 3043, S. 1710); Consolidated Appropriations Act, 2008 (H.R. 2764). http://thomas.loc.gov/. Accessed May 19, 2008.

Utilization of the PreDx™ DRS to Prevent Diabetes: Improving Outcomes and Reducing Costs

A statement submitted for the record of the Senate Finance Committee Hearing on July 17, 2008: "The Right Care at the Right Time: Leveraging Innovation to Improve Health Care Quality for All Americans"

Tethys BioScience
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TETHYS
BIOSCIENCE

July 17, 2008

The Honorable Max Baucus, Chairman
The Honorable Charles Grassley, Ranking Member
United States Senate
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Baucus and Ranking Member Grassley,

Thank you for holding a hearing on how innovation can be leveraged to improve health care quality. Recent scientific discoveries, advances in biomedical technology and investments in large-scale projects such as the Human Genome Project have led to numerous opportunities to reduce the burden of disease and improve the quality of health care for all Americans. We applaud you in your efforts to foster this discussion on the role of innovation in improving health and offer our assistance as you continue to explore areas of health reform.

At Tethys Bioscience, our goals are to reduce health care costs and prevent severe health consequences by identifying those at risk for common diseases, which then allow for opportunities to intervene early and even prevent the onset of illness. We recently launched the PreDx™ Diabetes Risk Score (DRS), a multi-marker model based on a simple blood test that identifies patients who are at low, intermediate, and high risk of developing diabetes within five years. This test can help optimize healthcare resources by focusing interventions on the relatively few patients at high risk of developing diabetes and avoiding unnecessary treatments and expenses for low risk patients.

With 24 million Americans currently diagnosed with diabetes and an estimated 57 million at risk for developing diabetes, it is crucial that we address this costly epidemic now. The American Diabetes Association estimates that in 2007, the annual cost of managing diabetes and lost productivity was $174 billion. Innovative diagnostics such as the PreDx™ DRS can not only significantly reduce the growing cost of treating diabetes, but save thousands of Americans from suffering from the downstream health consequences of the disease.

Enclosed is a white paper summarizing the strain on our healthcare system caused by the growing epidemic of type 2 diabetes coupled with an example of an novel diagnostic capable of not only reducing this burden on the system, but also improving the quality of health care for Americans. We hope this example of innovation will inform your work in today's hearing and beyond, and please do not hesitate to call on us if we can be of assistance in the future.

Best Regards,

Mickey Urdea, Ph.D.
Chairman & Chief Executive Office

Executive Summary

As the new 2007 prevalence data released by the CDC makes clear, diabetes is a public health concern of epidemic proportions – with 24 million people diagnosed with diabetes, and another 57 million at high risk of developing the disease. The most rapidly growing chronic disease of the early 21st century, diabetes is now the seventh leading cause of death in America, and is a leading cause of blindness, kidney failure, heart disease, nerve damage, and limb amputations. Given the staggering cost of treating diabetes – $174 billion in 2007 – it has never been more urgent to develop cost-effective strategies for screening and treating those at high risk for developing diabetes to alleviate the ever growing burden of diabetes in the U.S.

It can take many years to develop diabetes – a progressive disease associated with high blood glucose – and an individual can suffer significant health consequences years before diabetes is diagnosed. Fortunately, studies have shown that the onset of diabetes in high-risk individuals can be delayed or even prevented by sustained lifestyle modifications and/or medications. The key, of course, is to identify those individuals who are at high risk for developing the disease so that they can be offered effective interventions.

The PreDx™ Diabetes Risk Score (PreDx DRS) is based on multiple markers measured in a fasting blood sample that provides an objective assessment of an individual's risk of developing diabetes within the next five years. Unlike current practice that relies on blood glucose as a single marker of risk, the PreDx DRS uses a collection of serum biomarkers to provide a personalized risk score that distinguishes between people at high, moderate, and low risk of developing the disease. This allows physicians to focus on the relatively few patients that genuinely are at high risk of developing diabetes and to avoid unnecessary treatments and expenses for patients who are not likely to develop diabetes within the next five years.

