SECOND ANNUAL ACHIEVING PATIENT-CENTEREDNESS

IN CER FORUM

The Reserve Officers Association
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MR. COELHO: Good afternoon, everyone. If everyone will take their seats, we'll go ahead and begin so we can end on time.

Thank you for joining us today for our second annual Achieving Patient Centeredness in CER Forum.

I'm Tony Coelho, Chairman of Partnership to Improve Patient Care.

As I think all of you know, PIPC is a broad-based coalition dedicated to advance in patient-centered, comparative and clinical effectiveness research. I'm delighted to be back today at our second annual forum on patient-centered CER.

We've all made a lot of progress since our event with Senator Baucus last summer. The Board of Governors of the Patient-Centered Outcomes Research Institute was named and started meeting last November.

PCORI is in the process of establishing a definition of patient-centered outcomes research and started work on setting research priorities.
No less important than all of that, they had the good fortune of convincing Dr. Joe Selby to join them as the institute's Executive Director. Joe, we're honored that you could join us today and look forward to hearing from you and having a dialogue with you.

Like PCORI, PIPC has also been busy over the last year. Following our work to support enactment of CER provisions in the Affordable Care Act, we developed and released a new resource on our Website, the CER inventory that provides a single, comprehensive database of federally funded CER, and we released white papers on a procedural framework for CER and on best practices in priority setting. We have copies of those in the back.

Now, let's face it. We can't still slap the words "patient-centered" on the title and, presto, it magically becomes patient centered. I think PCORI has taken a number of important steps to establish a program that is truly patient centered.

Many of us representing patients and people with disabilities feel very positive about the initial
steps that have been taken. We're also looking to these to get translated into concrete PCORI policy. We appreciate the progress that has been made, and we're looking forward for the progress to continue.

Last October in a Health Affairs article, I highlighted some of the strengths of the health reform laws, CER provisions from the patient's point of view. I noted that the new CER law gives patients something they haven't had before when it came to government-sponsored CER: a voice and, more importantly, a vote.

The law's provisions give patients a direct, meaningful role in setting research priorities, overseeing the research program, and communication of study results. I concluded that the Affordable Care Act sets the gold standard for patient centeredness in CER. I'm pleased at the progress that PCORI has made in meeting this high standard, committed to naming a chief patient officer and seeing and publicly releasing comments on the draft research definition are just two examples.

I'm even more pleased that PCORI found an
Executive Director so eminently qualified to put his
gold standard into practice. Indeed, some have
suggested that the only high mark against him is that
he agreed to take this job.

(Laughter.)

MR. COELHO: As a family physician, clinical
epimentol -- whatever it is -- and health services
researcher, Joe has more than 35 years of experience in
patient care, research and administration. Prior to
joining PCORI, Joe came from Kaiser Permanente,
Northern California, where he was Director of the
Division of Research for 13 years, and I want him to
know that I won't hold that against him because it was
an HMO and primarily because it was from Northern
California and one of my best friends, who still is one
of my best friends worked there for 15 years.

So, Joe, in all seriousness, we're honored to
have you today, and we are waiting to hear your
remarks.

(Applause.)

DR. SELBY: Thank you, everybody. Really you
don't have to worry about me. Everywhere I go people ask me, "Well, how are you doing? Are you hanging in there?" as if, you know, this really was a short-term death sentence.

You know, it has been totally enjoyable. There's a little bit of stress. There's a lot of excitement. The excitement sort of makes up for the stress, and two months and a week into it, things are going very well.

Tony, your comments couldn't have set up my slides and my comments any better. So we'll get started. I just want to say in leading off that there's three reasons why today is a very special day for PCORI. The first is that this morning we released our first major funding announcement, and this is equivalent actually overall to about $26 million in funding over two years. It's called PCORI pilot project.

So we don't have a research agenda yet, as you'll see. So we are not funding comparative effectiveness research yet, but this funding is to
build up the methods for doing patient-centered comparative effectiveness research. So if you go to our Website, you'll see the announcement. There's eight different areas of interest, and they all focus on different aspects of how we actually do engage patients and other stakeholders in every aspect of the research process. We're not talking about patient-centered care. We're talking about patient-centered research. That's number one.

Number two, today in the New England Journal there is a very nice summary of PCORI's activities together written by our Board Chair and Vice Chair, and you know, it still feels good, relatively good, to get something into the New England Journal, even if our research is different. I mean, we do have to affect the health care community at a level at that in using strategies like putting things in the New England Journal. So that's number two.

Number three is that I'm here. I'm very excited. This is where we've been talking a lot about engaging patients, and this is one of the biggest
groups of patient representatives that I've spoken with thus far, and I'm here basically to talk to you about ways to make that happen intensely, particularly over the next few months.

So I titled this "What's in a Name?" As some of you may know, Senator Baucus considered for a while calling it "FRED," calling PCORI FRED, but ultimately they settled on the Patient-Centered Outcomes Research Institute, and part of the gist of my comments today is that that made a big difference, and I want this group to know that.

So this is a slide that I inherited when I got here on July 11th. So this is a product of that board that started meeting last November and has just worked just incredibly over these last months to figure out what patient-centered outcomes research was going to mean, what PCORI was going to be doing. This is the way they see it, and we intend to hold true to this framework.

And that is that the first thing PCORI does is engages patients to understand the choices that
patients face. That engagement and the information that PCORI gets from that engagement is what drives our research, and the research, we aim to align the research that we fund and the methods that we use with the needs that are expressed so that our research answers practical questions, practical questions that patients and their clinicians face day in and day out.

Too much of research answers other people's questions or sometimes you wonder if it answers any questions in the end. So a key goal of PCORI is to make certain that the research is practical or pragmatic, that it addresses questions that patients vetted in advanced, prioritized as being important.

And the third is that when we get the findings, we don't sit on them. We're not satisfied with publishing in the New England Journal. We invest in dissemination in partnership with the Agency for Health Care Research and Quality. WE disseminate so that we can provide this information, and I'm not saying just the information PCORI funds, but good, practical, relevant information in general to patients
and providers so they have it at the point where
they're making their decisions.

So that's the vision. That's the framework, if you will. This is the mission statement I also worked on before I got here, but I just draw your attention to the words they chose, the bolded words near the end of it, that PCORI aims to produce and promote high integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader health care community.

That is radical. That's very different than the guiding lights of research up to this point in time.

So Tony mentioned the definition of patient-centered outcomes research. There was not a satisfactory, widely accepted definition when the institute was named or when the board was brought together. So this is a definition developed by the Methodology Committee of PCORI, and again, the bolded part expresses this unique perspective that PCOR, patient-centered outcomes research, is research that
allows patients' voices to be heard as we assess the
value of health care options.

They go on to say that this research answers
four patient-focused questions. Number one, given who
I am, my personal characteristics, conditions and
preferences, what should I expect will happen to me?
In other words, prediction, prediction for people with
no conditions; prediction for people once they get a
condition; prediction for people perhaps if they have a
complication.

You'll notice that's not really comparative.
That's more the old epidemiology that you mentioned,
but in our judgment, it's important information, and
it's the kind of foundation on which people do make
decisions.

Number two, what are my options? And there
you can read treatment options, and what are the
benefits and harms of those options?
Number three, what can I do to improve the
outcomes that are most important to me? What can I do?
So there the emphasis is on the word "I." We're
talking about behaviors and other preventive measures and self-management measures the patients can take. Which ones work particularly to get the outcomes that I'm most interested on?

And, fourth, how can the health care system improve my chances of achieving the outcomes I prefer?

So this is our working definition. We say working because we did put it on the Website. We got 600-plus responses on the Website. I believe those 600 responses are now posted on the Website. But the other thing we did is we actually did our very first RFP. So the first funded research, the first research that we funded was an RFP to solicit a group of researchers to take that input and synthesize it, to cull through it, to look for the common themes, to pull out questions and common themes and concerns, and I'm fully expecting that we're going to find that this definition did not make everyone happy.

This qualitative research will pull out the common themes and send them back to the Methodology Committee. The Methodology Committee will work to
revise the definition, and that definition will be
taken out again to patient focus groups and other for
a, all done by the end of this year, to see how the
revised definition of patient-centered outcomes
research sits with patients.

And so we may be getting back to you as a way
of getting input on the revised definition. It's
important because this is the definition we'll lean on
going forward as we fund research, and as most of you
know, we have a lot of funding to do and a lot of
funding to disperse over the next seven to eight years.

In July, the first board meeting I was really
employed by PCORI and in attendance, the board suddenly
seized on the notion that we had to make a very clear
statement that patient engagement was our business, and
the best way to do it was that among our earliest hires
would be a Director of Patient Engagement.

Tony used the phrase Chief Patient Officer,
and that is the phrase that came up in July at our
board meeting. We did change it to Director of Patient
Engagement, but a working group on patient engagement
was formed. That group created a job description for that Director.

We quickly said, yes, it's crucial to have a Director of Patient Engagement, but we also need to be engaged with other communities, with caregivers, with clinicians, with health care systems and payers and government providers of health care, researchers, and industry. So we crafted a parallel job description for a Director of Stakeholder Engagement who will oversee managing to relationships with other stakeholders, and added a third job description for a Director of Communications.

Those three people together we consider our external relations arm. We actually had those job descriptions up before our first scientist description was up, and it just emphasizes that, indeed, PCORI takes engagement very seriously, that we're very interested in fortifying and building the infrastructure for that front end of getting input on what research questions are important, what research we should fund.
The Methodology Committee, as you know, the GAO didn't just appoint a governing board. They also appointed a separate Methodology Committee. We're working in close relationship. The Methodology Committee has to produce a methodology report, which is the standards for doing patient-centered comparative effectiveness research, and it's due in May. So they've got a huge burden. There's 16 of them. They're very conscious of the amount of work they've got to do. This is supposedly going to set national standards.

