Briefing:
The Reality and Potential of Evidence-Based Medicine
January 12, 2005

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ED HOWARD: Hi, let's get started if we can, I'm Ed Howard with The Alliance for Health Reform and on behalf of our Chairman Jay Rockefeller, our Vice Chairman Bill Frist, and the rest of our board I want to thank you for coming today to this briefing to look at one of the few topics, I think, in health policy were disagreements tend not to occur on partisan lines these days. That is the current and potential usefulness of evidence based medicine. Our partner in today's program is the policy journal *Health Affairs*, you see the logo on the screen who's January February issue just released features evidence based medicine as its theme and we're pleased to have with us John Igleheart, founding editor of *Health Affairs* and the national correspondent for *The New England Journal of Medicine.* That's one person, holds both those things. He's one of the most informed and thoughtful people in health policy today and I want to ask him to offer us some introductory remarks at this point.

JOHN IGLEHEART: Thank you Ed and good afternoon ladies and gentleman. Thank you for coming to this event. During the course of the year it took us to put this thematic issue together it became clear to all of us that the pursuit of evidence is accelerating in the health care systems. And though 3 of our 4 speakers today our government leaders they could just as well be a private sector executive from large

health care systems, like a Kaiser Permanente or a large purchaser like GE and others, all of whom are increasingly searching for better value in health care. So again, I appreciate your coming. I also want to acknowledge the support that *Health Affairs* derived to do this issue from The Agency for Health Care Research and Quality and that agency of course has a large role and a large stake in the pursuit of evidence. With that I'll turn it back to Ed.

ED HOWARD: Thank you John and thanks for your help in putting this program together and convincing our distinguished panel of speakers to actually become speakers. Over the course of next couple of hours you are going to be a lot of very sophisticated, very well-informed commentary on evidence based medicine. Sort of the state of the art, what next steps ought to be, how health care in the United States can be improved using it, but keep in mind there's basically one idea here we're talking about our health care system needs to deliver health care that works. Sometimes we don't know what works. Sometimes we know it but the system delivers something else and the result is the same care that's either too little or too much or just wrong. So we're going to examine today what's being done and what could be do to be sure that the care we get is backed by the soundest evidence available and that that evidence gets stronger and that it gets communicated to patients and practitioners alike.

So, just a couple of quick logistical items before we get to our program; you'll find in your packets wonderful biographical information about all of our speakers which will partially give me forgiveness for not introducing them in the style to which they should become accustomed. You should, if you haven't gotten it, get a copy of the January/February *Health Affairs* issue that has not only a wealth of information about evidence based medicine but the signal article on health care spending that you read about in the papers over the last couple of days. By the end of today you'll be able to see a web cast of today's session on Kaisernetwork.org, you'll be able to look at electronic copies of the materials that you find in your packets both on that web Site and on ours which is allhealth.org. Call your attention to both the green question cards you can use to write a question, to the microphones that you see at either side of the podium for when we get to the Q&A to actually ask your question in person, and to the blue evaluation forms that are at the back of the right hand side of your packets which we hope you'll fill out before leaving so we can improve these sessions.

So, we have with us an incredibly good line up of speakers to help us understand the very substantial issues involved in evidence based medicine. Someone pointed out to me that three of our speakers are part of the Department of Health and Human Services and they are involved in very different

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aspects of evidence based medicine and we're going a lot from all three. And besides if there is a balance question we can count on you to raise whatever issues our speakers don't cover once we get to the Q&A.

Let's start with Mark McClellan. Dr. McClellan this month is finishing his first year as head of the Centers for Medicare and Medicaid services where he's responsible, among many other tasks for implementing the Medicare Modernization Act. He's a board certified internist, former medical school professor, he's an economist, and a former member of the president's council of Economic Advisors and, oh yes, he ran the Food and Drug Administration for awhile as I recall. Mark, welcome back to the Alliance podium and thank you so much for joining us.

MARK McCLELLAN: Ed and John, it's great to back be here with the Alliance and thank you for organizing this very important event. It's a special privilege to be here with David Brailer and Gail Shearer and Carolyn Clancy, who have all been working very hard to improve the evidence base and make some important contributions through these very timely papers in the health affairs issue to help us take steps to address our common mission towards better evidence. This is a very important need today and I can tell from the strong attendance that you have you how much people on Capitol Hill and in Washington generally believe that this is a very important and

timely issue as well. We need to know more about what works in medicine so that we can help doctors and patients make more effective decisions about their health, about the individualized medical treatments that they receive. We need to get better care for our money and better supported decisions is what is going to make that possible. And I firmly believe that at CMS, the Centers for Medicare and Medicaid Services we can assist in moving this effort forward by supporting the development of better evidence as part of our coverage and payment processes. We can do this by supporting the collection of practical, clinical information as what should be an increasingly routine part of the provision and payment of medical services. The idea of pushing toward better evidence is very much incorporated in some of the recent coverage decisions in Medicare. We're taking advantage of this opportunity because there are today more opportunities than ever, thanks in good measure to the work of my colleagues up here today. So that I'm more confident than ever that we can get to a health care system where patients can expect to be able to make personalized decisions about their care based on evidence about the risks and benefits and costs of up to date treatment options. That's how you have an innovative and personalized and affordable health care system. And I want to spend a few minutes today filling you on some of the details of the work that we're doing to get there. We're working with our

colleagues up here on the dais as well as patients and doctors and product developers to develop more clinical data through simple, practical trials and registries as part of our coverage process. The goal is better health which means making safe and effective medical technologies available more quickly through faster coverage decisions and then to support the effective use of these technologies by helping our beneficiaries and health professionals make the best decisions for their own needs. We've used this kind of approach, as I've mentioned in some of our recent coverage decisions, for example involving some important colon cancer drug of Aston and Urbatak [misspelled?] where we provided some coverage of studies of unproven but important uses that are not listed on and not listed in any drug compendium and just to be clear this coverage for the experimental treatments would apply only when these treatments are not provided for free through a manufacturer program or manufacturer participation in the trial. We proposed this approach as well for implantable cardiac defibrillators, these are the devices that can give a shock for people whose hearts arrest, it's a leading cause of death in the country today and some recent studies have shown that overall the use of these devices on a large scale can save lives but clinical experts have identified a important number of areas where we can use further evidence to help our beneficiaries work with their physicians to determine how to get the most out of this

potentially very valuable technology. We've used this for certain uses of PET scanning this is an innovative imaging procedure where the experts have concluded while it is a valuable treatment in some settings the imaging tool's value has not been established in many others but by doing the studies, by answering the questions we can help resolve the practical uncertainty in patient care. We're providing new support to answer questions where the experts agree that the clinical evidence is week but the treatment may be important for our beneficiaries as is the case in some of these off label uses that I mention. And we're providing support in cases where clinical experts believe that additional information about the risks and benefits in particular types of patients will lead to better decisions to get the most benefit and to avoid important side effects that go along with virtually any medical treatment. Treatments that have been shown to be safe and effective may still be even more beneficial if we can learn more about there uses in elderly patients and patients with co-morbidities, in patients who are getting these treatments under real world conditions of use that may be quite different from those in the pre-market ideal clinical trial.

