Which Treatment Works Better?
A Look at Ways to Improve the Quality of Medical Decisions
Alliance for Health Reform and Commonwealth Fund
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ED HOWARD, J.D.: Welcome my name is Ed Howard with The Alliance for Health Reform. Jay Rockefeller is our Chairman, Susan Collins is our Co-Chairman and the rest of the board along with them welcomes you to this briefing on efforts to find out the healthcare therapy that works the best and let patients and providers and payers know about it. The effort sometimes called comparative effectiveness. We are trying to identify what works best in healthcare and while that doesn't seem like such a revolutionary idea it's not as motherhood and apple pie as it sounds. What works best for some might not work best for all, how you decide these issues certainly is proving to be particularly sensitive. Remember though the Food and Drug Administration now decides whether to approve the new drug by deciding that it is effective; measuring its effectiveness against literally nothing that is, a placebo. If it is better than nothing that is good enough, so, there seems to be some room for progress for those of us who are poor country lawyers. Today our goal is to help you sort out the options for pursuing that progress.

Our partner today is the Commonwealth Fund of Respective Philanthropy that I think is its focus on improving the quality of America's healthcare as any entity in the

country. You are going to hear from Stu Gutterman from the fund in a moment. In fact, a moment has arrived. Stu.

STUART GUTTERMAN: Thanks Ed. In the course of doing our work at the Commonwealth Fund we've put together a lot of evidence on the performance of the American health system and one conclusion that we have reached is that at least on one dimension the American health system far outstrips any other health system in the world and that is in spending money on healthcare. If you look more deeply than that on what we get for that money the conclusions are a little more troubling and so we set out to think about what we can do to improve that situation. One of the things we have done in the last few years has formed a commission on a high performance health system which consists of a dozen and a half experts from around the country who meet several times a year to discuss where the health system should be going and how to get there and we as Commonwealth staff use our resources to support that effort as well as the other efforts that the Commonwealth fund is focused on.

On this particular issue there's been a lot of discussion of Comparative effectiveness particularly in Washington and I think it arises from the recognition that we need to have better information and make better decisions and there is dissatisfaction with the mechanism in place to do

that. And in particular it seemed that people where sort of gathering together and talking about this, there was a lot of buzz about Comparative effectiveness but it seemed to us that if someone sort of fired a starters pistol and said “Okay let’s go do what we have to do.” The people weren’t necessarily facing the same direction so you find sort of all running off in different directions and saying “Okay here’s our task.” So, our effort today and if we have an ongoing series of work in this area is to try and help clarify the situation. At least identify questions that people should be discussing and talk about a mechanism perhaps for getting the kinds of information and better kinds of decisions made and in addition to producing information I think the challenge that faces us when we talk about this kind of mechanism is how we get the information that is produced used in decision making because that’s work like (inaudible) and others that show that frequently we don’t use the information we already have to help provide better care to our population so that is all I am going to say and I will let Ed introduce our illustrious panelist.

ED HOWARD, J.D.: Thank you Stu. I should say and should have said before that Stu is not only representing the Commonwealth Fund as the Senior Program Director for their program on Medicare’s future he is also one of the most

respected health services Analyst in town. So, we are very pleased to have him co-moderating today.

A couple of logistical things, you know the packets are filled with very good information including reprints of a number of articles from health affairs written by some of the speakers and others that were I think if anything sort of the germ of the set of ideas that impelled us to put this program together. All of that will be on our website allhealth.org and the kaisernetwork.org website if it isn't already. There will be a webcast as of close of business today, by six o'clock, [Audio interference], manuscript in a couple of days and a podcast and anything else you will be wanting to do with the material that you will be hearing and seeing today. You won't find Gail's slides in your packet today, they arrived a little bit too late but they will be posted on both websites. But, before I introduce our panel I want to say one thing. We obviously have a very distinguished line up of speakers but there actually are a lot of people who could be up here but aren't on the formal agenda. Everyone from folks from CMS, particularly from the Agency for Healthcare Research and Quality, the Drug Evaluation Project in Oregon, Consumers Union, AARP, individual health plans especially the Blue who has been doing this for a long time. They are actually doing a lot of the things that you are going to be hearing about,

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refinements of, comparative evaluation, as well as several members of Congress who have introduced legislation along these lines. You just can't have everybody who is relevant to the discussion up on the [inaudible]. We would have to turn it this way and extend it the entire length of the room. So, what we can do is encourage those of you who are from those entities or any other group I didn't happen to stumble on that is doing relevant work to get to the microphones and add your voice to this discussion because I think it will be a rich one and we can profit from hearing from your views as well. So, I delayed the good part of the program for too long, I want to get to our speakers. We are going to start with Dr. Sean Tunis whose the Founder and Director of the Center for Medical Technology Policy in San Francisco has a long list of academic and career accomplishments which I commend to you from the materials including service as an Advisor for the Senate Health Committee and at the late lamented office of Technology Assessment until the Fall of 2005, Dr. Tunis directed the office of Clinical Standards at CMS where he was also the Chief Medical Officer so we are very happy to have you here to start us off Sean, welcome back.

SEAN TUNIS: Very well, thanks for the opportunity to be here and I am looking forward to listening to the hour long exchange as well because there are a lot of folks in the

audience that have had a tremendous amount to do with bringing the ideas, you know developing the ideas around Comparative effectiveness forward. Some day someone will write the interesting intellectual history of how the sort of forces has converged to make Comparative effectiveness sort of a topic for everybody's mind talking about healthcare. I was just thinking up here as someone who has been in the technology based assessment evidence business for a large number of years including having the interesting experience of being one of the casualties when OTI was shut down and I see some of the others of you in the audience. So I feel like I have been talking about some of these ideas not under this terminology for a while, you know not to such a responsive audience and it reminds me of Peter Sellers as Inspector Queso who went in to try and get a room at an inn and he said he wanted a room, and the Inn Keeper said, what a room a [Inaudible]. And the Inn Keeper said, oh a room, why didn't you say that in the first place. So, I feel like it's a message that has been out there and now thanks to Gail's work and some others work really the relevance and the potential impact of it is understood. So most of you in the audience are familiar with the Dartmouth Atlas showing the geographic variations in care and I am not going to spend time going through it other than to say that this is kind of a visual manifestation of the potential

opportunity to either reduce cost of care by finding out what works and doing more of that and finding out what doesn't work and doing less of that. But in any case these rates of procedures in this case percutaneous coronary interventions varying by geographic region following adjustment for known co-morbidities and age and gender, etc suggest that there is variations in care that are not determined by the patients' clinical need and therefore represents inefficiencies and the delivery of care.

Now there are a number of factors that contribute to geographic variations but I would sort of point out two major contributors to variation. One is that we have good evidence about what works and for one reason or another it is not used and the work by Beth McGlynn I think reflects underuse of care of known effectiveness but so there is a whole series of policy interventions and organization interventions that can deal with that first problem. Electronic health records for example is a good way of getting evidence to clinicians at that time they need to make a decision and get guidelines etc. in front of them.

The second problem is more difficult which is that part of the variation in practices because there isn't evidence of sufficient quality or the evidence is unavailable. And for that I think that is the source of variation that we really

want to focus on in relation to the need for Comparative effectiveness research. So let me, just to make it concrete let me give you, I want to illustrate the importance and to some degree the prevalence of gaps in information for decision making which obviously would lead to variations in care. I use this example a lot but in part because of my work at Medicare where treatment of chronic wounds both related to diabetes, pressure ulcers, etc are incredibly common, incredibly costly to treat, they cause a tremendous amount of morbidity and in the US its estimate we spend about 20 billion dollars a year on treating chronic wounds. Medicare and other payers spend money on lots of different technologies and services to manage chronic wounds and they include lots of letters of the alphabet. So there is Hyperbaric Oxygen, Negative Pressure Wound Therapy, Electrical Stimulation, there's Magnetic Stimulation, Platelet Derived Growth Factors and then actually one of my kind of perennial favorites is NNWT which stands for Noncontact Normothermic Wound Therapy which means you don't touch it, you don't heat it, you just leave it alone it gets better. But we pay for it. Someone figured out how to package it as a piece of durable medical equipment and we pay for it. So you know not to pick on anybody in particular, but I, there was negative pressure wound therapy I focused on because it is in the list of the top twenty spending categories of durable

medical equipment for Medicare and a few years ago the Agency for Healthcare Research and Quality commissioned a systematic review to look at all the evidence on the question of; “Is negative pressure wound therapy better than standard wound care at healing wounds”, and in this systematic review they were able to identify six randomized trials all of poor methodological quality for one reason or another and five of them with sample sizes fewer than five. It is hard to image you couldn’t get a larger trial if you are spending 20 billion dollars a year on wound care but that was the largest study. Now interestingly, you know Medicare is currently addressing the issue of durable medical equipment payment etc, they have not taken this on as a coverage issue, but you know one could argue that with the quality of evidence available that the right answer here might be, you know a coverage issue. But they are dealing with the issue of what is the appropriate price. There is a whole bunch of important messages in this example and I won’t belabor them now but one just a lot of relevance in terms of where you spend your money in Comparative effectiveness research. One thing to pay attention to is the systematic review which is a form of Comparative effectiveness research, what it identified here is a lack of information, it wasn’t able to determine is the technology effective or not, it just identified that there wasn’t that evidence.