An economic assessment of the utilization of the PreDx DRS in clinical practice – which uses the personalized risk score to tailor an effective diabetes prevention program for each patient according to their diabetes risk – has shown that this approach can improve disease outcomes and save lives while remaining cost-effective over current practice. These results support a preventive approach using the PreDx DRS to screen adults at risk of developing diabetes.

◊

"It is concerning to know that we have more people developing diabetes, and these data are a reminder of the importance of increasing awareness of this condition, especially among people who are at high risk." – Dr. Ann Albright, director of the CDC Division of Diabetes Translation[1]

◊

Type 2 diabetes: a serious and costly public health concern

Type 2 diabetes mellitus is a serious, costly disease that has reached epidemic proportions. Nearly 24 million people in the United States have been diagnosed with diabetes and another 5.7 million people have diabetes and don't know it, according to the latest estimates by the Centers for Disease Control and Prevention (CDC).[2] Even more alarming, an estimated 57 million people are considered to be at risk for developing diabetes.[3] Now the seventh leading cause of death in America, diabetes is the most rapidly growing chronic disease of our time – with about 1.6 million new cases of diabetes diagnosed in people aged 20 years or older in the U.S. in 2007,[4] which equates to 4,383 new cases per day. By 2050, it is projected that 48.3 million people in the U.S. will be diagnosed with diabetes.[5]

As obesity has become more common, so has type 2 diabetes.[6] Indeed, estimates show that for every 1-kg increase in weight, the prevalence of diabetes increases by 9%.[7] In the U.S., only about one-third of adults are considered to be at a healthy weight, while over 65% are overweight or obese.[8] Because population increases in diabetes have coincided with increases in obesity and because weight gain is a key determinant of diabetes, there is little debate that obesity is a key factor driving the diabetes epidemic.[9]

Diabetes is a major risk factor for numerous health complications, including blindness, kidney failure, heart disease, nerve damage, and limb amputations. In fact, diabetes is the leading cause of new cases of blindness in adults between the ages of 20 and 74, and it accounts for 44 percent of people who have kidney failure.[10] Cardiovascular disease is two to four times more common among people with diabetes, and is the leading cause of diabetes-related deaths.[11] The risk of stroke is also two to four times

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[1] Centers for Disease Control and Prevention, Press Release, Number of People with Diabetes Increases to 24 Million, http://www.cdc.gov/media/pressrel/2008/r080624.htm.
[2] National Diabetes Fact Sheet, 2007. Department of Health and Human Services, Centers for Disease Control and Prevention.
[3] *Id.*
[4] *Id.*
[5] Narayan KM, Boyle JP, Geiss LS, Saaddine JB, Thompson TJ: Impact of recent increase in incidence on future diabetes burden: U.S., 2005-2050. Diabetes Care 29:2114-2116, 2006.
[6] Geiss LS, Pan L, Cadwell B, Gregg EW, Benjamin SM, Engelgau MM: Changes in incidence of diabetes in U.S. adults, 1997-2003. Am J Prev Med 30:371-377, 2006.
[7] Mokdad AH, Ford ES, Bowman BA, Dietz WH, Vinicor F, Bales VS, Marks JS: Prevalence of obesity, diabetes, and obesity-related health risk factors, 2001. Jama 289:76-79, 2003.
[8] Hedley AA, Ogden CL, Johnson CL, Carroll MD, Curtin LR, Flegal KM: Prevalence of overweight and obesity among U.S. children, adolescents, and adults, 1999-2002. Jama 291:2847-2850, 2004.
[9] Gregg EW, Cadwell BL, Cheng YJ, Cowie CC, Williams DE, Geiss L, Engelgau MM, Vinicor F: Trends in the prevalence and ratio of diagnosed to undiagnosed diabetes according to obesity levels in the U.S. Diabetes Care 27:2806-2812, 2004.
[10] *Id.* at 10.
[11] *Id.*

higher in people with diabetes, and 75 percent of adults with diabetes have high blood pressure.[12] About 60% to 70% of people with diabetes have mild to severe forms of nervous system damage (including impaired sensation or pain in the feet or hands, or other nerve problems), and more than 60% of non-traumatic lower limb amputations occur in people with diabetes.[13]