Now, I want to tell you a little bit more about why we've undertaken these efforts and what we hope to achieve and why it's critical that our process here be as transparent and collaborative and public as possible with broad participation

outside of our agency. We can help these efforts get going at CMS but we're going to need the participation of the broader medical community to succeed in creating a more evidence based health care system. First is to be clear about why we're undertaking these efforts in our coverage process. As you all know many of the new medical products that have been coming available have been approved for a certain use but could go on to have widespread medical applications that were not anticipated by reasonable clinical trials done before the treatment work was approved and started being used. These additional uses can be very good for patients; it's a very important part of a dynamic and innovative health care system. The treatments may have important benefits that were hard to anticipate at the time of approval, yet it often takes many years to demonstrate all these clinical benefits and in many cases the studies never get done the benefits only remain suspected they're never clearly defined. On the other hand slowing down the approval process or the payment process means denying patients access to potentially beneficial treatments based on the best evidence that we have available and I don't think that's the best answer either for a dynamic and innovative health care system. For many of the questions about effectiveness and safety and particular types of patients or questions about comparative effectiveness it's just not possible to answer these very well before a product is approved

and on the market anyway. That's not what standard clinical trials under carefully controlled conditions are good at answering. Questions about comparative effectiveness, about risk and benefits under specific real world circumstances of use for specific types of patients could be very costly to try replicate and very time consuming before a product is approved and that's even after the product has been shown to be safe and effective for many types of patients. Instead we don't want to delay or deny access to safe and effective therapies but I think we owe it to patients to guarantee them that we're going to keep learning more and more about how every patient can get the most out of medical care after the products are approved. The patient should have confidence that any important remaining questions about a treatment that's shown to be safe and effective overall should be quickly and reliably sorted out in the post market setting but too often this just doesn't happen today. And one way to change it is to provide new support by coupling patient payment for important therapies with opportunities to continue to learn about them through registries and practical trials and other evidence based approaches. The good news today is that modern information technology and other steps are making this kind of data collection much easier. We're developing the infrastructure to have cheaper, seamless approaches, to developing better evidence within the practice of medicine. Clinical research

networks that have an information infrastructure are becoming more widespread and more capable of supporting ongoing practical research not just costly one-off clinical studies. Many of the people here today, David, Carolyn, others, are doing a tremendous amount to help move this process along. Some of this happening under the story of Medicare Modernization Act that was signed into law a year ago. Most of you know that under the MMA we have to require drug plans participating in our new prescription drug benefit for example to support electronic prescribing by 2009. That means widespread use of electronic data and hopefully electronic records in conjunction with this. But we're working to accelerate that schedule, we expect to have rules in place to support the standards that already in widespread use for e-prescribing before the drug benefit begins in 2006 and we expect to push along pilot programs even this year, ahead of the drug benefit being implemented. We're also considering some regulatory reforms intended under the Medicare Modernization Act to help hospitals, medical practices and health plans provide physicians with the software and hardware that they need to support e-prescribing. To help build this infrastructure for learning more about how treatments can be best used in actual practice to inform clinical decision making. Now I don't think that the steps I've described towards better practical evidence are the whole story, simple

protocols like the ones I've been talking about can't answer all the important medical and scientific questions about the safety and effectiveness of medical products. There are limitations to what we can learn from practical design. But these types of approaches, I think, can be an important way to augment standard clinical trials that are used and that often provide much of the evidence that we have available today. So it's time for us to take some steps to get to better evidence now. In all these efforts, I just want to reiterate, our approach is not to limit coverage or restrict access to effective treatments new or otherwise, it's just the reverse. It's to help doctors and patients use an increasingly broad array of medical treatment which should be increasingly personalized to the needs of patients. We know that we need to work together with all of the stake holders in our health care system to achieve the goal of better evidence supporting our medical decisions. For example at CMS we know that there are some unique challenges to using practical data to draw insights about drugs and that's why we want to collaborate with the broader scientific community, including patient advocates, consumer groups, health care payers and purchasers, and product developers to find the best ways to collect evidence that can be used to develop information for doctors and patients and is not burdensome on our health care system. Medicare is not in the business of developing our own research agenda or taking

ownership of data analysis but we can uses our resources and mechanisms that we have in place to help support and encourage evidence development to better our health care system. So we need this to be a collaborative effort, where we can do our part but we need help to succeed and we've asked for public comments on our proposed decisions, the ones that I've mentioned before. We're using those comments and other public input we've received to help identify and determine the best ways to collaborate. We're going to use all this input as a basis for developing a draft guidance document, an agency guidance document, summarizing our policy on this approach to developing better evidence while we expand coverage. This process will enable us to work as effectively as possible with other stake holders to get the best results for patients and we expect to have that draft guidance completed and out for public discussion and to help drive this whole process forward by March of this year. By linking coverage to the gathering of important clinical data, Medicare can cover treatments more effectively and more broadly than we otherwise could have. And that means greater access to promising medical technologies and better information, better evidence, for patients, physicians, and policy makers to make informed decisions about what our health care system has to offer. In turn that means more benefits from the treatments we use, fewer missed opportunities because of unnecessary or ineffective treatments, all because

we're empowering doctors and patients. And that means better health for what we spend in our health care system. I'm looking forward to working together with all of you to make sure that happens. Thank you very much.

ED HOWARD: Thank you Mark, excuse me. As I understand it you've got a commitment that's going preclude you from being here the entire time so if you're game, what I'd like to do and I've talked to the other panelists about this as well, allow the audience to take a few swings at you.

MARK McCLELLAN: Remember this a collaborative effort, this is collaborative.

ED HOWARD: However that metaphor goes. But if you have questions specifically for Dr. McClellan let's take something from the regular order and let you try it now. Let me remind you there are microphones write here, you don't have time to write them out. Yes, go ahead, could you go to microphone Miles? And please identify yourself.

MILES BENSEN: Miles Bensen [misspelled?] with *Newhouse Newspapers.* Dr. McClellan could you tell me if you're doing any serious thinking about long term reform of Medicare and whether in your judgment it's going to be possible to make the same promise about Medicare reform that was made about Social Security reform, namely that the changes would not affect current or near-term but –

MARK McCLELLAN: We're not only thinking about long

term reforms of Medicare, we're implementing this year as a result of the Medicare law we have brought Medicare's benefits up to date so instead of seniors only having access to fee for service coverage the reflected the practices of the 1960s, without preventive medicine, without care coordination, and most importantly without prescription drug coverage, we now have benefit packages in Medicare at least a year from now that will reflect all of these aspects of modern medicine. I think that that's the foundation for making the program sustainable for the long term that making sure it's offering up to date coverage as effectively as possible. By building on better care coordination, more of a preventive orientation, and taking steps to keep people out of hospitals and to use the available medical technologies more effectively we're going to make Medicare much more sustainable. I think there's further steps that we can take, we've got built into the new Medicare law provisions for the president to submit to congress and congress to act on further reforms to make sure that Medicare's benefits stay secure. But you want to do that from a foundation of an up to date, integrated, prevention-oriented, 21st century, benefit package and we've got a lot of catching up to do to get there and we're going to do that this year.

MILES BENSEN: Will current beneficiaries be affected by changes?

MARK McCLELLAN: Current beneficiaries are getting

better benefits as a result of the changes that are being implemented now. They've had to, own their own pay for prescription drugs, on their own pay for preventive benefits, on their own try to coordinate care across different health care settings, with paper records and no support for Medicare for getting more coordinated for chronic diseases. That's all changing now and the result is going to be more help for beneficiaries in a more efficient way of delivering care in our health care system.

ED HOWARD: Thank you. We have other questions for Dr. McClellan on evidence based medicine.

ROBERT DeMAKLUSTRUM: Dr. McClellan this is Robert DeMaklustrum [misspelled?] of the Brain Injury Association of America and I think it's important to say that we feel good that you're going toward evidence medicine but my concern is that when dealing catastrophic injury and I'm not sure the evidence is there. That we don't have evidence regarding to re-train a brain cell, to requiring and function – what can you tell me that I can assure my members, my families, and networks regarding how this is going to benefit this group of people.

MARK McCLELLAN: Yeah, there are many areas of medicine including catastrophic injuries that affect nerve cells where the treatments that we have available now are far from ideal, where we don't have cures. We don't even have, in many cases, good treatments to ameliorate the symptoms and influence the

course of disease maybe at best we can provide some supportive care. We need to do better than that. I think the good news is, especially coming from FDA, I've seen that there are more treatments in development than ever before, including for many types of brain injuries, many types of severe neurologic damage, but those treatments are still in the experimental stage. When they've gone from the experimental stage to getting to market, I think that's where CMS can really help. So, if a new technology is shown to be effective for a certain kind of patient, but for good reason doctors and health care experts may think that it could be extended to other uses as well, well those are cases where we'd like to develop more evidence as quickly as we can rather than have doctors and patients forced to make decisions year after year off of a very limited evidence base, primarily from the pre-market setting. So the kinds of things that I'm talking about for making registries and simple clinical studies a more routine part of the way that Medicare supports the delivery of health care, the way that we finance health care, can extend the benefits of new technology to these other areas by helping doctors and patients make more informed decisions.