The second point is that in the systematic review the first thing that it did was exclude all observational studies, all claims, data studies, etc, anything that was retrospective under the argument that you couldn't do a sufficiently well controlled study you couldn't rely on that information and so that has some implications in terms of investing in Comparative effectiveness research in terms of what source of methodology, so let me get to that then.

Well what is Comparative effectiveness research? I think now that there is potentially thanks to Gail to four to six billion dollars being tossed around as a level of support, lots of people want to be Comparative effectiveness research. So I think you know some of the Amtrak security services believe they are in this [Inaudible], but in any case I would just for the sake of argument and I think I have seen this definition, you know sort of amalgamated this definition from lots of other folks. It is basically comparing the benefits and risks of Healthcare Option A to Healthcare Option B or C, where these options A and B are usually a drug, a device or a diagnostic procedure. It could be a medical service but for the most part I think when people are thinking about Comparative effectiveness research they are really thinking about you know, high cost technologies or things we spend a lot of money on, not so often about medical services but there is

no reason why you couldn't include medical services in this list. You could, Option A and B could even be Disease Management Programs or for that better Paid for Performance Programs. Again I think in common use when people talk about this they are thinking about technology, so that's what it is comparing A to B in terms of risk and benefits and perhaps costs but Steve Pearson will talk a little bit more about that issue. But then there are a whole bunch of methods by which Comparative effectiveness studies are done so there is prospective clinical studies, clinical trials, randomized trials, registries, there's observational studies using preexisting data from electronic health records or claims data and then there are systematic reviews and modeling. And it is important to keep these categories of Comparative effectiveness research separate because they answer different kinds of questions, they cost different amounts of money, you can use the information for different things and so it is important when you are going to be thinking about, you know funding a program of Comparative effectiveness, you know, you are going to have to think carefully about in which of these activities do you invest under what circumstances. The other thing is there is no, a prior reason to think that all of these activities belong under the same roof, I mean you could argue that there should be one agency to do all of this but you know

there is no reason to jump to that conclusion. And again, you know there is lots of terminology out there that is used interchangeably Health Technology Assessment, Outcomes Research, Evidence Based Medicine, Health Service Research and then you know I think that head to head trials is what a lot of people mean when they say Comparative effectiveness research because it's been used in the context of you know, formulary design under Part D and you know an alternative to federal price negotiation Comparative effectiveness research was presumably what they are looking for as head to head comparisons. But again the main thing, the main message here is that when you are talking to folks about Comparative effectiveness research, or when people use any of these terms just take a minute and say, "Now what exactly do you mean by that?", you won't sound ignorant you will sound, well you might sound ignorant, but anyway it will be useful. And so there is lots of capacity in Comparative effectiveness the NIH does head to head studies, the Life Science industry does a ton of this kind of work, Veterans' Administration. ARC does mostly systematic reviews and observational studies; they do some prospective studies and then lots of organizations that do systematic reviews including Cochran and then Blue Cross Blue Shield Association, Eckery Hayes, the Drug Administration Review Program and the Institute for Clinical and Economical

Review which is something that Steve has been putting together over the last year. So, lots of existing capacity and the question is, and I'm about to run out of time that is why my pace of speech has picked up. What is their perception of, why do we need to do something different and here is a whole list of things you can look through, we can talk about it in the discussion period but you know what do we need to do different that we aren't doing now given that we have lots of capacity to do a Comparative effectiveness study? Well, it is we either need to involve decision makers more, we need some kind of more authoritative creditable politically protective body, and we need to reduce duplication of effort, faster cheaper methods. One thing I think is important is better matching of priorities to gaps in evidence including cost effectiveness because there isn't much capacity for that and the last one lots more money for this. Again before we, I think as one is going forward and thinking about building new capacity for Comparative effectiveness it is really important to think about what is missing around what we currently do and I have some thoughts about that I can give in the Q and A. And then the last thing to know is that good evidence is necessary, it is essential for all the things you want to do about getting better healthcare quality and value, but obviously by itself it isn't sufficient you need good provider accountability, quality measurement,

quality public recording, you need systems and organizational support, electronic health records, alignment of financial incentives and of course expanded access to coverage for people who don’ have coverage you know, so no one’s arguing that Comparative effectiveness and creating the evidence is by itself going to revolutionize the system but is a necessary ingredient as all of these other health system changes are being put in place as well. I will leave it there and thanks. Thanks very much.

ED HOWARD, J.D.: Thank you very much Sean. Next up is Steven Pearson, Senior Fellow at America’s Health Insurance Plans and in 2006 he founded and now directs something Sean mentioned the Harvard’s Medical Schools Institute for Clinical and Economic Review. Hi Sir, which actually does appraisals for of medical innovations for their clinical and cost effectiveness. He has also advised CMS on technology and coverage policy and we are very pleased to have Steve Pearson with us as part of our discussion, Steve.

STEVE PEARSON: And thank you very much again everybody. We are here today to talk about generating and using the best evidence possible to help move our healthcare system towards both higher quality and to move us towards a more honest discussion of value and among the many partners in this cause I would say our private health plans.

Now recently, we have came out with proposals to expand access to affordable health insurance but it's really important they realize also to link such efforts to expand access to comparable initiatives to improve the safety, the quality and the affordability of healthcare. So last week AHIP did come out with another plank in its platform if you will, it talks about advance in quality and safety in healthcare. And the first goal within this set of proposals is to access safety and quality and to do so in a way that supports innovation by determining what procedures and technologies are safe and most effective. Now you will see that there are three generalizations under that goal, two of which has to do with many people's perceived ideas about how to strengthen the FDA's role but the first piece there is to establish a national entity to evaluate new and existing healthcare treatments and technologies. Now why is that at the top of the list, why do many health plans in this room and others elsewhere feel that's important? Well, you will hear probably from all of us some of the background, but I want to introduce a specific example because I'll use it in some of my talk in just a minute. This is a new device that is being tested currently it is called Watchman, it is a little filter that is inserted into a vein and placed into a part of the heart in patients who have Atrial Fibrillation, that's a shaking of a part of the heart so that

the heart doesn't have a regular rhythm and the purpose is to keep blood clots from forming in that part of the heart that can then break free and create embolisms, strokes etc. Currently patients who have Atrial Fibrillation take a drug called Warfarin and it thins the blood but it has some risks associated and so this is in trials and I happened to read an article about it and the cardiologist involved said, "The data aren't in yet but I'm absolutely convinced that this will revolutionize the care of our patients". He may be right but as many of you know in the process that we have set up both through FDA, well largely through FDA, procedures do not come through with any specific review at all, devices often come through with a less formal or rigorous type of review than drugs and even the drugs often come through without a lot of what we consider to be important information about their comparative clinical and cost effectiveness. So we might know that they're good but we really need to know which is better and that's what a lot of this is about and we are also here today because we in the United States are truly among a very few set of developed countries who do not have a really formal identifiable program to judge the comparative clinical and cost effectiveness of new devices, procedures and drugs.

