THE BROOKINGS INSTITUTION

IMPLEMENTING COMPARATIVE EFFECTIVENESS RESEARCH:

PRIORITIES, METHODS, AND IMPACT

Washington, D.C.

Tuesday, June 9, 2009

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SEN. MAX BAUCUS (D-MT)
United States Senate

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ROBERT E. RUBIN
Former Secretary, U.S. Department of the Treasury
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Presenter:

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Discussants:

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Discussants:

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ELLEN SIGAL
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STEVEN PEARSON
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Closing Remarks:

MARK MCCLELLAN
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P R O C E E D I N G S

MR. McCLELLAN: Good morning, everyone. I'd like to welcome you here to The Brookings Institution this morning. I'm the Director of the Engelberg Center for Health Care Reform here at Brookings, and on behalf of Bob Rubin and The Hamilton Project we'd like to welcome you to today's event on one of the key issues for Health Care Reform: Implementing Comparative Effectiveness Research.

We're delighted to have such distinguished participants to discuss this issue today, and that, of course, includes all of you here, all of you in the overflow room. I know we've got a lot of participants on-line as well.

Comparative Effectiveness Research has vaulted to the front lines of the Health Care Reform debate. As you'll hear from some of our upcoming speakers, it could even be a game-changer, a key part of bending the health care cost curve, and comparative effectiveness research is moving forward. The American Recovery and Reinvestment Act of this year,

the economic stimulus legislation invested $1.1 billion in federal initiatives to conduct comparative effectiveness research and expand current activities. This includes an effort to coordinate new and existing efforts in comparative effectiveness research.

The legislation created a new Federal Coordinating Council, which has begun its work. The Institute of Medicine will produce its recommendations under the law for national priorities for national comparative effectiveness research efforts by the end of this month. But fulfilling that promise of comparative effectiveness research for better quality, better outcomes, and value in health care will require answering some important questions that have not yet been tackled. There are some differences in views about whether comparative effectiveness research can have a substantial impact on the health care cost growth curve, and there are some further concerns about whether that happening is a good thing, whether such restrictions on cost growth would be a good thing.

As we'll talk about today, what kind of impact can come from comparative effectiveness research may come down, not just to whether we spend the money but how it's done. Such questions include what research issues should be prioritized, what methods are appropriate for comparative effectiveness research, and where will the data come from, and how can comparative effectiveness research findings be used to maximize the impact on clinical and health policy decisions.

We're going to talk about potential answers to these questions this morning with the help of an impressive and diverse set of participants. We're delighted to be joined by Senator Max Baucus and OMB Director Peter Orszag to give their perspectives on how comparative effectiveness research and the availability of better evidence on health care can help shape the health care system in years to come.

Then we've got three Commission papers and discussants for those papers -- these are peer-reviewed papers. All of these participants have

distinguished records. Their bios are in your conference material, so I'd take the whole morning to summarize them, I'm not going to try. But finally, and most importantly, we look forward to hearing from you about the best ideas and concerns for moving this health care reform debate forward.

We've got a full agenda, a limited amount of time. We're not going to have any scheduled breaks. If you need one, please feel free to take it, particularly during the brief transitions between the panels. This is a large group. We're going to set this meeting up in a way, though, that has some time for questions and open discussion.

We'll have roaming microphones in the audience. Please raise your hand if you have a comment, but it's imperative that you keep your questions brief and also please identify yourself when you ask a question.

The event is seen webcast-wide. It will be archived on the Engelberg Center website. We also have a number of press in attendance, so please be

aware that all the remarks are on the record. And, finally, I want to alert our speakers -- not you, Senator Baucus, but other speakers -- that there's a timekeeper in the front row who will be making sure that you stay right on time.

So with that I'm very pleased to introduce Senator Max Baucus, who will be giving the day's opening keynote. Senator Baucus, as all of you know, has a distinguished record of service for Montana and the country in the Senate since 1978. He's Chairman of the very important Senate Finance Committee where he's leading an effort in conjunction with ranking member Senator Chuck Grassley to get consensus on a comprehensive bipartisan health care reform bill in the coming week.

As part of that effort, Senator Baucus has been a passionate advocate for comparative effectiveness research done right, sponsoring his own legislation with Senator Conrad during the last congressional session, and also including provisions

to address the appropriate use of cost information in comparative effectiveness research.

In addition to all of this, he still finds time for ultra-marathons, which is probably pretty good preparation for what he's trying to accomplish now.

Senator Baucus, we're very pleased to have you back at Brookings for this opening keynote.

(Applause)

SENATOR BAUCUS: Thank you, Mark, very much, and thank you very much for inviting me to your session today to talk about an issue I think of great transformative effect, and that is comparative effectiveness research.

Cynthia Nelms once said, "If men liked shopping, they'd call it research." Think about it. From cars to television, when Americans go shopping, they're readily able to find and evaluate information about the quality and effectiveness of almost anything, but not so for health care.

Why shouldn't Americans have information on what works and what doesn't when it comes to their health? That question is especially important when one considers that health care for Americans spend one in every six dollars that we spend in a year. Since the Finance Committee began to pray in for a comprehensive health reform last year, comparative effectiveness research has been mentioned very often. It's almost constantly mentioned, and it has raised almost as much controversy. It's a hot topic, so much so that senators on my committee on both sides of the aisles suggested that we stop using the name, stop calling it "comparative effectiveness research." They suggested that we switch to something else that is a little less controversial in its branding.

So we talked about this one day and I, just off the top of my head, said let's call it FRED. That might be more palatable and less ominous. Another name we could use is Patient Centered Outcomes Research, we could call it

P-COR. At least it would reflect the intent of the research, or we could just call it "shopping." Whatever we call it, one thing is certain: We need to address the very real concerns that this research might help, but very real concerns that this research might be used to, quote, "ration health care."

People talk about cost-effectiveness versus clinical effectiveness. People talk about whether the research can be used to make coverage decisions. These concerns boil down to one underlined issue: rationing. This is serious and needs to be addressed with integrity. There are several ways: The first is to make sure that the research is patient-focused. The research must consider patient preferences for how they want treatments to work. Patients must be actively involved in studying the research priorities and in designing the research study. The research findings need to be relevant for patients.

We should assist patients so that they can participate in the process for developing priorities and designing studies. Patients' representatives

should be given training on technical matters so they can interact with researchers and other stakeholders on these matters. In short, patients much be at the center of the questions about medical care that we want answered.

Next, practicing physicians need to be at the table, not just researching physicians but those who use and prescribe medical care. They know what questions to ask, and they are key to making the research meaningful for the decisions that we make with patients.

Third, we need safeguards: safeguards, when it comes to the use of research in federal health care programs. Medicare and Medicaid should not be allowed to create automatic links to any single study. These programs need to be open, transparent, and thorough in how they use patient standard research. Nothing should be done behind closed doors without public input.

We should not build walls around the research. We should not bar any federal program from

using it in a responsible and transparent way, but we should build in very clear lines in the road so that the agencies only use the research in an open and deliberative way.