ED HOWARD: Let's take these two questions represented by the two people at that microphone and then we'll get going with the rest of the speakers. Go ahead Tom.

TOM MILLARD: Good. Tom Millard [misspelled?] Joint

Economic Committee. The second stage of evidence based medicine is not necessarily what works in theory if you did the best medicine for someone but the best doctors, but how it's actually delivered in practice. So that next stage that I'd like to ask you about kind of has been an interesting discussion at a couple of MedPac [misspelled?], which is whether there's a way to tease out some better evidence, not just kind of on a one time basis, but over time, which physicians, which providers are doing a better job of delivering care in the best cost effective highest value measure. There may be some complications, as you know, in being able to get that data available but folks in the private sectors say they like to kind of have greater critical mass and be able to access it. My question in that regard is, is there a regulatory route to making that more effective or is this going to wait for legislation this year as perhaps something like a sustainable growth rate adjustment.

MARK McCLELLAN: Tom, that's a very good question. There's certainly some steps that we can and that we are pursuing as fast as we can under our current authority. As you know, we've worked together with other key stake holders, including much of the private sector for better measures of hospital quality for example and those are incorporated in Medicare's payment system now. They're 10 measures of quality that were developed through a collaborative process. It

involved us but it was by no means public only, it involved the hospital industry, health professional groups, consumer groups, health plans, and others all to get consensus around what would be the most useful, consistent way to develop evidence that could be used, not at the level of individual treatments but the level of health care providers. That model is something that we're applying in other contexts too. We've recently expanded our nursing home quality effort to include some additional measures that were developed in the same way. And right now we've got out for public comment, thanks to help from the American Medical Association and MVQA, as well as the other parts of the private sector a whole set of measures on physician and ambulatory care quality. And I'd like to see more work in this area, in home health, in other areas too but the provider groups are, I think being much more forthcoming and much better ideas about validated measures that we can get together and then try to pursue jointly to have a better evidence based system when it comes to identifying high quality providers and encouraging or rewarding them. Now there are obviously further steps that we could take. If there were, you know, financial incentives for example behind this, what we saw with the hospital measures, if you put in a 24% add on to payments and 99% of hospitals respond, maybe financial incentives. And there's certainly been a lot of efforts tried in the private sector. Many health plans are now rewarding

providers based on getting better outcomes and the result is big improvements in measurable quality of care and reductions in total cost issues. We're starting a pilot program in Medicare right now, in the fee for service program, our chronic care improvement program, where the entities that are providing care coordination services, I think is an essential part of 21st century medicine and delivery care efficiently are only getting paid if they improve quality, improve patient satisfaction, and lower total costs. We've got over 75 bidders and this is going to get up and running this year. So, there's clearly some momentum behind this. There clearly could be more done with further legislation and I think given MedPac's interest in the topic and my discussions with many of this room on both sides of the aisle, I think there is going to be a lot of interesting [INAUDIBLE].

BRIAN LUIS: Brian Luis [misspelled?] from MedCap [misspelled?] International. We're all really excited about policies that are coming out especially with respect to developing the new evidence that you've mentioned. I want to ask about the implementation of that, what you see coming out of the guidance document. Who's going to be paying for the actual research itself and will CMS be providing or making data available for that research?

MARK McCLELLAN: We certainly want to understand better what the costs are of doing analysis based on the coverage that

we support. CMS is an agency that covers medical treatment but in doing that, I think there are a lot of steps that we can take, as I mentioned earlier to reduce the cost of developing and using that evidence on top of it. As we move towards more of an infrastructure for selecting information this gets less costly. For example the evidence that we propose to collect on ICDs, on implantable cardio defibrillators, can be done through the same infrastructure that we set up for reporting to QIOs on hospital quality. So by the incremental cost is low and in fact if the hospital has an electronic data system we're providing the software that makes the incremental cost zero. Beyond that the registries need to be housed, the data needs to be handled confidentially in a way that fully protects patient confidentiality, there are good models out there for doing that but I think we need some further public discussion about how that could be done as effectively as possible and how the cost of those types of efforts can be kept to a minimum.

BRIAN LUIS: Do you see that being done by the private sector or –

MARK McCLELLAN: I see that being done, that's why I emphasize this as a collaboration. Medicare is not in the business of running research analyses and defining a research agenda, this is something that needs to be done collectively with public and private support. I think we can help move this process along through our guidance development. I know AHRQ

and others are also interested in working on hosting workshops and pursuing and supporting this whole effort as well. That's what I mean by this needing to be a partnership. We can do our part but to get to an evidence based health care system we're going to need collaboration from all the other major stake holders in our health care system.

BRIAN LUIS: Thank you very much.

ED HOWARD: Thank you Mark and you do have leave, we appreciate your coming and we will look forward to hearing this topic further as it develops. One of the partnerships Mark mentioned is represented by our next speaker. Maybe the most prominent one, Dr. Carolyn Clancy is the Director of the Federal Agency for Health Care Research and Quality, AHRQ. In many ways Carolyn's more responsible for our being here today than anybody else. She had AHRQ support the *Health Affairs* issue on evidence based medicine. She's fostered a lot of research on the topic through the agency. Found the process of implementing the new congressional initiative, what is it section 10-13 of MMA that's supposed to look at the effectiveness of various medical interventions and we're very pleased you helped us put us together today. And we're very pleased, also, that you're back as a panelist. Carolyn.

CAROLYN CLANCY: Thank you very much. Good afternoon. I'm really thrilled to join my colleagues to discuss the January/February issue of *Health Affairs* which focuses on

evidence based decision making. We at AHRQ were very pleased to sponsor this issue and I really want to thank *Health Affairs* and The Alliance for Health Reform for their commitment to insuring that the valuable information between its covers reaches the widest audience possible. But before you read that, just think for a moment about what's happening in health care settings around the country or around the world for that matter, as I stand before you or as you're checking your Blackberries [Laughter]. Millions of decisions are being made about a whole host of issues for example; should a patient take an over the counter pain reliever for a headache or is a prescription medication required? Is chemotherapy the best treatment for a patient with best cancer or should she be treated radiation and chemo and which chemo, right? There's just a new study out that suggests we may have something better now. What type of screening for colorectal cancer should be covered? We'll leave that to Mark especially since he left [Laughter] but these questions go on and on and on. Patients and consumers struggle with even more basic decisions, which provider to see, when to seek to care, and which option is best for their needs. And because of our massive investments in biomedical science the array of options has proliferated dramatically but knowing which is one best for your needs, you need good evidence about what's going to work for you. Now, many of these decisions are difficult even under the most ideal

circumstances when there is sufficient time to find and asses good, reliable information. However, I think as all of us know these decisions frequently have to be made at times and places when the information isn't available and time is of the essence. In addition we often don't know whether the information before is reliable or whether such information exists or whether it exists and it's simply not accessible when we need it. I'm sure many of you struggling under a deadline on the hill struggle with this same sort of dilemma on a regular basis. In clinical terms though, the point was brought home to me by a very recent personal experience my 14 year old niece is an elite, competitive, gymnast and at a recent competition away from home she fell and fractured both bones in her forearm. Moreover she had the poor judgment to do this on Friday night. Decisions had to be made very quickly about finding the right doctor and hospital to treat her, whether she needed to be treated immediately in another state or whether she could come home and so forth and needless to say my sister's family does not carry around an Internet connection and even if they did it would have been completely useless to them. Now my niece had an advantage over other patients in this situation, me [Laughter]. Moreover my roommate from medical school is an orthopedist and happened to be immediately available by telephone so she was able to step in as a senior advisor. What we need to do and can do is much more to help

the majority of individuals who don't have that kind of connection. The good news is that we're at a very exciting time when the promise of science alongside the promise of technology. We need to harness the power of health information technology so that the evidence for medical treatment is readily available at the point of care or point of decision making. And the power of that information technology will help insure that there is easy access to patient's medical information wherever they go and you'll hear much more about that from Dr. Brailer. Information technology will also help us provide safe, effective, and appropriate health care services. So this issue of *Health Affairs* explores important questions such as, what do we mean by evidence? How do we apply and interpret it? What do we do when the evidence is inconclusive? We heard a very eloquent question about that, asked of Dr. McClellan. How do we marry the largesse of our investments in new discoveries with the promise of information technology? All of these questions in turn point us in the direction of getting at the better question which is how do we harness the power of information technology so that individuals can have easy access to information regarding which innovations are most likely to meet their new needs?