So, I want to talk a little bit about the functions of comparative clinical and cost effectiveness this is the way

that AHIP frames it and again you will hear about different ways to target the actions of Comparative effectiveness. I want to talk about this because a lot of people want to know what's the role of costs in what we are talking about. So first of all, comparative clinical and cost effectiveness really is as Sean said, it's doing two things; prospective research comparing head to head two different, again, drugs, devices, approaches to caring for patients. But it is also, there is an assessment side to Comparative effectiveness a pulling together of the evidence that we do have and trying to make sense of it for patients, for clinicians, and for health plans and others. Now, some people say why do we actually need assessments if we are doing the trials won't they give us the answers that we need. But part of the issue is that most of the time I would say, even very large well designed trials may not provide a clear cut conducive answer for patients, clinicians and others. There are a lot even systematic reviews that try to pull together evidence sometimes end up shrugging their shoulders because there is not enough data or there is conflicting data etc. So there really is a need for Comparative effectiveness to include assessment as well as forward looking research head to head. Well what kind of assessment do we want? We really don't want to just put in a scale and say well there are ten trials that said "x" and eight trials that said "y" and it is

up to you to figure this out. What we really want are assessments that bring together all the benefits all the harms; patient values too because again often drugs and devices will have some benefits but different kinds of side effects and it is very hard in a sense to pull that together. Unless you do a certain kind of assessment that puts all these together in a model and helps to in a sense grapple with them together. The other thing we need from assessments is to put all of these together with downstream system effects. Because we all know something will look really good or bad up front but if you really look at it over the long course of a patient's therapy or how it affects other parts of the healthcare system it could look great. And so once you do the kind of modeling to get at this, that's actually caused cost effectiveness. You don't even actually have to plug in the cost but many people say, "Well do we want to, do we want to look at all the harms benefits and systems effects and not look at cost?" Well some people say "Let's do that because others can plug in the cost later on, they might have different cost, it'll be easier they can just plug it in and figure it out for themselves." But it's really not that easy to do that because you need really good research on the assessment side to put together a model with all the different kinds of costs and it's not that easy for someone just to take it and kind of plug in one cost and

make it work. But a related question is what are we going to do with this information anyway? And this is where people sometimes get their backs up a little bit. I want to talk about what we could do with the cost information because I think the answer is a lot.

I think we can use the cost information to support innovation and value at the same time, so let's talk about Value Based Decision Making and let's use that Watchman device and the reason I like to use it because I have absolutely no idea if it is the greatest thing since sliced bread or if it's absolutely something to run away and hide from, I have no idea, so take all of this with that grand hypothetical. But let's say we did an assessment of the Watchman and we were comparing it to the usual care with drugs, now we could find that the Watchman was actually very expensive upfront, much more expensive to do certainly than having patients taking cheap pills for awhile, but if you do the right kind of assessment and you look at it in a cost effectiveness mode you would find that over the time of a patients care and throughout the rest of the healthcare system it's a great deal. So, we need to do cost effectiveness to learn that about Watchman. Let's say we're looking at Watchman compared to a competing device and they both essentially seem across all harms and benefits to do the same job but Watchman is less expensive, now again I say

less expensive not up front but when looked at over its different effects throughout the healthcare system it might require fewer follow up visits no matter what the case may be. Well that's what we need to know. We need to know that they produce the same overall benefit if you will, not benefit but if Watchman is cheaper, let's buy it, let's encourage patients and doctors to use I; P for P if you will. Let's lower the co-pays for it. Let's do everything we can. Let's drive value through the healthcare system by understanding the full picture around new devices, drugs, etc. And then sooner or later there will be Watchman2, there always is. And let's say it is more expensive than Watchman1, don't we want to know what the marginal value of that improvement is, and don't we really want to know how much better it is and how it compares to the cost throughout the healthcare system? I think we do and I think therefore to look at Comparative effectiveness in the way that will bring the greatest benefits to your healthcare system we have to be honest and say that we want to look at value and the best way to do that is usually to look at some kind of model. So, to sum up briefly before I show you a picture of one approach to doing this at the federal level; I would just say that comparative clinical and cost effectiveness really is about creating better evidence that will lead to better care for individuals. I think it will send a very clear signal to

manufacturers and we will hear from one person who works with a drug manufacturer today. I think it helps send more clear signals about what the market, what consumers, what patients and doctors want. I do think it encourages dialogue over our best use of healthcare resources and will lead us to a higher quality more affordable system with innovation as a key part of that. So I am out of time, so let me just say in the same amount that Sean ran over, this is a model and it is in your packets. Public and private partnerships either through perhaps something like a federal reserve board type model or a commission model like MedPac, something that creates a Comparative effectiveness board that has real oversight and can drive the prioritization of work, give it political insulation but be transparent and engage with stakeholders at the same time. It works if you include all of these intersecting activities working very closely along with components of the Comparative effectiveness system such as ARC, CEC, IOM, NIOH and others with dissemination as the key piece. So, I think health plans are very much on board with the idea that we need a public private partnership to create a trusted resource for all Americans to get creditable, objective and reliable information on really what works best and what produces the best value, so I think this is an idea whose time has come and

its really exciting to see the interest growing and maturing among folks like you.

ED HOWARD, J.D.: Thank you Steven. Thank you very much Steve. Our next speaker is Gail Wilensky, and most of you have heard her speak on a number of occasions here at the Alliance. You probably don't know that she is spending most of her time these days on military healthcare issues that is not in the biographical sketch in your packet, she is co-chairing a Congressionally mandated task force on the future of military healthcare, she is a member of the Dole Shalala Commission and coincidentally not necessarily having to do with that she is the author of the Lead Health Affairs article on Comparative effectiveness that we are using as the basis of which to jump into this discussion, so on a number of fronts, no pun intended, we are very pleased to have you back with us, Gail.

GAIL WILENSKY: Thank you Ed and thanks to Stuart Gutterman and his continued support and predecessor Barbara Cooper at the Commonwealth Fund Financing. Some of the work I've been doing and that Sean has been doing giving me the advices I go along in an area that is not exactly obvious for an economist to be mucking around in, that is talking about the generation of Comparative Clinical Effectiveness information. One of the reasons that my handout arrived too late to be included in your packet but is available. I find every time I

talk about this issue very long with people I learn a little more, hear a nuance or something is said that causes me to modify some part of what I've been doing so these were finished late last evening so they are proverbial "hot off the press".

Let me explain why I have been working in this area as much as I have and that is the recognition that if we want to try and slow down spending growth rates in the United States it will be hard to do that as important as realigning financial incentives are and changing the reimbursement system if we don't have the information we need in order to be able to spend smarter, so I look at the issue of Comparative Clinical Effectiveness as a basic building block, we need that if we are going to do the other things that we need to do in order to learn how to spend smarter which we desperately need to do because we can't have the same two to $2^{1/2}$% points of growth in healthcare faster than the economy that we've had for the last 40 to 45 years for the next 40 or 45 years it will just overwhelm both the economy to say nothing of the federal budget and the entitlement programs. So when I look at this issue it is trying to get better information and this is very consistent with what Sean and Steve have said about what works when, for whom, provided by if that matters, there are some things where a care is provided in an entity that specializes in it will provide clinical outcomes that are considerably different than

if your regular community hospital does, for some things that doesn't matter. And knowing in which kinds of treatments is important and when it's not is all part of the notion of Comparative Clinical Effectiveness. It is also in a society in which we tend to think in binary terms, you're licensed or you're not, you're approved or you're not. This is fundamentally not the right way to think about Comparative Clinical Effectiveness. What it means is recognizing that technology is rarely always effective for everyone under all circumstances and hardly ever certainly if it needs FDA approval never effective. And the question is trying to get better evidence about which group it really matters for and how much it matters and whether it matters where it is done; and that as it turns out is not so easy even though we have done a lot of scientific trials, if you pick up a Journal in anyone of the major medical areas there seems to be no shortage of technical studies that are done but not really answering the kinds of questions that we need to in order to be able to address these issues of Comparative Clinical Effectiveness. Now this is an area where other countries are ahead of us sort of. That is if you look at what other countries have done UK with NICE, Germany has its center, France, you can look at the commonwealth countries Australia and New Zealand, you can look also at Canada has been working in this area. They tend to

have entities that do some Comparative Clinical Effectiveness not surprisingly mostly they're in centralized processes, they tend to do a lot of literature reviews, they tend to focus much less on supporting new research and are usually part of government which is not a surprise since these are mostly countries that have national health insurance systems. They tend to differ on whether the recommendations that come out are mandatory either in terms of coverage or reimbursement and they differ a lot in the terms of the transparency of the process that is in terms of how the data is collected what the studies actually showed and the amount of appeals that are possible. But another thing for me where they really differ is they tend to focus on new drugs and devices. Now that's fine if you want to look at new drugs and devices but because I am looking at this as an economist mostly as a strategy for learning how to spend smarter, I can't ignore where all the money is and the fact of the matter is most of the money is not in drugs and devices, most of the money is associated with medical procedures that is technology broadly defined. So, new drugs and devices are fine, existing drugs and devices are fine but I want to be sure that this is understood to include medical procedures new and existing otherwise I'm not sure it is really worth the political capital to get this all started. So, I see something that is quite different than the models that are out

there in European countries or the Commonwealth fund countries. I see this as a center that focuses on medical conditions rather than specific interventions and therapeutics. And as I just indicated very importantly it must include procedures not just drugs and devices and the answer is really simple, that's where the money is; to not include that is to miss the point as to why you are really doing this. And there needs to be recognition that this is a dynamic process, it's not you invest in a particular issue along the cardiovascular disease chain of options and think that you are done forevermore. Just as the procedures themselves are modified sometimes in small ways sometimes in big ways in a frequent basis the investment in trying to understand better what works when is also going to need to be a dynamic process; and I see this obviously helping commissions make better decisions on their part as well as patients, but I see this importantly as a reimbursement tool and I'll explain that more rather than as a coverage tool.

