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**What Role for Industry: Setting the Comparative Effectiveness
Agenda
Center for Science in the Public Interest
July 11, 2008**

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SHANNON BROWNLEE: Thank you for coming for this session of the Center for Science in the Public Interest Meeting. This has been a terrific meeting year-after-year and I am really pleased to be a part of it.

I am Shannon Brownlee. I am a Senior Fellow at the New America Foundation in Washington D.C. New America is a nonpartisan think tank and I write about issues involving healthcare.

I wanted to sort of set the agenda here to start with. We really have a very distinguished panel here, and they represent many of the constituencies that are involved in this whole question of comparative effectiveness research.

We have a couple of physicians, we have policymakers, we have a journalist, a lawyer, we have someone from industry and people involved in the government. But there is one person missing and that is someone representing patients. But in fact, the patient should be in upper most in everybody's mind because the whole point of all of this is to improve the lives of patients.

So, what is comparative effectiveness research? Gail Wilensky who is here with us today has been called the "mother" of the term, but let me see if I can kind of define it and then Gail will modify that.

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All of us will modify my definition, I am sure. But let me define in a reverse way which is here as what comparative effectiveness is not. It is not only head-to-head trials of one drug against another it is not just trials of Prozac versus Zyprexa to see which one is more effective.

It is not only testing surgical versus non-surgical treatments for something like, say, back pain. If you know the history of this field, you know that back pain is kind of a key issue, and it is not just testing the efficacy of new devices like GE's super fast CT scanner.

You may have seen this story in the "New York Times", the Sunday before last about the CT scanner that can take an image of the coronary arteries and there is a lot of controversy around the use of this device.

In fact, comparative effectiveness is all of the above. It is really a systematic effort to find out which medical treatments, surgeries, tests and drugs work best and in which patients.

So today, we are going to focus on four main issues. The first one is why do we need comparative effectiveness research? And we have Mark Gibson. I will introduce Mark a little more formally in a moment, but he is going to talk about that issue and others revolving around his work in Oregon.

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Who should pay for comparative effectiveness research and how much is it going to cost us? How should this research be administered and who should be conducting it? Do we need a new agency to be able to foster this research and finally; How can we ensure the integrity of not only the research, but also the process of setting priorities for what the research ought to be and possibly linking price to the effectiveness of treatments, drugs and tests?

So, for example, another *New York Times* story, you may have seen a drug called Avastin is a drug that extends the life of some cancer patients by a matter of weeks, worth spending thousands, and thousands, and thousands of dollars per month on.

This is a great panel, a knowledgeable panel and you can find their full biographies in your program, but I am going to introduce them very briefly.

Mark Gibson will be going first, contrary to what is in the program and he is the Program Director for the Milbank Fund and Director for the Center for Evidence-Based Policy at Oregon Health Sciences.

Gail Wilensky is an economist and a Senior Fellow at Project HOPE, and a long-time healthcare policy analyst.

Zeke Emanuel is a breast oncologist and Chair of the Department of Bioethics at the Clinical Center at the

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National Institutes of Health; and as a fellow author, I feel I need to do this. Zeke is also the author of a book that is just out, "Healthcare Guaranteed: A Simple, Secure Solution for America." It is well worth reading. It has important contribution to the policy debate about covering everyone.

But I have one added little thing for Zeke, who we will all be working with on the fall. He is one of a trio of extraordinary brothers. And as the mother of a 12-year-old, I want to know what Mrs. Emanuel was putting in your Wheaties you were still boys.

And we have Rick Smith who is a lawyer and a Senior Vice President for Policy Research and Strategic Planning at the Pharmaceutical Research and Manufacturers of America. It is also known as PhRMA.

And finally, Gregg Bloche, who is a lawyer and a physician trained as a lawyer and a physician, is a professor of law in Georgetown University and an adjunct professor at the Johns Hopkins Bloomberg School of Public Health.

Two of our panelists consult with the presidential candidates and I want to make it clear that they are not here as surrogates for the candidates and they are not necessarily representing the healthcare views or plans of those candidates.

So, Mark is going to layout some definitions for us

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and talk about the importance of comparative effectiveness.
Mark Gibson.

MARK GIBSON: I thank Shannon. It is a pleasure to be here. I hope we can help elevate everybody's mood a little bit after all the good news at lunch.

Basically, what I am going to do today is talk a little bit about the work that a couple of state collaborations are doing. So, groups of states that have gotten together to collaborate around comparative effectiveness research to inform their policy.

I will explain a little bit about why they have taken those steps and then share a few lessons learned. Before I get into the meat of those comments however, I want to share a couple of caveats and that is what the states are doing in by definition incomplete. More needs to be done clearly. And there are number of reasons for that.

There are limitations in the existing research that they are able to use. There is a great need for additional primary research that the states do not have, the resource or the capacity to perform, and what the states are working on is targeted at a very specific population, the Medicaid population, which is by definition folks of a low social economic status and so, sometimes what they do is not broadly applicable. However, I think there are some lessons that can

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be learned.

The other caveat I would say is that comparative effectiveness research is no panacea obviously. There are huge market failures in our current system and policy failures as well, and folks do not have to look any further than current Medicaid decisions around coronary CT angiography or the ruckus that is going on over durable medical equipment in the federal government paying more than what devices can be bought for over off the web to recognize that there are other big failures that good information will not necessarily solve.

So, there are other big issues that have to be taken but as a foundation, good comparative effectiveness research can be very constructive.

Onto the state collaborations, there are two that I will talk about today. The first is called the Drug Effectiveness Review Project, and this is a collaboration of 14 states in the Canadian Office for a technology assessment in drugs and other health technologies.

These folks came together to do systematic reviews of the existing research evidence comparing the effectiveness and the safety, and the effect on subpopulations of drugs within classes. Now, some research have been done comparing drugs and drugs and classes to each other, that is drugs from

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one class to another prior to this effort by the states, but this was primarily focused on drugs within classes, so, comparing one kind of hard drug to its brothers and sisters in that particular class.

The pattern, there are systematic reviews after the work done at the US Preventive Services Task Force and they utilized as a research capacity the evidence-based practice centers that are designated by AHRQ is particularly well-qualified to do this systematic review of existing research.

The process that the states use is highly-transparent. It starts out with a public process to define the key questions and also has a place for industry and others to participate in terms of providing information to the process itself through what we call dossiers.

The industry sends in any information or any research they think is important to the deliberations. The only caveat there is that any information that is included on our evaluation will be shared on request with the public.

Then, throughout this process, we go to great lengths to make sure that the people who are actually doing the research are insulated from any kind of lobbying activity but that any communication is always in writing and is part of the public record.