The cost of treating diabetes is staggering. According to the American Diabetes Association (ADA), the annual cost of diabetes in medical expenses and lost productivity rose from $98 billion in 1997 to $132 billion in 2002 to $174 billion in 2007.[14] One out of every five U.S. federal health care dollars is spent treating people with diabetes.[15] The average yearly health care cost for a person with diabetes is $11,744, of which $6,649 is attributable to diabetes.[16] The indirect cost attributable to diabetes is estimated at $58.2 billion, including costs associated with absenteeism, reduced productivity, disability and premature mortality.[17] Even so, the estimated national burden of diabetes is likely an underestimate because it omits the social costs of intangibles such as pain and suffering, care provided by non-paid caregivers, excess medical costs of undiagnosed diabetes, and healthcare expenditures such as healthcare system administrative costs, over-the-counter medications, clinical training programs, and research and infrastructure development.[18]

Diabetes pathogenesis and prevention

It can take many years for an individual to develop type 2 diabetes, and studies have shown that microvascular damage occurs years before diabetes is diagnosed.[19] The good news is that type 2 diabetes can be prevented or delayed in high-risk individuals by lifestyle modification or medications used to treat diabetes. The key, of course, is to identify those individuals who are at risk for developing the disease so effective interventions can be initiated before irreversible damage has occurred.

Type 2 diabetes is a progressive disease in which blood glucose (often called blood sugar) is too high.[20] Glucose comes from breaking down sugars and starches in food and is the basic fuel for the cells in the body. There is always some glucose in blood because blood carries glucose to all the cells in the body. Normally, glucose gets into the cells with the help of insulin, a hormone made in the pancreas. However, if the body doesn't make enough insulin, or if the insulin doesn't work the way it should, glucose isn't taken up by the cells and it remains in the blood. These defects in insulin action and insulin secretion are present long before type 2 diabetes develops, they ultimately cause the disease, and they continue to worsen after the diagnosis of diabetes is made.[21]

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[12] *Id.*
[13] *Id.* at 11.
[14] American Diabetes Association, Economic costs of diabetes in the U.S. in 2007. Diabetes Care 31:596-615, 2008.
[15] *Id.* at 607.
[16] *Id.* at 609.
[17] *Id.*
[18] *Id.* at 611.
[19] Weyer C, et al.: The natural history of insulin secretory dysfunction and insulin resistance in the pathogenesis of type 2 diabetes mellitus. J Clin Invest 104:787-794, 1999; Festa A, et al.: The natural course of beta-cell function in nondiabetic and diabetic individuals: the Insulin Resistance Atherosclerosis Study. Diabetes 55:1114-1120, 2006.
[20] National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Your Guide to Diabetes: Type 1 and Type 2, http://diabetes.niddk.nih.gov/dm/pubs/type1and2/index.htm.
[21] The diagnosis of diabetes is based on the elevated levels of glucose in blood – 200 mg/dl or higher as measured with the oral glucose tolerance test, or 126 mg/dl or higher as measured with the fasting plasma glucose test. American Diabetes Association, All About Diabetes, http://www.diabetes.org/about-diabetes.jsp.

Clinical trials have shown that the onset of diabetes in high-risk individuals can be delayed or even prevented by lifestyle modifications and/or medication. The Diabetes Prevention Program (DPP)[22] and the Diabetes Prevention Study (DPS)[23] convincingly demonstrated that intensive lifestyle modifications designed to reduce caloric intake and increase physical activity reduced the risk of diabetes by 58% in a high-risk population. Similar risk reductions were achieved by medications that modify insulin resistance – the TRIPOD study showed that troglitazone reduced the risk of diabetes by 55% in Hispanic women with a history of gestational diabetes,[24] and the recently completed DREAM study showed that rosiglitazone, together with lifestyle recommendations, reduced the risk of diabetes by 60% in men and women at high risk for diabetes.[25] Drugs that primarily lower blood glucose levels proved less effective – metformin reduced the risk of diabetes by 31% in the DPP study[26], and acarbose reduced the risk by 25% in the Study To Prevent Non-Insulin-Dependent Diabetes Mellitus (STOP-NIDDM) trial.[27]

Identifying those at risk: single marker or multiple markers?