They see it as an iterative process. Version 1 will take a stab at it. They see they're a standing committee. They see themselves continuing to work to be the source of good methodology for doing this research. But you'll notice that they divided themselves quickly into three groups, and one of them was patient centeredness.

The Patient Centeredness Working Group is going to write the section of the methodology report that covers the standards for methods related to
incorporating the patient perspective into all aspects of patient-centered outcomes research. So even our methodology report talks about the methods for getting patients involved in research.

That might not have happened. You know, you might not have seen that working group if we were not called the Patient-Centered Outcomes Research Institute. So what's in a name?

The first thing the Patient Centeredness Working Group did was issue to RFPs. So these are our second and third RFPs. They're still posted. I think it closes, if I'm not mistaken, tomorrow or possibly a week from tomorrow, maybe a week from tomorrow, but you'll see these two RFPs are closely related. One is for a thorough review and synthesis of the literature on eliciting the patient's perspective in patient-centered outcomes research, and the next is conducting expert stakeholder interviews to identify evidence for the very same purpose, for eliciting patient perspective in patient-centered outcomes research.

So you see the next two things we funded also
had to do with the patient centered part of patient-centered outcomes research.

The pilot projects that were announced today had eight areas of interest. I'm just going to show you the six that spoke directly to incorporating the perspectives of patients. So that the first one, in fact, it's about incorporating the perspectives of patients and stakeholders into the development of national priorities. We will get back to that in a moment.

The next is refining methods for bringing together patients, caregivers, clinicians, including nontraditional partners and other stakeholders in all stages of the research process.

The third one is about evaluating patient-centered approaches for assessing patient preferences for various outcomes, including the use of decision support tools' shared decision making. And, again, this is not particularly to address a specific CER question. These are not CER studies. These are methods that will inform and make CER studies better
once we get the research agenda done.

The next three, identifying, testing or evaluating patient-centered outcomes instruments. So how do we measure outcomes, including risk prediction outcomes?

The next one is how do we assess patient perspectives around research on behaviors, lifestyles, and choices that are within patients' control.

And the last one is how do we study, methods for studying the patient care team interactions in situations where there actually are multiple options. So how do we talk about comparative effectiveness when the patient and their clinician are, indeed, faced with choices?

So all of that is just to say that, again, the research that we funded to date has a very distinct and consistent theme of engaging patients in the research process, all steps in the research process.

And now I want to get on to the notion of the national priorities. This is critically important, and it's really our central work over the next four months.
The reason it's central is because we can't really get started funding what legislation calls our primary research until we've elaborated a set of national research priorities from a patient perspective.

The national priorities, you can think of them as fairly broad. Then from the national priorities comes our research agenda, which begins to narrow down what we're going to fund particularly early on, and from that research agenda then you can expect the RFAs to come, the funding announcements.

There have been a lot of other efforts to specify national priorities for CER. You may be familiar with the IOM's effort or AHRQ's prioritization or the National Priorities Partnership or the National Quality Forum to the National Prevention Council, to name a few.

So the first thing we did was, in fact, to develop a candidate framework of priorities that came from all of this previous work. So that's going to be our starting point. That work is well underway right now.
The next phase, which is on the brink of beginning and will go through at least November, possibly somewhat into December, is engaging stakeholders. So engaging patients, engaging patient organizations, engaging clinicians and the other stakeholders I've mentioned to help us put a patient-centered voice on our priorities to make certain that we've got the right priorities, to make sure we've got the priorities prioritized, if you will, ranked.

And by legislation, once we've got a pretty good shot, our take on the national priorities, we put that out for a 45 to 60-day public comment period, and by March we fervently hope and we think and possibly even a little sooner, we will have the national priorities finalized.

But I just emphasize this stage between now and the end of November, early December. It needs to be very intensive from our perspective at engaging patients and other stakeholders.

This is the work we've done to date. Down the left-hand column, I hope you can read that. Down the
left-hand column are the previously priority generating efforts from the IOMs to the federal coordinating committees, AHRQs, the National Quality Forum, the National Prevention Council, and Priorities Partnership.

And across the top are recurrent priorities that came out of these, and you'll see they are very broad indeed: prevention, acute care. The first four are kind of you could call them parts of the patient lifecycle, from prevention to dealing with acute care situations, to dealing with chronic conditions and their care to dealing with palliative care.

And the rest of these -- and then to coordination of that care -- and the rest of these are cross-cutting: engaging patients at every aspect of that care; issues related to the safety of medical care, to the appropriate use of care, to the use of health information technologies to improve the patient experience; and the impact of new technologies on patient outcomes.

So those are ten we're now calling them
candidate priorities that emerged from our assessment of the work that's gone on over the last few years, the prioritizations of others.

Okay. This is our work over the next two to three months. Again, down the left-hand -- or not "again" -- down the left-hand column now are those candidate priorities. They may be with us in the end. We may jettison all of them and recast them, but we will in the end have a set of priorities. We start with these that came, as I said, from previous efforts.

We then apply a set of criteria to these, and I hope you can see this, read this, but there are ten criteria here. The eight that are in white type are criteria that are specified. We have to pay attention to these in the legislation. So these are all called out in the legislation as important criteria for driving our priorities. So they have to do with the impact of health, that is, the burden of the particular condition or the particular priority area.

The second one is the probability that funding for research in this area could lead to improvement.
Some may just have more potential, maybe lower hanging fruit in terms of a little bit of research or a lot of research would really make a difference.

The next is that the priority pays attention to different subpopulations.

The fourth is that current gaps in knowledge are evidenced by wide variation in care so that we see across the country that a particular condition is handled differently. That suggests that we really don't know what's best, and so gaps in knowledge that research could address.

The fifth is that the research in this priority area may have an impact on health system performance, in other words, that with research the health system could achieve better outcomes or achieve outcomes more efficiently.

The sixth is that there are disparities, that this priority area points us to disparities. Eliminating disparities is one of the best ways to improve outcomes and improve quality of care.

The next is that the research has the
potential to influence decision-making at the patient point of view.

And the last is that the research actually responds to an expressed need for research, a need expressed by patients or other key stakeholders.

We've added two. The ninth one is that research in this area would advance comparative effectiveness research methods or I should probably even say patient-centered comparative effectiveness research methods. We think that enhancing the methods of doing this research is going to be a central necessity if CER is really going to cover the waterfront, cover it effectively, and serve patients.

And the last is that the priority and research in that priority could fit nicely into our patient definition of PCOR.

In the end, we'll come out with a revised set of priorities, and these aren't our guesses as to what they'll be. These are simple examples that they may be cast in different language. They may be expressed more from the patient's point of view, but we'll have a set
of priorities that have been through this sieve, if you will, this framework of applying criteria to a set of candidates.

So we're at the point now where we're about to engage stakeholders. Our principles in engaging stakeholders include that we want a balanced representation within each stakeholder group, that we want to obtain feedback from a diverse set of patients, clinicians, payers, et cetera, that we want from a diverse and representative range of all stakeholders.

Number two, that we're transparent in the process, that enable an open engagement process that makes clear how participants can get involved and what we're going to do with the input.

And third, that we make it easy to participate, that we provide easy accessible forums.

In the spirit of making the input representative, we will use a variety of methods. You'll see us conducting focus groups. You'll see us showing up in meetings like this with an exercise to go through, with a framework to go through. You'll see a
survey very likely. You'll see opportunities for input on our Website, and you'll probably see us doing some sort of social media outreach by way of crowd sourcing. Different ways: bottom-up ways, top-down ways to hone in on the perspectives of patients and other stakeholders as to what's important in these priorities.

Who are our key stakeholders? Well, I've already really mentioned them. First of all, patients, individuals with illnesses, their families, their caregivers. We'll access those patients through patient organizations and by other means, as I said. Patient organizations and advocacy groups bring additional set of insights as you well know, that by being organized and by working in this area, you generate insights and perspectives that are crucial that add to what we get from one-on-one interviews or input from patients and the general public.

Part of our mission is about prevention, and so the general public not at the moment considering themselves patients are also stakeholders.
And in professional organizations -- or other stakeholders I'd call that -- we're talking about practicing providers, health systems, employers, other payers, that is, insurers, the research community, government at the federal, state and local level, Congress, and of course, industry. All of those are key stakeholders, and we intend to keep all engaged in the process of setting priorities and conducting the research.

So just in closing, in case you were wondering, we got the name patient-centered outcomes research when you read the legislation. We're supposed to do comparative clinical effectiveness research.

So will PCOR be CER? I'm here to tell you that I've concluded that PCOR essentially is almost 100 percent overlapped with CER. As I suggested, there may be a very small amount of patient-centered outcomes research that a purist would not call comparative effectiveness research, but it will be research that supports patient decisions, and I think that our emphasis on engaging patients in this research is going
to help insure that it really is CER, and by that I mean that this emphasis on engaging patients and having a true patient focus will help make sure that the questions, indeed, are practical or pragmatic, and I think they will usually be comparative, as I said.

Number two, that engagement of patients is going to make sure that we really considered the variety of outcomes that patients value and that we don't overlook some.

Number three, it will help to insure that the patients we study are representative.

And, number four, it will help to insure that we pay attention to possibility that different treatments work better for different patients. We'd call it the heterogeneity of treatment effectiveness, but those are really the four pillars of CER, and I think that there's a strong case that engaging patients in the research endeavor will strengthen each one of those four pillars.

So with that I'll close and turn it back to you, Tony. Thank you very much.
(Applause.)

DR. SELBY: And I'll just say that my favorite part is always the Q&A after this. So I look forward to it.

MR. COELHO: Thank you, Joe.

