

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

Monday,  
November 19, 2012

The Fairmont Copley Plaza Hotel  
138 Dartmouth Street  
Boston, Massachusetts 02116

[Transcribed from PCORI Webcast.]

B&B REPORTERS  
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## PRESENT:

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Lawrence Becker  
Carolyn Clancy, MD  
Francis Collins, MD, PhD  
Leah Hole-Curry, JD  
Allen Douma, MD  
Arnold Epstein, MD  
Christine Goertz, DC, PhD  
Gail Hunt  
Robert Jesse, MD, PhD  
Harlan Krumholz, MD  
Richard E. Kuntz, MD, MSc  
Sharon Levine, MD  
Freda Lewis-Hall, MD  
Steven Lipstein, MHA (Vice Chair)  
Grayson Norquist, MD, MSPH  
Ellen Sigal, PhD  
Eugene Washington, MD, MSc (Chair)  
Harlan Weisman, MD  
Robert Zwolak, MD, PhD

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P R O C E E D I N G S

[8:36 AM EST]

1  
2  
3 CHAIRMAN WASHINGTON: Good morning,  
4 everyone, and welcome to the Board of Governors  
5 Meeting of the Patient-Centered Outcomes Research  
6 Institute. We're pleased to welcome everyone  
7 that's here in person as well as those that are  
8 participating via our webcast proceeding.

9 This is our 14th public meeting, which  
10 includes 12 face-to-face meetings and two special  
11 Board webinars. For those of you who are joining  
12 us via the webcast, I want you to know that you can  
13 reach us online, today, via a toll-free number  
14 that's listed on the Board meeting page on our  
15 website at [www.pcori.org](http://www.pcori.org).

16 I'm also pleased to remind you that, as  
17 with all of our public meetings, today we will have  
18 a public comment period from 4:15 to 4:45 Eastern  
19 time and we have several individuals already  
20 registered, but if there are additional individuals  
21 who would like to register, if you're on site, you  
22 can just walk up and register in person by 3:00

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1 p.m., and if you're watching online or listening on  
2 the phone, you can alert the operator. And, as a  
3 reminder, that number to call in is 1-800-875-3456.

4           As I indicated, this is our 14th meeting  
5 and for those of you who are joining us and those  
6 of you who've been following us, in particular, you  
7 will note that we've made significant progress from  
8 our first meeting in September of 20 -- 3 [sic],  
9 and one of the topics that we are going to be  
10 talking about today, in addition to conducting  
11 general business, is a movement toward some focused  
12 areas of research.

13           On a business note, I'd like to seek  
14 approval of the minutes, first, from May. If you  
15 remember, there were some revisions you wanted to  
16 make, and so can I have a motion? Second? Or is  
17 that comment?

18           UNIDENTIFIED BOARD MEMBER: [off  
19 microphone - inaudible.]

20           UNIDENTIFIED BOARD MEMBER: [off  
21 microphone - inaudible.]

22           CHAIRMAN WASHINGTON: Okay, I have a

1 motion and a second. Comments?

2 DR. COLLINS: Just one correction. I am  
3 noted as having been present in May, and I had  
4 hoped to be, but in reality, I was not in Denver,  
5 so maybe the record should be corrected.

6 You felt my presence, I'm touched. Thank  
7 you.

8 CHAIRMAN WASHINGTON: Okay, with that  
9 correction, all in favor?

10 [Chorus of ayes.]

11 CHAIRMAN WASHINGTON: All opposed?

12 [No audible or visual response.]

13 CHAIRMAN WASHINGTON: Okay, any  
14 abstentions?

15 [No audible or visual response.]

16 CHAIRMAN WASHINGTON: Okay, the motion  
17 carries and with that modification the May Board  
18 meeting minutes are approved.

19 And September?

20 UNIDENTIFIED BOARD MEMBER: So moved.

21 CHAIRMAN WASHINGTON: Okay, it's been  
22 moved, and second.

1 UNIDENTIFIED BOARD MEMBER: [Off  
2 microphone.]

3 CHAIRMAN WASHINGTON: Comments?

4 [No response.]

5 CHAIRMAN WASHINGTON: All in favor?

6 [Show of hands.]

7 CHAIRMAN WASHINGTON: All opposed?

8 [No audible or visual response.]

9 CHAIRMAN WASHINGTON: Okay, any  
10 abstentions?

11 [No audible or visual response.]

12 CHAIRMAN WASHINGTON: And so, the motion  
13 carriers and September minutes are approved.

14 Well, with that, welcome. I'm going to  
15 turn it over to our esteemed Executive Director,  
16 Dr. Joe Selby.

17 DR. SELBY: Thank you, Gene. Good  
18 morning, everybody. It's lovely to be here in  
19 Boston, a beautiful city, a beautiful time of the  
20 year.

21 So, we do have an action-packed agenda, as  
22 usual. If you recall at our last meeting in

1 Washington, D.C. in September, we spent a good part  
2 of the first day on engagement. We've agreed, as a  
3 Board, that engagement is a strategic imperative  
4 for our activities, that it's one of the ways that  
5 we distinguish ourselves and one of the ways that  
6 we make patient-centered outcomes research more  
7 patient-centered and more relevant.

8           One of the sets of activities that  
9 engagement leads to is the generation of topics for  
10 research and the prioritization of those topics,  
11 and we heard about that a good deal last -- at the  
12 last meeting, and we will be hearing a bit more  
13 about it today when we hear a presentation later on  
14 today about the formation of external advisory  
15 committees to help us with them, particularly with  
16 research prioritization.

17           But today we're not going to talk as much  
18 about engagement, we're going to talk more about  
19 methodology, hear from the Methodology Committee,  
20 talk about research that we are funding and are  
21 about to fund, and talk about the budget for next  
22 year.

1           But one topic that I really -- that this  
2 meeting can't go by without mentioning is the  
3 workshop that was held in Washington, D.C. on  
4 October 26 to 28. It was entitled "Transforming  
5 Patient-Centered Research, Building Partnerships  
6 and Promising Models" and this was really one of  
7 the first manifestations of our engagement program.

8           We brought a total of 170 persons, more  
9 than we had aimed for, actually, this meeting was  
10 oversubscribed. Patients and other stakeholders  
11 from 40 states were represented, this included  
12 patients -- individual patients, patients from  
13 organizations as large as the American Heart  
14 Association, patients who were engaged in research  
15 networks and other partnerships with researchers,  
16 250 additional persons that attended the conference  
17 by webinar each day. Videos of these meetings are  
18 available at [pcori.org](http://pcori.org), and happy to say that there  
19 was really outstanding attendance by the Board,  
20 five Board members, essentially the entire COEC,  
21 Communications Outreach and Engagement Committee,  
22 as well as a Methodology Committee members were

1 present and participated in the meeting.

2           And these are just pictures of one of the  
3 panels and one of the breakout sessions. And now  
4 let me just see -- good, this is easy. I've got  
5 something to show you, but I haven't rehearsed it,  
6 so -- but it's so easy that I don't have to.

7           [Video shown.]

8           DR. SELBY: So, I think the video  
9 captures, to some extent, the energy and the  
10 passion that was there that day.

11           We learned a number of things from that  
12 day. First, and most obviously, we encountered a  
13 patient community from across the country that was  
14 very clearly ready for this engagement, ready for  
15 the partnership, enthusiastic about working with us  
16 to transform the research enterprise, to change the  
17 way that research is done.

18           We presented our proposed strategies for  
19 engagement, the same strategies that we had  
20 presented to the Board in September. In general, I  
21 think it's fair to say that they were endorsed, but  
22 in almost every case there were some refinements

1 that really had a ring of authenticity to them,  
2 that were offered throughout the day.

3           Some critical additional points were  
4 added. Researchers -- patients were quick to point  
5 out that researchers, as well as patients, need  
6 training on how to get engaged, so it wasn't that  
7 they disagreed that patients needed training, they  
8 called for that, but they also called for  
9 researchers to receive training to engage more  
10 constructively with patients.

11           They made a couple suggestions, I haven't  
12 captured quite all of them here, one of them was  
13 the idea of micro grants, and micro grants are very  
14 small amounts of money, but given locally, to  
15 partnerships that spring up between patients and  
16 elements in the research community with the purpose  
17 of starting to build partnerships so that they can  
18 eventually proceed to conduct larger research  
19 studies.

20           Another suggestion that came out of the  
21 meeting that we're pursuing is the notion of PCORI  
22 ambassadors, patients who would be particularly

1 engaged with PCORI and represent us locally  
2 throughout the country.

3           Patients also suggested an even stronger  
4 role, I think, than we had in mind for how they  
5 would engage in the research. For example, it was  
6 suggested that you might actually ask the patient  
7 participants in a research project to write a  
8 portion of the application and to be responsible  
9 for coauthoring the lay report of the research when  
10 it was done.

11           So, engagement continues and I wanted to  
12 just mention the next two major events. On  
13 December 4th in Washington, D.C., we will have an  
14 event, which is called, "What Should PCORI Study?"  
15 And this will be a meeting that includes more non-  
16 patient stakeholders -- the first meeting was  
17 predominantly patients, this second meeting will be  
18 much more balanced. All stakeholders will be  
19 engaged. And the topic on December 4th is exactly  
20 how do we get the ideas, what are the various ways,  
21 how do different segments -- different stakeholder  
22 communities -- what works best for them in terms of

1 getting their ideas to PCORI?

2           So, that's December 4th, and the very next  
3 day we will have a methods workshop in partnership  
4 with the Methodology Committee to -- with invited  
5 methodologists, invited patients and stakeholders,  
6 and there we'll talk about PCORI's evolving  
7 research prioritization process.

8           So, you heard in September about our long-  
9 term process for identifying high-priority research  
10 that the Board should consider for targeted  
11 funding. This day will be a day devoted to those  
12 methods. We are trying something, I'd say, in many  
13 ways more challenging than anyone has tried before  
14 because we're considering research across a broader  
15 spectrum than has been considered before.

16           So, the methods are challenging and this  
17 day will bring together experts and stakeholders to  
18 review where we've gotten. We've actually been  
19 pilot testing the prioritization process and we'll  
20 go over that and hopefully at the end have a clear  
21 picture of how we're going to implement research  
22 prioritization.

1           So, those are the next two engagement --  
2 major engagement events coming up.

3           Engagement has taken on an even bigger  
4 place in our activities than we originally thought,  
5 so I'm happy to inform you today and to announce  
6 that we have created a position called the Chief  
7 Officer for Engagement. This just recognizes the  
8 growing role of engagement in our organization.

9           The responsibilities for this position at  
10 an executive level will be to lead the continued  
11 development of our strategic imperative of  
12 engagement across the broad range of stakeholders,  
13 to build on the engagement efforts that you've  
14 heard about to date, the impressive efforts, and to  
15 support our engagement team, to support our  
16 directors of patient and stakeholder engagement in  
17 implementing this program.

18           This person will serve as the principle  
19 spokesperson and represent PCORI with all major  
20 stakeholder organizations, bring these  
21 organizations together to help plan and conduct our  
22 research, and they will work closely with the Board

1 of Governors, its COEC, and the Methodology  
2 Committee, to strengthen our ongoing relationships  
3 with the community and particularly to evaluate  
4 what we do in the realm of engagement.

5 We may hear a bit later this morning from  
6 the Methodology Committee that there's a lot of  
7 interest in actually learning when engagement  
8 works, how it works best, what are the best methods  
9 for this new set of activities.

10 So, Dr. Anne Beal has been overseeing and  
11 supporting the engagement work, among many other  
12 tasks that she takes on, and so, I'm also very  
13 happy to say that bringing on the Chief Officer for  
14 Engagement allows us to recognize Anne's many  
15 contributions and to announce that actually she's  
16 had a title change and she is now the Deputy  
17 Executive Director as well as Chief Operating  
18 Officer for PCORI and in that role she'll be able  
19 to take on a number of tasks supporting me and the  
20 executive team as well as continue to oversee  
21 contracting, finance, communication, HR, and  
22 facilities.

1           So, Anne just celebrated her one-year  
2 anniversary with us and I'd like to congratulate  
3 her.

4           [Applause.]

5           DR. SELBY: And I also want to show you  
6 just -- that we continue to grow. We're now at  
7 just over 40 employees. I think we will probably  
8 be 250 by the end of the year, and so we've added  
9 in the last two months research associates and  
10 administrative assistants, several scientists, so  
11 we've had three new senior scientists join us in  
12 the last three weeks and it really transforms the  
13 way it feels around the office. Many of these  
14 folks are here today, but not all of them.

15           And I want to just show you the way the  
16 organization is shaping up, the organizational  
17 chart is changing to some extent, I want you to be  
18 aware of the latest.

19           So, now there are three positions at the  
20 officer level. The Chief Science Officer and the  
21 Chief Officer for Engagement are not yet in place.  
22 Anne, obviously, has been here for the year.

1 Active searches with search firms are underway for  
2 both of these and I think with PCORI's future now  
3 just a little bit clearer and more solid, we're  
4 very optimistic that in the next several months  
5 we'll have these positions filled, so the Chief  
6 Science Officer and the Chief Officer for  
7 Engagement.

8 Anne will, as I said, oversee all of these  
9 activities -- finance, contacting, IT, HR, and  
10 communications.

11 The Chief Science Officer will oversee the  
12 five program areas, each led by a director, that  
13 correspond to PCORI's five research priorities,  
14 three of those are filled by David Hickam, Chad  
15 Boulton, and Romana Hasnain-Wynia. We're still  
16 searching for the director in the area of  
17 communications and dissemination research and the  
18 director in the area of accelerating PCOR.

19 In addition, Dr. Lori Frank is our  
20 Director for Engagement Research and it reflects  
21 the fact that we take evaluation of our engagement  
22 activities very seriously. We think it's in our

1 strategic interest to identify what's working, to  
2 demonstrate to the public and the research  
3 community what works, and to refine it so that it  
4 works better.

5           And the Chief Officer for Engagement will  
6 enjoy having Sue Sheridan and Susan Hildebrand as  
7 Director of Patient Engagement and Stakeholder  
8 Engagement, and this is that sector.

9           So, that's the engagement -- that's the  
10 entire executive team.

11           And I will just close by giving you a  
12 brief preview of today. We're going to hear from  
13 the Methodology Committee, who has been busy over  
14 these last several months incorporating, examining  
15 the public comments from the Methodology Report,  
16 which was posted for nearly two months during the  
17 summer. You've received the revised standards and  
18 an overview of those revisions and Dr. Gabriel will  
19 update you on that very shortly.

20           Then, as I said, you're going to hear  
21 about the PCORI advisory committees, the first  
22 PCORI advisory committee charters. In September

1 you instructed us to prepare charters and three  
2 charters have been prepared and Dr. Beal will  
3 present those to you next.

4           Then we'll have a discussion of the  
5 proposed budget for 2013 followed by updates on  
6 both the PCORI pilot projects, and then the  
7 research applications that we've received and now  
8 reviewed for the first cycle of our broad PCORI  
9 funding announcements.

10           Then we will have the discussion that Gene  
11 mentioned of a proposal for some targeted PCORI  
12 funding announcements, some targeted, PCORI-  
13 sponsored research. And lastly, today, a report  
14 from the nominating committee on committee  
15 assignments for 2013.

16           So, Gene, I think that's it. I'd just  
17 like to ask if there are any questions from the  
18 Board. Harlan?

19           DR. WEISMAN: Yeah, first of all, I  
20 thought the workshop was fantastic and the video  
21 was great because it just brought me back into the  
22 moment of that experience, so thank you for sharing

1 that with it.

2           The only thing I would add to everything  
3 you said about it was that we learned that there  
4 already are existing, not a large number, but  
5 existing patient-centered research efforts that  
6 have started, driven by patients, that we can learn  
7 from and others can learn from.

8           Also, it was interesting to observe that  
9 the participants themselves spontaneously started  
10 their own interest groups and started working  
11 together and learning from each other as well as us  
12 benefitting from them.

13           And then finally I would say that -- and I  
14 don't know whether the rest of the Board would  
15 agree with this -- but it started seeming that  
16 PCORI, beyond being a research institute, is really  
17 becoming the nidus for a growing movement driven by  
18 patients and their clinicians -- primary care  
19 clinicians -- to improve healthcare, their  
20 healthcare, by changing the way research is done,  
21 and there's a tremendous amount of excitement about  
22 that too, and started crystallizing at that

1 meeting.

2 DR. SELBY: Thanks, Harlan. Other  
3 comments or questions? Okay.

4 CHAIRMAN WASHINGTON: Okay, I forgot to  
5 mention at the beginning, I've been reminded by  
6 several Board members that we should practice  
7 better meeting behavior, and in the last couple of  
8 months I've been in meetings where the mantra was  
9 sit for 60, move for three.

10 Now, Joe, I think we have us sitting for  
11 about 90 and then moving for five, but we are going  
12 to stick to it, I see Harlan, because Harlan's one  
13 of the Board members that reminds me after each  
14 Board meeting and he sends me articles and links  
15 about best practices -- and so we are, today, going  
16 to adhere to our program timeline.

17 And it's my pleasure to introduce our next  
18 presenter, Dr. Sherine Gabriel -- it's always fun  
19 to hear from the Methodology group and one of our  
20 co-leaders of that group, but it's a great pleasure  
21 for me to introduce her now as Dean Gabriel.

22 For those of you who had not heard, Dr.

1 Gabriel is now the new dean of the medical school  
2 at the Mayo Clinic, so we want to congratulate you,  
3 Dean.

4 [Applause.]

5 I'll turn it over to you.

6 DR. GABRIEL: Thank you. Thanks very  
7 much. So, thanks for that clip, also, this  
8 morning. That was really a wonderful way to get  
9 the day started. And actually one of the most --  
10 one of the phrases that will stick with me from  
11 that clip is the patient advocate who said, "PCORI  
12 listens." And I think there's -- that was really  
13 quite a compliment.

14 So, I hope you'll find -- in our  
15 presentation today, I hope you'll see in our  
16 presentation today that with respect to the  
17 comments regarding the methodology standards and  
18 recommended actions, that the Methodology Committee  
19 not only listened, but we learned a great deal from  
20 the comments made in the public comment period, and  
21 as a result of that, we've made some important  
22 changes that I'll try and summarize here very

1 quickly.

2           So, our goals for today, I'll give you  
3 just a high level overview of what we've been up to  
4 for the last several months since the public  
5 comment period has opened. I'm going to share with  
6 you not every single step of the way, because  
7 that's an enormous amount of detail, but give you  
8 an overview of the themes and the changes that have  
9 been made to the methodologic standards and the  
10 recommended actions that you all saw earlier.

11           You should all have with you a seven-page  
12 sort of overview of the approach and the themes and  
13 the changes as well as a redline and a clean  
14 document of the standards and recommended actions  
15 highlighting what's been changed.

16           And so, what I'm going to propose is  
17 adoption of the standards and recommended actions  
18 and hope that the Board also agrees with us  
19 beginning a dissemination effort along with the  
20 COEC. Last night there was a lot of discussion  
21 about implementation and I think 7:45 this morning  
22 I got two slides that kind of helped highlight the

1 dissemination directions that the Methodology  
2 Committee, working with the COEC, hopes to move  
3 forward in order to disseminate the standards with  
4 the hope and the expectation, really, that these  
5 will change practice and will be a major driver for  
6 how research is done differently.

7           Now I'm just going to give you a sense of  
8 our next steps going forward.

9           This is just a reminder slide, so, this  
10 slide you saw before at my last presentation, I  
11 think, back in May, just to give you a sense of how  
12 we got to the initial draft methodology report. As  
13 you know, there were a number of methodologic areas  
14 that were identified, working groups were assigned,  
15 we prioritized a variety of methods and  
16 methodologic questions to be examined, a lot of  
17 information gathering involving not only our team  
18 and the staff, but many external researchers and  
19 contractors, and then a process of internal review  
20 and deliberation and debate that led to the  
21 standards that you saw in May and that we received  
22 public comment for over the summer.

1           And I have to say, sometimes methodologic  
2 standards are a little bit dry, if you will, I  
3 don't think ours are, but the topic can be, and I  
4 was a little worried about not receiving much  
5 public comment, and we -- those worries were soon  
6 vanished.

7           So, you'll see that we had 124 groups,  
8 over 1,400 comments in all that came in. What  
9 we'll focus on today is the comments that are  
10 directly applicable to the topics of the  
11 methodologic standards and recommended actions.  
12 That's sort of the heart of the report and that's  
13 really what requires Board endorsement.

14           A number of the other comments really were  
15 about the language of the report, how we explain  
16 things, and we will, and are in the process, of  
17 addressing those as well, but really the focus for  
18 today is the standards themselves, the recommended  
19 actions themselves, and the specific comments that  
20 we got to change things or modify things.

21           And here you can see on the right-hand  
22 side of the slide, the 12 areas, the 12 topics of

1 the standards, and just the number of comments in  
2 each. Everybody's eye will go to the 143 under  
3 trials, but let me just point out that our specific  
4 standard with respect to trials was on adaptive  
5 trials.

6           The comments -- the majority of the  
7 comments that you see there were really not that  
8 specific to adaptive trials. There were many  
9 comments that really spoke to, you know, the  
10 strengths of adaptive trails versus observational  
11 studies, the usefulness about observational studies  
12 in certain situations where trials maybe fall  
13 short.

14           And so, they weren't -- it's not what it  
15 appears, I guess is what I'm trying to say. Many  
16 of these comments were helpful, but many of them  
17 were actually fairly general.

18           We did engage the help of AIR to help us  
19 analyze the comments and make some recommendations  
20 to us and I'll show you some of the work -- some of  
21 the results of that work.

22           So, basically there were five major themes

1 from the public comments. Most of the comments --  
2 well, first of all, I'll say that the majority of  
3 the comments were really very supportive of our  
4 standards. But the themes were as follows: many  
5 of them pointed to the importance of  
6 implementation, and, again, we talked about this a  
7 good bit last night and I'm actually excited about  
8 the proposed work that we hope to do with the COEC  
9 to disseminate and eventually implement these  
10 standards.

11           So, a lot of the comments are in that  
12 area. There were a lot of questions about what are  
13 these standards going to mean for research funding,  
14 and so that pertains to how are we going to  
15 implement them in the work of the institute, how  
16 are we going to work with the staff to effectively  
17 implement them, what kind of advice are we going to  
18 give reviewers as they're reviewing the grants in  
19 order to properly account for the standards, what  
20 advice help are we going to give the investigators.

21           There were a number of gaps that were  
22 identified, many of them we knew and I think we

1 shared with the Board back in May that we couldn't  
2 cover, we didn't intend to cover the entire  
3 waterfront, but there were some important gaps, and  
4 this is a reminder to remind you that this is  
5 version one, so there will be additional work as we  
6 go on to update, add standards, go through this  
7 process again, and really continually improve the  
8 methodology report and the methodologic standards  
9 and actions.

10           And then accessibility. There were a  
11 number of comments about accessibility of the  
12 document. Parts of it were accessible to, I think,  
13 a broad audience, but parts of it, especially the  
14 analytics standards, were somewhat less accessible  
15 and there was advice to improve that. And then  
16 finally, feasibility of the standards to produce  
17 patient-centered research findings. And, again, it  
18 reminds me of our discussion not only last night,  
19 but when the Methodology Committee met yesterday,  
20 one of our primary agendas for the coming year is  
21 to really build a program for evaluation to  
22 determine -- to study and determine how these

1 standards really help us reach our ultimate goal of  
2 producing patient-centered research findings and  
3 information that people can use to make better  
4 decisions.

5           And so, those were kind of the -- this was  
6 the advice that we got, at least the five themes,  
7 and just to give you a sense of what we've been  
8 doing, very abbreviated, the 12 topics that I  
9 showed you before, kind of the bottom of that  
10 graph, we had multiple Methodology Committee, full  
11 Methodology Committee teleconferences to discuss  
12 and debate how we're going to deal with these  
13 themes, how we're going to divide ourselves up to  
14 address them.

15           We sort of divided ourselves up in those  
16 12 groups. Obviously, there is only 17 of us, so  
17 many of us were on many groups. The working groups  
18 met and went through each of the comments, proposed  
19 revisions iterate back and forth, and came up with  
20 a set of proposed recommendations to the standards  
21 and recommended actions.

22           In a couple of situations, several,

1 actually, we solicited outside expertise, so  
2 sometimes the actual commenters themselves where we  
3 went back and said, you know, help us understand  
4 exactly what you meant by this. Other times it was  
5 the contractors that helped us write the initial  
6 set of standards, or at least informed the writing  
7 of the initial set of standards, just to make sure  
8 that we were understanding things as clearly as  
9 possible, particularly in the area of research  
10 prioritization, heterogeneity, diagnostic testing,  
11 and adaptive trials, those were the areas where we  
12 solicited external expertise to help understand and  
13 better respond to the comments.

14           And then the work -- at the end of all of  
15 that, the working groups drafted proposed  
16 revisions, and in October, we came back as a full  
17 committee to review everything the various working  
18 groups had proposed as a full committee, and on  
19 October 31st, which was what was supposed to be a  
20 face-to-face meeting, but thanks to Sandy we ended  
21 up doing it virtually -- Hurricane Sandy, that is,  
22 and anyway, it worked out very well, and we came

1 together, at least virtually, for a whole day and  
2 really went through everything and came up with a  
3 final set of standards.

4           Now, you know, for months people were  
5 saying, make sure that we respond to Dr. Epstein's  
6 concerns about -- I know, I know -- about exactly  
7 how the process played out. And with respect to  
8 how we reached a unanimous consensus regarding the  
9 endorsed set of revised standards and recommended  
10 actions that you have before you, I just wanted to  
11 point out that while there were -- you know, there  
12 are many, many standards and you'll see the numbers  
13 herein a moment -- while there were some  
14 disagreements standard-by-standard, we worked  
15 through all of those and at the end of the day, we  
16 asked the Methodology Committee to approve the  
17 final set, or at least endorse the final set to go  
18 forward to the Board.

19           So, whereas some of us didn't agree on  
20 certain components of certain standards, we wanted  
21 to be certain that the level of disagreement or  
22 dissent didn't rise to the level that, you know, it

1 couldn't -- didn't keep you up at night and it  
2 wasn't enough that you would not endorse the entire  
3 set to come forward to this body.

4           So, I don't want to send the message that  
5 we agreed with absolutely every word that was  
6 written by every working group, but the  
7 disagreements were such that the group, as a whole,  
8 was comfortable at the end of the day after much,  
9 much discussion and debate, unanimously endorsing  
10 the set of revised standards and recommended  
11 actions that you have.

12           So, we delivered that to the Board and  
13 would ask you to consider adopting these standards  
14 so that we can move forward with dissemination and  
15 implementation.

16           We've also drafted public comment themes.  
17 As you saw, there were 1,200 or 1,400 or so  
18 comments. We identified certain themes of those  
19 comments and we tried to summarize those in a  
20 document, little executive summary that you also  
21 received.

22           So, just at a very high level, revisions

1 to the methodologic standards, 21 of our standards,  
2 I know you may recall that we started with over 60,  
3 21 were revised, 14 of those were major changes  
4 with respect to the content, 7 of them I guess we  
5 call just wording changes, although I think some of  
6 those were substantive as well, 19 standards were  
7 either deleted, expanded, or consolidated, and 21  
8 of the 60-some were unchanged.

9           So, it really did end up, at the end of  
10 the day, to be some very significant changes. This  
11 is just a clip -- I'm not going to go through this  
12 line-by-line -- but it's just a little bit of what  
13 we call our working document. So, we have a very  
14 detailed working document that specifies each  
15 standard, the summary of the revision, and how we -  
16 - how the standard ended up being changed.

17           And so, just as an example, this is the  
18 causal inference standard, and what we heard from  
19 one commenter was that this particular standard  
20 focuses on point exposures and didn't really  
21 address time varying treatments. And PCORI's  
22 mission talks about longitudinal problems and

1 longitudinal outcomes and why is it that the  
2 standard really addresses an event that would occur  
3 only at one point and not something that might  
4 change over time. And we agreed with this, as we  
5 agreed with many of the comments, and you can see  
6 that the resulting standard really has been changed  
7 quite a bit to talk about, you know, prospect of  
8 studies and the fact that some exposures do change  
9 over time and that that should be specified and is  
10 included.

11           And, I mean, I don't need to go through  
12 all of this. This is with -- I think in the same  
13 standard, I think these are all causal inference  
14 standards that should be expanded to include  
15 assessment of common support, that is variables  
16 that overlap. And, again, we agreed -- in the  
17 propensity scoring standard, and again, we agreed  
18 with this and made some changes that addressed  
19 overlap and balance across various groups.

20           And here is a relatively minor, but I  
21 think also important, comment that we -- some of  
22 our standards talk about interventions, which

1 suggest a treatment or some sort of intervention,  
2 but really to broaden that so that we're talking  
3 about exposures that might affect outcome of  
4 patients, which could be interventions or other  
5 things, and so we kind of changed the language  
6 there.

7           So, there are, you know, many hundreds of  
8 these and I just wanted to give you a sense of what  
9 we did and what that working document looks like.

10           In addition to standards, there are also  
11 recommended actions. Again, at a high level, 13 of  
12 these were revised, 25 deleted, expanded, or  
13 consolidated, and sometimes we looked at something  
14 that appeared to be a methodologic standard and we  
15 really realized that it fit better in the  
16 recommended actions category, and 30 were  
17 unchanged.

18           So, again, just to give you a sense of the  
19 level of change.

20           Actually, before I go on, I just thought,  
21 if I could ask Sharon-Lise if she had any comments  
22 on the process.

1 CHAIRMAN WASHINGTON: Please.

2 MS. NORMAND: I have actually nothing to  
3 add. You were very complete about it. So, we  
4 worked hard, we had a lot of solicited outside  
5 help, and everybody was very generous with their  
6 time. So, you've covered it all. Thank you.

7 DR. GABRIEL: So, just a couple more  
8 slides before we ask for questions, but again, the  
9 idea is to provide the deliverable to the Board at  
10 this meeting and following Board adoption, what the  
11 Methodology Committee spent all day yesterday doing  
12 is trying to figure out what our next round of  
13 priorities ought to be for the coming year,  
14 implementation, dissemination come up very high,  
15 evaluation, really developing a detailed evaluation  
16 plan to ensure that the standards really achieve  
17 their intended purpose. And then, as I mentioned  
18 early on, many of the comments that we received  
19 were not specifically about the standards, but  
20 about the language of the report and some of that,  
21 and we're going to be working on that also.

