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Setting Priorities for Comparative Effectiveness Research: Congressional Briefing Health Industry Forum November 29, 2007

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ROBERT MECHANIC, MBA: Thank you everybody for coming to the Health Industry Forum's Congressional Briefing on Comparative Effectiveness. Where did my nametag go? I'm Stuart Altman. I've had surgery with high technology medical care. I'm now 12 inches taller, 40 years younger, and I feel great. Unfortunately, my boss is stuck at the airport. He's on his way. We hope he will make it here before too long, but in his absence, I'm going to give a slightly less entertaining version of his presentation.

Just to provide some context to this, now the forum is a group that works with public policy analysts, academics, pharmaceutical firms, and health insurance plans. We actually all work together as a group to look at issues that affect the effectiveness and efficiency of the health care system. This is actually now our fourth or fifth meeting on comparative effectiveness research.

The first one, which was in April of 2006, we invited Dr. Michael Rolands [misspelled?] from the U.K. to come and talk about what they were doing, and the question there was, should we do something like this in the United States, actually fund and develop a capacity to do comparative effectiveness research. And I think the answer coming out of that meeting was we should do something.

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In November of 2006, we brought together yet another multi-stakeholder group. We asked the question, if we were going to do something, what should we do? If there were going to be an entity, where should it be located? How should it be funded? And what should it do? Should it do systematic reviews? Should it do randomized clinical trials? Should it do guidelines? Should it consider costs? Or, should it not consider costs? Should it be involved in payment coverage decisions? Though we talked through a whole series of options, and we actually have executive summaries that go through those meetings.

The third meeting we had was this summer where we asked the question, how are users going to deal with this? What do patients, physicians, and health insurance plans— People have to make decisions. What do they think about this? How would they use this and what are their concerns? And, some of the concerns had to do— Everybody sort of felt, in general, the area of agreement— We really need this information in the health care system. In a lot of ways we are flying blindly about technologies. We need better information and head-to-head information. But the concern was well how is this going to be used for coverage and payment?

Now this meeting, where actually we, as all of you know, we have a number of bills that are actually seriously

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considering establishing a capacity here. And we're going to talk a little bit about priorities. And we have a number of speakers today. And these are speakers who are not hairy-fairy [misspelled?] academic economists like Stuart and myself and the rest of the gang at Brandeis. These are people who are out there in the real world, doctors, government policymakers, people from insurance plans, to talk about how they would use the information. What's the value of this kind of research? If they could get this kind of research, what's the value for them? And then to talk a little bit about if we're going to do this, what are some of the initial priorities? What should we do first? It will help them; again, improve the effectiveness and efficiency of the health care system.

Could I have the first slide please? Keep on going. Keep on going. Okay, so this— The red line here is health care spending in the United States over the last 40 years. And you'll see it dips down and dips up a little bit, but essentially health care spending has been growing persistently over the last 40 years by two and a half percent above the rate of the national economy. And Stuart says this is determined by a higher power. No matter what we try to do, we tried regulation in the 70s. We tried competition in the 80s, managed care in the 90s. And there have been some small blips where it cuts down but it's still— And now in the first five

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years of the 21st century, it's actually going up at a higher rate than it has during that entire period. So, health care spending is a persistent concern.

Next slide please. And there are a lot of negative consequences to this excess growth. Could we go back? Next slide. And so this is, I think, really where the rubber hits the road, which is the gap between health care spending and wages. The white bars are the cumulative growth in health care costs, starting at 2,000 going forward. And over the seven years we see that it's almost, I actually can't read this, but it's almost a hundred percent since 2000 whereas wages are growing at about a quarter of that. And so we create a gap between the wage base that funds the Medicare Trust Fund and that pays for employer-based health insurance and what the costs are. And so this is consuming more and more of the real growth in the economy is going to health care.

Next slide. And so negative consequences, we see that right now as health care costs go up, employer-based insurance goes down. And from a high in 2001 of about 65-percent of workers covered by employer-based health insurance. We're now down well below 60-percent, and the trend is going in the wrong direction to the extent that employers are covering people less. That puts them either in the category of the uninsured or it puts them into public programs. And that turns back

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around and increases the pressure on the public budgets. So as Stuart said, has the meltdown begun? If we have persistent health care costs for another 40 years above the rate of the economy, what is going to happen to the economy and employment and is there going to be a meltdown that's going to require a dramatic regulation or dramatic reorganization in the health care system.