Doing more with what we already know from the medical literature is only our first challenge. Identifying what we don't know is also another hurdle and with over 18,000 clinical

trials published just in 2004 it is a Herculean task to discover what we know and where gaps will remain. I'm very proud that AHRQ has been a leader in synthesizing clinical evidence and a wide range of health care issues that have addressed a critical need for information. Moreover I'm very excited that Medicare Modernization Act provides us with an incredible opportunity to do more of this important work. Under section 10-13 as Ed just mentioned AHRQ will conduct research on effectiveness and comparative effectiveness of health care interventions and services of importance to the Medicare, Medicaid, and SCHIP programs and we'll be doing this with a strong partnership through CMS and our other partners in the department. However the information that will be generated by this effort will be vital to the healthcare community as a whole. So I really want to thank and commend the U.S. Congress for underscoring the importance of evidence based decision making in drafting section 10-13. AHRQ will support systematic reviews on key questions for a list of ten priority conditions determined by Secretary Thompson and you'll find a press release in your packet which lists the 10 conditions. These reviews will be kept current and they'll be disseminated to a wide variety of audiences in formats that can be used whenever and wherever they're needed. These reviews will also highlight gaps in our knowledge and this information will fuel future research efforts.

The merging of scientific evidence with technology is already changing how we gather evidence and make it available to improve health care. We can no longer accept a 17 year timeline from a time that a research study first is started to the time it actually is turned to the benefit of patient care. It's really breathtaking that how much power bringing together science and technology offers us. A couple of weeks ago I spoke to Barry Meyer [misspelled?] whose article from the *New York Times* is in your packet today. We were discussing the uses of evidence and how different states are going to be using the same information generated by an evidence based practice center in Oregon for different purposes, which is exactly what you would expect in evidence based decision making. Then he asked a very important question and that was, "Why now?" And I gave him a very quick answer of course but have given it more thought since that time and I think the answer to the question, "Why now?" is that we have the capacity in terms of having established the methods and tools for synthesizing and developing evidence and moreover for developing tools to use that evidence. We're now developing and accelerating, seeing a great acceleration of information technology throughout health care and Dr. Brailer will say more about that and frankly there's growing public demand as represented by Gail Shearer's best efforts. So together we can improve the quality and safety of health care services for everyone. Thank you.

ED HOWARD: Thank you very much, Carolyn. Well let me just pick up exactly where you left off and turn to Dr. David Brailer. Since last May he has served as the National Health Information Technology Coordinator within HHS, known popularly as the IT Czar, his charge is nothing less than to bring about substantial improvements in safety and efficiency in our health care system. And personally, I should say he allows us to set a new Alliance record, never before in the same program have we had two panelists who hold Doctorates in both medicine and economics. So, we're very pleased to have you here. If that makes you feel inadequate, why, join the club [Laughter]. I suspect that Dr. Brailer's feeling more upbeat than he might have a few days ago after an administration spokesperson said just a while back that the $50,000,000.00 requested for the IT office hadn't been omitted from the Omnibus Appropriations Bill it just had been included in another category. So if you see him searching through a large book, you'll know what he's doing [Laughter]. Dr. Brailer, thanks for being with us.

DAVID BRAILER: Thank you Ed and let me thank both the Alliance and *Health Affairs* for bringing us together with both the razor's edge of precise and disciplined thinking with very creative brainstorming. Just to comment on the introduction those of you know the real reason that there are to M.D. PhDs in Health and Human Services and that is, I'm there in case Mark gets hit by a bus [Laughter]. Okay, well the beauty of

going third is that I don't have much else to say so I'll just say everything over again but I will use different jokes than Carolyn did so at least the laugh lines are in the same place if you want to go ahead.

I view my comments in terms of three questions I'd like to pose because they're ones that I spent a lot of time thinking about and cut to the very core of our short term, mid term, and long term agendas for my office and the growing armada of federal agencies that work in our groups and in our efforts. First is, where does the patient data that guilds the evidence machine come from? Both in terms of the research and investigation but more importantly at the point of care when a clinician is with the patient. And you might say well, we have it today. We do, but it's becoming increasingly complex and I'd like to illustrate that. We're in the end of the first generation of evidence and that evidence I would describe as simple rules. Rules of thumb that were intuitively accessible, one may not remember that you give beta blocker in certain types of patients but with a relatively straightforward prompt can infer their way to other end of that and know what to do. We also are, at the end of this generation where the information was not difficult to ascertain, a lot of it were fixed characteristics of the patients, their age, their sex, maybe a laboratory value. And like all low hanging fruit, we've now plumbed a large share of the evidence that can be fed

by relatively straightforward patient data. So we're now moving into a world in the second generation of evidence where the information that feeds this is both complex and changing. For example, as we develop rules for evidence that support decision making we could include what kind of work or exercise output that person performs. It's important in overall metabolism and there are key absorption or distribution characteristic of drugs that depend on that. It could depend on other behaviors, like how well they're taking other medications and if you looked at various forms of asthma or lung disease it could depend on information about ambient air pollution or the weather which we know are significant modulators of disease and it's not surprising to that which evidence rules apply may depend on the situation and the environment of that patient. And that patient situation depends on their location and their location changes. And by that chain of evidence you begin to see that like almost everything around us, you know, when I grew up my father looked at the stock market and kind of said, "Okay there it is." Now of course, you know, people day trade and look at the stock market every two minutes and like that evidence is the same. It's a dynamic property and collecting and incorporating this information, all of the examples that I just described by the way are things that we believe are in the road map for the broader concepts of the health record; ambient air pollution,

the environment around you, work situation, stress, exercise. They become important modulators of evidence.

Secondly the information is quite complex. For example we are now entering a world, we're there, with a pharmacogenomics where information that's derived from very complex essays develop response curves. It's no longer do take aspirin or do you give someone Coumadin or Warfarin to be able to thin their blood to a certain parameter, but the way we do that and the desired range depends on their genetically profiled P450 enzyme system, which are the enzymes that metabolize these drugs. And it turns out, that depending on one's genetic disposition the response curve to Warfarin is remarkably different and one can't intuit their way through and say, "Oh well I know what to do in this patient. I learned in residency a few rules of thumb about giving people Coumadin." And it doesn't work anymore, it leads to too gross of an application. And my point is that these the therapies, as we become more patient specific, and we've become to plumb more and more complex and situational evidence, the dynamic information requires an infrastructure to collect and make this data available. And this is one of the many motivations for having an infrastructure of health information technology that can incorporate these kinds of facts and bring them forward.

The second question is, how do we industrialize the development of evidence and Carolyn spoke a lot about this.