Because time is short, I am going to move on to— I

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will just make one other point. As we gained experience to the comparative effectiveness process on these drugs, we had sort of four major results that came out of that.

We had classes of drugs in which we had good evidence that showed that all the drugs in the class were virtually the same. We had classes where there was evidence that there were marginal differences. Then, we had classes where there were significant differences.

In many of those cases, you can tell that there is really a way forward for a smart purchaser or smart clinician is readily apparent. There were other classes where there is really no good comparative evidence and so, a lack of good primary data was a real impediment to actually comparing the drugs one to the other.

The second project is called the Medicaid Evidence-Based Decisions Project. It is very similar to the drug project, although it tries to encompass a look at any other subject other than drugs within the healthcare system. So, it covers everything from durable medical equipment to diagnostics, from back surgery to alcohol and drug treatments and from disease management programs to dental care.

So you can see it is a very broadly-based look. Once again, at existing evidence and it relies heavily on research especially systematic reviews done outside of the projects.

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So where the drug project created its own systematic reviews and built those from the ground up, the Med Project was more successful in finding research outside of the project itself and was able to utilize those than outside information.

Once again however, what can be determined for certain is often hindered by the fact that there is less than the best primary evidence available. So in many cases, we were able to look out there and find that there are very few studies of good quality that can be included in our comparative review of particular interventions.

Now, why do the states do it? Very quickly, states have to balance their budgets and that is pretty much the end of the story. I mean, there is no open-ended entitlement for healthcare at the state-level. They cannot deficit spend to maintain benefit levels.

Every healthcare dollar they spend has to be balanced against some expenditure for the environment, for public safety, or for education for example. So the tradeoffs are very real.

In addition to that, the states really are painfully aware that everyday of every week of every month of every year, they ration healthcare. They either do that through eligibility for programs by changing the income levels for

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qualification for state health support, or they do it by under-reimbursing providers, or by denying certain benefits.

So, they are very painfully aware that every dollar they spend for something that does not produce a real improvement, a health outcome improvement is a dollar that has huge opportunity cost in terms of where health can be improved elsewhere.

About four quick lessons learned from the state efforts. States can help, I think, that some of the work that they have done in terms of setting priorities and bringing folks together to collaborate around this work can be helpful and as people think through how we might do something like this at a federal level.

Reviewing the literature is not enough. That is we do need better primary research out there, better studies, trials and we cannot just depend on systematic reviews of existing literature to give us all the answers we need.

They have also learned that an explicit commitment to the public interest and an explicit commitment to good scientific evidence have made sustaining, sometimes controversial policies possible. So, some of the difficult choices that lie ahead, this information can be useful if the decision-making process is dedicated using it appropriately.

The final two strict conflicts of interest do not

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constrain capacities. States have been able to get the researchers they need to do this work and industry input can be managed constructively and to the satisfaction of both the state policymakers and those in the industry who need to have a seat at the table.

So, the biggest challenge that we are facing really is determining where the burden of proof lies. Is it incumbent upon the folks that are selling something to the states to demonstrate that benefits exceed harms before the states purchase or vice versa? Should the states have to prove that benefits do not exceed harms before they are required to purchase medical interventions? Thanks very much. [Applause]

SHANNON BROWNLEE: Thank you, Mark. Next, we have Gail Wilensky. And I am glad you guys are keeping to your tight schedule here.

GAIL WILENSKY: I am not sure I have ever been referenced before as a mother of comparative clinical effectiveness. I have to think about that, but thank you Shannon. You will stick in my mind for quite a while.

It is a pleasure for me to be here and address this group. What I would like to do is to explain why I, as an economist, primarily worrying about funding, financing healthcare in large part of financing Medicare. I have been

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spending so much time on comparative clinical effectiveness because it really shapes how I look at it and the issues that are important to me within that set of parameters.

For me, understanding what works when, for whom, under what circumstances provided in various settings which is what I regardless comparative clinical effectiveness is all about is one of the key ways to learn how to spend smarter and get better clinical outcomes.

Getting better clinical outcomes is a good idea particularly when I think of myself as a patient. Learning how to spend smarter is absolutely critical for someone like me as I contemplate our future where healthcare spending has been increasing for the last 45 years at two to two-and-a-half percentage points faster than the economy. Absolutely unsustainable rate of growth in spending and at the same time we know we have serious patient safety and clinical outcome difficulties.

I look at comparative clinical effectiveness then as a strategy as an elemental building block to learning how to spend smarter, along with changing the financial incentives, how we reimburse clinicians in institutions, how we incent and interact with patients as consumers.

I say that because for me, it really does color how I look at questions about what should be looked at, how should

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it be done, how should it be financed, where should it be housed, et cetera?

It is critical that we focus on conditions rather than on specific interventions and therapeutics, although when you focus on conditions and think about how alternatively you might treat a particular medical condition, you will obviously, at some stage, begin to compare different therapeutics or interventions.

It is very important for someone like me that this not be regarded as only limited to a head-on-head comparison between drugs or between drugs and devices. And as for me, a very simple reason, it is not where the money is.

The serious money is in medical procedures. And therefore, in thinking about comparative clinical effectiveness, it is absolutely critical that we think about this in terms of the broad array of strategies that can be used to treat a medical condition.

Yes of course, at some point in the comparison, it may well involve considering how two different drugs or how a drug and device fair in terms of improving certain symptom groups of patients. But it is not the primary activity of comparative clinical effectiveness.

This is a big issue. I had assumed that while the first step as a researcher would always be to review what is

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out there, that would not be a huge stumbling block. I have focused primarily on the need for new data and new research because there is no group or agency that is responsible for this broad look at comparative clinical effectiveness.

It is only the FDA that looks at the narrow comparisons, but we do not require particularly from medical procedures any such comparable information.

I had awakening in January when the Institute of Medicine published a study that was led by Hal Sox and Barbara McNeil that indicated the huge issues that are raised in terms of appropriately doing systematic reviews. The kind of data that should be included, the kind of methodologies that need to be allowed and it has forced me to step back and recognize more explicitly that making better use of existing data is of course the first step in terms of assessing what else needs to be done as we go forward.

My notion is that because so much needs to be done, because we have not over the last 40 or 50 years, as so many innovations have come on the market required information that looks at comparative clinical effectiveness, we have a lot of work ahead of us, and we ought to make use of a lot of different data.

All data has errors, we need to recognize that, we need to be very clear about the kind of data that is being

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used, the biases that exist, the robust nature or not of the methodology and have that kind of information available.

I have assumed the place to think about this is in a Center for Comparative Clinical Effectiveness. It could be lodged in an existing agency of government like AHRQ. It could easily be a separate freestanding part of the executive branch like the FTC or the Federal Reserve. It could be completely separate as an independent agency.