Next slide please. And again the GM story retiree benefits, we're already seeing that going from about two-thirds of workers in the mid-1980s to about less than a third today. And again, heading south, as we've just seen with General Motors and the recent deal with the United Auto Workers.

So have the next slide. So, yes, the problem's equally serious for government. I don't know if Phil Ellis [misspelled?] is here, but we stole this slide from him. Could we have the next slide? And this slide shows federal spending as a percentage of the national economy on Medicare and Medicaid. And to the left is the actual federal spending. To the right, if you look at the bottom line, the dotted line, people talk about well Medicare's going to blow up because the aging and baby boomer and the demographics— The bottom line which is the dotted line is actually the impact on Medicare and Medicaid spending of demographics through the next 45 years or so. And it's really not that big a deal. It's increasing, but

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it's not increasing sharply. If you look at the yellow line, which is the sharply rising line, that assumes now the differential growth in health care. So the bottom line we're assuming that health care costs are growing at the rate of the economy. The top line is growing at two and a half percent of the economy, which is the historical rate. Now, imagine this. Today Medicare and Medicaid combined are between four and a half and five-percent of the national economy of gross domestic product. If this trend continues for another 40 years, and I know 40 years is a long time, it's beyond the term of this current Congress, but another 40 years, Medicare and Medicaid spending would equal more than 20-percent of gross domestic product. That means Medicare and Medicaid spending would be equal to the entire size of the federal government today relative to the U.S. economy. And I think most people believe that that really can't happen. Before that happens there's going to be some kind of meltdown, something serious. And when something serious goes to government, what is it? It's usually something that is a blunt instrument. It's cuts in payments, cuts in payment rates for providers.

Ah, here he is. I guess the medical technology didn't work. He's aged. He's lost a few inches. And so— Come on up, Stuart. But he's still the chief.

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All right, so according to these trends, and economists are frequently wrong, but we're headed to a meltdown. And this two and a half percentage points, that's been persistent for 40 years and so what are we going to do about it that isn't going to be a me-axe [misspelled?] approach?

May I have the next slide please? Okay, so the future policy debate, let me just make a point here. At one time there was an organization, I mean there's a lot of medical research bending in this country. And I would say about a hundred billion dollars annually goes towards some type of medical research and of federal and private money. And it brakes out in three ways of this hundred billion. About roughly 30 billion is through the National Institutes of Health, and that research is for basic science, discovery, lab-based work, and that basic science and discovery and discovery of new things is roughly 30-percent. Then there's drug and device company research. And that's mostly focused on getting products developed and getting them through the FDA approval process so they can market them. And again, that research is focused on the regulatory process. Now, what about asking the question, what really works? Because the entity that used to do technology assessments, something called the office of technology assessment, it started in 1972, but it was defunded in 1995 and one of their popular, or I should say, unpopular

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pronouncements was only 20-percent of the medicine that is practiced in this country is supported by valid clinical research, only 20-percent. When you do to the doctor, when you go to the hospital, 20-percent is actually based on good quality research. Well the OTA is now DOA. They're gone because they upset the wrong people. But I think that issue we're spending two trillion dollars on health care, much of what is done right now does not have evidence. There've been studies from the IOM and others that show there's overuse, there's misuse, there's under use. So having more research that's focused on decision makers, patients, doctors who provide the treatments, and then people who have to make decisions about health care resource allocation, would be very helpful.

So the future policy debate in the U.S., next slide, is should public funds be used to pay for services of limited or no value? And today it's very difficult to know what those services are for the 80-percent of services that don't have valid clinical research that looks at their efficacy compared to other competing treatments.

Next slide please. So we believe and we've been spending a lot of time thinking about this comparative effectiveness information is really important because it's going to help the people who deliver care, provide appropriate

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services, not just more services. Today the incentives are fee-for-service, you do more, you get paid more. But providers want to do the right things. They want to provide good care. And we need more information that's directly relevant on a day-to-day basis. And our speakers are going to talk about that today to provide appropriate. It's just opposed to more services.