Many patient groups see the value, indeed the need, for more of this type of research. Let's take prostate cancer. Men with prostate cancer have a choice among three common treatments: surgery, radiation, and chemotherapy. Each approach yields different outcomes in terms of survival and quality of life. Some areas of the country tend to use one approach; some use other approaches, and some of these are more costly and less effective than the others. Comparative effectiveness research would compare the clinical outcomes of each approach in a systematic way. That way doctors and patients would have more information about how options work and for whom. Patients want to know what the best options are, and this type of research would help.

So what is the future of patient-centered outcomes research? We have two choices: We could

continue to hope that each year Congress appropriates scarce dollars to federal agencies and that the studies they produce are ones of national import; or we can put this type of research on more solid ground by removing it from political influence and funding eclipse by setting the ground rules for how the research is identified and conducted.

I prefer the second approach, and that is why I introduced Comparative Effectiveness Research Act of 2008 as Mark said, along with my colleague Kent Conrad. He and I share a passion for this. We believe it is fundamental to transforming our health system from one that is falling and driven to one that is evidence-based. There are many, many other components of moving in that direction, but comparative effectiveness research is clearly a part of it.

This year we plan to reintroduce the bill. We've been discussing it constantly with staffs, on the committee, and elsewhere. We are close to coming to an agreement, and that's important because I intend

to include my bill, that is the comparative effectiveness research bill, in the Comprehensive Health Reform bill that we'll mark up in the Finance Committee later this month.

And that brings me to my last point: the need for comprehensive health reform. The Finance Committee has spent many hours, many days, weeks and months laying the groundwork. We had 12 hearings over the last year, all-day summits at the Library of Congress. We held three public roundtable discussions, at least three documents outlining options for reform, totally accusive, totally bipartisan. I've never participated in a more inclusive endeavor in my life, and we're coming to one fundamental agreement that something must be done.

In 2008 America spent $2.4 trillion in health care. That's one-sixth of our economy, yet we rank last among major industrialized nations in the Commonwealth Funds national scoreboard on health system performance, which ranks the number of deaths that could be prevented before age 75 through

effective health care. Last. The United States ranks last.

Some analysts estimate that as much as 30 percent of our spending is for ineffective, redundant, or inappropriate care. That's care that does nothing to prove the health of Americans. Our system leaves nearly 50 million Americans without health insurance, 25 million more with inadequate coverage. Most bankruptcies and foreclosures in America are related to medical costs. Our system needs reform. If we fail to act, health care studying will account for 20 percent of our economy in 10 years; or put another way: 45 percent of the family's budget will be spent for a health care premium. Rising health care costs will swamp federal and state budgets, businesses and American families alike.

The exchange of expense at this rate, it's only fair that we ask ourselves what are we getting for our money, and what are we not getting for it? It's time for America and the doctors to use the world's most advance science so that the most personal

health care decisions are made with access to the best available information.

Okay, I'll admit it. The experience of going to a doctor will not be quite as much fun as shopping for a car, but let's make sure that because we spend one out of every six dollars in America, let's' make sure that it is at least as efficient as the way we buy that car or that TV, and that way not only will we get a better experience if we go to the doctor but we also get a healthier America.

Thank you very much.

(Applause)

MR. McCLELLAN: Thanks very much, Senator, and Senator Baucus has graciously agreed to stay for a few questions, so if you could raise your hand, as I said, we'll have roving microphones around the room. So hands up if any questions.

Yes, up here in front. Ellen. We have the mikes coming.

MS. SIEGEL: Thank you. Ellen Siegel, Center for Cancer Research. First I want to thank you

for all of your work on comparative effectiveness, it's really appreciated.

Question: The Senate bill on the RF funding had clinical effectiveness. It was taken out of the House side. Perhaps you can address that or address the importance of clinical effectiveness and some of the nuances,

SENATOR BAUCUS: Yes, the real issue here -- and that was a big battle, frankly, in the stimulus bill -- is it rationing or is it not rationing in political terms? And that came down to due to which cost-benefit analysis will not be included in a clinical effectiveness research.

And some members of the Congress, especially in the Senate, even also in the House, were fearful that that would be used to ration this cost-benefit analysis. And I made it very clear that, no, this is clinical effectiveness, and, clinically, does this procedure, does this prod- -- you know, does this, you know, medical device, is it better than the other or not?

I'm fond of explaining how FDA analysis reviews a drug application, looks only to see whether it's safe and if it works, and it compares it with a placebo and not against any other drug. And I think we need to do some comparison here, not just drugs and medical devices, and develop some procedures to see which is more effective. And so we have much more evidence-based medicine in America, based more on value and reimbursement is based more on quality and value than volume.

And I think that we'll be able to get this included in health care reform as comparative effectiveness research, FRED we're going to call it, as long as we make it clear that there's no cost-benefit analysis here; this is purely a clinical comparison.

MR. McCLELLAN: Senator, to follow up on that, there are some people who have argued that if you don't have a focus on cost as well, then it's going to make it more difficult to use comparative effectiveness research to get savings. It sounds like

from your presentation earlier with all the evidence on ineffective care, the wrong care that you cited that you don't agree.

SENATOR BAUCUS: I think that costs will come in and decisions made by patients, by providers, will take cost into consideration, that they will know what one procedure and one costs compared with another, what one drug costs compared with another. Patients will know, too. Insurance companies will know. But that's a decision that they're all going to have to make when they have the clinical comparison. It's up to them to look at cost, but it's not up to the agency itself to prescribe, you know, hat should or should no be used on the basis of cost.

MR. McCLELLAN: A question in the back? Yes?

MS. GAOUETTE: Thank you, Nicole Gaouette from Bloomberg News. We know that that Senate Republicans sent a letter to President Obama I think just yesterday voicing their concern about a government-run health care plan. I want to know how

you plan to bridge that divide. I know that there are a lot of meetings going on this week about that, but how, specifically -- and what you feel about this opposition. I know you're very close to Senator Grassley

SENATOR BAUCUS: Well, I didn't think it would take very long before I got that question. (Laughter)

You know, it's interesting to me, I'm very, very pleased, like, for example, this morning, front page, both The New York Times and The Washington Post, articles about the need to transform our health care system. And that reflects the view of senators on both sides of the aisle. We know -- and not to be presumptuous about this, Republicans also know and deeply know -- that we need to transform our health care system. A quote by Senator Gregg this morning, there's good evidence of that, a good example.

And we're trying mightily to find a resolution, and it's all -- requires a lot of education. One of my biggest problems in getting a

health care legislation passed is it's so complex, so difficult. We all have a fairly steep learning curve here, and for some of us it's near vertical. So we have spent a lot of time, and that's why we had all these sessions, all these meetings getting people up to date, up to speed, and how does this work? What works? What's good? And, you know, ignorance breeds fear, and so the more we dig into it, and we've had a lot of meetings on so-called public option. We meet daily, I do, with other senators, particularly key senators, especially senators like on the Republican side who I think, who I know are trying to find a solution here to see how we, you know, thread that needle.