Like those, it could be a free-standing or new agency in the executive branch. It could be quasi government linked to the Institute of Medicine.

It is important here as with data to understand that there are no perfect answers. To my mind, it is a question of close to government, but not too close to endanger either the credibility or objectivity that the public and other interested parties has in the data, and to recognize that there will be tradeoffs in terms of whether to go with existing bureaucracy so that you do not have to build new ones, but you may make those more vulnerable if you do that.

And that ultimately, the credibility and accountability is critical if it is going to be of any value. And that how the governance goes forward will be very important.

You are going to need to have the major stakeholders

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at the table involved from industry, from the patient-advocacy group, from the clinical and academic communities. If they are not there, they will be spending their time lobbying grenades trying to blow up whatever occurs. They rightfully have a seat at the table and it is going to be critical to make sure that they are there.

People have asked me what I am thinking about in terms of funding. Let me just indicate when I am thinking about in terms of money because that will indicate something about the challenge of the funding.

To my mind, to stir up this process, we probably are talking several hundred million dollars, but when fully-funded, I am assuming a number that is closer to \$4 billion, or \$5 billion, or \$6 billion a year on an annual basis because of all that we have in order to be able to learn how to spend smarter, all that we have to do.

That is not a trivial amount of money. It is one of the good things about having \$2.4 trillion being spent on healthcare by comparison to the overall spend rate. It is a very small investment to be made in terms of learning how to use what is coming on a market in a better way.

The preference to funding, it would be by direct appropriation like the NIH, but realistically, that is not likely to happen and because the pairs, public and private,

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are the most immediate beneficiaries of such an activity, although clinicians and patients also are very close behind them.

I think you could easily justify a mixed funding of appropriation, a contribution from the Medicare Trust fund, fragile though that is, and a small fee assessed on all privately insured individuals. But it needs to be on all privately-insured individuals. If you cannot get around the ERISA preemption and you only get those who are not self-insured, you will make that problem even worse.

Let me indicate what I am assuming the center is not as I have envisioned it and let me explain why I think it is important to view it that way. I am not assuming decisions get made in the Center for Comparative Clinical Effectiveness.

It is my belief that you will have different pairs making different decisions, but preferably based in large part on the same body of information in terms of what we know about comparative clinical effectiveness.

I do not regard it as a cost effectiveness center, although I regard cost effectiveness as an important part ultimately of the decision-making. I do not impart because I think it is the surest, quickest death now to such a center. And secondarily because the kinds of investments on

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generating new information on comparative clinical effectiveness are very significant compared to what are relatively modest investments needed in order to have good cost of effectiveness studies done.

I would use the same funding stream to fund CMS, or AHRQ, or some other group to do that. It is important to build it in, but just do it separately.

In terms of setting priorities for such a center, I would look, again, remember why I am looking at this, which is a way to learn how to spend smarter and have better healthcare, I would look in the first instance at a high cost medical conditions with a lot of variation in terms of the treatment patterns.

That is usually the clue that we do not know nearly enough in terms of what should be known before medical procedures are being used. Therefore, I would start as a proxy with the conditions that have the highest-class DRGs with substantial geographic variation.

I would also allow, by the way, private funding of comparative clinical effectiveness assessments, but subject to all the rules and guidelines in terms of proper methods and proper data in very much the same way that industry can fund studies that are submitted to the FDA. You need to have an audible set of data and you need to follow the guidelines

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in terms of going forward.

Will this provide the answer that we need in order to learn how to spend smarter? No. But it will provide some of the critical data that we need. Again, to my mind, trying to go forward means having a better understanding of what works when, under what circumstances, using that information for setting reimbursement rates.

I would do that rather than coverage rates, and then understanding that we need to fundamentally realign the financial incentives, so we will reward the institutions and clinicians who provide high-quality, efficiently produce care and begin to also reward healthy lifestyles on the part of patients.

It is a big road ahead, but when you think about some of the other alternatives that might be available, they very quickly become very ugly and this is something conceivably that just might happen. Thank you. [Applause]

SHANNON BROWNLEE: Thank you Gail. Zeke Emanuel?

EZEKIEL EMANUEL: I want to thank Merrill Goozner for having me here and Shannon Brownlee for pushing my books, saving me the ignominy of having to do it myself. And it is a tremendous honor to be on this panel.

A lot of what I am going to say derives from an article that Allan Garber and Vic Fuchs and I wrote about a

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year ago in JAMA, advocating center office institute for technology and outcomes assessment.

And a lot of what I am going to say reinforces some of the things you have heard, maybe that is because of who put the panel together, but it is also I think reflects a lot about— if you really think about this area, it is quite quickly, you come to some very important consensus about what is needed.

The first thing I want to do is reemphasize this point about quality and cost being at the center of the concern for regarding technology and outcomes assessment. In this country, we know we have tremendous haphazard delivery of quality of care. Lots of studies showing that your chance of getting the right care for hypertension or for cholesterol is about 50/50 if you are an adult, and that if you are a kid, your chance of getting right primary care in many very simple procedures is less than 50/50.

Second, we also know that there is a lot of use of unproven therapies, therapies that are not proven to advance treatment. I am I think Shannon mentioned an oncologist. So, let me just give you a couple of examples. I am a breast oncologist, so I will take the opportunity to pick on the prostate cancer doctors and not say a word about my breast cancer colleagues.

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But two quick examples, early-stage prostate cancer, lots of different choices of therapy. You can have surgery. You have radiation. You can do watchful waiting.

And inside of radiation, there are three or four options. You can get traditional 3D conformal radiation geared to the prostate. It costs about \$11,000. You can get brachytherapy, little seeds planted in the prostate of about \$15,000. You can get something called IMRT, a version of external beam radiation therapy at \$42,000.

You can now get proton beam therapy at who knows how much. Those machines cost \$100 million to build. They are on a football field sized plot, isolated because they are having to generate protons through a cyclotron.

We know almost nothing. There has never been a head-to-head comparison of those four different treatments. No one believes that one, at least four times the cost, maybe 10 times the cost of the others actually adds anything to longevity and we only have single institution studies looking at the side effects of each one and whether in fact the more expensive reduces side effects.

So we know virtually nothing and yet the price differences are enormous. Or consider, again, early-stage prostate cancer and the use of androgen blockade either by a orchiectomy removing the testicles or by chemical castration

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giving androgen blockers.

We know this adds absolutely nothing to longevity of life. And most recent study published at the end of 2007 showed that about a third of doctors were giving this medication to their patients. Not a very good practice. So, lots of quality problems and we really need to address them and partly, we need to address them with better information.

Then, there is the cost problem. Everybody who has looked at the increase in healthcare cost come to roughly the same conclusion. At least 50-percent of the increase in healthcare cost is driven by changes in technology. Not necessarily improvements in technology, just changes.