Next slide. So we need comparative effectiveness to help patients and doctors provide appropriate treatment choices, to help people who are charged with making resource allocation decisions, payors, make value-based decisions, not just I mean today you have to make all or nothing coverage decision. You cover it. You don't cover it. And there are a lot of treatments that don't get covered that may be helpful. For some patients, we need more research to understand that better. And finally to help drug and device manufacturers, comparative effectiveness can be helpful but it also needs to be transparent and it needs to be predictable and it needs to be consistent so that they can make pricing and more importantly investment decisions.

Next slide. So we think that in addition there's a debate about do we just look at the effectiveness of treatment or do we look at cost? And from the past slides, in Stuart's slides, we have a real cost problem. And so we personally

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believe that comparative effectiveness analysis should include both the clinical effectiveness but also we should look at the cost effectiveness in the value. Now we're not like the national, like the U.K., where they have their National Institute of Clinical Excellence that does technology reviews. But when NICE makes a decision it accounts for the whole National Health Service. That's one decision for the whole country. Our country doesn't work like this. We have 350 insurers. We have public programs. And so what we're talking about in a market-based sense is providing— This is information that has not been generated by the market in adequate amounts. And so what we're talking about is a federal commitment to provide more information so that the marketplace, that the multiple payors can use this to make decisions, but independently. So this is not making national decisions. This is not setting rates. This is providing better information on clinical treatments and their relative value and putting it out there for everybody to use: patients, doctors, and policymakers.

Next slide. Well, that's the end. Stuart, do want to make any comments?

STUART ALTMAN, PH.D.: [Inaudible] fantastic
[inaudible].

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ROBERT MECHANIC, MBA: Okay. Well, our first speaker who is going to talk now about really the key issues and the state of play and the debate over comparative effectiveness is Murray Ross. We've known Murray for a long time. He is the director of research at the Kaiser Permanente Institute for Health Policy. But Murray has a long history here in Washington. He was the executive director of the Medicare Payment Assessment Commission here in Washington advising the Congress, and he was a senior analyst at the Congressional Budget Office. Murray is knowledgeable, thoughtful, and with this I turn it over to you.

MURRAY ROSS, PH.D.: You always hate to come up after you've been alleged to be knowledgeable and thoughtful because that's a high bar. I think my job, if I understood it correctly, was to do some level-setting here to get everybody on the same page before the two panels we have coming up. And as I look around the room, I see a whole bunch of very familiar faces from past meetings and continued involvement in this discussion so there may be less level setting but I'm going to drag you through it anyways.

Go to the first slide please. And I do apologize to anybody over 40 in the back row. I was envisioning a large screen, but I can't bring myself yet to do the slides that my C.E.O. does that have one word on them in 48-point font. So—

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It's either no or yes to most of the time. So— As I'm told, these will be available on the website after the meeting so you'll be able to get these.

So what do I want to cover? I want to do a little bit of the what and the why of comparative effectiveness research and talk about some areas where the discussion seems to be coalescing and we're operating here on real time and some of those discussions are going on even as we speak in this room. I want to talk about a few of the unresolved issues, both at the legislative level and things that need to be dealt with a little bit farther down the road. And then offer a bit of a segue to the two panels on setting priorities.

Let me go to the next slide please. So why are we talking about comparative effectiveness research? I was going to say Stuart supplely laid out the problem, but Rob laid out the problem very much on the cost side. But it's more than just unsustainable spending. It's about the value we get. We've been living in a world where spending growth exceeds income growth by, as Rob said, a couple percentage points over decades long span. We are the world's highest spender both as percentage of GDP and in absolute terms. It would've got a lot of evidence that we're not getting all that we could for that. I didn't, for a change, steal the slides from Beth Maglin [misspelled?] that show appropriate care 50-percent of the time

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or 55-percent of the time. I didn't put up a map, any of Jack Wenberg's [misspelled?] maps that show the unwarranted geographic variation and services.

We have a lot of reason to think that we're not getting all we could for the amount of money we spend in health care. So how would comparative effectiveness research help all this? Well it's the two key words, comparative and effectiveness. Comparative meaning being able to look at treatment option A versus treatment option B, instead of just treatment option A versus zero. In many instances safety and efficacy is the high bar of evidence now. And effectiveness, it's not just how to things work in trial conditions and laboratory conditions, it's how the interventions work in the real world. And the notion being that if you get information and look into this, you can provide useful guidance to clinicians and patients where the clinicians can make better treatment recommendations. Patients can make more informed decision, both on costs and treatment effects. Payors can think about using this information to tailor reimbursement more closely to the value of the services being provided and hopefully avoid some of the zero-one decisions that we face now where you are covered or you are not because we don't really know how to evaluate interventions, one against the other.