What we want to do now is to have each of our panelists speak for about eight to ten minutes, eight minutes, and then after that I'll ask some questions based on each of their presentations, and then we'll open up to questions from the audience.

What I'd like now is for Shawn Bishop to make some comments. Shawn was one of the principal staffers in drafting the legislation. She worked as senior staff member for the Senate Finance Committee for six years, primarily advising Chairman Max Baucus.

She was prior to that a principal analyst at the Congressional Budget Office. She developed models to estimate the cost of legislative proposals related to Medicare private plans and competition. She worked in federal health payment policy at the Centers for Medicare and Medicaid Services, and she worked at the
Prospective Payment Assessment Commission, which is now MEDPAC, and she was in the private sector at Pricewaterhouse.

She currently serves as Senior Vice President at Marwood Group, a consultant to financial investors, but more importantly, she has a Master's degree in public policy from the University of California at Berkeley.

(Laughter.)

MR. COELHO: So, Shawn, it's yours.

MS. BISHOP: I don't have a presentation, but thank you for that introduction. It's good to be here.

I came here a lot when I was on the Hill and always had great meetings here. So happy to be here and happy to see some familiar faces, too.

I want to say one thing. It is such an honor to be here because this is a day where PCORI is actually something real, tangible. It's something that not only we can go to their Website, but it has an Executive Director and obviously that is Joe.

As you know, if there are staffers in the
room, what that feels like to write legislation and it's so abstract, and then to have it be something that becomes concrete and is actually going to help people. So it's really an honor to be able to be here and to see this come to fruition.

I want to say a couple things about Joe. One of the things that we thought a lot about when we were writing the legislation was who's going to run this place, and you can't put, you know, anybody's name in a statute or you can't put a job description, but you want to because you know that we know especially with the first time executive director that that person is really going to create the culture of the institute and it's going to really drive sort of, you know, the long-term vision, and we really sat around the table when we were writing the legislation and thought about who this person would be, and I couldn't be more pleased that they had the insight to hire somebody like Joe because his integrity with the research community is so high and he's very diplomatic because his job is going to be obviously to bridge the research community and be the
diplomat for PCORI and to try to, you know, balance all of the different voices that are not only on the board, but the voices that want to be heard through this institute, and he's going to be the person who is going to try to balance all that out, and he has the right, you know, diplomatic skills to do that. So anyway, we're really fortunate to have him as the first Executive Director.

I'm going to be brief, and that's hard for me, but I want to have these other august panelists speak to you and then have the Q&A. I just want to give a really quick overview what the intent of the statute was.

Basically the intent of the statute when we sat and decided that -- when we got the authority from Senator Baucus to really write the statute, when we sat and decided that we got the authority from Senator Baucus really to write this legislation was to improve the health care delivery system of the United States. I mean, we had a very broad, you know, charge.

And as a staffer, I mean, you couldn't be more
happy to be able to do something that would, you know, help the health care delivery system of the United States. Senator Baucus said start with a blank piece of paper and do what's right, do what's best.

And, again, as a staffer, that's the kind of, you know, direction and latitude you want from your boss, and so we sat down and we said, okay, what is it that we're trying to accomplish here, and basically as Joe outlined and all of the different activities that PCORI is doing is simple. It's to generate more evidence for patients and providers when they make health care decisions. That's it: to generate more evidence for patients and providers.

And why did we want to do that in the context of all the other issues that we were working on in the Senate Finance Committee? It's because the other activities of the committee overseeing Medicare and Medicaid, really I think Senator Baucus, the chairman, he really saw his role kind of beyond that, really to improving the health care delivery system at large; that we were going to be putting in new concepts, if
you will, into the public programs and hopefully into
the private sector that really try to encourage the use
of evidence-based medicine to improve the quality of
care in the United States.

Because as you know, when we started to look
at what the health system needed, we had a crisis of
quality in the United States and cost. So how are we
going to improve? What are we going to do to affect
those two problems that we saw in the health care
system?

We needed to bring more evidence into the
system and reward that. So a lot of the things that we
were doing in the health care reform law were trying to
change the delivery system through the public program,
through the private sector, but also this, to generate
more evidence that feeds into those processes.

So if you're going to be rewarding evidence-
based care and more coordination of care, maybe we
thought that there should be more generation of the
evidence used in that process. So that's how PCORI
fits into the whole sort of theme of delivery system
reform and health care reform.

It does stand on its won. I feel like even if we didn't do health care reform, I felt like there was a need for PCORI, but its whole mission is really tied into the need to better the health care system at large.

The structure of PCORI is unique. As you all know, we looked at a lot of different models to structure PCORI. We looked at creating a federal agency. We looked at creating what's called an FFRDC, which is sort of like what the Defense Department uses to fund research that they need to create whatever they need to do, their weapons and things like that. We looked at different models.

None of those seemed to fit kind of what we thought was going to be appropriate here. So we decided to create a nonprofit entity that is, as Joe was saying, that is overseen by a stakeholder board, and that's because the research needed to be something that obviously had balance, that it wasn't going to be from one perspective; it wasn't going to be from the
researcher's perspective or from the payer's perspective; that everybody's voice needed to be heard.

So we decided to put the stakeholder in charge of the institute, to oversee and to basically be the ones that -- the board members are going to be the ones to decide what the priorities are for the institute.

That's their major charge, and of course, Joe is going to run the institute and provide all of the staffing for that, but the board is going to make the priorities and set the research agenda.

Now, you know, a nonprofit institute isn't that, you know, unique. We have nonprofit institutes in the United States all the time. What's unique about PCORI is the stakeholder board, but also the fact that it's funded through a trust fund that actually sits within the Treasury, you know, in the Treasury Department. The funds come from a variety of sources. For the first couple of years, the funds come from mandatory appropriations, and that's basically funds that are available in the Treasury.

Beginning in 2013, the funds are going to be
coming from the Medicare trust funds and also from a per capita fee that's going to be charged to all health insurance providers that cover lives in the United States, and the reason why we have this sort of multi-source funding scheme for PCORI is because we felt that the research is going to benefit everybody. It's going to benefit the public sector, the private sector. It's going to benefit, you know, the veterans' programs, Department of Defense. So everybody needed to contribute, and that's sort of the way that we decided to fund the institute. So that's sort of unique.

But basically other than that, the mission of PCORI is simple. It's to generate evidence and to do that by setting national priorities and to then set a research agenda, and then its third charge is to go out and get that research.

So other types of institutes and other types of stakeholders have been able to put together sort of recommendations on what types of research should be funded, and that's sort of how maybe AHRQ and NIH, some of those agencies have operated. They've asked for
input from stakeholder groups.

This institute operates differently in that not only are the stakeholders making the decision, but they have the funds and the resources, as I described, to go out and get that research, and that's their charge, not only to decide what the priorities are and hope that that research is funded by somebody, but to say, "We're going to go get it. If it's a priority, if it's a national priority and we decide it is, we're going to get the study funded." And not only that; they also have the charge to disseminate.

You know, PCORI, since it is so new and, you know, it's sort of a unique structure, it's going to, you know, need oversight by Congress as the staffers in the room know; that once Congress sets, you know, a new law, that it's also its responsibility constitutionally to oversee that law. And so all of the folks in the room here, not just the staffers in the room, but also the groups that care about this, it's your responsibility now that the law is written, now that PCORI actually exists, it's real, is to keep involved
in what PCORI is doing and make sure that PCORI is fulfilling its promise and its potential, and that's really the role that you all have now, is to make sure that it adheres to its mission, it adheres to its statutory authority as well because a lot of competing interests are going to want PCORI to be one thing or the other, and it's going to up to really the congressional staffers to make sure that PCORI stays on course, also obviously, Joe's responsibility, but to stay on course and to adhere very closely to what the statute intended for it.

Just one comment about patient centered. Joe had put on his slide that they have a working definition and they're asking for input on that definition, and I didn't send any comments on that. I don't interact with PCORI that way, but I do have a comment here just generally.

That patient centered isn't defined in the statute, and that's sort of kind of frustrating I know because patient centered is such a big focus and a big theme of the institute, and as staffers in the room
know, it's hard to foresee every question that's ever
going to be answered of any piece of legislation. It's
hard to write everything down.

So maybe if we had thought about it a little bit more we would have defined what patient centered
was, but it's not. So they're trying to figure out
what does that mean and how is it different from CER.

I think I'm very encouraged to hear that Joe
said that the overlap between patient centered and CER
is 100 percent because that was actually the intent.
And really the intent of patient centered, the reason
why we called it patient centered is because there's
many different dimensions of patient centered in PCORI.
So the patients are part of the board. That's one way
that PCORI is patient centered, and the research will
be patient centered, because they'll have a voice.

Another way is that PCORI is mandated to
provide funding to facilitate the participation of
patient groups. That's another way that PCORI is
patient centered.

Another way that PCORI is patient centered is
that it is supposed to disseminate findings that are understandable to patients. That's another dimension of patient centered. It's not that there is one particular definition of patient centered. What we meant was that in everything that it does, in its board, in the research questions that it asks and the findings that it produces and disseminates, that those should have patients in mind, and that's what we really intended by patient centered, was to have a very broad, you know, focus on patients and not just necessarily on the research questions themselves.

So with that, I will turn it over to you, Tony.

(Applause.)

MR. COELHO: As a former staffer, I love good staffers.

So next I'd like to introduce Marc Boutin. Marc is Executive Vice President and Chief Operating Officer of the National Health Council, and whenever you think of patients, you think of Marc. The National Health Council is well known by all of us who are
patients or work with patient groups as the one that you go to who represents our best interests.

The National Health Council is a one of a kind organization. It brings all segments of the health care community together to provide a united voice for more than 133 million people with chronic diseases or disabilities and their family caregivers together. It's made up of 100 national health related organizations. Its core membership includes 50 of the nation's leading patient advocacy groups, and as someone with epilepsy, it includes the National Epilepsy Foundation.