Let me give you a crystal clear example of that. If you look at drug prescribing habits across all the developed countries, United States doctors are more likely to prescribe a medication out less than five years, so, approved by the FDA or equivalent less than five years, 40-percent more than any other country, the number two country.

So, we are very heavily going to new drugs often in the absence of any evidence that they are better. Hypertension is a great case where off patent diuretics have been shown to be just as good as the latest and greatest.

We have a lot of cost— we have haphazard quality and we do not know, and so we need to get our arms around both

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those issues to improve the healthcare of Americans and to improve the physical sustainability of the healthcare sectors, as well as free up money from many other things.

Before I say a bit about my view of technology and outcomes assessment, you heard that I work for the US government and so this is my disclaimer.

I have not cleared these comments with anyone at the NIH, much less the HHS, much less the White House. No one has any idea what I am going to say. They are my comments and they merely represent the truth. [Laughter]

So, technology and outcomes assessment in our country has had a very checkered career. As many of you know, in the 1990s, some agencies were shut down that did technology and outcomes assessment, came under political pressure.

We have a lot of different technology and outcome assessment efforts going on around the country, some private like the Blue Cross and Blue Shield Tech, some public like worked on by the states or done by AHRQ. That cacophony is not necessarily that good. Sometimes, it is just repetitive work. It decreases the legitimacy of any single study. It also wastes a lot of money by doing repetitive things.

Finally, the current effort can only be described as woefully under funded.

If you think that we are spending \$2 trillion on

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healthcare, we are spending at least \$200 billion on drugs. We are spending at least \$100 billion on research and development at various stages through the drug companies, the NIH and other organizations. We might be spending a billion dollars in tech assessment. It is just woefully inadequate to the task at hand in my opinion.

If you look at that collection of problems, I think you come up with about five or six conclusions. And here I am going to both echo some things already said and slightly diverge.

First, I think we need an independent agency, independent in the sense that the board, the people responsible has to be appointed by the President, but not political appointees, confirmed by the Senate for long, staggered terms that cannot be removed for political causes.

It could also be a public/private agency. I think there are some very good compelling reasons for that. But it has to be as independent as possible from pressure and political influence, so that policy decisions are made on policy grounds, not on political grounds.

So, I do not think therefore, it should be housed in an existing agency, subjecting it to either pressure or the existing agency to pressure. There has been a talk about housing it at the NIH. I just do not think that is a good

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idea for a whole series of reasons, this being one of them. So that is the first point, independent and independent from influence and pressure as much as possible.

Second, I think there should be dedicated funding, and I do think there should be an all-payer tax as that basis. A set fraction as an all-payer tax dedicated to this project. I do not think the annual appropriations are the way to go because annual appropriations could be stopped and allows a lot of political pressure.

I agree with something that Gail Wilensky said which is, if you think about the magnitude of the problem, my own view is we ought to have a 0.5-percent tax, or fee, or however you want to phrase it, on payers to go to this. If you calculate that out, that is roughly in current dollars about \$5 billion. It is a nickel for every \$10 spent. Not a lot of money and very well needed.

But I do think having it dedicated and not subject to annual appropriations is important and I think having an all-payer contribution is also important because what the information that is going to be generated is public knowledge, it is a public good, and if you do not get everyone to pay and yet everyone benefits, a lot of people are going to run for the door or you are never going to get such legislation enacted.

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And so I think what Gail said about ERISA plans also contributing, is very, very important. Right now, they represent half of the workers in this country and so they are very big component of the payer mix.

Third point, and again, to emphasize something that the first two speakers mentioned, you cannot simply rely on existing data. I just give you the existing data about radiation therapy for early-stage prostate cancer. We simply do not have enough data.

One of the reasons to have an organization in the \$5 billion range is because it can therefore sponsor a lot of research which we need. The existing data is going to have a lot of useful information, but we are definitely going to have to sponsor additional studies and you are going to therefore need a budget in the \$5 billion range. I think whatever the organization or agency is, however it is created, it needs to have the authority to sponsor research and to undertake research.

Fourth, what is the linkage that ought to be with either coverage decisions, what benefits people are provided, or how we pay doctors, hospitals and other healthcare providers? In England, the NICE decisions, the National Institute for Clinical Effectiveness are directly linked with the coverage decisions.

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In Israel, their tech assessment is similarly directly linked with what they call the basket of services that are covered by the government plan.

I think coverage in the United States cannot be so linked with the technology assessment because some of the technology assessments will be ambiguous and I do not think that we are going to be monolithic. I think this agency ought to provide information and different payers ought to decide how they want to use that information.

I think we ought to have it de-linked from coverage or payment decisions. Medicare, independent health insurance and health plans will then decide how they are going to link it to their benefits and their payment structures.

Fifth, I think I am on five, what to do about various interest groups and this is a typical code word, what do you do about the drug and device manufacturers? Do they get a seat at the table? Do they get to offer their data? Do they get to offer their perspective? And my answer is, of course.

Because frequently, they have a lot of valuable data and I think as Gail said, if I heard her correctly, you got to have them inside the tent. Otherwise, they are going to be outside the tent just attacking the legitimacy of this organization.

I think for most drug and device manufacturers, this

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is a long-term process. They are part of the existing structure. They are not simply a make or break on one decision. They are going to be part of a long-term process. And so they can be very constructive members, and I think ought for very good advice. Most of the people who I have interacted really care about doing the right thing.

What they want to know is what are the ground rules and I think of agency like this helps them know what the ground rules.

Similarly, I think the providers need to be in the game. So a lot of the people who are going to be affected by this are doctors and I think we have to answer that.

So, let me conclude with two more points. One is what do we do about evaluating cost and you have heard from Gail, her preference, I think, for not having cost-effectiveness my preference is for having cost-effectiveness, but if it is a deal-breaker, being willing to give it up.

I do think we need to know a link to cost-effectiveness. I think it is very important information that not every organization can repeat, but again, clinical effectiveness, getting that data is very important and we should not lose that opportunity or possibility for having such an agency unless for the issue of whether it can do cost-effectiveness or not.

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And let me conclude with again, echoing something that has been said. This is not healthcare reform. This is an element of healthcare reform. This will not save the healthcare system as it currently exist. This will not cover everyone. This will not curtail cost alone. This will not improve quality alone. This is one of what I think of seven or eight different building blocks, all necessary to move us in the right direction.

But it is an essential building block and I do not think we can get cost under control and have high quality care guaranteed to all Americans without agency, or institute, or a center for technology and outcomes assessment funded and being an independent group. Thank you very much.
[Applause]

SHANNON BROWNLEE: Thank you Zeke. Rick Smith is next and I am going to ask our last two speakers, sorry in making you guys at the back clean up but if you could really keep tight to your time and we can have some time for questions.

