



1           SECOND ANNUAL ACHIEVING PATIENT-CENTEREDNESS

2           IN CER FORUM

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5           The Reserve Officers Association

6           One Constitution Avenue, N.E.

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## P R O C E E D I N G S

3 MR. COELHO: Good afternoon, everyone. If  
4 everyone will take their seats, we'll go ahead and  
5 begin so we can end on time.

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

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

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

15 We've all made a lot of progress since our  
16 event with Senator Baucus last summer. The Board of  
17 Governors of the Patient-Centered Outcomes Research  
18 Institute was named and started meeting last November.  
19 PCORI is in the process of establishing a definition of  
20 patient-centered outcomes research and started work on  
21 setting research priorities.

1                   No less important than all of that, they had  
2   the good fortune of convincing Dr. Joe Selby to join  
3   them as the institute's Executive Director. Joe, we're  
4   honored that you could join us today and look forward  
5   to hearing from you and having a dialogue with you.

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

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

20                  Many of us representing patients and people  
21   with disabilities feel very positive about the initial

1 steps that have been taken. We're also looking to  
2 these to get translated into concrete PCORI policy. We  
3 appreciate the progress that has been made, and we're  
4 looking forward for the progress to continue.

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

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

21 I'm even more pleased that PCORI found an

1 Executive Director so eminently qualified to put his  
2 gold standard into practice. Indeed, some have  
3 suggested that the only high mark against him is that  
4 he agreed to take this job.

5 (Laughter.)

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

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

20 (Applause.)

21 DR. SELBY: Thank you, everybody. Really you

1 don't have to worry about me. Everywhere I go people  
2 ask me, "Well, how are you doing? Are you hanging in  
3 there?" as if, you know, this really was a short-term  
4 death sentence.

5 You know, it has been totally enjoyable.

6 There's a little bit of stress. There's a lot of  
7 excitement. The excitement sort of makes up for the  
8 stress, and two months and a week into it, things are  
9 going very well.

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

19 So we don't have a research agenda yet, as  
20 you'll see. So we are not funding comparative  
21 effectiveness research yet, but this funding is to

1 build up the methods for doing patient-centered  
2 comparative effectiveness research. So if you go to  
3 our Website, you'll see the announcement. There's  
4 eight different areas of interest, and they all focus  
5 on different aspects of how we actually do engage  
6 patients and other stakeholders in every aspect of the  
7 research process. We're not talking about patient-  
8 centered care. We're talking about patient-centered  
9 research. That's number one.

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

19 Number three is that I'm here. I'm very  
20 excited. This is where we've been talking a lot about  
21 engaging patients, and this is one of the biggest

1 groups of patient representatives that I've spoken with  
2 thus far, and I'm here basically to talk to you about  
3 ways to make that happen intensely, particularly over  
4 the next few months.

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

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

20 And that is that the first thing PCORI does is  
21 engages patients to understand the choices that

1 patients face. That engagement and the information  
2 that PCORI gets from that engagement is what drives our  
3 research, and the research, we aim to align the  
4 research that we fund and the methods that we use with  
5 the needs that are expressed so that our research  
6 answers practical questions, practical questions that  
7 patients and their clinicians face day in and day out.

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

14 And the third is that when we get the  
15 findings, we don't sit on them. We're not satisfied  
16 with publishing in the *New England Journal*. We invest  
17 in dissemination in partnership with the Agency for  
18 Health Care Research and Quality. WE disseminate so  
19 that we can provide this information, and I'm not  
20 saying just the information PCORI funds, but good,  
21 practical, relevant information in general to patients

1 and providers so they have it at the point where  
2 they're making their decisions.

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

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

14 So Tony mentioned the definition of patient-  
15 centered outcomes research. There was not a  
16 satisfactory, widely accepted definition when the  
17 institute was named or when the board was brought  
18 together. So this is a definition developed by the  
19 Methodology Committee of PCORI, and again, the bolded  
20 part expresses this unique perspective that PCOR,  
21 patient-centered outcomes research, is research that

1 allows patients' voices to be heard as we assess the  
2 value of health care options.

3 They go on to say that this research answers  
4 four patient-focused questions. Number one, given who  
5 I am, my personal characteristics, conditions and  
6 preferences, what should I expect will happen to me?

7 In other words, prediction, prediction for people with  
8 no conditions; prediction for people once they get a  
9 condition; prediction for people perhaps if they have a  
10 complication.

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

16 Number two, what are my options? And there  
17 you can read treatment options, and what are the  
18 benefits and harms of those options?

19 Number three, what can I do to improve the  
20 outcomes that are most important to me? What can I do?  
21 So there the emphasis is on the word "I." We're

1 talking about behaviors and other preventive measures  
2 and self-management measures the patients can take.  
3 Which ones work particularly to get the outcomes that  
4 I'm most interested on?

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

7 So this is our working definition. We say  
8 working because we did put it on the Website. We got  
9 600-plus responses on the Website. I believe those 600  
10 responses are now posted on the Website. But the other  
11 thing we did is we actually did our very first RFP. So  
12 the first funded research, the first research that we  
13 funded was an RFP to solicit a group of researchers to  
14 take that input and synthesize it, to cull through it,  
15 to look for the common themes, to pull out questions  
16 and common themes and concerns, and I'm fully expecting  
17 that we're going to find that this definition did not  
18 make everyone happy.

19 This qualitative research will pull out the  
20 common themes and send them back to the Methodology  
Committee. The Methodology Committee will work to

1   revise the definition, and that definition will be  
2   taken out again to patient focus groups and other for  
3   a, all done by the end of this year, to see how the  
4   revised definition of patient-centered outcomes  
5   research sits with patients.