22 Just a word on dissemination and

1 implementation of the standards. So, anticipating  
2 moving these -- we're anticipating moving forward  
3 with dissemination and implementation. Again, as  
4 we discussed last night, we understand that  
5 adherence to these standards is not going to be  
6 entirely simple. It will require changes in the  
7 way we solicit research, in the way investigators  
8 design research, certainly in the way it's reviewed  
9 and funded and monitored, et cetera. And that's  
10 going to require a coordinated effort -- a multi-  
11 stakeholder coordinated effort, and so we hope to  
12 work with the staff and with the guidance of the  
13 COEC, including bringing together advisory groups  
14 as needed to really understand how best to  
15 disseminate and implement these and prioritize and  
16 stage our dissemination activity going forward.

17           And so, in addition to your consideration  
18 of the standards, we ask that you endorse our two  
19 groups to work together to continue the work that  
20 they actually already started yesterday, to develop  
21 an initiative for widespread dissemination and  
22 implementation of the standards and I think the

1 group also is asking to convene a new advisory  
2 group for this initiative that will hopefully  
3 involve some of you.

4           So, I think this is my last -- second to  
5 last slide. I only had one other comment, just to  
6 kind of remind you what we're asking for today,  
7 requesting your consideration of endorsement of the  
8 standard -- adoption, I guess it should say, of the  
9 standards and recommended actions and the  
10 dissemination initiative aligned with that and just  
11 to provide some overview of our next steps.

12           So, this is my last slide, if I may -- uh  
13 oh -- this is the Methodology Committee vice chair,  
14 Sharon-Lise Normand's last meeting and I just --  
15 last public meeting with the Board, and yesterday  
16 at the Methodology Committee meeting we had a very  
17 nice tribute. I didn't actually know that she  
18 could turn red, but she kind of turned a little bit  
19 red, and we had, every single one of us, shared a  
20 story about our experiences with Sharon-Lise -- all  
21 but one. One of us actually shared an operetta,  
22 which was lovely. Steve Goodman, who I'm sure you

1 all know is a very accomplished opera singer  
2 actually created a little operetta just as a  
3 tribute for Sharon-Lise and we played that, and we  
4 really -- to a person, commented that we have  
5 learned an incredible amount from Sharon-Lise and  
6 we'll miss her wisdom greatly and we will just miss  
7 having her around. And so, it's been wonderful.  
8 Thank you very much for everything.

9 [Applause.]

10 CHAIRMAN WASHINGTON: Sherine, can I just  
11 add some comments on behalf of the Board regarding  
12 Sharon-Lise?

13 Shortly after Sharon-Lise announced to me,  
14 to Steve, to Joe, that she was going to be stepping  
15 aside I sent her a note in which I expressed our  
16 deep gratitude and heartfelt thanks for all that  
17 she had contributed in terms of her wisdom and  
18 insight and the knowledge, but I also commented  
19 that because of Sharon-Lise, I mean, the bar had  
20 been set very, very, very high, and that will be an  
21 enduring and endearing memory of your legacy on the  
22 Board. And, again, thanks. And just know that we

1 know where to find you. You can run, but you can't  
2 hide.

3 So, again, thank you from everybody on the  
4 Board.

5 [Applause.]

6 CHAIRMAN WASHINGTON: And before we go  
7 into discussion, I want to underscore that this has  
8 been a tremendous amount of work and I think it has  
9 drawn on our values of engagement and transparency  
10 and particularly the value of rigorous methods.  
11 And it has been a truly collaborative effort led by  
12 the entire Methodology Committee, and so I'm going  
13 to ask the Methodology Committee, before we get  
14 into comments, if you would stand, please, those of  
15 you who are here. And accept our appreciation and  
16 thanks also.

17 [Applause.]

18 CHAIRMAN WASHINGTON: Okay, with that, I'm  
19 going to open it up. There is a proposal on the  
20 table that we would first adopt these and the  
21 second part of this would be that we would endorse  
22 this concept, which Sherine, I don't think it

1 really needs an endorsement, we would just  
2 encourage you to go forward and continue your work  
3 with the COEC and the Methodology Committee.

4           So, we're going to focus on the changes  
5 that have been proposed and adopted and the current  
6 recommendation from the Methodology Committee that  
7 this be the current standards coming from the  
8 group.

9           Let me start with Dr. Collins.

10           DR. COLLINS: Thank you, again, for this  
11 hard work and the nice presentation on what's been  
12 done as far as responding to the comments and  
13 input.

14           Just two questions. So, first of all,  
15 you're putting forward now the expectation that  
16 with these standards in place that there will be a  
17 desire to see researchers adhere to them and one of  
18 my questions is, how are you going to assess, going  
19 forward, whether in the real world of research  
20 these standards, A, are being adhered to, and B,  
21 that that's actually working as opposed to real  
22 world experience, which sometimes leads you to need

1 to revise what, in a more ideal kind of think tank  
2 approach, you might have hoped could happen?

3 So, what's the process going to be for  
4 revisiting these in context of reality?

5 Second question, not quite related to  
6 that, but I'm just curious, in terms of the  
7 translation table, which was one of those things in  
8 the statute that the Methodology Committee was  
9 asked to do, can you give us a quick snapshot on  
10 where that stands?

11 DR. GABRIEL: So, with respect to your  
12 first comment, and I'm probably going to rely on my  
13 colleagues here to help out, it actually is one of  
14 the -- it was one of the themes of the public  
15 commenters, as you saw, so how are we going to  
16 implement this? How are we going to ensure that  
17 these standards really will lead us to the intended  
18 goal of improving patient-centered outcomes and how  
19 are you going to evaluate it?

20 One of the, I guess, fortunate things is  
21 that we have already -- PCORI has already funded  
22 research before the standards were implemented, and

1 so as I alluded to yesterday, we spent a good part  
2 of the day thinking about what we're going to do in  
3 the coming months, and one of the key activities is  
4 going to be to develop an evaluation plan to assess  
5 exactly those questions. So, we're methodologists,  
6 we're going to do this -- we're going to develop a  
7 research plan, if you will, to consider ways of  
8 determining, testing, evaluating, exactly how these  
9 standards are being used, have been used, compared  
10 to what happened -- what we've done in the past and  
11 to use that information to continually improve the  
12 process.

13 Now, I'm going to ask, I'm not sure  
14 exactly who, but --

15 CHAIRMAN WASHINGTON: Sharon-Lise has her  
16 hand up over here.

17 DR. GABRIEL: Oh, Sharon-Lise is going to  
18 comment.

19 MS. NORMAND: So, part of it is we had a  
20 discussion yesterday about -- so, first of all, we  
21 want to collect information from the peer review,  
22 so we're going to -- the hope is to collect

1 information about patient representatives or  
2 participants. So, collect a lot of data on the  
3 review cycle, what's happening there.

4           The other aspect is natural experiment.  
5 We do have a pre-post. We know problems with the  
6 natural experiments, but at least we do have that  
7 ability to look at adherence to the standards, were  
8 they being adhered to prior and post, but we also  
9 need to think about what are our metrics and what's  
10 the metrics that we're going to measure success and  
11 implementation, and there's, of course, the far  
12 reaching, did we improve healthcare, which seems to  
13 be pretty far out, but nonetheless, we were  
14 definitely thinking about adherence, do we try to -  
15 - do we find more completion, do we find more  
16 successful studies. So, we were actually thinking  
17 about the metrics to do that with.

18           And, Sherine, if you don't mind, I think  
19 that Mike Lauer had some very --

20           DR. GABRIEL: Yeah, Mike had proposed,  
21 actually, some experimental approaches that we're  
22 going to consider and I'm also going to ask Brian

1 to comment on the implementation piece and then  
2 we'll get to the translation table question.

3 DR. LAUER: Thank you, Michael Lauer from  
4 NIH and from the methods committee. There is a lot  
5 of interest in how scarce resources should be used  
6 to fund research and the reality is, is that we do  
7 not know what is the best way to do this.

8 There have been a number of very profound  
9 thinkers including John Ioannidis, from our  
10 committee, who have actually called upon funding  
11 agencies to engage in prospective trials, maybe  
12 even randomized trials to look to see whether or  
13 not different approaches to making decisions about  
14 funding research yield different outcomes.

15 In other fields, like in economics,  
16 development economics, there are people who are  
17 actually doing randomized trials have different  
18 ways of giving out monies to see what impacts these  
19 different approaches actually have.

20 So, there's a movement afoot to go ahead  
21 and do this.

22 Now, PCORI is in a fabulous situation

1 because we've actually prospectively defined a set  
2 of standards for research that we certainly would  
3 like to see from our institute as well as  
4 potentially from other institutes as well, and  
5 given that we have defined the standards in a  
6 rather explicit way, we're also in a position to  
7 engage in some experiments and so this is something  
8 that we've been talking about and thinking about is  
9 to use adherence to standards for applications or  
10 contract solicitations or contract responses, use  
11 these as our endpoint and see whether or not  
12 different approaches yield better likelihood to  
13 adhere to these.

14           So, the fact that we're in the position  
15 that we're in and that we've put out this document  
16 puts us in a really unique position to do something  
17 which would be arguably unprecedented for a bio  
18 medical research agency.

19           DR. GABRIEL: Brian?

20           MR. MITTMAN: Brian Mittman, Methodology  
21 Committee. So, just to follow up and elaborate on  
22 my colleague's comments, we have a good source of

1 guidance and how to go about designing studies to  
2 evaluate the dissemination, implementation,  
3 outcomes, effectiveness of these standards and that  
4 is the field of implementation science and studies  
5 of dissemination and effectiveness of other  
6 standards for professional activity, namely  
7 clinical practice guidelines. So, as the joint  
8 Methodology Committee-COEC group gets together and  
9 begins to think through the questions you've asked,  
10 to lay out different kinds of studies, as Mike has  
11 described, we will turn to that body of literature  
12 for guidance and identifying methods, identifying  
13 outcomes and measures and so on.

14 DR. GABRIEL: And just with respect to the  
15 translation table question, which has also been a  
16 big part of our discussions, I'm going to defer to  
17 Sebastian, who's really led some of those  
18 discussions and I know we've sort of maybe changed  
19 the direction just a little bit to make it  
20 hopefully more applicable.

21 DR. SCHNEEWEISS: This is Sebastian  
22 Schneeweiss from Harvard Medical School from the

1 PCORI methods committee. Many people of the  
2 methods committee, of course, very involved in  
3 these considerations, I just speak for many of us.  
4 We, in the methods report, we have provided a  
5 framework for a translation table and the  
6 considerations that have to go into building a  
7 translation table. While doing that, we realized  
8 this is a very difficult endeavor that we embarked  
9 here.

10           The comments that we received from the  
11 public were largely laudatory, they agreed that  
12 this is a helpful exercise, but also folks wanted  
13 to have more details to make the translation table  
14 more hands on and user friendly and fill it with  
15 more life.

16           So, we had many follow on discussions  
17 internally in the methods committee and charted out  
18 several pathways forward here and I think yesterday  
19 the majority really thought that we need to  
20 understand better what the target audience is, what  
21 the consumers really want from a translation table  
22 because that will decide which way we will go of

1 the pathways that we have charted out here.

2 So, that is certainly one of the first  
3 priorities for us to engage stakeholders from the  
4 entire spectrum to learn more about the uses of the  
5 translation table.

6 CHAIRMAN WASHINGTON: Okay. I have Ellen  
7 and then Carolyn and then Leah.

8 MS. SIGAL: So, first I wanted to thank  
9 the committee for its good work. It's an important  
10 report and I'm pleased about the fact that we'll  
11 finally get to use it.

12 So, specifically the question would be is  
13 that we have not been able to even advise -- and I  
14 understand why, up until now -- that the standards  
15 not be part of our PFAs. As we go forward, we are  
16 currently going to be talking about PFAs and we  
17 have others that are going to go through. Will  
18 this be now required? Have we looked at what we're  
19 looking at and what we're doing and whether these  
20 are even amenable to what we're trying to do? And  
21 will this just be a core requirement of any PCORI  
22 grant?

1           CHAIRMAN WASHINGTON: I would just say, I  
2 see that as a broader question for the Board.  
3 Please comment on it, but that's why I was turning  
4 to Joe.

5           DR. GABRIEL: Right, that's really what I  
6 was going to say. You know, the statute stipulates  
7 that the standards become adopted by the Board and  
8 once the Board takes that step, then we will be  
9 working with -- we, the Methodology Committee, will  
10 work with staff to figure out exactly how best to  
11 implement them into the funding mechanisms.

12           I will say, it's not as straightforward as  
13 saying, you know, here are -- I can't remember what  
14 we ended up with -- 40-some standards, these are  
15 all required. They differ somewhat and each -- so,  
16 implementing them and providing the right advice to  
17 reviewers on exactly what it means to comply with  
18 each standard, is going to take some work and so  
19 that will happen after the Board adoption.

20           MS. SIGAL: Just a comment, and we'll, I  
21 assume, discuss it at the full Board level, but it  
22 seems to me rather strange that we would have this

1 methodology report that we can't adhere to with our  
2 own work.

3 DR. GABRIEL: Oh, absolutely. I mean,  
4 that's the goal, but I guess all I'm saying is it's  
5 really a Board decision. That's the goal and  
6 that's the expectation of the -- as specified in  
7 the statute.

8 DR. SELBY: Sherine, if I could just add  
9 to that. At the staff level where we support the  
10 peer review process, we're very excited that these  
11 standards are just about adopted and we're very  
12 excited about the opportunity to work with the  
13 Methodology Committee to determine the best way to  
14 prepare our peer reviewers.

15 We haven't said it yet, but really one  
16 good way of disseminating standards is to require  
17 them and then give feedback in the form of peer  
18 reviews as to how well applicants did or didn't  
19 adhere to those standards. But as Sherine says, we  
20 need to make certain first how we instruct them to  
21 adhere.

22 DR. CLANCY: I think Joe may have just

1 answered my question. I was thinking through the  
2 practical steps, although it does strike me with  
3 the upcoming workshops you also have an opportunity  
4 to frame that in terms of what the report is  
5 proposing, if not totally finalized. I guess we're  
6 recommending to or voting to adopt today the two  
7 early December workshops, and I also wanted to  
8 thank the Methodology Committee. Since I work  
9 closely with one of the members, I have probably a  
10 better inkling than some about just how much time  
11 it is.

12 CHAIRMAN WASHINGTON: Yeah, I'm going to  
13 ask you to give your name, please. I'm sorry.  
14 I've been calling first names, but this is being  
15 recorded and there are others in the audience who  
16 can't see you. So, Leah.

17 MS. HOLE-CURRY: Leah Hole-Curry, Board  
18 member. So, my question was along the same lines,  
19 Joe. I think, just a little bit more specificity  
20 about -- Gene, you mentioned that it would be a  
21 Board discussion, so is it timely to have the Board  
22 discussion about our expectations of it being

1 included as a funding requirement?

2 CHAIRMAN WASHINGTON: Yes, there will be a  
3 Board discussion, but that would come forth from  
4 the staff as a different presentation.

5 MS. HOLE-CURRY: Okay.

6 CHAIRMAN WASHINGTON: It's a different  
7 question. The question on the table now is  
8 adaptation of the standards, in which case they  
9 become the standards of PCORI, then it's a question  
10 of how are we going to use them. And we would  
11 expect that the staff would come forward with a  
12 proposal.

13 MS. HOLE-CURRY: So, since we're having  
14 the PFAs on an every four-month cycle, I think the  
15 work of -- starting to work with the COEC on  
16 dissemination is very exciting and I support that  
17 wholeheartedly, but I think the primary task at  
18 hand -- so, I'm just making sure it's not getting  
19 missed, is to work directly with staff on how it  
20 would be implemented, since we do have that  
21 statutory requirement related to post-adoption.

22 CHAIRMAN WASHINGTON: That's a good point.

1 MS. HOLE-CURRY: I think it is the primary

2 --

3 DR. GABRIEL: And now I'm actually a  
4 little bit confused because my understanding was  
5 that post-adoption, they would be implemented  
6 because that is a statutory requirement.

7 Now, I understand it's not as easy as  
8 just, here we go, we're done, implement them, and  
9 we expect that there will be some work and some  
10 collaborative work between the Methodology  
11 Committee working with the staff to ensure that  
12 they're implemented in exactly the right way to  
13 make sure that investigators have the information  
14 they need and that reviewers have the guidance that  
15 they need.

16 But I'm assuming that that's just sort of  
17 an automatic next step post-adoption.

18 DR. SELBY: It is automatic, and the only  
19 thing that's not is the good point you made that  
20 it's not as simple as just instructing the peer  
21 reviewers to grade each application on their level  
22 of adherence. We have to go through the standards

1 one-by-one and figure out how to work with peer  
2 reviewers.

3           An advantage we have is that we're doing  
4 the peer reviews ourselves, so we just finished  
5 training peer reviewers for the first round of  
6 reviews and it's a wonderful opportunity to build a  
7 community of peer reviewers who see things the  
8 PCORI way and this will be part of it.

9           CHAIRMAN WASHINGTON: Harlan -- I have  
10 others, but is yours on this point?

11           DR. WEISMAN: [Off microphone.]

12           CHAIRMAN WASHINGTON: Excellent point,  
13 Leah, in terms of what is the immediate next step  
14 and I think we would all agree that it is  
15 implementation in the form of expectations  
16 regarding the PCORI funding announcements. And Joe  
17 and the group will sort that out.

18           Zwolack and then Lewis-Hall and then  
19 Krumholz.

20           DR. ZWOLACK: Bob Zwolack. First, I want  
21 to congratulate your group. This is spectacular.  
22 There's a lot more clarity surrounding exposures

1 and I thought that overall the draft report was  
2 excellent, but this one is even better organized  
3 and much better, so I'd like to offer my  
4 congratulations.

5 My question has to do with next steps  
6 after adoption by the Board, in particular,  
7 dissemination to the rest of the world and how we  
8 might foresee these getting adopted more broadly  
9 and if there's some method by which PCORI can help  
10 offer a tailwind to facilitate rest of the world  
11 adoption of these standards.

12 DR. GABRIEL: Well, we'd love a tailwind,  
13 that would feel pretty good right now, but I think  
14 one of the first steps, as you saw in our kind of  
15 next steps flow chart, is to go back to the  
16 wrapping around the standards, if you will, the  
17 language and the descriptions and the explanations,  
18 the actual text of the report.

19 We did receive many comments about that,  
20 you know, you could explain this better such and  
21 such a way, and we're now going back to the process  
22 of doing that, and I think just as the comments

1 that we received on the standards and recommended  
2 actions have improved them, I think those comments  
3 will improve our explanation and hopefully make the  
4 entire document more accessible.

5           So, that's a sort of an easy -- the task  
6 won't be easy, but it's an easy to envision next  
7 step.

8           A piece of that, and again, a lot of the  
9 comments that came around that -- and I might in a  
10 minute ask Mark to add his thoughts -- was around  
11 the stories. You remember that we had put a lot of  
12 patient stories in our report. We got a lot of  
13 comments about those. We're not really experts at  
14 writing patient stories or these kind s of  
15 narratives, and we're in the process of engaging  
16 some narrative medicine experts, they're, you know,  
17 who really do this for a living and have a real  
18 deep expertise in doing that right, if you will.

19           And so, along with the comments that we've  
20 received from the public and with external  
21 expertise in narrative medicine, we hope to improve  
22 those.

1           So, the first response to your question is  
2 that the report, we hope, will be that much better  
3 than what you saw in May just as the standards are  
4 that much better based on what we learned from the  
5 outside.

6           And then after that, I think we will need  
7 to sort of sit down and figure out, you know, what  
8 would constitute that tailwind. Are there some --  
9 I don't know -- apps, or are there some creative  
10 ways that we could maybe modularize bits and pieces  
11 of the content and make it accessible to different  
12 audiences. We've only had preliminary discussions  
13 about that. But if it's all right, may I ask Dr.  
14 Helfand to comment?

15           CHAIRMAN WASHINGTON: Absolutely.

16           DR. HELFAND: I don't have a lot to add  
17 except that we were encouraged by the, sort of,  
18 interest people have in our doing a better job of  
19 exemplifying what we're talking about, both on the  
20 level of, can you give me an example where a story  
21 where making missing data -- doing missing data  
22 right made a big difference in people's lives, but

1 also on the level of, we keep talking about  
2 listening to patients or listening to the people  
3 and sort of how does that translate into research  
4 methodology. How is that relevant -- you're saying  
5 that you want to hear stories, you want to hear  
6 what people say about themselves, about their  
7 illness. How does that -- how do researchers turn  
8 that into changes in research design?

9           And so, the interest that we got  
10 encouraged us to do, I hope, a good job of  
11 exemplifying -- showing what we're seeing, not just  
12 telling people what we're seeing. And I don't have  
13 more to add unless there's a question, but that  
14 kind of is the overall picture of that.

15           CHAIRMAN WASHINGTON: To that point,  
16 Weisman?

17           DR. WEISMAN: Yeah, just --

18           CHAIRMAN WASHINGTON: Name.

19           DR. WEISMAN: Harlan Weisman, member of  
20 the Board, and just a suggestion, maybe. At both  
21 the workshop, but also at some of the visits the  
22 Board has made to various groups around the

1 country, we have seen good examples of patient-  
2 centered research and how it has made a difference,  
3 and it might be worthwhile for the Methodology  
4 Committee, in looking for these narrations, to turn  
5 to whatever recordings we have of those  
6 interactions, including at the workshop where there  
7 were several groups already doing this kind of  
8 research where it made a difference.

9 CHAIRMAN WASHINGTON: Okay.

10 DR. GABRIEL: That's a great idea. Thank  
11 you.

12 CHAIRMAN WASHINGTON: Lewis-Hall and then  
13 Krumholz.

14 MS. LEWIS-HALL: Freda Lewis-Hall, Board.  
15 I actually have three questions, two process and  
16 one on implementation. I'll do the process ones  
17 first. It sounds as though, after public comment,  
18 these standards have changed, in some cases, quite  
19 dramatically. Is there any need to or intent to or  
20 was it not a part of our original design to reach  
21 back out for kind of this dramatically changed  
22 environment or is the feeling that we press ahead?

1           So, originally, I don't recall, so I'm  
2 asking the question, I'm not sure we anticipated  
3 such dramatic changes in the standards as have been  
4 made as a result of some of the comments that we've  
5 received and then addressed.

6           I'm assuming that we've made the decision,  
7 or the Methodology Committee has made the decision  
8 that we're confident in the changes that were made  
9 against the public questions and that we're ready  
10 to move forward without asking, and I'm putting in  
11 air quotes, the public again.

12           MS. NORMAND: The answer is yes.

13           MS. LEWIS-HALL: Yes. Okay. So, I just  
14 wanted to say that again and hear that answer  
15 again.

16           DR. GABRIEL: See, this is why I'm going  
17 to miss her. You know, I'm scratching my head and  
18 she says, the answer is yes.

19           MS. LEWIS-HALL: So, then the second  
20 question is, again on process, there were a number  
21 of things that were not addressed, that were not  
22 actually standards, right, there were a lot of

1 comments that were about non-standard issues in the  
2 backdrop or the environment of research. How do we  
3 intend to address those moving forward?

4 DR. GABRIEL: So, that's coming. So,  
5 you'll see that -- I'm not sure. Yeah, go ahead,  
6 Mark.

7 DR. HELFAND: Yeah, I think you're  
8 referring to comments, for instance, like, we don't  
9 like the example you used on page 14 or this  
10 description of causal inference is not detailed  
11 enough, or this one is too detailed. There were  
12 all kinds of comments that weren't directly about  
13 the standards --

14 MS. LEWIS-HALL: Right.

15 DR. HELFAND: -- but really were about the  
16 report that the standards were explained in. And  
17 until we revised -- we have looked at all of those  
18 and, of course, the AIR has looked at all of those,  
19 and the public's looked at all of those. Every  
20 comment is out to the public. It came in -- was  
21 posted on the web 15 minutes after it came in for  
22 the whole summer.

1           So, the only way to respond to those  
2 comments, really, is to do something with them,  
3 that is, if we change the example on page 15, our  
4 response would be, we agree, we did that, and if we  
5 don't, we would say why.

6           So, those -- the responses to those  
7 comments are more in -- the timing of that is in  
8 the revised report, which is several months down  
9 the road.

10           MS. LEWIS-HALL: Okay. And then the third  
11 question is -- I'm sorry.

12           DR. GABRIEL: I was just going to say, I  
13 sort of alluded to that before. Those will help us  
14 explain the standards and sort of put them in a  
15 better context and perhaps create a better story,  
16 patient story, or a more illustrative story around  
17 them, they won't really change the substance of the  
18 standard.

19           MS. NORMAND: And I just want to follow  
20 up, it's Sharon-Lise Normand, on that. Just to  
21 underline, in case it wasn't clear, for every  
22 comment, we have a response that we're going to

1 post, just so you know, every single comment there  
2 will be a response to it, as Dr. Helfand indicated.  
3 We're not going through all of them right now, but  
4 every single comment, there will be a --

5 MS. LEWIS-HALL: So, the ones that didn't  
6 result in change will also have a comment that is  
7 recorded.

8 MS. NORMAND: Exactly, exactly.

9 DR. GABRIEL: Absolutely every comment  
10 will be addressed.

11 MS. LEWIS-HALL: That's a good  
12 clarification. And then last, but not least, is  
13 not least is on implementation. As you did this  
14 amazing work to consolidate these and to clarify  
15 them, was there any assessment that was going on  
16 about how that might change the landscape for  
17 researchers that would be responding to our RFAs  
18 and RFPs over time?

19 So, any idea of how many researchers are  
20 able to meet these standards? How including  
21 patients in research might alter the ability to  
22 meet the standards? Or are those non-issues?

1 DR. GABRIEL: No, no, those are critical  
2 issues and, again, that sort of relates to maybe  
3 what Dr. Collins was asking a bit ago in our  
4 discussion yesterday about how do we build out a  
5 detailed evaluation plan. I mean, you heard Mike  
6 talk about experiments that we might be able to run  
7 to really demonstrate the impact of implementing  
8 these standards on the research.

9 Another part of the evaluation is going to  
10 be just to assess -- you know, we haven't done it  
11 yet, we haven't required it yet -- to assess the  
12 impact on investigators we might include surveys of  
13 the investigators or focus groups. So, that's all  
14 part of this evaluation plan that we are going to  
15 put in place and already have a lot of bits and  
16 pieces, not enough to share -- to put in place now.

17 And, you know, as Joe said, we have the  
18 advantage of having our own peer review, we've  
19 already been collecting data on how it's worked so  
20 far, and so we have a really unique opportunity to  
21 study it and be able to demonstrate using rigorous  
22 methods, what works and what doesn't work with

1 respect to implementation.

2 CHAIRMAN WASHINGTON: Sharon-Lise wanted  
3 to --

4 MS. NORMAND: Yeah, I just wanted to --  
5 Sharon-Lise Normand, outgoing Methodology Committee  
6 vice chair. I just want to emphasize the  
7 following, that there is nothing in our standards  
8 that hasn't already been implemented successfully  
9 somewhere. So, these are all doable, and so really  
10 what we're trying to do is to push the science and  
11 raise so that everybody engages in this type of  
12 research. So, just to be clear, it's not that  
13 researchers won't be able to do it, it's out of  
14 their reach, that's just not the case.

15 CHAIRMAN WASHINGTON: Sharon-Lise, we  
16 noticed the emphasis on outgoing. Okay. Joe, did  
17 you have a comment on this? I saw you reaching for  
18 your mic.

19 DR. SELBY: Only in response to Freda's  
20 first question about will we put the revised  
21 standards out for another public comment. As we  
22 read the legislation we don't think that it

1 suggests that, and it could get pretty circular and  
2 never stop --

3 MS. LEWIS-HALL: It'll be 2015 before we  
4 get it.

5 DR. SELBY: Or later. But I think that it  
6 is true that, I mean, in fact, these redlined  
7 revisions of the standards and the overview  
8 document are, I believe, already posted online  
9 right now or they will be any minute, and when  
10 they're adopted, those will be posted immediately,  
11 and we're always open to comment and I think I  
12 speak for the Methodology Committee too. As they  
13 go around disseminating and talking to the public  
14 about these, they will get input. And so, there is  
15 an ongoing way to provide input about --

16 DR. GABRIEL: Right, and the one thing  
17 to -- the one comment that I would like to add to  
18 that is that we did receive a number of comments on  
19 gaps, you didn't address this and that, you need a  
20 new standard on this. Now, should we develop a  
21 brand new standard, I think that would have to go  
22 out for public comment. So, those sorts of

1 comments, we sort of reserve for version two, and I  
2 think that's the category where I think it will  
3 have to go out for public comment, because it's a  
4 brand new topic, not fix this.

5 CHAIRMAN WASHINGTON: Okay, Krumholz and  
6 then Norquist and Hunt.

7 DR. KRUMHOLZ: I just want to make two  
8 quick comments. One, first, I have to acknowledge  
9 the great works. That, I think, goes without  
10 question, but the issue of the implementation just  
11 got me thinking about these GIA standards and, you  
12 know, the Guideline Implementation Appraisals, and  
13 the degree to which, as written, it's poised for  
14 adoption and use and it may be that we would  
15 benefit from thinking in the ways that some people  
16 have spent working with guidelines in trying to  
17 understand whether they're ready for being  
18 implemented. And that doesn't change the content.  
19 The content is fantastic. Just thinking about how  
20 does it get positioned in a way so that it can be  
21 used and checklists or whatever tools might be able  
22 to be used, you've got this -- I mean, you've got a

1 lot of ways in which it's already being done, but  
2 just make it easier for people to use.

3           And along those lines also with regard to  
4 being able to get this adopted and put into  
5 practice, I wonder if we should be thinking about  
6 standardization of that. So, with respect to our  
7 own grant-making, if this is just about training  
8 people on the peer review, I think we are going to  
9 fail to implement a standard approach to really  
10 looking at this. And the question is, can we get a  
11 prescreen so that there is a group of experts who  
12 go through the -- maybe they get graded first so  
13 that if people get filtered out early, for some  
14 reason or another, that there's sort of a quick  
15 review.

16           So, you're left with a group of  
17 competitive grants and then those get a little  
18 deeper look in a very standardized approach that's  
19 very much testing whether they're in alignment with  
20 our own standards. And then that's given to the  
21 peer review group with a little bit of annotation  
22 so that that helps them take it to the next level

1 of evaluation.

2 I know that adds levels, but if we really  
3 want to create a standardized assessment that's in  
4 line with the methodology report and communicate to  
5 people that we're truly serious about them paying  
6 attention to these standards in the work that's  
7 been done, I just wonder if you'd need some system  
8 in place beyond just training the peer reviewers  
9 but putting a process in place that ensures that  
10 there's been assessment that we've done.

11 I know, Sharon-Lise, you were nodding your  
12 head. Did you want to -- sorry, Gene, I don't mean  
13 to usurp.

14 MS. NORMAND: So, just to be clear, I  
15 believe, and Brian Mittman will echo this. Our  
16 thought is not targeted just to the peer reviewers.  
17 Our ideas and these standards that we have are  
18 targeted to everybody. So, I'll make that clear.