Very much, and this is thinking that it has been helped a lot by some of the work that Sean has done, I want to use all sorts of data that is out there, it's just going to be a hard problem there is a lot of stuff to look at and I think there is, we need to be willing to look at data as it exist, the double blinded randomized control trial, that is fine for some things. The fact of the matter is that most of the randomized

clinical trials are one very narrowly defined intervention versus another. Unfortunately when most of us show up as patients we have this nasty habit of having a variety of co-morbidities. There may be multiple problems that are being presented, they are rarely apart of randomized clinical trials something that Sean has been working on in his real world; randomized clinical trials. But we also need to be willing to look at what we can learn from observational studies, epidemical logical studies, from medical record analogies and put forward when this information is available we need to be clear about the basis in which the information that is shown is made available and hopefully something about the certainty of the decision making will relate to the strength of the data that is underlying it. A lot of ideas on where to place this, it could be part of AHRQ with their existing center, like ARC's and stuff where some of the work is being done right now. It could be as a federally funded research and development center attached to an existing entity like ARC or the NIH. There are some that are quite large and quite old. Lawrence Livermore Labs is a little under four billion dollars a year has been around for a long time. It could be a freestanding agency in the Executive Branch, like the Federal Trade Commission or the Reserve Board. It could be quasi government that is attached to something like the Institute of Medicine and the National

Research Council. For me and I will explain this in terms of what I think the data needs to look like close to government but maybe not too close and exactly where that is depends on what you think is most important. There are advantages and disadvantages with every place you can think of and they all have trade-offs. If you use existing bureaucracy that is an entity that exist, well you don't need to create new bureaucracy and that has a real attraction to it. You need to worry about how vulnerable such an agency will be to political pressures and other types of pressures. Having the information be regarded as an objective incredible is really critical if it's not why are we bothering with this. And the question is, "Is this better if it's inside government or outside government." Now you might think you know the answer you might assume that industry would like it as far away from government as possible. Those on the right side of the political spectrum might assume to want it there. To my interest and surprise I found that a number of people whom I would in my own classification terms identify left of center politically are equally nervous about having this too close or too much a part of government. So this issue about close enough to have accountability, to have creditability but not so close as to be captured and not so close as to be vulnerable is in my mind not so easy. I'm personally inclined to the FFRDC attached to

something or the IOM but I'm not really wedded to any of those. Those are the issues that I think you need to look at.

Governance issues are also important and there are a variety of places that you can use or think of in terms of how decision making occurs in terms of where to look and where to start. For sure you need to have the major stakeholders including the practitioners but importantly including industry and the advocacy community be a part of this to have them outside the tent is really a bad idea. You can have appointments by the Executive Branch with confirmation by the Senate or something else. You could use or think about having special scientific advisory boards that would be convened for special issues and that would be the way that Medcap now does it when they make coverage recommendations for CMS. And I think you ought to have an entity that has both intramural and extramural functions. There is something important about having expertise inside the agency; my assumption is a lot would be done outside of the agency, contracts through the usual suspects. You could either think about ARC or the NIH as models where there are important intramural and extramural pieces. My preferred strategy for funding such a center would be having direct appropriation because if there is anything that is a public good it is this kind of information but might not work, might not be enough to have on a regular basis the

way the NIH is funded and I think you can make an argument that you can have a mix of funding using user fees from the private sector, that kind of model which would mean private insurers. You want to make sure that risk exempt insures are not excluded from this and a tap on the trust fund since Medicare would clearly be a beneficiary and some direct appropriations.

Let me explain what I think the center is not and this is my last slide but because it is here where I differ, I want to take a minute to explain why and why I think it is really important to think about it this way. I am not looking at this center as adding another layer in terms of coverage. I think that what the FDA does is in terms of safety and efficacy is enough of a coverage determiner. I am thinking about this primarily as a strategy for reimbursement, to my simple mind way of thinking if it doesn't do more why would anyone want to pay more, so you can't take that position if you don't know this kind of information. I don't see this as a kind of decision making center. I see this as a place where information is provided so that decision makers, public and private can make decisions, but I assume they will make different decisions or at least they should be allowed to make different decisions. Yes, I understand what Medicare does frequently leads what the private sector does but actually sometimes is the other way around, what happens in the private sector drives what Medicare

does. Here is an area where I really do although I respect Steve's opinion on this and we've had many discussions, differ in terms of cost effectiveness. Yes, I think it is very important and I understand this is not just a plug in I am an Economist after all. In fact it's because sometimes cost effectiveness can be so much more ephemeral as a concept that I think having this done by the pairs in a serious way with some serious funding by CMS, by the Tech Center for the Blues or anywhere else is better than having [Inaudible], clinical cost [Inaudible] effectiveness. Where am I in terms of the life cycle of technology? [Inaudible] Where am I in terms of production level and importantly who you are as a principal determines what it would cost you if you were actually to use the device or drug so I think it's important. I want it funded. I want it taken seriously. I just want it separately and oh yes I think it's much healthier politically if it's done separately. So, I don't question the importance of cost effectiveness in terms of making smarter spending decisions by reimbursers. I think it's so critical that we have comparative clinical effectiveness information as the basis on which to make these smarter reimbursement, I don't want to do anything that I think will undermine it and keeping it separate seems to be the better idea. Thank you.

ED HOWARD, J.D.: Thanks very much Gail. Our last speaker Ian Spatz from Merck and Company also no stranger to [Inaudible] program, he's the Vice President of Health Policy at Merck where he is responsible for their health policy efforts and incredibly wide range of issues. Of course what these folks have all been talking about is doing stuff to his company's products; it's their effectiveness and cost effectiveness that are likely to be assessed if this kind of initiative goes forward, so we thought it'd be a useful counter point or at least compliment to what you have heard to have Ian on this panel. So, Ian what do you think?

IAN SPATZ: Well thanks Ed. Ed I want to appreciate the invitation from the Alliance the Commonwealth Fund. Appreciate being asked to be a reactor which of course means that I didn't have to prepare slides and I can selectively quote from the previous speakers to make my points, so I appreciate that. When Ed originally called me and asked me to speak I suggested that it would be better if he found someone from industry who would talk about comparative effectiveness as the work of the devil and also describe a center like Steve is describing or Gail is as the devil incarnate, but I have to disappoint you because we don't feel that way and in fact what I want to talk about is six points that I believe are part of what's an emerging consensus around this issue and that's kind

of fun in Washington because we are so polarized often on these issues and I think the fact that there is an emerging consensus gives us hope.

The first point is that we agree and think there is a consensus around that more and better information is absolutely necessary in this area as the previous speakers have said, of course there is no guarantee that more or better information will be translated into clinical practice but it can't, there is no chance of it if it doesn't exist, so I think one of the points of consensus here is more information is necessary. This is not just about collecting the existing information, organizing the existing information, assimilating the existing information; the big problem is that we don't have enough information on comparative effectiveness. We need to generate more quality information in that area so that's number one.

Number two which we're extremely glad is a part of the emerging consensus is that this is not just about pharmaceuticals. Sometimes we feel just a bit oppressed. But here I think there is widespread agreement that yes it should be about pharmaceuticals, were something in many ways is fairly easy to compare and so there's been more work on that than in other areas and certainly more attention but as Gail was saying and others were saying the real money is in lots of other places, so we're not trying to be exempt, but we are also want

to not be completely focused on in this area and some of the countries have tended to have that kind of focus on pharmaceuticals and to some extend devices. So number two is this isn't just about drugs it needs to be more broad based and again I think there is a consensus around that.

The third point which is often easier around health researchers and I'm not one is that we need more money but this is one where there is incredible agreement and you think about the amount of money we are obviously spending on health interventions that aren't really worth it we have to be able to invest this kind of money and we have to find a place to come up with it. Of course there are various proposals for that; that we have already heard a little bit about but this is in many ways a public good. There isn't any one place in investing this money and I say that coming from an institution that invests a lot of money in comparative research. We do a lot of this work, if I could risk disagreeing with Ed in one point here, a lot of our comparative work is not just to nothing or a placebo it is to another intervention, whether it is a non-prescription drug intervention or another prescription drug we are doing it because the pairs like Steve's folks are demanding that we do it. So we are doing it but of course there are legitimate questions about the objectivity of our research which projects we choose to do. We think we do get

research but we don't think we should be the only ones spending money on this so come on bring on some more money bring on some more players in this area. That is point number three.