Marc builds a consensus among the patient advocacy groups enabling them to speak with one voice on systemic policy initiatives resulting in legislation and regulations that address the collective needs of patients and their family caregivers.

Marc.

MR. BOUTIN: Well, good afternoon, everybody.

PARTICIPANTS: Good afternoon.

MR. BOUTIN: Very low energy crowd. Come on.
Let's kind of see if we can amp it up a little bit.

Good afternoon, everybody.

PARTICIPANTS: Good afternoon.

MR. BOUTIN: Much better. Thank you.

I want to thank the coalition for inviting me, and I want to thank Tony in particular. I think many people know that he's done incredible things for people with disabilities and people with chronic conditions. So we thank you for all the work that you've done and all of the work that you continue to do.

Tony told you a little bit about the National Health Council. So I'm going to jump to three points that I would like to make that I think are incredibly important when you think of comparative effectiveness research and its impact on patients, and speak to the challenges that Joe and his staff and his board -- and I see one board member out there now -- will have to deal with over the next several years.

First is this. When we talk about patients, we often don't define what a patient is. At the National Health Council we have defined what patients
are. Patients for us are people with chronic disease
and disabilities. As Tony said, there are 133 million
of them. They're often confused with consumers and
with good reasons. Consumers and patients represent
opposite ends of the same spectrum.

A consumer is somebody who uses the health
care system when they need it, sometimes for acute
care, sometimes because they have hay fever. A person
with a chronic disease or disability is going to use
the health care system on an ongoing basis until they
die. It's a very different perspective.

And the information that they would like to
receive is very different. When you look at a
consumer, they're often looking for the least costly
alternative that's going to get the job done,
especially if you're looking for something like hay
fever. If you're looking at a person with a chronic
disease, somebody with a rare disorder like Alpha-1,
Parkinson's, MS, Alzheimer's, cancer, those people are
looking for the treatment that's going to get them to
what they want in terms of living a more normal life.
Their perspectives are very, very different.

And so having a focus on the patient is important, but we have to recognize that a consumer focus, while equally important, is very different.

The second point I'd like to make is the distinction between a patient and a patient organization, and I think this is critical because a patient looks at the health care system through the lense of where they are in their condition at that very moment. It isn't necessarily going to take a holistic view. It may, depending on the patient and depending on the stage of their disease.

But take, for example, somebody with Parkinson's, newly diagnosed. The symptoms tend to be quite mild, and they can often live for five to ten years without experiencing major implications as a result of the condition or major side effects as a result of the treatments. They can continue to live a fairly normal life.

But ten years out, the medications that they're taking, the condition that they have are now
impacting their ability to walk, ability to talk, their exhaustion levels, their ability to have a job, their ability to be as active within their family as they would like. Their perspective on the disease suddenly becomes very different.

The reason I raise that point is when you engage patients, you're looking at a snapshot of where they are as it relates to their condition. It's part of the reason why patient advocacy organizations are so important in this discussion. A patient advocacy organization doesn't look at the snapshot of a condition as it exists at any given point in time. They look at the life cycle of that condition. They look at it from the beginning to the end, from early diagnosis, actually even a step back from prevention to diagnosis to treatment, on to death. They look at it from different segments of the populations, different subpopulations. They're able to synthesize -- try that again -- all of that data and to provide a perspective that is more holistic. So having them at the table is critical.
Furthermore, when you look at a patient, and we've done research on this and it has been collaborated by many other organizations out there, and you ask them about comparative effectiveness research, their first reaction is, "Well, we already do that. We know the treatment we're getting is the best."

Completely inaccurate, but that's the perception of people with chronic conditions, and when they start to learn that, no, we're not really doing as much comparative effectiveness research as you would think and you may not be getting the best treatment for you, they start to become concerned. Well, I would like to have better information, but will that information be used to deny me access to the care that's most appropriate for me?

So there's a huge fear factor, and so as we start talking about how we're going to engage patients, you have to recognize that they don't understand where we are in the continuum of comparative effectiveness research. You have to teach them what it is, thus the myth that is already being conducted, and then overcome
the concern of how it might be used inappropriately. So there's a lot of challenges engaging patients. Patient advocacy organizations have dealt with these issues for decades, and so there will need to be a strong partnership moving that issue forward. The third issue really relates to what is important to people with chronic conditions, and I have a slide and I'm guessing it's going to come -- yes. This slide demonstrates from a patient perspective what is really important. What you see is the patient and care team at the center. They want the system to focus on them, and I can tell you currently the system rarely focuses on the patient. We have a lot of mis-incentives and a lot of what was done in health reform actually gives us an opportunity to start to correct many of those.

But the patient wants to have the best evidence with decision support not only for the patient, but for their provider and family caregivers at the point of care in real time, which again happens so seldomly (ph).
But perhaps most importantly, they want that information to be provided to them in the context of what is important to them. That requires a sophisticated comprehensive assessment of what's going on in that patient's life, which goes way beyond simply their health. And you need to be able to match what is best in terms of evidence with what that patient actually needs.

So an example I've used before, and I'll give it again, is -- and this is based on a true story -- a woman in her mid-50s. She's a single mom. She has two children, one in college, one in high school. She's employed. She has diabetes and multiple complications as a result of her diabetes. She's not being compliant with her health regimen, and it is the best evidence. If she does what she's being told or asked to do, she will have the best health outcomes possible, and she's not doing it.

And every time she goes in for a hospital or medical appointment, they scold her for not doing what's important. Well, nobody took the time to do a
comprehensive assessment of this woman. The reason
she's not being compliant is that her medical regimen
makes her drowsy and lightheaded, and she happens to be
a bus driver in a major transit system.

We don't want her to be compliant with that
regimen. We need to figure out what is best for her,
given the context of the fact that she needs to stay
employed. She needs to make sure that her child gets
through high school and her other child gets through
college.

The application of this research is
tremendously important. How you get that to the point
of care is incredibly difficult, and it's why I'm so
heartened to hear that some of the early research is
really focused in on identifying those methods. It's
going to be incredibly important to make sure that we
get the best information so that good decisions can be
made within the context of the individuals affected.

The last thing I will say is this, and it's
not directly related to comparative effectiveness
research, but it's incredibly important, and it's the
conversation we haven't had. Now, CER as it's charged
for PCORI is not to look at cost effectiveness,
although we know ultimately we're going to have to make
some tough decisions about care that's delivered, and
insuring the delivery of care meets the individual
needs of patients in the context that their life is
going to be really important.

We've got to look at reimbursement metrics.
They're going to encourage the development of new
treatments. We can't simply stop where we are. When
we ask people with chronic disease and disabilities,
they'll tell you two things. They want access,
meaningful access to what exists, and we have an
opportunity starting in 2014 to actually do that.

But they also want treatments to get better.
Nobody with a chronic disease or disability is
satisfied with the current state of treatments. We've
got to build into the systems metrics that allow
innovation to continue and allow us to fund the
development of new treatments that get better not only
to determine what is best out of what exists now, and
that's a push-pull that relates to comparative
effectiveness research that's incredibly important to
people with chronic conditions.

So like my predecessors, I look forward to the
Q&A. Thank you.

(Applause.)

MR. COELHO: I told you it would be
interesting. Now it's my pleasure to introduce Dr.
Allen Taylor. Allen is Director of Advanced Cardiac
Imaging at Washington Hospital Center and MedStar
Research Health Institute here in Washington. He's a
Board certified cardiologist and clinical researcher
specializing in cardiovascular imaging and prevention.

Dr. Taylor obtained his medical training at
Johns Hopkins University in Baltimore, followed by
internal medicine residency training at Walter Reed
Army Medical Center and cardiovascular disease
fellowship at the University of Virginia in
Charlottesville.

His work on national writing groups and task
forces include multi-society guidelines on cardiac CT
training, terminology and performance quality standards for imaging performance in radiation protection, appropriate use criteria for diagnostic testing, and national standards in cardiovascular disease management and prevention.

Dr. Taylor, please.

(Applause.)

DR. TAYLOR: Thank you, Mr. Coelho. It's a pleasure to be here.

I had a 20-year Army career actually, and I keep getting invited to these panels at the Reserve Officers Association. I'm starting to think my dues may not be paid up, and they're trying to catch me in the lobby as I pass through.

(Laughter.)

DR. TAYLOR: But I'm a clinical cardiologist, and so I think my role here is to kind of present the physician-patient view of this effort, and I do work in MedStar, which is a health care system, and it's a system evolving within this idea of health care reform and patient centeredness. So I hear these terms and
these themes every day.

I also work at the Research Institute where we try to innovate, and I have a teaching position at Georgetown and do that every day. So my role is pretty broad about trying just to bring health care along within systems and with the patients in mind.

So the scope of my clinical practice is I do detection and prevention. Are you at risk for heart disease? How are we going to treat that? And it spans all the way to working on the heart transplantation service, putting in $100,000 left ventricular assist devices like they're like that (snapping fingers), and that's a pretty broad span of practice, but that gives me a pretty good perspective on, you know, how we try to inhibit disease or prevent disease, and what happens when we don't at the far end where someone needs a heart transplant.

So I can really appreciate sort of the need to be broad in our thinking about patients. I do conduct comparative effectiveness research and have done so for quite a while, trying to compare interventions in...
clinical trials, and I conduct clinical trials and I conduct clinical trials on an ongoing basis, and I perform cost effectiveness analyses, and I know the strengths and the limitations of those.

And the context of all this work occurs both in NIH funded trials as well as in industry trials. So I can understand how there's lots of players doing research and how we all have to work together to kind of get information for patients.