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

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

18                Tony used the phrase Chief Patient Officer,  
19   and that is the phrase that came up in July at our  
20   board meeting. We did change it to Director of Patient  
21   Engagement, but a working group on patient engagement

1 was formed. That group created a job description for  
2 that Director.

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

13 Those three people together we consider our  
14 external relations arm. We actually had those job  
15 descriptions up before our first scientist description  
16 was up, and it just emphasizes that, indeed, PCORI  
17 takes engagement very seriously, that we're very  
18 interested in fortifying and building the  
19 infrastructure for that front end of getting input on  
20 what research questions are important, what research we  
21 should fund.

1                   The Methodology Committee, as you know, the  
2   GAO didn't just appoint a governing board. They also  
3   appointed a separate Methodology Committee. We're  
4   working in close relationship. The Methodology  
5   Committee has to produce a methodology report, which is  
6   the standards for doing patient-centered comparative  
7   effectiveness research, and it's due in May. So  
8   they've got a huge burden. There's 16 of them.  
9   They're very conscious of the amount of work they've  
10   got to do. This is supposedly going to set national  
11   standards.

12                  They see it as an iterative process. Version  
13   1 will take a stab at it. They see they're a standing  
14   committee. They see themselves continuing to work to  
15   be the source of good methodology for doing this  
16   research. But you'll notice that they divided  
17   themselves quickly into three groups, and one of them  
18   was patient centeredness.

19                  The Patient Centeredness Working Group is  
20   going to write the section of the methodology report  
21   that covers the standards for methods related to

1 incorporating the patient perspective into all aspects  
2 of patient-centered outcomes research. So even our  
3 methodology report talks about the methods for getting  
4 patients involved in research.

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

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

21 So you see the next two things we funded also

1 had to do with the patient centered part of patient-  
2 centered outcomes research.

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

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

15                  The third one is about evaluating patient-  
16 centered approaches for assessing patient preferences  
17 for various outcomes, including the use of decision  
18 support tools' shared decision making. And, again,  
19 this is not particularly to address a specific CER  
20 question. These are not CER studies. These are  
21 methods that will inform and make CER studies better

1 once we get the research agenda done.

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

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

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

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

19 And now I want to get on to the notion of the  
20 national priorities. This is critically important, and  
21 it's really our central work over the next four months.

1     The reason it's central is because we can't really get  
2     started funding what legislation calls our primary  
3     research until we've elaborated a set of national  
4     research priorities from a patient perspective.

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

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

17                So the first thing we did was, in fact, to  
18    develop a candidate framework of priorities that came  
19    from all of this previous work. So that's going to be  
20    our starting point. That work is well underway right  
21    now.

1                 The next phase, which is on the brink of  
2 beginning and will go through at least November,  
3 possibly somewhat into December, is engaging  
4 stakeholders. So engaging patients, engaging patient  
5 organizations, engaging clinicians and the other  
6 stakeholders I've mentioned to help us put a patient-  
7 centered voice on our priorities to make certain that  
8 we've got the right priorities, to make sure we've got  
9 the priorities prioritized, if you will, ranked.

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

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

20               This is the work we've done to date. Down the  
21 left-hand column, I hope you can read that. Down the

1 left-hand column are the previously priority generating  
2 efforts from the IOMs to the federal coordinating  
3 committees, AHRQs, the National Quality Forum, the  
4 National Prevention Council, and Priorities  
5 Partnership.

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

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

21 So those are ten we're now calling them

1 candidate priorities that emerged from our assessment  
2 of the work that's gone on over the last few years, the  
3 prioritizations of others.

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

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

20               The second one is the probability that funding  
21 for research in this area could lead to improvement.

1 So some may just have more potential, maybe lower  
2 hanging fruit in terms of a little bit of research or a  
3 lot of research would really make a difference.

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

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

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

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

21 The next is that the research has the

1 potential to influence decision-making at the patient  
2 point of view.

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

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

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

17 In the end, we'll come out with a revised set  
18 of priorities, and these aren't our guesses as to what  
19 they'll be. These are simple examples that they may be  
20 cast in different language. They may be expressed more  
21 from the patient's point of view, but we'll have a set

1    of priorities that have been through this sieve, if you  
2    will, this framework of applying criteria to a set of  
3    candidates.

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

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

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

17               In the spirit of making the input  
18   representative, we will use a variety of methods.  
19   You'll see us conducting focus groups. You'll see us  
20   showing up in meetings like this with an exercise to go  
21   through, with a framework to go through. You'll see a

1 survey very likely. You'll see opportunities for input  
2 on our Website, and you'll probably see us doing some  
3 sort of social media outreach by way of crowd sourcing.  
4 Different ways: bottom-up ways, top-down ways to hone  
5 in on the perspectives of patients and other  
6 stakeholders as to what's important in these  
7 priorities.

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

19 Part of our mission is about prevention, and  
20 so the general public not at the moment considering  
21 themselves patients are also stakeholders.

1                   And in professional organizations -- or other  
2 stakeholders I'd call that -- we're talking about  
3 practicing providers, health systems, employers, other  
4 payers, that is, insurers, the research community,  
5 government at the federal, state and local level,  
6 Congress, and of course, industry. All of those are  
7 key stakeholders, and we intend to keep all engaged in  
8 the process of setting priorities and conducting the  
9 research.

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

14                  So will PCOR be CER? I'm here to tell you  
15 that I've concluded that PCOR essentially is almost 100  
16 percent overlapped with CER. As I suggested, there may  
17 be a very small amount of patient-centered outcomes  
18 research that a purist would not call comparative  
19 effectiveness research, but it will be research that  
20 supports patient decisions, and I think that our  
21 emphasis on engaging patients in this research is going

1 to help insure that it really is CER, and by that I  
2 mean that this emphasis on engaging patients and having  
3 a true patient focus will help make sure that the  
4 questions, indeed, are practical or pragmatic, and I  
5 think they will usually be comparative, as I said.