Given the alarming statistics on diabetes, the task now is to implement a preventive approach by developing effective strategies for screening and treating those at high risk for developing the disease so that resources can be focused on those individuals with the greatest need and for whom early intervention is most likely to reduce the serious health consequences of diabetes.

The current gold standard method for identifying individuals at risk is the oral glucose tolerance test (OGTT) – a test that involves measuring an individual's blood glucose level after he/she drinks a solution containing 75 grams of glucose. A person is diagnosed with diabetes if his/her blood glucose level is 200 mg/dl or higher two hours after ingesting the glucose. Those with a blood glucose level less than 200 mg/dl but greater than or equal to 140 mg/dl are diagnosed with a condition called impaired glucose tolerance (IGT). However, the OGTT is limited as a tool for identifying those at high risk for diabetes because only 30 to 40% of those identified as having IGT actually go on to develop diabetes.[28] Moreover, the OGTT has limited use in routine clinical practice because it is time-consuming, costly, and inconvenient – not only do many patients find the experience of consuming a 75-g glucose solution unpleasant, but it has proven difficult and costly for staff to monitor patients as they are being tested over the course of a two hour time period.[29]

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[22] The Diabetes Prevention Program Research Group: Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 346:393-403, 2002.

[23] Tuomilehto J, et al. for the Finnish Diabetes Prevention Study Group: Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. N Engl J Med 344:1343-1350, 2001.

[24] Buchanan TA, et al.: Preservation of pancreatic beta-cell function and prevention of type 2 diabetes by pharmacological treatment of insulin resistance in high-risk hispanic women. Diabetes 51:2796-2803, 2002.

[25] The DREAM Trial Investigators: Effect of rosiglitazone on the frequency of diabetes in patients with impaired glucose tolerance or impaired fasting glucose: a randomised controlled trial. Lancet 368:1096-1105, 2006.

[26] The Diabetes Prevention Program Research Group, *supra* note 22, at 398.

[27] Chiasson JL, et al. for the STOP-NIDDM Trial Research Group: Acarbose for prevention of type 2 diabetes mellitus: the STOP-NIDDM randomised trial. Lancet 359:2072-2077, 2002.

[28] Edelstein SL, et al.: Predictors of progression from impaired glucose tolerance to NIDDM: an analysis of six prospective studies. Diabetes 46:701-710, 1997; Ramachandran A, et al.: Significance of impaired glucose tolerance in an Asian Indian population: a follow-up study. Diabetes Res Clin Pract 2:173-178, 1986; Unwin N, et al.: Impaired glucose tolerance and impaired fasting glycaemia: the current status on definition and intervention. Diabet Med 19:708-723, 2002.

[29] Stern MP, et al.: Predicting future cardiovascular disease: do we need the oral glucose tolerance test? Diabetes Care 25:1851-1856, 2002.

The ADA no longer recommends the OGTT in routine clinical practice for risk assessment.[30] Instead, the preferred test is the fasting plasma glucose test – a test in which an individual's blood glucose level is measured after he/she has fasted overnight.[31] With this test, an individual is diagnosed with diabetes if their fasting plasma glucose level is 126 mg/dl or higher. Those with fasting plasma glucose levels ranging from 100 to 125 mg/dl are classified as impaired fasting glucose (IFG) and considered to be at risk for developing diabetes. Although widely adopted, the fasting plasma glucose test is not without its challenges in terms of predictive power. Studies performed prior to 2003 found that the fasting plasma glucose test identified fewer individuals at risk for diabetes than the OGTT, and that the two tests do not necessarily identify the same individuals.[32] Moreover, the OGTT was a better predictor of mortality.[33] In 2003, the lower threshold for defining the "at-risk" IFG category was set to its current value of 100 mg/dl fasting plasma glucose in order to optimize its sensitivity for predicting future diabetes.[34] However, this had the effect of lowering the specificity of the fasting plasma glucose test, and now a very large fraction of the U.S. population is identified as "at risk" even though relatively few actually will progress to diabetes.[35]