19 The second thing I'd like to state is that  
20 we'd also sort of want -- you know, again, we have  
21 this idea of experimentation that we'd like to be  
22 able to utilize. The third thing is, there are

1 standards and, as I said, these are all  
2 implementable, so we didn't pick anything -- I  
3 would say, sort of unlike the guidelines, they're a  
4 little more rubber meets the road in terms of the  
5 standards that we have proposed.

6           And I do think that we do want to have an  
7 opportunity also to add -- permit some creativity  
8 so the researchers should be able to be creative  
9 about things, and so these standards do permit  
10 that.

11           So, just to underline the fact, these are  
12 not just for the peer reviewers.

13           DR. KRUMHOLZ: Right. Harlan Krumholz  
14 from Yale, there are a couple things, one is the  
15 idea about the peer review is not that this was  
16 narrowly focused in that direction but is a way to  
17 provide that tailwind that will tell people we're  
18 serious and we want them to be implemented, so  
19 anyone who wants to apply for funding will have to  
20 pay close attention to them.

21           I think when you think about what you've  
22 just said, that's what's going to be most important

1 to communicate. Where are those areas where there  
2 is great latitude? And where are those areas for  
3 which it's nonnegotiable? And then that's the -- I  
4 think the value of our standardized evaluation of  
5 the grants, and particularly if we're trying to get  
6 grants from groups that may not traditionally be  
7 submitting grants or not have the great depth of  
8 experience, we want them to rely on this document  
9 to help guide them in the approaches that they may  
10 use.

11 But my suggestion here is that there may  
12 be means by which we can boost the implementation  
13 and use because we actually have the money, so we  
14 didn't just produce this and ask people to use it.  
15 The question is, how are we using it, and model  
16 that for other organizations.

17 CHAIRMAN WASHINGTON: Okay, good point.  
18 We have five minutes and three comments. I'm going  
19 to limit it to three that were already -- Norquist,  
20 Hunt, and then final comment from Normand, and I'm  
21 going to call the question.

22 DR. NORQUIST: Yeah, this is Gray

1 Norquist, member of the Board. So, I actually read  
2 these, if you can believe that, on the plane, and  
3 so I would say to Freda that actually listening to  
4 the public does make a difference, it did make some  
5 reasonable changes. So, I would say that, and I  
6 would also congratulate you on your work.

7           The other thing in here, and I may have  
8 missed it, but there are a lot of recommendations  
9 and there are a lot of things to do like have some  
10 training and stuff, and what I didn't see and I'd  
11 like to see at some point, is a prioritization of  
12 some of those other steps you're recommending,  
13 because we don't have all the money in the world,  
14 we've got a lot of other activities, and it would  
15 be nice to know from the committee, like, what your  
16 priorities would be for some of those  
17 recommendations that you had.

18           And then I was going to do, Gene, you had  
19 five minutes and I wanted to make sure -- and I was  
20 going to make the motion that we accept the  
21 standards and then kind of move on from there. So,  
22 anyway --

1           CHAIRMAN WASHINGTON: Okay, well, we have  
2 a motion on the table, but can we hear from Gail  
3 and --

4           MS. HOLE-CURRY: Second.

5           CHAIRMAN WASHINGTON: We also have a  
6 second. Okay, so we have a motion and we have a  
7 second. And now we're going to open it up to  
8 discussion starting with Gail.

9           MS. HUNT: Gail Hunt, member of the Board.  
10 I -- we have, in many public forums, now, gone and  
11 talked about how we expect people proposing to  
12 involve patients from the very beginning all the  
13 way through the process, and we've stated this, and  
14 we've said it a zillion times at the patient  
15 engagement forum, for example.

16           Can you -- my sense, from reading the  
17 standard that you put in, you have stepped back  
18 from that. So, we would be in the position of  
19 stating one thing, which is that you will follow  
20 this, and the other is that we're also saying you  
21 have to -- the proposers have to adopt the  
22 standards, have to be sure that they have the

1 complete standards, they meet the complete  
2 standards that you all have suggested, but it is at  
3 a lesser level and I mean, it's maybe just because  
4 that's where I focused, but it's 4.1.1. I mean, I  
5 see the shaking of the heads, so you know what I'm  
6 talking about.

7           And I think we need to, at least in my  
8 view, we need to adhere more strongly than what you  
9 have put in here in terms of patients.

10           DR. GABRIEL: Yeah, so, yes, you're  
11 referring to 4.1.1. We got a lot of comments about  
12 that and just to be clear, that reads "engage  
13 people representing the population of interest and  
14 other relevant stakeholders in ways that are  
15 appropriate and necessary in a given research  
16 context." So, the stepping back might be in a  
17 given research context.

18           So, there were a couple of things that we  
19 heard and this was a subject -- this particular  
20 standard was a subject of lots and lots of  
21 discussion and debate and back and forth. One  
22 topic -- one comment was the initial standard, if

1 you remember, didn't have other relevant  
2 stakeholders in the title and we heard a lot about,  
3 yes, of course, we're the Patient-Centered Outcomes  
4 Research Institute, but there are other relevant  
5 stakeholders that you may need to bring in  
6 depending on the research context.

7           So, that was an important change. The  
8 other important change -- or the other thing that  
9 we heard was sometimes patients from the population  
10 of interest have already been engaged in similar  
11 studies and we can kind of rely on patient  
12 engagement work and knowledge that's been gleaned  
13 from prior efforts, and so, you know, are you  
14 really requiring us to redo it all?

15           So, I think what you see as a stepping  
16 back is the acknowledgement that it depends on the  
17 research context. If it's a methodology study  
18 perhaps the context is different. If it's a study  
19 where the work has already been done, perhaps they  
20 don't need to redo it, but they would have to  
21 justify that to the reviewers.

22           And so what you see here is the same set

1 of, you know, stakeholders should be engaged in the  
2 processes of formulating research questions,  
3 defining essential characteristics, monitoring  
4 study conduct, designing, suggesting plans. So,  
5 that's all still there.

6 MS. HUNT: Gail Hunt again. Now it says,  
7 "stakeholders can be engaged," not even should, so  
8 that's the kind of thing I'm talking about in terms  
9 of stepping back and I think that it should be --  
10 there should be something that talks specifically  
11 about patients and caregivers and their requirement  
12 to participate, and then other stakeholders too,  
13 and then talk about the other relevant  
14 stakeholders, but -- and also, the -- stepping back  
15 on the language.

16 The reason I'm sensitive to this is that  
17 Christine and I were on webinars about the pilot  
18 projects and people asked specifically, are you  
19 going to take points off if you don't involve  
20 patients, and we said, yes.

21 So, this is saying, oh, you only need to  
22 do it if you deem it as appropriate and relevant,

1 and I think this will be something that people will  
2 just move right into that gap.

3 DR. GABRIEL: Well, I think what it will  
4 speak to and --

5 MS. HUNT: Mark?

6 DR. GABRIEL: -- is the implementation, so  
7 how are we going to implement this so that we could  
8 actually make reasonable decisions across a whole -  
9 - a broad variety of studies and still be true to  
10 our central principles? So, Mark is going to --

11 DR. HUNT: Mark is going to die if he  
12 doesn't get --

13 DR. HELFAND: No, that's okay. Gail, the  
14 only thing I wanted to disagree with or correct,  
15 you know, it doesn't say "if the researchers deem  
16 it necessary." What I can tell you is that the  
17 thought behind these changes is that PCORI has a  
18 broader -- PCORI's bigger than its methodologic  
19 standards. PCORI, let's say, has an incredibly  
20 effective engagement activity with cardiac patients  
21 and a -- I'm just hypothesizing -- and a study  
22 comes along where there's already a great group of

1 stakeholders for cardiovascular disease working  
2 with PCORI and a study comes along and says, as may  
3 have happened a few years ago, you know, maybe if  
4 you stop that Clopidogrel after one year you're not  
5 doing the patients a great service. Maybe it should  
6 be continued two years, at least we've got some  
7 data to suggest that. And that group say --  
8 engaged and everything says, PCORI, please, do a  
9 study to figure that out. And the study design is  
10 to go back into a database and reexamine it in a  
11 different statistical method and at what steps do  
12 the people want to be engaged in that particular  
13 kind of study if fast, retrospective analysis of  
14 the database? And that's what we meant by the  
15 research context.

16           It isn't the investigator saying, we don't  
17 need engagement at this point, it's PCORI saying,  
18 you know what, we need engagement at all these  
19 points or in this kind of study we need it in fewer  
20 points, and this doesn't even cover the engagement  
21 in prioritization in the first place.

22           So, it isn't leaving it up to the

1 researcher to decide engagement, yes or no, it's  
2 allowing flexibility for the public as how they  
3 want to be engaged in different types of research  
4 studies and different -- in different contexts.

5 CHAIRMAN WASHINGTON: We have a motion and  
6 a second and we --

7 DR. WEISMAN: This is Harlan Weisman, and  
8 I want to make sure I know what we're voting on. I  
9 know we're voting on the sections that have to do  
10 with the methods, but there's also the section on  
11 recommendations, which have clear actions and  
12 obligations on PCORI.

13 I think, having gone through them, for  
14 myself, personally, they're not controversial, but  
15 they have budgetary implications and I want to  
16 know, are we voting approval of the  
17 recommendations, which to me implies an obligation  
18 to follow the recommendations? Or are we only  
19 voting on the methods part of the report? So, that  
20 was it. The other thing is, I totally agree with  
21 Gail and her point.

22 CHAIRMAN WASHINGTON: Okay, I thought we

1 were voting on the standards.

2 DR. SELBY: That's what we're called on to  
3 adopt.

4 CHAIRMAN WASHINGTON: Okay, so we're  
5 voting on the standards. Thanks for clarifying  
6 that, Harlan. There's a motion and a second.

7 MR. BECKER: What are we doing relative to  
8 Gail's comment?

9 CHAIRMAN WASHINGTON: Well, that's going  
10 to be inherent in how you vote.

11 DR. GABRIEL: Well, I guess I might  
12 suggest, and I don't know how quite you do this,  
13 but an amendment of some sort that reflects the way  
14 we implement this particular standard, you know,  
15 because it really comes down to implementation. If  
16 it's an example that was -- like Mark gave or like  
17 was given in the comments, it's -- this is  
18 perfectly reasonable. If it's an example, like you  
19 gave, and I don't think we have any loophole for  
20 the kind of -- you know, for an investigator's  
21 discretion, that's not acceptable.

22 So, to me, what really matters is how we

1 implement this particular standard and to make sure  
2 that it's implemented in alignment with, you know,  
3 PCORI's mission, vision, and values, which we'll  
4 do.

5 CHAIRMAN WASHINGTON: That just provides  
6 some context for how you vote, but it's not really  
7 a modification because it's about implementation  
8 and you're either voting on the standards as  
9 recommended or you're not, with those comments in  
10 mind, unless there's a recommendation to modify the  
11 standards, then -- which I don't think I'm hearing.

12 MS. NORMAND: Right, okay. Thank you.

13 MS. HUNT: We convened on this -- oh, Gail  
14 Hunt. We convened on this end of the table and  
15 came up with a terrific suggestion that in the  
16 first sentence of that 4.1.1, that you insert the  
17 word all, "all ways that are appropriate and  
18 necessary in a given research context."

19 So, not just -- it's to suggest that the  
20 proposer be sure to include them in all ways that  
21 it's relevant.

22 And just wanted to mention one thing. You

1 brought in the new stakeholders or the other  
2 stakeholders, that's true, but when you look --  
3 when you read it now, it sounds like they have the  
4 option -- the proposers have the option of not  
5 involving patients and caregivers, just involving,  
6 say, primary care docs or cardiologists who are  
7 stakeholders. They are definitely stakeholders,  
8 but I think we've always talked about it as if  
9 there were patients and caregivers involved as well  
10 as --

11 CHAIRMAN WASHINGTON: Okay. Christine had  
12 a hand and then I'm going to propose how we move  
13 forward here. Okay, Christine.

14 MS. GOERTZ: Thank you. Christine Goertz,  
15 Board member. I very much understand Gail's  
16 perspective. I was on those calls with her and I  
17 think it's critical that we address this issue in  
18 the correct way.

19 At the same time, I am opposed to the  
20 language change because I think to say "all ways,"  
21 I mean, you're putting -- it's a quagmire for  
22 reviewers and for investigators because, you know,

1 there are always alternative ways to do it and to  
2 say that they have to do it in all ways, I think  
3 would be really hard to implement.

4 I also agree that this is an  
5 implementation issue and as long as, you know,  
6 you've brought it up, we're very cognizant of what  
7 the issue is, I think it can be addressed through  
8 implementation in a way that you would feel very  
9 comfortable with.

10 CHAIRMAN WASHINGTON: Okay. There is a  
11 motion and a second and Gail just provided some  
12 comments, others have provided comments, we're  
13 going to vote on that motion first and if that  
14 motion doesn't pass, then there is a second motion,  
15 Gail, which would be my approach, that says we  
16 insert all, but there is a motion on the table.  
17 And if I have my *Robert's Rules of Order* correct,  
18 we've got a motion and second and we're going to  
19 vote.

20 UNIDENTIFIED BOARD MEMBER: This is Gray's  
21 motion you're talking about.

22 CHAIRMAN WASHINGTON: This is Gray's

1 motion. And the motion is that we adopt the  
2 revised standards, not the specific, that are being  
3 recommended by the Methodology Committee. Are we  
4 clear?

5 CHAIRMAN WASHINGTON: All in favor?

6 [Hands raised.]

7 CHAIRMAN WASHINGTON: It's an overwhelming  
8 majority, but I have to record, 16. All opposed.

9 [Hands raised.]

10 CHAIRMAN WASHINGTON: Four. Abstaining?

11 [No visible hands.]

12 CHAIRMAN WASHINGTON: Okay, so the motion  
13 carries and we've adopted it.

14 Sharon-Lise has asked to make --

15 MS. NORMAND: Yeah, so I just wanted to,  
16 again, as the outgoing Methodology Committee vice  
17 chair, I wanted to indicate my gratitude and honor  
18 being part of this organization. It's been a lot  
19 of fun and it's very rough sitting here looking at  
20 a picture of yourself, I have to tell you that, so  
21 I can't wait until we move on to the next screen.

22 I will be remiss if I didn't say the

1 following, I said this yesterday in the meeting  
2 with the Methodology Committee, we've all been  
3 parts of large groups and committees. I have to  
4 say that the Methodology Committee has been very,  
5 very delightful to work with. I can honestly say,  
6 there is no ego in that group. We come in, we  
7 listen to each other, there are no eyes rolling,  
8 everybody listens to everybody and it's just been  
9 an endearing and creative group of people and I  
10 just want to say that I'm so grateful to have the  
11 opportunity to work with them. So, thank you  
12 again.

13 CHAIRMAN WASHINGTON: Our vice chair gets  
14 the last word this morning and then we're going to  
15 break until -- we're going to take 15 minutes, so  
16 we're going to break until 10:30.

17 VICE CHAIRMAN LIPSTEIN: So, my name is  
18 Steve Lipstein. I am the not-yet-outgoing vice  
19 chair of the PCORI Board and I don't want to talk  
20 about the Methodology Committee or its report, I'd  
21 just like to talk about Sharon-Lise for a minute.  
22 Because we vice chairs, we are kindred spirits. We

1 do everything that our chairs ask of us, but in  
2 Sharon-Lise's case, she's done everything that we  
3 could have asked of her and a whole lot more.

4 I remember we were sitting next to each  
5 other at a methodology workshop and I leaned over  
6 to her and I said, Sharon-Lise, what is VOI, and  
7 she said, that's what I do. And so it has given  
8 this hospital administrator great street  
9 credibility to explain value of information  
10 research, but I just want to acknowledge that  
11 personally -- you get to know people, not just  
12 through committee members, but you get to know  
13 people, and so it's been terrific to have you as  
14 part of our family, part of our group, and since I  
15 am the chair of the nominating committee -- I  
16 haven't asked the rest of the nominating committee  
17 for permission to do this, but since Sharon-Lise is  
18 the first and only member of the PCORI alumni  
19 association, I would like to make her our honorary  
20 Chairperson.

21 Sharon-Lise, thank you for everything.

22 [Applause.]

1           CHAIRMAN WASHINGTON: Thanks to the entire  
2 Methodology Committee for just a herculean effort  
3 and, I think, a tremendous outcome.

4           Break until 10:30.

5           [Recess.]

6           CHAIRMAN WASHINGTON: Welcome back to this  
7 Board of Governors meeting for the Patient-Centered  
8 Outcomes Research Institute.

9           In this next segment we are going to  
10 return to a presentation and a discussion about the  
11 important activities of establishing advisory  
12 panels.

13           And Board members recall, at the last  
14 meeting we endorsed the idea that staff would  
15 develop two specific ones and gave them latitude to  
16 come back with a third one if they deemed that  
17 appropriate.

18           And so today, I understand that, in fact,  
19 we have a proposal for three advisory panels, as  
20 well as at least a proposal that we consider some  
21 additional ones going forward. So, we're going to  
22 be looking for an endorsement of that idea as well.

1           And to present, we have our Executive  
2 Director, Dr. Anne Beal.

3           Thank you, Anne.

4           DR. BEAL: I'm the Deputy, not the  
5 Executive Director.

6           CHAIRMAN WASHINGTON: Beg your pardon?  
7 Oh, Deputy Executive Director. That's right.

8           DR. BEAL: Yeah, right. I got you, Joe.  
9 All right. So thank you Gene.

10           As Gene mentioned, this was something that  
11 we talked about at the last Board meeting. And so,  
12 the first couple of slides are really just to  
13 remember what it was that we discussed and to  
14 remind ourselves that this discussion around the  
15 advisory panels really comes from the language in  
16 the authoring legislation which helped to create  
17 PCORI. But essentially, as we discuss the purpose  
18 of these advisory panels are to really allow us  
19 access to National experts on a number of different  
20 issues, to really help us with thinking about our  
21 research activities, as well as to help us with  
22 identification of topics and prioritization of

1 those research topics.

2           In addition, there is language in statute,  
3 which talks about having advisory panels related to  
4 randomized clinical trials as well as related to  
5 rare diseases, which we're going to talk about  
6 later on, and in addition, whenever we have  
7 specific or very special research projects, we've  
8 thought that we wanted to be able to have access to  
9 these advisory panels.

10           So, as you all will recall, our proposal  
11 was really to develop advisory panels, which will  
12 be made up from anywhere from 12 to 21 members,  
13 depending upon what the requirements and the  
14 activities are of the panels, and that our process  
15 would be to have a group of nominees that are  
16 presented to the Board for your approval.

17           In addition, as we talked about how we  
18 would populate these panels, we wanted to make sure  
19 that we would pay a lot of attention to the  
20 diversity of interests and expertise and views that  
21 we would want to make sure are included in the  
22 panels, and we also talked about the fact that we

1 would want to compensate members for their time and  
2 that when people are appointed to these advisory  
3 panels, they would be appointed for one-year terms.

4           In addition, much of our discussion at the  
5 last meeting also focused on issues related to  
6 conflict of interest and more specifically what we  
7 wanted to make sure is that individuals'  
8 participation on advisory panels would be  
9 structured in such a way that it would not preclude  
10 them from applying to us for any funds. If there  
11 was going to ever be a situation where the work of  
12 the advisory panel did then have someone become  
13 disqualified for inclusion or for applying to any  
14 of our funds, we would make sure that that is  
15 something that would be clear and evident up front  
16 before people ever engage with the advisory panel.

17           And then lastly, as Gene said, that at the  
18 last Board meeting, you all then voted to allow us  
19 to establish up to three advisory panels with  
20 discussions about more to come in the future.

21           So, as we talk about the advisory panels  
22 that are in front of you today, there are two

1 specific questions that we want you all to  
2 consider. First is the scope of the work that's  
3 outlined in the three advisory panel charters  
4 appropriate, and secondly, we're going to have a  
5 discussion about additional advisory panels that we  
6 would like to develop in the first quarter of 2013.  
7 So, as we have today's discussion, just recall that  
8 these are the specific questions that we would like  
9 to pose to you.

10           So, you'll also recall from the last Board  
11 meeting that we talked about a timeline and set of  
12 processes for developing our advisory panels, and  
13 so what we agreed upon is that first we would draft  
14 a charter and submit it for the creation of an  
15 advisory panel and would get the appropriate input  
16 from the various committees that are involved with  
17 the different advisory panels to help create that  
18 charter.

19           We would then submit a request to the  
20 Board for approval of an advisory panel charter,  
21 and that is the activity that we are engaging in  
22 today, and then the Board may either authorize the

1 charter or they may request revisions to the  
2 charters. So, that's the discussion that we're  
3 going to be having today.

4           Assuming that today we do authorize the  
5 charter, then the next steps that the staff will  
6 participate in is activating the nomination process  
7 and selection process of our panel participants,  
8 and again, one of the things that we've talked  
9 about is the need for transparency in this process,  
10 so it will be one where we have a call for  
11 nominations that occurs on our webpage, that we  
12 would ask nominees to submit an expression of  
13 interest, and that we would evaluate the nominees  
14 in order to make sure that we have the diversity of  
15 interests and skills represented on the various  
16 charters to meet the needs of the charters.

17           Then once we've gone through that process  
18 and have selected a proposed slate of panels, we  
19 would then bring it back to the Board for the Board  
20 to then authorize and approve the nominees for  
21 panel membership and then also for the Board to  
22 select a chairperson to chair that panel.

1           So, the first three advisory panels that  
2 we are proposing, which we actually discussed at  
3 the last Board meeting, is the advisory panel on  
4 patient engagement, the advisory panel on  
5 comparative assessment of options, and the advisory  
6 panel on health disparities.

7           If you all look in your Board books,  
8 you'll see that in the appendix section of this  
9 particular part of your Board book, you have the  
10 individual charters for each of those as well as a  
11 recommendation from the engagement team as to our  
12 process for nomination of advisory panel members.

13           So, going into a bit more detail -- and as  
14 I say, you have the actual language in the appendix  
15 -- but one of the first ones that we thought was  
16 important to establish is the panel on patient  
17 engagement. Essentially, one of the things that we  
18 thought is that it would be very important to have  
19 a patient advisory board, if you will, which is  
20 really engaged to help us determine what are the  
21 patient engagement standards and what is the  
22 culture of patient-centeredness in all aspects of

1 PCORI's research and dissemination activities.

2           One of the things is that we currently  
3 have staff who are working in this area, we  
4 currently have, obviously, the work of the  
5 Methodology Committee in this area, but we thought  
6 that it was important also to make sure that we  
7 hear from the patient community to ensure that we  
8 have that kind of input in our work.

9           In addition, as we've thought about it,  
10 there are other advisory panels that we're going to  
11 be developing for the work of PCORI and for many of  
12 these advisory panels we're going to ensure that we  
13 have patient representation on these other advisory  
14 panels. And so, some of our thinking is that for  
15 this patient engagement advisory panel that we  
16 would have patients who are able to serve on both  
17 advisory panels to be able to bring information  
18 back from the different advisory panels that we  
19 have to then this patient engagement advisory  
20 panel.

21           So, what we are proposing is that this be  
22 an advisory panel of between 12 to 21 members with

1 an assurance that at least 75 percent, or a  
2 supermajority, of the people who participate on the  
3 panel be patients or caregivers or folks from  
4 advocacy organizations, and then their balance be  
5 people who represent perspectives from researchers  
6 or stakeholders.

7           Then, the advisory panel that we're  
8 proposing on comparative assessment of options is  
9 really an advisory panel which is going to be more  
10 focused on helping us to identify and prioritize  
11 critical research questions, and so, as we've  
12 thought about the work in terms of -- as you all  
13 know, our funding announcements are very broad, and  
14 so part of what we're now engaged in is the  
15 activity of really getting to much more targeted  
16 and specific calls and much more targeted and  
17 specific opportunities for research within our  
18 broad funding announcements.

19           And so, we would be very interested in  
20 having an advisory panel to help us with this  
21 process towards getting to more specificity. So,  
22 this is one in which the term would actually be for

1 two years and we would have its membership between  
2 15 to 21 members, and in this case, at least 25  
3 percent of the members will be patients,  
4 caregivers, and advocacy organizations. However,  
5 the balance or the majority of them would really  
6 represent individuals who come from either clinical  
7 research or other stakeholder backgrounds.

8           And then the third advisory panel also is  
9 really designed to help us with our critical  
10 research questions and to help us identify what  
11 might be targeted research proposals that we would  
12 develop going forward.

13           I think one of the things to highlight in  
14 terms of the work that we're doing in terms of  
15 disparities is that historically a lot of the work  
16 in health disparities research has really been  
17 somewhat descriptive and what we really want to do  
18 is make sure that the focus of the work that we're  
19 doing here at PCORI is really informing and  
20 identifying best strategies to eliminate  
21 disparities rather than to do studies that really  
22 describe the problems of disparities.

1           The other thing that I think is worth  
2 mentioning is that part of our emphasis on these  
3 panels as some of the first ones that we're  
4 interested in developing is because, as Joe  
5 mentioned earlier, we just hired our program leads  
6 in these areas, and so part of the task that  
7 they're going to be engaging in very early on is  
8 really developing the funding priorities and the  
9 funding strategies within each of these areas, and  
10 so they're keen to have access to the expertise,  
11 which would be available through these advisory  
12 committees.

13           So, again, this particular advisory  
14 committee will have between 15 to 21 members that  
15 will include patients, caregivers, and advocacy  
16 organizations as well as researchers and  
17 stakeholders. And, again, in this case, it will be  
18 a combination of the two, both patients and  
19 stakeholders, as members of the committee.

20           So, before we open it up for discussion,  
21 one of the things that we wanted to present to you  
22 all is that we now have these three charters in

1 front of us for advisory panels and would like to  
2 then focus on four charters that we would like to  
3 then bring back to you over the next two Board  
4 meetings.

5           And so, as you noted at the last meeting,  
6 one of the advisory panels that's really required  
7 by the statute is a panel on randomized clinical  
8 trials, and so that would probably be the next one  
9 where we would focus. But as we looked at rare  
10 diseases, which is also mentioned within this  
11 statute, when we went back to look at it, what  
12 actually became evident is that the language is  
13 such that it says, "when we embark on research that  
14 is focused on a particular rare disease, the  
15 recommendation is that we then develop an advisory  
16 panel for that rare condition."

17           As you all know, we currently have a  
18 number of proposals that are under review that we  
19 plan to be announcing within the next six to eight  
20 weeks, and so included among those may be projects  
21 that are focused on rare diseases. And so, as a  
22 result, if we have some projects that have scored

1 well that focus on rare diseases, then we would  
2 want to be able to have the latitude and the  
3 approval from this Board to be able then to develop  
4 the charters to be able to create the advisory  
5 panels for those.

6           The other area that we're interested in  
7 developing an advisory panel is in health systems.  
8 As I mentioned, we do have our new program leads in  
9 the three areas of options for prevention,  
10 treatment, and diagnosis, disparities, and in  
11 health systems. So, we would like to also develop  
12 a charter for our health systems program.

13           And then we just kept a placeholder, TBD,  
14 to be determined, because while we do have plans  
15 for developing a rare disease advisory panel, the  
16 reality is, is that we may have more than one  
17 project in this -- or even more than one project --  
18 in this next round of projects that focus on rare  
19 diseases, so we just wanted to be able to have the  
20 flexibility to develop those advisory panels if  
21 needed.

22           So, with that, I'll just take it back to

1 the questions, which is, again, asking about, is  
2 the scope of the work that is outlined in the  
3 materials that you have for the three advisory  
4 panels appropriate? And then we're asking you to  
5 comment on our proposal for additional advisory  
6 panels for us to develop in the first quarter of  
7 2013.

8           CHAIRMAN WASHINGTON: Okay. Thank you,  
9 Dr. Beal. I'm going to ask that we organize our  
10 comments around the two questions but separate them  
11 and focus on the first question first, and so,  
12 right now we're just going to limit it to comments  
13 related to the three advisory panel charters, and  
14 keep in mind that two of them we had already  
15 discussed, and there's a third one that's been  
16 added by the staff, which was within their purview  
17 given the direction they received from us at the  
18 last Board meeting.

19           And I see quite a few. Why don't I start  
20 with Krumholz and just work our way around to  
21 Collins -- no, I'm sorry, Kuntz. I meant Kuntz.  
22 Sorry.

1 DR. KUNTZ: Freudian slip there.

2 CHAIRMAN WASHINGTON: Just for the record,  
3 many in here know that I have blurred vision right  
4 now, so you're all kind of blurred on that side.

5 DR. KUNTZ: I'm in agreement. I think  
6 they're great categories. I just want to ask about  
7 the patient engagement part. I think the  
8 involvement of patients is equally important for  
9 all these. I'm just curious as to why the patient  
10 engagement has 75 percent patients.

11 I think that the patient engagement is a  
12 very serious and evolving science and I want to  
13 make sure that whatever the balance is that we have  
14 the same efforts to develop the rigor of the  
15 science, and just because the word is patient  
16 engagement, I'm not quite sure that's enough to  
17 flip the membership of 75-25 and I think that  
18 they're all equally important to develop the  
19 discipline of that area to get as much expertise as  
20 possible.

21 DR. BEAL: So, let me just make sure that  
22 I understand. So, are you saying that we should

1 change the profile of the patient engagement panel?

2 DR. KUNTZ: I think that if you look at  
3 patient engagement, which I think is an evolving  
4 science, 25 percent researchers is not enough to  
5 bring in the methodological expertise and while I  
6 think it's important to have patients in every one  
7 of these -- patients and caregivers in every one of  
8 these panels, which you have, I don't know why one  
9 would be more -- why you would have a higher  
10 representation of patients in one versus another.  
11 I think they're all important disciplines to work  
12 out.

13 CHAIRMAN WASHINGTON: So, just to follow,  
14 we'll table this, but Rick, what the logical  
15 recommendation extends from what you're saying be  
16 at least 50 percent were patients so that that  
17 would leave, you know, the other 50 percent --

18 DR. KUNTZ: Sure, I was just thinking from  
19 a practical perspective you had the range was 12 to  
20 21 members, 25 percent would be three researchers,  
21 and as a standing panel on the science of  
22 engagement, I'm not quite sure that's enough. So,

1 50 percent would be obviously a lot better I think.