The fourth point of consensus I think is that we need to organize this in a way that fits US Healthcare and I didn't say the US Healthcare system because as many other people have said we don't really have a system we have US Healthcare and because of that we can't set up something like we establish in another countries perhaps the UK which has a national health system, now I know some people here want a national health system but we don't have one now and we probably won't be having one in the near future, so we have to establish this in a way that fits and not one entity, one national body that's going to make all of these decisions. The other problem is if we have one place you have the dangers of centralization and I think those are some of the political issues that Gail talked about. And you know in this country we always say we want things done by government but we don't want them politicized. Well you can't have it both ways, one of the strengths of our system is that our government is answerable to people that's what politics is about but this is something that we don't want politicized so again I think part of the emerging consensus here is that we may need to insulate this a bit from government

and from the political system, recognizing that our healthcare is not provided all by the government or government system.

Fifth, I think part of the consensus is that we need to use the information that comes out of comparative effectiveness in a way also that fits how US healthcare is delivered and there I do agree with Gail and what she said, we want to really avoid having any kind of a central decision maker, negotiator. I think there is a lot of consensus around that also and again that deals with the politicization issue the more you have that the more you have problems that are going to occur. We need to let different players in the health system, I said it, have their own take on this, so I am more on the side of not having this be about cost effectiveness because the cost and benefits do vary from your prospective in the system. Are you in the Medicare world where you are looking at people who are aging and the cost that are going to occur from the aging and disabled? Are you an HMO who thinks that the people are going to come and go in your system every year or two? Are you an individual who wants to pay for things and wants to make decisions based on that, your cost and benefits will vary? I'm not suggesting that we shouldn't be looking at cost and benefits but we shouldn't be having a body that reaches conclusions on that because we need to respect the different perspectives that exist.

And point six and I think again a point of consensus is we have to understand the limits of comparative effectiveness. We don't have sort or probes that we insert into drugs, devices or medical procedures that precisely measure their comparative effectiveness, in many ways this is an emerging field it's much more of an art than a science and we certainly talked about the need to invest in the tools and techniques. If you could do a retrospective work in medical records it may not provide the kind of answers we are looking for or the same way that randomized trials may not provide us all the answers that we are looking for. We really have to understand the limits here and that should make us humble about how we use the information, if we are looking to make decisions that truly are life and death we may need a very much higher level of evidence than if you are making a decision about which pain reliever that you take. So those are the kinds of questions that we might want to be humble about and recognize as Gail said that a lot of these things are not binary in this area. I mean it's not just one or zero depending on whether you are this patient or that patient you may have different perspectives. I mean this is not woebegone where we are all above average and in fact this isn't an area where we all are average; we're different we are men, we're woman, we're different colors,

ethnicities, we react differently to treatments we have to respect that in the system.

So those are the six points that I think I would make and react to in this panel; is that there is a lot of consensus, there's a lot of ideas that we have that are ways of moving forward. The panelist here I really compliment. I thank AHIP for putting out their proposal last week. I think they have advanced the state of this. I think the work that Gail has done in health affairs has really moved us forward so I would sort of challenge my fellow panelist and all of you out there that do this to say "Now what"? What are we going to do because we don't need lots more panels? Sorry Ed. Sorry Stu. We needed this one on this topic but on this topic I think it is time for action. I think it is time for the hard work of drafting the legislation, thinking about the funding sources and dealing with the very specific design issues that the panel has raised today because we can't spend more time waiting on this we need to advance this. It's completely clear and I believe its sufficient consensus for us to move forward.

ED HOWARD, J.D.: Thank you Ian. Before we go to mark up we want to hear from some of our other panelist in this program that is to say we are now at the Q&A session if you want to give us a question in writing there is a green card in your materials that you can fill out and hold up and someone

will snatch it from you. There are microphones in the back and in the front that and in the middle that we urge you to go to and ask your question; if you do that please identify yourself and keep it as brief as you can, direct it if you care to one or another of the panelist. We have somebody at a microphone, would you like to start? Uh no we don't.

MALE SPEAKER: We have two, they're all over.

JENNIFER BRIGHTWITH: Hi, I'm Jennifer Brightwith [misspelled?], Mental Health American and also a convener of the working group of patient organizations that are very interested in this area. I was really glad to hear both Steve and Gail mention the importance of inclusiveness and a wider stakeholder base, but I was a bit disappointed as I am often when I come to programs like this because there isn't a full patient perspective brought forward because I think ultimately all of us are patients, but I particularly represent millions of Americans that deal with severe mental illness in its various gradations.

And I think what I'm most frustrated by as an advocate and as a family member and a consumer is that we talk about that, about the importance of inclusion but I have yet to hear really the brass tax of how to make that happen and I would put forward that – there is a question coming, I promise – I would put forward that there is a role for patients, particularly in

the chronic illness areas at every level of evidence generation. To Ian's point, we need better evidence. Well, if we start asking patients about what their real health goals that might drive better formation of what's being studied.

If we ask patients what they really care about we might get manufacturers to focus on things that actually matter patients rather than just trying to come up with the tweak version of their particular therapeutic. If we ask patients for what they really value we might look beyond, as Gail says, to look at conditions, how we treat conditions rather than Option A versus Option B. So I would love to hear from the panelists about how these concepts are really going to make patients a part of it and not just window dressing, but really an active part of the solution.

ED HOWARD, J.D.: Start with Gail.

GAIL WILENSKY: I have the advantage that Jennifer and I have had this exchange of times in the past, so I have had an opportunity to think about the very legitimate issue she's raising, which is how patients and patient advocates are to be included in this process. For me it's the following. First, in terms of the governing board, either if it's a commission or if it's a governing board as part of an FFRDC or external to Arc or wherever it's located, patient representatives from some of the major patient groups ought to be included among the

stakeholders, as is industry, in addition to the more obvious academic health center representatives, researchers and practitioners.

Yes, that's where I would have the first role in terms of helping to decide what are the areas to look at and for me there are two criteria to make an area right for study. One is that it costs a lot of money, again sort of the economist in me. But the second is there are alternative ways of treating something. That there isn't just one accepted way, that there are issues that you want to understand. Now fortunately in almost every area that's not a problem, but that would make it right for conclusion.

To me, let me say where it isn't appropriate and then where it is when the evidence on comparative clinical effectiveness ought not to be influenced on patient preferences, per say, what we know about the clinical outcome, unless there is something about the way that the condition is treated that has an impact on compliance, which in and of itself would impact the clinical outcome.

If there is enough of a relationship that the clinical outcomes would be affected, then it has to be directly a part of an analysis of comparative clinical effectiveness. Otherwise, the very important role has to do with reimbursement decisions where patient preferences, in addition to costs and

what are known about comparative clinical effectiveness, ought to play a very important role. So I see the primary role is on helping to focus where to look at, what are the issues that are important and in terms of the reimbursement. In terms of including the elements of clinical effectiveness, the elements of costs and the elements of patient preference as being important but not in the actual generation of the comparative clinical effectiveness unless there's a direct link.

FEMALE SPEAKER: I'd just like to say –

ED HOWARD, J.D.: Why don't we let – No, go ahead, go ahead.

FEMALE SPEAKER: I wanted to say thank you for that answer, I appreciate that very much. I'd like to suggest to everybody that we possibly change the terminology from patient preferences? Because I think it sounds squishy and people dismiss it out of hand. And we might start talking about patient experience, because we need to come up with a better term that really embraces what we're talking about, which is the unique status co-morbidity patient history. Those are the things that are relevant to what we're talking about. The preferences sounds too much like bad attitude or inability to comply or all those things. Sorry to insert.

STEVEN PEARSON: No. The power of words is very important in this area. I agree. I'll just say briefly that I

agree with Gail in terms of particular areas that are ripe for comparative effectiveness or where there are established alternatives in patients and physicians are trying to navigate those choices together. I think it's an obvious target in a way for us to focus things. The other element about patient experience, I can now use that, because it's at the root of the modeling approach that is cost effectiveness. It basically has to look at how patients value the side effects of different kinds of treatments.

How can clinicians really know that unless we include it in the structure of the evaluations we're doing? And I'll give you a concrete example that I heard about when I was at NICE. They had a group looking at the outcomes of anti-seizure medicines for children and the outcome that had been studied was "seizure free days." This was the standard outcome measure and every drug was being matched on how many seizure free days you got before you had another seizure. And NICE had mothers of kids with seizures in the room and they said, "That's the wrong outcome because when our kids don't have a seizure all day long, they're zombies. They're snowed at school and they can't learn. We'd much rather have a seizure every couple of days and have them alert in school."

That was critical event for that group and it just goes to show that I think there's a vital role for patient

experience. It has to be hardwired into this and that's one of the reasons that I personally favor cost effectiveness as a route towards making sure that that happens.

ED HOWARD, J.D.: Sean?