RICK SMITH: Okay. Thanks. We will give it a shot on the time.

I do want to start with one correction to my bio which is I happen to have a JAD, but I am not a lawyer.
[Laughter] So, I do not want the D.C. Bar Association

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waiting for me out there. Okay.

Good afternoon and thanks for the opportunity to participate today. Let us start by noting that PhRMA supports the development in use of high quality evidence including comparative effectiveness research for healthcare decision-making.

CER including government supported research can be a useful tool to promote better quality and value in healthcare. We have developed very specific positions around this. We can not go into all of it today due to time limitations. Maybe we'll get to some of it in Q&A, but there's a great deal up on our Web site, Phrma.org board principles. It's built in for the healthcare reform platform we released yesterday. So you can look for that there.

Before discussing particular aspects of CE, I will note two points: First, there is a great deal of existing evidence that new medicines are an important part of the games that we have made it at health outcomes in recent years.

For instance as one example, the Standards for Disease Control has stated, "Factors contributing to the decline in heart disease and stroke mortality include better control of risk factors, improved access to early detection and better treatment and care including new drugs and

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expanded uses for existing drugs.”

In November 2006, the Congressional Budget Office did a major study around the pharmaceutical sector, noted that many examples exist of major therapeutic gains achieved by the industry in recent years.

Evidence suggests that the rapid increases that have been observed and drug related R&D spending have been accompanied by major therapeutic gains and available drug treatments.

Of course, not all of the medicines used currently are new. In fact, it will probably surprise you to know that nine of the 10 most frequently prescribed medicines in America are generic. And two out of three of all prescriptions used in America are in fact generic medicines. At one time though, those were innovator drugs and of course the remaining share used are the newer medicines.

The advances made to date highlight why as we consider CE. It is important to do so ways that foster continued medical progress.

PhRMA's position on comparative effectiveness research is centered on meeting patient needs and improving quality. And since cost containment is so-often discussed in connection with CER, I will note that our perspective is perhaps best captured by paraphrasing RAND Research for

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Elizabeth McGlynn, who said, "If you wanted to control cost, start by improving quality."

I will now turn to the subset of issues that we are focusing on today. Regarding structure, we support an independent public/private partnership to oversee government supported comparative effectiveness research. It should be governed by a board that includes all stakeholders as we have heard from those who preceded me and should operate through open transparent processes. It is also important to have a balance of independence and accountability.

Turning to the scope of research, a broad scope is key to improving care and my colleagues on the panel have spoken about the broad scope of research concerning treatments and concerning disease condition-focused issues.

I will cover another aspect that has not yet been mentioned that I think is worth mentioning. That is looking at the organization, management, and delivery of care. Because it is not only the specifics of medical interventions but it is how our delivery system has put together that is really critical to determining what care patients get, why they get it, when they get it, till they get the right care at the right time?

This broad review, in fact, is explicitly included in the legislation that created AHRQ's current comparative

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effectiveness program. And it is being recognized by leading experts in the field such as Elliot Fischer and Peter Neumann.

And one reason it is important is that our health system actually often fails to deliver care known to be effective. That is a little different than the other problem we have which is we sometimes deliver care that we do not know enough about its effectiveness, but we quite often do not deliver care that is known to be effective.

These quality gaps of adversely effect patient outcomes and finding ways to close this gap between care that we know works and care patients received, it is a major opportunity for better outcomes, better value in the system.

I just noticed an example that in 2003 New England Journal article, the then Director of the National Heart, Lung and Blood Institute, sited under-use of screening and treatment for heart disease patients to illustrate the lack of success we have had in translating research findings into medical practice in personal behavior. And it concluded that as a result, we are not reaching the full public health benefits of our own investment and research.

This is an instance in which we had knowledge not being applied, making its way through to clinical practice, as well as patient behavior and an opportunity to take

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existing knowledge and find ways to get to better results.

CER, I think, can help us understand factors contributing to these gaps and the different approaches to closing them. For instance, research could compare varying approaches to care coordination quality improvement, financial incentives, benefit design, prevention and adhering strategies and other factors that directly impact patient outcomes.

I think this is so critical because developing new knowledge about medical interventions themselves without increasing our understanding about with approaches to the organization management and delivery of care are most effective at supporting evidence-based practice will be unlikely to yield improvements in care.

I think Dr. Emanuel's example of particular types of prostate cancer treatment where there is some knowledge. I might be mixing up my examples but it is not really question there of knowledge perhaps but a question of [inaudible] into the system and these are the things that can really translate that knowledge into the system.

I will just turn quickly to the use of research results. As I stated earlier, decision-making at all levels of healthcare should be based on the best available evidence. So, we recognize that the results generated by any new CER

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entity will be used by a wide range of decision makers who already apply medical evidence.

The results will add to rather than replace the full body of medical evidence from many sources if they already taken in to account and any CE entity should make research results available to decision makers rather than itself making policy decisions as I think has already been discussed.

Related to this, the entity should focus on questions of clinical effectiveness and patient health outcomes rather than cost or cost effectiveness. Decision making is centralized that could prove quite challenging to making technical and valued judgments affecting access to care of the health system level.

I think my read of the experience from other countries that have centralized these decisions has been that it provides some caution in going down the road of creating centralized decisions rather than generating information that the variety of decision makers can use.

Policy on CE also must recognize a need to use results in a manner sensitive to differences in patient needs and preferences. Patients of course, vary in how they respond to treatment, centralize decisions, all are in always best at recognizing those individual differences. So, of

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course, they need to add to the information. It is available in all levels of the system. We still need to individualize treatment.

I will close out by noting two points. First, it is important to recognize that single studies will very rarely yield definitive results for all patients in all situations. I think as we see the medical literature develop, we see a back and forth.

And I think actually the example that Dr. Emanuel offered about hypertension offers a good example of how you see a real back and forth and a development in the medical literature just like in the rest of the scientific literature in which findings today are challenge-modified, pulled together with other findings and so forth.

Then finally, to support continued medical innovation, comparative effectiveness must recognize the dynamic, often step-by-step nature of medical advances. Much of the progress that we have made in areas like oncology, as well as others, is the result of evolving uses of new treatments such as combining new and existing therapies and smaller steps adding up to larger strides. Since this is typically the way care advances, it will need to be recognized as we develop approaches to developing and using comparative effectiveness research.

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So with that, I will yield the podium. I very much appreciate the opportunity to be part of the discussion and look forward to your Q&A. [Applause]

SHANNON BROWNLEE: Thank you so much. Gregg Bloche is our last speaker.