Indeed, the basic underlying assumption upon which both the OGTT and the fasting plasma glucose test are based – that there is a threshold of glycemia (blood glucose) that distinguishes between people at high and low risk for diabetic microvascular complications – has now been drawn into question.[36] Type 2 diabetes is a progressive disease, and by the time the body is no longer able to regulate blood glucose to the point that diabetes is diagnosed according to blood glucose thresholds, a significant number of people have already experienced serious health consequences.[37] Accordingly, the focus is shifting away from relying solely on blood glucose as a single variable for defining the risk of diabetes and towards developing individual risk scores in which measures of blood sugar are combined with other risk factors in order to identify those at risk for developing diabetes.[38]

This multifactorial approach to defining diabetes risk is especially promising given the complexity of the disease. A large number of molecules in several metabolic pathways are known to be dysregulated in diabetes,[39] and some of these dysregulations occur years if not decades before the onset of diabetes.[40] Encouraging results from recent studies suggest that several markers may be useful in

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[30] American Diabetes Association: Standards of medical care in diabetes--2008. Diabetes Care 31 Suppl 1:S12-54, 2008.
[31] American Diabetes Association, All About Diabetes, http://www.diabetes.org/about-diabetes.jsp.
[32] Benjamin SM, et al.: Estimated number of adults with prediabetes in the U.S. in 2000: opportunities for prevention. Diabetes Care 26:645-649, 2003; Gabir MM, et al.: The 1997 American Diabetes Association and 1999 World Health Organization criteria for hyperglycemia in the diagnosis and prediction of diabetes. Diabetes Care 23:1108-1112, 2000.
[33] Coutinho M, et al.: The relationship between glucose and incident cardiovascular events. A metaregression analysis of published data from 20 studies of 95,783 individuals followed for 12.4 years. Diabetes Care 22:233-240, 1999.
[34] The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus: Follow-up report on the diagnosis of diabetes mellitus. Diabetes Care 26:3160-3167, 2003.
[35] Nichols GA, et al.: Progression from newly acquired impaired fasting glucose to type 2 diabetes. Diabetes Care 30:228-233, 2007.
[36] Wong TY, et al.: Relation between fasting glucose and retinopathy for diagnosis of diabetes: three population-based cross-sectional studies. Lancet 371:736-743, 2008; Mohamed Q, Evans A: Retinopathy, plasma glucose, and the diagnosis of diabetes. Lancet 371:700-702, 2008.
[37] Wong et al. *supra* note 36, at 741.
[38] Mohamed Q, Evans A. *supra* note 36, at 701.
[39] Petersen KF, Shulman GI: Etiology of insulin resistance. Am J Med 119:S10-16, 2006; Rhodes CJ: Type 2 diabetes-a matter of beta-cell life and death? Science 307:380-384, 2005.
[40] Martin BC, et al.: Role of glucose and insulin resistance in development of type 2 diabetes mellitus: results of a 25-year follow-up study. Lancet 340:925-929, 1992; Goldfine AB, et al.: Insulin resistance is a poor predictor of type 2 diabetes in individuals with no family history of disease. Proc Natl Acad Sci U S A 100:2724-2729, 2003.

developing a better test for identifying those at risk for diabetes.[41] Clearly, a multifactorial test that could precisely and accurately predict future development of diabetes would represent a major medical advance.

PreDx™ Diabetes Risk Score: a simple, multifactorial approach

Early prediction of the risk of type 2 diabetes is now possible with the PreDx™ Diabetes Risk Score (PreDx DRS). The PreDx DRS is a multi-marker model that predicts the likelihood that an individual will develop type 2 diabetes within the next five years. Simple and convenient, the PreDx DRS measures a collection of biomarkers in a fasting blood sample to calculate a personalized risk score. If routinely used as a screening tool to identify patients at high-risk, the PreDx DRS may improve patient outcome by facilitating early interventions (lifestyle modification and possibly medication if approved for early intervention) that can delay or prevent type 2 diabetes.