And this does go beyond this health information technology proper, but the one thing that I've learned about my task, is that there's actually very little that we do that is health information technology proper, most of it leads into nearly every part of where the healthcare apparatus is working today. We call this the evidence supply chain and just like many businesses have developed relatively complicated mechanisms for procuring parts that are then assembled and refined and adapted and then put into another part and then eventually ending up just in time to be put into a car that rolls off the assembly line, we view the future of evidence being part of a supply chain. Or said another way, today the industry is comprised of hunters, of people going around hunting for relevant evidence. We need to develop a system, and Carolyn's far along the way in doing this, of having it be a farming system, which means that we're able – yeah, that doesn't mean farm subsidies though necessarily [Laughter]. That means that we have a systematic way of identifying evidence gaps. Today we're opportunistic, we hunt, if trials are done we find the evidence and then we deploy it. The reverse process is determining where we have evidence gaps and going back and systematically directing the search towards that. Carolyn's been on the forefront of that but we have a long way to go to be able to actually develop this farming system, to develop those, and structuring the evidence. Today, you know, evidence is usually out of the pure

form is in a peer reviewed publication and it has some magical process by which it ever ends up in a computer system or in someone's mind. If they have a process for doing that and there are a couple of projects, the National Science Foundation is supporting a project called SAGE, which is quite intriguing but it's one of only a few that are happening and you know whether we enter a world where part of the peer review journal submission includes a sample rule of evidence that would go along with the finding of the paper we have to have a broad process for being able to review that. Disseminating this, taking it right to the point of care, is a very complicated task; which rules are made available, by who, who decides, how to they flow forward? We could be in a world quite easily where there are thousands or tens of thousands of potentially applicable rules or sets of evidence. This is not something that we can just simply pass forward on a CD once a month. And so the question is, how do we go forward? And I remind you that nearly every implantable device in patients bodies today examines the question, should they contain wireless data collection in those devices that's then transmitted some place. So this is becoming a property of many parts of the industry today?

The final question is – this is the one that I think is most intriguing and a segue to Gail – which is how do we package evidence for consumers to be part of this process?

It’s one thing to have a highly structured obscure jargonistic rule that a clinician can figure out what it means and applies it but it’s a wholly different thing for us to bring consumers into this. And in fact not use evidence to create a barrier to consumer participation. And you know today the standard in the industry that people go on the Internet and some of you know the Kaiser Family Foundation report recently that showed the still growing breadth of internet use for health care guidance and consumption, but largely people read on-line text books. It’s not customized to that person’s height, weight, sex, age, other characteristics which means they have a lot of ferreting to do to make decisions about themselves. But we have to be able to make this interactive so that these evidence rules can help guide and empower individual decision making. But beyond that the question becomes right back to the core of the evidence origination is, how do we make evidence culturally appropriate, through the ethnicity, through the social morays, through the religious beliefs that will influence uptake and consumption of health care. I think this is not a task that’s far beyond the age of where we are with information technology. I don’t think it’s unreasonable to ask, if someone was looking at a site and reviewing evidence that might be applicable to them for a pop up to come up and say, “People who like this evidence also liked the following 5 points of evidence, would you like to look at them?” We do it with CDs and my point, not

to make fun of that, is that we have a long way to go but we've done this in other industries to date. So I hope we'll go forward and we're moving very quickly towards this. We have the RFI our today for the National Health Information network asking industry how we develop a broad, rich, and secure network to move around mountains of secure private patient data as they choose to have it directed and to make it available to people that want to make decisions. How do we make that available in aggregated forms for research and for investigation? For quality monitoring? For performance assessment? We think this is a revolutionary component of the agenda that we can't realize the goals that we have without this being done. How do we bring the electronic health records and insure that they're able to use this evidence? And one of the things I would ask you to look at is the work of The Certification Commission for Health Information Technology, tchit.org, there's a private sector group that's developing for the first time standards for what a minimum electronic health record is and an inspection process to be able to put it in premature on those products that actually cross that line. We think this is a remarkable effort in the private sector that we've had the privilege of being supportive of and we're in the very early foothills of developing the requirements, the components, of what that interactive personal health record looked like. I've had the privilege of working with Consumers

Union and many of the other consumer's group to do this but we have a long way to go together. In short I would just argue, not that I'm a science fiction reader at all, but Issac Asimov once said it a very long book about a war between man and robots that ultimately everyone came to realize that the question wasn't whether it was man or machine but the two together. And I think that's very much a part of what the evidence debate is today. Thank you.

ED HOWARD: Thank you very much David. I've never seen a panel that fed so nicely from one to the other, they don't really need introductions substantively but just a moment in terms of persona. We're going to hear from Gail Shearer, excuse me, who directs Health Policy Analysis in the D.C. office of Consumer's Union. She's been a thoughtful and forceful consumer advocate for the better of two decades for CU and under her direction Consumer's Union has just launched one of the most promising projects for consumers combining evidence based medicine if you will with cost effectiveness measures on prescription drugs. The web site and I think we listed it incorrectly on that source list, it's crbestbuydrugs.org – did I get it right? Is frankly setting the standard for getting comparative information into consumers' hands when they need it the most and we're glad to deliver Gail Shearer into your tender hands for her presentation. Gail, thank you very much for being with us.

GAIL SHEARER: Thank you very much Ed for including me today, it's truly an honor to be on a panel with Dr. McClellan and Dr. Clancy and Dr. Brailer each have whom shown such leadership not only in the area of evidence but in the area of health care quality. I'm going to tell you today about a new publication education program that Consumer's Union launched on December 9th. It's called Consumer Reports Best Buy Drugs. And this project was designed to translate complex evidence based medicine for consumers and their medical providers so that they can make use of it in the market place. And let me just ask, how many of you are aware of this project? Were aware before you came here? Good to see. I'm not sure if this is working. Thank you, I think Laura might rely on you again for that. Before I get into a discussion of Consumer Reports Best Buy Drugs I wanted to just mention that the announcement to this session talked a lot about consumer driven health care. It sites the need for evidence based medicine, evidence based information, in order to support so-called consumer driven health care systems. And typically this type of system involves high deductibles, choice of health plans, health savings account, and tax credits in the individual market place. We think that in most cases a better name for consumer driven health care is defined contribution health care and we're concerned that consumer driven health care can mean further segmentation of the market place. Dividing the healthy

from the sick and the rich from the poor. I would be remiss if I did not point out that our strong support for evidence based medicine, for that approach, is not linked to a so-called consumer driven model. In contrast, we believe that an evidence based system is needed to go hand in hand with a health care system in which all Americans have health coverage. In which the state and the federal governments are free to negotiate these discounts for prescription drugs and in which all Medicare beneficiaries have comprehensive prescription drug coverage and even all Americans have comprehensive prescription drug coverage that is easy to understand and comprehensive.

I'm now going to turn to section 10-13 of the Medicare Act, the topic of today's session. Over the past four years there's been a very strong and growing bi-partisan support for the notion of federal funding to support that look at the comparative effectiveness of drugs. Getting better value for prescription drug dollars is a concept that should appeal to every member of congress whether their interest is in providing financial relief to constituents or making needed medicines more affordable or whether their interest is in reigning in government spending and the spiraling federal deficit. We believe that AHRQ is off to a very good start with its publication of priorities and we hope that our work will be complimentary. We're especially pleased with the provision in the Medicare Act that calls for making the analyses and

findings available to individual consumers so that they are easily understood. In other words, AHRQ is charged with providing findings about comparative effectiveness of drugs based on the evidence that consumers will be able to use and this is very important, since critical findings about comparative effectiveness are of little value to consumers if they are hidden away in health policy journals. Informed consumers who are in a position to open conversations with their medical providers about choices are needed in order to accelerate the pace of which evidence based results are used as the basis for market place decisions.

Consumer Report Best Buy Drugs is about providing information so that consumers working with their doctors can identify affordable, effective, and safe drugs. And our ultimate goal is to save consumers, tax payers, and employers and other payers, money by increasing the use of cost effective medicine. Our primary database is the Drug Effectiveness Review Project, its come to be known affectionately as DERP and this now based at the Oregon Health and Science University. It was the establishment of this database that has made our work possible. DERP has done systematic review based on rigorous, unbiased methods that examine studies of the clinical effectiveness of drugs. Before there was section 10-13 it was a pioneering work in Oregon under the leadership of Governor John Kitzhaber that led to legislation in Oregon in the 2001.