And then I also serve as editor-in-chief for the Journal of Cardiovascular CT. So I'm involved in dissemination, getting the information and getting it out at least to physicians and clinicians so they can use it, and the dissemination piece is really important.

So I'm here representing actually the American College of Cardiology, however, and in your audience is also Jen Burnell (phonetic), if you want to raise your hand, Jennifer, who is one of the staffers from ACC, and Jim Visoulus (phonetic), who you may know is our photographer advocacy, and he would be here and he's
taller and more imposing than I am. So you're lucky you got me today.

But in fact, it's a 36,000 patient or 36,000 member organization, which spans primary care to advanced specialty care of cardiovascular disease, you know, the number one killer of Americans today. And it's highly involved in development of registries and guidelines, dissemination.

And if you can think about these professional organizations, they are the conduit to tens of millions of patients. A message goes to them. They partner with you and it goes out to all their patients simultaneously. So whereas we're talking about the patients, the professional societies which have patients and physicians at stake, and that's the patient centeredness that we're talking about here, they're a conduit for the success of these efforts.

So I have three rights to tell you about in patient-centered research, outcomes research. It's: what's the right question? What are the right methods? And what's the right way to disseminate the information
if we're going to be successful?

So let me give you some of my thoughts on those. The first is in terms of the right questions. I think physician and patient engagement here is incredible important. What's on your patient's mind? As you sit with a patient, they tell you what's on their minds, and when it comes to research, it's great to hear what do patients need to know. Where are the gaps in their thinking? Where are the gaps in their health that we need to solve?

And physicians, because they're the ones who have to implement it or at least partner in implementing it. So I think physicians and patients involved in the conversation are very important, which is why I really enjoy reading about in the PCORI language, and thanks, Shawn, is the issue of this conversation, this open dialogue on developing these questions, and in a moment I'll highlight a few, some of my concerns, more of my concerns about that.

And transparency is key, making sure we're getting the right question asked. We're far more
transparent now than we used to be. Things like clinicaltrials.gov, knowing what's going on out there is a huge advance. It was so resistant, but now it's so helpful in seeing what's going on so we don't have duplicate of efforts and we also know what to expect and when it will come out.

So that's the right question. How do we get it? I think we involve patients and physicians in the dialogue.

Right now the right question has come out of the hallowed grounds of NIH, and I'm not sure we're getting our money's worth. I'm going to tell you about that in a moment.

The second is what are the right methods, and I think that, you know, these are big issues, these public health issues. They have to be efficient in getting these questions. I think sometimes trials these day tend to be overdesigned and we don't necessarily get what we pay for, and you know, they have to be relevant in terms of the methods to complex patient populations.
It was mentioned previously about how every patient is unique. All of you in this room are unique. Everyone has got different conditions, and a trial tells you what the average patient does, but a trial can't tell you how it applied to the individual patients, and where this has to come down to to get this very broad information about complex patient populations is probably registries so you can survey the nation and find out how the nation gets its care through registries.

And currently registries are underdeveloped, and so one way professionals societies can help is, in fact, to develop the common terms and support those registries and get their members, the physicians, to input the data into the registries, get their members, the hospital systems, to develop the registries and participate in the registries so we can have the data to mine.

And in the end, we'll be able to answer these very complex questions on an increasingly complex patient base so that the answers we get apply to the
broad population. So, you know, I want to put a plug in for the right methods, and I think registries are an important way to do this.

Now, some questions have to be answered in the context of a clinical trial, that trial you hear about, that randomized, double blind, placebo controlled trial. They're necessary. They exist in the continuum of evidence.

But these days I'm not sure we're getting our -- we may not be getting our money's worth out of some of these trials. I can tell you the last billion dollars of NIH clinical trials in cardiovascular medicine have all been a flop, and the reason for that is because they're overdesigned and they are applied to narrow populations and, you know, they are coming out of the catacombs of NIH, and there's not that physician and patient engagement to make sure the right question is being done.

A bit of an editorial commentary, but I'm going to tell you that there's more confusion about those trial results than there's clarity, and no one
trial ever answers the question, and that's something
that's very clear. No one trial ever answers the
question, which is where until we have five trials all
with consistency do we really know, because trials can
be right and trials can be wrong because the design in
conducting them is so important.

So that's why I think registries are a big
foundation of what we do and tells us really what
applies and what doesn't apply in the real world.

And the last piece is the right dissemination,
and I think this is a huge problem. This is a huge
problem. Now, I read the journals. You guys read the
paper. What's in the paper is very rarely what's in
the journals. I'm quoted often in the paper. What I
say is often wrong in the paper. It's an amazing gap
in our translation, and I could give you example after
example.

But I think there's an important dissemination
piece which is missing. The professional societies are
here to help get that right message out, but making it
adjustable and relevant to patients is so important,
and getting the messaging right, and too often we're focusing on a headline.

I mean, physicians are even guilty of this, you know, this pantomiming the headline and not knowing the details, and the details do matter. So as we do this, we have to invest in dissemination just like we have to invest in the infrastructure to conduct the sort of broad, clinically relevant questions, and this is all within what PCPI is trying to do and what PCORI is trying to do.

So I think you can feel really good about these dissemination pieces, part of the effort here, because the best information locked in the journal somewhere is useless. The best information in a journal that gets out in the wrong way is damaging, and so making sure the communication is correct and the right people get it is incredibly important. So don't miss the communication piece. Communication in the end is the only way to make this effective.

And we need research on the best ways to disseminate. Maybe we shouldn't let the USA Today
publish anything about medicine because they always get it wrong.

(Laughter.)

DR. TAYLOR: The only thing I'll rely on USA Today for is the life section to know what pop star is in trouble, and they usually get that right. They get the medicine wrong. They get the dirt right.

Well, you know, I do a lot of traveling. I do a lot of speaking, and I usually start off with like this. I'm from Washington and I'm here to help. And that gets a huge laugh everywhere I go, but we are all from Washington, and we all are here to help, and I think this is one area we can feel really proud that this is going to help.

Right now we have 1.5 percent of our research budget globally going to CER. Ninety-eight, point, five percent is going in other directions. So we're under investing in CER, but we get a big return on a little investment if we do it right.

This is not about spooling up more big clinical trials at NIH to get narrow answers to
patients that don't existing in the real world. This is about finding ways to get practical, relevant information from real world data systems that are robust and get information out in a timely fashion in the right way, and it really is needed and it's going to work.

But I have four concerns. The first is regarding the current environment in health care financing and regulation. Hospitals and physicians are suffering, suffering greatly. Our hospital tries to make a one percent margin on a billion dollar a year of health care, and it can't do it. A loss to us is when it snows. The big snow storm put Washington Hospital Center in the red last year. That's all it took. That's the narrowness of the margin.

And hospitals say they can't invest. Our hospital can't invest because they think they're making tons of money, and they're really not. And if we're going to translate this to care, we have to be mindful of the people that are supposed to implement these things and let them invest and not just hit them with a
stick when they don't do the right thing, but provide

   enough of a carrot to do the right thing.

   The incentives right now to implement EHRs,
   for instance, are paltry. The pay for performance
   reimbursements are paltry. They are not making people
   saying, "Woo, woo, sign me up for that one percent
   bonus, that one percent bump for quality." It doesn't
   move the needle. It doesn't move. It doesn't move.

   And I think if we want to translate this to
care, we're going to have to be mindful of the folks
that will implement this and permit them to operate in
a less regulated, a better financed environment to do
it.

   The second is innovation, and we have to
really think about innovation. I don't think we with
CER are really talking that much about innovation.
We're talking more about getting return on investment
for the things we already know or the things that we
don't know how to compare.

   Innovation, maybe that's where innovation
belongs, is at the NIH, and the translation piece
belongs with PCORI, and I think that's really what's been missing.

Thirdly is the opportunities, and if 1.5 percent of research is going to CER, we need to amp up the opportunities. You know, there's not enough money out there for the right people to do this broadly, and we need to fund this, and I think the funding so far has been generous on a start-up basis. We need to continue to pump money.

And let's pump money into infrastructure, the things that pay off downstream, developing the registries, developing the data mining tools, developing the methodologies, that infrastructure.

So while the IOM would like to say, "Let's go after these five questions first," I'm thinking, "No, put the money in the infrastructure that will reap benefits over time. Put the money into research networks. Put the money into data networks. Put the money into hospital systems so they can get the data out, demonstrate their quality, demonstrate their comparative effectiveness."
And lastly, again, is the infrastructure investment I think is critically important. So I might have gone over my eight to ten minutes, but I was from Washington, and I was here to help, and I appreciate the time to talk to you.

(Applause.)

MR. COELHO: Thank you very much.

Before I get into some questions, I'd like to use my prerogative to introduce a patient advocate who is important to us all because she has a vote on the PCORI Board and she's here today, and I'd like to make sure that all of you know that Gail Hunt is with us today.

So, Gail, why don't you raise your hand and let everybody know you're here.

(Applause.)

MR. COELHO: We appreciate her advocacy on the Board because we are doing well on the Board. So we appreciate her advocacy.

Okay. We're going to now take a few moments to go into some questions of the panel, and then we'll
open up to questions from the audience. You have some
cards out on the table. So fill out the cards and
people will go around to collect the cards, and we'll
then ask those questions if you have any from the
table.

What I'd like to do is to ask the panel that
if you were to go two years out or three years out,
what would you say is the success for PCORI if you're
three years out. What would you claim is success?

Joe?

DR. SELBY: Well, I think first of all that it
would be very crystal clear to everyone that we have
changed the way research was done so that the research
that we funded, indeed, people would agree in this room
that it was truly informed by patients and clinicians
and other key stakeholders; that we had actually not
only done that, but we had written about and
disseminated the ways that it's done so that others
could do it. So that's number one.