But it's -- that letter is just, I think to be honest about it -- it's just kind of indication, it's somewhat -- I don't want to overstate this because somebody's going to jam this down my throat -- but it's somewhat positioning, getting ready for a resolution, ready to come up with. But we'll find a resolution.

MR. McCLELLAN: Time for one more question in the back here.

MR. PUCK: Gary Puck with National Minority Quality Forum. In 2020, 40 percent of the U.S. population is going to be African American.

SENATOR BAUCUS: I'm sorry, I can't see you. Would you raise you -- oh, yes, I'm sorry.

MR. PUCK: In 2020, 40 percent of the U.S. population is going to be the African American or Hispanics. When you look at clinical trials today, last count six percent of the clinical trials African American, about three percent Hispanics. How do you do comparative effectiveness in that environment?

Even more importantly, how do we prepare the health care system for a diverse population with patient vulnerability?

SENATOR BAUCUS: Well, clearly, a comparison analysis has to take that into consideration and make an affirmative effort to make sure that if -- its trials are representative of the whole population, as a whole. And it's -- you know, I am very excited. We

are on the even of doing something terrific here in America, health care reform. It's so transformative it's going to be game-changing, and a lot of it is liberty system reform.

I see Peter Orszag here, and he's got us thinking about this some time ago, and it's true. I am very heartened, too, I'm so happy that somebody gave me this article to read -- man, it's a great article. And it turns out the President read it, too, about the same time and, independently, both came to the same conclusion, and I got to tell you, it's the rage among senators interested in health care reform right now. That's the Gawande piece in The New Yorker, the June 1 issue. And -- Peter? No, he's not here. I want to tell him what a good job he did.

MR. McCLELLAN: Yeah, we'll hear about it.

SENATOR BAUCUS: Okay.

MR. McCLELLAN: We will hear about it in just a minute.

SENATOR BAUCUS: Okay. It's not perfect, nothing's perfect, but, man-oh-man, we're moving in

the right direction, and I'm very confident that because of the basic understanding of the goodwill members of the House and Senate that we're going to get health care reform passed this year. It takes work. It is complicated, it's really complicated for people to understand it. We're also going to have to help educate the American people. You know, that's who we work for, they're our employers, you know, they're our bosses, and that's going to take a lot of work, too.

I remember talking to Bill Maveley, formerly the head of AARP, and that's one thing he learned very quickly, that his membership just doesn't quite understand all that's going on here, and we've got to take that bit of information to heart here as we work to make sure the American people understand it with us about as well.

So thanks, everybody. I'm glad you're doing this. It's so important, and thanks for your effort.

MR. McCLELLAN: Senator, thank you so much.

Thanks, Senator Baucus.

Now it's a real honor for me to introduce my co-Chair for this event, Robert Rubin. Bob joined the Clinton Administration in 1993 serving as Assistant to the President for Economic Policy and the 1st Director of the National Economic Council. He also served as our nation's 70th Secretary of the Treasury from 1995 to 1999, where he played a leading role in many of the nation's most important policy debates and also was my boss back then.

Subsequently, from 1999 to 2009 he's served in a number of other roles including recently being named co-Chairman of the Council of Foreign Relations and serving for Mt. Sinai Medical Center, Harvard, and other groups as well. Bob was one of the founders of The Hamilton Project and the Economic Policy Project at house here at Brookings and continues to offer strategic vision and innovative policy proposals on how to crate a growing economy that benefits more Americans.

Bob?

(Applause)

SECRETARY RUBIN: Thank you, Mark. As Mark said, I'm Bob Rubin. I'm here on behalf of The Hamilton Project, and I join with Mark in welcoming all of you to what I agree with Max Baucus' comments as being that this is a really very important subject and a very useful event.

We're deeply honored to have had as our speaker, our first speaker, Max Baucus. He's an old friend. I've spent many, many months fishing the waters of Montana. I have set a state record for leaving flies in the trees along the rivers of that wonderful -- of that wonderful state.

We are also deeply honored to have with us Peter Orszag, the Director of the Office of Management and Budget, and I'll introduce Peter shortly.

Let me first, however, step back for a moment from today's discussion and agree with something that Senator Baucus said. I've been around economic issues in various regards for a long, long time, and I don't think there is any question that is absolutely imperative that we have major reform of our

health care system, to address wasteful expenditures, to reduce the rate of increase of health care costs, to improve outcomes, and absolutely critically to move toward accomplishing universal coverage.

The rapid rate of increase in our nation's health care costs is, in my view, a grave threat to our economic future, both by undermining competitiveness and by fueling the steep rise in federal health care expenditures which, as I'm sure Peter will tell you, is at the heart of an unsustainable long-term fiscal position in our country.

I am certainly not an expert on health care reform, and as Max said -- Senator Baucus said -- it is a very complex subject. But many, many such experts believe that comparative effectiveness research, the subject of our discussion today, has the potential over the longer term to materially reduce the rate of increase of health care costs and at the same time to improve outcomes.

The papers that will be discussed by the outstanding group of panelists that Mark has put together today, and the overarching paper, which I would strongly recommend you read, by Mark and by Joshua Benner raise various points of view and various issues with respect to the impact of comparative effectiveness research and various ways of using and constructing that research and the uses of that research.

As I've already said, I am a lay person, not an expert on health care, but I'd like to spend just a couple of moments drawing on my own experience to expand on or emphasize a few of the questions that will be discussed in the panels today.

Firstly, I had at one time a potentially disabling back problem. It turned out to have a highly idiosyncratic cause that required multiple diagnoses and multiple approaches to treatment to finally figure out what was going on and, fortunately, to reach a totally successful resolution. But I remember the doctors who treated me saying that the

key to my situation was that there was a very specific cause that was very rare, and that would occur with almost no one else who had my symptoms.

So my first question would be, how does comparative effectiveness research capture that individuality in its studies and in its treatment?

Relatedly, as many of us have experienced -- and I know I certainly have, different individuals can react very differently to the same medications based on body chemistry or on comorbidities. And, as was raised by one of the questions to Senator Baucus, different groups in our society can have very different medical circumstances in many highly important ways, again, how does comparative research address these aspects of individuality with respect to both the studies and with respect to treatment?

Thirdly, comparative effectiveness research -- and as you read more about this I think it comes through fairly clearly, very often in the discussions conflates two separate purposes, and Senator Baucus alluded to this. One is putting together a body of

knowledge that can provide useful guidance to patients and to doctors, and the other is cost-benefits judgments about the cost that additional treatments may have. The obvious question is, to what extent will this research leave doctors and patients free to make their own decisions in each particular case as to what they think works best, and, I should say or, to what extent will this research create constraints on those choices?

To go one step further, what role, if any, should this research play in addressing the seemingly inevitable imbalance between fully meeting all medical care needs and any reasonable projection of the resources that will be available for medical care?