M. GREGG BLOCHE: Thanks Merrill and Shannon for having me. It is an honor to be a part of this distinguished panel.

I want to start with some health policy context. First of all, there is reason, dare I say it, for a lot about optimism. A consensus is forming around the need to improve the value we get from healthcare by slashing administrative costs, eliminating pointless test and treatments, and better coordinating care for a complex of illnesses.

I'm [inaudible] I mean, Gail and I last saw each other at a surrogates event where we were each speaking on behalf of two different presidential candidates and here we are in a basic agreement.

Most casual observers of health policy now know about the Dartmouth 30-percent, the estimate by Jack Weinberg's group, that 30-percent of what America spends on medical care is wasted on services that are of minimal or no value.

Most of these casual observers know about the studies that show that 25-percent or more of our medical spending

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goes toward administration compared to the five or 10-percent that is spent on administration and well-run public systems.

This data suggests the potential to trim about 15-percent or more from our spending, simply by running things better. Add up these numbers, the Dartmouth 30-percent that is spent on pointless care plus the 15-percent of more that is spent on excess administrative activity and there is the potential to reduce our medical spending by up to 45-percent if we do things right. That is about a trillion dollars a year, an extraordinary opportunity.

Here is where comparative effectiveness research comes in. We know that we waste 30-percent of what we spend on test and treatments, but we do not know nearly enough about which tests and treatments are wasteful.

The secret we doctors have kept from the rest of America until now is that most medical decisions do not rest on sound science. They are the product of tradition and habit and subjective experience and gut instinct. Experience and intuition will always play crucial roles in medicine, but the lack of the science-base for most of what we do is unacceptable.

Gail Wilensky on this panel whether or not, she is the mother of comparative effectiveness research, does deserve a great credit for her efforts to develop a broad way

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acceptable strategy for building the science-base. And she has also been quite courageous especially on the Republican side and speaking to stakeholders who worry a lot about this.

What is crucial though is not just that we commit the resources needed to do this. We need to assure that the agenda for a comparative effectiveness research and the design of the studies themselves is driven by clinical need and scientific opportunity, not the marketing agendas of the many stakeholders that benefit hugely from current wasteful spending.

And we need to make sure that the translation of research into clinical practice is not captured by those who profit from pointless spending and there are hard lessons here to be learned from past failures. And here, I will plug Shannon's book because she has pointed eloquently to a number of these past failures.

These include industry-funded clinical trials that have been designed to clear regulatory hurdles and to market drugs and devices, and not to objectively compare the value of tests and treatments.

The neutering of the agency for healthcare policy and research which once had the authority to develop evidence-based protocols, the neutering of this agency by device makers and especially in societies and others who lobby

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Congress back in the mid-90s to strip it of its ability to issue practice protocols.

Shannon has artfully told the story of the back surgeons who arch their backs after the agency issued a proposal protocol that would have cut back on surgery for lower back pain. Back surgeons played a leading role in the lobbying campaign that took away the agency's power to right protocols.

We all know about the elimination of the office of technology assessment and the lobbying of CMS and Congress by drug and device makers, and specialists, and others to keep the agency from making evidence or even evidence development a condition for Medicare coverage. The heart scan saga of the last few weeks is just the latest example.

But what is to be done? I am developing a proposal which I will say out in a Brookings chapter in a book I am editing with Lesley Meltzer. And here are just some of the main themes and I am going to skip over a lot here.

First of all, it is some thing that is common too much that has been said on this panel. A committed multi-year funding stream, sufficient to support a large board program of imperative effectiveness research. I think the numbers we have been hearing \$5 billion range are reasonable. Notice how small that is as a proportion of what we spend on

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healthcare, something like a quarter of a percent.

And a variety of legal mechanisms could reduce the vulnerability of this funding stream to efforts by stakeholders to cut it off if they become unhappy with the results, and these include assigning us a tiny percentage of Medicare spending to comparative effectiveness research and there by taking it out of Zeke's point which I agree with taking out of the annual appropriations process and making multi-year allocations to an independent board, modeled on the Fed as Senator Daschle has proposed.

Second, management of the overall Federal comparative effectiveness research agenda by an independent council on clinical standards appointed in bipartisan fashion from a pool of accomplished clinicians and medical and health services researchers and scholars of health policy. I do not think that this body should be simply a body that represents all the stakeholders because this is not a matter of making at the back of some political interest.

Substantial conflicts of interest including stock options and consultancy relationships with industry ought to preclude participation in the pool of people potentially appointed to this. And this independent council should identify in creating questions for comparative effectiveness research of inquiry.

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Third, a competitive grant-making process with specialized study sections modeled on the NIH, but this thing is again separate from NIH, for funding proposals to address these research questions and again, substantial conflicts of interest should preclude involvement in this study sections.

The same independent council that manages the comparative effectiveness agenda could set an agenda for the development of clinical practice protocols and healthcare quality benchmarks for Medicare and Medicaid. I agree, we do not want this do a one-size-fits-all set of protocols for the private sector, but doing it for Medicaid, moreover on the English example, the NICE example is appealing.

To develop these protocols and benchmarks in systematic fashion though, the council should formulate cost-benefit tradeoffs principles. And then specialized panels of leading clinicians and researchers could develop particular protocols and benchmarks pursuant to the council's cost-benefit tradeoff principles.

Now, notice a key crucial feature of this proposal I am coming to now. I agree with what has been said about pulling the stakeholders in, giving them a voice within the system and here is a quasi legal way to do this. Create the opportunity for input by permitting drug makers, device makers, especially in societies and others, anybody who wants

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to submit public comments to the specialized panels as they go about the task of developing a protocol.

And also allow them to submit critiques of draft protocols and benchmarks while these drafts are under development. Follow in essence, a notice in comment rulemaking model. The informal rulemaking model set forth by the 1946 Administrative Procedure Act, require each protocol writing panel to take public comments into account in recent fashion and put this to the test by holding the protocol writing panels to administrative laws "arbitrary and capricious" standard, and even permit judicial although with this quite differential standard, the arbitrary and capricious standard.

And that way you have mechanisms for the stakeholders, the interest groups to work within the system at multiple stages in that sense were here channeling discontented to the system rather than to outside actors like Congress with the power to scuttle efforts to achieve a high value evidence-based healthcare system.

Finally, some caveats. I worry a lot that comparative effectiveness research gets oversold as an answer to our cost containment and that is in our low value healthcare myth. It is fractal geometry, if you will, of comparative effectiveness research. It is necessary to put

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patients into clinical categories for the purpose of comparing treatments, but patients and responses to treatment will often be clinically diverse within these categories.

Much has been said about personalized medicine. We may not be there, but the push to personalize medicine underscores this new fractal geometry problem.