Number two, that we'd have a portfolio that
you could look at and say those are critical questions,
and I can't wait for the answers because, you know, that's really the key.

We lament at NIH as we do the research and it takes 17 years for a practice to change. I think part of it is what Allen was saying, that the research wasn't quite as good as they maybe thought, wasn't quite as germane, quite as street ready as they thought, but the second is that there really are translation barriers, and there wasn't buy-in at the beginning.

If there's buy-in at the beginning, there should be people waiting around for the ninth inning when the results come out.

And third, that you know, the person on the street, the patient on the street has heard of PCORI. That would be a nice thing for two or three years out.

And maybe the last is that part of our mission to synthesize research that already exists. So I think it's realistic that some of the research we funded, some of the synthesis research, will be available and be being disseminated by us, and that's one of the
vehicles through which we will become known.

But as you know, research, good research, some
of which will even be clinical trials, I predict, does
take a while. So I think to be able to point to the
portfolio is probably more realistic than saying we
will have changed practice radically in three years.
That's a slightly longer term goal.

MR. COELHO: Shawn.

MS. BISHOP: I think I agree with what Joe is
saying. I think that for me three years is not a long
time. So it's hard to think about that time frame. I
guess I would hope that PCORI obviously is -- I'm still
operating.

(Laughter.)

MS. BISHOP: This is a tough environment. So
all of my eggs are into PCORI being around in three
years. That's my first thing.

But I think that I would like PCORI to have a
process established and in place that it would use to
prioritize research that makes sense to folks that
aren't necessarily researchers; that people on the
outside could say, "You know what? That's the kind of a process that we need in the United States, that we need as part of our health care system."

And I know that three years down the road, three years from these three years that we'll have research that matters so that people can look at it and say, "This is something that the process is something that I actually agree with."

And so that would be my hope.

MR. COELHO: Marc.

MR. BOUTIN: First, I agree with what's been said. I think the challenge here is in order to accomplish what I would hope for PCORI, it interplays with other issues that are to a large extent outside of PCORI's bailiwick. But first and perhaps foremost is an understanding of what it is, and by the "it," that is, why is comparative effectiveness research important to me as a patient, and when you look at issues like this, we tend to think of it in terms of the arc of public engagement, which really has three components.

One, you have to understand that a problem
exists. You have to have a meaningful solution to solve that problem, and it has to be important to the stakeholder groups involved.

The challenge in the patient community as I alluded to earlier is that we don't recognize that there's a problem. Interestingly enough, the solution could potentially be incredibly helpful, and it's incredibly salient.

So you have to focus where the weak link is, and that is we need to make sure people understand that there's a problem. When they're given care, they're not necessarily given the best care for them, and that "ah-ha" moment is going to take us tremendously forward.

But it has to also be in the context of good delivery systems. It has to be in the context of access to care. It has to be in the context of developing new and better treatments. So parts of this are outside of PCORI's control, but certainly part of their early work can help us to frame the problem, address the solution raise the salience and start to
really engage patients in the delivery of their own
care.

MR. COELHO: Allen.

DR. TAYLOR: Yeah, I think three years is a
short time horizon, you know. You can't even get a
trial conceived, written, funded and started in three
years.

MR. COELHO: The reason I chose three years,
as everybody knows --

DR. TAYLOR: Right.

MR. COELHO: -- three years, that's an
election. It's probably a new Congress, and I think
that Shawn answered it correctly.

DR. TAYLOR: Yeah, I think three years --

(Laughter.)

DR. TAYLOR: Three years is relevant though I
think. In three years what could you expect? I think
if you wanted to try to go to your bosses in three
years and say, "Here's what we've done. Here's why we
need to continue to invest in PCORI," it's because
you've laid the groundwork with the foundation of
infrastructure, a foundation of methods, and a mindset that this is the way forward, and that we can't come to them with a few small wins where we got ROI. We can say we've got an infrastructure. We're ready to go for the long haul.

Because this is a long haul issue. We're getting older. We're getting sicker. Healthier is getting more expensive. We've got to get some -- if we're going to have a return on investment down range, it's going to come from these early investments.

So let's say in three years we've invested. We've got an infrastructure. We've got methods. We have a process. We have public investment, and we've got dissemination methods set up so that when these information become available, they're going to make a difference, and I think in three years that's achievable.

MR. COELHO: It was brought up about transparency. There have been some struggles in regards to transparency. Some people question it. The issue is what progress do you think, Joe, we've made on
transparency, and for the rest of the panel, how do you feel about it?

DR. SELBY: In fact, if you could just clarify, do you mean with respect to PCORI?

MR. COELHO: Yeah, to PCORI.

DR. SELBY: Okay. Well, I think that it's a principle that the Board completely subscribes to, and the efforts include open Board meetings complete with, you know, the stored Webcasts of those meetings so that you can look at them after the fact, a Website that solicits input across a variety of issues.

I would say that it's, you know, one of our most closely held goals. I think to be transparent we also have to succeed in getting the world to look at us, and that might be -

MR. COELHO: A task.

DR. SELBY: -- even more challenging, yeah.

MR. COELHO: Allen, Shawn?

DR. TAYLOR: Yeah, I have a comment on this. I think to understand this issue of transparency, I think there's been immense transparency already. So
congratulations. I mean, just these sorts of discussions and the sort of public commentaries and listening, sounding boards and so forth have been tremendously transparent. I think transparency will pay off.

I wanted to maybe put a challenge to Joe for an additional opportunity for transparency, which actually is needed, and this is the issue of analysis registration.

Right now we have clinicaltrials.gov, and so when we do an efficacy trial, that is, does something work or doesn't it work, you have to register your trial on clinicaltrials.gov. Journals won't even take your paper if you haven't registered your trial. That's a tremendous step in transparency to say, "Okay. We knew you were doing it. Now, where are the results?"

Now, the problem is with CER we don't have that transparency, and that's a piece of transparency which questions, you know, "Look. I'm guilty here."

You doing an analysis doesn't look very good or doesn't
work out very well and you say, "Oh, well. So much for that idea. On to the next thing."

And we need analysis registration for PCORI to have a Website, to have people to register their analyses, just like clinicaltrials.gov for CER so we know what analyses have been attempted. We know what initiatives are being funded.

Right now clinicaltrials.gov helps register efficacy trials. Does something work? Does something not work? The difference is effectiveness. Effectiveness is very, very, very different. Does it work in the real world, and we have to know what's been tested in the real world and what hasn't been tested, and it's a simple step of transparency to not just vet these ideas, but then post them so that we've got a list and we know what's going on out there. We have control, and that's a good -- in Washington, that wins a lot of votes. We have control of the situation.

And so I think that that would be a place where PCORI could get a handle on what's going on and be the clearing house for this sort of CER work because
clearly PCORI won't be the only place the CER is done, but it can be the place that the standards, these methods and so forth are put in a public forum that goes way beyond PCORI's borders and looks over this because I think a lot of people are trying to do this in other contexts.

So I think that's a challenge to broaden the transparency, which has already been in place and to take it to the next level.

I saw a lot of people writing. So that's called the Taylor Rule.

MR. COELHO: Marc or Shawn?

MR. BOUTIN: Yeah, just a slightly different take, not that I disagree with that comment at all. Transparency from the patient advocacy community really is focused in on decision making, and I think there's a lot of anxiety over what will the research agenda be, and I've shared this with staff before PCORI, but I think it may have predated you, Joe. So I'll take the opportunity now.

Being the Chief Operating Officer of an
association where the 120 member organization, several
of which are international, many of them have
affiliates in every state. They're very interested in
what we do in public policy, and they want to make sure
that they have input into it and they need to
understand it, and it requires a level of transparency
in decision making that's incredibly important, and
it's too early to expect that PCORI would have this in
place now, but it's not too early to expect that PCORI
would create this, and that is to have a structure
where obviously we know the Board is ultimately going
to be responsible for policy making. You have the
Methodology Committee and its role, but where are the
points of engagement on an annual basis? Where are
those points of engagement? When will they happen?
How will the forms of engagement be? Will it be in
person, electronic, letters, what have you? What is
the expected impact of that engagement?

So you can imagine almost a structure where
you've got the Board methodology, you've got the staff,
you've got the different stakeholders; when can they
engage? And then define that on an annual basis so that we know exactly where those points are. We know what and how we can engage, and we know what to expect from it, not necessarily that it will ultimately be the decision, but we know it will inform the decision. Staff can take it to the next level, and it goes through.

With that kind of process transparency and decision making, anxiety can go down tremendously, and I use by way of example because this has not existed, and again, it couldn't exist yet because it's too new. About nine months ago there was an eruption of turmoil with a number of stakeholders that PCORI was about to announce its research agenda, which is completely false, but there was no structured approach to really understand that.

So I think it helps with managing expectations and it gives you a very clear point of connection.

MR. COELHO: Go ahead, Shawn.

MS. BISHOP: I'll try to be brief here.

I fully agree with what Marc just said. I
think those are excellent comments, and I want to use what he said as a way to sort of clarify my comment about process because I think that process could mean different things depending on who's listening to it.

What I mean that PCORI -- and I mentioned about hopefully you'll have a process in place within three years that people understand and that people can believe in and say, "This is what we think is going to work."

And when I mean process, I mean more what Marc is talking about. I don't mean a scientific process of comparing priorities on a list. That's not what I'm talking about. I'm talking about the public process, the actual process that they will use to create their priorities and engage with the public, and I mean public meetings, public forums, advisory. They need to set up their structure. The Board is just the decision making body, but the structure of the institute is what I'm talking about, and that's going to create their process.

And I think you're absolutely right. Process
is what's going to -- is actually very much related to transparency. It creates expectation. It gives people the understanding of how it works, and I think that's going to be very, very important.