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

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

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

20 So with that I'll close and turn it back to  
21 you, Tony. Thank you very much.

1                             (Applause.)

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

5                             MR. COELHO: Thank you, Joe.

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

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

16                            She was prior to that a principal analyst at  
17                            the Congressional Budget Office. She developed models  
18                            to estimate the cost of legislative proposals related  
19                            to Medicare private plans and competition. She worked  
20                            in federal health payment policy at the Centers for  
21                            Medicare and Medicaid Services, and she worked at the

1      Prospective Payment Assessment Commission, which is now  
2      MEDPAC, and she was in the private sector at  
3      Pricewaterhouse.

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

9                (Laughter.)

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

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

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

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

21               As you know, if there are staffers in the

1 room, what that feels like to write legislation and  
2 it's so abstract, and then to have it be something that  
3 becomes concrete and is actually going to help people.  
4 So it's really an honor to be able to be here and to  
5 see this come to fruition.

6 I want to say a couple things about Joe. One  
7 of the things that we thought a lot about when we were  
8 writing the legislation was who's going to run this  
9 place, and you can't put, you know, anybody's name in a  
10 statute or you can't put a job description, but you  
11 want to because you know that we know especially with  
12 the first time executive director that that person is  
13 really going to create the culture of the institute and  
14 it's going to really drive sort of, you know, the long-  
15 term vision, and we really sat around the table when we  
16 were writing the legislation and thought about who this  
17 person would be, and I couldn't be more pleased that  
18 they had the insight to hire somebody like Joe because  
19 his integrity with the research community is so high  
20 and he's very diplomatic because his job is going to be  
21 obviously to bridge the research community and be the

1 diplomat for PCORI and to try to, you know, balance all  
2 of the different voices that are not only on the board,  
3 but the voices that want to be heard through this  
4 institute, and he's going to be the person who is going  
5 to try to balance all that out, and he has the right,  
6 you know, diplomatic skills to do that. So anyway,  
7 we're really fortunate to have him as the first  
8 Executive Director.

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

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

21 And as a staffer, I mean, you couldn't be more

1 happy to be able to do something that would, you know,  
2 help the health care delivery system of the United  
3 States. Senator Baucus said start with a blank piece  
4 of paper and do what's right, do what's best.

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

14 And why did we want to do that in the context  
15 of all the other issues that we were working on in the  
16 Senate Finance Committee? It's because the other  
17 activities of the committee overseeing Medicare and  
18 Medicaid, really I think Senator Baucus, the chairman,  
19 he really saw his role kind of beyond that, really to  
20 improving the health care delivery system at large;  
21 that we were going to be putting in new concepts, if

1 you will, into the public programs and hopefully into  
2 the private sector that really try to encourage the use  
3 of evidence-based medicine to improve the quality of  
4 care in the United States.

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

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

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

1 reform and health care reform.

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

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

15 None of those seemed to fit kind of what we  
16 thought was going to be appropriate here. So we  
17 decided to create a nonprofit entity that is, as Joe  
18 was saying, that is overseen by a stakeholder board,  
19 and that's because the research needed to be something  
20 that obviously had balance, that it wasn't going to be  
21 from one perspective; it wasn't going to be from the

1 researcher's perspective or from the payer's  
2 perspective; that everybody's voice needed to be heard.

3 So we decided to put the stakeholder in charge  
4 of the institute, to oversee and to basically be the  
5 ones that -- the board members are going to be the ones  
6 to decide what the priorities are for the institute.  
7 That's their major charge, and of course, Joe is going  
8 to run the institute and provide all of the staffing  
9 for that, but the board is going to make the priorities  
10 and set the research agenda.

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

21 Beginning in 2013, the funds are going to be

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

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

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

1      input from stakeholder groups.

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

12              You know, PCORI, since it is so new and, you  
13     know, it's sort of a unique structure, it's going to,  
14     you know, need oversight by Congress as the staffers in  
15     the room know; that once Congress sets, you know, a new  
16     law, that it's also its responsibility constitutionally  
17     to oversee that law. And so all of the folks in the  
18     room here, not just the staffers in the room, but also  
19     the groups that care about this, it's your  
20     responsibility now that the law is written, now that  
21     PCORI actually exists, it's real, is to keep involved

1   in what PCORI is doing and make sure that PCORI is  
2   fulfilling its promise and its potential, and that's  
3   really the role that you all have now, is to make sure  
4   that it adheres to its mission, it adheres to its  
5   statutory authority as well because a lot of competing  
6   interests are going to want PCORI to be one thing or  
7   the other, and it's going to up to really the  
8   congressional staffers to make sure that PCORI stays on  
9   course, also obviously, Joe's responsibility, but to  
10   stay on course and to adhere very closely to what the  
11   statute intended for it.

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

18                   That patient centered isn't defined in the  
19   statute, and that's sort of kind of frustrating I know  
20   because patient centered is such a big focus and a big  
21   theme of the institute, and as staffers in the room

1 know, it's hard to foresee every question that's ever  
2 going to be answered of any piece of legislation. It's  
3 hard to write everything down.

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

8 I think I'm very encouraged to hear that Joe  
9 said that the overlap between patient centered and CER  
10 is 100 percent because that was actually the intent.

11 And really the intent of patient centered, the reason  
12 why we called it patient centered is because there's  
13 many different dimensions of patient centered in PCORI.  
14 So the patients are part of the board. That's one way  
15 that PCORI is patient centered, and the research will  
16 be patient centered, because they'll have a voice.