And finally, a question particularly addressed to Peter, is there any reasonable way to estimate the benefits that comparative economic research can have in meeting the objectives of health care reform even if those benefits are not officially recognized by the Congressional Budget Office and its accounting?

I have an impression as a lay person who's now taken the trouble to read a fair bit about the subject. The comparative research can be a very powerful tool for health care reform, but there are, obviously, a lot of questions that need to be explored and resolved. With that, let me introduce Peter Orszag. I first met Peter when he stood out for his intellect, his thoughtfulness, his industriousness, and to some extent, his sense of humor, while working at the White House in the latter years of the Clinton Administration.

Later in the post Clinton years, Peter and I worked together in opposing tax cuts that we thought were fiscally unsound and opposing a social security proposal that we also thought was fiscally unsound, as well as being unsound with respect to retirement security.

Out of that effort came the decision to found the Hamilton Project, which Peter led with such enormous distinction, and which was aimed at developing a strategy and then policies pursuant to

that strategy to promote economic growth, much broader based participation in that growth then we've been experiencing, and increased economic security.

We then lost Peter to what some at least viewed as a higher cause, when Peter was named Director of the Congressional Budget Office, and now, of course, Peter is the Director of the Office of Management and Budget. In that role, Peter is absolutely central in providing leadership and dealing with the immediate economic crisis, in dealing with the enormous shortfalls our nation has with respect to absolutely critical public investment, and in dealing with the federal government's unsustainable long term fiscal position which is such a threat both to the capacity for public investment and with respect to economic growth.

I don't think there is any doubt that Peter will lead us to successful resolution on all of these fronts. So without further adieu, let me introduce the distinguished Peter Orszag. Thank you very much.

MR. ORSZAG: Thank you, Bob, and good morning to everyone. I am delighted to be here. I want to start today with a story which was invited in a recent New Yorker article, but I found it so compelling, and the President found it so compelling, I followed up by asking the researchers at Dartmouth College for additional information. So I just want to talk for a few moments about this story.

There are two towns in Texas, El Paso and McAllen, Texas, they are both – have similar demographics, they both have about 700,000 people living there, and in 1992, not too surprisingly, given their overall similarities in their populations, Medicare expenditures were – patterns were fairly similar in the two cities in Texas. Since then, however, there's been a dramatic difference. McAllen, Texas has grown much more rapidly than either the rest of the country or El Paso, and the result is that now McAllen spends more than twice as much as that comparison city in terms of Medicare spending per

beneficiary and more than twice as much as the U.S. average.

And you can see that difference showing up in all sorts of medical indicators, from hospital stays, to physician visits, to labs and testing, to home health care, and you can continue down the list.

Now, those additional expenditures would be worth it if the result was higher quality and better outcomes in McAllen. But as the New Yorker article emphasizes and as the data suggests, we are not getting higher quality for those additional expenditures in McAllen, and if anything, actually quality is lower in McAllen than in El Paso.

I think a central fact surrounding our health care system is that higher cost does not mean higher quality. We are oriented towards more intensity and more, rather than better, health care. And one of the key things that has to change is that we need to reorient the system towards higher quality rather than just more. Now, how can we do that and how can we address this regional variation? I think,

again, if you read that article, there are at least four steps that would be helpful. The first, and it was stunning, when Atul Gawande went and interviewed doctors and hospital administrators in McAllen. Many times they were not even aware that they were more intense users of the health care system or they were doing more tests and more procedures and more days in the hospital than elsewhere.

Simply providing information and benchmarking against comparison cities or against comparison hospitals or against comparison doctors can help. And I'll come back in a moment. And actually, let me just pause.

For example, Bob raised a series of very interesting questions. One of them was the idiosyncratic nature of the back pain that he faced. I would note, and I'm going to come back to this, that it would be useful for the physicians and the doctors that Bob was visiting to have more information about what was likely to work in the first case, but even for that particular case, we have dramatic variation

that is not explainable by medical evidence. I think an interesting example is, when I visited Mass General last year, folks reporting lower back pain and admitted to Mass General are admitted almost randomly, not quite, either to see a nerve specialist or a bone specialist, because after all, it could either be a nerve or a bone problem that's effecting your back.

It turns out that they had never measured before, that the rate of spinal MRI ordering was dramatically different depending on whether you entered the hospital through the nerve mode or the bone mode, and whether you saw a neuro radiologist or a muscular skeletal radiologist.

When they finally sat the radiologist down and said, why are these so dramatically different, even for the same clinical notes, they were able to reduce that variation, eliminate many of the spinal MRI's that were unnecessary, which not only drive up cost, but actually also pose potential risk to people. You don't want to get unnecessary tests done or spend

unnecessary time in the hospital because that poses a health risk.

So I will come back to this, but the point is, sometimes just simply providing information and comparisons can help to address regional variation and move towards a quality oriented system. Sometimes, however, we don't know what works, we don't know whether that spinal MRI is or is not warranted, and that's what the focus of today is, that we need much more information provided to the medical system so that doctors and hospitals know what works and whether those additional procedures are or are not warranted.

Finally, as the article emphasizes, in some cases, and this is not a derogatory statement, it is natural that doctors and hospitals also do not do things that are, you know, that disadvantage them financially. And we have a set of incentives currently that rewards more intensity and then actually financially penalizes those providers that are more efficient and that approach – that adopt lower intensity, even if they are more effective,

health care procedures. We need to change that, and I'll come back to that also.

And then finally, I think there are questions about the overall way in which we set health care policy in the United States. The Administration has put forward a proposal to empower MEDPAC, the Medicare Payment Advisory Committee, with fast track protections under congressional consideration so that we can move towards a system in which you are constantly keeping up with the dynamic evolving health care market and addressing the kinds of disparities that open up between McAllen and El Paso through an evolutionary process in which changes are adopted, you see what works and what doesn't, and then more changes are adopted.

All of this is very important and I'm going to come back to the patient centered health research that is at the heart of today's conference. But I do want to pause because I think there's been a lot of confusion about how the Administration is going about

undertaking health care reform and what we see as the key priorities.

In addition to addressing regional variation and moving towards a more efficient system, there is a moral imperative to expand coverage and reduce the ranks of that in short.

In order to finance that expansion of coverage, we will have hard CBO scored offsets. So I want to be very clear. The package – the reform plan as a whole will be deficit neutral under CBO scoring over the next five to ten years. There is no ambiguity about that. I think many people have confused our efforts to lead to a more efficient health care system and address regional variation with the hard offsets, that is reductions in payments for Medicare advantage plans, reductions in payments for other types of providers, some changes in Medicare beneficiary cost sharing that we have proposed, and additional revenue with the changes that are necessary to lead to a more efficient health care system. We need to do both. We need to offset the full cost of

any changes over the next five or ten years in a deficit neutral way, through hard score able savings. This is not make believe, this is not untested proposals, this is – these are proposals that have been scored by an appropriately skeptical Congressional Budget Office. And on that basis, the package must be deficit neutral.