2 DR. WEISMAN: Can I make one comment?

3 CHAIRMAN WASHINGTON: Sure.

4 DR. WEISMAN: This is completely related.

5 CHAIRMAN WASHINGTON: Give your name,  
6 please.

7 DR. WEISMAN: Harlan Weisman, Board of  
8 Governors. At the patient engagement workshop --  
9 or the patient workshop we just had, one of the  
10 comments that was recurring, it came up a number of  
11 times from the people we had there, is that they  
12 were somewhat disappointed that it was only -- the  
13 majority were patients, they really said, the next  
14 time you have a meeting like this you've got to  
15 include the researchers, you've got to include the  
16 clinicians, because they need to hear from us and  
17 we need to hear from them, and I think that is very  
18 much in accord with Rick's comments.

19 CHAIRMAN WASHINGTON: Collins.

20 DR. COLLINS: Francis Collins, Board  
21 member. Two comments, one very straightforward,  
22 one much more general. So, the straightforward one

1 is the proposed panel on comparative assessment of  
2 options. That title just confused the heck out of  
3 me about what are you talking about. I think  
4 you've got to have a title there that really  
5 explains what it is this panel is doing, and I  
6 think it's research priority, so why don't you just  
7 say that?

8           The broader question is, I'm still quite  
9 concerned about how these panels are going to  
10 provide input into PCORI's decision-making because  
11 you're going to assemble a lot of busy people,  
12 you're going to bring them together, you're going  
13 to ask them to provide advice. The advice may, in  
14 some instances, not be concordant with what the  
15 Board wants or what the staff wants. I don't see  
16 how those various pathways of input are going to  
17 get merged and synthesized.

18           And what you don't want to do is to  
19 assemble panels and then essentially have them  
20 conclude that they're window dressing and they're  
21 not really being listened to. Help me with that in  
22 terms of how you would actually implement this in a

1 way that their advice is going to be synergized  
2 with all the other things PCORI's trying to do.

3 DR. BEAL: So, one of the things that we  
4 talked about at the last Board meeting was that as  
5 we engage people to come in for these advisory  
6 panels that they are, in fact, that, advisory  
7 panels here to give advice to the staff and to the  
8 Board.

9 And so, frankly, it would be part of the  
10 job of the staff to take that information,  
11 synthesize it and then present it as we talk about  
12 some of our priorities going forward, particularly  
13 related to some of the specificity in terms of our  
14 funding priorities.

15 I think one of the things, though, that we  
16 also have to keep in mind, though, is that because  
17 these are leading experts in the country around  
18 various topics, we want to make sure that they will  
19 be able to provide input and advice to us that is  
20 general and help with guidance and general  
21 directions, but then when we get down to the level  
22 of real specific funding announcements, that's

1 where we would maintain a firewall to make sure  
2 that they're not precluded from applying to us.

3           And so, I think that as we structure this,  
4 we have to be very clear and careful in making sure  
5 at the level at which we're going to engage them,  
6 the kinds of directions, the kinds of questions,  
7 and make sure that it really helps us with general  
8 directions for our work but not getting down to the  
9 specific level of then our funding announcements.  
10 That has to occur at the staff level.

11           CHAIRMAN WASHINGTON: Joe wants to add.

12           DR. SELBY: Yeah, that's exactly right,  
13 and that's why the language in each charter says  
14 these committees are only advisory. We certainly  
15 see the Board taking the input from these  
16 committees, but also a lot of other considerations  
17 before making decisions about directions for  
18 funding.

19           The other thing to be said, though, is  
20 that these advisory committees advise us on more  
21 than just what to study, they take a look at the  
22 portfolio we've got, they help us think through

1 gaps and new directions, and particularly  
2 important, they help us think about dissemination  
3 when we have findings. So, they have a broad range  
4 of responsibilities. Prioritization, we tend to  
5 think of a lot because it's early in the process.

6 CHAIRMAN WASHINGTON: So, just picking up  
7 on Francis' point, at some point I think it would  
8 be nice if we were quite explicit and laying out,  
9 essentially, sort of, the advisory panel roadmap in  
10 which we laid out just what you described in terms  
11 of the roles and levels of engagement, but also in  
12 terms of process, how the information might be used  
13 from just, you know, you had one meeting on -- to  
14 give advice to how it might influence an RFP/RFH or  
15 how it might influence a Board decision.

16 I think we should be explicit about what  
17 the potential universal steps are. So, that's a  
18 very good question. And we don't have all the  
19 answers yet, but it should be laid out in an  
20 explicit way.

21 Just to keep -- rather than going around  
22 in an orderly fashion, to keep this group alert,

1 I'm going to just sort of jump around. I'm going  
2 to look at my list and you're not going to know  
3 whether I'm going to call on Becker.

4 MR. BECKER: So, two things, and they're  
5 process questions. Larry Becker, member of the  
6 Board, and for this question, chairing conflict of  
7 interest, and I know you made a couple of comments  
8 about conflict of interest, but I thought it was  
9 important to note that people who serve on these  
10 advisory panels will need to make disclosures about  
11 conflicts of interest and they will be published,  
12 they will be made public, and I thought that was  
13 important for people who are thinking about  
14 serving.

15 The second point, also to process, was  
16 that -- and Carolyn whispered this in my ear before  
17 she had to leave -- we both serve on NQF and she  
18 was asking about a process diagram about how these  
19 advisory panels will fit into the flow of  
20 everything that occurs because, for example, at  
21 NQF, we have got steering committees and various  
22 kinds of advisory committees, and sometimes those

1 things get conflicted a bit. And so, really, a  
2 process diagram of how this all fits.

3 Thank you.

4 MS. HUNT: Yeah, Gail Hunt, member of the  
5 Board. A couple of points, actually kind of tying  
6 in with what Larry just said, and Eugene, about the  
7 process, and that's -- my concern is when I look  
8 at, for example, health disparities, just--it's  
9 actually also true of the other comparative  
10 assessment. For example, it talks about  
11 identifying and prioritizing research questions for  
12 possible funding under PCORI. And yet, those  
13 people, even though they are -- they're coming up  
14 with possible research areas, they are going to be  
15 able to bid on some of those because somehow  
16 there's a firewall even though they're coming up  
17 with these ideas.

18 I just think it's something that maybe we  
19 need to clarify. I mean, I know that you guys are  
20 sensitive to that issue, and also I think that it's  
21 important to have the panels be able to talk to  
22 each other, not just so the staff staffs the health

1 disparities and they do their decisions and it  
2 comes to the Board, and then comparative assessment  
3 is doing its issues and it comes to the Board  
4 through the staff, but that there's some connection  
5 among the advisory groups so that at least  
6 someone's responsible for knowing that there's not  
7 duplication of effort, for example, across the  
8 panels.

9 CHAIRMAN WASHINGTON: Okay, good point.  
10 Levine and then Douma.

11 DR. LEVINE: This was just a small point.  
12 Rick made the comment that if the three scientists  
13 isn't enough on the patient engagement advisory  
14 panel and I just want to be clear that this isn't  
15 just about scientists and patients, it's patients  
16 and other stakeholders. So, I think, when we think  
17 about the numbers and percentages, we need to  
18 realize it isn't just about how many scientists do  
19 we need to solve a problem or to be in the room.

20 MS. HUNT: Is that a joke?

21 DR. LEVINE: If I could -- I was trying to  
22 come up with one but they're just so much better

1 when you use psychiatrists that I don't want to  
2 dilute the impact.

3 CHAIRMAN WASHINGTON: Okay, Douma and then  
4 Barnett.

5 DR. DOUMA: Allen Douma, Board. With  
6 regard to patient engagement, I'd just like to get  
7 confirmation that patient there is shorthand for  
8 people with health concerns, including prevention  
9 and self-care, whether or not they're part of the  
10 medical care delivery system. Is that true?

11 DR. BEAL: [Off microphone.] I'm going to  
12 actually ask my patient engagement team as they  
13 defined patient for the -- and they're nodding yes.

14 DR. DOUMA: Okay, good.

15 CHAIRMAN WASHINGTON: Barnett.

16 MR. BARNETT: Kerry Barnett. My comment  
17 was actually fairly similar to Gail's. You know,  
18 Anne, have you given some thought as to how to  
19 integrate these panels? You know, if you look at  
20 their charters, what they're being charged with,  
21 substantively it all touches a number of different  
22 places, and I think in order to drive the highest

1 value work product, we don't want them all marching  
2 off in completely different directions from a  
3 policy standpoint.

4           So, making sure they're talking to each  
5 other, maybe getting them together once or twice a  
6 year so they're talking about these issues sort of  
7 in conjunction with one another, I think would be  
8 very valuable.

9           We don't want to put ourselves in a  
10 position where we convene these advisory groups,  
11 they come back to us with very different policy  
12 perspectives, and we wind up having to say, thanks  
13 very much, but no thanks, we're not going to honor  
14 or be in concordance with what you've come to us  
15 with.

16           So, how we manage this over the long run,  
17 I think, is going to be very important that we  
18 don't put ourselves in a difficult position.

19           DR. BEAL: So, I will say that we had  
20 actually thought about having patients on all of  
21 the panels and then come back to the patient  
22 engagement, but you all are talking about

1 essentially taking it to another level of  
2 coordination, so we'll definitely think about that.

3 CHAIRMAN WASHINGTON: Just one thought  
4 that Joe just broached was the idea that, to the  
5 degree that you could have all of them meet on the  
6 same day, even if it was once a year, so that there  
7 was like a preliminary session in the morning and  
8 then the individual groups met, the same way that  
9 Boards do with their various committees, would be  
10 one way of getting at Gail's excellent suggestion.

11 Okay, Zwolak.

12 DR. ZWOLAK: Bob Zwolak, Board member. I  
13 understand that these scopes have to be pretty  
14 broad, but my concern is how we actually shape  
15 these groups; how we assign them their tasks; who  
16 does; how they fit into the organization, and I'll  
17 be very brief because my comments are a lot like  
18 what Francis just said. I just want to make sure  
19 that we continue to operate efficiently and the  
20 question is: who decides what they do? Who do they  
21 report to? Do they report directly to the Board?  
22 Do they coordinate? Does engagement coordinate

1 with CEOC? Does the comparative effectiveness  
2 integrate with methodology?

3 The reporting structure really troubles  
4 me.

5 DR. BEAL: So, what I will say is the way  
6 that they've been structured so far is that it  
7 really would be staff taking the lead on  
8 management, so it was individual staff who took the  
9 lead on writing the charters and then what we would  
10 be seeking is then the Board input on, you know,  
11 who sits on the panels. What I'm also hearing is  
12 that there's going to be a lot of interest in terms  
13 of regular updates and thinking about the  
14 activities of these organizations, but I would  
15 say -- organizations -- of these panels, but I  
16 would say that generally it would be the staff  
17 responsibility to ensure the communication issues,  
18 as well as the work stream issues, as well as then  
19 to report back to the Board.

20 CHAIRMAN WASHINGTON: Could I just clarify  
21 one point? It's not input from the Board on the  
22 panel, the Board approves the panels. Okay, but

1 the expectation is that these panels and chairs  
2 would really be reporting to the staff from day-to-  
3 day, but we actually approve -- there's nobody at  
4 the Board level that -- at least I was anticipating  
5 -- that any chair or Board -- I mean, panel member  
6 -- would report to.

7           And your question regarding the various  
8 committees is a good one. I don't think at this  
9 point, and Joe and Anne, you can correct this, that  
10 there was an intent that any panel would identify  
11 with any one committee or working group, although  
12 there may be some that they would work with.

13           DR. BEAL: Exactly.

14           CHAIRMAN WASHINGTON: Okay. So, I see  
15 Sigal and then Lewis-Hall and then Hunt.

16           MS. SIGAL: Ellen Sigal, Board. So, I  
17 think I understand why we have these panels, but I  
18 must say that I'm a bit concerned about how it's  
19 going to work within the whole ecosystem and how it  
20 really functions because, as an example, the  
21 patient engagement, I mean, it's going to take a  
22 while to set it up, we already are committing major

1 resources for patient engagement. I don't know how  
2 it really interacts with ongoing things or things  
3 that are planned, and specifically even the PFAs.  
4 So, it's just -- it may be just overwhelming to  
5 manage these panels, to integrate them, and for  
6 them to be useful.

7           So, I just exactly don't know how that  
8 works. As an example, patient engagement, will  
9 they look at what we're doing? Will they comment  
10 on it? Will it be too late? Will they be able to  
11 change things? Will they make recommendations to,  
12 you know, I guess their chair and then the Board?  
13 How does that all work?

14           DR. BEAL: Right, right. So, I'll say, in  
15 all honesty, we are creating this de novo, and so  
16 some of the specificity, I think, we're going to  
17 have to work out these details, and as I said, what  
18 I'm hearing loud and clear is that we're going to  
19 have to come back to the Board as many of these  
20 details get worked out.

21           What I can actually just point to is my  
22 own experience having, as a funder, relied on

1 advisory panels before. They're an excellent way  
2 to really help with refining of thinking,  
3 crystallization of thinking, to really just get  
4 input from a broad range of individuals who may  
5 represent different opportunities in terms of what  
6 they think about. And also I think the other thing  
7 that Joe talked about, which is very important, is  
8 as we talk about dissemination, really hearing from  
9 different types of organizations or entities who  
10 might be very eager to hear about the type of work  
11 that we are producing, so sometimes they help very  
12 much at the front end as we're developing work to  
13 understand whether there's a ready audience for the  
14 work that we're developing.

15           So, I can say that in previous settings  
16 where I've been, I've actually used these before  
17 and they've been very useful. In all honestly,  
18 where I've used them before, they were a once-a-  
19 year meeting and I think we're talking about  
20 something which is going to be meeting a bit more  
21 frequently than what we've talked about, and  
22 there's also the issue of coordination that's been

1 mapped out here.

2           And so, as we move ahead, we will  
3 definitely be providing the details with the sort  
4 of specificity that you all are requesting.

5           CHAIRMAN WASHINGTON: Okay, one option we  
6 could consider -- I'm not proposing it, but I'll  
7 just put it on the table and we can come back to it  
8 -- is that there would be a Board member on each  
9 one of these and so I'll just put it on the table  
10 and we'll come back to that.

11           I do know of other situations where there  
12 have been expert groups appointed by an overarching  
13 body and there was an ex officio or some member  
14 from that governing body appointed with it.

15           Lewis-Hall.

16           DR. LEWIS-HALL: Freda Lewis-Hall, Board.  
17 Anne, I think you answered the question that I was  
18 going to ask but I want to maybe ask it in a little  
19 bit of a different way, and that is, it sounds like  
20 synthesizing comments that people have made, they  
21 were concerned about three things. You know, what  
22 are the real critical questions that we intend to

1 ask these boards, when and how? And then, what are  
2 we going to do with that? And then, the second is  
3 really around the who and whether or not we'll have  
4 an opportunity to revisit or be made aware of who  
5 we're proposing on these slates once we've -- okay,  
6 so we'll approve each of the slates and you'll  
7 bring us a slate for approval or a group of people  
8 that will get honed down and it will all be worked  
9 out over time?

10 DR. BEAL: So, I think realistically,  
11 given the three that we currently have, many of  
12 them were already vetted by the respective  
13 committee, so we're going to do then the call for  
14 nominations, vet the call for nominations, then vet  
15 it with each of the respective committees as well  
16 as then among the people who are proposed, there's  
17 also going to be a chair as well.

18 So, that will also then get vetted through  
19 the respective committees and then brought here,  
20 though, for final approval.

21 DR. LEWIS-HALL: And then the third one is  
22 really the interconnectedness, and I'd really like

1 to suggest, you know, a real chart of how we expect  
2 them to work together and to work with us, because  
3 essentially we're introducing, you know, near 60  
4 people into an already large and complex  
5 environment to give ongoing advice and input, and  
6 that, you know, we've all had examples of amazing  
7 advisory boards that were highly productive, and  
8 everybody in the room has also been involved with  
9 advisor boards that were just disastrous in more  
10 ways than we can recount.

11 We want the first kind, not the second  
12 kind.

13 CHAIRMAN WASHINGTON: There's a recurring  
14 theme here, Anne and Joe, of effectiveness of these  
15 advisory panels, and so with our Methodology  
16 Committee being composed of the best and the  
17 brightest in this whole area, we should be maybe  
18 thinking about how, in fact, do we measure, because  
19 these advisory panels, again, they've been created,  
20 and have been for years, all around the country and  
21 we tend to think of it as a way to enhance patient-  
22 centered research and ultimately patient-centered

1 care, way to test it in some kind of way, and so we  
2 should be thinking about a rigorous evaluation of  
3 this whole exercise that we're about to undertake.

4 Hunt, please.

5 MS. HUNT: Thanks. Gail Hunt, on the  
6 Board. I thought, and I guess I was part of the  
7 group that was working on the charter for patient  
8 engagement -- I thought that these were advisory  
9 groups for the Board, and we'd talked about --  
10 Board and staff, but not that they were sharing  
11 their ideas or that somehow they were staff only,  
12 that they were -- we were signing off on who the  
13 people would be, but then they were actually  
14 serving as an advisory to us, because we talked a  
15 lot about the fact that we have to make sure they  
16 understand, they're advisors to the Board, they're  
17 just giving input, that sort of thing. Now it  
18 sounds like we're kind of saying, oh, they really  
19 don't have a relationship to the Board, they really  
20 are just staff -- you know, staff interacts with  
21 them and staff gets information from them.

22 So, I think we should clarify that, that

1 they -- somehow we have input to the Board too, and  
2 also, could you just mention, this is a tiny thing,  
3 but who appoints the chair of each of these?

4 DR. BEAL: Okay, so, to answer your first  
5 question, so the specific language is that they are  
6 advisors to PCORI and so then that means -- and  
7 then we specifically map out in each of the  
8 charters, we talk about that they will provide  
9 advice and recommendation to the Board of  
10 Governors, the MC, other PCORI advisory panels, and  
11 to the Institute staff. That's specifically the  
12 language within the patient engagement advisory  
13 panel.

14 So, as we've thought about it, it really  
15 would be something that is managed by the staff but  
16 that they really represent an advisory role to  
17 PCORI in all of the elements of PCORI.

18 So, including Board, but not exclusive to  
19 Board.

20 So then, in terms of the question that you  
21 asked about the chair, that would be something that  
22 would be worked out at each of these committees --

1 with each of the committees, and then again working  
2 with the staff to make those recommendations. But  
3 then obviously then brought forward to the Board  
4 for final approval.

5 CHAIRMAN WASHINGTON: On page five in the  
6 book, which is the diagram that Anne had up  
7 earlier, it shows, again, the process, and it ends  
8 with the Board approving both the composition and  
9 the chair of the panel.

10 But to Gail's point, and it's an important  
11 point, and you clarified, and to me it's related to  
12 the question that was asked, maybe one of the first  
13 questions from Francis, what's the role and in this  
14 case, what's the reporting relationship, and that  
15 may vary, and that's what I heard you just saying.  
16 That makes some sense. It really is advisory to  
17 PCORI.

18 Ultimately, it is to the Board, but there  
19 would be situations where they would just work with  
20 the staff, other times with the committee, and then  
21 there would be times when I expect we might have a  
22 chair presenting to this group. That's what is to

1 be determined, Gail, is what I'm envisioning.

2 Is that --

3 MS. HUNT: [Off microphone.]

4 CHAIRMAN WASHINGTON: Okay. Debra and  
5 then Sherine. Thank you, Harlan.

6 MS. BARKSDALE: I have two questions. One  
7 is relatively easy. In the descriptions it is  
8 stated that they will have monthly meetings and  
9 that meetings will be open and the monthly meetings  
10 will be webinars or conference calls. Will those  
11 be open to the public as well?

12 DR. BEAL: So, from a conflict of interest  
13 perspective, we wanted to essentially have our  
14 default setting be that everything be in the open,  
15 so therefore nobody has any early knowledge of any  
16 of the activities of PCORI. So, that's really our  
17 default for all of these activities.

18 MS. BARKSDALE: And my second question,  
19 you might not be able to answer at this time, but  
20 during those monthly meetings, what will they be  
21 talking about? Would they be reacting to something  
22 specifically brought to them? Or will they be

1 generating ideas as an independent entity? I'm not  
2 quite sure what's going to happen every month.

3 DR. BEAL: So, you're right, I can't  
4 answer that at this moment. So, it really does  
5 depend upon the individual panel and what are the  
6 needs and the questions that we want to have  
7 answered, so sometimes it might be prioritization,  
8 sometimes it might be process. I mean, they're  
9 here to be able to provide advice. So, the agendas  
10 will become known as we then work to develop them.

11 And some of them will actually be  
12 dependent upon who's a member of the advisory  
13 panels, so what kind of advice we would want to be  
14 able to pull from them, but everything will be  
15 available and out in the open.

16 CHAIRMAN WASHINGTON: Just jump in, Joe.

17 DR. SELBY: Thanks. So, unlike Anne, I am  
18 trained in predicting the future. I can see the  
19 future, so I can answer that question with a little  
20 more detail.

21 They will be -- among the things that  
22 they'll be doing are actually prioritizing research

1 topics that come through the process that we  
2 discussed last month and we will be discussing on  
3 December 4th and 5th. So, they will have real work  
4 to do applying a set of criteria to a set of  
5 questions and discussing, you know, why they scored  
6 them as they did. That will certainly be done in  
7 public.

8           So, part of what they'll be doing is that  
9 prioritization work. Part of what they will be  
10 doing, I think, is more general conversations based  
11 on their expertise and they will be interacting  
12 with staff and if there's a Board member on the  
13 committee, with the Board in their area.

14           CHAIRMAN WASHINGTON: Okay, we have  
15 Gabriel and Epstein.

16           DR. GABRIEL: Sherine Gabriel, Methodology  
17 Committee. I just wanted to underscore the  
18 importance of coordination and making sure the  
19 interconnectedness between all of our activities is  
20 in place. I mean, the last thing we want is a  
21 number of disconnected bodies. It's just highly  
22 inefficient. And with respect to vetting, the

1 Methodology Committee has not had an opportunity to  
2 review these, so these haven't been reviewed with  
3 us, and I think that we have a real opportunity to  
4 contribute not only on the evaluation side, which  
5 is a great idea, but contribute methodologic  
6 knowledge and methodologic input and even input in  
7 terms of the structure and goals.

8           So, I'd just ask that these be vetted with  
9 us in the future.

10           CHAIRMAN WASHINGTON: Sounds great.  
11 Epstein.

12           DR. EPSTEIN: Yeah, when I read these, to  
13 me they seemed to have really different challenges  
14 I want to reflect on and maybe get your comments,  
15 Anne. I have the bias that in the hard work ahead,  
16 for choosing where we use our resources, the most  
17 important and difficult decisions will be  
18 determining where they can make incremental gains  
19 that will be important and it won't be figuring out  
20 areas where there's a lot of morbidity or  
21 mortality.

22           We had the example of the postmenopausal

1 symptoms, and if I had an advisory board there of  
2 people who were specialists in women's health and  
3 OB/GYN, I would think they could teach us a lot  
4 about the ripeness of that area for further  
5 investigation.

6           Disparity seems like one of those areas  
7 also. It's big, but I know a lot of people work in  
8 the field and then get their hand around the whole  
9 thing, but the comparative effectiveness is the one  
10 that really -- I mean, huh? No one's going to know  
11 about more of these areas and if the real task that  
12 we need to do is figure out where with 152 studies  
13 being done, where additional incremental resources  
14 can make -- is the Board going to help us in that  
15 kind of area?

16           DR. BEAL: When you say, is the board  
17 going to help, in terms of participating in the  
18 advisory panel or the advisory panel --

19           DR. EPSTEIN: Sorry, I meant an advisory  
20 panel help the Board, making tough decisions about  
21 -- between areas in which they're not going to have  
22 any expertise, per se, because no -- unless a

1 tightly appointed Board -- advisory panel around a  
2 specific area, it will be impossible.

3 DR. BEAL: So, I think this question about  
4 the major priorities and future directions actually  
5 is very much a Board decision, but then what needs  
6 to occur then is so then what is our process to  
7 getting towards that specificity? And it's going  
8 to be a process where we're likely to want to have  
9 input, it's going to be a process whereby the staff  
10 are going to be providing some support in terms of  
11 that decision-making.

12 And so, I think we're all feeling that  
13 same level of desire and anxiety to get to that  
14 specificity. So, I think that with our internal  
15 discussions, we've been very clear that this will  
16 be a Board level decision, but we need to then  
17 determine what are the kinds of resources that we  
18 need to bring to the Board to be able to get to  
19 that decision. I don't know if you have other  
20 things to add, Joe?

21 DR. SELBY: I would -- first of all, I  
22 agree with you, Arnie, that the task of the

1 committee with the difficult name, that's related  
2 to our first priority, is the most challenging.  
3 It's the most challenging to us as a Board as well.  
4 It's the most challenging to the whole notion of  
5 PCORI that nothing in the legislation says anything  
6 about which directions we go.

7           We have been criticized roundly and  
8 repeatedly and for a year and a half about doing  
9 things in non-transparent ways, about making  
10 decisions without adequate stakeholder input, about  
11 the reaching conclusions about funding  
12 announcements without getting stakeholder input.

13           This is the formal response to, in a  
14 sense, those criticisms and to our own feeling that  
15 our research agenda ought to be guided by patients  
16 and other stakeholders. And, you know, it fits, I  
17 think, with other efforts that we've seen, but we  
18 recognize that it is more challenging because of  
19 the breadth of the possibilities.

20           Nonetheless, I think that as one -- having  
21 -- for the Board to have as one stream of input  
22 into what funding directions we take, an advisory

1 panel in this area is essential.

2 CHAIRMAN WASHINGTON: Normand?

3 MS. NORMAND: Sharon-Lise Normand,  
4 Methodology Committee member. I just wanted to  
5 follow up -- I'm glad you made that clarification,  
6 Joe. I just want to politely remind the Board that  
7 the Methodology Committee had put together a whole  
8 scope of work on the value of information. There's  
9 a science on how you prioritize things. There is -  
10 - it's very science-based and I'm not sure what has  
11 happened to that particular stream where I'm  
12 thinking of the workshops that we had, how you  
13 prioritize. There's a lot of science behind all of  
14 this and I just -- I want to remind you -- I don't  
15 know what happened to it. Are you --

16 DR. SELBY: We're very, very cognizant of  
17 that. Rachel Florence is working closely with  
18 David Meltzer, in particular, and that's what the  
19 December 5th meeting is all about. So, it's not as  
20 easy as it sounds when you read one paper about  
21 VOI. How do you get information put together in a  
22 dossier that allows you to do the VOI calculation

1 is not straight forward, but that's what we are  
2 talking about.

3 CHAIRMAN WASHINGTON: Weisman.

4 DR. WEISMAN: Harlan Weisman, member of  
5 the Board. I mean, Arnie's comment got me thinking,  
6 along with Ellen's, by your response, that we're  
7 having this meeting -- we're having the two  
8 meetings in December around prioritization, and I'm  
9 not clear -- that's to help us prioritize and think  
10 about it as well as methods, and I'm not clear how  
11 this all comes together and what the process is  
12 myself.

13 And we have the whole body of work on  
14 prioritization that the Methodology Committee used.

15 At some point, you know, there is -- you  
16 have -- none of this is totally algorithm and  
17 method driven. There's human judgment that always  
18 comes into this, and at some point we have to just  
19 say, these are all the inputs, and we were  
20 appointed, our staff was appointed to make some  
21 calls. But what would help me, maybe, and  
22 everyone's talking about organizational flow and

1 governance, maybe you could just show how an idea  
2 flows through this system of workflow -- I'm sorry,  
3 workshops, internal deliberation, advisory  
4 committees, to end up as a priority. What is that  
5 process, that flow of things? Because then maybe I  
6 would understand how it all could come together.  
7 It's just a suggestion, because right now I'm  
8 seeing a galaxy of different stars doing it sounds  
9 like the same thing, and I'm not seeing the  
10 constellation.

11 CHAIRMAN WASHINGTON: Okay, thank you.  
12 Levine, last comment. We are behind here.

13 DR. LEVINE: So, three quick comments, if  
14 I can remember the third one. I don't think we  
15 should lose your point, Gene, about an opportunity  
16 for a Board member to be an ex officio member of  
17 each of the advisory panels. I think that that  
18 will enable us as a Board to learn from -- second  
19 point, there must be a robust literature on best  
20 practices in organizations using advisory panels,  
21 and I think before the first meeting convenes, that  
22 we ought to have a sense of what that means in

1 terms of how this work goes on, and I assume  
2 somebody may be looking at that now.

3           And the third question or concern I have  
4 is, seven seems like a lot. Even six seems like a  
5 lot of advisory panels to get up and running, to  
6 schedule, to staff, to coordinate in terms of their  
7 work, and I'm just wondering about the pace of work  
8 given everything else that we're looking at as we  
9 review the budget planned activities for 2013. Is  
10 this a realistic number for the first year?

11           CHAIRMAN WASHINGTON: Okay, before we get  
12 to that question, because I think that question,  
13 Joe, I've learned to read the body language here,  
14 is on the mind of quite a few people sitting around  
15 the table.

16           Just a show of hands or support for moving  
17 forward with these three with the timeline then  
18 that Anne and Joe would move forward to begin to  
19 compile the names and come back with the slate. Is  
20 there a modification to that?

21           DR. BEAL: I just wanted to respond to  
22 Rick's comment about the composition of the patient

1 engagement panel, that the actual language in the  
2 charter says super majority. Our 75 percent was a  
3 goal that we have but we have flexibility. Simply  
4 super majority.

5 CHAIRMAN WASHINGTON: Okay. [Off  
6 microphone] -- in support for the idea. On page  
7 five, again in your book, under the advisory panel  
8 there's a [inaudible] that says, we would authorize  
9 them essentially to open up a nominations process  
10 via the web and other communications, people would  
11 submit names, the staff would evaluate them for  
12 some criteria, and then they would bring them back  
13 to the Board.

14 What we would be doing today is  
15 authorizing them to move to step three in this  
16 diagram. Okay.

17 DR. KRUMHOLZ: Harlan Krumholz. I just  
18 want to be clear. As I listen to the discussion,  
19 the thing that I'm uncertain about as we develop  
20 that hierarchy of decision-making is to what degree  
21 does the Board get deep into this? If the staff  
22 feels that they need these advisory groups, we're

1 mandated by the legislation -- I'm speaking in  
2 support of this -- that we say to them, here's some  
3 concerns, you're tapping into some of the expertise  
4 of the Board who are expressing some thoughts and  
5 potential landmines out there, but God bless.

6           You know, that we make sure that we're  
7 focusing in those areas as a Board that are large  
8 and strategic, but this seems to me to be -- I'm  
9 just struggling a little bit about the level that  
10 we can -- we should be getting in with staff when  
11 they're identifying this as something they feel  
12 they would be helped by and so in that way I'm  
13 speaking in support of this but also just wondering  
14 about how long we talk about stuff like this once  
15 the staff comes and says, we've thought about it,  
16 this is what we'd like to do, they get some input  
17 from us that says, hey, you know, warning here,  
18 warning there, you need to think about these  
19 issues, and then just say, fine, this isn't really  
20 big enough to spend a lot of time on for us.