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

21 Another way that PCORI is patient centered is

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

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

14 (Applause.)

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

17 So next I'd like to introduce Marc Boutin.  
18 Marc is Executive Vice President and Chief Operating  
19 Officer of the National Health Council, and whenever  
20 you think of patients, you think of Marc. The National  
21 Health Council is well known by all of us who are

1 patients or work with patient groups as the one that  
2 you go to who represents our best interests.

3 The National Health Council is a one of a kind  
4 organization. It brings all segments of the health  
5 care community together to provide a united voice for  
6 more than 133 million people with chronic diseases or  
7 disabilities and their family caregivers together.

8 It's made up of 100 national health related  
9 organizations. Its core membership includes 50 of the  
10 nation's leading patient advocacy groups, and as  
11 someone with epilepsy, it includes the National  
12 Epilepsy Foundation.

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

18 Marc.

19 MR. BOUTIN: Well, good afternoon, everybody.

20 PARTICIPANTS: Good afternoon.

21 MR. BOUTIN: Very low energy crowd. Come on.

1 Let's kind of see if we can amp it up a little bit.

2 Good afternoon, everybody.

3 PARTICIPANTS: Good afternoon.

4 MR. BOUTIN: Much better. Thank you.

5 I want to thank the coalition for inviting me,

6 and I want to thank Tony in particular. I think many

7 people know that he's done incredible things for people

8 with disabilities and people with chronic conditions.

9 So we thank you for all the work that you've done and

10 all of the work that you continue to do.

11 Tony told you a little bit about the National

12 Health Council. So I'm going to jump to three points

13 that I would like to make that I think are incredibly

14 important when you think of comparative effectiveness

15 research and its impact on patients, and speak to the

16 challenges that Joe and his staff and his board -- and

17 I see one board member out there now -- will have to

18 deal with over the next several years.

19 First is this. When we talk about patients,

20 we often don't define what a patient is. At the

21 National Health Council we have defined what patients

1 are. Patients for us are people with chronic disease  
2 and disabilities. As Tony said, there are 133 million  
3 of them. They're often confused with consumers and  
4 with good reasons. Consumers and patients represent  
5 opposite ends of the same spectrum.

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

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

1        Their perspectives are very, very different.

2                And so having a focus on the patient is

3        important, but we have to recognize that a consumer

4        focus, while equally important, is very different.

5                The second point I'd like to make is the

6        distinction between a patient and a patient

7        organization, and I think this is critical because a

8        patient looks at the health care system through the

9        lens of where they are in their condition at that very

10      moment. It isn't necessarily going to take a holistic

11      view. It may, depending on the patient and depending

12      on the stage of their disease.

13                But take, for example, somebody with

14      Parkinson's, newly diagnosed. The symptoms tend to be

15      quite mild, and they can often live for five to ten

16      years without experiencing major implications as a

17      result of the condition or major side effects as a

18      result of the treatments. They can continue to live a

19      fairly normal life.

20                But ten years out, the medications that

21      they're taking, the condition that they have are now

1 impacting their ability to walk, ability to talk, their  
2 exhaustion levels, their ability to have a job, their  
3 ability to be as active within their family as they  
4 would like. Their perspective on the disease suddenly  
5 becomes very different.

6                 The reason I raise that point is when you  
7 engage patients, you're looking at a snapshot of where  
8 they are as it relates to their condition. It's part  
9 of the reason why patient advocacy organizations are so  
10 important in this discussion. A patient advocacy  
11 organization doesn't look at the snapshot of a  
12 condition as it exists at any given point in time.

13 They look at the life cycle of that condition. They  
14 look at it from the beginning to the end, from early  
15 diagnosis, actually even a step back from prevention to  
16 diagnosis to treatment, on to death. They look at it  
17 from different segments of the populations, different  
18 subpopulations. They're able to synthesize -- try that  
19 again -- all of that data and to provide a perspective  
20 that is more holistic. So having them at the table is  
21 critical.

1                   Furthermore, when you look at a patient, and  
2   we've done research on this and it has been  
3   collaborated by many other organizations out there, and  
4   you ask them about comparative effectiveness research,  
5   their first reaction is, "Well, we already do that. We  
6   know the treatment we're getting is the best."

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

16                  So there's a huge fear factor, and so as we  
17   start talking about how we're going to engage patients,  
18   you have to recognize that they don't understand where  
19   we are in the continuum of comparative effectiveness  
20   research. You have to teach them what it is, thus the  
21   myth that is already being conducted, and then overcome

1 the concern of how it might be used inappropriately.

2 So there's a lot of challenges engaging  
3 patients. Patient advocacy organizations have dealt  
4 with these issues for decades, and so there will need  
5 to be a strong partnership moving that issue forward.

6 The third issue really relates to what is  
7 important to people with chronic conditions, and I have  
8 a slide and I'm guessing it's going to come -- yes.

9 This slide demonstrates from a patient perspective what  
10 is really important. What you see is the patient and  
11 care team at the center. They want the system to focus  
12 on them, and I can tell you currently the system rarely  
13 focuses on the patient. We have a lot of mis-  
14 incentives and a lot of what was done in health reform  
15 actually gives us an opportunity to start to correct  
16 many of those.

17 But the patient wants to have the best  
18 evidence with decision support not only for the  
19 patient, but for their provider and family caregivers  
20 at the point of care in real time, which again happens  
21 so seldomly (ph).