Second, much of the most expensive treatment is provided in highly-individualized contexts, like the intensive care unit, which are not readily amenable to categorization for the purpose of comparative effectiveness research design.

Third, there is a tension which we as a society have to deal with and we have not yet dealt with it between the appeal of a quality adjusted life here approach to cost benefit tradeoffs and the moral and legal force of what I think of is ADA values, American's with Disability Act values that has objections to discounting the value of life based on disability. We are going to have to talk about this tension and somehow resolve or at least manage it.

Also, the translation of evidence-based protocols into real world practice poses profound challenges that are beyond the scope of this panel as a series of studies from RAND has shown, American doctors adhere to existing well established protocols and benchmarks only slightly more

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within 50-percent of the time.

Comparative effectiveness research and protocol development are not anywhere near the whole solution. We are going to have to develop much more powerful tools for reshaping real world practice along evidence-based lines without giving doctors the sense that they are being disrespected.

The challenges here include first learning lots more about how practice styles propagate across networks of doctors and developing strategies that take account of this.

Second, we need doctors from industry-funded continuing medical education, which for doctors outside large academic or organized system is the principle way to practice styles of to propagate.

Third, developing pay for performance schemes that encourage good practice without devaluing physicians' sense of professionalism.

Still, first-rate, high-powered comparative effectiveness research would set the table for all of these efforts. I am optimistic that in 2009, whoever wins this presidential election, we are going to be taking big steps in this direction. Thank you very much. [Applause]

SHANNON BROWNLEE: Thank you. Let us take some questions. If you have burning questions, come up and ask

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them and if not, I am going to ask a starter question.

We know that the journals are filled— is anybody at the microphone yet?

Alright, we know that the journals are filled with a lot of bad studies and a lot of bad research, basically marketing studies. My question is how do you make sure that the research that is funded by such an agency is not co-opted by industry? If it is conducted by a contract research organizations or by academics who continue to have financial relationships with industry, is transparency alone going to be enough to ensure that it is really good and high-quality research and valid that we can go to the doctor with?

Anybody? Mark.

MARK GIBSON: Well, I think part of the answer to that was covered in the last presenter's comments and bare out from some of the experience we have had. I think that there is no question that the industry and consumers and practitioners all need to be able to put information, and research and criticism into the process. I think however, the folks that govern the process have to be dedicated exclusively to the public interest.

So, there has to be a very clear firewall between the governance and decision-making that takes place around priority setting, what gets studied, what questions are asked

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and so on and so forth, and the interested parties, whether they would be us as patients or otherwise. I think that somehow we have to set the public interest above all of that and make sure that whomever it is that governs this process has that one sole commitment.

GAIL WILENSKY: Okay. I do not think you actually have to do that. I think you can look at models like MedPAC, the Medicare Payment Advisory Commission, which has been a very successful advisory group to the Congress, in existence now for the last 11 years, which by its very nature is made up of multiple people having clear conflicts of interest.

And yet through the transparency process of voting made public of all meetings held in the public and with requirements that have individuals that are not conflicted be the bulk of the majority of the membership allow for active participation by people who have an important stake in the process but not be able to dominate the process.

Second point, I think, it is very important is to understand that there has been some inclination or a tendency to regard information that is not of the most narrowly defined matter that is randomized or controlled trials, double-blinded, which we regarded as tainted or suspect.

But we need to recognize where we are in this process of trying to improve our information both of what exists and

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what we next need to know and to recognize that they represent important ways to get new information for some things and that there is a lot of new creative thinking that is going on.

Including more use of basing in a probability theory in terms of doing randomized controlled trials or real-life controlled trials that will have people who are actually likely to present themselves with comorbidities and other complexities the reflective of the comparative clinical effectiveness and that while you may remove and taint of by having one disease at a time be studied since people tend not to show up.

That way, when they are actually in a clinician's office, you may have very bad guidance in terms of what is likely to actually affect that patient.

SHANNON BROWNLEE: Gregg, do you want to comment?

M. GREGG BLOCHE: Yes. I think disclosure is essential, but it is not enough and one I guess mildly disagree with Gail on the MedPAC example because think of difference between MedPAC and the rather high-density, packed in scientific judgments that a board or council overseeing comparative effectiveness research would make a difference here is that inherently, it is much more possible to scrutinize breast trade press scrutiny, other press scrutiny

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et cetera.

Scrutinize the judgments that MedPAC makes. These scientific judgments are much harder. They are not going to be tracked. Robert Pahre of the New York Times is not going to go into the details of every agency decision with respect to comparative effectiveness funding.

And I do agree with Mark that the government structure, and I said this in my remarks, ought to be free from conflict of interest. I also think that conflicts of interests which need to be fully disclosed. It ought to be fair of game in evaluating grand proposals pursuant to the model I set forth study sections looking at comparative effectiveness research proposals.

SHANNON BROWNLEE: And Rick?

RICK SMITH: A couple of points. One, I think it is certainly the case that transparency is going to be important. I think that the fact is nobody comes to this issue without a particular starting point, whether it be my sector, whether it be practitioners, whether it be payers.

And I think we need to recognize that there are a variety of perspectives that I think each have legitimacy. Of course, the data upon which those varying legitimate perspectives are sorted out needs to be high quality. And I would note that, in fact, today in the PhRMA sector, we

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actually have FDA review that does not really exist for the rest of healthcare with extensive clinical research that needs to be conducted before medicines reach patients.

With key trial protocols reviewed and approved by the agency and results that need to meet agreed upon statistical ends to ultimately lead to a drug being approved. We also need to have every claim made in labeling carefully reviewed by the FDA. Manufacturers can make any product claims that are not supported by the FDA-approved labeling.

I think it does raise an issue that there is other outside of this very narrow area of the system that is governed by the set of standards, and of course, we can always talk about what the exact standards ought to be. But outside the part of the system that is currently governed by these standards, we do not really have any and I think that that is an issue that will need to be addressing.

SHANNON BROWNLEE: I think that is a very good point. Surgery does not have to be subjected to FDA approval.

We have time for one question. Merrill?

MERRILL GOOZNER: Just one?

SHANNON BROWNLEE: Well, it is 3:15 now. We have started five minutes late. So if I can steal five minutes.

MERRILL GOOZNER: Yes, we will steal five minutes.

SHANNON BROWNLEE: Okay.

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MERRILL GOOZNER: I want to ask mine very quick.

SHANNON BROWNLEE: Good. [Laughter]

MERRILL GOOZNER: Because I do want to let somebody else talk, but very specifically, I would like to hear Dr. Wilensky and Dr. Emanuel. You have called for stakeholders on the board, very different model than what Dr. Bloche has laid out there.

I am curious. Do you see a board that included a stakeholder board being entirely insulated from the actual work of the agency and somehow being some kind of super governance structure, or do you see them being involved in the actual process?