21           I'm just wondering, but I'm having trouble  
22 calibrating, that's why.

1           CHAIRMAN WASHINGTON: Okay. Douma.

2 Sorry, and then I want to comment on --

3           DR. DOUMA: This is really just kind of an  
4 FYI. I just pulled up the statute itself and it's  
5 interesting to note that they're suggesting,  
6 through the use of the word "shall" that these  
7 advisory committees act as advisors to the  
8 researchers as well and in particular, it says,  
9 such panels shall be available as a resource for  
10 technical questions that may arise during the  
11 conduct of research. So, it has a different flavor  
12 to it than I think what we normally think with an  
13 advisory panel.

14           CHAIRMAN WASHINGTON: And so, following up  
15 on the point you just made, Harlan, I'd like to  
16 propose that at this point, this is not about a  
17 vote. We had already authorized or encouraged,  
18 endorsed the idea, and so the staff is moving  
19 through a process and it's checking in with us for  
20 input, and ultimately will come to us for a vote,  
21 which is what it's called for. And I'm just going  
22 to bring this to closure and thank all the Board

1 members for your comments to staff regarding these  
2 three.

3           Now, I do think the staff are asking us  
4 for our thoughts on taking on another four, and  
5 Sharon has expressed certainly the concern that  
6 I've had just sitting here thinking about this  
7 discussion. This is going to be a great deal of  
8 work and if efficiency is really going to be one of  
9 our values, the idea that we're going to, you know,  
10 have three and then do another four without some  
11 form of experimentation and feedback is really a  
12 question. And it's really more a question for the  
13 staff, because I agree with Harlan, but I sense  
14 that there are others who share the same just  
15 concern about timing.

16           DR. SELBY: I'll just say one thing  
17 briefly. Each of these committees has natural  
18 sponsors on the staff; so for example, the one  
19 that's dedicated to comparative effectiveness has a  
20 program director, David Hickam, who would oversee  
21 the relationships with that one. The patient  
22 engagement one, likewise, the disparities one,

1 likewise, if we go to one with improving health  
2 systems, likewise.

3           And I sense from the program directors  
4 some enthusiasm for getting started with these as a  
5 way of beginning to shape, hand-in-hand with  
6 stakeholders, some thoughts and ideas to bring to  
7 the Board about specific research directions.

8           So, in terms of work, I think that we can  
9 expect that we will and would like to be authorized  
10 to proceed with those panels that we feel some  
11 urgency to get started.

12           In the case of the clinical trials panel,  
13 it's interesting, we wouldn't start that one  
14 without the Methodology Committee. They've  
15 identified it as a keen area of interest there. It  
16 is in the legislation that we create a clinical  
17 trials advisory panel and we would like to get  
18 started on that with the Methodology Committee as  
19 soon as they are ready, but that one, absolutely,  
20 is a partnership.

21           And rare disease, we are -- I would say,  
22 we've reexamined the legislation and with respect

1 to rare diseases, our read of the legislation is  
2 that if we fund a study, there should be a small  
3 advisory group for that study. If we fund ten  
4 studies, there should be ten small advisory groups.  
5 There is not a call in the legislation for one  
6 advisory panel on rare diseases, although we happen  
7 to think that idea has some merit.

8           But I think, Anne, what you were saying is  
9 that we're not going to move -- we're not proposing  
10 to move ahead right now with an overarching panel  
11 of rare diseases.

12           CHAIRMAN WASHINGTON: Okay, last comment  
13 from Weisman and then I'm going to summarize where  
14 we are with the second question.

15           DR. WEISMAN: Okay, Harlan Weisman, Board  
16 member. Maybe a suggestion, and it picks up from  
17 where Harlan was, because it sounds like you guys  
18 need this advice, you feel a compelling need for  
19 it, but, you know, we're experimenting as we go.  
20 There's no textbook that tells any of us how to set  
21 this up and getting this enterprise of PCOR going,  
22 is to not lock into a two-year timeframe. I mean,

1 it makes sense, and that probably should be the  
2 intent of what we expect, but in doing an  
3 experiment, you may find that one advisory  
4 committee or how it operates isn't exactly what you  
5 were thinking it ought to be or that, you know  
6 what, these two advisory committees are basically  
7 doing the same thing so we want to continue but we  
8 want to bring them together.

9           And I think building in, maybe in the  
10 charter or somewhere, or even in the discussions  
11 with the people who are potential members that you  
12 build in the flexibility so that we have the  
13 agility to make adjustments as we go.

14           DR. SELBY: The terms are already just one-  
15 year, the terms in the charters for each are one-  
16 year of individuals, but I think what I hear you  
17 saying is, make the initial charter -- have a one-  
18 year duration and reexamine at the end of one-year,  
19 and that's a very good suggestion.

20           CHAIRMAN WASHINGTON: Okay. So, Joe and  
21 Anne, to summarize, what you've heard from Board  
22 members, as their input, is the concern regarding

1 the amount of work and the need to coordinate at a  
2 time when so much else is going on, taking on, you  
3 know, another four. And so, you know what your  
4 needs are and in that light we ask that you  
5 evaluate what the next steps are going to be.

6 I think the suggestion that a Board member  
7 be appointed, ex officio, whatever we would call  
8 them, is one -- I see nodding of heads, and I know  
9 that you and Joe would support it, is one that we  
10 would incorporate into the activities as you come  
11 back. And so, the process could be as simple as,  
12 as you are developing these, you'd send out an  
13 email to see -- I don't know, should that be  
14 nominating, Steve? No, I think it should be more  
15 informal than that.

16 DR. BEAL: Actually, my question was,  
17 should it go out to the entire Board or should we  
18 do it through the committees?

19 CHAIRMAN WASHINGTON: I think it should go  
20 to the entire Board myself.

21 DR. BEAL: Okay.

22 CHAIRMAN WASHINGTON: Yeah, I just don't

1 think we should segment it by committees, and we  
2 won't choose everybody, but we'll be able to  
3 explain it, we'll know what the interests are.

4 Steve, does that sound --

5 VICE CHAIRMAN LIPSTEIN: Sounds good.

6 CHAIRMAN WASHINGTON: Okay. Thanks for  
7 that input on this question.

8 Kerry and group, we are behind 35 minutes  
9 and so we're scheduled to break at 12:00 o'clock,  
10 and we can think of your presentation -- you know  
11 it better than I do -- as two parts, in which case  
12 we could go to 12, 12:10, but I don't think we can  
13 complete it if it really is an hour presentation.

14 MR. BARNETT: Well, I think there's a lot  
15 to talk about here.

16 CHAIRMAN WASHINGTON: Okay.

17 MR. BARNETT: Frankly, just there are  
18 about four or five issues that Anne's going to  
19 cover that are pretty significant to be brought to  
20 the Board's attention and then, of course, whatever  
21 other issues arise. But my suggestion would be,  
22 let's just jump in and if we need to pen some of it

1 for later this afternoon, we can do that.

2 CHAIRMAN WASHINGTON: Okay, I think that's  
3 what we should do. Right now our plan is going to  
4 be a half an hour, which brings us to 12:10. We're  
5 going to break at 12:10. From 12:10 to 1:00.

6 MR. BARNETT: Let me -- in the interest of  
7 time, I'm going to be extremely brief and just pass  
8 it to Anne. The first thing that I want to say is,  
9 is really just acknowledge the great work that Joe  
10 and Anne and Pam have done on this budget.

11 I think you can take a look at it and  
12 immediately see that we are light years beyond  
13 where we were a year ago for the 2012 budget.  
14 There is far more thought and planning and detail  
15 in this particular budget than we've seen before.

16 Obviously, it still needs to be refined,  
17 there still needs to be some more detail here and  
18 there to make it fully operational, but we've  
19 obviously come a great, great way.

20 Last time around, the budget process  
21 really consisted of going around to the Board  
22 committees and saying, what are you thinking about

1 doing next year and how much money do you need to  
2 do it, and then there was some thrashing that went  
3 on behind the scenes and we had a budget.

4           This budget really represents a passing of  
5 the baton from that former and, frankly, outmoded  
6 model to the model that we're in today,  
7 acknowledging that we've got professional staff on  
8 board, that this needs to be a staff proposed  
9 budget and that's exactly what we've seen.

10           To varying extents, the committees have  
11 reviewed this, and I know some of the committees  
12 may feel like that they haven't had enough of an  
13 opportunity to review. If that's the case, we'll  
14 make sure that there is an appropriate level of  
15 review from the individual committees.

16           The FAAC has reviewed the budget, but I  
17 want to be very clear, we haven't burrowed into  
18 each and every number, that's not possible to do.  
19 We don't see that as being our function and we  
20 haven't done that.

21           The real focus of the discussion here this  
22 morning and maybe later on this afternoon, I think,

1 needs to be far more about words than numbers. It  
2 has to be about to what extent is this budget, as  
3 it takes shape -- to what extent does it fit the  
4 strategies that we've been talking about as a Board  
5 and the activities and objectives that we see  
6 ourselves addressing in 2013. And we need to be on  
7 the lookout for any sort of a mismatch between what  
8 are expectations are and the resource allocation  
9 that you see here.

10           And then as I mentioned a minute ago, Anne  
11 is going to talk about a half a dozen sort of key  
12 issues that we wanted to make sure that the Board  
13 had an opportunity to review relating to, for  
14 example, the staffing structure, the amounts being  
15 specifically spent on research, and overall cash  
16 flow issues.

17           So, I'll stop there and pass the baton to  
18 Anne and she'll do all the lifting from here.

19           DR. BEAL: So, first I want to recognize  
20 the great work of Pam Goodnow, who's our Director  
21 of Finance, who's really been such an asset to the  
22 organization. So, I want to thank her for all that

1 she's done to help pull this budget together.

2           So, these are the key points that we're  
3 going to talk about today in terms of, as Kerry  
4 said, as we thought about this budget we wanted to  
5 really make sure that we focus on key strategies  
6 and essentially strategic implications in terms of  
7 what it is that we're discussing.

8           We actually took an approach called  
9 performance-based budgeting, which really builds  
10 upon the fact that rather than being able to look  
11 retrospectively at what we've done in the past  
12 year, which is what many people do when they are  
13 building a budget, what we said is, okay, we're  
14 going to look prospectively and ask ourselves what  
15 are some of the strategic objectives that we have  
16 for the organization? What are the activities that  
17 we want to engage in to sort of meet those  
18 strategic objectives? And then, as a result, then  
19 what are some of the budgetary requests that we  
20 would be making in order to meet those objectives?

21           And so, as you'll see here, what we then  
22 did is presented the overall budget as well as some

1 support for some of the different types of  
2 questions that we want to raise with you.

3 I think the other thing that's worth  
4 pointing out, and this is where Pam, in particular,  
5 will be very important for this discussion, is  
6 understanding the cash flow issues related to our  
7 commitments and outstanding obligations and then  
8 what this means then in terms of our cash flow both  
9 in terms of the long-term and the short-term.

10 So, there really is, as Kerry said, five  
11 key points that we want to pull out of this budget,  
12 so there are a lot of numbers here and you all  
13 received the Board budget packet which has the  
14 details and then the breakdown by each of our  
15 priority areas, and so it has all of the details  
16 that we've been able to provide to date.

17 But hidden -- or not hidden, but within  
18 those numbers is essentially five key messages that  
19 we want to make clear. So, one is that as we were  
20 developing this budget, we really wanted to make  
21 sure that it was aligned with the strategic goals  
22 that we've set for the organization and that in

1 terms of thinking about what it is that we're  
2 trying to achieve, we really want to think about  
3 many of the requests in here as really being the  
4 placeholders for saying these are the activities  
5 that we want to engage in.

6           In addition, one of the things that we  
7 wanted to highlight, and this comes out in some of  
8 the cash flow analyses and the revenue analyses  
9 that Pam did, is we wanted to highlight the fact  
10 that we had to adjust to lower cash flow  
11 expectations, and what that means is that in the  
12 early days, as we talked about, the money's coming  
13 from the PCORI trust fund to help support the  
14 activities of the organization, there were  
15 expectations that in 2013 our budget was going to  
16 be around \$300 million.

17           In fact, given the differences in terms of  
18 when the monies are applied and when they come into  
19 the trust fund, in fact it means that within 2013  
20 we're going to have significantly reduced revenues  
21 and it will be closer to \$147 million.

22           And so, ultimately those monies will come

1 into us, but not within 2013. And so, all of the  
2 adjustments that we've done in terms of the budget  
3 and what -- the monies that we're working on are on  
4 this relatively conservative estimate that we will  
5 have \$147 million, and I'll speak a little bit more  
6 around that.

7           In addition, one of the things that we've  
8 built into the budget was some flexibility for our  
9 quick turnaround and rapid response funding, and so  
10 essentially what we wanted to do was to develop a  
11 fund for special projects that really would be  
12 available and utilized at the discretion of our  
13 executive director up to some of the already  
14 approved funding limits that he has available to  
15 him, but essentially what we wanted to recognize is  
16 that in 2013, we are really developing the  
17 refinements for our scientific program.

18           As you heard Joe mention earlier today, we  
19 just hired our scientific leads. We are engaging  
20 and bringing on our advisory panels to help us with  
21 creating greater specificity in terms of our  
22 scientific programs, and so what we wanted to do

1 was to essentially be able to build into our budget  
2 flexibility to be able to make investments in terms  
3 of our scientific work that we, at this point,  
4 cannot really anticipate but wanted to make sure  
5 that we have that flexibility in our funding.

6 In addition, we've talked about trying to  
7 set a target for overhead administrative expenses  
8 at around 10 percent and we'll be able to talk a  
9 little bit more about that.

10 And then, lastly, in 2013 we're going to  
11 be spending a lot of time really focused on  
12 building the infrastructure and operational core  
13 for the organization recognizing that we are  
14 building, but also recognizing that in 2014 we do  
15 expect a significant infusion of revenues and so  
16 really need to be staffed up and prepared to be  
17 able to manage that major influx of monies for the  
18 awards that we want to make going forward.

19 So, again, this is the definition of  
20 performance-based budgeting and as I said, the  
21 really key take home message is that rather than  
22 looking prospectively -- I'm sorry, retrospectively

1 and saying, how did we do last year and what are  
2 the adjustments that we want to make going forward,  
3 that this is somewhat different in that we are a  
4 developing organization, so we really don't have  
5 that retrospective information to be able to look  
6 at that really helps to define where we are going  
7 prospectively.

8           So, our process that we engaged in in  
9 terms of building this budget was really to start  
10 with the strategic plan and to really think about  
11 the strategic pillars that we have in our plan.  
12 So, as we've talked about engagement, as we talked  
13 about it we thought about advancing rigorous  
14 methods, we talked about funding PCOR,  
15 communication and dissemination, and then also  
16 thinking about our infrastructure.

17           And the process that we went through to  
18 really develop the budget was to go to each of our  
19 directors and to say, what is it that you think are  
20 your needs and activities for the upcoming year  
21 both in terms of staffing and in terms of funding,  
22 and then we built the budget in that way.

1           As Kerry mentioned, this was a significant  
2 departure from the process that we went through  
3 last year where we really tapped into each of the  
4 respective committees and asked the committees to  
5 be able to help create the budget.

6           This year it really started with the staff  
7 who was then vetted by the committees and then what  
8 you're seeing here is that process. That really  
9 comes from that process.

10           So, one of the first things that's worth  
11 pointing out is that as we've thought about the  
12 staffing model, we said that we anticipate that  
13 there's going to be significant need that we  
14 previously did not really anticipate, and so you've  
15 heard Joe talk about this before, that in the early  
16 days as we talked about what the organization was  
17 going to be about and the activities that we were  
18 going to engage in, we thought that much of what we  
19 were doing in terms of reviewing the projects as  
20 well as in terms of follow up might be something  
21 that we would be able to outsource.

22           It's become abundantly clear as we've

1 really defined the PCORI way of doing research and  
2 talk about doing research differently, that we  
3 actually want to do this internally, and so we are  
4 now expanding our a capacity for proposal review  
5 and are developing that in-house capacity to be  
6 able to do that as well as recognizing that in  
7 terms of the ongoing follow up of these different  
8 projects that we are developing, that we're going  
9 to have significant reporting from our awardees,  
10 that we're going to want our scientific staff to be  
11 able to provide overview and oversight to them,  
12 that we want them to be able to pull out the  
13 lessons earlier rather than later, and also that we  
14 want them to essentially be a resource and provide  
15 guidance and to be able to take our awardees  
16 questions and be able to help them in terms of the  
17 process of really doing patient engagement  
18 research.

19           So, all this really means that as we've  
20 thought about particularly the staffing needs that  
21 we're going to have in the scientific part of our  
22 organization, it is going to be a bit larger than

1 we had initially thought about a year, year and a  
2 half ago.

3           So, in addition, one of the things that's  
4 emerged as the PCORI way of doing work has really  
5 been put into place, we've actually made  
6 significant use of contractors. And so, as we  
7 looked at it and looked at the financial  
8 implications of using a lot of contractors, and  
9 many of these people are full time contractors,  
10 realized that it was not the most cost efficient  
11 way for staffing and meeting the needs of PCORI.

12           And so, taking you through this chart,  
13 what you'll see is that currently we are at 34  
14 permanent staff for PCORI and 38 contractors for a  
15 total of 72 FTEs. What we're proposing is that we  
16 both shift the model as well as expand it a little  
17 bit.

18           So, first the shift is that we would like  
19 to change the proportion of contractors who are  
20 doing the work of PCORI to really bring those  
21 people on board or bring people like them on board  
22 as full time staff for PCORI. And so, we're

1 proposing that we actually increase our staff from  
2 34 to 88. But at the same time reduce our reliance  
3 on contractors to take it from 38 down to nine.

4           And so, the net effect of this is because  
5 the contracting model for staffing the organization  
6 is actually a very expensive model, what we've done  
7 are the calculations and determined that in fact by  
8 reducing the number of contractors and really  
9 switching them over to full time FTEs that it will  
10 actually lead to a \$700,000 per month savings in  
11 cost, which then allows us to make the investments  
12 in terms of the expansions in staff.

13           And so, although the number of staff would  
14 increase significantly, the net effect is actually  
15 relatively flat line in terms of our monthly  
16 expenditures for staffing.

17           VICE CHAIRMAN LIPSTEIN: Anne, can I just  
18 comment here?

19           DR. BEAL: Sure.

20           VICE CHAIRMAN LIPSTEIN: One of the  
21 reasons -- so, as we've worked with staff over the  
22 last couple years, one of the reasons we haven't

1 been able to move to more of a staff model earlier  
2 is because the legislation that created us was a  
3 little bit in question and, as you know, it wasn't  
4 until certain decisions were made by our judiciary  
5 that we were able to really get ourselves on a  
6 little bit more stable footing, and certainly now  
7 in the aftermath of the election, even more so.

8           So, now, it's taken us a little while, but  
9 we're in a different place than we were when we  
10 started, so if you're wondering why it took us so  
11 long to get here, that's part of the explanation.

12           DR. BEAL: Absolutely. Thank you, Steve.

13           So, the other thing that I'd like to point  
14 out from the budget, and you'll see this  
15 particularly mapped out in the slides that are  
16 coming up, is that we had set a target for overhead  
17 administrative costs at 10 percent, and what I'm  
18 learning from Pam is that there are a very specific  
19 set of guidelines as to what can be counted as a  
20 administrative versus programmatic and we've done  
21 very careful accounting to make sure that things  
22 are appropriately allocated.

1           And so, what we've determined is that as  
2 we think about really what are some of the best  
3 practices, when you look at, for example, nonprofit  
4 organizations, in general they try to keep their  
5 administrative expenses at anywhere between 10 and  
6 20 percent, and we had actually set a goal for  
7 ourselves at 10 percent.

8           So, from the perspective of the  
9 performance based budgeting, we're also requesting  
10 significant investments, and many of these are one-  
11 time large investments with then smaller ongoing  
12 support, but really a lot of it is really related  
13 to the IT infrastructure that is required for doing  
14 a number of activities.

15           And so, many of those are listed here, but  
16 in the broadest strokes what it is that we're  
17 thinking is that we need to have the infrastructure  
18 that allows us to manage and coordinate all of the  
19 awards that were given, we need to have the  
20 infrastructure around dissemination of the work  
21 that's being produced by PCORI, and particularly by  
22 the Methodology Committee, and we need to have also

1 the internal infrastructure in terms of financial  
2 oversight for the work it is that we are doing.

3 And so, these represent, as I said,  
4 significant investments, which actually would then  
5 add to the overhead costs that we're anticipating  
6 for 2013.

7 DR. COLLINS: A point of information, the  
8 researcher data mark, that's not a term that some  
9 of us are familiar with. Can you quickly say what  
10 that is?

11 DR. BEAL: Actually, Pam, you want to take  
12 that?

13 MS. GOODNOW: I'm sorry?

14 DR. BEAL: The researcher data mark.

15 MS. GOODNOW: I'm sorry, the question is?

16 DR. COLLINS: What is a researcher data  
17 mark?

18 MS. GOODNOW: It was in the request from  
19 one of the groups. I think it's on the Methodology  
20 Committee.

21 DR. BEAL: Okay, so, one of the questions  
22 around this is, so it came from the staff who are

1 providing the support for the Methodology  
2 Committee. One of the challenges is that the  
3 Methodology Committee has not yet had a chance to  
4 review their portion of the budget because, as you  
5 know, they've been busy working on the revised  
6 standards. And so, a lot of what is being  
7 requested that comes specifically from the MC is  
8 actually right now a placeholder and they plan to  
9 be able to review this in detail within the next  
10 month or so.

11 But, Lori, you were saying that the data  
12 mark itself is --

13 DR. KRUMHOLZ: I think it's okay because  
14 we don't want to slow you down. It was just --  
15 just that there are things listed on here that just  
16 float forward and we're not quite sure what they  
17 are yet.

18 DR. BEAL: Okay. Right. Okay.

19 DR. KRUMHOLZ: Is that what you were  
20 saying?

21 DR. BEAL: Yes. Okay.

22 So then in terms of the appropriations

1 that we're expecting will come in, so as you know,  
2 PCORI has two lines of revenue that comes into the  
3 organization, so first are our appropriated dollars  
4 and then the second are the monies that come into  
5 the PCORI trust.

6 So, when we talk about revenues, one  
7 source that we have will be the \$120 million, which  
8 is coming in from appropriated dollars, and those  
9 are a pretty stable source of revenue for us.

10 But the other thing is that we do have  
11 these monies that are coming in from the PCORI  
12 trust and really what is the bottom line in terms  
13 of all of these statements here is that there is a  
14 lot of variation in terms of when monies will come  
15 in through the fees that are levied, when they  
16 actually then get handed over to the PCORI trust,  
17 and when they end up coming to us.

18 This is something, actually, that we've  
19 been working quite a long time with the FAAC is to  
20 try to get some real specificity regarding this,  
21 and so the bottom line, though, is that as we've  
22 looked at what our revenue assumptions can be for

1 2013 that we can rely on, we are working with a  
2 number of \$147 million.

3           You can be sure that as we get more  
4 details and more specificity from the PCORI trust  
5 as well as from the Treasury, then we will bring  
6 that information back to this Board, but we wanted  
7 to flag that for you as an issue that we're working  
8 with.

9           And so, in terms of the 2013 budget, in  
10 terms of our expenses -- I'm sorry, in terms of  
11 goals, objectives, and activities, one of the  
12 things that we wanted to point out, as I mentioned,  
13 is that we went to each of the different committees  
14 to really make sure that they had an opportunity to  
15 provide input.

16           Now, with that said, the Methodology  
17 Committee has not yet had that opportunity to do  
18 that, but as we've also gone to some of the other  
19 committees, there were a lot of questions and  
20 particularly at the level of the COEC there were a  
21 number of questions in terms of the budget and the  
22 activities that we were proposing.

1           So, you all have your book that has all of  
2 the details in terms of what is being proposed for  
3 communications and engagement, and one of the  
4 things that there's been actually about five  
5 different things that the COEC has asked us to  
6 engage in as ongoing activities for refinement of  
7 this budget. So, one is that while there are long  
8 lists of activities that we are proposing, they're  
9 asking us actually to prioritize these lists into,  
10 if you will, Tier 1, Tier 2, and Tier 3 activities  
11 so that if we determine that there are some that  
12 are going to fall off, we've been able to determine  
13 which those are based upon the priorities.

14           In addition, similar to the conversation  
15 that we had around the advisory panels, much of  
16 this is new activity and so what they've asked us  
17 to do is to develop a project plan and work stream  
18 around these specific activities to make sure that  
19 we can achieve all of these within the timeline  
20 that we're talking about as well as then to define  
21 what would be the measures of success for the  
22 different activities that they're proposing

1           Lastly, one of the things that came out of  
2 the discussions that we've had with the COEC is  
3 that we should definitely evaluate all of the  
4 activities to see that we're having the desired  
5 impact from these various activities and that we  
6 may, in fact, need to adjust and change, not only  
7 based upon the learning that we have from this  
8 evaluation, but also to adjust and change as the  
9 environment changes and as the needs of PCORI  
10 changes.

11           And so, we're planning, certainly, for  
12 this part of the budget to really engage in close  
13 tracking and follow up and we may have to make  
14 adjustments that would go back, obviously, to the  
15 COEC and then ultimately to the Board. Allen, you  
16 were going to say something?

17           DR. DOUMA: Yeah, Allen Douma, Board. I  
18 don't want to interrupt but it's with reference to  
19 language that was in a previous slide about the  
20 money, not the appropriation, but the other money -  
21 -

22           DR. BEAL: Yes.

1 DR. DOUMA: Yeah, I'm a little confused  
2 about the second bullet. It says we're going to be  
3 receiving 25 percent of the money between August  
4 15th and October 15th, and then the balance, and  
5 the balance will be received in 2014. What's  
6 happening between October 15th and the end of the  
7 year?

8 MS. GOODNOW: The first year that the fees  
9 are levied on is only from October 1st to December  
10 31st of 2012 and we've been working with the  
11 Treasury Department and others to try to understand  
12 the flow of the money, but we do know that the IRS  
13 came out with regulations that said for that first  
14 year, which is only a quarter of a year, and we  
15 don't know how many plans actually have year ends  
16 during that October 1 to December 31, that the  
17 first monies will be coming out. The excise tax  
18 return that is going to -- employers are going to  
19 report these dollars on, will be done the following  
20 July 31st.

21 And so, they've told us that based on  
22 their estimates at Treasury, between August 15th

1 and October 15th, they will give us some of those  
2 monies, they'll be deposited into the trust, but  
3 then there is a six to eight month period of time  
4 because the excise tax return actually collects  
5 Federal Highway taxes and a lot of other taxes.  
6 So, the Treasury needs about eight months to decide  
7 whose money is really what, and so we'll get some  
8 portion between August 15 and October 15th, on  
9 estimate, and then the rest of it in 2014 with that  
10 six to eight month lag.

11 UNIDENTIFIED BOARD MEMBER: Aren't you  
12 glad you asked?

13 DR. DOUMA: Yeah, I'm really glad I asked.  
14 So, will we -- going forward, will we -- our  
15 expectations be that this money is calculated on an  
16 annual basis and we get it with a lag, or we'll  
17 also go back -- and the only reason this looks like  
18 it's quarterly is because that was the end of that  
19 year? Is that correct?

20 MS. GOODNOW: It was the first year an  
21 assessment was, that short year.

22 DR. DOUMA: Right.

1 MS. GOODNOW: The next year it will be a  
2 full year, but still, the 2013 -- all of the money  
3 from 2013, all plans, will not even come in on a  
4 report to the IRS until August -- July 31st of  
5 2014.

6 DR. DOUMA: So, just to be specific, the  
7 answer to my question is it will become an annual  
8 event versus a quarterly event?

9 MS. GOODNOW: Yes, and we actually were  
10 thinking initially, at least from the Congressional  
11 Budget Office projections, that it was an ongoing  
12 flow of money because we thought that they were  
13 going to be reported on quarterly but we would get  
14 money like the Federal Highway and others who have  
15 an estimating process that's based on historic  
16 that allows them to get money on a regular basis.

17 CHAIRMAN WASHINGTON: So, we have ten  
18 minutes for questions before we break. Anne, is  
19 now a good time for questions or do you want to  
20 keep going?

21 DR. BEAL: Yes, because actually we're  
22 going to then get into the real specifics of the

1 numbers and I think that having discussed the big  
2 picture issues, I think, this is a natural time.  
3 Or I could go into the numbers.

4 CHAIRMAN WASHINGTON: You have done the  
5 unbelievable, you have overwhelmed the Board with  
6 the presentation. Steve, do you want --

7 VICE CHAIRMAN LIPSTEIN: I think the  
8 reason we're quiet is because there's just a lot  
9 more detail and explanation behind the math this  
10 year because we just know that much more about what  
11 it takes to operate PCORI and we also know that  
12 we're at just a different place than we were a year  
13 ago.

14 So, I think you'll find as we go through  
15 the next several pages, Gene, actually, that the  
16 explanations and the math are good budgeted  
17 amounts, but unlike the federal budget -- this is  
18 always important -- a budget authorization in the  
19 case of PCORI doesn't mean we're going to spend the  
20 money, okay.

21 I know it means that when we do that at  
22 the federal level, but when we do that at PCORI it

1 means that we're giving you our best estimates of  
2 what we're going to spend, and then you will find  
3 that during the course of the year there's certain  
4 elements of this budget where the staff will have  
5 to come back and seek approval to spend individual  
6 amounts, like the investment in infrastructure is  
7 an example.

8 CHAIRMAN WASHINGTON: Sigal, please.

9 MS. SIGAL: So, I get that, but it  
10 concerns me, so I know that it's hard to be  
11 specific and we may rethink it, but it still  
12 allocates a large sum of money that may be not  
13 diligent to begin with and because we have it we'll  
14 probably spend it, so I don't know -- I mean, it's  
15 hard to anticipate all of our needs, but when you  
16 put these large sums of money in that haven't been  
17 vetted completely or, frankly, agreed to, human  
18 nature is to spend that money.

19 And I don't know how that we're supposed  
20 to over -- kind of agree to a budget that is that  
21 large that we may not spend or, frankly, may not  
22 need or hasn't been fully vetted.

1 DR. BEAL: So, one of the things I think  
2 that Ellen's comments points out that I think is  
3 important is that as we created this budget, it is  
4 definitely an aspirational budget, and as we  
5 thought about what are the activities, what are the  
6 things that we want to do, what are the goals that  
7 we're trying to achieve here in the ideal world is  
8 what it is that we would like to be able to  
9 accomplish.