The PreDx DRS shares the simplicity of the ADA's currently recommended fasting plasma glucose test – both tests are performed on a blood sample taken after a patient has not eaten for at least eight hours – but the PreDx DRS offers far superior predictive value. Although the fasting plasma glucose test distinguishes between persons with IFG (presumably "at risk" for diabetes) and persons with normal fasting glucose (NFG, not considered at risk for diabetes), this distinction is not useful because there are simply too many people classified as "at risk" by this test. The fasting plasma glucose test, applied to subjects who are overweight and over 40 years old, classifies more than half of those tested (56%) as "at risk" for diabetes when in fact relatively few go on to develop the disease. The PreDx DRS is more discerning – the personalized risk score distinguishes between those who are truly at high-risk of developing diabetes (11% of the population) from those at moderate or low risk (31% and 58%, respectively). The objective assessment provided by the PreDx DRS thus allows physicians to focus on the relatively few patients that genuinely are at high risk of developing diabetes and to avoid unnecessary treatments and expenses for patients who are not likely to develop diabetes within the next five years.

The story behind how the PreDx DRS was developed is one of ingenuity, persistence, and discovery. After combing over 1600 abstracts from the scientific literature for biomarkers that were implicated in diabetes, an initial set of 58 serum molecules plus seven clinical variables were selected for evaluation. These 65 biomarkers are associated with five different pathways that are involved in diabetes disease progression – cardiovascular disorder, cell death, inflammatory response, metabolic disorder, and obesity. The initial set of 65 biomarkers was subjected to a statistical selection process[42] that evaluated the performance of the biomarkers when tested against 672 samples from a population

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[41] Festa A, et al.: Elevated levels of acute-phase proteins and plasminogen activator inhibitor-1 predict the development of type 2 diabetes: the insulin resistance atherosclerosis study. Diabetes 51:1131-1137, 2002;
Krakoff J, et al.: Inflammatory markers, adiponectin, and risk of type 2 diabetes in the Pima Indian. Diabetes Care 26:1745-1751, 2003; Liu S, et al.: A prospective study of inflammatory cytokines and diabetes mellitus in a multiethnic cohort of postmenopausal women. Arch Intern Med 167:1676-1685, 2007.

[42] Biomarkers were selected for inclusion in an algorithm on the basis of performance in 1) univariate logistic regression analysis, exhaustive enumeration of small (≤6) multivariate logistic models, and 3) frequency of selection within 100 bootstrap replicates using six different heuristic model building methods – forward, backward, and stepwise selection, Kruskal-Wallis test, random forest, ELDA – with three different learning algorithms – logistic regression, linear discriminate analysis, and support vector machines.

that had been monitored over the course of five years for the development of diabetes.[43] A subset of biomarkers that proved the most useful in separating patients that developed diabetes from those who did not were then selected for building mathematical models that could predict the likelihood of developing diabetes. After extensive testing and validation, a final model was created – the PreDx DRS – that is capable of providing a personal assessment of the risk of developing diabetes within five years.

Research studies have shown that the PreDx DRS has better performance than any single baseline risk factor (such as fasting plasma glucose or BMI) or any other non-invasive assessment of diabetes risk.[44] Available as a simple test done on a fasting blood sample, the PreDx DRS provides doctors and patients with an objective, quantitative assessment of diabetes risk.