And their work has now grown to include partners in 12 states from all across the country. They do evidence based reviews contracted through AHRQs evidence based practice centers. These systematic reviews pay careful attention to the credibility of the underlying research, to safety considerations, and to the impact of various drugs on different segments of the population. They are conducted in a fully transparent process with opportunities for broad input. They are unbiased and independent. The fact that the systematic review is conducted at the earliest stages of DERP led to decisions in Oregon and Washington to exclude Vioxx from the preferred drug list in those states two years before it was pulled from the market place speaks to the soundness of the process and to the need for greater reliance on an evidence based approach. I'm going to skip over quickly some of our other process issues, but let me assure you that we have medical input, intense medical input, at every step of the way including an excellent medical consultant and each of our reports is peer reviewed by two or three doctors and pharmacists.

To identify our best buy drugs we have a Consumer's Union team that reviews the effectiveness and the cost data and identified one or more drugs that are in the top tier of effectiveness, have a safety record as good as others in the category, and has an average for a month's supply that is

significantly lower than the most costly drug. So far we have prepared reports in three different areas, statins for lowering cholesterols, proton pump inhibitors which are for acid reflux and ulcers, and NSAIDs which of course are for arthritis and pain. In the case of statins we've identified best buy drugs, two of them, one a generic lovastatin for those who need a moderate reduction in their cholesterol, and atorvastatin or Lipitor for people who need a greater reduction. And what I wanted to do with this slide is just give you a sense of the potential savings. We're talking about real money here in terms of potential savings. We did a calculation estimating how much a typical consumer who switched from one of the high priced drugs, one of the popular high priced categories, to the best buy to the Consumer Reports Best Buy Drug and as you can see in the statin category a person can save about $1,300.00. A person switching drugs in the proton pump inhibitors could save about $1700.00. And for the arthritis and pain drugs there were potential annual savings of about $2,200.00.

So we have been begun with our first three reports and our plan is to prepare an additional report each month and post it on our web site and then work with a talented advisory board, a talented outreach time, and 11 national organizations that have agreed to partner with us to get into the hands of people who need it the most. We're hoping to transform the market place so that this will be a new model for providing

information to consumers. This is the old model, this an old Vioxx ad and of course this is the main way that consumers have been getting information in the market place. We want to transform this to a new model which is our Consumer Reports Best Buy Drugs Report and we think that implementation of section 10-13 will make it possible for the government and other organizations working together to speed the availability of this type of information.

The key messages that I would like to close with, first finding the best way to translate evidence based findings so that consumers can understand and use the results remains an enormous challenge. We look forward to working with AHRQ to help meet this major challenge and it's critical that the administration and all participants in the health policy arena support increased appropriations to fund this important work.

ED HOWARD: Thank you very much Gail. Those of who are searching of, it's been mentioned a couple times now, the Oregon based project that is doing such work, it is part of the Oregon Health Sciences University, Center for Evidence Based Policy and John Kitzhaber is the head, Mark Gibson who many of you know from the Nobank [misspelled?] Fund is also involved in it and they are doing a great deal of good work for a variety of folks who are contracting it.

We are now at the point where you can asks questions of any of our panelists. Some of you have already written some in

advance, you can write on the green cards, you can come to one of the microphones that are close to the podium, and I'll also take this opportunity to tell you that if you do have to leave sometime during the Q&A session we'd like very much for you to fill out the evaluation form before you do. As we're getting folks coming let me just pick a pre-submitted question which I guess goes first to Dr. Brailer.

An article in Forbes, this says, predicts that health care IT spending will hit 60 billion dollars in 2005. Can government really hope to guide IT policy by spending 50 or 100 million?

DAVID BRAILER: That's a great question. First, I don't think we have the information, at least in the government, to know how much is being spent. And so one of the things that we have to do is actually understand what the level of adoption and spending is in the industry so we can adjust policies. But the answer is, of course, yes. Governments engage in the oversight, development, structuring of competitive market places in every part of our economy. And often do so without spending much money at all. The question, I think, is how do we accomplish the goals of developing health information technology adoption in a way that develops the industry itself so that we have better products that are cheaper with more money spent on R&D that are offered at the price to doctors and hospitals and do so with the minimum

amount of government regulation? I think there's where the catalyst effect of the money is important but so far we have made great progress in our working groups by being catalysts and partners for the private sector. And I'll give you the example I already mentioned of the certification commission. We did not offer a line of regulation nor a penny of money, we did it because we found partnership and I think there's a very common spirit of moving forward at this point. So we're using every available tool and technology that we can to be able to this and I think on the margin the money is quite helpful. But it's certainly not the mainstay of what we're doing.

ED HOWARD: There's actually a related question, at least related in tone directed to Dr. Clancy. $15,000,000.00 it says seems far too modest an amount given the billions Americans and state and federal governments spend on drugs and other treatment. The value in providing needed information to doctors and patients and the MMA section authorizing $50,000,000.00 with additional amounts in subsequent years, do you foresee additional dollars being made available to expand this edition?

CAROLYN CLANCY: Thanks for the question. We take it as great first step that we've got an appropriation this year. I would agree if you contrast the resources available with the array of questions and the need for information there is something of a gap there. I would refer you to Dr. McClellan's

discussion of how we're both working with many private sector partners. I think once people begin to see this, whether they're looking at some of the results on the Consumer Report's site, whether they're getting the information directly from AHRQ or from some other infomediaries [misspelled?] there's going to be a huge demand because frankly this kind of information simply has not existed. When you were making choices about different treatments or diagnostic options you enter the world of opinion really, really quickly. And I think once people have access to evidence based information that's clearly presented and maps on to their decision, the demand for it will continue to grow and I predict that the resources will follow.

ED HOWARD: We've got a question from one of the pre-submitted questions from one of the cards. In it's patient safety report the Institute of Medicine last year said, "There are gaps and inconsistencies in the medical literature supporting one practice versus another as well as biases based on the perspective of the authors." So the question is how good is the evidence in evidence based medicine?

CAROLYN CLANCY: That would have to be my favorite question. Thank you for asking it whoever wrote this on their green piece of paper. A big part of the development over the past few years has been actually been to be as clear and transparent as possible in answering that question: how good is

the evidence? If you were to pick up the technical version of any of our evidence reports you would see this very long, highly detailed, really good for insomnia if you suffer from that problem, it describes in very clear detail how the team identified sources of information, studies that they're reviewing, what databases they searched to identify those studies, what fugitive sources they went to, and so forth. And then they walk through, similarly, a very detailed description of how they evaluated the quality of those studies. Like any scientific endeavor, this can be replicated and that's why they go to such exhaustive detail to do that and as a result of all this effort there is now a growing consensus that we can actually identify which sources of evidence are best and which are not. And that will be a very key part of the information that's communicated to decision makers of all types.

ED HOWARD: Maybe I can just follow up. There have been attempts in the past to have government develop, not only develop the evidence but perhaps formulate the guidelines, and I wonder if any of our panelists would like to comment on the appropriateness of government's role in this entire process. Whether it should be facilitator or data gatherer or the yeast in the dough or the spender of the dough?

CAROLYN CLANCY: Well I haven't thought through precisely enough David's wonderful metaphor moving from hunting to farming so I'm not sure I can place it in that context. The

government clearly has some very major roles in health care as a payer, as a convener of multiple parties in a multi-payer system and frankly strong supporter of scientific evidence. So to that extent I think the government has a very key role and responsibility in making sure that the products of that evidence to all of the tax payers who supported its development. Clearly you've heard David describe a more catalytic role in supporting efforts to accelerate the adoption and effective use of information technology as a very key part of distributing that knowledge. So I think it depends precisely what you mean. Just to speak for a moment we did have an experience previously where we facilitated the development of clinical practice guidelines and I think that where we had some challenges frankly is where the evidence stopped short and where panels of leading experts would then come up with their best judgments. Now this happens in every day life but I think there was some sensitivity to the government codifying that as a rule or a regulation by any other name. So that for reason our evidence reports simply stop with the facts and again make it very transparent where the evidence comes from, how strong the quality is, what inferences can be drawn, and where frankly we need to draw more.