10 As we thought about it, we decided that it  
11 would be better to have monies budgeted and we have  
12 the flexibility to meet the aspirations rather than  
13 to try to have a budget where then if we exceed  
14 where we think we're going, then there's really no  
15 monies available. But one of the things that we're  
16 definitely building in is the capacity to come back  
17 and to be able to provide updates to see are we  
18 hitting the targets. And I would say both with the  
19 FAAC as well as with the larger Board.

20 VICE CHAIRMAN LIPSTEIN: And, Ellen, when  
21 we go through, the way our decision-making matrix  
22 is structured, you will find that staff needs to

1 return to the Board for expenditures in excess of  
2 \$500,000, so while we budget in the millions, there  
3 are other opportunities for the Board to look at  
4 the major categories of expenditure. But I also  
5 think, in picking our leaders, in picking our  
6 staff, we expect them not to be wasteful and to be  
7 prudent expenditures of the money and, at least in  
8 my experience working with them, I wouldn't say  
9 they're cheap, but they watch our dollars -- they  
10 watch our dollars as if they were their dollars,  
11 and so they have been very good stewards of our  
12 resources.

13 But I wanted to assure the Board that  
14 certain categories of expenditure return to the  
15 Board throughout the course of the year.

16 CHAIRMAN WASHINGTON: Okay, it's 12:05.  
17 I've got three cards up and then Kerry is going to  
18 wrap up, and so -- well, I mean, you're going to  
19 get the last comment.

20 MR. BARNETT: Well, I'm not sure we're  
21 close to the last comment yet.

22 CHAIRMAN WASHINGTON: No, I was talking

1 about in five minutes.

2 MR. BARNETT: Well, if I could just -- my  
3 suggestion was going to be that Anne take the few  
4 minutes to at least get through the section on  
5 commitments, the grant commitments, which, when you  
6 look at the totality of the budget, that's where  
7 the real money is.

8 It's pretty easy for us to get really  
9 focused on relatively small administrative  
10 expenses, the major expenses, and what we're  
11 proposing to do with respect to grants. So, my  
12 suggestion would be to hold the questions and the  
13 discussion until we resume, but to make sure we get  
14 that out on the table.

15 CHAIRMAN WASHINGTON: Okay. You can do  
16 that in five minutes? It's a question, otherwise,  
17 we can break and come back, because --

18 DR. BEAL: Well, let me -- I'll jump  
19 ahead. So, essentially the bottom line, and this  
20 is where Kerry is taking us, is that as we think  
21 about what will be our outstanding commitments, we  
22 have the monies that are from the pilot projects

1 that we've committed, we have the monies from the  
2 funding announcement that we approved in May, which  
3 is about to yield a number of projects that we will  
4 be approving in the next six to eight weeks, and  
5 then we're going to have at least two funding  
6 cycles for the broad funding announcements in 2013  
7 that will be paid for and committed within 2013.

8           And so, as we look at it, we're expecting  
9 that we're going to have commitments outstanding of  
10 about \$427 million, that we would have, on that  
11 \$427 million, made at least preliminary payments of  
12 \$123 million, but our standing at the end of 2013  
13 is that we're going to have \$304 million in  
14 committed dollars that will be out of PCORI and  
15 focused on doing the work that we're here to do.

16           CHAIRMAN WASHINGTON: Kerry, is that what  
17 you wanted --

18           MR. BARNETT: Yeah, absolutely.

19           CHAIRMAN WASHINGTON: -- on the table?  
20 Okay. Since we have a couple minutes left, I'm  
21 going to hear from Weisman and, did you put your  
22 card down, Sherine?

1 DR. GABRIEL: [Off microphone.]

2 CHAIRMAN WASHINGTON: Okay, we can still  
3 hear from the three that were on the table --  
4 Weisman, Gabriel, and Levine, and then we'll break.

5 DR. WEISMAN: So, as an alternative to  
6 what Steve said, one thing that I suggested  
7 yesterday, at least at the COEC, is because it is  
8 aspirational and, in fact, we want to encourage  
9 them to have stretch goals, but it would be  
10 unlikely, in all probability, to hit every stretch  
11 goal, but some of them will, is that we put some  
12 kind of probability on the budget and say that  
13 instead of funding it 100 percent, which is  
14 unlikely that we'll actually spend the money, we  
15 fund it -- I don't know what the right number is,  
16 I'm just going to say arbitrarily we fund it at 80  
17 percent with the idea that it gives you the  
18 latitude to keep going after everything, but not  
19 everything is actually going to pan out. And if,  
20 additionally, we could consider putting in a  
21 contingency part of this 80 percent budget which is  
22 releasable based on, you know, where we are. But

1 that does two things, one of them is, it's more  
2 likely to be what our actual fund is, but two, it  
3 forces us to really think about our priorities and  
4 make sure that we really hit those priorities and  
5 not have the kinds of concern that Ellen has.

6           So, you operate as if you've got the money  
7 for the 100 percent with the knowledge that, you  
8 know -- and we'd monitor it quarterly -- but with  
9 the knowledge that, in all likelihood, not  
10 everything's going to work the way you wanted it to  
11 and that's basically the idea.

12           CHAIRMAN WASHINGTON: Okay. Gabriel and  
13 Levine.

14           DR. GABRIEL: Sherine Gabriel. Anne  
15 already alluded to this but I just wanted to be  
16 sure that everybody on the Board was aware, since  
17 the question came up earlier, that the Methodology  
18 Committee budget on here really has not been  
19 discussed with the Methodology Committee yet. That  
20 will likely happen in the near future. It's sort  
21 of a placeholder put together by the staff.

22           CHAIRMAN WASHINGTON: Levine, last

1 comment.

2 DR. LEVINE: Last comment. And Ellen's  
3 comments were really -- and the concerns and  
4 questions both she and Gray raised about the  
5 budget, we spent several hours yesterday talking  
6 through at the COEC, and Anne briefly summarized  
7 the requests that we made in terms of giving us  
8 more comfort with moving forward, including  
9 Harlan's suggestion, the fact that we've asked for  
10 quarterly reports around where we are in terms of  
11 projections.

12 One of the concerns that we had, and this  
13 was reflected by a number of people, is the number  
14 of actual events or activities that are driving the  
15 size of the budget and whether, in fact, there's  
16 sufficient opportunity, sufficient staff and  
17 sufficient opportunity to really, in a high  
18 integrity way, learn from each event in terms of --  
19 rather than, for example, scheduling four events in  
20 four parts of the country that are the same, to  
21 ensure that we have a process in place to  
22 understand the metrics of success, whether we're

1 meeting them, and what that means about the  
2 subsequent schedule.

3           And so, with the five elements that Anne  
4 reflected, I think we were comfortable -- and Ellen  
5 unfortunately wasn't able to be there -- to move  
6 ahead and say, this is an aspirational budget.  
7 We've asked for prioritization. We've asked for  
8 kind of baseline, activity-based accounting,  
9 target, and the aspirational, and to think -- and  
10 that we will evaluate and work with staff over the  
11 year to ensure that the investments are delivering  
12 the return that we expect.

13           CHAIRMAN WASHINGTON: We'll -- to be  
14 continued. We are going to reconvene -- thank you,  
15 Sherine, thank you, Anne, but you will be returning  
16 to the same hot seat.

17           We're going to reconvene at 1:10. We're  
18 going to take our entire hour for lunch and see you  
19 then.

20           [Whereupon, at 12:13 p.m., the meeting was  
21 recessed, to reconvene at 2:10 p.m., this same  
22 day.]

A F T E R N O O N S E S S I O N

[1:15 PM EST]

1  
2  
3 CHAIRMAN WASHINGTON: Welcome back to this  
4 meeting of the Board of Governors for the Patient-  
5 Centered Outcomes Research Institute also known as  
6 PCORI. And we are going to continue our discussion  
7 about the budget for 2013.

8 Kerry Barnett, chair of the Finance and  
9 Administration Committee, is going to provide us  
10 with a summary of where we are and context for  
11 thinking about the remainder of the discussion.

12 And before you do that, Kerry, I just want  
13 to let everyone know, we will stick with our break,  
14 which is scheduled for 3:00, and the idea is that  
15 we will finish the other two topics in about 50  
16 minutes or so, so it allows us a good 50 minutes  
17 for continued discussion of the budget if  
18 necessary.

19 Kerry.

20 MR. BARNETT: It sure got quiet there all  
21 of the sudden, didn't it?

22 You know, I just want to start by saying,

1 and Anne, help me with this, this slide that's been  
2 on the screen there shows a \$10 million -- what  
3 looks like a net loss for the year. And several of  
4 you during lunch have commented on it. And that's  
5 fully accurate, but of course accurate in a  
6 misleading way, because all that reflects is that  
7 in fact the operating revenue for 2013, that will  
8 come in in 2013, is projected to be actually \$10  
9 million less than the proposed expenses, but what  
10 that doesn't take into account are two very  
11 important things. Number one, there's a very  
12 substantial carryover of funds from 2011 and 2012  
13 to the tune of \$200 million? What's the number,  
14 just roughly? Round numbers is fine. It's a large  
15 number.

16 MS. GOODNOW: Opening cash, \$233 million.

17 MR. BARNETT: Two hundred and thirty-three  
18 million dollars. And it also doesn't take into  
19 account the fact that in -- that much of our 2013  
20 revenue, as you heard from Pam and Anne earlier, is  
21 actually not going to come in until 2014. So, from  
22 a cash flow perspective, we have a very substantial

1 amount of resource to allocate and to work with,  
2 and I don't want anybody to be confused about that.

3           As we kind of open up the discussion and  
4 dialogue, I just wanted to sort of reset what I  
5 think we're trying to do over the course of the  
6 next 20 or 30 minutes max, and that is to really  
7 identify what the next steps are for this budget to  
8 get us to a point where the Board feels comfortable  
9 approving the budget.

10           I don't think there's an expectation that  
11 at the end of 20 or 30 minutes there's going to be  
12 an up or down vote on this particular budget, but  
13 we've already begun with a couple important, I  
14 think, do items for the staff.

15           One of them is that the Methodology  
16 Committee, as you heard from Sherine, has not had  
17 an opportunity to fully vet the budget, and we'll  
18 make sure that that occurs over the course of the  
19 next several weeks so we get all of your feedback  
20 and input.

21           And the second thing that we've heard loud  
22 and clear is kind of focusing on the COEC

1 discussion that occurred yesterday in some detail,  
2 a belief that we're looking at some very  
3 substantial levels of activity relating to  
4 communications.

5           And the first concern that I've heard is  
6 that we want to make absolutely sure that we're not  
7 sort of -- that our eyes aren't bigger than our  
8 stomachs, that we're not kind of biting off a level  
9 of activity there that is either, A, unattainable  
10 given where we are as an organization right now,  
11 or, B, frankly just not as high value as should be.  
12 And so what we're probably going to have to do is  
13 make some decisions sort of as we go.

14           So, the goal is to ultimately identify a  
15 body of activity relating to communications that is  
16 both reasonable and aspirational, we hope those two  
17 come together, but that that's something that we  
18 need to make sure we've bounded appropriately. And  
19 so, there will be some follow up discussions  
20 between staff and the COEC committee to make sure  
21 that we've done that.

22           And then the final thing that I want to

1 say, and then I'll finally shut up, is just a  
2 reminder to everybody as to what a budget really  
3 is. I know we've all dealt with budgets and I know  
4 we all understand this, but a budget is a decision  
5 that we make that's largely a snapshot in time  
6 based on what we know today. And it would be a  
7 real mistake if we made a budget decision at some  
8 point towards the end of 2012, and then felt that  
9 we were bound by that decision throughout 2013.

10 To the contrary, there are a number of  
11 forks in the road that we will experience as we  
12 need to reevaluate kind of the flow of activities  
13 and the resources that are available for those  
14 activities, and those need to be staff discussions,  
15 and those need to be Board discussions as well, and  
16 so if there are certain areas where we want to do  
17 more and spend more, we have the freedom and  
18 flexibility to make that decision.

19 And where we decide that maybe we're  
20 spending some dollars in an area that may not be of  
21 the highest value, we have the opportunity to pull  
22 back in those areas as well. And so, in fact, when

1 we think about some of the communications  
2 activities, it is very important that the  
3 communications committee is basically getting a  
4 full download from staff at least on a quarterly  
5 basis, to provide an opportunity to kind of  
6 reevaluate those activities. The town hall  
7 meetings are the perfect example. After we have  
8 one or two of them under our belt, we'll make  
9 decisions -- you need to make decisions -- as to  
10 whether or not we want more of them or fewer,  
11 whether they should be larger or smaller, whether  
12 they should be more robust or, frankly, less  
13 expensive. Those are all decisions that I think we  
14 need to be prepared to make on an ongoing basis and  
15 we shouldn't feel like we're tying our hands by  
16 decisions that we may be making today or in the  
17 near future.

18           Okay, so with that, Mr. Chairman, I'll  
19 stop and we can open it up for comments and  
20 discussion.

21           CHAIRMAN WASHINGTON: Okay. We have a  
22 round of questions and then, Anne, I understand you

1 want to continue --

2 DR. BEAL: It's just about three or four  
3 more slides in terms of the numbers, but if the  
4 Board has actually already reviewed them, then  
5 there's no need.

6 CHAIRMAN WASHINGTON: Okay, well, why  
7 don't we go with Weisman first?

8 DR. WEISMAN: Harlan Weisman. Kerry, I  
9 really like what you just said and I agree with it.  
10 It was a very articulate way of putting everything  
11 into perspective around the budget and what it  
12 actually is. How do you take what you just said,  
13 though, what is your proposal, Kerry, on how we  
14 would move forward in a formal sense with that kind  
15 of idea? You know, I had proposed one way of  
16 thinking about it. Do you have a proposal for how  
17 the Board should go forward?

18 MR. BARNETT: What I think would be great  
19 is if the Board could, in an informal way, indicate  
20 that the budget that you've seen here today is  
21 directionally correct and at the same time identify  
22 those areas of kind of further analysis or further

1 refinement or further detail that might be good to  
2 do.

3           You know, we've already heard two of them  
4 about the Methodology Committee and COEC, and there  
5 may be others. For example, one of the key issues  
6 is the determination around the level of grant  
7 commitments that we intend to make through the PFAs  
8 in 2013 -- in fact, maybe you could just leave that  
9 slide up, it's a couple of slides later I think --  
10 which is sort of a central issue with respect to  
11 this budget, but I think in terms of what we can  
12 try to get out of today's meeting it would be that  
13 notion that this is directionally correct and here  
14 are some two or three or four areas where we can do  
15 some further work.

16           DR. WEISMAN: Thank you.

17           CHAIRMAN WASHINGTON: Okay, Sigal and then  
18 [off microphone].

19           MS. SIGAL: So, Ellen Sigal, Board. I'm  
20 challenged by how it could be directionally correct  
21 if we're concerned about certain line items or  
22 certain categories. I just don't know how that can

1 be, I mean, unless we say it's directionally  
2 correct with a caveat that we think one category  
3 may be excessive or needs to be re-looked at. I  
4 don't know what we're doing when we say it's  
5 directionally correct. It just doesn't seem to  
6 make a whole lot of sense to me.

7 Other categories may be easy and they have  
8 to be tweaked, but others may not be. So, how can  
9 you say directionally correct unless you do  
10 category by category? You can do that.

11 MR. BARNETT: Well, I can try to respond  
12 to that only by saying, to the extent you have some  
13 concerns, please voice them, either now or after  
14 the meeting, to staff, so they know what to do with  
15 your concerns. It's obviously hard for them to  
16 know what the next steps should be without kind of  
17 having identified for them the areas where they  
18 should go into some more detail.

19 MS. SIGAL: Well, I mean, for me, I'm one  
20 of 21, I have been very specific on concerns, in  
21 writing and vocally among the people. Now, I may  
22 be right, I may be wrong, it may be irrelevant, but

1 it would be very hard to vote on a budget and say  
2 it's directionally correct.

3 I think maybe one thing you may want to  
4 look at is the sub budgets or the different  
5 categories, that may be one thing we can do. I  
6 just don't know how to do that.

7 CHAIRMAN WASHINGTON: We are not voting  
8 today. This is another step in a process of trying  
9 to get to a budget that we would vote on, and so  
10 the idea, relative to the communication parts of  
11 your concern is that they would take them and now  
12 they would work on them. But we're not voting on a  
13 budget, and so I apologize if we haven't been clear  
14 about that.

15 So that's what Kerry meant, directionally,  
16 and I understand exactly what you're saying, I  
17 think they do too, is that overall -- now if all of  
18 -- if we had major concerns in each one then, yeah,  
19 we'd have to stop today, but the goal now is that  
20 they would take these specific concerns that you  
21 have raised, and you have been specific and  
22 explicit, and we appreciate that, and began to

1 address them.

2 But we're not voting on a budget today.

3 Rick?

4 DR. KUNTZ: Yeah, Rick Kuntz, Board  
5 member. I think this is good. I'd just -- we  
6 focused on some of the administrative elements  
7 about the expenses, but the budget is really a  
8 revenue budget. You know how we're saying is that  
9 we haven't really gotten into the meat of the  
10 expenses yet. So, I just wonder if you can comment  
11 on what the process will be. For example, you  
12 know, how are we going to distribute the research?  
13 Are we going to get dollars into infrastructure?  
14 Are we going to have an intramural program? Those  
15 kind of things.

16 CHAIRMAN WASHINGTON: Okay. [Off  
17 microphone.]

18 VICE CHAIRMAN LIPSTEIN: No, I think I  
19 also wanted to get a dialogue with Ellen just a  
20 little bit because I think I -- as I look through  
21 the budget, when I think of directionally correct,  
22 you know, programming the budget into categories of

1 the Methodology Committee, research, engagement,  
2 program development, evaluation, and then we did  
3 make a suggestion, and it is in your book under  
4 Item B, that for the line items above a million  
5 dollars, a certain threshold, that we would provide  
6 the Board with greater specificity, but I do think  
7 it would be helpful, since we all have different  
8 thresholds, perhaps, of materiality, how much  
9 detail per line item staff needs to provide to the  
10 Board.

11           Because, for example, I'm comfortable with  
12 buckets, so long as the buckets that staff has  
13 identified, there's nothing missing or there's  
14 nothing in there that I think is appropriate, then  
15 our discussion really is strictly about the dollar  
16 amounts in each bucket.

17           And I think what I'd like to suggest is  
18 that we should give the staff direction so they'd  
19 know how to respond, which is, if we're interested  
20 only in those line items above a million dollars as  
21 a threshold, then they know how to respond. If  
22 we're going to ask them to respond for every

1 expenditure over a half a million or over \$250,000,  
2 but that was the suggestion I made, and so I do  
3 think we need to give them greater clarity, because  
4 that's -- we are scrubbing this in the Finance  
5 Administration and Audit Committee at a more  
6 detailed level than we scrub at the Board, and so I  
7 think we have to figure out as a Board how detailed  
8 we're going to scrub so that staff can really -- we  
9 give them a fair shot at coming back and meeting  
10 our expectations.

11 CHAIRMAN WASHINGTON: Okay. Well, I'm  
12 just going to ask Board members to take note of  
13 Steve's comment and if you feel like there's not  
14 sufficient detail, you need to provide that  
15 feedback to the staff.

16 Anne, would you present, please?

17 DR. BEAL: Sure. So, there are just a  
18 couple of outstanding details that I wanted to  
19 point out.

20 So, as Kerry said, this represents the  
21 budget for 2013 and while, based upon our revenues  
22 and expenses, there would be a deficit of \$10

1 million. What we also highlighted in the asterisks  
2 at the bottom is that we do have monies carried  
3 over from 2012. So, this just represents the  
4 expenses and revenues for 2013.

5 Then the other point is that we just made  
6 some back of the envelope projections for 2014, but  
7 really the bottom line is that as we pointed out in  
8 the previous slide, our administrative overhead  
9 rate is going to be around 13 percent, so you can  
10 see that here, I'm sorry, 13.3 percent, but we  
11 project that in 2014, when we are stable in terms  
12 of staffing as well as with the increase in  
13 revenues that we're going to be down at 8.4  
14 percent, which actually exceeds the threshold that  
15 we've set of our administrative overhead.

16 DR. WEISMAN: Can I ask a clarification  
17 question?

18 DR. BEAL: Sure.

19 DR. WEISMAN: The headcount increases that  
20 you're requesting or that were in Joe's overview  
21 this morning, are they in the budget from a budget  
22 standpoint? Are they phased in over time?

1 DR. BEAL: Yes.

2 DR. WEISMAN: And how did you do that?

3 And would looking at the phasing of bringing on new  
4 staff, would that help us in any way in terms of  
5 how we're managing and seeing how we're doing along  
6 the way? In other words, did you assume -- did you  
7 just divide it by four quarters or did you say --  
8 did you frontload it, did you backload it? How did  
9 you do it?

10 DR. BEAL: So, we assumed that we would be  
11 fully staffed up with the numbers that we projected  
12 by the end of second quarter, but Pam can provide  
13 more details.

14 MS. GOODNOW: Anne, the assumption for  
15 your end is that we would have a staff of 55, so  
16 between January 1st and the end of the second  
17 quarter, we'd be up to 88 from that number, and I  
18 just took certain positions and put them in  
19 gradually assuming that we had a radical addition  
20 of staff through that period until we got up to the  
21 88.

22 DR. WEISMAN: Because the timing of

1 hiring, obviously, affects the budget?

2 MS. GOODNOW: Sure.

3 VICE CHAIRMAN LIPSTEIN: They didn't hear  
4 it.

5 DR. BEAL: Sorry.

6 MS. GOODNOW: The assumption was that we  
7 would have about 55 on staff -- not about -- 55 on  
8 staff, that we would be fully staffed by the end of  
9 the second quarter of 2013, and then I took -- we  
10 literally have positions with assumptions on how  
11 much that type of position would make, and I put  
12 them in in sort of a chronological order, what it  
13 looked like, and we can't hire everybody on day  
14 one, so I spread them out through the quarter not  
15 knowing when we would be hiring specific staff, but  
16 always having the higher end person coming in  
17 before the lower end, so that as you get out to the  
18 second quarter, it's the lower level, less  
19 expensive employees that are coming in at that  
20 point.

21 DR. BEAL: And then I'll add, also  
22 included in that calculation were some of the fixed

1 costs associated with staff in terms of computers  
2 and benefits and things like that. So, that was  
3 also part of the calculus.

4 DR. KUNTZ: Just a quick question on your  
5 benchmark. If your G&A benchmark is at 10 percent,  
6 and I'm just kind of wondering how that -- how you  
7 get that number. In organizations that raise  
8 money, most of the dollars on the raising money  
9 part, and then there's a linear relationship with  
10 dollars because if you increase your revenue it  
11 means you have more activities to raise money, and  
12 so some of that 10 percent makes sense. We don't  
13 have that issue.

14 On the other hand, we have a burden, which  
15 is we're actually doing a lot of science  
16 internally, more than other groups are, so while  
17 the 10 percent may or may not be right, I just  
18 wonder how you can actually develop a better  
19 benchmark to look at efficiencies because, you  
20 know, being about 10 percent then lower than 10  
21 percent is really a function of the fact that we're  
22 going to get more money. And I just wonder if

1 there's a better way to measure efficiency rather  
2 than use a charitable granting agency's 10 percent  
3 GNA as a standard.

4 DR. BEAL: So, when we thought about the  
5 10 percent, we actually looked at not so much those  
6 that do fundraising, but those that just do grant  
7 making, and so the standards actually vary from  
8 organization to organization and is somewhat  
9 dependent upon their operating model.

10 So, there's some organizations which have  
11 an overhead administrative rate of around 20 to 25  
12 percent. Those have very robust internal research  
13 capacities. There are other organizations that  
14 actually do nothing but internal research, so  
15 they're more in the 80 to 90 percent, and there are  
16 those that just do significant grant making.

17 So, we took 10 percent as sort of looking  
18 at the foundation world as well as looking at the  
19 nonprofit world, but it really is, as you said,  
20 very much contingent upon what is the operating  
21 model.

22 And so, right now our operating model is

1 that the vast majority of our monies do go out the  
2 door and we do have some internal program work as  
3 well as in evaluation work, and so I think the 10  
4 percent is a good benchmark compared to that.

5 CHAIRMAN WASHINGTON: I hear Rick asking a  
6 slightly different question. Using the benchmark  
7 against those similar organizations is just one  
8 measure of efficiency, and he's asking you, beyond  
9 just using that measure, had we thought about  
10 others. And I think it's a great question for us,  
11 again, given that one of our values is rigor and  
12 rigorous methodology, to at least have that on the  
13 table.

14 DR. BEAL: Yeah. So, I would say that in  
15 terms of robust metrics, we haven't yet gotten to  
16 that point. And, in fact, one of the issues that  
17 we've been talking about in terms of the values for  
18 the organization and so we have to think about what  
19 are the metrics that we want to develop to reflect  
20 those values. So, more to come.

21 CHAIRMAN WASHINGTON: Douma?

22 DR. DOUMA: Allen Douma, Board.

1 CHAIRMAN WASHINGTON: And then Clancy.

2 DR. DOUMA: Yeah, you just indicated that  
3 at the end of the second quarter we'll be fully  
4 hired up, but I presume that's on board and not  
5 just offers. But will that be the same time at  
6 which we -- our consultants will be down to nine  
7 and it will be a linear drop off from now until  
8 then?

9 DR. BEAL: Yeah, so, much of that is an  
10 exact trading out of one type of full time  
11 equivalent for another type.

12 DR. DOUMA: Okay, so they'll --

13 DR. BEAL: Yes.

14 DR. DOUMA: They'll go hand-in-hand from  
15 month-to-month.

16 DR. BEAL: Exactly.

17 DR. DOUMA: Okay.

18 CHAIRMAN WASHINGTON: Okay, Clancy.

19 DR. CLANCY: So, let me just acknowledge  
20 how much work went into this.

21 CHAIRMAN WASHINGTON: Carolyn Clancy.

22 DR. CLANCY: Sorry, Carolyn Clancy, Board

1 member. Just wanted to acknowledge Pam and Anne's  
2 and the work of the committee, that hard work that  
3 went into it.

4           So, Kerry, if I understood this correctly,  
5 you're looking for some signal from the Board that  
6 this is directionally correct, it will be coming  
7 back to us, and as Steve has pointed out, the FAAC  
8 actually sees way more back up detail.

9           I'm also sympathetic to Allen's request  
10 for specificity, but it strikes me that a big piece  
11 of that is going to be actually having performance  
12 metrics, which we are not anywhere near. I mean,  
13 all we can really count now is outputs.

14           So, I, for one, would be very comfortable  
15 knowing, frankly, how hard all of you are working,  
16 but I also know the FAAC is pretty tough as a  
17 committee, which I would think is their charge as a  
18 Board committee. But I do think we can't let the  
19 notion of performance metrics slide because that's  
20 what I think a lot of -- have to answer for. We're  
21 not making a profit here for, but we are holding  
22 ourselves accountable for what we're buying and

1 investing in.

2 CHAIRMAN WASHINGTON: Excellent point.  
3 Allen?

4 DR. DOUMA: Just need to follow up with  
5 that. Yes, the FAAC is a really tough committee  
6 and --

7 DR. CLANCY: You're on it.

8 DR. DOUMA: Well, I'm the softie on the  
9 committee, but I think it's something that Kerry  
10 indicated in his open remarks. It's important to  
11 know that the FAAC committee doesn't really vet how  
12 the money is going to be spent on various programs.  
13 That's done at other committee levels and it's  
14 brought to us as a number that we make sure it  
15 fits, but we don't decide whether that was a good  
16 expenditure of money.

17 CHAIRMAN WASHINGTON: Zwolak.

18 DR. ZWOLAK: Bob Zwolak, Board.  
19 Contractors are expensive and if we're talking  
20 about directionally correct, I think reducing the  
21 number of contractors is a key issue, but my  
22 question for you is, how did you decide what the

1 landing zone was? So, we go down from 38 to 9.  
2 How did you decide what positions should remain at  
3 the relatively expensive contractor level and who  
4 we would -- why we wouldn't replace them with  
5 hires?

6 MS. GOODNOW: Sure. Actually, we did it -  
7 - we have a schedule from each of the -- we have a  
8 schedule, by department, of what we think the hires  
9 will be and they've outlined what those positions  
10 would be, and the contractors that are still left  
11 over, for instance, in the research area, we know  
12 that we're not hiring on senior research officers  
13 to do all of the work for the grant making.

14 So, the answer is, that those -- of the  
15 nine, I think six of them that I've left in as  
16 going on in some sort of contracting capacity, are  
17 those that we know that we're not going to hire for  
18 internally. So, if there is a consultant doing  
19 some work now that is not in a position that was  
20 identified coming out of any individual department  
21 as a need for a full-time hire, those are the  
22 consultants that are left in for the remainder of

1 the year.

2           And that work may not necessarily be  
3 something that was a need for the rest of the year,  
4 so those contractors may go away just by virtue of  
5 the fact that the job is done there, but I took  
6 them out FTE by FTE.

7           CHAIRMAN WASHINGTON: Anne, is that the  
8 end of your presentation?

9           DR. BEAL: Yes.

10          CHAIRMAN WASHINGTON: Okay. Kerry, you  
11 want to wrap this up for us, please?

12          MR. BARNETT: Well, just very briefly.  
13 Appreciate the comments that have been made and  
14 obviously there's some more work to be done. I  
15 would really encourage if there are some specific  
16 areas that just don't feel right for whatever  
17 reason, shoot Anne an email and let her know so  
18 staff can begin to drill into it, but the more  
19 specific we can be about where we want staff to do  
20 their drilling, the better off that we are.

21                 I think we've got a pretty good list of  
22 about a half a dozen items, areas that we need to

1 work on. Some of these, I think, need to be worked  
2 on very specifically between now and approval, but  
3 some of them are more ongoing, things like  
4 establishing key performance metrics and that sort  
5 of thing, but I think -- and Anne, you're nodding  
6 your head, so I think you've got a good sense of  
7 what the next steps are -- and then we will figure  
8 out whether to bring this back to the Board at a  
9 telephone Board meeting between now and the end of  
10 the year, or if it can wait until February -- our  
11 goal would be not to have it wait until February.

12 CHAIRMAN WASHINGTON: Krumholz.

13 DR. KRUMHOLZ: Harlan Krumholz. I just  
14 wonder if, just in truth in advertising as we  
15 discuss this, we're reporting the percent that's  
16 going to administrative expense, but we also are  
17 clear on what percent of our funding is going  
18 toward research, because we have a lot of other  
19 activities, as you see on the pie.