1                   But perhaps most importantly, they want that  
2 information to be provided to them in the context of  
3 what is important to them. That requires a  
4 sophisticated comprehensive assessment of what's going  
5 on in that patient's life, which goes way beyond simply  
6 their health. And you need to be able to match what is  
7 best in terms of evidence with what that patient  
8 actually needs.

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

19                   And every time she goes in for a hospital or  
20 medical appointment, they scold her for not doing  
21 what's important. Well, nobody took the time to do a

1 comprehensive assessment of this woman. The reason  
2 she's not being compliant is that her medical regimen  
3 makes her drowsy and lightheaded, and she happens to be  
4 a bus driver in a major transit system.

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

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

19 The last thing I will say is this, and it's  
20 not directly related to comparative effectiveness  
21 research, but it's incredibly important, and it's the

1 conversation we haven't had. Now, CER as it's charged  
2 for PCORI is not to look at cost effectiveness,  
3 although we know ultimately we're going to have to make  
4 some tough decisions about care that's delivered, and  
5 insuring the delivery of care meets the individual  
6 needs of patients in the context that their life is  
7 going to be really important.

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

15 But they also want treatments to get better.  
16 Nobody with a chronic disease or disability is  
17 satisfied with the current state of treatments. We've  
18 got to build into the systems metrics that allow  
19 innovation to continue and allow us to fund the  
20 development of new treatments that get better not only  
21 to determine what is best out of what exists now, and

1 that's a push-pull that relates to comparative  
2 effectiveness research that's incredibly important to  
3 people with chronic conditions.

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

6 (Applause.)

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

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

20 His work on national writing groups and task  
21 forces include multi-society guidelines on cardiac CT

1 training, terminology and performance quality standards  
2 for imaging performance in radiation protection,  
3 appropriate use criteria for diagnostic testing, and  
4 national standards in cardiovascular disease management  
5 and prevention.

6 Dr. Taylor, please.

7 (Applause.)

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

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

15 (Laughter.)

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

1 these themes every day.

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

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

18 So I can really appreciate sort of the need to  
19 be broad in our thinking about patients. I do conduct  
20 comparative effectiveness research and have done so for  
21 quite a while, trying to compare interventions in

1 clinical trials, and I conduct clinical trials and I  
2 conduct clinical trials on an ongoing basis, and I  
3 perform cost effectiveness analyses, and I know the  
4 strengths and the limitations of those.

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

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

16 So I'm here representing actually the American  
17 College of Cardiology, however, and in your audience is  
18 also Jen Burnell (phonetic), if you want to raise your  
19 hand, Jennifer, who is one of the staffers from ACC,  
20 and Jim Visoulus (phonetic), who you may know is our  
21 photographer advocacy, and he would be here and he's

1 taller and more imposing than I am. So you're lucky  
2 you got me today.

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

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

18 So I have three rights to tell you about in  
19 patient-centered research, outcomes research. It's:  
20 what's the right question? What are the right methods?  
21 And what's the right way to disseminate the information

1 if we're going to be successful?

2 So let me give you some of my thoughts on  
3 those. The first is in terms of the right questions.

4 I think physician and patient engagement here is  
5 incredible important. What's on your patient's mind?

6 As you sit with a patient, they tell you what's on  
7 their minds, and when it comes to research, it's great  
8 to hear what do patients need to know. Where are the  
9 gaps in their thinking? Where are the gaps in their  
10 health that we need to solve?

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

20 And transparency is key, making sure we're  
21 getting the right question asked. We're far more

1 transparent now than we used to be. Things like  
2 clinicaltrials.gov, knowing what's going on out there  
3 is a huge advance. It was so resistant, but now it's  
4 so helpful in seeing what's going on so we don't have  
5 duplicate of efforts and we also know what to expect  
6 and when it will come out.

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

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

14 The second is what are the right methods, and  
15 I think that, you know, these are big issues, these  
16 public health issues. They have to be efficient in  
17 getting these questions. I think sometimes trials  
18 these day tend to be overdesigned and we don't  
19 necessarily get what we pay for, and you know, they  
20 have to be relevant in terms of the methods to complex  
21 patient populations.

1               It was mentioned previously about how every  
2 patient is unique. All of you in this room are unique.  
3 Everyone has got different conditions, and a trial  
4 tells you what the average patient does, but a trial  
5 can't tell you how it applied to the individual  
6 patients, and where this has to come down to to get  
7 this very broad information about complex patient  
8 populations is probably registries so you can survey  
9 the nation and find out how the nation gets its care  
10 through registries.

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

19               And in the end, we'll be able to answer these  
20 very complex questions on an increasingly complex  
21 patient base so that the answers we get apply to the

1 broad population. So, you know, I want to put a plug  
2 in for the right methods, and I think registries are an  
3 important way to do this.

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

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

19 A bit of an editorial commentary, but I'm  
20 going to tell you that there's more confusion about  
21 those trial results than there's clarity, and no one

1 trial ever answers the question, and that's something  
2 that's very clear. No one trial ever answers the  
3 question, which is where until we have five trials all  
4 with consistency do we really know, because trials can  
5 be right and trials can be wrong because the design in  
6 conducting them is so important.

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

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

18 But I think there's an important dissemination  
19 piece which is missing. The professional societies are  
20 here to help get that right message out, but making it  
21 adjustable and relevant to patients is so important,

1 and getting the messaging right, and too often we're  
2 focusing on a headline.

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

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

20 And we need research on the best ways to  
21 disseminate. Maybe we shouldn't let the *USA Today*

1 publish anything about medicine because they always get  
2 it wrong.

3 (Laughter.)

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

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

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

20 This is not about spooling up more big  
21 clinical trials at NIH to get narrow answers to

1 patients that don't existing in the real world. This  
2 is about finding ways to get practical, relevant  
3 information from real world data systems that are  
4 robust and get information out in a timely fashion in  
5 the right way, and it really is needed and it's going  
6 to work.