And I'd point out, by the way, that it's not just the President's insistence that the plan be deficit neutral. But even if you look at likely congressional configurations, it seems to me implausible that a plan that is a big deficit increaser, again, under CBO scoring, would pass the U.S. Senate, because you either need 60 votes to pass, in which case deficit concerns are likely to be particularly salient for many of the senators who would be considering voting for the package, or one relies on reconciliation as a backstop. Reconciliation must be deficit reducing. So either way, even without the President's insistence, I think deficit neutrality is going to be a key part of the

overall package. And, again, the President is insistent anyway. So the confusion that has arisen about whether this will actually be deficit neutral I think is misplaced, it will be under CBO scoring. But if that's all we did, if all we did was expand coverage and pay for it in a sort of traditional, within the box kind of way, we would be perpetuating a system in which the McAllen's and El Paso's of the world, those differences were projected forward in time, and that is an unsustainable system.

So in addition to addressing the moral imperative of coverage, and paying for it in a responsible way, we also need to address the inefficiencies in regional variation that arise in the system, and that has to do with this other bucket of activities, what we're calling the long term game changers, which we believe, over time, will lead to a more efficient health care system.

And I would put to you that I have been at enumerable Brookings conferences, and Institute of Medicine meetings, and CBO conferences, and so on and

so forth; if we are leaving something off the list that you believe would actually help to drive a more efficient health care system, let me know, because we are trying to dial up these long term game changers as much as possible, and I believe we are reflecting the best knowledge that is out there about what would work, admittedly, it's uncertain, precisely because we have never tried to transform this health care system into something that would work better, but we are reflecting the considered judgment of people who have studied the system for decades and trying to do the best job that we can.

So I would welcome additional suggestions to the extent that they exist, but again, I want you to appreciate that we are trying to do as much as possible, and I think this is the most aggressive set of game changers that has ever been put on the table either by an administration or in a legislative process.

So let me return to, again, more information being key. We have $19 billion in the Recovery Act

that will go towards health information technology and moving towards a universal system of health IT.

We also need more information about what works and what doesn't; I'm going to turn to that in a moment. Changes in financial incentives, we have already put forward a variety of proposals involving bonus eligible organizations, penalty incentives to reduce hospital readmission rates, other bundled payments that will help to change the financial incentives facing providers so that they're more oriented towards quality and less towards quantity. And then, again, we have put forward a proposed change in the process for decision-making so that we can keep up with a dynamic health care system over time.

The focus of today's conference is one of those key pieces, which is that too much of the health care delivered in the United States is not backed by any evidence that it works better than an alternative, which is one key reason why you have this dramatic difference between McAllen, where there's a lot more done, but you don't get better results for it.

And, in fact, the variation seems to occur as this Atul Gawande quotation suggests and as the evidence underscores, the variation seems to be largest precisely in those areas where we don't know what works and what doesn't, where it's clear what should happen, the variation is less extreme, where there's a lot of ambiguity, there's more variation, and then again, we have a payment system that accommodates the more intensive approaches, even if they are not backed by evidence that they work. And I think you can see this in a variety of ways. For example, the American College of Cardiology and the American Hospital Association have clinical practice guidelines, only about half of which are backed by hard evidence that they are justified. Similarly, the Institute of Medicine has suggested that a very large share, and again, perhaps as large as half of the health care delivered in the United States across the board is not backed by specific evidence that what your doctor is recommending or what is being done actually works better than an alternative.

We spend, as the papers for this conference suggests, a very tiny share, .1 percent or less of total health care spending in the United States, trying to examine whether what we're doing works, and that needs to change.

We have $1.1 billion in the Recovery Act to expand this kind of research. The goal is precisely to provide, returning to some of Bob's questions, more information about what's likely to work in that kind of case.

Now, I would note, let me try to be directly responsive to some of the excellent questions that were raised both during the previous session and by Mr. Rubin. First, it seems to me critically important that we not just look at national averages. There is a huge amount of variation in what's likely to work for different types of people. What that will necessarily entail is, as Sean Tunis points out in the papers -- by the way, I did read the papers for this conference last night, they were very good – in Sean Tunis' paper, that we are likely going to have to

adopt different types of evidence procedures for this research effort, and randomized control trials will not be – cannot be the only standard by which we judge things, because in order to get a wider array of evidence brought to bear, we are likely going to have to struggle with different types of evidence.

And what I find fascinating, by the way, is exactly at the same time that the field of economics is moving away from panel data econometrics in which you're trying to tease out causal relationships from large data bases, and moving towards randomized control trials whenever possible, the medical profession I believe is going to have to move, to some degree, in the opposite direction and rely on the panel data that will come out of a more expansive set of health information technology precisely to examine, it won't be able to get exact individualized recommendations, but what would be more likely for a fly fishing distinguished former public servant suffering from back pain so that you – with a rich enough data base, the sub samples of different types

of people become more – it becomes more possible to study what will work and what won't.

I think the other thing that we do need to pay attention to, and this was a key part of one of the other papers by Alan Garber and David Meltzer, where are we going to put the dollars that have already been appropriated and any future dollars that will be appropriated? The value of information concept that they put forward strikes me as making a lot of sense. You should put the research dollars towards the areas where there's a lot of uncertainty about what will work or what the right thing to do is and where there is a lot of money going into that kind of procedure, test, what have you.

So it's the combination of the biggest payoff comes where, again, we don't really have a good – we don't have a lot of information about what's working and what's not, and we're spending a lot of money on that stuff. And then beyond that, obviously, there are a variety of other priority settings that needs to occur. I finally want to speak directly to

some of the critics of this effort. It strikes me that this is not about getting in the way of you and your doctor, it strikes me that it's not about a government run dictated on/off switch, but rather, it is precisely about making sure that your doctor and you have as much information as possible on what is likely to work for you.

It's not always going to be right, but under the current system, you lack a stunning share of cases, that information does not exist. And providing your doctor and you with information, for example, about back pain, that this procedure is more likely to work and this is not, it's difficult for me to see how that could be something that is a problem.

And, in fact, it's difficult for me to see how we will get at the McAllen/El Paso variation without knowing more about precisely what types of procedures, tests, and other medical procedures are likely to work for subsets of the population and then allow for individual variation beyond that.

I want to just, again, sum up by saying two main things. First, we cannot perpetuate a system in which, as you saw from McAllen versus El Paso, we spend twice as much in some areas than others and don't seem to get anything in return for it. Addressing that is going to be very difficult. You can't write down a full list of proposals today that will address it in any kind of definitive way. But we conceptually know, based on the work that has been done here at the Institute of Medicine and elsewhere, the types of things that seem the most auspicious, we are trying to do as much of that as possible, and then perhaps just as importantly, put in place a change in the process so that we can keep up over time with an evolving health care market.

Separate and apart from that, the health reform that will be adopted at some point this year, working with Senator Baucus and others, will be deficit neutral based on CBO scoring of very clear offsets in terms of Medicare and Medicaid savings and additional revenue.