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Next slide please. The discussion of establishing, and I will apologize for the acronym, CER [misspelled?] capacity has really focused on two kinds of functions that some newly created or newly designated entity would undertake. One is to my largely executive, if you will, the subjective side of the science. It's about prioritizing among the health conditions you want to explore. It's developing evidentiary standards and thinking about how you're going to do this work, and how you're going to make judgments about it. It's evaluating research findings, and ultimately it will be disseminating findings and recommendations. And I think not everyone would immediately link to disseminating results being synonymous with recommendations but in some way, shape, or form, when you characterize the result, you'll be making a recommendation even if it isn't explicit.

The second piece of this is more the taking action, the performing or commissioning or funding of the actual research. And I show these here as sort of executive top and action taking, I guess executives take action but, as the second panel. In fact the sequence is a little bit different. There's a set of executive tasks around setting priorities. Then there's the work that has to be done. Then there's the evaluation of that work when it comes in. Then what establishing CER capacity does not mean is not NICE. I don't

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think anyone is talking about, as Rob mentioned, an entity that has the same capacity and mandated influence that the National Institute for Clinical Excellence does in the U.K. What we're talking about is an advisory body. This wouldn't make coverage decisions. It wouldn't set or negotiate prices. It would make information available to private payors, to clinicians, to patients.

Next slide please. Now in contrast to a lot of other areas in health policy, there seems to be substantial agreement in a good chunk of this discussion. Maybe the first point is ignorance is not bliss. We can all benefit, clinicians, patients, payors, from better information about what works, what does not work, or maybe to be a little bit more open-ended what works well or what works better than other options.

Second I think there's pre-general agreement that this is not just Coke versus Pepsi. It's condition-based. It's thinking about, if you can continue that analogy, the treatment of thirst and looking at all the options that are available on the table. So it's looking at drugs, it's looking at devices, biologics. It's looking at procedures, imaging, medical interventions of one sort or another. People are pretty agreed on inclusiveness. I was liking it to sort of the Noah's arc theorem, but we have to have two of everybody in the room to talk about these things. But it's more than just having

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stakeholders from a wide variety of perspectives and, if you will, interest group participation. It's that there are a lot of important sources of expertise and there are different perspectives out there that will need to be part of this process. Trust is paramount. You need to have buy-in for this to work. Again, for an advisory body to have influence, people have to believe it. It has to have scientific credibility, but even more than that it has to have political credibility. Funding needs to be stable and broad-based. I think it goes without saying that funding that's not stable leads to very unhappy entities that can't plan and can't make decisions. But more than that, it's about sending a signal that this isn't just a one off exercise, this is about changing the rules of the road and providing ongoing capacity that is going to help shape decisions going forward. And last but not least, this is not about saying no. Comparative effectiveness research is about driving value, and it's about giving signals or making information available that the market will use to send signals that will reward not just mousetraps but better mousetraps. So, I like the term productive innovation. I realize that's a little bit weaselly because we can all quibble about what productive means. But the point is this isn't about choking things off. There are lots of ways to do that, if that was the objective. This is actually about driving value.

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Next slide please. So the legislative issues that are on the table. Rob mentioned the cost issue. I think it boils down to something very simple which is are we serious about addressing unsustainable spending trends or are we not. I've seen a lot of different proposals that have in the preamble all the words about spending are out of control and it's growing faster than income and all of that. And then AS [misspelled?] scrupulously avoids mention of cost anywhere thereafter. I can only say as an economist, I don't know how you can even have this discussion without having cost be part of the equation. But that's obviously a judgment point that needs to be made, but you're not going to get that far if you're not willing to look at the cost side of this.

The second piece of this governance, I think this has occupied a lot of the discussion in Washington over the past 11, 12, 18 months. Where should this thing be located? Do we want a new entity? Do we want to create an entity inside of an existing organization, inside government, outside government, or as Gail Lewonski [misspelled?] puts it, close but not too close to government. This is really about— There are two issues underlying all of this. One is if you're going to put federal money on the table, how do you combine needed fiduciary oversight of that federal money without excessive political meddling? I was going to say congressional tinkering but that

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wouldn't be polite in this room. My short answer is you can't. If federal money is on the table, you're going to have federal oversight that comes with it. But that's the sweet spot you're trying to hit.