SEAN TUNIS: Jennifer, thanks for bringing this up in the conversation. As I was speeding through my last couple of slides, the first bullet I had on "Perceived Needs" was involving decision makers and by decision makers I always mean clinicians, payers and patients. And in some of the work that Steve and I are actually doing together, I'm focusing more on the design of prospective compared to effectiveness studies and the workgroups that we have that are designing the studies have patient consumer folks as well as payers.

And so we are trying to build the patient perspective actually into the design of the primary research itself. And I do think that that's a critical thing to focus on in building this activity, is how to make sure that not just at the sort of governing board level, but at every level, including the study design levels that the patient experience, I think that's the right terminology, obviously is vacant from the beginning and not second class. If anything, the first order consideration.

FEMALE SPEAKER: Thank you.

ED HOWARD, J.D.: In case some others are acronym impaired, NICE as I understand it is the National Institute for

Clinical Effectiveness, which is part excellence. Thank you. Which is part of the National Health Service, or is advisory to the National Health Service of Great Britain. Yes, in the back.

GAIL SHEARER: Thank you. I'm Gail Shearer and I'm from Consumer's Union and I direct consumer reports for "Best Buy Drugs" project. I was wondering if Gail, and Steve especially, could expand on the whole notion of what the implications for reimbursement policy are. We've all see how dramatically tiered formularies can shift market share to more cost effective drugs in many cases. Do you think this country is ready for referenced pricing? Do you think we might see the notion of tiered formularies applied beyond the prescription drug world?

GAIL WILENSKY: I think it depends how the reference pricing is set up, although I have learned that it is such a loaded term to someone in industry that if we could figure out a better way of describing it, it would probably be helpful. As I said, I looked at this whole when I started that the reason I see this is to help make the kind of decisions about how you should reimburse. And I see the information very much as just the example of tiering according to clinical effectiveness, instead of tiering according to where the PBM got the best buy.

Right now we are used to seeing different co-payments depending on the use of generic preferred brands and other brands. Too often, at least from the perspective of the outside observer, it has less to do with what might be the most clinically, effective, appropriate step and more on the buy. Now presumably it's because there's been an agreement by some that the things in the class are all the same.

The issue really becomes how you define what's regarded as the same. If there is clinical effectiveness information that there is little or no differences, then I think this notion of only pay more if you get more when you start to get evidence of different clinical effectiveness for at least some populations, then you need to consider the issue of how much does it cost for this additional clinical effectiveness. And I very much see the notion of reference pricing. That is that for those things that are clinically the same, I don't believe in saying no. If people want to buy up for something that does not appear to be a different therapeutic, they ought to be able to do so. I don't see why there should be reimbursement by someone else.

And I see it as a way to try to make it easier to get right for the patient, even if it means a very expensive therapeutic or device or medical procedure when the clinical evidence is there and more expensive for those that don't. But

how the insurance plan will decide that I think will differ among insurance plans and maybe between public and private and that's how it should be.

STEVEN PEARSON: I'd just like to add, if this works, it will work. The way that we're talking about it will provide credible information. As Gail said, the marketplace will use that in different ways. But tiering is a way to make this something that engages with patients and consumers. It could also be behind the scenes in negotiations between purchasers and manufacturers. I've even talked to some patient advocacy groups that want to take this information and march themselves into the offices of manufacturers and ask for a dialogue around the cost and the price that they're asking for.

So I think there will be a variety of ways. But tiering, when done well with credible information, transparently, is one of the reasonable, innovative approaches I think that we would look to come out of this kind of information.

ED HOWARD, J.D.: Yes, sir. Go ahead.

BOB ROWAR: I'm Bob Rowar with BMJ. I almost get the sense of looking in the rearview mirror listening to some of this. It's great to hear the need to include co-morbidities and how that impacts effectiveness, but how is this approach going to handle the added complexity coming down the road of

individualized, personalized medicine based upon genomics, proteomics? All of the wonderful possibilities that are starting to show up there and starting to show up in the clinic and how is it going to guard against the risk of excluding people or forcing them to go through sort of a tree of trying different drugs which are more effective when in fact it may not be particularly effective for that particular individual because of their genetic nature?

GAIL WILENSKY: I actually think it's very apropos to this issue, particularly when at least at where we are now is frequently not individualized, that is to the person. But what you're talking about is what will be effective to people either within a certain metabolic classification, which may be one of five metabolic classifications or people who have a particular genetic marker.

It's very different and I think sometimes people use the term "personalized medicine" and the non-clinical or scientific have the idea that it will be different for each of the 270, or I guess now the 300 million of us, where as it really is defining those classes. So again, if we start to think about what the clinical effectiveness is for variously defined classes of people it will be now we tend to do them by symptom co-morbidity and maybe a gender or ethnic or racial or age classification as we are more sophisticated. And it can be

either genetic or metabolic that will make it a much more precise or better predictor.

I think it's very much consistent with how we get information again about what works well for whom under what circumstances. So I see it as totally consistent and not contradictory.

ED HOWARD, J.D.: Anybody else? Steve?

STEVEN PEARSON: Not the rearview mirror. We need this to get a hold of this because physicians and patients will have a very hard time I think understanding the different types of evidence that may be generated around personalized medicine. So I think the group, at a very high level of group standards, working to try to establish the methods by which we assess these new kinds of innovations. I think that's an equally important role for this.

ED HOWARD, J.D.: We have some questions that you've sent forward on cards that we're going to try to get here. Go ahead.

SEAN TUNIS: We have a three part question. Part one is, who in Congress is sponsoring comparative effectiveness legislation? What would the bill do? And, is the legislation likely to see any action this year? Well, let's hold that one.

ED HOWARD, J.D.: If any of you represent such a person you should get to a microphone and tell us.

SEAN TUNIS: I think we have potential co-sponsors here. Can you give one or two specific examples of how comparative effectiveness studies apply to pay for performance? Let's do them one at a time. Steve?

STEVEN PEARSON: The connection to pay for performance right now is theoretical. There's not a specific pay for performance. Well, maybe I could go back and look at the list that's being considered. The conceptual link is that if we can identify a certain alternative, let's say it's the watch man, and we feel that that's a really high quality that's cost effective, what we want to do is the best value. Then pay for performance could be linked to encourage physicians to provide that procedure, to provide it well, etc. Or at least to discuss it with patients. So there are different ways to link the concept in, but the overall goal is that this information would be part of communicating to the clinical world what is deemed to have good effectiveness, good value.

GAIL WILENSKY: I think it's more. This information is the intermediary. In order to get the kind of information you would want to see for pay for performance, which is going to be good clinical outcomes for people with chronic disease or with certain types of medical conditions. And how that occurs, how that's treated, I suspect will be less part of pay for performance. Although a lot of pay for performance actually

uses process rather than clinical outcomes.

And if there was overwhelming evidence that certain kinds of strategies were so much more clinically appropriate, you could use it in that way to the extent though, if focuses on clinical outcomes and I think they'll be just an indirect. This is what will allow clinicians and patients to have a much better idea about what's likely to happen prior to an actual clinical intervention. So I see this more indirect, except when there's process measures that are being used.

STEVEN PEARSON: At least a couple of examples of where comparative effectiveness information is already being used in pay for performance. As any of the pay for performance demonstrations, including the premier hospital demonstration, used as the measures, Beta blocker use and acute MI aspirin and acute MI. Those are measures because they have been proven to be associated with reductions in mortality in large well designed, randomized, controlled trials. So the availability of highly reliable information on comparative effectiveness is crucial to the development of meaningful measures that will be used in pay for performance.

IAN SPATZ: I was just going to just address the political question that you raised, which is any members of Congress doing this. I think it's fair to say there's a lot of interest on the hill. Some of that's long lasting for members

like Senator Clinton, for example, or Senator Baucus, who included a comparative effectiveness provision in the recently considered Medicare negotiating authority legislation. So I think there's a lot of interest, but I have not seen anyone put forward a proposal along the lines of what I described as this emerging consensus. I think that there's some technical reason behind it, but I also think one of the barriers is going to be cost. That it's difficult in this current environment to pay for something unless you find a way of saving money somewhere else.

And while we're all going to believe in our hearts that doing this work will save enormous amounts of money in the health care system, as Gail was talking about, that may be a difficult thing to convince the Congressional Budget Office up front. So I think that's a serious challenge that we all have to face, is how do we get that legislation introduced? How do we find a way to pay for it? And another part of the consensus I didn't mention is I think there's some agreement of starting modestly and ramping up over a period of time and I think that will make a big difference.