We have already put on the table $635 billion in scored savings, scored offsets. The President indicated last week that we will be putting $200 to $300 billion more on the table in the very near future in terms – with specifics behind that. And you can easily do the math to see that you're then quickly getting into the range of the sorts of packages that are under discussion on Capital Hill. Do not confuse those two things, we need to do both. We need to address the moral imperative of expanding coverage and pay for it, and we also need to make the health care system more efficient. Thank you very much.

SECRETARY RUBIN: Peter, that was terrific. Peter has about five minutes to respond to some questions before he has to get to a White House meeting. And in his administration, meetings apparently start on time.

MR. ORSZAG: Are you going to be recognizing people?

SECRETARY RUBIN: Okay. Well, you can recognize people.

MR. ORSZAG: It's whatever you like.

SECRETARY RUBIN: Okay, it doesn't matter to me.

MR. THORE: Thank you very much and I appreciate your comments this morning. Bill Thore with the American College of Radiology. I just wanted to be sure to clarify that, in the example you cited as Mass General, the selection of to get or not get an MRI is not the decision of the radiologist, that is, it's ordered by the bone tract or the neuro tract, and just be sure that that was clear.

MR. ORSZAG: I didn't mean to blame the radiologist, let's just be clear.

MR. THORE: My question, though, is, recognizing that both of our first two speakers have commented on what a complex problem and issues these are, we hear comments from the Hill with regards to a bill surfacing in July that may be passed by August,

and that speed I think makes some of us a little bit uneasy; can you comment on that?

MR. ORSZAG: Sure; I think, look, the committees have been hard at work, I see some of the Committee staff members in attendance here. This has been – they have been engaged in discussions for several months, and obviously, there was a lot of work even before the process began this year.

My understanding is that it is likely that the committees will be marking up and moving to floor consideration over the next, you know, before the August break. And there will be plenty of attention paid to exactly what is or is not in that legislation as it moves through the process.

So what I would say is, for example, the Finance Committee, under Senator Baucus, has been putting forward white papers that I think provide pretty clear indications of where they are intending to go. And for those who are interested in what the major contours of reform are likely to be, I would refer you to those white papers at least with regard

to the Finance Committee. But you are right that the next month or two is going to be where you're going to see the reform packages coming together.

SECRETARY RUBIN: Alice.

MS. RIVLIN: Alice Rivlin, Brookings. Peter, as you know, there's a long history of congressional resistance to doing things like competitive bidding on durable medical equipment, and things that the MEDPAC has recommended have gone nowhere. Do you sense that there's a new mood on Capital Hill and a different understanding of the necessity of doing some of these cost saving things?

MR. ORSZAG: Yes; and let me answer that in two ways. Yes, I think there is wide spread appreciation that, first, that the reform must be at least deficit neutral, and therefore, contain cost savings; and second, I think there is a surprising recognition, not surprising, there is a significant recognition that a change in the process would also be beneficial.

Senator Baucus, for example, has spoken about the fact that he doesn't feel, both because of understandable, but nonetheless, you know, real lobbying pressure, and because of the technical nature of many of the medical analyses that need to be done, that the Finance Committee may not be the ideal location for deciding upon the reimbursement rate for durable medical equipment, for example. That is one of the motivations for the proposal that we have put forward, to take the MEDPAC recommendations, and rather than having them sit on a shelf somewhere, have them protected under a fast track procedure, voted up or down as a package, and considered within a limited period of time so that they become much more relevant, they're relevant to some degree, but much more relevant as a decision-making process. I'll choose someone, how about over here, I choose you. Over here. I'm not even allowed to choose anyone.

MR. USDIN: A quick question, Steve Usdin from BioCentury. A lot of your analysis is about regional variation and the data that you use to

discuss regional variation comes from Medicare. To what extent do you know or can we know whether that is actually applicable to the whole health care system, or is it just an artifact of Medicare? And if you have a government plan, would you also have that kind of perpetuation or regional variation would just be exacerbated?

MR. ORSZAG: Thank you for asking that question. A couple things, first, there is substantial variation in overall health care spending, not just in Medicare. And, in fact, if you go out and ask any large employer to look at their own health expenditures across the country, even within an employer setting, they also experience very dramatic variation. In Medicaid also, very substantial variation on the same order of magnitude as the Medicare variation.

Now, there was an assertion in a Wall Street Journal editorial yesterday that the places that have high Medicare spending tend to have low other

spending. I don't believe the facts bear that out. There will be a more exhaustive response to that.

But suffice it to say there is very significant variation, not only in Medicare spending, but also in overall health care spending. And I want to, again, emphasize, we often compare ourselves to other countries, or people often compare our health care expenditures to other countries. There are significant geographic areas in the United States, and many hospitals, and many doctors that are delivering health care at lower cost relative to income and better quality than other countries.

Our problem, to the extent we have one, is that that is not a universal phenomenon within the United States. The key is to spread those best practices that already exist within the United States. This is not a theoretical abstraction. There are places in the United States today that are delivering health care in a relatively efficient way, and then there are other places that are not. We need to move

the whole country towards those places that are doing a good job already within the United States.

MR. ORSZAG: now I get to pick someone. How about over here?

MS. BERGOUSKI: Hi, I'm Linda Bergouski from the Veterans Health Administration.

MR. ORSZAG: And I'm told you have the last question.

MS. BERGOUSKI: Oh, okay. And I think it's the best one. The -- both of the previous speakers and yourself talk about the variations that are unsustainable and unacceptable, but I would contend that one of the reasons that McAllen and El Paso are so different has to do with the medical litigation environment. And I would like to know how you feel about scoring the potential offsets from medical litigation reform because in the past, CBO has not seen them as saving very much.

MR. ORSZAG: Well, a couple of things. First, I think if you ask any doctor in the United States, they quickly point to medical malpractice as a

key driver of defensive medicine. It turns out that academic literature on this question, in terms of the impact of medical malpractice on cost or on this variation, is not as compelling, in favor of that proposition, as the view among doctors would suggest. That having been said, however, there does seem to be some role and I think the American Medical Association, for example, has put forward, or has at least floated informally, ideas about how the system could be tweaked or changed. And I think that's one of the things that will be under discussion as part of reform.

And beyond that I think, again, over the next month or two, more details will be forth coming and one needs to see an overall package. But it is clearly an issue that medical professionals immediately point to. It did come up in the Gawande Article also. And it will inevitably be part of the reform discussion over the next month or two.

SECRETARY RUBIN: One follow up question; I know you have to run. Isn't there also enormous

variation amongst states with respect to medical malpractice costs?

MR. ORSZAG: Yes; so just to get wonky for a second. One of the reasons that -- I'm going to give you a yes, no, yes answer. So yes, doctors think this is important. The literature tends to find less of an impact in part because the variation -- if you look at a map of healthcare spending, that variation is not correlated that well with the stringency of medical malpractice laws in different states or in different areas within a state. That having been said, I think one of the reasons that medical malpractice may influence this variation is it leads to norms among doctors. I'm going to do what the guy down the hallway is doing because that way I won't get sued. And in that kind of case, if that's correct, the sociology among medical professionals is influenced by that legal environment.