By process I mean how is PCORI going to actually structure itself. Now, the statute isn't prescriptive necessarily on exactly how it's going to do it, and we wanted to give them flexibility because there are so many different ways of communicating and engaging, and we wanted them to be open to any of those possibilities, but it has a very strong mandate for transparency in the statute. The meetings have to be public. They have to conduct public forums. They have the ability to do advisory committees. Their research findings have to talk about the cannot be withheld. Anything that PCORI finds must be published.

This is not the kind of research like you said that if it doesn't look good; it doesn't matter. It's going to be out there. This is publicly funded, and the findings are going to be there.

So there are a lot of transparencies, a theme
in the statute, and I hope that PCORI takes very
seriously. I know that they already do, but in terms
of I couldn't agree with you more Marc in terms of
creating a process that is understood and acceptable is
what PCORI's mission is in its first couple of years.
It's trying to create itself through that, quote,
process of engagement.

MR. COELHO: Joe, you talked about the patient
officer and then you talked about the advisory groups.
Could you give us an idea when this staff position
might be created?

You said you were going to do it. I think you
even put out a notice for people to submit application,
but do you have any idea when you might be making a
decision on that and probably the other two positions
as well?

But on the Advisory Committees, what do you
intend to do with those? Give us a little more
description on what the purpose of those might be and
when you intend to create those, a little more flesh on
those if you can.
DR. SELBY: Well, first, I'm glad you gave me the opportunity to say that the positions, the Director of Patient Engagement and the Director of Stakeholder Engagement and Communications, are all three posted right now.

MR. COELHO: Right.

DR. SELBY: So it's still open. So it strikes me that there are people in this room who may well know people who would be good candidates for each of those positions. Please encourage them to go to the Website and apply.

I am hopeful that we would be able to announce who these directors were well before the end of the year. So you know, we're going to keep it open for a while, and then there's just the process of getting the selected person on board. But I think before the end of the year is very realistic.

As you know, the statute encourages us to have advisory groups, particularly when we begin to fund a bit of research. If we conduct research on rare diseases, we are to have an advisory board that focuses
on rare diseases. Similarly, if we start funding clinical trials, we need an advisory board on clinical trials. We anticipate that we will convene a number of advisory groups. Some of them will be short term. They'll have a specific mission. We need a product. We need a group of patients or a mixed group of patients and providers and possibly other stakeholders to address a particular topic.

One of the places you'll see advisory groups in early 2012 is related to the work of the Methodology Committee. They want advisory groups on aspects of the methods that go into the report.

I think you will see some of the first advisory groups, and there's a sense, of course, that you're making things up as you go along. You know, every darn thing you do is a first. This is the first time I've ever been in this building.

(Laughter.)

DR. SELBY: And we will be doing a lot of stakeholder engagement in the next two to three months. When I talk to you, if I talk to you, on December 1st,
I'd be able to point to the first Advisory Committee meetings around the national priorities, but that's about what I can say at this point, Tony, that they are on the immediate horizon, and I think they'll be convened by us for a range of reasons.

One of the line items in the job description for the Director of Patient Engagement and the Director of Stakeholder Engagement is the convening of advisory panels. So that work will fall, you know, first to them.

MR. COELHO: Any comments by any other panelists on that?

(No response.)

MR. COELHO: I should just tell everybody at PIPC we're starting a position roundtables where we're going to be involved with physicians in getting their viewpoint because in my view the relationship between physicians and patients is critical, and I think that's what the law basically was talking about, and I feel very strongly that those two components are critical to making this whole thing work.
So we're going to be pursuing that as we move forward.

One of the things that --

DR. SELBY: Tony.

MR. COELHO: Yes.

DR. SELBY: Can I just say that PCORI shares that view completely?

MR. COELHO: Great.

DR. SELBY: We strongly feel the same way.

MR. COELHO: We'll keep you informed as we keep moving on.

One of the things that was heavily discussed in the establishment of the legislation and has been avoided periodically by folks that don't want it raised, and then was raised lately, and, Joe, I'd like you to comment on it, and, Shawn, I'd like you to comment on it as well, is that PCORI used the word "value," and then the Center for Medical Technology Policy applauded you for using the word "value" and suggested that that meant that you should consider cost.
And then the American Medical Association wrote in and said that the interpretation of value included the definition of should not consider cost at all, and you then commented on it later, and you made some comments and basically said that if you're considering whether or not a year of life saved between 40 and 50 or a year of life saved between 80 and 90, we should stay away from that. That's not what we're all about.

But if you're looking at saving between the number of days spent in a hospital or something like that, that is of value, that we should look at that.

Can you discuss that a little bit? That is obviously something that is of great concern to those of us with disabilities, in particular, in most patients, and I'd like to have Shawn comment on it as well.

DR. SELBY: Sure. You know, if you read the legislation, the explicit language in the legislation says that we will not -- it actually says that CMS will not use measures such as cost per quality adjusted life.
year saved so the basic metric of most cost
effectiveness analyses to make decisions about
coverage, and I think you could easily say from there
that PCORI shouldn't engage in that kind of research,
although it doesn't quite say that.

I couldn't agree more. PCORI couldn't agree
more. PCORI has no interest or intentions to ever fund
a cost effectiveness study. Cost effectiveness is very
sensitive to, among other things, some subjective
measures of value or so-called utility, and cost
effectiveness is also really susceptible to changes in
cost, which can sometimes happen overnight.

So it's really more a matter of policy making,
which PCORI doesn't do, than it is of research, which
PCORI does do. So you can take it to the bank that
PCORI will never ever do a cost effectiveness analysis.

Now, the phrase "cost analyses" is an
extraordinarily loose term, and it's used by people.
Some people suggest that PCORI should never do anything
that could be called a cost analysis. As I said, that
term means absolutely nothing. But if it did, I'll
give you an example of something that one could consider a cost analysis, and you tell me if this is a patient-centered piece of research.

The patient that Marc was talking about, the bus driver who had diabetes and complications has been getting her insurance from Metro, from the public tran -- I take it every day, but I don't know the name. It says Metro on the bus, right? No, from Circulator, they get it from Circulator, and suddenly in 2012 Circulator decides to change the driver's insurance so that she now had a high deductible product and she has, you know, three to $5,000 worth of deductible before she gets a payment, and it's going to be that way now for the rest of her life.

Well, you tell me whether or not that change in the way her health care is covered might be considered a patient-centered outcome. Might that affect her ability to get her medications and take them? Might that affect adherence? Might that affect clinical outcomes?

I'd say it might. This is not a part of
PCORI'S policy at this point. This will be hammered out over the next few months and over the next few years, and it will be hammered out with patients in the room in a fully transparent manner. We'll see what patients say patient-centered outcomes are, and we'll pursue them.

MR. COELHO: Shawn.

MS. BISHOP: Okay. Put me on the spot, but I know Joe was on the spot, too, here. This is a complicated issue because it's controversial, and the research, as Joe was mentioning, is complicated, too. It is not a straightforward type of research.

We talked about this issue a lot in crafting the legislation. This was something that was very much discussed, and there's a lot of different views on this, and as Joe said, the legislation has a prohibition on QALYs, the quality adjusted life years.

What it doesn't have, the legislation does not have, it doesn't have an explicit prohibition on cost analysis. It doesn't have that. It's like why would we do that. Well, it's because the way we defined, we
decided to take kind of the positive view of legislating to say, well, we're going to define what PCORI does, and in defining what PCORI does, that implies what PCORI doesn't do.

And then the issues around quality adjusted life years were so intense and they were so controversial that we had to put a prohibition in there, and believe, in the five years that I worked on this legislation, we were asked every single meeting that we had about this legislation, and we talked to everybody, "Please put a prohibition for this. Please put a prohibition for that."

And if you look at the language, we didn't do any of that. We stayed away from that because the whole thing was going to be fraught with can't do this, can't do that. You know, we just didn't want to go down that path.

But we did put the quality adjusted life years in there because we wanted to signal like that is definitely not, but why didn't we put something on cost effectiveness or cost analysis? It's because we wanted
to define it in the positive sense, like I said, but also there is a way in which PCORI could fund a study that maybe is looking at new and old treatments. It could be looking at something relatively new in a cardiology setting. That field is evolving all the time versus something that's relatively old and maybe cheaper.

And if we had had a prohibition that said you cannot do cost, could they have been prohibited from doing the study like that? Maybe, because somebody could have maybe taken that language and used it in a way that wasn't intended, and that's one of the reasons why we didn't put a strict prohibition.

But I'll tell you honestly we weren't trying to be too clever, you know, for our own good by not putting the cost effectiveness prohibition there. The statute does not authorize PCORI to do cost analysis. The way that the research is defined, it's clinical comparative effectiveness, and the outcomes are health related.

So in other words, looking at doing value
based benefit design, looking at whether or not, you know, high co-pays for an insurance leads to better clinical outcomes, the clinical outcomes is what's important. Now, doing cost analysis, that's different. That's not cost analysis in my view, even though it's broadly defined. That to me is appropriate for PCORI if down the road there is relevance for looking at value based benefit designs.

I think that there's a lot more research that can be done on treatments, you know, out of the gate, but that's for PCORI to decide. That's for the Board to decide, but in terms of looking at cost analysis, it's not intended for the outcomes that PCORI is looking at to be cost related. It's intended for them to be clinical and health related even if, even if the research community and even if -- and I don't want to be, you know, too controversial here in this crowd -- even if the patients, even if the patients want cost analysis to be part if PCORI, it's not authorized in this context.

Those comments by Sean Tunis, Dr. Tunis, whom
I know and admire very much, about the fact that PCORI should be doing that is a valid comment. Everybody is entitled to their opinion, and there's lots of opinions about PCORI, and that's what Joe and the Board are going to have to weigh through constantly.