The second is when you have stakeholders participating from, again, a wide range of perspectives. How do you engage them in a way that nobody co-ops the process and that nobody dispairilizes [misspelled?] the process? And that's what this discussion about where do you locate this thing is all about. And I have my own preferences, I think reasonable minds can differ but everyone's trying to solve two of these. And we'll get there, I think.

Then the third piece, and of course this is the fun one in Washington, is the funding one. What's the appropriate amount of resources to put behind this effort? I won't pretend to know the right number, but I'll give you some perspective. Over the next ten years we are going to spend somewhere between \$25 and \$30 trillion dollars on health care in this country. And if you think about that number ask what sort of investment in knowing what that money's buying would be appropriate? Is it a hundred million? Is it a billion? Is it \$10 billion? I don't know. The numbers that have been floating around the course of the year started out— At our meeting last November, we started at \$5 billion dollars and worked our way down. So I

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think everybody agreed that wasn't going to happen any time soon.

As a former CBOer [misspelled?], I am well aware of the impact of the Budget Act on decision-making here, but I guess all of us should keep in mind we're talking about the \$25 to \$30 trillion dollars spent. We shouldn't be afraid to make a useful investment there. Then there's the procedural questions about whether that's mandatory spending or discretionary spending. Is it subject to an annual appropriations process or is it a tap on the trust fund. I'm taking it as a given that this is a substantial public good here and that there would be federal money on the table. There is a continuing discussion about whether there should be private money as well. If so who should the private contributors be? And when should they contribute? Do they contribute initially? Do you start off with federal spending as seed money to get going and then bring in the private's actors later?

Next slide please. Then there's the whole host of issues and I won't pretend that this is an exhaustive list. There's a whole host of issues that can't be resolved and shouldn't be resolved legislatively. But this new entity or whatever it ends up being is going to have to address. And I will just touch on a couple of these. One is that technologies differ. I'm using the technology term here to include, again,

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procedures and the full spectrum of interventions. As an example, technologies differ in how they come to market. Drugs come on and stay largely, if I can use the term, unimproved for a period of exclusivity. Devices, on the other hand, come to market and go through continual evolutionary improvements.

At issue for comparative effectiveness research is how do you make sure that what you're evaluating is actually what's still in the marketplace, having the live options. A second is that the quality of the evidence available to you is going to vary. If you're talking about many pharmaceuticals, you're talking about tests that have been done in randomized controlled trials. If you talk about medical interventions, surgical interventions, for example, you're talking about things that have been done on pre-selected patients, small groups of very particular types of people. If you're being asked to think about well how do I decide whether surgery or a drug course is appropriate here? You're going to have a very different quality of evidence to make that judgment. And that's just a reality, and this new entity will need to deal with it. The influence of clinicians, patients, and the technologies themselves, almost nothing out there has an independent impact on health outcomes. They all contribute.

It's important to sort things out. Is the device malfunctioning because it's being implanted by careless

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surgeons? Or is it the device itself that is not functioning properly? This is not, again— This is not just sort of the Coke versus Pepsi, but this is looking trying to get the whole field out there. Is the issue excess consumption of salt? Is it too much wine the night before that led to the thirst that's leading to the resolution? It's a difficult set of issues.

We live in an uncertain world. How do you decide what better means? There's statistical uncertainty. Anything we do at best is going to have samples and trials, and we never know for sure if we can bound the right answer, we think, with some confidence. But we won't know the right answer. How do you extract light results from study populations to a larger population? What currency do you use when you're trying to think about better, talking about benefits and risks and costs? Of quality adjusted life years is one of the matrixes that's out there. It's nice. It's clean. It's analytically convenient. But it's also a judgment call. There are different ways to evaluate the qualities, as they're known. Over what time horizon are you going to look at? When are an intervention and its downstream effects stop? 30 days? 60 days? A year? Ten years? These again are issue that will need to get sorted out if you're going to make fair comparisons. And then having done all that, having commissioned the research, sifted through the results, how does