GAIL WILENSKY: There are a number of individuals in the Congress and committees that are working on this. I know because I've been contacted and I know that Shawn and others have talked to me. So it is brewing. We'll see whether it

comes forth this session or next session. It does seem to be one of those areas that is attractive to both parties and to both houses of Congress. That's not the same as having it either introduced and certainly not the same as having is passed. And there's no question that I will not emerge full blown in terms of what is a likely or hopefully to be the ultimate run right and will have to ramp up.

I don't know whether it will happen. I'm hopeful. Legislation will at least emerge in this session because it frequently takes a session or so of Congress in order to have something come to fruition. But I'm encouraged by the amount of interest in both houses and I actually think that these kinds of meetings and others have been very helpful in allowing the interest to generate and to get bounced around different viewpoints and perspective and that's helped drive the interest. I think it is actually close to being ready to burst forth, whether it actually goes anywhere this session is something else.

SEAN TUNIS: Although on the optimistic side, I have heard the new director of this Congressional Budget Office quoted as referring to this kind of process in a favorable light and I know that the issue has come up in discussions at MedPac [misspelled?]. Next question for Ian is, do you see any signs that FDA may be moving toward requiring head to head

studies for certain products?

IAN SPATZ: No. I think Joe Biden said yes. But I just can't stop with that. Again, I think if you look at how FDA regulates and makes it decisions about whether something is safe and effective. Again, often times it is in comparison to existing therapies, that that is de facto what they do. But no, I don't see the prospect that the FDA would sort of add on to it's existing process of safety and efficacy by saying, "And we would like to see these things tested against other products."

There's sort of a practical problem with it, which is often times we're developing products at the same time as others trying to race to get them to patients and get them to market. We don't have access to their products to do clinical trials, that doesn't quite happen yet. And then you could also, you could say well, let's test against something that's out there. By the time you're on the market they may not be the best and most relevant comparator. So we believe this has to go on post-approval for whether it's a device, a procedure or a drug. So we don't believe in adding it to the FDA process and I don't believe the FDA believes in that.

SEAN TUNIS: Could I make just one comment?

ED HOWARD, J.D.: Yes, go ahead.

SEAN TUNIS: Along the lines though, I think Steve made

a very important comment about how sort of the evidence framework, particularly in the value calculations, we'll send a very strong signal back to the manufacturers about what they do in their design of their pivotal trials. So for example, if you know in advance that you are going to be referenced priced at whatever the existing alternative is on the marketplace, you don't need FDA to tell you to do a head to head trial to show superiority, you will pay for that trial yourself.

IAN SPATZ: That's exactly right.

ED HOWARD, J.D.: Thank you. Let's get some questions from the real live people here. We have about 15, maybe 20 minutes left. I want to remind you there is an evaluation form in your packets that I would very much appreciate your taking a few moments over this last 15 or so minutes to fill out before you go so we can make these programs as useful as we possibly can for you the next time out. Yes, you've been very patient.

JEFFREY COONBURN: I have question. If I were a member of the House, what data would be helpful for me that I could build a consensus? When you speak of consensus, you said that there's a consensus on issues. What I would ask the other panelists is what is the data that we can all get our arms around, that we can all understand at the district level that we can develop this consensus to move legislation forward upon this issue?

ED HOWARD, J.D.: That's a good question.

STEVEN PEARSON: Did Ian state a consensus that the other panelists share? For example?

SEAN TUNIS: So as I understand your question, it's what data exists now to help create greater consensus? Is that right?

JEFFREY COONBURN: We're going to move legislation forward. I need to be able to look at where my other colleagues have the same issue in terms of finding quality of measure and quality in 435 dissents. That's the key to moving legislation forward. We can develop consensus and where we can find the commonality all across the country. In the Senate it's very easy, but not in the House.

ED HOWARD, J.D.: Let me rephrase and probably distort your question a little bit. Several of you have talked about the need to do both new investigations and synthesis of existing evidence. What's the mix? Ian, you talked about the gaps. In effect, how big are the gaps and what is there that's already that that we can use as kind of a critical mass to justify putting together a new governmentally connected entity? Is that consistent with what you were trying to get at?

IAN SPATZ: No.

GAIL WILENSKY: Let me try and take an initial crack at how you try to assess whether there's a consensus. I think in

terms of whether there exists agreement that this is missing information and how various groups respond to the notion, can occur as easily as any other way through town meetings. It's really one of the ways whenever Medicare changes have been proposed, members of Congress have frequently gone back to their districts to talk about, with town meetings, do people think this is a problem, would this help them.

In this case you want to be sure the various groups, the constituencies are represented and it means industry of the manufacturers. It means the clinicians, who I know I'm just starting myself to reach out and speak to them to see where they are about this, as I was doing that earlier this morning. To talk to patient advocates, they are clearly feel affected and need to be part of the discussions about how they would have input.

But a lot of this is really as a way to try to get better, smarter health care spending. So it is reaching out in the context of this is one way to try to get better, smarter health care spending, which is critical both in terms of our interest and expanding coverage and in trying to have a better future.

So it depends on whether you're thinking about doing this directly or whether you're thinking about this as a strategy to help you get to some of these bigger political

issues that you might find this important. Ultimately, any of the specific legislative specifications that would be included in a proposal need to reflect discussions about the various affected stakeholders. And that would definitely be one place to start.

STEVEN PEARSON: I would offer three pieces of evidence. That is, at least drive us all up here in that direction. One is, when you look at health care spending in the United States and you look at what we get for it you're left with the overwhelming conclusion that we've got to be able to do things better than this and better decision making is just a logical way to respond to that situation. Secondly is, you look at, as Ian's mentioned and several of the folks up here have mentioned, there is a lot of spending to do this sort of thing. It's done by a lot of different people and not necessarily in a coordinated way so it just again makes logical sense that doing it in a better, more coordinated way might be an improvement over the situation now.

Although given that a lot of people are doing pieces of it, each of those entities might have their own ideas about how to put it together that looks more like the way they're doing it. But that's the details, but the argument for doing something like that is there. And the third is that, more concretely, the Commonwealth Fund actually has asked questions

about this on our surveys in terms of national priorities. In our health care opinion leader survey we got back a very strong response that doing more in this direction would be something that most of the people we asked think would be a good thing to do. So I think that's where we've reached a conclusion, that there's a building consensus in this direction.

ED HOWARD, J.D.: I want to try to get to everybody who's already standing at a microphone anyway. And I believe you were standing the longest.

CAROL MCGOTHEN: Carol McGothen, National Minority Quality Forum. That was a good discussion about consensus because in representing an organization, my boss, Gary Peckwin, at the National Minority Quality Forum, an issue that really I need to remind everybody of is that most clinical trials were not and are not adequately powered to include minorities. So all the evidence we have, it's not that it's wrong, it's just we don't know. The science isn't there when it comes to most of our treatments and whether or not they are effective in minority populations.

There's a lot of smaller studies to indicate there are major differences and some of our most commonly accepted measures really don't work in minority populations. So that's one thing that we need to be thinking about as we start crafting what we mean by evidence and the ability to parse out

the impact on minorities. I'm reminded of one of the first Arc studies on the old and new generation drugs for depression and a review, like a clinical trial, has to come out with a very clean recommendation. It was, clinically, the impact was the same, but they completely disregarded the impact of side effects of the different drugs. And most of the old generation ones were ones that were intolerable in most people, let alone trying to figure out which people would be acceptable of those kinds of things.

So I just worry about the kinds of evidence reports we'll be coming out with and how we're going to nuance the findings sufficiently so we take into account, as another speaker said, patient perceptions of what they are willing to tolerate in certain medications and reactions in looking at minority responses to some of these because we really don't have the evidence. And I worry about trade offs in money and policy changes that don't that into account.

GAIL WILENSKY: If you don't know you can't do anything about it. The first thing is knowing whether or not those differences actually exist for different populations. A gentleman earlier was talking about whether you have genetically determined differences or whether it's ethnic or racial determinate differences. And the question is, are these or are these important in terms of understanding whether there

are different clinical outcomes. That is an empirical question and you can't answer it hypothetically.

ED HOWARD, J.D.: Yeah, Tom.

TOM MILLER: Tom Miller, American Enterprise Institute and a relatively new member of Arc's Advisory Council. There's a kind of bias when we approach these subjects and maybe it's the nature of medical training or the scientific process. We think of it as kind of a matter of engineering or manufacturing. Once we get the right answer the rest will flow from there. It's maybe not quite so easy a caveman could do it, but kind of in that direction. My question is the unit of analysis and what you're focusing on in terms of your key variables. And given there's going to be a heavy lift in any case where the investment should be.

Gail and Ian both suggested that this should not be a binary process. We've had some discussion about the variation among patients. The ways in which there's a not a single answer. A different way of looking at this is to say, we don't care how you cured me. I want to know did I get cured and what did it cost. And when you look at that my question is, is the more important variable, given what we now about the failure in practice to apply what might evidence, the variation who's treating you? Some people do it better, some people do it worse. Rather than invest so much in finding a right clinical

answer, should we focus more on which clinicals relatively speaking are more effective or more efficient.