DAVID BRAILER: I've learned one thing in my near year office and that is that government is a collection of many

different phenomenon and health care so Carolyn just described to you the role of government and research. I think which is research is a public good and governments have traditionally had roles in various types of public goods. So I think in this case it's quite strong. From a Medicare perspective where Medicare operates as a social insurance fund I think Medicare clearly is acting under Mark's leadership to correct a series of mechanisms that have resulted from it creating distance in its evidence for research and leading to an asymmetric market and so it has to come back to a neutral case at the minimum. If we think of government in a traditional way as a regulator, I don't think anyone's made the case for why there has to be a regulatory solution to this. But we also operate government delivery systems and government security apparatus and those delivery systems themselves have the same challenge for the DOD and VA beneficiaries that they have the same level of evidence available and that they can make it useful in their settings as we do the rest of the American public. And also on the security side there's a great deal of evidence that results in the responses that we have BT, bioterrorism, or other types of potential catastrophes, a radiation even, that have a significant amount of medical evidence that might have to be disseminated quickly. And so there are multiple roles and the answer is absolutely yes, but hopefully not the traditional role of either doing it or of just regulating it into

existence.

ED HOWARD: Yes, Gail go ahead.

GAIL SHEARER: You're mentioning the VA is a good reminder that there is a long track record of the government using evidence based information and the basing decisions on it. And of course that model is so different because in the VA system the doctor makes the decision there's not any need for translation to consumers. I think this new challenge that we now face of how do you actually translate this information so that consumers and doctors can make the best use of it is a huge challenge that we're just beginning to [inaudible].

ED HOWARD: Thank you, yes.

DIANE DUSTIN: Hi, my name's Diane Dustin [misspelled?] I'm with Prudential Equity Group and I'm a little confused about the relationship between say the FDA's Office of Drug Safety and the work that you're doing. It sounds like some that there is – for anyone on the panel – it sounds like there is overlap perhaps and I'm wondering if you talk to each other and if the problems that surfaced with Vioxx relating to the Office of Drug Safety will be answered by the work that you do rather than changing things at FDA? That may be beyond what you can say but still.

CAROLYN CLANCY: Just to set to set the record straight we do talk to our colleagues at FDA on a very, very regular basis. In fact in area several years before the recent

discussion, specifically in the better area of developing better information in one's product before releasing it into the market. And indeed we actually co-funded an earlier study of Vioxx showing an increased risk based on the Medicaid population that was published a couple of years ago. A very important area where we've collaborated with FDA is in the area of risk communication and risk management. In other words how do you get information to the right people to let them know, not only that there is perhaps an increased risk of an untoward event in the particular agent, but who is likely to have that untoward risk. And if you think about how David was describing the industrialization of not only developing evidence but actually also its delivery you can see the very near future the possibility of not only making information more widely available but in a much more customized fashion similar to the Amazon style pop-ups, which he was describing. So that's an area where we can collaborate in a sense very, very closely. I think there's a lot of very exciting work to do and both we and the FDA are looking forward to doing it.

ED HOWARD: Yes, go ahead.

BRIAN LUIS: Hi, I'm still Brian Luis from MedCap International. A lot of us are really pleased about the Best Buy Drug concept of informing consumers. I totally agree that the consumers need a lot better information to make informed decisions in the market place. But there is a disconnect as I

see it between relying on the Rand Weiss [misspelled?] Controlled Data which the review project does solely I think for effectiveness and they don't get into cost effectiveness at all. And what Dr. McClellan was talking about in terms of real world research, with the trials and as well as a lot of the evidence based practice centers as it views based evidence and systematic reviews which include synthesis through model and so forth, better understand what the evidence means in the real world. I'd like to hear a little bit of dialogue between the two or you and then specifically whether Consumer's Union sees what they're doing as an evolutionary process to improve what your premiums to market, they're so important.

GAIL SHEARER: Let me, let me begin. What we are doing, we are at the very earliest stage of what we are doing and we expect we're going to be learning with each new report. Yes, it is certainly the case the drug effectiveness review project, their reports are looking solely at the comparative effectiveness and my understanding under section 10-13 is that similarly AHRQ will be focusing on comparative effectiveness. That's where groups like Consumer's Union to add the cost information so this really can have the potential in the market place so that it can be understandable and really useful to consumers. So the big picture to answer your question is yes. We're at the earliest stage of learning how to do this and we expect that we'll be learning as we go.

CAROLYN CLANCY: I guess I would just add to that, again keying on David's observation that historically the output of randomized control trials is a peer reviewed publication and which may or may not be accessible to you at all and for many decision makers will not be that comprehensible. Where we've moved to since then is actually very clearly developed message, which you've been an important contributor to, to synthesizing the products of multiple of those studies. But now in addition to that, building on that set of methods is trying to communicate it to a variety of audiences and that's why I'm thrilled that the Consumer's Union is doing this and I expect to see many other groups doing the same thing. And was begin to develop better information from the process of delivering care as Mark was describing I think that will continue to fuel that whole machine. So I think it's going to be an exciting evolution.

ED HOWARD: Yes sir.

CRAIG KENNEDY: Hi I'm Craig Kennedy [misspelled?] with the National Association of Community Health Centers and I tried to scribble out this question but it got it kind of garbled so I'll just do it in public. This for Dr. Brailer and I think a lot of this discussion is very, very good except for the fact that it assumes a lot of IT infrastructure in some of our facilities. We'd love to be part of this type of discussion and I think some of our Community Health Centers are

a part of these discussions of as you referred to it the supply chain in, and getting the evidence back out. The question is, a lot of our centers, non-profit or low income places, see that information technology purchase as a zero sum game. They buy a system and they've lost some level of patient care because they didn't have the money to transfer around. How can we take this type of discussion and move it into an IT discussion as well for health centers that isn't just a zero sum game where we're going to help you with evidence based medicine, we're going to help you if you buy this infrastructure but you've got to take it out of your patient care for today. See, that's what they're looking at today. How can we get away from that type of discussion into the positive evidence based medicine discussion with them?

DAVID BRAILER: Great questions. I appreciate it very much. You know this is an area where I think I can say that the economics of health information technology and evidence adoption treat everyone equally badly. In that the trade off, if you would, of margin versus mission. Of doing the right thing versus paying the bills is a dilemma that goes up to some very large health systems and some ones that appear externally to be quite well financed. It is a challenging decision. The thing that strikes me about the Community Health Center network after having spent two years as a principal supporter of the $500,000,000.00 California endowment effort to support IT

adoption in the Community Health Centers in California is that there are numerous barriers that they faced to being able to not just put in the technology but to re-engineer their business in a way that leads to the kinds of operational and clinical results we want. And I found that there were three big factors that were really bothersome to me and we tried to speak to these. One, products that are on the market treat community health centers as an orphan market. There particular issues about how clinic work in general, but how those clinics work that need to be incorporated into products and we actually developed a set of model specifications that are still be used in California and we're trying to incorporate that thinking into how we push product certification to make sure that various sub-markets have coverage and we have also expanded and will be doing more shortly in public on the commitment to bring the Veteran's Administration VISTA System into a public domain much more aggressively. That's a supply.

Secondly the question of finance is a really challenging one but one of the things that we really try to encourage in the community health centers that happens everywhere in the private sector is the consolidation of back office operations of the community health centers so they can share these very scale dependent investments in technology. And actually found great benefit and that's happening in a lot of places in the U.S. but it needs to happen faster.

Thirdly and I think this is the hardest [inaudible] next step is the managerial know how. The depth of IT experience of even management process. And the nature of these make it very difficult because they're very passionate people that get attracted to these settings and it's been so difficult to be able to bring the kinds of management skills and I think I would relate that to a broader question that we haven't touched on today is that: As we look at the build up of information technology of evidence we're facing a significant man power crisis as the kind of clinician informatist [misspelled?] and at the kind of bachelors degree level about how to do this and I think community health centers just stand out more than other small practices or small settings about that. I don't have a particular solution about that but this is on our wish list of things that we're trying to find out what to do. So hopefully that's something that many of you can think about.