20 I mean, when I first started looking at  
21 pie charts, I said, well, god, the research, what  
22 is -- I mean, it looks like it's about 75 percent,

1 but I don't know how to benchmark that. I know  
2 these are activities we're mandated to do, it's  
3 about engagement and other important things, but  
4 just for the public to know, of this money, how  
5 much of it is actually being plowed into direct  
6 research versus other things? And that's worth, I  
7 think, us, you know, having an appreciation for  
8 that balanced, because in the end, to me, that's  
9 what I really want to know, which is, you know,  
10 what are we doing to report the research and then  
11 how much are we actually able to put into the  
12 research given that balance?

13           And, I mean, clearly, 10 percent is very  
14 efficient on the administrative side, but we have  
15 to be thoughtful about that allocation, I think.

16           MR. BARNETT: Yeah, I think that's a great  
17 point, and, you know, that's a classic issue, I  
18 think, higher-level issue for the Board. You know,  
19 you've got three areas, you've got administration,  
20 you've got program, and then you have research.  
21 And having kind of general agreement as to how much  
22 of our budget should be expended in each of those

1 areas is sort of a fundamental budgeting question.

2 So, if anybody thinks that what's been  
3 proposed kind of misses the mark, please surface  
4 that.

5 DR. BEAL: And then the only thing I would  
6 add is that it is a fundamental question that  
7 really would need to be addressed by the Board, so  
8 it's not the kind of answer that can come from  
9 staff. So, we can put up a straw man to say here  
10 are the activities that we want and here are the  
11 ramifications, but if the Board said, absolutely,  
12 we want no more or no less than X percent on  
13 program or no more or no less than Y percent on  
14 administration, then that would be the direction  
15 that would be helpful.

16 DR. KUNTZ: Just a quick question,  
17 actually, Carolyn, I was going to ask you. For a  
18 benchmark, I mean, you do a lot of programming and  
19 a lot of support and engagement in AHRQ. What  
20 percent of the AHRQ budget goes directly towards  
21 research?

22 DR. CLANCY: So, since we don't actually

1 set the categories by ourselves, I'll just say we  
2 have less latitude and flexibility, but your  
3 comment -- or question actually builds on what I  
4 was going to suggest.

5           It would be helpful, for your question, to  
6 know how do other entities, foundations, and so  
7 forth, account for this because I think that's  
8 probably a more relevant comparator because the  
9 federal government has got its own set of stuff  
10 which may or may not be terribly relevant here, but  
11 whether that's Commonwealth, AETNA Foundation, RWJ,  
12 or anyone else.

13           So, for example, the programming that goes  
14 into developing a program in a particular area,  
15 does that count as research or not? Now, you could  
16 have a metaphysical debate about that, but what I  
17 think would be helpful would just be to know  
18 concretely how others do that.

19           CHAIRMAN WASHINGTON: Good point.

20           MS. GOODNOW: And as far as those costs  
21 that are in the budget as programmed, there is  
22 actually a definition that nonprofits use so that

1 we can be recording those expenses systematically  
2 whenever you look at anyone's financial statements.  
3 So, there are definitions and any particular costs  
4 that falls into a program category is one that can  
5 be directly related to the mission, and those that  
6 are in administrative, including things like the  
7 annual report or just plan -- the back office  
8 accounting people are in the administrative budget.

9 DR. KRUMHOLZ: This is Harlan Krumholz  
10 again. And to be clear, I'm not questioning the --  
11 I mean, we have endorsed that and we are behind it.  
12 The question is about the allocation and how we, as  
13 a Board, think strategically about exactly how many  
14 dollars, and I think that Carolyn's brought up a  
15 really good point. I mean, if you're investing in  
16 dollars to develop the research proposals, should  
17 that legitimately be considered part of your  
18 research expense or not, but even with that we  
19 should know at the end, of the awards we've made,  
20 what percent of our total budget does that account  
21 for, just so we can sort of stay on target with  
22 that and give staff direction.

1           But this is not criticism at all of -- or  
2 of this budget allocation, but just starting to try  
3 to think about how do we keep track of it and how  
4 do we prioritize appropriately?

5           CHAIRMAN WASHINGTON: Okay. Levine and  
6 then Selby gets the last.

7           DR. LEVINE: Just a quick comment, and  
8 this is really for after we have worked and  
9 approved the budget, but it might be helpful to do  
10 kind of a side-by-side matrix -- I'm channeling  
11 Freda here, wherever she is -- a matrix of line  
12 items that appear in multiple budgets that track to  
13 the same category of work.

14           So, for example, patient engagement, it's  
15 part of the Methodology Committee budget, it's part  
16 of the COEC budget, there's staff who are dedicated  
17 to it. And so to be able to look at an overall  
18 picture of all of the program and research  
19 expenses, or expenditures planned around patient  
20 engagement, as one example, but communication will  
21 attach to a number of things, it might give us a  
22 more nuanced picture of kind of the tapestry of how

1 things connect and, quite honestly, help to do what  
2 we've been trying to do, which is coordinate what  
3 are currently not intentionally, but by fiat, kind  
4 of siloed activities.

5 CHAIRMAN WASHINGTON: Okay. Thanks to  
6 Anne and Pam and all the other staff involved and  
7 to Kerry and all the other members -- Larry and  
8 Allen and Freda -- of the FAAC, for all your work  
9 and for developing this draft that we're working  
10 with today.

11 The Board will hear more about this in the  
12 next couple of months or so as we move toward  
13 adopting a budget.

14 Would you introduce this next section,  
15 please?

16 DR. SELBY: Yes, I'll introduce the next  
17 two presenters, in fact, because I may be out for  
18 an interview as we transition.

19 Dr. Lori Frank is going to go first, and I  
20 believe Lori has presented to this Board before.  
21 Lori is our Director of Engagement Research, so she  
22 has a big job of working with staff, with the

1 Methodology Committee and others, on evaluating  
2 over time how our engagement activities are  
3 impacting the quality and the outcomes of our  
4 research.

5           We really want to keep, in an ongoing way,  
6 we want to keep in front of the Board what we're  
7 learning about our research as we review it, and  
8 then once it's funded, as it gets conducted.

9           So, Lori is going to fill you in on the  
10 latest information from our Pilot Projects,  
11 including more data on what happened in the review  
12 process and some -- an update on how we're  
13 monitoring these projects.

14           Then Martin Dueñas, Director of Contracts,  
15 is going to update you on the submissions we've  
16 received and the review we've gone through for the  
17 responses to our first round of broad PFAs. I just  
18 want to say -- and at the end of that presentation  
19 we're going to talk with you about our proposed  
20 approach to identifying those projects under each  
21 priority that we're going to fund. Same kind of  
22 conversation we had with the Pilot Projects,

1 needing to account primarily for the scores that  
2 these applications receive, but also looking at  
3 other considerations important to the Board and  
4 important to patient-centered outcomes research.

5           And since also I'm not going to be here, I  
6 just wanted to tell you that because Martin  
7 probably won't, that we had an extraordinarily  
8 exciting day of peer review last Thursday where  
9 approximately 150 technical reviewers, patient and  
10 stakeholder reviewers came and convened in five  
11 committees for an entire day and wrestled with the  
12 question of, what's good patient engagement and  
13 what's good patient-centered research. So, very  
14 exciting to observe, and we will be evaluating that  
15 over time.

16           But Lori is going to go first and tell us  
17 about the Pilot Projects. Thank you, Lori.

18           MS. FRANK: Okay. Thanks very much, Joe,  
19 and I will move quickly through these slides in the  
20 interest of time. I thought about presenting them  
21 backwards so that we could rewind the clock, but  
22 I'll just move quickly through them.

1           So, there are really two points I want to  
2 address with regard to our pilot projects. The  
3 first is the evaluation of our unique review  
4 process that did involve stakeholders for these,  
5 and the second is an update on the status of the  
6 Pilot Project management.

7           So, the Pilot Projects will advance the  
8 field of patient-centered outcomes research by  
9 exploring methods, a focus on methods for PCOR, and  
10 also help us to identify gaps, to inform the PCORI  
11 research agenda going forward with regard to  
12 methods.

13           And 50 Pilot Projects were awarded, over  
14 two years, approximately \$31 million will be  
15 expended.

16           So, the Pilot Project call for  
17 applications addressed each of these eight areas  
18 and applicants were allowed to respond to one or  
19 more of these areas: informing the national  
20 priorities for PCORI; bringing together patients,  
21 caregivers, and other stakeholders across the  
22 research continuum; translating evidence-based care

1 into healthcare practice in a way that accommodates  
2 patient preference; identifying gaps in comparative  
3 effectiveness knowledge; evaluating specific  
4 patient-centered outcomes instruments; assessing  
5 the patient perspective when conducting research on  
6 behaviors, lifestyles, and choices; studying  
7 patient care team interaction when multiple options  
8 exist; and advancing analysis of CER data.

9           Awards were made across seven of these  
10 eight areas. For the one area where awards were  
11 not made, that's number four there, PCORI will be  
12 pursuing other ways to get answers to those  
13 relevant questions.

14           Here's just a screenshot from our website  
15 and I encourage you to go to it, and if you mouse  
16 over the green position indicators, then you can  
17 drill down and get more information about each of  
18 the projects. So, that's actually kind of a cool  
19 way to get more information.

20           So, we asked some questions of the  
21 reviewers at the conclusion of the review process.  
22 We had 354 scientific reviewers and 45 patient and

1 other stakeholder reviewers, so there were about 3  
2 stakeholder reviewers per panel for this.

3           The first question was: have you  
4 previously participated in a Center for Scientific  
5 Review process? So, the NIH-CSR helped us with  
6 this first set of reviews. And about 70 percent of  
7 the scientific reviewers reported that they had and  
8 only six out of the 45 stakeholder reviewers  
9 reported that they had.

10           This next slide addresses the question to  
11 what extent were scientific reviewers receptive to  
12 the comments made by stakeholder reviewers, and  
13 what's really striking here is the similarity in  
14 response. The scientific reviewers are presented  
15 on the left and the stakeholder reviewers are  
16 presented on the right there, and in each case,  
17 close to 90 percent of both groups reported that  
18 the stakeholder reviewers thought that the  
19 scientific reviewers were receptive to their  
20 comments as did the scientific reviewers.

21           Turning the question around -- yeah,  
22 sorry.

1 DR. DOUMA: Yeah, Allen Douma, Board.  
2 What's the breakdown of the stakeholder reviewers?

3 MS. FRANK: Oh, what sorts of stakeholders  
4 were they?

5 DR. DOUMA: Ah-ha, patients --

6 MS. FRANK: It was a combination, so it  
7 wasn't just patients or caregivers, so other types  
8 of caregivers -- I'm sorry -- of stakeholders could  
9 be included, and I'm looking to Christine who is  
10 very familiar with the different categories of  
11 stakeholders for this.

12 DR. DOUMA: Do you know what the breakdown  
13 is, though?

14 MS. FRANK: Someone does. I don't have  
15 that right here with me in terms of overall  
16 numbers.

17 DR. SELBY: I think it was very close to  
18 half and half. You noticed, there were only three  
19 patient or stakeholder reviewers per panel in the  
20 pilots. We beef that up in the PFAs, but there was  
21 only, you know, a total of 43, and they were about  
22 half patients, I'm quite sure.

1 DR. DOUMA: Okay.

2 MS. FRANK: Okay. So, this next question  
3 turned it around. To what extent were the  
4 stakeholder reviewers receptive to the comments  
5 made by scientific reviewers. So, what you see  
6 here is that over 90 percent of the stakeholders  
7 thought that they were, in fact, receptive to the  
8 scientific reviewer comments.

9 In the case of the scientific reviewers,  
10 30 percent said they just didn't know. Now, it is  
11 the case that the stakeholder reviewers weren't  
12 necessarily introduced as such in all the panels,  
13 but among the rest of the respondents, those among  
14 the scientific reviewers who gave a response, then  
15 the vast majority said that they thought the  
16 stakeholder reviewers were, in fact, receptive to  
17 the scientific reviewer comments.

18 This next -- yeah.

19 DR. KRUMHOLZ: Harlan Krumholz. Just --  
20 you're going fast and I just want to distill this.  
21 So, what you're saying is that the scientists  
22 didn't feel the stakeholders were listening to

1 them, but the stakeholders thought the scientists  
2 listened to them?

3

4 MS. FRANK: Actually, no. So, there were  
5 similarities. So, this first question was, to what  
6 extent did the scientific reviewers listen to the  
7 stakeholders, and what we were pointing out here is  
8 the similarity --

9 DR. KRUMHOLZ: It's similar, right, but  
10 when you reversed it, the scientists felt that the  
11 stakeholders were not incorporating them to the  
12 extent that the stakeholders thought that they  
13 were.

14 MS. FRANK: Essentially, but there's the  
15 big don't know piece of the pie there.

16 UNIDENTIFIED BOARD MEMBER: [Off  
17 microphone.]

18 DR. KRUMHOLZ: I don't want to slow you  
19 down, I'm just interested --

20 [Overlapping speakers.]

21 DR. WEISMAN: -- the groups that they  
22 didn't -- they actually didn't know who they were.

1 Do you know that?

2 MS. FRANK: We don't know that and --

3 DR. WEISMAN: So, would it be safe to  
4 subtract or not or we just don't know whether you  
5 could do that?

6 MS. FRANK: Yeah, I don't think that --

7 MS. GOERTZ: Most of them did know. There  
8 are one or two review groups where it was unclear,  
9 but most of the review groups did know.

10 CHAIRMAN WASHINGTON: I'm sorry, Lori, but  
11 there seems to be some confusion.

12 MS. FRANK: Sure. Let's clear it up.

13 CHAIRMAN WASHINGTON: Sharon -- I mean,  
14 Levine.

15 DR. LEVINE: So, the scientists were less  
16 confident that the stakeholders were receptive to  
17 their comments than the stakeholders felt they were  
18 actually receptive to their comments?

19 MS. FRANK: Yeah. So, if you look at the  
20 numbers, there are about two-thirds of the  
21 scientific reviewers who said that the stakeholder  
22 reviewers were receptive to their comments, to some

1 extent or to a great extent. What's going on with  
2 that other third? They said, I don't know. So, it  
3 was really only four percent of the scientific  
4 reviewers who said that it was a small extent to  
5 which the stakeholders were receptive to their  
6 comments.

7 DR. DOUMA: And I think it's really  
8 important what you're saying about the "don't know"  
9 is because presume scientists are more evidence-  
10 based and they didn't have the evidence because  
11 they didn't do a survey of the stakeholders.

12 MS. FRANK: Right. It's an interesting  
13 point, and then, of course, all the stakeholders  
14 knew who they were, so we didn't have a problem  
15 with that piece of the data.

16 Okay. So, the next question was, compared  
17 to other reviews you've participated in, to what  
18 extent did having an emphasis on patient engagement  
19 impact the overall scoring? And only 1 percent  
20 said, to no extent. So, the vast majority, over 90  
21 percent, thought that patient engagement impacted  
22 overall scoring to some extent or to a great

1 extent.

2           Okay. On this we asked, how would you  
3 describe the degree of emphasis stakeholder  
4 reviewers placed on the patient perspective  
5 relative to that placed by scientific reviewers?  
6 So, if you go to the bars on the right, which  
7 represent the responses of the stakeholder  
8 reviewers, you see essentially a 50/50 split. So,  
9 about half of the stakeholder reviewers placed more  
10 emphasis on the patient perspective compared to  
11 what the scientific reviewers did by their report.

12           And about half thought that both types of  
13 reviewers looked at this in the same way.

14           Now, if you look on the left, about 27  
15 percent of those scientific reviewers said, I don't  
16 know, I'm not going to answer this because I don't  
17 have the information. Of the rest there was also  
18 essentially a 50/50 split, but in this case,  
19 slightly more scientific reviewers thought both  
20 types of reviewers placed the same emphasis on the  
21 patient perspective -- slightly -- proportionately  
22 less scientific reviewers thought that the

1 stakeholders emphasized the patient perspective  
2 more than they did.

3           Okay, so Mike Lauer conducted some  
4 additional analyses of the scoring criteria, along  
5 with the colleagues noted at the bottom of this  
6 slide. The scoring criteria were the approach to  
7 the research question, the significance of the  
8 research question, stakeholder involvement,  
9 innovation of the research, and investigator  
10 qualifications.

11           And so what they found, using a mix linear  
12 model was that the approach really had the greatest  
13 association with the final score coming out of  
14 those review panels.

15           They also took those data and used a  
16 random forest method, a machine learning data  
17 classification method, and analyzed the data the  
18 same way, and here's a comparison of the data from  
19 the prior slide with the random forest. So, random  
20 forest is represented with the orange bars, the  
21 blue bars represent what you just saw. So, the  
22 results are similar in that approach was associated

1 with the final score out of those review panels to  
2 the greatest extent; investigator qualifications,  
3 much less so. In the case of the random forest  
4 analysis, the significance of the research question  
5 and the innovation also appear as drivers of that  
6 final score.

7           Okay, so --

8           DR. DOUMA: Are you going onto the next  
9 subject?

10          MS. FRANK: I am. I don't have to.

11          DR. DOUMA: Before you do, can I ask a  
12 question?

13          MS. FRANK: Sure.

14          DR. DOUMA: How are we going to implement  
15 or apply the results of this into what we do next?

16          MS. FRANK: Yeah, so I want to say there's  
17 more analyses we would like to do of this.  
18 Martin's about to share with you our Cycle I  
19 reviews, and so we'll have more review data then to  
20 work with. Remember, these are just the scoring  
21 data out of the Pilot Project round.

22          DR. DOUMA: Right. So, what you're

1 saying, basically you don't have enough data?

2 MS. FRANK: We would like to collect some  
3 more data, but there's still plenty that can be  
4 done with the Pilot Project scoring data.

5 CHAIRMAN WASHINGTON: Okay.

6 MS. GOERTZ: You know, a lot of this --  
7 we're just presenting the data that we -- we had a  
8 pretty good sense of this after the review process  
9 occurred, and in fact, much of how we approached  
10 the next set of reviews that Martin is going to be  
11 describing is based on our general impression that  
12 we hadn't been as stakeholder driven as we would  
13 like to be eventually with the review process, and  
14 that we probably hadn't done the type of training  
15 that would be ideal about what it was that was  
16 important to us.

17 And so much of -- I think there are still  
18 many things that we can learn by continuing to look  
19 at the data, but sort of the gestalt of it we  
20 already knew and have already incorporated into our  
21 -- into the review process.

22 MS. FRANK: Thank you for that. Yeah,

1 there were a lot of learnings out of this and the  
2 number of patient and stakeholder reviewers was  
3 increased substantially for the PFA merit reviews.

4 CHAIRMAN WASHINGTON: Okay, Normand and  
5 the Lewis-Hall.

6 MS. NORMAND: Sharon-Lise Normand,  
7 Methodology Committee member. I wanted to ask --  
8 maybe push a little bit more on that in terms of  
9 Allen's question in terms of -- how are the -- so,  
10 yes, more analysis could be done, but what's the  
11 purpose of it?

12 Let me throw something out, and I'm not  
13 saying this is right at all, so if we look at that  
14 particular graphic that you currently have up, it's  
15 talking about which components weighed the most in  
16 terms of the final scores. Is that the right  
17 distribution as a Board that we want? Do we want  
18 it mostly -- I'm not saying the approach should be  
19 the heaviest weighed, but do we want the  
20 stakeholder to be much more?

21 So, again, whose -- how can we utilize the  
22 data? What are you -- can you give us some

1 examples of some questions that you'd like to  
2 answer with the data to go forward?

3 MS. FRANK: Yeah, that's part of why I  
4 would really like the data out of this round that  
5 Martin's about to discuss because the merit review  
6 criteria were refined for the PFA review. So,  
7 another question is, are we training the reviewers  
8 appropriately? Are we giving them the right  
9 information about the criteria? And then, yes, are  
10 they using the criteria in the way that we hope?  
11 Or should there be some explicit weighting as part  
12 of the instructions?

13 I would say, there's a limit to what we  
14 want to conclude out of this based on this dataset.

15 MS. NORMAND: I'll say one more thing, I'm  
16 sorry, it's just that typically -- and I know  
17 you've done this -- is usually we have the  
18 questions and we collect the data, not get the data  
19 and then -- so, but, I just wanted to get the sense  
20 of the questions that you may have in your head  
21 proposed.

22 MS. FRANK: Yeah, so coming out of the

1 Pilot Projects, this was largely descriptive. So,  
2 it's just an update, what did we learn out of it,  
3 and then is there something there that can inform  
4 the program going forward. And, you know, Martin  
5 has reviewed these and taken it on board as well.

6 CHAIRMAN WASHINGTON: I have a comment  
7 from Mike, Methodology Committee.

8 DR. LAUER: Thank you. Mike Lauer,  
9 Methodology Committee. We're definitely looking  
10 forward to getting more data and exploring this  
11 further. But it was interesting, at the same time  
12 that we were doing this, I happened to be reviewing  
13 a big grant for the Medical Research Council of  
14 Australia, and I had never reviewed for them  
15 before, and they gave me very explicit instructions  
16 about how I was supposed to review their grant down  
17 to 35 points for this category, 10 points for this  
18 category, 5 points for that category, so they told  
19 me exactly what they wanted, what they cared about,  
20 you know, whether I agreed with that or not, and it  
21 was just interesting at the same time that I was  
22 reviewing that grant we had this.

1           So, it's a possible mechanism. This could  
2           lend itself very well to a variety of experiments.

3           DR. LEWIS-HALL: Freda Lewis-Hall, Board.  
4           I actually had two quick questions. One is, back  
5           to the stakeholder engagement, I guess Christine,  
6           you almost pre-answered it for me, but I just want  
7           to check my understanding of whether or not we had  
8           some conceived notions about what that data would  
9           have told us, and then whether or not we have any  
10          goals about how that should actually look and/or  
11          benchmarks against kind of other organizations that  
12          do this work so that we -- I'm assuming that we  
13          want to be kind of the best at it, so what that  
14          would look like against not just ourselves, but  
15          others as benchmarks.

16          And then the same, to Mike's point, which  
17          is, do we have a notion about how we would actually  
18          set goals across those criterion and then figure  
19          out ways to meet those?

20          MS. FRANK: Right. So, we're using this  
21          to help establish some hypotheses moving forward.  
22          So, in this case we asked ourselves, what would

1 success look like? What do we want to move here?  
2 So, that gets into some philosophical discussions,  
3 which would take longer than we have right now, but  
4 we're very much looking forward to having some more  
5 data and then working more on what implications  
6 this has for our merit review criteria.

7           Okay, so the other piece I wanted to  
8 address was our active portfolio management. So,  
9 PCORI is very interested in making sure that we  
10 learn as quickly as possible out of all of our  
11 funded work and as part of this we're pursuing very  
12 active portfolio management with these Pilot  
13 Project awardees.

14           So, we are partnering with Academy Health  
15 to facilitate cross-learning, and as part of the  
16 work, we're also developing a framework for patient  
17 and other stakeholder engagement in research.  
18 Throughout, we'll be eliciting the patient view of  
19 research engagement.

20           With Academy Health, PCORI will be  
21 learning specifically about facilitators, barriers,  
22 and the impact of involving patients and other

1 stakeholders in the full cycle of research,  
2 developing this conceptual framework that I  
3 mentioned for PCOR.

4           We are very interested in the cross-  
5 learning possibilities here. There's going to be  
6 lessons learned. We want to learn them quickly, as  
7 quickly as possible, and then disseminate them  
8 across the other awardees, for example, and  
9 obviously keeping an eye on the implications for  
10 the PCORI research agenda moving forward.

11           So, here's a timeline. Back in the  
12 summer, we put out a request for proposal and  
13 received a lot of competitive proposals in  
14 response. Academy Health was selected. They got  
15 to work right away reviewing the Pilot Project  
16 content and starting on a literature review.

17           Through this fall, as the awardee  
18 contracts had been finalized, we've been working  
19 with Academy Health to identify topic or method  
20 themes that would make sense for grouping the  
21 awardees so that we can form reasonable subgroups  
22 to facilitate this cross-learning goal, and we're

1 very much looking forward, moving forward, to  
2 exploring options for communication among these  
3 awardee thematic groupings and for planning for  
4 subgroup convenings.

5           So, I mentioned that establishing a  
6 conceptual framework is part of our goal, and as  
7 part of that work, Academy Health has been  
8 conducting a literature review. They're well  
9 underway with that.

10           They've developed a draft framework  
11 already, which I'll show a few points out of in  
12 just a moment. As part of their work, they  
13 obtained input from their own patient, consumer,  
14 and researcher roundtable, and all aspects of this  
15 work are completed with attention to patient  
16 involvement.

17           So, using structure, process, and outcomes  
18 to organize their framework, here are their  
19 structure elements. Of particular interest are  
20 number four and five: What does engagement  
21 infrastructure look like? And what's the training  
22 needed to help use that infrastructure? Number

1 seven: How do we evaluate it?

2 And I'll move through these very quickly.

3 For the process elements, all of these are  
4 of interest, but particularly looking at the  
5 culture of engagement, what does that mean and what  
6 does it mean to the different stakeholders  
7 involved? And are there specific areas across the  
8 research continuum where patient engagement is  
9 optimal, for example?

10 And then, last, but certainly not least,  
11 are the outcomes components. So, those four at the  
12 top are more near term outcomes: attitudes of  
13 researchers, clinicians, patients, other  
14 stakeholders towards engagement in research. What  
15 relationships are forming that weren't there  
16 before?

17 The longer-term outcomes that we're very,  
18 very interested in is: what is the impact on  
19 quality of the research and relevance of the  
20 research? Is there an impact on uptake of the  
21 research results? Will there be improvements in  
22 dissemination of an access to the research? Are

1 their policy implications? And of great interest  
2 to us, will there be improvements in health  
3 outcomes that are demonstrably associated with the  
4 engagement effort?

5 DR. DOUMA: Allen Douma, Board. Could you  
6 take, for example, concept appeal and take us  
7 through once we've measured -- that's an outcome --  
8 once we've measured it, what are we going to do  
9 with it?

10 MS. FRANK: I could. This is a draft  
11 framework and I'm just wondering about with  
12 reference to time if this might be a conversation  
13 we could better have after this particular  
14 framework has been refined with some more input?

15 DR. DOUMA: It's certainly your choice.

16 CHAIRMAN WASHINGTON: Other comments?  
17 Questions?

18 [No response.]

19 CHAIRMAN WASHINGTON: Okay, well, Lori,  
20 thank you --

21 MS. FRANK: All right, thank you very  
22 much.

1           CHAIRMAN WASHINGTON: -- very much for this  
2 update. [Off microphone.] It's going to be from  
3 Martin. Joe had to step out for an interview. And  
4 I'm going to ask you to just introduce yourself,  
5 Martin, to the group and to the audience and  
6 present.

7           MR. DUEÑAS: Good afternoon. I'm just  
8 looking at the technical aspect here. This is  
9 basically an update on the Cycle I funding and it's  
10 basically an operational and process update.

11           As you know, we -- well, let me start with  
12 the questions that we're going to ask of you.  
13 There's two things that we're going to do -- that  
14 I'm going to do in my presentation, one is just  
15 give you an update of what happened with the Cycle  
16 I PFAs that were launched, and the last part is  
17 going to be to show you the selection criteria that  
18 we're going to use to select the applications that  
19 we want to fund.

20           So, that is the two questions, feedback  
21 regarding the selection criteria. And as has been  
22 mentioned from Lori's presentation, we're

1 collecting a lot of data, and I'm going to show you  
2 some of that data that we're collecting, and then  
3 if there's any ideas of any other data that we  
4 should be collecting and any other questions that  
5 you may want to ask.

6 This is another view of what I'm going to  
7 discuss, so I'm going to go through this quickly.

8 As you know, May 22nd we released four  
9 PFAs that are listed here. We did get about 500  
10 applications and this is the timeline of where we  
11 are in the process. June 15 is when we received  
12 the letters of intent, and it has gone through a  
13 process of internal control, a scientific review,  
14 an impact review they just finished, as Joe  
15 mentioned, last Thursday, November 15, and we're  
16 currently analyzing the data for -- to bring to the  
17 Board for approval, so this is the last one there.

18 The applications we reviewed through the -  
19 - as Lori was mentioning, there is a complete new  
20 review criteria, and I've been asked to mention  
21 this, eight, because it's important for you to  
22 listen to. Impact on the condition on health of

1 individuals and populations was criteria number  
2 one. Number two was innovation and potential for  
3 improvement of research. Number three was impact  
4 on healthcare performance. Number four is patient-  
5 centeredness. Number five is rigorous research  
6 methods. Number six is inclusiveness of different  
7 populations. Number seven is research team and  
8 environment. Number eight is the efficient use of  
9 research resources.

10 So, all the applications were scored  
11 according to these eight criteria and the reviewers  
12 were trained according to these criteria. That was  
13 Phase I that involved only scientists as reviewers.

14 Phase II, we asked them to focus on impact  
15 and we pulled three of the criteria that we need to  
16 focus on, number two, number four, and number  
17 seven.

18 So, there were, out of the almost 500  
19 applications that were received, there were 152  
20 applications that moved into Phase II, about 32  
21 percent of the applications.

22 So, there's a lot of data collected during

1 these applications and it was the basic data, has  
2 the organization and the project started, the  
3 funding opportunity, the name of the PI, but also  
4 the, if you see here on the right side, this line,  
5 you see the study design, the analytical methods,  
6 the specific aims, technical abstracts.

7           So, let me go through some of that data so  
8 you can see what it looks like.

9           So, geographic data was collected. So,  
10 these represent all the applications that we're  
11 moving to Phase II. It represented 30 states plus  
12 Canada. This represents the population that's  
13 being studied in these applications. These  
14 represent the conditions that are being studied and  
15 they can pick multiple, that's why you can see it's  
16 more than the methods being studied, the design,  
17 and there's a question, so before -- I can answer  
18 the question before I go into the selection of  
19 approach and action.

20           DR. KRUMHOLZ: So, I'm listening carefully  
21 to you, but I just want to be sure that I  
22 understand how this happened. So, to get to Phase

1 II, was there a target percentage that was  
2 identified? Or these are the ones that hit an  
3 absolute standard on the Phase I criteria?

4 And then, just to remind me, because I  
5 know we've said this before, the target number of  
6 grants from the 152 that we would expect to fund  
7 would be?

8 MR. DUEÑAS: So, the target was 109 and  
9 about \$96 million.

10 DR. KRUMHOLZ: The target's 109. And was  
11 there an attempt to get like 30 percent to get  
12 through the first phase?

13 MR. DUEÑAS: The top 10 percent, so, yeah,  
14 about 30 percent.

15 DR. KRUMHOLZ: But that was -- I mean, it  
16 was not an absolute -- it wasn't an absolute, but  
17 you were going to take the top third?