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

16 And hospitals say they can't invest. Our  
17 hospital can't invest because they think they're making  
18 tons of money, and they're really not. And if we're  
19 going to translate this to care, we have to be mindful  
20 of the people that are supposed to implement these  
21 things and let them invest and not just hit them with a

1 stick when they don't do the right thing, but provide  
2 enough of a carrot to do the right thing.

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

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

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

20 Innovation, maybe that's where innovation  
21 belongs, is at the NIH, and the translation piece

1 belongs with PCORI, and I think that's really what's  
2 been missing.

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

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

14 So while the IOM would like to say, "Let's go  
15 after these five questions first," I'm thinking, "No,  
16 put the money in the infrastructure that will reap  
17 benefits over time. Put the money into research  
18 networks. Put the money into data networks. Put the  
19 money into hospital systems so they can get the data  
20 out, demonstrate their quality, demonstrate their  
21 comparative effectiveness."

1                   And lastly, again, is the infrastructure  
2   investment I think is critically important. So I might  
3   have gone over my eight to ten minutes, but I was from  
4   Washington, and I was here to help, and I appreciate  
5   the time to talk to you.

6                   (APPLAUSE.)

7                   MR. COELHO: Thank you very much.

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

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

16                  (APPLAUSE.)

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

20                  Okay. We're going to now take a few moments  
21   to go into some questions of the panel, and then we'll

1 open up to questions from the audience. You have some  
2 cards out on the table. So fill out the cards and  
3 people will go around to collect the cards, and we'll  
4 then ask those questions if you have any from the  
5 table.

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

10 Joe?

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

20 Number two, that we'd have a portfolio that  
21 you could look at and say those are critical questions,

1 and I can't wait for the answers because, you know,  
2 that's really the key.

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

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

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

17 And maybe the last is that part of our mission  
18 to synthesize research that already exists. So I think  
19 it's realistic that some of the research we funded,  
20 some of the synthesis research, will be available and  
21 be being disseminated by us, and that's one of the

1        vehicles through which we will become known.

2                  But as you know, research, good research, some  
3        of which will even be clinical trials, I predict, does  
4        take a while. So I think to be able to point to the  
5        portfolio is probably more realistic than saying we  
6        will have changed practice radically in three years.

7        That's a slightly longer term goal.

8                  MR. COELHO: Shawn.

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

14                  (Laughter.)

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

18                  But I think that I would like PCORI to have a  
19        process established and in place that it would use to  
20        prioritize research that makes sense to folks that  
21        aren't necessarily researchers; that people on the

1 outside could say, "You know what? That's the kind of  
2 a process that we need in the United States, that we  
3 need as part of our health care system."

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

9 And so that would be my hope.

10 MR. COELHO: Marc.

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

21 One, you have to understand that a problem

1 exists. You have to have a meaningful solution to  
2 solve that problem, and it has to be important to the  
3 stakeholder groups involved.

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

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

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

1 really engage patients in the delivery of their own  
2 care.

3 MR. COELHO: Allen.

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

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

10 DR. TAYLOR: Right.

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

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

15 (Laughter.)

16 DR. TAYLOR: Three years is relevant though I  
17 think. In three years what could you expect? I think  
18 if you wanted to try to go to your bosses in three  
19 years and say, "Here's what we've done. Here's why we  
20 need to continue to invest in PCORI," it's because  
21 you've laid the groundwork with the foundation of

1 infrastructure, a foundation of methods, and a mindset  
2 that this is the way forward, and that we can't come to  
3 them with a few small wins where we got ROI. We can  
4 say we've got an infrastructure. We're ready to go for  
5 the long haul.

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

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

18 MR. COELHO: It was brought up about  
19 transparency. There have been some struggles in  
20 regards to transparency. Some people question it. The  
21 issue is what progress do you think, Joe, we've made on

1 transparency, and for the rest of the panel, how do you  
2 feel about it?

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

5 MR. COELHO: Yeah, to PCORI.

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

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

16 MR. COELHO: A task.

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

18 MR. COELHO: Allen, Shawn?

19 DR. TAYLOR: Yeah, I have a comment on this.  
20 I think to understand this issue of transparency, I  
21 think there's been immense transparency already. So

1 congratulations. I mean, just these sorts of  
2 discussions and the sort of public commentaries and  
3 listening, sounding boards and so forth have been  
4 tremendously transparent. I think transparency will  
5 pay off.

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

10 Right now we have clinicaltrials.gov, and so  
11 when we do an efficacy trial, that is, does something  
12 work or doesn't it work, you have to register your  
13 trial on clinicaltrials.gov. Journals won't even take  
14 your paper if you haven't registered your trial.

15 That's a tremendous step in transparency to say, "Okay.  
16 We knew you were doing it. Now, where are the  
17 results?"

18 Now, the problem is with CER we don't have  
19 that transparency, and that's a piece of transparency  
20 which questions, you know, "Look. I'm guilty here."  
21 You doing an analysis doesn't look very good or doesn't

1 work out very well and you say, "Oh, well. So much for  
2 that idea. On to the next thing."

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

8 Right now clinicaltrials.gov helps register  
9 efficacy trials. Does something work? Does something  
10 not work? The difference is effectiveness.

11 Effectiveness is very, very, very different. Does it  
12 work in the real world, and we have to know what's been  
13 tested in the real world and what hasn't been tested,  
14 and it's a simple step of transparency to not just vet  
15 these ideas, but then post them so that we've got a  
16 list and we know what's going on out there. We have  
17 control, and that's a good -- in Washington, that wins  
18 a lot of votes. We have control of the situation.