    People are going to want it to be this or that, but the statute is going to have to decide what PCORI -- the context and circumscribe really the scope of PCORI, and it's not authorized by the statute to do cost analysis.

    MR. COELHO: Joe?

    DR. SELBY: Yeah, I think your comment, Shawn, just a point you made I think is really important, which is that costs and clinical outcomes are often intertwined in ways that you just can't separate them. Co-insurance and cost sharing is one way.

    Another way though is a new treatment. Let's say a new imaging treatment in cardiology on its face may look like it costs more, which a patient might be concerned about. If, in fact, it replaced two or three older style imaging studies down the road and actually
also maybe it had not a difference on other clinical outcomes, but it simply replaced those other forms of utilization, I mean, that drives innovation. That is important to patients.

So that's why I think the phrase "cost analysis" doesn't mean much, and I think when people stop to think about it, they will see things that clearly are not authorized in the legislation and other things that patients really need to know the answers to.

DR. TAYLOR: Having done these, they're completely useless. Clinicians never change what they do based on a cost effectiveness analysis, and you can get whatever answer you want. Tell me what you want. Tell me what answer you want, and I can build the assumptions into it and get that answer.

And if you're the society or payer or the patient, your perspective on what is and isn't cost effective is completely different. Sudden death is a completely cost effective outcome from the standpoint of the payer.
(Laughter.)

DR. TAYLOR: You didn't get admitted to the hospital. You cost me no money. Good job.

(Laughter.)

DR. TAYLOR: Okay? And it's a bad societal outcome. It's an even worse patient outcome.

So I think we have to be really careful about cost. You are though, Joe, going to have to show some value for your program, and having said that, what is value as a clinician? To me value is to say my health system now uses Treatment X versus Treatment Y or Approach A versus Approach B more now than they used to since we now know it's more effective.

And my registries, my health system data demonstrate that change in practice. So we can look at how much we're spending globally, and that's the big doll; that's the big cost. We just have to know we're getting value, and that's that we're applying the things we learn that we know improve effectiveness on a broader scale.

And you're going to have to look for partial
wins here. It's not going to be all or none. You're not going to get 100 percent translation, but that translation piece becomes pretty important and measuring how effectively we translate it is what we're going to have to do to show because you're not going to be able to show that we improved cost effectiveness across the spectrum of care, and if you did, you'd be showing it from a perspective which other people would completely disagree with and you'd just have a fight on your hands.

DR. SELBY: I certainly didn't mean to suggest that we'd be doing cost effectiveness analyses, but there are analyses that look at resource use downstream --

DR. TAYLOR: That's the right --

DR. SELBY: -- that don't have anything to do with cost effectiveness.

DR. TAYLOR: That's the right way to do it.

DR. SELBY: That's what I meant.

MR. COELHO: Okay. A lot of the questions that were submitted were answered prior, I assume, to
your writing the questions. I have a couple more
questions and then we'll wrap up.

One of the things that was discussed was the
research that is done. Can it be put together in a way
that doctors can understand it and patients can
understand it and then disseminate it in a way that it
can reach the people that need to get it, and that when
it gets there they can do something with it?

So, Joe, the question is: is that something
that you folks are looking into? Can we expect
something to come out of PCORI's result there?

DR. SELBY: Yeah, definitely you remember the
first slide I showed where the original vision included
the dissemination of findings of information, both ours
and others. How we do that is under intense discussion
within the PCORI Board and staff.

Now, as you know, in the legislation a portion
of the money that goes to the PCORI trust fund goes
actually directly to AHRQ, and AHRQ is charged with
dissemination.

MR. COELHO: We know that.
DR. SELBY: So we are -- that's what I said.

As you know -- we go from there to a discussion as you also know. We are fortunate to have the heads of both AHRQ and NIH on our governing board as active members of our governing board, and I actually think that that's hopeful in the sense of, you know, seeing more comparative effectiveness research art NIH, but with respect to dissemination we're now engaged in a discussion with Carolyn Clancy from AHRQ and with Board members about what will PCORI do by way of dissemination.

I think there is no doubt we'll fund research on dissemination, how you do dissemination. How much dissemination PCORI does itself is, I would say, at this point a matter under discussion. It kind of depends on what AHRQ does with its funds, and what PCORI's Board judges that to be.

I think in concert with Carolyn from AHRQ we will ask the question of whether PCORI would dedicate some of its resources beyond that 16 percent to dissemination or whether there are ways that we can
work with AHRQ to, you know, plan the expenditure of
those 16 percent.

MR. COELHO: I often say to the disgust of
AHRQ and NIH that a lot of this, based on conversations
I have with doctors as a patient and as an advocate,
that a lot of doctors say that they get this
information from the ivory towers. They can't
understand it, and they don't know how to explain it to
the patients.

And it seems to me, based on the legislation,
legislation is basically asking you to look into that.

Now, Shawn, is that correct?

MS. BISHOP: On the spot again, and I think
that everything that I've heard Joe say today speaks to
this. I think that the question that you're asking,
Tony, is about how to make -- is this research going to
be usable --

MR. COELHO: Yeah.

MS. BISHOP: -- for clinicians at the point of
care and at patients when they're trying to make a
decision?
And that's the challenge of PCORI, and I think that the hope maybe if we could go back to that question, it's like the hope is that everything that it's trying to do, the way that it's structuring itself, it's going to be creating information that's usable.

Dissemination is important, and you can have very keen ways of disseminating, very technical information and technical findings, but if the findings aren't usable at the point of care when they're making the decision, that was our intent. That's what we had always had in mind, and I think that that's what PCORI is going to try to do, is make the questions structured in a way that the answers are saying as a clinician I need to know this when I'm making a decision.

DR. TAYLOR: This has already been occurring, and let me just let you know. I mean, we've been doing this for decades now, and they're called clinical guidelines and other things, and the professional societies organize this and put these out, hundreds of guidelines just in the ACC alone about how to perform
best care.

Now, what we need is more evidence that informs those guidelines, and so I would rely on the professional societies to collate, you know, to write these guidelines, to then vet them to their members.

I heard about the NIH. That just scares me about them doing comparative effectiveness research because they're about efficacy, and they can't design a clinical pragmatic trial that is relevant enough to the real world within the constraints of randomized clinical trials and all the controls you have to put in to get an answer in the end, and that's where the failures have come.

So I am putting it out there that I think there's efficacy. There's efficacy and there's innovation within those walls of NIH, and there's effectiveness in the real world of pragmatism, which is what we've been lacking and which is where PCORI comes in. So that's where I think there's a clear difference.

And if we're all trying -- we're going to
overlap efforts. We're going to try to compete.

There's going to be competing questions, and I just think that PCORI just needs to take on the CER question and let NIH innovate. Let NIH, you know, establish efficacy, but not establish effectiveness. They can't do it. I'm telling you they can't do effectiveness. They're not able to do pragmatic work well enough, and we've seen that over the last decade.

I hope nobody is here from the NIH now.

(Laughter.)

DR. TAYLOR: No, if you are, I mean, I think that that's become evident. There's too much variability in the real world, and you can't get the broad enough relevant questions amongst the chronically ill patients with all those disease conditions to really make it relevant to people.

MR. COELHO: All right.

MR. BOUTIN: Could I just make a quick point?

MR. COELHO: Go ahead, Marc.

MR. BOUTIN: Usability at point of care, that's been the mantra of the patient community for the
last six years, and so I love hearing that here, but I also just want to make the point that it's contextual, which is why this is so difficult and why it will require research on how best to disseminate information so that it is, in fact, usable at the point of care.

But I also have to remind ourselves that comparative effectiveness research is not a panacea. It's one component that impacts your decision making in a larger, health care ecosystem that from a patient perspective goes beyond the health care ecosystem. It goes to your family. It goes to your community. It goes to your workplace.

So usability of point of care is a tough, tough issue, but it's something where we've seen advances that have had tremendous improvements. So there's a real opportunity here, but it's a challenge, and I would encourage us to think of when we disseminate this information that it be imbedded in other pieces of information.

In other words, we see all the time the FDA comes to the patient community and says, "We've got a
safety risk on this medicine," or this diagnostic or
this device. "Will you tell your community?"

Well, no, we're not going to tell our
community about a one isolated issue. We'll put it
into the context of messages about safety that are
holistic. That's how our patients will engage with
that information and make it usable.

So just disseminating pure CER information in
isolation is probably not going to work, but if it's
disseminated contextually and we do the research to
figure out what works well, I think we have some real
opportunity.

MR. COELHO: Thank you very much.

I'd like to just thank all our panelists and
Joe for their presentations today. I'd like to
summarize by saying that I thought this was an
excellent presentation. I appreciate Marc for a lot of
his comments. I particularly appreciate him drawing
the distinction between patient, patient groups, and
consumers. I've never heard it so distinctly put
before. I think that is something that we need to be
reminded of periodically, and I think it's good for Joe
to hear it as well and for PCORI to understand it.

I thought it was good for Shawn to remind us
of why the legislation was drafted, how it ended up
being and to remind us that it's nice to dream of what
you want, but the legislation is the legislation, and
if you want to do something else, you should go back
and try to rewrite it. Good luck.

(Laughter.)

MR. COELHO: And I appreciate Allen's
perspective on from the doctor's point of view of what
they need to have in order to provide the best health
care for those of us who are patients.

I appreciate Joe and his leadership in
bringing PCORI to reality. This is something that we
in the patient community have wanted for a long time,
being able to get PCORI up and going and running and
having his leadership to make it a reality is an
extremely positive step for all of us. We appreciate
his leadership. We particularly appreciate his being
here today and sharing his views with us.
So thank you all for coming and participating.

Thank you.

(Applause.)

(Whereupon, the forum was concluded.)

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