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this entity convey them to the world? The idea of sort of a big digital binder where you commission a whole bunch of studies and you, whatever the digital equivalent of is, print them, collate them, and put it out there for people to use. That's not useful. This exercise requires more than that. That means somebody has to work through it, translate it for appropriate audiences, and make sense of it and it's going to involve recommendations and therefore judgment. And this new entity in filling out its functions is going to have to think about how it does that and be reasonably consistent in doing it so it maintains trust and integrity. These, and again I said this is not an exhaustible list and if you pursued any one of those streams of thought, you'd say that this stuff gets complicated and it gets difficult in a hurry. But I don't think any of these is a showstopper, and I say that in large part because I asked what's the alternative? Do we continue in ignorance? That can't possibly be the right answer. So the answer is go forward. Do research. Understand that there're going to be limitations and be aware of that as you do the work.

Next slide please. I won't talk too much about priority setting, since you have two panels coming up but I just wanted to offer a couple of general thoughts. And hopefully these will strike you as non-controversial. As

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you're thinking about a new entity with a small amount of money to begin doing research, where should it begin? Well there is some sort of obvious places it should go. It really helps if you look at conditions that have alternative treatments available because that's the kind of the point of this. It helps to look at conditions that have significant clinical or financial impacts. Again, that's kind of the point. A more difficult one is you want to think about areas where once you've done the research, once you've put it out there and made some recommendations, you hope that the results will actually change provider, clinician, and patient behavior. If the research is just going to get it ignored for one reason or another, it's not going to be that useful. And I think that argues for focusing more on newer technologies and interventions than on older ones. It's harder to displace behavior among clinicians who've been practicing a certain way for a long period of time. I wouldn't look to that exclusively, but the other piece, I guess, is just sort of tactical this new entity to be successful. It's going to need to get some early winds and taking on issues in which some of the practices have significant invested financial interests right off the bat. That's going to be an uphill slog.

You want to think about doing research in areas where you're likely to get useable results. And by that I mean there

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are many treatments out there that are somewhat idiosyncratic. Again, I'm not a physician, so I'll say this as much out of ignorance, but thinking in the mental health arena where you try drug after drug after drug because you're just not sure which one is going to work. That makes this a little bit harder to do. That's not to say you don't go there, but you want to think about actually sponsoring a research that will get you somewhere.

And then— Last slide please. Prudent use of federal resources suggests that you focus on things where the outcome isn't obvious. There was an article in the *Adversh* [misspelled?] *Medical Journal* a couple years ago, very tongue and cheek, looking at randomized control trials for the benefits of parachute use to prevent death and major trauma related to gravitational challenge. We don't need to do randomized control trials for parachutes. We can look and know the answer. But there are plenty of other things out there for us to work on. So with that I will stop and we can have discussion. Stuart, do you want to—

STUART ALTMAN, PH.D.: Do you want a question and answer [inaudible]?

MALE SPEAKER: Do you have any examples of gold standard practice [inaudible]? A and all the time. B is clinical practice? C that include outcomes and reduce cost?

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MURRAY ROSS, PH.D.: Off the top of my head I'm not sure I'm going to be the one to give you an example of gold standard but I'm not sure that we're operating in a world that needs a gold standard. I might be willing to settle for a silver standard.

MALE SPEAKER: [Inaudible] good example. [Inaudible] just in case you [inaudible] decision on say VBAC, [inaudible] drugs were, they all had [inaudible] trials of. There was a lot of head to head studies that had been conducted by [inaudible] and had been funded to find [inaudible] tried to make a clinical decision without [inaudible] combined cost and benefit, so I'm just—

MURRAY ROSS, PH.D.: Well I think—

MALE SPEAKER: [Inaudible] you got some track record of this [inaudible].

MURRAY ROSS, PH.D.: Well it's difficult to know exactly how the U.K. experience would translate into our world because when you're operating a world where recommendations have a little bit more legal force behind them than being truly advisory, it's going to play out a little bit differently. I mean I could tell you even within Kaiser, we spend a lot of time looking at evidence trying to measure best practices, trying to translate that and then feed it back into other parts of our delivery system. It's never easy, and there's always,

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whether it's in us or whether it's in the community, there's innate physician resistance. My patients are different, et cetera, et cetera.

MALE SPEAKER: The other question I had was I know Kaiser has been doing a lot of extra work integrating genome-based [misspelled] tests and select patients from particular treatments and now they actually increased the knowledge of patient variation.