19 And so I think that that would be a place  
20 where PCORI could get a handle on what's going on and  
21 be the clearing house for this sort of CER work because

1 clearly PCORI won't be the only place the CER is done,  
2 but it can be the place that the standards, these  
3 methods and so forth are put in a public forum that  
4 goes way beyond PCORI's borders and looks over this  
5 because I think a lot of people are trying to do this  
6 in other contexts.

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

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

12 MR. COELHO: Marc or Shawn?

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

21 Being the Chief Operating Officer of an

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

19 So you can imagine almost a structure where  
20 you've got the Board methodology, you've got the staff,  
21 you've got the different stakeholders; when can they

1 engage? And then define that on an annual basis so  
2 that we know exactly where those points are. We know  
3 what and how we can engage, and we know what to expect  
4 from it, not necessarily that it will ultimately be the  
5 decision, but we know it will inform the decision.  
6 Staff can take it to the next level, and it goes  
7 through.

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

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

19 MR. COELHO: Go ahead, Shawn.

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

21 I fully agree with what Marc just said. I

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

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

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

21 And I think you're absolutely right. Process

1 is what's going to -- is actually very much related to  
2 transparency. It creates expectation. It gives people  
3 the understanding of how it works, and I think that's  
4 going to be very, very important.

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

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

21                 So there are a lot of transparencies, a theme

1       in the statute, and I hope that PCORI takes very  
2       seriously. I know that they already do, but in terms  
3       of I couldn't agree with you more Marc in terms of  
4       creating a process that is understood and acceptable is  
5       what PCORI's mission is in its first couple of years.  
6       It's trying to create itself through that, quote,  
7       process of engagement.

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

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

17                  But on the Advisory Committees, what do you  
18     intend to do with those? Give us a little more  
19     description on what the purpose of those might be and  
20     when you intend to create those, a little more flesh on  
21     those if you can.

1 DR. SELBY: Well, first, I'm glad you gave me  
2 the opportunity to say that the positions, the Director  
3 of Patient Engagement and the Director of Stakeholder  
4 Engagement and Communications, are all three posted  
5 right now.

6 MR. COELHO: Right.

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

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

18 As you know, the statute encourages us to have  
19 advisory groups, particularly when we begin to fund a  
20 bit of research. If we conduct research on rare  
21 diseases, we are to have an advisory board that focuses

1 on rare diseases. Similarly, if we start funding  
2 clinical trials, we need an advisory board on clinical  
3 trials. We anticipate that we will convene a number of  
4 advisory groups. Some of them will be short term.  
5 They'll have a specific mission. We need a product.  
6 We need a group of patients or a mixed group of  
7 patients and providers and possibly other stakeholders  
8 to address a particular topic.

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

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

18 (Laughter.)

19 DR. SELBY: And we will be doing a lot of  
20 stakeholder engagement in the next two to three months.  
21 When I talk to you, if I talk to you, on December 1st,

1 I'd be able to point to the first Advisory Committee  
2 meetings around the national priorities, but that's  
3 about what I can say at this point, Tony, that they are  
4 on the immediate horizon, and I think they'll be  
5 convened by us for a range of reasons.

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

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

13 (No response.)

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

1                   So we're going to be pursuing that as we move  
2 forward.

3                   One of the things that --

4                   DR. SELBY: Tony.

5                   MR. COELHO: Yes.

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

8                   MR. COELHO: Great.

9                   DR. SELBY: We strongly feel the same way.

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

12                  One of the things that was heavily discussed  
13 in the establishment of the legislation and has been  
14 avoided periodically by folks that don't want it  
15 raised, and then was raised lately, and, Joe, I'd like  
16 you to comment on it, and, Shawn, I'd like you to  
17 comment on it as well, is that PCORI used the word  
18 "value," and then the Center for Medical Technology  
19 Policy applauded you for using the word "value" and  
20 suggested that that meant that you should consider  
21 cost.

1                   And then the American Medical Association  
2                   wrote in and said that the interpretation of value  
3                   included the definition of should not consider cost at  
4                   all, and you then commented on it later, and you made  
5                   some comments and basically said that if you're  
6                   considering whether or not a year of life saved between  
7                   40 and 50 or a year of life saved between 80 and 90, we  
8                   should stay away from that. That's not what we're all  
9                   about.

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

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

18                  DR. SELBY: Sure. You know, if you read the  
19                  legislation, the explicit language in the legislation  
20                  says that we will not -- it actually says that CMS will  
21                  not use measures such as cost per quality adjusted life

1 year saved so the basic metric of most cost  
2 effectiveness analyses to make decisions about  
3 coverage, and I think you could easily say from there  
4 that PCORI shouldn't engage in that kind of research,  
5 although it doesn't quite say that.

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

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

17 Now, the phrase "cost analyses" is an  
18 extraordinarily loose term, and it's used by people.  
19 Some people suggest that PCORI should never do anything  
20 that could be called a cost analysis. As I said, that  
21 term means absolutely nothing. But if it did, I'll

1 give you an example of something that one could  
2 consider a cost analysis, and you tell me if this is a  
3 patient-centered piece of research.

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

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

21 I'd say it might. This is not a part of

1 PCORI'S policy at this point. This will be hammered  
2 out over the next few months and over the next few  
3 years, and it will be hammered out with patients in the  
4 room in a fully transparent manner. We'll see what  
5 patients say patient-centered outcomes are, and we'll  
6 pursue them.