Small variations in how stringent the law is from one area to another may not influence the strength of that social norm and so medical

malpractice could wind up influencing the regional variation, even though the studies suggest that it doesn't. And on that note I will depart for the White House; thank you.

MR. MCCLELLAN: All right; thank you, Peter. We're going to continue this morning with the next steps in our discussion about comparative effectiveness research. You've heard from some of the policy leaders who -- about the current status of reforms that relate to comparative effectiveness research. Bob Rubin has raised some great questions for us to address in more depth and we're going to try and do that with the remaining panels this morning. This is going to get a little bit more technical, a little bit more wonky, in Peter's term, but I want to emphasize that, as heard already this morning, how we move forward on comparative effectiveness research has some very important practical implications. And with that in mind, I want to go to our next panel, which I'm going to kick off with a few framing remarks about

the context in which comparative effectiveness research reforms are being considered.

As you heard this morning, a big motivator for healthcare reform now is the projected increases in healthcare spending from close to -- from over 17% today to one fourth of GDP by 2025, with big pressures on the Federal Budget as well. And you heard, especially in Peter's remarks, about the connection between what appear to be opportunities for improving outcomes without increasing costs, in fact with reducing the overall healthcare cost trends at the same time based on this evidence from Dartmouth, -- substantial variations and medical care exists from area to area.

As you also heard this morning, many of those variations are not related to say simple using a brand name drug instead of a generic or even elective surgical procedures at different rates, but rather more subtle differences in medical practice, such as how often you see your intern, which kind of specialist you refer to and when, what lab tests get

done, how often imaging procedures like MRIs are performed; not the usual kinds of discrete treatment decisions that have often been the subject of comparative effectiveness research in the past.

So that means that we're dealing with a broad set of questions, as Bob Ruben said, that relate to individualized application of a broad range of different medical technologies; how we figure out what's your best in particular circumstances. Well, that's lead to all of this emphasis on comparative effectiveness research and there are a lot now, a lot of definitions, floating around about what comparative effectiveness research really is.

This one was borrowed from the recently implemented Federal Coordinating Council for Comparative Effectiveness Research; it's research comparing different interventions and strategies to inform patients, providers, and decision makers about which interventions are most effective for which patients under their specific circumstances by assessing a comprehensive array of health related

outcomes for diverse patient populations. That is a very broad and challenging charge for applied research.

And so that matter leads to the questions of will comparative effectiveness research have a substantial impact on rising healthcare costs. Will it bend the trend? And will comparative effectiveness research improve health outcomes and are -- can we accomplish those two goals together, which would be the real benefits of these new steps in comparative effectiveness research?

There are several answers to this question out there and you heard some of the views -- the different views about the impact of comparative effectiveness research expressed this morning. One answer is yes; Peter Orszag was very articulate about the fact that expanded comparative effectiveness research evidence could support doctors and patients in making better choices; better choices lead to better outcomes and if they're -- those choices

involve more effective treatments that may cost less, that can lower healthcare spending.

Senator Baucus said even if the focus isn't directly on comparing costs among these alternative treatments, if people are thinking about the cost information, along with information on which treatments really work better for them, that can have an impact. It could usher -- it could lead to that -- changing that Peter Orszag was talking about.

I would also add that comparative effectiveness research, I think in some form, done right, is going to be essential for ushering in the era of personalized medicine that we've all been hearing so much about in recent years. The idea of GenoMex and other personal characteristics influencing treatments and giving people great confidence that they are getting the best combination of treatments for their particular circumstances, that's an era that has turned out to be slow in coming.

It's starting to come to certain aspects of Cancer care, but by no means are we there yet in terms

of being able to make those kinds of confident decisions about particular patients and it would seem that unless we figure out better ways to achieve the goals of comparative effectiveness research, the things that were included in that definition of the previous page, knowing what works best in particular types of patients within broad populations, we're not going to get there. We're not going to get to that era of personalized medicine.

On the other hand, there are a lot of people who think that the answer may be no. Opponents have -- people -- critics have argued that there will be some real obstacles to even substantial new spending on comparative effectiveness research making a big difference. After all, 1.1 billion dollars in the Stimulus Bill may seem like a lot of money; on the other hand, that remains a tiny fraction of overall healthcare costs, further, the costs of conducting clinical trials as we've seen in the number of recent examples and we'll talk more about this morning, is very substantial.

And doing these trials on a one off basis may lead to results that take a long time; that may be obsolete or regarded as obsolete by the time that they're available. They may not be relevant to particular subgroups of patients and therefore, they may not have an impact on the actual delivery of care.

Some of the studies that were done by groups that Peter cited, have also pointed out that where evidence does exist, where we do have clinical guidelines, including Evan's based clinical guidelines, in many cases, those guidelines are not followed. So even where the evidence exists, there may not be a substantial impact on treatments and on healthcare costs.

There also are some further concerns about comparative cost effectiveness research; concerns that in addition to just developing the evidence, maybe the next step would be using this evidence to set a threshold below of which certain treatments wouldn't be paid for if they weren't cost effective enough in terms of dollars per year of Y for some other cost

effectiveness standard. But that doesn't answer -- and that further doesn't answer the question of how comparative effectiveness research should be used by those who make decisions. So that's a key part of this issue as well.

And so that's why I think a lot of the conclusions now about -- or a lot of the views now about comparative effectiveness research is will it have an impact? Well, maybe. It depends; and some of the key questions involved in the implementation of a large scale comparative effectiveness research strategy for the United States remain unresolved, and that's what we want to focus on this morning.

How do we get to comparative effectiveness done right; getting to that positive impact of knowing what works in particular patients, being able to spend healthcare dollars more confidently, having a greater impact on health without unnecessary healthcare costs? How can we get there?

Well there are a few particular themes that we want to emphasize in our discussion this morning.

One of these is governance. It's not just a matter a governance, but coordination of spending on research, coordination not just within the Federal Government, but remember that there are a lot of private sector activities under way relevant to comparative effectiveness research, analysis studies done by companies, studies done by health plans and others that are contributing to this effort.

It's not just governance, it's also priorities; identifying the highest priority gaps in evidence that can be addressed. It's methods and infrastructure; finding more effective ways to conduct comparative effectiveness studies. It's incentives, it's creating the support for not only developing the evidence, but using it effectively, and it's impact. It's making sure that we're actually having an effect from the types of evidence that is generated.

In terms of priorities, as you'll hear about in the second panel this morning, in particular, with Alan Garber and David Meltzer, priorities should assure that the most important clinical and policy

questions are addressed. And by the way, that definition of comparative effectiveness research that I mentioned earlier includes not just comparing the effects of particular treatments or combinations of treatments in the individual patients, but also comparing the effects of different policies, formulary designs, benefit designs, payment reforms, that may influence how treatments are used within a population and thus influence health outcomes and cost.