Hopefully that it is not that. Do you think that the comment and rulemaking model that he laid out might be a real good way to go?

GAIL WILENSKY: I do not see the governance structure as indicating the actual process of the research that is being done but rather discussing the priorities and this is a general governance board. At some point, there would be a further scientific board that would relate to the actual conduct of the studies.

I do think the point that Rick Smith just raised, that was very important and that you can allow different actors into the proceedings under strict rules in terms of

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how you participate and having audible data and when it has to be subjected to, and in particularly to me t politically, I think this is just a mistake to think you ought to exclude major stakeholders, so it is my view of the wide observation that I do.

But more importantly than that, we have these standards that are however questionable you may have with regard to the drug industry, that by comparison enough are up here and hello, ladies and gentlemen the healthcare that you have provided where we are spending 85-percent of the actual healthcare dollars that are in patient care, it is a complete free-for-all.

That is in exaggeration in a sense that, yes, there are standards in accreditation and you have quality review committees. But they are extremely variable and subject to the efforts of the institutions and that by comparison with what we see at the FDA and the drug industry is so much more strict and rigorous than what goes on in advanced area in which healthcare is provided.

I do not mind critiquing and making that better than it has been but I really think people are losing sight of the fact that almost all of the money and all of the care is in a much, much worse position than what we see going on in drugs.

EZEKIEL EMANUEL: I do not know, Merrill that I said

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that they should be on the board. I said they should be included and exactly where you include them, I think, is an issue. I think it is clearly required to allow them to comment on protocols, to comment on results, to comment on decisions and evaluations of data.

I think I would not preemptively exclude them from a board because I think there are at least three levels or four levels of running such an agency. One is going to be the big board. One is going to be the actual administrator who should do it day-to-day. And there is going to be the people who are actually collecting the data, analyzing the data, crunching the data. And last, there will probably going to be contractors, academic organizations and others generating lots of data.

Now, if you look, in my humble opinion, at where we have a problem with the conflict of interest of pharmaceutical companies, device manufacturers, et cetera, and where that conflict holds. It actually does not hold in the science that is involved for reasons that Rick mentioned which is that you have there an FDA, you have not agreed upon protocol.

It is all about dissemination. That is where the industry really, I think, screws up and where the conflicts really come home to lose. They want to control data

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specially the adverse data, and this process with its transparency, its openness will not permit them to control that element of it.

So that seems to me suggest that you have safeguards but I do not think there is any way of going forward with this in a legitimate manner without including them in the process and having a role where they can really feel like the results have been fair to them because I think if it does not happen, you are going to have a built-in enemy that can undermine the legitimacy of this process and kill it. I think it is that simple a calculation.

SHANNON BROWNLEE: I am going to give Rick a chance for a short comment.

RICK SMITH: Yes. I got this. I will try to give it to you in real short fragments.

Number one, I would encourage people to go to our Web site which I believe is clinical trials, if you go to PhRMA Web site, you will find our clinical trials database which includes results in over 500 medicines that both includes published and unpublished results.

I would also note that when you go to the Web site, you will find the new code of marketing conduct that we released yesterday, NICE press reports about it.

And I would also note that at the end of the day, I

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think that there is a fundamental independence that is very easy to demonstrate in a physician decision-making about which medicines patients obtain. And it goes back to a point I made earlier, nine out of the 10 most commonly prescribed medicines in the United States are generics. Two out of every three medicines that patients use in the United States are generics.

It is clear that physicians are looking at a wide range of information and reaching a set of judgments and I think that what we can usefully do is generate more information through comparative effectiveness initiative for those judgments as well as judgments about the full-range of medical care as well as the judgments about how we are going to organize the delivery of services.

SHANNON BROWNLEE: Thanks. In the interest of transparency, I think it is important to know that that clinical trials data that are published on PhRMA are woefully inadequate. They do not include everything that one would wish. So, next question?

BOB ROY: I am Bob Roy [misspelled?] BMJ. We have had a fairly grim picture here of lack of transparency of information, standards of care not being implemented at clinical practice levels. Are there any situations, any disease groups and any practices within the United States

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that might serve as examples that are doing better?

I am thinking particularly of HIV, say, in the disease group and Kaiser Permanente in terms of practices. What are some models we can look to within this country?

SHANNON BROWNLEE: I am going to ask that one or two per people comment and keep them really short, okay, in the interest of time. I think Zeke raised his hand first. Go ahead.

EZEKIEL EMANUEL: I mean, I think there are good groups. Part of the problem is we do not have consistent data across all groups in all areas. There are certainly groups that have gotten in places where we have had some pay for performance experiments that have done extraordinarily well and there are a lot of groups that are trying to implement quality standards across various areas.

In the oncology community I headed a task force for the American Society of Clinical Oncology that went out and evaluated both breast cancer and colorectal cancer treatments and hired independent contractors, RAND and Harvard, to do the evaluation and show us how well we were doing.

It was nice to know we were doing better than primary care doctors about 80 to 90-percent of the time we were doing it well, whether it was chemotherapy or surgery.

But that meant that 10 or 20-percent of time we were

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not doing it well. Inside the group on a whole group of private practitioners have banded together to create a quality group where they are rigorously tracking their data. They are trying to put in improved methods and to evaluate themselves quite rigorously.

I know this in oncology and I think there are separate initiatives in a number of different areas. I think lots of specialty groups have realized they have to do something and they would have to try to justify what they are getting their money for.

So, I am not as pessimistic, but the problem is, we do not have a database that allows us on real-time to compare these various groups and part of the whole effort to suggest an institute, an agency, is get this data on a real-time basis across the whole country and not just in very selected elements.

SHANNON BROWNLEE: I want Mark to address this but just one specialty group comes to mind the Academy of Pediatrics.

GAIL WILENSKY: I was to say thoracic surgeon.

SHANNON BROWNLEE: Yes.

GAIL WILENSKY: Necessarily, this is probably the most. STS is probably the most prone to...

SHANNON BROWNLEE: Mark, can you address this

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question?

MARK GIBSON: Yes. I think another system that can be looked at and it depends on where you are looking in terms of tertiary care or primary care across the board. I really think the folks should not ignore the Veterans Administration and the work that has been done there.

So, I think Kaiser is a good example. I think there is a lot of controversy around the Vets right now because of the problems of under-funding and Iraq veteran's returning and so on and so forth, but in terms of a system that handles the basics of care well and provides a good foundation of primary care and as a result achieves good outcomes in a very difficult population, high comorbidity and otherwise, I think that is another example that should be looked at.

SHANNON BROWNLEE: Great. Thank you all very much and thanks for – [Applause]

[END RECORDING]