7 MR. COELHO: Shawn.

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

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

18 What it doesn't have, the legislation does not  
19 have, it doesn't have an explicit prohibition on cost  
20 analysis. It doesn't have that. It's like why would  
21 we do that. Well, it's because the way we defined, we

1 decided to take kind of the positive view of  
2 legislating to say, well, we're going to define what  
3 PCORI does, and in defining what PCORI does, that  
4 implies what PCORI doesn't do.

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

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

18 But we did put the quality adjusted life years  
19 in there because we wanted to signal like that is  
20 definitely not, but why didn't we put something on cost  
21 effectiveness or cost analysis? It's because we wanted

1 to define it in the positive sense, like I said, but  
2 also there is a way in which PCORI could fund a study  
3 that maybe is looking at new and old treatments. It  
4 could be looking at something relatively new in a  
5 cardiology setting. That field is evolving all the  
6 time versus something that's relatively old and maybe  
7 cheaper.

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

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

21 So in other words, looking at doing value

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

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

21 Those comments by Sean Tunis, Dr. Tunis, whom

1 I know and admire very much, about the fact that PCORI  
2 should be doing that is a valid comment. Everybody is  
3 entitled to their opinion, and there's lots of opinions  
4 about PCORI, and that's what Joe and the Board are  
5 going to have to weigh through constantly.

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

11 MR. COELHO: Joe?

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

17 Another way though is a new treatment. Let's  
18 say a new imaging treatment in cardiology on its face  
19 may look like it costs more, which a patient might be  
20 concerned about. If, in fact, it replaced two or three  
21 older style imaging studies down the road and actually

1 also maybe it had not a difference on other clinical  
2 outcomes, but it simply replaced those other forms of  
3 utilization, I mean, that drives innovation. That is  
4 important to patients.

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

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

17 And if you're the society or payer or the  
18 patient, your perspective on what is and isn't cost  
19 effective is completely different. Sudden death is a  
20 completely cost effective outcome from the standpoint  
21 of the payer.

1                   (Laughter.)

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

4                   (Laughter.)

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

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

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

21                  And you're going to have to look for partial

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

11 DR. SELBY: I certainly didn't mean to suggest  
12 that we'd be doing cost effectiveness analyses, but  
13 there are analyses that look at resource use downstream  
14 --

15 DR. TAYLOR: That's the right --

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

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

19 DR. SELBY: That's what I meant.

20 MR. COELHO: Okay. A lot of the questions  
21 that were submitted were answered prior, I assume, to

1 your writing the questions. I have a couple more  
2 questions and then we'll wrap up.

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

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

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

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

21 MR. COELHO: We know that.

1 DR. SELBY: So we are -- that's what I said.  
2 As you know -- we go from there to a discussion as you  
3 also know. We are fortunate to have the heads of both  
4 AHRQ and NIH on our governing board as active members  
5 of our governing board, and I actually think that  
6 that's hopeful in the sense of, you know, seeing more  
7 comparative effectiveness research at NIH, but with  
8 respect to dissemination we're now engaged in a  
9 discussion with Carolyn Clancy from AHRQ and with Board  
10 members about what will PCORI do by way of  
11 dissemination.

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

18 I think in concert with Carolyn from AHRQ we  
19 will ask the question of whether PCORI would dedicate  
20 some of its resources beyond that 16 percent to  
21 dissemination or whether there are ways that we can

1 work with AHRQ to, you know, plan the expenditure of  
2 those 16 percent.

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

10 And it seems to me, based on the legislation,  
11 legislation is basically asking you to look into that.  
12 Now, Shawn, is that correct?

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

18 MR. COELHO: Yeah.

19 MS. BISHOP: -- for clinicians at the point of  
20 care and at patients when they're trying to make a  
21 decision?

1                   And that's the challenge of PCORI, and I think  
2                   that the hope maybe if we could go back to that  
3                   question, it's like the hope is that everything that  
4                   it's trying to do, the way that it's structuring  
5                   itself, it's going to be creating information that's  
6                   usable.

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

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

1 best care.

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

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

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

21 And if we're all trying -- we're going to

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

9 I hope nobody is here from the NIH now.

10 (Laughter.)

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

17 MR. COELHO: All right.

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

19 MR. COELHO: Go ahead, Marc.

20 MR. BOUTIN: Usability at point of care,  
21 that's been the mantra of the patient community for the

1 last six years, and so I love hearing that here, but I  
2 also just want to make the point that it's contextual,  
3 which is why this is so difficult and why it will  
4 require research on how best to disseminate information  
5 so that it is, in fact, usable at the point of care.

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

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

20           In other words, we see all the time the FDA  
21 comes to the patient community and says, "We've got a

1 safety risk on this medicine," or this diagnostic or  
2 this device. "Will you tell your community?"

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

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

13 MR. COELHO: Thank you very much.

14 I'd like to just thank all our panelists and  
15 Joe for their presentations today. I'd like to  
16 summarize by saying that I thought this was an  
17 excellent presentation. I appreciate Marc for a lot of  
18 his comments. I particularly appreciate him drawing  
19 the distinction between patient, patient groups, and  
20 consumers. I've never heard it so distinctly put  
before. I think that is something that we need to be

1       reminded of periodically, and I think it's good for Joe  
2       to hear it as well and for PCORI to understand it.

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

9                     (Laughter.)

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

14                 I appreciate Joe and his leadership in  
15       bringing PCORI to reality. This is something that we  
16       in the patient community have wanted for a long time,  
17       being able to get PCORI up and going and running and  
18       having his leadership to make it a reality is an  
19       extremely positive step for all of us. We appreciate  
20       his leadership. We particularly appreciate his being  
21       here today and sharing his views with us.

1                   So thank you all for coming and participating.

2   Thank you.

3                   (APPLAUSE.)

4                   (Whereupon, the forum was concluded.)

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