CRAIG KENNEDY: Happy to work with you, thank.

DAVID BRAILER: Thank you.

ED HOWARD: Got two related questions that came up on cards. One is a brand name drug is duplicated by a generic will the competing generic drug inherent the evidence, if you will, of the brand name version. Which this questioner says seems logical. On the other hand, someone asks, what's been the reaction of the drug industry to evidence based medicine.

Is there a danger that this approach may pick winners i.e. a drug gets on a formulary when another drugs may also have benefits and therefore not be available? And if we have representatives from the drug industry and the audience would like to try to respond to that we'd love to have you do that as well.

CAROLYN CLANCY: Well let me just say from my perspective the pharmaceutical industry has a long history, industry rather, has a long history of not only sponsoring studies but of also contributing substantial intellectual capital to a lot of research efforts and we've certainly benefitted from that in the work that we've done both in what we've sponsored and then collaboration with FDA. And we've had some very constructive dialogue, both with pharma as well as individual manufacturers indeed one is having an upcoming seminar and I expect that there will be more on evidence based decision making and what are the common principals we can agree upon and so forth. I really think the key to all of that successful and ongoing dialogue in a constructive fashion is transparency. That we're transparent about the principals of evidence based decision making, what it can achieve and how the evidence is collected and assessed so forth.

ED HOWARD: And is there a real answer, a single answer, to the question about generics and whether or not the evidence that's developed for a brand name drug is applicable

to a generic? How do you treat that on the Consumer's Union web site.

GAIL SHEARER: Well our findings are based solely on, not solely on the Drug Effectiveness Use Project findings, so whatever findings there basic research has, and I can't really answer that very well. I think it's important on the question of preferred drug lists to understand that evidence based findings tend to be global. You have the big picture findings and then each state has to take into drug effective review project into the 12 partner states. And they shape their preferred drug list based on their own criteria and different states have different preferences. For example, one state might prefer the pain reliever to kick in quickly that's what they weight heavily. There may be winners and losers but they may not be the same in every state. [Inaudible] in our case we are not, we are providing information in the market place so it's just their decision.

ED HOWARD: Yes, Allen.

ALLEN GLOCK: Allen Glock [misspelled?] Senator Biden. We're in a era of tremendous concern about the overall costs of health care and I wanted to, in that regard, and downward pressure trying to put on the overall cost and I want to ask Dr. Clancy about the potential impact of evidence based medicine on total health care costs. It seems to me that some of the things that we're talking about have, although cost

effective in the long run, actually increase total health care costs in the short run. Whether it's treating the 10,000,000 under treated or untreated, hypertensive or I was interested to see that the CMS decisions on lung volume reduction surgery which is the epitome of how cost effectiveness and evidence based medicine should work estimates it's going to cost them somewhere between one and ten billion dollars just for that. So can we institute evidence based medicine without also instituting evidence based budgeting.

CAROLYN CLANCY: Well let me just start off and again I'm very much stimulated by the earlier questioner who asked about treatments for traumatic brain injuries and related types of disorders. One of the things that makes very many nervous about this kind of question is the burden of proof issue. If we only covered based treatments we would cut costs dramatically and profoundly but we would also increase harms in the system pretty dramatically and profoundly and have a pretty negative impact on health overall. I don't think anyone is suggesting that that's what we do because there's an awful lot of what is provided in routine health care today which we don't have a very good evidence base. So then the question is to whom does the burden of proof fall. What you heard Mark McClellan describe is their interest in developing better evidence for lot of these. But then the question is still going to be what's going to be the impact on overall costs. I

don’t think that we have a thoughtful answer to that. What I do know is that right now, many consumers as a routine part of their daily decisions about health care have these decisions right in their face because they face significant cost sharing for pharmaceuticals in the most common type and I think increasingly we’ll see that for hospitalizations and other services. Now there’s a strong interest in linking that to quality. If you pick the highest quality, then you can have a lower co-payment and I think many people think that’s a great idea. There’s also an idea which has never been operationalized but I predict will be sort of debated more which is that we have higher co-payments for selected services that for which the evidence base is weaker. If you have a strong belief that the evidence base is not tremendous, fine, you can have that service but you pay more. If the evidence is very, very strong that it has an impact on health then the copayment will be lower or zero. I don’t think anyone has the systems in place to make that happen but those are the types of levers that could actually help link evidence based decision making to overall health care costs. But I don’t have a comprehensive view for you although I might turn to my economist colleague [Laughter].

DAVID BRAILER: The answer is 3.2 [Laughter]. Health care is a grand experiment. We don’t know the answer to your question because of many competing factors in the short term

but if we look at the other industries where we call it evidence based medicine, but telecom went through a decade of what was called knowledge re-engineering where business processes were defined and there was very good data collection about what things worked in terms of negative management and what things didn't. The revolution was similar, it led to a vast change, automation of the industry and lo and behold the Federal Reserve now has been reporting in December there was an issue of the *New York Feds Journal* published from Dale Jorgensen [misspelled?] that showed ongoing systematic productivity returns in telecom and a number of other industry sectors largely because of their investment in IT and business process re-engineering. It took a decade for it work all the way through but we get these sustainable out of the capacity of the industry. And the question we've been asking is while my opinion and many of my economist's friends opinion is in the short term there are savings that come from investing in evidence in the IT capacity because if it off sets an error that could be quite expensive it doesn't take many of those to pay for the infrastructure and the change, in the end it's probably a debatable question among people that have different assumptions because it's a very data free question. But the question that we're focusing on is: Is there a reason that health care can't go through the industrialization, automation experience of other industries and get those big productivity

returns and to date, with a pretty large degree of analysis including a report we'll be releasing soon there's no reason to believe it won't. To me that's what we're ultimately after and if we can pay as we go by getting savings from evidence and other things, but I think we're after a transformation that's much larger than that.

ED HOWARD: Gail.

GAIL SHEARER: If I could just add, I think it's important not to lose sight of the 45,000,000 or so people who are uninsured. This is not just about people with health insurance, this is about making health care more affordable to people who have no health insurance at all. One figure that we've seen is that something like 22,000,000 people do not use a cholesterol reducing statin because they can't afford it. Well one of the powers of evidence based medicine is that through DERP and through our work we've identified a statin that's available for dollar a day that's very effective. And we think that greater spreading of this information could help people who have no health insurance at all have access to medicines that they need.

ED HOWARD: Thanks Gail. And now we have our last question.

FEMALE SPEAKER: It's an easy one, I sort of [inaudible], and it's a decision probably above her significant paid rate. Everybody's talked a lot about section 10-13 and

people crowed when it passed even people who didn't like the MMA agreed that that was a good and worthwhile section and while 15,000,000 is a great down payment, it was 50,000,000, and the administration I believe didn't fund it in their budget. We had to fight very hard in the last days of the Omnibus to get to 15, I think it was 25 and then dropped to the last minute to 15. So I'm wondering if you know when the administration will put it's money where it's mouth is and put the full amount in the budget.

CAROLYN CLANCY: The only thing I'd object to in your question was that comment about significant pay rates [Laughter].

FEMALE SPEAKER: No, not significant, I know we're all government employees here. I mean you have a good amount of authority but I know that the budgetary decisions to don't come from you.

CAROLYN CLANCY: What happened initially who don't necessarily bear scars from MMA is that this, the MMA and the '05 budget appropriate process were on parallel tracks and didn't intersect so that's why really was in not in the '05 budget. You'll get to see the '06 budget soon and I can't comment on that now. I think everything that Mark was saying earlier indicates a very strong interest in building on section 10-13 and we're very much looking forward to doing that. So, again I think that the proof is going to be in the results that

the people get and I'm fully confident of an administration support for this.

ED HOWARD: So we'll pick that discussion up on February 7th. Well thank you very much for being here and thank our panelists for an incredibly good discussion [APPLAUSE].

[END RECORDING]