SEAN TUNIS: There's couple things about that. It's absolutely right that there is a huge variation and how well providers do things, particularly surgical procedure. Obviously, the outcomes of corroded endarterectomy, the right answer there is it's a good surgery to have as long as you go to a center that has a mortality rate less than 2-percent. All that's absolutely right. It's also true, simultaneously true, that if you don't have the basic information, the right answer, all the rest of the stuff doesn't matter. You're measuring foolishness because nobody has.

So for example, the recent courage trial that rigorously compared and patients will stable [inaudible] versus medical therapy. That's not a question that you should answer by trying to look at variation and practice and see who gets the best outcome. If you want to answer that question you've got to try to answer that question with a study design to answer that question. So I'm not saying it's an either or and I'm also agreeing with you that having the answer or doing the right study, very rigorously is even. It's not enough, but we shouldn't talk about it, as if one is better than or one works without the other. They're both necessary.

GAIL WILENSKY: I think it really is a notion of an

elemental building block. And we know that there are practices that have wide clinical effectiveness that are not used and we know empirically. But you would know also by presumption that there is going to be a distribution in terms of how well individual practitioners will practice as surgeons or anything else and different outcomes, mortality rates with regard to institutions. And all of that is important in terms of making decision making.

But if you don't know based on the medical condition how likely, for different groups of individuals have done, of procedures done in various settings or not, you are to get good clinical outcomes like in cardiovascular disease, conservative medical treatment, angioplasty, use of stints with or without drug alluding attachments versus bypass.

Those kinds of comparative clinical effectiveness for whom, under what circumstances, done where, all white complex are different than the kinds of questions that typically get picked up in medical journals which are focused on something very different. And if you want to have that kind of information available, it is going to be sponsored by – it has to be sponsored either publicly because it's a public good. It's the kind of thing that payers have a reason to be interested in, but they are the wrong group to be sponsoring it because there is no way to remove the taint, in my view, if a

payer is involved in providing that information. It is the first building block and everything else that we have been talking about, including what you've raised, is very important if we don't get improvements in our health care system. But it's not either/or.

ED HOWARD, J.D.: Yes, sir?

BOB ROSENPLATT: [Inaudible] Suppose you have six drugs, all of approved to treat cancer, all safe by the FDA with one offered by Merck cost 50-percent more and it has some side effects. The question is A, should Medicare refuse to pay for the Merck drug, should it pay only for the Merck drug as much as it would pay for the rest? B, should insurance plans refuse to pay for that Merck drug or only pay for up to the level of other drugs? And for Ian Spatz, what would Merck do if Medicare [inaudible] stopped paying for your drug?

GAIL WILENSKY: Let me share how I would respond Bob, in terms of the reimbursement. As I've indicated, I regard this as information to be used with regard to reimbursement, not with regard to coverage. So the first is when do we know that and how well do we know it? I've suggested that during the time when we're trying to generate this information I would let companies come in that think they have a new oncologic drug or whatever, that if they are sufficiently certain about it and want to claim higher reimbursement they ought to do it and go

at risk while the information is being generated and at the end of the time have to true up in terms of whether they're increased clinical effectiveness for the group they've specified shows that it is there or not.

With regard to whether or not they ought to pay for it or pay more, I wouldn't pay more if it doesn't do more. And the question is, can they identify who will it do more for on a reasonable, probabilistic basis. And to the extent that you can, that's the group that you're willing to pay more for. There is a small history of Medicare doing this, but not very much. One that happened when I was at Medicare now 16 years ago, in terms of whether or not to pay differentially for a high osmolar [misspelled] or low osmolar contrast media. A

And the American College of Radiology provided us probably not with the kind of data I would now regard as meeting what I'm talking about, but with the data that existed, the six or seven medical conditions where the more expensive contrast medium appear to have important clinical effects and Medicare paid more in those six instances, otherwise told hospitals they can use whatever contrast medium they want, but Medicare's going to pay at the lower rate.

So I think this is exactly the kind of way that you can see a smart reimburser trying to say we'll pay more and the circumstances which there appears to be clinical evidence of

improved outcomes. How you judge how to treat the side effects is much harder. I'd have to think harder about that in terms of the improved clinical outcomes. It maybe as much, who wants to try to use it if it is clinical outcomes that affect quality of life, but not mortality of life. That's a different harder one.

SPEAKER: Ian, you want to take a quick minute?

IAN SPATZ: Well, I'd just say that our business strategy revolves around just this issue, which is providing real value and hopefully being rewarded where we demonstrate that value or can demonstrate that value and recognizing we're not going to be rewarded where we can. I think Steve said it best, this is about sending signals to us about what it's done. Obviously, we'd like this evaluation to be done fairly. We don't want it to be done in a way that says, well since that trial hasn't been, since the evidence doesn't exist, we're going to assume there's no difference.

When we may have evidence or indications of difference from our own clinical trials. So we want this done well, but if it's done well that is what patients need, what we need, what everyone needs is align our interests that when we develop things of real value we're rewarded because that sends us the message that the developed things are real value. So this is consistent with our business strategy.

GAIL WILENSKY: Would you be willing to go at risk?

IAN SPATZ: Gail was just saying, would we willing to go at risk. The beauty of the pluralistic system we have now is that actually Steve doesn't negotiate with us. Each one of his members does and they each can speak to us. But I think there's a danger in Medicare. I think Medicare is a special case and I think we always have to look at that way when you've got something that is 85-percent of a population that often drugs devices or procedures are targeted for.

I think it requires special caution to make sure we're getting it right.

ED HOWARD, J.D.: are now, as our friends at BC United might say, in penalty time. So we're going to make Bruce's question the last question. No, go ahead.

BRUCE STEINWALD: I'll make it brief. I'd like to draw an inference, I'm not sure it's legitimate.

ED HOWARD, J.D.: You might tell those of us who don't know who you are, who you are.

BRUCE STEINWALD: I'm sorry. I'm Bruce Steinwald, Government Accountability Office. There seems to be a consensus about more on comparative effectiveness research and how it should go about is unclear. But it's often observed that we spend a lot more of our research dollars in this country on discovery as opposed to effectiveness research. So

I'm wondering if the panel would agree, given limited resources, that there should be a shift in the balance of our research funding in the direction of effectiveness research and away from discovery.

GAIL WILENSKY: I'm not sure I want to take that political fight on.

MALE SPEAKER: Yes. We woefully under fund the evaluation of what we do and we only have limited resources, it's one of those trade off situations. I think there might be creative ways to create money to let this happen and not have to fight the political battles. But in the big picture going forward we need a health care system that does a better job of evaluating for patients and doctors and others what really works and that's what this is about.

GAIL WILENSKY: It's insane that you have a system where 50-percent of our $2 trillion dollars of spending or 48½-percent is paid for publicly and we're not willing to have public investment in this and we're spending roughly $30 some billion dollars a year in NIH ginning up more new information and we're debating whether to spend $1.5 million with an M on comparative effectiveness. So the notion that it makes any sense what we're doing is very easy to answer. I'll leave it to Congress to figure out where it wants to get the money from.

IAN SPATZ: I guess I would prefer that instead of

saying we should take it out of discovery and put it into evaluation as you might is that we take it out of wasteful health care spending and put it into evaluation because I think that's the right trade off to make there, rather than to slow discovery at all. But align those incentives around discovery, but take it away from the waste.

GAIL WILENSKY: But you won't know until we do the [inaudible].

MALE SPEAKER: I would say the same thing. Although, given the difficulty of identifying what's good. I do agree with you that the zero sum should be about what we pay for health care, not necessarily what we invest in research. But the other thing that I would also argue in relation to the basic research and the applied research is that there's got to be a better connection between what we invest in, in terms of discovery and proof of concept. There's needs to be a continuous flow into applied research to look at value and you can't just keep throwing stuff out there and then hoping people figure out how to use it.

SEAN TUNIS: Well, my comment has two parts. One is that I think that's exactly one of the reasons that the entity that's funding the evaluation shouldn't be the same entities that are funding the discovery end of it. And so you sort of separate those pots of money a little bit. And secondly, I

agree that the object of the evaluation is to free up money that's currently wasted. So there's no reason that it should be a zero sum gain.

ED HOWARD, J.D.: Well, some pretty big thoughts at the end of a very stimulating session. I want to that Stu and his colleagues at the Commonwealth Fund not only for their support of this session, but their active shaping of it. I want to thank you for sticking through this very useful discussion and ask you to join me in thanking our panel for an excellent presentation.

[END RECORDING]