How can we set up a process for putting the expenditures where they will get the most bang for the buck? In their paper, setting priorities for comparative effectiveness research, Alan Garber and David Meltzer proposed to some principles and a process for establishing national comparative effectiveness research priorities.

As Peter mentioned briefly earlier, what they talk about is a value of information concept; estimate the value of information gained from potential studies and use that to prioritize topics that have large implications for clinical outcomes for patients and

perhaps for cost, while at the same time, focus on studies that are feasible in terms of time for completion, budget, and so forth. So it's a value of information and the feasibility that should guide decisions about where comparative effectiveness research is dedicated. And we'll talk more about that on the second panel.

Also, a key issue is methods and infrastructure; improved methods and a more efficient infrastructure should enable much more bang for the buck in terms of evaluating clinical and policy questions. There are a lot of obstacles in our evidence development systems today for using data and methods to provide rapid, relevant, and compelling evidence for clinical and policy decisions.

And in our second discussion paper, Sean Tunis outlines a series of recommendations for improving methods and infrastructure for comparative effectiveness research. He highlights the importance of involving those with a stake in the decision under

study; that's something that Senator Baucus emphasized this morning.

A research process that is transparent and inclusive, or a research prioritization and a conduct process that is transparent and inclusive; the need for a new decision focus framework of evidence to help guide the comparative effectiveness research from evidence on best practices. And with these kinds of guidelines for best evidence in place, that should help make consensus methods and best practices emerge that can help us get more bang for the buck for comparative effectiveness evidence as well.

Related to this is the need for a national data collection infrastructure. And Sean talks about how this might be done through what's called a distributed data network where the individual identifiable information on patients stays where it is in terms of being used to actually improve care for those patients, but summary information is shared in a consistent way so that larger scale practical clinical trials can be conducted and those large scale

observational panel analyses that Peter mentioned can be conducted as well.

In addition to improved data and infrastructure is the need for incentives. Comparative effectiveness research should be implemented with other reforms that create incentives for the development and use of new evidence and this includes steps to assist patients and providers in developing, and identifying, and interpreting the available evidence for their particular cases.

It includes broader payment reforms that focus more accountability on better results, getting better outcomes at a lower cost. For example, the current fee for service reimbursement system provides limited incentives at best to use effective treatments that cost less. Virtually all of the treatments, big and small, that vary substantially from area to area, receive higher payments when they're used more often, not necessarily when they contribute to better results, in particular patient circumstances.

Benefit reforms could also have an impact and certainly under consideration now are changes in co-payments for treatments that are cost effective, many private plans have lowered the co-pays for drugs that can help prevent costly complications of illnesses because that's a more effective strategy for managing chronic diseases based on existing comparative effectiveness evidence. So there's steps like that that can be taken.

Related to this as well are steps to make sure that the evidence that is developed on comparative effectiveness research has an impact on outcomes, has an impact on improving the value of care; and Steve Pearson's paper deals with all of these kinds of issues. The impact of comparative effectiveness on costs and outcomes may require that the evidence be apply -- or will require -- the evidence will be applied consistently by all relevant decision makers. So Steve talks about this issue in his paper.

One potentially important mechanism, for example in applying comparative effectiveness research, is helping various audiences interpret the array of evidence that's out there, through reviews, through summaries, and the like, and Steve is going to make the case for expert ratings of the evidence in a leading role for clinician leaders, clinical experts, and the translation of evidence into guidelines which can then be used by patients and doctors in making their individual decisions.

Now there's a lot of questions that these issues raise. What are the thresholds and standards for evidence for making decisions on comparative effectiveness research and so forth? And we'll come back to those issues this morning.

Achieving all of these objectives is going to be challenging and that's why an evaluation process is also important. So we'll talk about that as well. Evaluation mechanisms for all of these elements of comparative effectiveness research strategies.

And again, I want to emphasize that comparative effectiveness research is one piece of a larger process for developing and applying evidence, actually using it to improve healthcare. With an improved healthcare evaluation infrastructure, which we've talked about, this data and evidence infrastructure, we can get better measures, and better information, and better evidence on the outcomes of care and potentially the costs of care as well through both randomized studies and better observational analyses, with better dissemination of these results.

If an opportunity to have an impact on payments, on benefits, and the whole environment for medical practice, but for most, better outcomes for patients and avoiding unnecessary costs and in turn, leads to an impact on health care systems and on treatment decisions and individual cases, which hopefully could create a virtuous cycle of continuing improvement in our healthcare system.

So that's an overview of the kinds of issues that we're going to talk about during the remainder of

this conference. And again, just to reorient you back to the panels that are coming up, there's been a lot of emphasis in the recent stimulus legislation and as you heard this morning in upcoming healthcare reform legislation on creating better support for comparative effectiveness research. The question is how are we going to do that right so that we have the most positive impact on patient health and avoiding unnecessary cost?

Some of the topics that we're going to focus on in answering that question include setting priorities for comparative effectiveness research, that's the second panel after this one. Strategies to improve comparative effectiveness research methods and data infrastructure; that's the third panel. And moving from better evidence to better care; how can comparative effectiveness research be used effectively to influence practice and policy. The bottom line goal from all of that is improving outcomes while lowering healthcare cost growth; back to those core

questions that Bob raised at the beginning of our meeting.

So with that I would like to ask our panelists for the first session to come up to the front here while I am introducing them briefly and we're going to start an overview discussion of these issues.

Our panelists include Carolyn Clancy who is the Director for the Agency for Healthcare Research and Quality, John Rother, the Executive Vice President of Policy and Strategy for AARP. Let's see, who's next; next is David Lansky, the President and CEO of the Pacific Business Group on Health, and finally, last but certainly not least, Kathy Buto, who is the Vice President for Health Policy on Government Affairs and Johnson and Johnson. And as I mentioned earlier, there are more detailed bios for each of these distinguished panelists in your packets. But I'd like to move right along into discussion and it looks like we've got at least two of our panelists -- so I'm going to get started.

Let me ask you each to address this general set of questions that we started with. Will comparative effectiveness research reduce the growth of healthcare cost, will it help us improve quality, what specific implementation steps are -- do you think are critical for achieving this outcome? This gets back to the questions that Bob raised; it gets back to the discussion we've had, so tell me what you think about where we're headed. Carolyn, can I start with you?

MS. CLANCY: Of course. So three questions all at once; I'll do my best. So -- not as rapidly as you were speaking but I will, nonetheless. Will it help us save money, I don't know. But I do recall a very --

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CERTIFICATE OF NOTARY PUBLIC

I, Carleton J. Anderson, III do hereby certify that the forgoing electronic file when originally transmitted was reduced to text at my direction; that said transcript is a true record of the proceedings therein referenced; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and, furthermore, that I am neither a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

/s/Carleton J. Anderson, III

Notary Public in and for the Commonwealth of Virginia

Commission No. 351998

Expires: November 30, 2012