MURRAY ROSS, PH.D.: Yes.

MALE SPEAKER: In multi [inaudible] and including and including clinical decision making. But I actually haven't seen that included in any of the discussions with any of the legislative options [inaudible] comparative effectiveness. I think that's an— Don't you think that should be included into other priorities?

MURRAY ROSS, PH.D.: I think personalized medicine offers a lot of opportunities and a lot of challenges for how do you do this? And people have expressed a lot of concerns about any studies you do that are population-based, how do you translate them? Particularly when you've done studies primarily on young men and you're trying to ask how does this work among women? How does this work among the elderly? Personalized medicine genome, it just introduces a whole new dimensionality to that. And I suspect others can correct it.

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People just haven't got that far in their thinking about how do we address that.

MALE SPEAKER: [Inaudible] Because by the time you get the study, I don't mean to monopolize it, but [inaudible].

MURRAY ROSS, PH.D.: Staying at the feet of the master—

MALE SPEAKER: [Inaudible] I'm being nice to you. I'm trying to stay set up and genome [inaudible] school we haven't gotten that much farther ahead—

MURRAY ROSS, PH.D.: Yes.

MALE SPEAKER: -in clinical testing using [inaudible] and we talk about mental health. This could be markers [inaudible] as this arises. Yet you could save a lot of time and money up front. So we should start thinking about it. I don't know how you do that.

MURRAY ROSS, PH.D.: Well there's another piece that you're raising here when you say by the time this thing gets up and running, and we should be skating to the puck here. And it's one thing to talk about establishing this entity today, but, yes, being realistic— When are those first recommendations and results going to come forward? When are they actually going to start impacting decision-making? We're a ways out on that. And the other thing that is changing very rapidly, at least in some environments, is electronic medical

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records, which are going to provide a whole source of data that is nonexistent right now which will help but on the other hand it'll give us sort of a sea of data to wade through and I think this is something our other panels could talk about. There's a gazillion things you could look at with a finite set of resources. Where do you begin here?

STUART ALTMAN, PH.D.: Do you have time for me? Let me thank you again.

MURRAY ROSS, PH.D.: Thanks.

STUART ALTMAN, PH.D.: Let me try. I spent more time at the New York Times than I normally do and I took [inaudible] Washington more. There's an interesting article in today's New York Times talking about the unfortunate situation that women have finally reached parity with respect to certain forms of heart conditions and there was an interesting sidepiece about lung reduction surgery. Now I think I would answer your question in the following way. I think there are clearly examples of where research has mattered a lot. It's not like we've never done this before. The question is whether we're going to do it systematically. Not whether it's been done. And I think maybe any of the physicians in the room can talk much more about examples. But that one was, just hit me about a, someone had an idea. Gee, let's cut out all the bad stuff and give room for the good stuff. And it seemed like a good

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idea. So all of a sudden we had almost an epidemic of lung reduction surgery and then there was clinical trials, which demonstrated this doesn't work on a lot of people but it does on some. So to me that was one example. So, I think the answer I would give you back is yes we have a number of examples of where this research has been helpful.

But what we have not had is a systematic attempt at the level. I mean ARC [misspelled?] has been trying with a very limited budget to do the best they can. But the issue is that what we're talking about is magnitudes higher than that and on a systematic way. The other thing, I mean this may be unfair for— I don't think I've ever— I've been in this business in Washington and the health care system for a long time, and I don't think I've ever run across such an obvious thing that we should be doing.

Now there are a lot of questions. I think Murray did a great job of laying out what the issues are and how to do it and that kind of stuff. But whether we should be doing it or not? At this stage it's hard to make the case and look yourself in the mirror and say gee, I don't think the U.S. should be doing this. Now, I would more than welcome, although I must admit I will do it with some— for somebody to get up and say gee I don't think we need to do this. But obviously they're all kinds of people on different sides of issues. Now

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with that said, I think I'm really looking forward to the panel. How we do it. Where we do it. What system— How— I think are very real legitimate issues that we need to go about, and I know the people in this building are really debating right now whether to put into legislative authority the beginning of moving forward on this.

So, I want to thank my good friends in Senator Kerry's office for making this room a possible, and I also want to thank the Kaiser Family Foundation for webcasting this event.

[END RECORDING]