Using PreDx™ DRS in clinical practice: a cost-effective way to save lives

With a powerful tool for assessing diabetes risk in hand, researchers then embarked on developing a cost-effective strategy for using the PreDx DRS to help reduce the death and suffering caused by diabetes. The strategy uses the personalized risk score provided by the PreDx DRS to tailor an effective diabetes prevention program for each patient according to their diabetes risk. By directing limited resources to the care of patients most at risk, the PreDx DRS may help to save lives while remaining cost-effective over current clinical practice.[45]

In accord with ADA recommendations,[46] the PreDx DRS would not be used to screen the general population but instead would be used to screen adults who are overweight or obese (BMI $\geq$ 25 kg/m^2) and have one or more additional risk factors for diabetes (physical inactivity, first degree relative with diabetes, etc.).[47] The PreDx DRS would stratify such a group of "at-risk" adults into three risk categories, each of which could follow a different plan according to their risk – low risk individuals (those with a 1% or less chance of developing diabetes within five years) would be re-screened in five years, moderate risk individuals (7% diabetes risk) would be more closely monitored with re-screening recommended in one, three, and five years, and high risk individuals (24% diabetes risk) would be followed much more closely with an individualized aggressive diabetes prevention program, which may include lifestyle modification or medication (Table 1).

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[43] The samples tested were from the Inter99 study, a population-based primary prevention study that was conducted to assess the effect of lifestyle intervention on heart disease in middle aged men and women. Jorgensen T, et al.: A randomized non-pharmacological intervention study for prevention of ischaemic heart disease: baseline results Inter99. Eur J Cardiovasc Prev Rehabil 10:377-386, 2003.

[44] Kolberg, J, et al.: Development of serum biomarkers for the prediction of type 2 diabetes: studies in the Inter99 cohort. submitted (2008); Kolberg, J, et al.: Training and validation of a multimarker algorithm for the prediction of type 2 diabetes from a 5 yr prospective study of 6,784 Danish people (Inter99), poster presented at the 68th American Diabetes Association Meeting (2008).

[45] Sullivan SD, et al.: Long-Term Cost-Effectiveness of a Diabetes Risk Score in Clinical Practice: A Preliminary Assessment, ISPOR, Toronto, May 5, 2008.

[46] American Diabetes Association, *supra* note 30.

[47] In those who lack additional risk factors, screening would begin at age 45 years. American Diabetes Association, *supra* note 30.

Table 1 – Possible plans for "at risk" adults screened with the PreDx™ DRS

Risk Category (percent chance of developing diabetes within the next five years)	Percent of Population	Recommended Course of Action
Low Risk (1%)	54%	Follow-up PreDx DRS screening recommended every five years.
Moderate Risk (7%)	36%	Close monitoring recommended with PreDx DRS screening in one, three, and five years.
High Risk (24%)	11%	Lifestyle modification and possibly medication. No additional screening necessary.

Even using a conservative estimate that treatment of the high-risk group results in a 43% reduction in the number of people who become diabetic in a five year period,[48] estimates show that this strategy reduces mortality, improves quality of life and reduces the overall cost per patient as compared to current practice. Because the cost of PreDx DRS testing would make up a relatively small percentage of the health care cost in this "at risk" population, this strategy remains cost effective even if reimbursement for the PreDx DRS were to be several times higher than the planned market cost of $775 per test. In conclusion, under a variety of scenarios, early prediction of type 2 diabetes with the PreDx DRS is cost-effective given certain assumptions regarding screening efficiency and availability and effectiveness of preventive treatment.

Conclusions

The prevalence of diabetes in the U.S. has reached epidemic proportions. Because of the serious health consequences associated with diabetes, it has become a major burden for the health care system. Diabetes can be effectively delayed or prevented by lifestyle changes and medications; however, new tools to identify patients at risk of developing diabetes are urgently needed. The PreDx DRS is a multi-marker model based on a simply collected blood sample tested at the Tethys Clinical Laboratory that identifies patients who are at low, intermediate, and high risk of developing diabetes within five years. This test can help optimize healthcare resources by focusing aggressive diabetes prevention programs on the relatively few patients at high risk of developing diabetes and avoiding unnecessary expense for low risk patients. The PreDx DRS has proven to be cost effective under a variety of analytical scenarios, and is a promising new tool for the fight against diabetes.

[48] The DPP study found a reduction in diabetes conversion of 58% with lifestyle modification and 31% with metformin treatment, for an overall mean reduction in diabetes conversion of 44.5%. The Diabetes Prevention Program Research Group, *supra* note 22.

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