18 MR. DUEÑAS: Correct.

19 DR. KRUMHOLZ: Okay.

20 MR. DUEÑAS: Which is what we did.

21 DR. KRUMHOLZ: Thank you.

22 CHAIRMAN WASHINGTON: Another question,

1 Martin.

2 MS. BARKSDALE: I have a question as well.

3 CHAIRMAN WASHINGTON: Name please.

4 MS. BARKSDALE: I'm sorry. Debra  
5 Barksdale, Board, the slide that looks at the focus  
6 on impact. Who were the reviewers for Phase I and  
7 Phase II different? Were there different types of  
8 reviewers?

9 MR. DUEÑAS: Yeah, good question. The  
10 first one was only scientific and it was a  
11 different panel than the Phase II. The first two  
12 included scientists and patient stakeholders.  
13 Completely separate.

14 MS. BARKSDALE: I find it curious in the  
15 criteria that you only chose -- there were only  
16 three listed for Phase II, and yet one on Phase I  
17 dealt with the impact as well. It's a pretty  
18 significant impact, but it is not -- was not part  
19 of Phase II. I guess I don't understand the logic.

20 MR. DUEÑAS: Yeah, so there was a lot of  
21 internal discussion of how do we move the -- how do  
22 we review the second phase? And the idea was to

1 review the impact, what was really that was going  
2 to change practice? And I don't know if Anne wants  
3 to add anything, but it's totally innovation.

4           And the three main things that we focus is  
5 the innovation of the project, the patient-  
6 centeredness is clear, and the last one is the  
7 research team environment. What that meant is, are  
8 you really involving patients into the process, so  
9 that was just what we decided.

10           CHAIRMAN WASHINGTON: Collins?

11           DR. COLLINS: Francis Collins, Board. Are  
12 you going to share with us what happened in terms  
13 of the scores from Phase I and the Phase II scores  
14 and how much reshuffling occurred?

15           MR. DUEÑAS: Not at this time. So, we're  
16 collecting all this data, we just finished -- we  
17 just finished the review on Thursday, but we have  
18 all that data that we will be presenting to you.

19           DR. COLLINS: And can you say again who  
20 were the reviewers in Phase I and Phase II?

21           MR. DUEÑAS: Phase I were all scientific  
22 reviewers. There were three reviewers per

1 applications. And Phase II, it was a complete new  
2 set of reviewers. There were two scientists, one  
3 patient, and one stakeholder per application.

4 DR. COLLINS: I think it would be very  
5 interesting to see -- I'm concerned like Debra that  
6 you've picked three of the review criteria out of  
7 your list of eight, it wasn't obvious to me why  
8 those were the right three.

9 MR. DUEÑAS: It's going to be fascinating  
10 to look at the data because, as you can see, for  
11 each application we can have eight data points from  
12 the overall score plus a data point in the second  
13 review, and then it's going to have patient  
14 stakeholders. So, I'm actually excited to see the  
15 data as well.

16 DR. COLLINS: But your plan is that it's  
17 the Phase II reviewers who determined who gets  
18 funded?

19 MR. DUEÑAS: So, we'll talk about that in  
20 the last slide that we're going to get to. Yeah,  
21 we'll hold that question for a second.

22 DR. COLLINS: I just want to flag that if

1 you have a grant that scores extremely well in  
2 Phase I and somehow it gets dinged in Phase II, you  
3 should worry a lot about that.

4 MR. DUEÑAS: Noted.

5 CHAIRMAN WASHINGTON: Okay, please  
6 continue.

7 MR. DUEÑAS: So, if we go to the selection  
8 criteria, which Dr. Francis just alluded to, so,  
9 the selection criteria is going to consist of a  
10 Selection Committee that is similar to the one we  
11 did in Pilot Projects. Selection committee will be  
12 Board members and staff. The idea is to collect  
13 the highest scoring, so they select -- the three  
14 basic criteria that we're going to use is final  
15 score for Phase II is the main one, so the ones  
16 that scored the highest will be funded, but also  
17 we're going to look at conditions of population  
18 study. And then after that, we're going to bring  
19 the proposal to the Board for approval, so I don't  
20 know if that answered your question, Dr. Francis.

21 DR. COLLINS: One other question. Were  
22 the Phase II reviewers aware of the scores from

1 Phase I?

2 MR. DUEÑAS: Correct. Yes.

3 CHAIRMAN WASHINGTON: Dr. Normand, do you  
4 have any comment on that?

5 MS. NORMAND: It's sort of an -- I'm just  
6 trying to understand the rationale for that. It's  
7 not necessarily what I automatically would think of  
8 doing. And I'm sure there's been thought put into  
9 it, but perhaps you can remind us of the rationale  
10 for that particular design to make them aware of  
11 the scores in the prior round.

12 MR. DUEÑAS: So, this model -- so, the  
13 statute requires to do peer review in a validated  
14 model. This model follows NIH editorial review and  
15 has been used many times. So --

16 DR. COLLINS: Say that again. This is not  
17 what our advisory councils do.

18 MR. DUEÑAS: Okay. So, you see --

19 UNIDENTIFIED SPEAKER: [Off microphone.]

20 MR. DUEÑAS: Dr. Francis doesn't know  
21 everything that happens at the NIH. The editorial  
22 review --

1 DR. COLLINS: That's not the right answer.

2 DR. DOUMA: No, I don't think --

3 MR. DUEÑAS: The editorial review was used  
4 during the new stimulus money that came in. What  
5 they did is, because they had a lot of  
6 applications, they basically did this review where  
7 the first phase was a mail review where you send  
8 the applications to the reviewers and they will  
9 review it online, there were three applicants and  
10 the second, and then the Phase II, is exactly what  
11 we did, it will be a complete new set of reviewers  
12 that will focus on the impact of it, and literally  
13 just use the critiques from the Phase I in this  
14 course to sort of make a decision on the  
15 applications.

16 DR. COLLINS: There's a relationship, but  
17 it's certainly not the same in that you've changed  
18 the characteristics of the reviewers for Phase II  
19 compared to Phase I.

20 DR. CLANCY: Carolyn Clancy, Board member.  
21 Martin, just a quick clarification question. So,  
22 if Arnie submits a grant, and we know he didn't,

1 and there are three reviewers and three scores,  
2 does the second committee see the three scores or  
3 do they see an average mean?

4 MR. DUEÑAS: They see all the scores.

5 DR. CLANCY: Great.

6 MR. DUEÑAS: They see the criteria and all  
7 the scores.

8 DR. CLANCY: I mean, off the top of my  
9 head, this doesn't sound all that different than if  
10 someone submits a grant and does well but not well  
11 enough, and then they resubmit. That second  
12 committee knows what they got the first time.

13 MR. DUEÑAS: So, the second reviewers not  
14 only see the scores, they see the applications and  
15 everything else.

16 DR. COLLINS: Except in a resubmission,  
17 the grant has been rewritten. Here it's the same  
18 proposal for both Phase I and Phase II reviewers.  
19 There's no response to Phase I in order to get to  
20 Phase II.

21 CHAIRMAN WASHINGTON: Okay, Norquist.

22 DR. NORQUIST: Gray Norquist. So, I think

1 there's some confusion. I would agree with  
2 Francis. That's not the way exactly it was done.  
3 It's just surprising to me because I didn't know  
4 this is the way this was going to be done and I  
5 would also -- Francis was concerned about a good  
6 score, I would also be concerned of the reverse.  
7 If I had been a very high impact but didn't do well  
8 with the scientific people, now I'm lost, so you're  
9 biased toward not getting necessarily highly  
10 innovative -- I mean, you could argue that  
11 direction.

12           So, that worries me a little bit too, like  
13 who got missed in that first group that didn't make  
14 it to the second. So, I don't know. I'm a little  
15 concerned here about -- and then now you've got a  
16 third process, which is in a Board of Governor's  
17 group that's got to pull this all together and I  
18 hope I'm not in that group.

19           CHAIRMAN WASHINGTON: Thanks for  
20 volunteering.

21           MS. GOERTZ: Christine Goertz. One of the  
22 things that we had talked about in the PDC when we

1 last met, we were talking about this process, and  
2 there are several of us who are wondering if maybe  
3 the process shouldn't be flipped and maybe have the  
4 stakeholder reviewers involved in the first round  
5 as well as the scientists so that we go first  
6 through the screen of is this exciting, you know,  
7 does it have high significance and also look at the  
8 science.

9           And so I think there are a lot of ways  
10 that this can be tweaked and improved upon as we  
11 move forward. And then just relative to the  
12 selection process, I think that the criteria that  
13 we have now makes sense at this particular phase of  
14 our development, but at some point this is going to  
15 get more complex because I think we're also going  
16 to have to be paying more attention to gaps, and  
17 right now we haven't funded much, so our portfolio  
18 is fairly wide open, but as our portfolio starts to  
19 fill in, I think we're going to have to consider  
20 what we've already funded and where we already have  
21 investments in addition to some of these other  
22 things as we move forward.

1           CHAIRMAN WASHINGTON: Okay. I don't see  
2 any more -- oh, Weisman.

3           DR. WEISMAN: Yeah, maybe a suggestion for  
4 the future for the next round also is that we have  
5 a Methodology Committee that is available to  
6 consult and help us on these kinds of methodologic  
7 issues, which this is, you know, grant selection  
8 and prioritization is a method, and we -- it would  
9 be a shame to not tap into the expertise of that  
10 group.

11           DR. SELBY: You know, I'm sorry I had to  
12 step out and miss the first part of this. It went  
13 faster than I thought. You guys really moved  
14 along.

15           We discussed with -- and I just wanted to  
16 say that we discussed this issue about having only  
17 scientific reviewers review in the first round and  
18 do it by mail back in Denver, and at that point we  
19 were anticipating something on the order of 1,300  
20 and we knew we couldn't do them all face-to-face.

21           We also discussed that -- and we had no  
22 patient or stakeholder reviewers in that phase, and

1 we discussed, in fact, that with the next round we  
2 will have patient and stakeholder reviewers whether  
3 we have one round -- whether we have one phase or  
4 two, whether we do the first phase by mail or not.

5           And with respect to Phase II, we talked a  
6 lot in the day before the reviews with the  
7 committee co-chairs about this, and yes, we did say  
8 to emphasize this time these three because the  
9 applications they were reviewing were the top third  
10 of those who had done well in the first review.

11           But we also said, because there's a lot of  
12 technical reviewers on here, if you see a flaw, if  
13 you see something that in your mind makes this a  
14 fatal flaw in the research, be sure and bring it up  
15 because it can't be patient-centered if it's wrong.  
16 It can't really serve the interests of patients if  
17 it's wrong.

18           So, they did bring up methodologic issues  
19 as well.

20           DR. WEISMAN: I meant the method of  
21 actually conducting a two-stage review, sort of the  
22 mechanics of it. But could you go back to that

1 slide? The one thing that concerned, I think other  
2 people said it, but if I heard them right, and it  
3 certainly concerned me, was going from seven to  
4 three in what seemed like maybe some arbitrary, you  
5 know, number one to me sounded like I'd like to  
6 know what stakeholders thought -- no, it was the  
7 review -- the one you had up for Joe, the one that  
8 was there when Joe was talking -- impact of the  
9 condition on the health of individuals in  
10 populations, I would have liked to hear what -- I  
11 mean, I would think stakeholders would have a point  
12 of view on that too. That was my only --

13 DR. SELBY: You know --

14 DR. WEISMAN: It's not just a scientific  
15 issue, I guess.

16 DR. SELBY: Well, the way we implemented  
17 it, it was -- you know, that's the one where  
18 prevalence and burden and costs come in  
19 substantially, costs both to the patient and  
20 overall cost to the country, come in.

21 We were really focused, in Phase II, on  
22 saying, is it likely that this research will make a

1 difference based on what's known, based on  
2 preliminary data, based on requests from patients  
3 or clinicians for this information, based on the  
4 results of evidence syntheses, is there a need for  
5 this information? Is there an audience waiting for  
6 it? Because we wanted to select research that  
7 would be likely to be put into practice, change  
8 practice, improve outcomes. And we certainly  
9 wanted to focus on, is this a patient-centered  
10 question? And we certainly wanted to focus on,  
11 have you engaged -- have they engaged patients and  
12 other stakeholders in the process?

13           So, that was what we emphasized primarily  
14 in round two. But as I said, we did say, if you  
15 see a scientific flaw in this, bring it up because  
16 that -- you know, that's overriding.

17           CHAIRMAN WASHINGTON: Kuntz?

18           DR. KUNTZ: Just a clarity question. Was  
19 the first -- is the first phase a screening  
20 process?

21           MR. DUEÑAS: A screening process --

22           DR. SELBY: Yeah, it's a type of screening

1 process.

2 DR. KUNTZ: Does it reduce the number?

3 DR. SELBY: It reduces the number by two-  
4 thirds.

5 DR. KUNTZ: So, if it does that, I'm just  
6 trying to think of what the cumulative process is  
7 for, you know, working on the knowledge obtained in  
8 the first screen, because what you do is you erase  
9 the process and then it gets reevaluated on just  
10 three criteria at the end. There's no cumulative  
11 use of the previous screen as knowledge other than  
12 the carry through with the score, right?

13 DR. SELBY: Well, and the pink sheets. And  
14 the pink sheets from the first round.

15 DR. KUNTZ: Were there instructions about  
16 how to process that and value? I mean, I'm just  
17 trying to think of like -- do the second people --  
18 does the second screen take into account what  
19 Harlan just said, the rigorous review of the seven  
20 criteria and then they add emphasis on the three,  
21 or does it start from scratch and just relook at  
22 those three?

1           MR. DUEÑAS: So, it doesn't start from  
2 scratch. The way they were trained is that look at  
3 the criteria, how it was reviewed before. So, they  
4 had that. Not only did they have the application,  
5 but they also had the pink sheet.

6           DR. KUNTZ: So, the general thrust was  
7 that there was a platform --

8           MR. DUEÑAS: Correct.

9           DR. KUNTZ: -- Phase I, that they built  
10 additional evaluation on, and that was instructed?

11          MR. DUEÑAS: Correct.

12          DR. KUNTZ: Okay.

13          CHAIRMAN WASHINGTON: Normand.

14          MS. NORMAND: Sharon-Lise Normand,  
15 Methodology Committee member. I just wanted to  
16 ask, on what basis or evidence of -- I'm still  
17 stuck on the second phase review having the so-  
18 called pink sheets and it's sort of a different  
19 group of characteristic of people who are reviewing  
20 at that second stage and they've got all this  
21 information from the first stage. My initial  
22 reaction was, oh, my god, why are you doing that?

1 Why are you giving that information to them? And  
2 I'm sort of still there.

3           So, I'm trying to understand the -- how --  
4 why did you feel the need to provide them with  
5 that? Can you just sort of -- just my automatic  
6 reaction, you shouldn't have, but I'm willing to be  
7 -- I can be wrong, obviously, so help me think  
8 through -- what did that provide?

9           DR. SELBY: So, we know from the data we  
10 showed you in the pilots and we know from work that  
11 others at NIH have done over time that a  
12 traditional study section weights the approach, the  
13 analytic approach. It's almost the only thing that  
14 matters. And, you know, from study sections, you  
15 go to study section and the game is to try to find  
16 a reason not to fund something, but usually based  
17 on methods.

18           And we're trying to get away from that, so  
19 we tried to identify a group and we may change this  
20 strategy, but we tried to identify the subgroup of  
21 all the applications that would do pretty well in  
22 that more traditional kind of review. We did have

1 all eight criteria, but I bet you that if you  
2 looked, number five, rigorous research methods,  
3 would probably drive those scores in round one as  
4 it did in the pilots.

5           And then we said, starting with a group  
6 that's done quite well in terms of the approach,  
7 please emphasis, please -- and this is hard. I  
8 mean, we really do want to shift the paradigm  
9 toward funding research that's likely to have an  
10 impact. We don't want methodologically elegant  
11 work that isn't going to have an impact. So,  
12 that's why we did exactly what we did. Please  
13 place an emphasis on the likelihood that this will  
14 change practice, place an emphasis on is this  
15 really important to patients, place an emphasis on  
16 have they engaged.

17           So, that's the thinking, that it's going  
18 to be very tough, no matter what we do, to break  
19 the paradigm. We don't expect, probably, that it's  
20 going to break it very much this first time. We're  
21 anxious to see.

22           MS. NORMAND: So, I'm not disagreeing with

1 that, it's a very -- in some sense, it's a very  
2 nerdy point. I'm just asking about providing the  
3 score -- like, the pink sheets, to the second  
4 group. What was the thinking behind that? That's  
5 the only -- this is the process that I'm asking  
6 about in terms of that piece.

7 DR. SELBY: Again, you know, this may be a  
8 function of how many we expected versus how many we  
9 actually wound up with, but I think we were not  
10 necessarily expecting the second round study  
11 section to peruse the entire application quite as  
12 carefully as the first round did.

13 And we also really, you know, frankly  
14 didn't want a whole lot of second guessing either.  
15 That didn't seem to make a lot of sense either.

16 MR. DUEÑAS: And that's exactly right.  
17 So, the idea is that we were expecting over 1,000  
18 applications. So, the idea was to sort of give  
19 them the critiques as the primary resource for them  
20 and that access to the application, but only if you  
21 have to, and that's one of the reasons why they got  
22 access to the pink sheet.

1 DR. SCHNEEWEISS: Sebastian Schneeweiss,  
2 methods committee. If you can go back to the  
3 bubble chart with those four big bubbles or five  
4 big bubbles, what I saw there that what is in this  
5 upper green bubble is CER, assuming that these  
6 proposals move proportionately on to be funded,  
7 right, that is 29 percent is actually the smallest  
8 absolute percentage of the research portfolio. Is  
9 that the research portfolio that we can expect from  
10 PCORI in the future, less than a third CER?

11 DR. SELBY: The denominators are switched  
12 here. The denominator is the number that were  
13 submitted and so the 61 -- it's, by far, the  
14 largest group, 61 made it through versus 26, 35,  
15 and 30.

16 CHAIRMAN WASHINGTON: Okay. And then  
17 Collins after Douma.

18 MR. DUEÑAS: Which one?

19 DR. DOUMA: It's the one -- yeah, it's the  
20 one that shows up what's next for us. We have a  
21 vested interest in that. No, you were just there.  
22 That one.

1 DR. SELBY: Okay, that one we haven't  
2 actually gotten to speak to yet. That's my job to  
3 speak to that one.

4 DR. DOUMA: Oh, okay. He'd already shown  
5 it.

6 CHAIRMAN WASHINGTON: Okay, Francis,  
7 please, first.

8 DR. COLLINS: Francis Collins, Board. I  
9 think the Board would love to see a simple plot of  
10 the average priority scores for each application  
11 for Phase I versus Phase II. Is R squared a large  
12 number or a very small number? If you have very  
13 limited correlation between the two reviews, then I  
14 think we really have to look very hard at whether  
15 this is a system that's plucking out the right  
16 proposals for PCORI to support.

17 Because I would have expected that a Phase  
18 II process, when it is already informed by what  
19 happened in Phase I, is sort of like council where  
20 you're trying to do some fine-tuning for what's a  
21 high priority, I mean, that's what we call it --  
22 high program priority, low program priority, sort

1 of at the margin where something -- well, it's all  
2 right at the borderline and do we want to fund this  
3 or do we want to fund something else and pull it up  
4 a little bit.

5           And if there's a great deal of reshuffling  
6 going on here, i.e. if R squared ends up being  
7 pretty small, then I think you really have to look  
8 hard at this process about whether it's doing what  
9 you need.

10           DR. WEISMAN: Francis, I don't think that  
11 that's true, I mean, based on what Joe said. Joe  
12 said they were shifting, so the assumption is  
13 everyone who made it through the gate, so to speak,  
14 had good methods. Now the criteria are based on  
15 these three factors and that his assumption is that  
16 the primary reason for making it through the gate  
17 was on methodologic rigor. That's what he said.

18           DR. COLLINS: The first phase had those  
19 eight criteria, I presume they were all being  
20 evaluated on the basis of science.

21           DR. SELBY: But if we talk about the  
22 overall scores from round one versus round two, in

1 round one, the overall score is going to be driven  
2 mostly by criteria number five, that is the  
3 approach, the methods.

4           Then having truncated the distribution and  
5 really decreased the variants among the scores, we  
6 bring them to Phase II, and I think I'll be happy  
7 if the correlation between the overall score in  
8 Phase I and the overall score in Phase II is no so  
9 high.

10           The components -- I'll be happy if the  
11 component scores are close, but the overall score  
12 it would be nice to be driven by something other  
13 than just the method.

14           DR. COLLINS: I'm going to worry, as Gray  
15 was, about projects that actually were sort of in  
16 your worst 10 percent as far as Phase I, but get  
17 pushed into fundable range in Phase II, which means  
18 there were considerable concerns --

19           DR. SELBY: They don't get to Phase II.

20           DR. COLLINS: No, I mean, they still made  
21 it to Phase II because they're in your top one-  
22 third, but they're at the worst part of your one-

1 third.

2 DR. SELBY: This may comfort you a little  
3 bit. As many as half or more, and this is, again,  
4 it's a function of the small numbers, but half or  
5 more than half of the projects, I think, in each  
6 area, are going to get funded, so -- from the Phase  
7 II review. It's --

8 DR. COLLINS: No, I got that.

9 DR. SELBY: Okay. So --

10 DR. COLLINS: I'm still worried about  
11 major shifts when you go to the second phase when  
12 Phase I was supposed to be your rigorous and  
13 scientific --

14 DR. SELBY: We certainly are going to  
15 study that and we'll have to -- if we see it, we'll  
16 have to decide whether it's a good thing or a bad  
17 thing.

18 CHAIRMAN WASHINGTON: Kuntz and then  
19 Clancy.

20 DR. KUNTZ: Rick Kuntz, Board member. I'd  
21 love to extend the linear regression discussion  
22 some more.

1 [Laughter.]

2 DR. CLANCY: I like the random forest  
3 myself.

4 DR. KUNTZ: And I think what Francis is  
5 saying is we do have consistency between two  
6 different groups that value things high, and  
7 because I think that there are a lot of moving  
8 parts in this process here and one is that you're  
9 putting a lot of faith in the second group and  
10 actually judging merit, which is a new composition  
11 of people who may not understand methods. So, if  
12 the first group is more scientific and the rigor  
13 has been established through some score, well,  
14 first of all, it would be hard to correlate because  
15 they'll all be high scores, so you may reduce the  
16 ability to correlate because you don't have any  
17 variance on the first component.

18 But the second part would be, that's where  
19 the experiment is. Take a novel group of  
20 individuals with a reduced set of criteria; can  
21 they still judge highly scientifically meritorious  
22 grants? And we should test that to see if what

1 people valued on the front end by the scientists  
2 were still somewhat valued at the back end, because  
3 it isn't just -- it isn't a process of we only get  
4 the most rigorous studies first and then from then  
5 you pick the best. There's a lot of questions as  
6 to whether or not the group -- it's an experiment.  
7 You know, can this group still pick meritoriously,  
8 scientifically rigorous studies?

9 CHAIRMAN WASHINGTON: [Off microphone.]

10 DR. KUNTZ: Only if you make a huge  
11 assumption that there's equivalent worthiness of  
12 the people who made it through the screen --

13 DR. WEISMAN: The screen is on scientific  
14 grounds and then the second group has a different  
15 set of weighting of the criteria.

16 DR. KUNTZ: If we can make the assumption  
17 that those are completely orthogonal viewpoints,  
18 that we're satisfied with the merit, they're all of  
19 A+ level, and the second part is now completely a  
20 separate -- I'm sorry for using this matrix terms,  
21 but a completely different dimension. But have we  
22 all agreed on that, that the second value of those

1 three criteria are what you're going to basically  
2 use to judge the grants at the end assuming that  
3 you've made this kind of rigorous threshold at the  
4 beginning? I think it's complicated.

5 CHAIRMAN WASHINGTON: I see a few hands,  
6 but can we hear from Mark Helfand? And then we'll  
7 come back to the table. We have Clancy and then we  
8 have Krumholz and Gabriel.

9 DR. HELFAND: Well, I'm counting the  
10 hypotheses that are being generated and I think  
11 Joe's hypothesis, it's pretty reasonable, that  
12 those that went forward all scored high in  
13 methodology is, I understand, would be very easy to  
14 test, right, there is a score for each component.  
15 So, if that's true or not, you should be able to  
16 answer that quickly.

17 And then the second concern about the  
18 relationship between the overall score in the first  
19 versus second, however you do it, correlation or  
20 whatever, should be pretty easy to test.

21 So, since, you know, once you get too many  
22 hypotheses, then we don't know what to do, I wanted

1 to get a few out there on the table before we get  
2 100 more. And I think, you know, the concern that  
3 I would look at is whether you -- your goal is to  
4 achieve, it says, more impact by the second phase,  
5 but you have kind of a new process and it's --  
6 there's no representation, there's only two or  
7 three people trying to represent a bigger community  
8 or set of communities than the research community  
9 alone.

10           And so I would worry about whether,  
11 instead of more impact, the half that went on after  
12 that process were more neutral, less risky  
13 methodologically or as far as their hypothesis or  
14 their goals, whether they had less chance of  
15 ruffling feathers, whether -- the difficulty in  
16 that process was not so much more impact, but more  
17 uncertainty about what research should go forward.  
18 And usually when people have more uncertainty, they  
19 get more afraid of risk and they pick more  
20 conventional or studies that won't ruffle feathers.  
21 And finally, whether it's less diverse, and I mean,  
22 you know, geographically and population wise than

1 the bigger ones.

2 Those are the four things that I'd add.

3 And the limit on hypotheses for this is six, so I  
4 think I've closed the door on anyone else.

5 DR. CLANCY: Carolyn Clancy, Board member.  
6 It's possible I'm missing something and I will  
7 disclose one bias. Having sat in many, many study  
8 sections and reviewing a lot of health services  
9 research papers, I will say that there's no  
10 shortage of papers that are methodologically  
11 rigorous and you get to the end and you think,  
12 "and?" or "so what?"

13 I think PCORI wants to fund work that is  
14 rigorous and relevant, and it is a tough position  
15 to be in review groups where people have said this,  
16 where they've said, I don't even know these methods  
17 but I'm going to assume they're flawless. But this  
18 is a really important question, and I think that's  
19 what the design was here.

20 And we have been encouraging the staff to  
21 be bold and edgy, so I'm not sure they ought to  
22 correlate. If they do, I suppose that means that

1 previous data from NIH study sections and from our  
2 own pilots that says that approach ultimately  
3 swamps everything else in terms of what this  
4 overall score turns out to be, perhaps was flawed.

5 But I actually think this was not a bad  
6 thing to do.

7 CHAIRMAN WASHINGTON: Thank you, Dr.  
8 Clancy. Krumholz and then Gabriel.

9 DR. KRUMHOLZ: Harlan Krumholz. I guess  
10 at the end, I want to get back to what Rick said,  
11 the issue is, did that first screen say that these  
12 are good enough, and then we don't care if they  
13 correlate. I mean, first when Francis told me that  
14 I was thinking it is important, but actually, if  
15 all those are good enough, if you think you can  
16 make valid inferences from all those study designs,  
17 then maybe I don't care about the distribution of  
18 quality among the top third. And the question, I  
19 think, Joe, would be, how might you later sort of  
20 follow up on that by sort of taking a deeper dive  
21 into the differences in the quality of the methods  
22 of those and were they meaningful differences or

1 did you really then get to a group that said, you  
2 don't have to worry so much about the methods,  
3 these are all good enough, now let's choose among  
4 this group of 32 percent that were left?

5           And I think that's really the question,  
6 but I do -- I wasn't in Denver, but I do remember  
7 at times we have discussed this idea about could  
8 you get to good enough, and now people could focus  
9 on the issue of impact, as Carolyn said?

10           CHAIRMAN WASHINGTON: Okay. Gabriel.

11           DR. GABRIEL: So, I like the idea and I  
12 understand the merits of the two-phase approach,  
13 but I guess I wanted to get back to something that  
14 Christine said. If there's an initial screening  
15 phase, it just seemed to make a good deal of sense  
16 to me to have that screening phase be what are the  
17 important patient-centered questions. And then as  
18 a second phase, look at the methods.

19           Because at the end of the day, if you have  
20 -- you know, and we'll end up, perhaps, in a  
21 similar place, but then those that don't get  
22 funded, we have an opportunity to go back to those

1 applicants and, you know, maybe pair them up with  
2 some methodologists and move forward on those  
3 important patient-centered questions in a more  
4 methodologically rigorous way.

5 I just wonder what happened to that  
6 because that really seemed to make a great deal of  
7 sense to me.

8 DR. SELBY: [Off microphone] -- last  
9 Thursday that you can -- it's kind of the  
10 researcher's perspective, maybe, versus the  
11 patients -- the traditional researcher's  
12 perspective, not yours, versus the patient's  
13 perspective, yours or Christine's, which is just  
14 give me the good science and we'll pick out those  
15 that are patient-centered, versus, just give me the  
16 patient-centered and then we'll pick out the good  
17 science.

18 And I agree with you that if all goes  
19 well, we'll wind up at the same place.

20 DR. GABRIEL: And help the others or some  
21 of the others.

22 MR. DUEÑAS: And just to say, we're going

1 to include patients in the Phase I for the next  
2 cycle.

3 CHAIRMAN WASHINGTON: Okay, well, we've  
4 been talking about Phase I and Phase II. I'm glad  
5 it's Joe's opportunity to tell you that there's a  
6 Phase III to this. So, Joe, will you --

7 DR. SELBY: Yeah, here we go. So, now we  
8 will have the applications ranked by the overall  
9 score from Phase II, that's what we're going to  
10 work with, and we have, and I think Martin probably  
11 showed you -- we have a lot of data that was  
12 collected on these that we can examine and you will  
13 recall from the Pilot Projects that we examined a  
14 number of variables and we actually set some  
15 criteria that we wanted a certain degree of  
16 balance, if you will, with respect to variables  
17 like vulnerable populations, the disease studied --  
18 we didn't want it to all be in one condition, for  
19 example.

20 And I think the same thing goes here.  
21 Last time we appointed a committee primarily  
22 composed of Board members with a Methodology

1 Committee member, and staff generated data that the  
2 committee looked at, and last time it worked out  
3 remarkably nicely that everything tended to kind of  
4 balance out on its own and we were able to just  
5 take the top 50 scores.

6 This time we'll hope for similar turn of  
7 events that if we take the top number we can fund  
8 within each priority area, that we'll get that  
9 balance.

10 But we will have the committee again,  
11 we'll look at those variables, and we're proposing  
12 that we essentially make the final selection on  
13 three criteria. First and foremost, the final  
14 score from Phase II, so that's in bold, that's the  
15 overwhelming driving determinant of what we fund.  
16 But we will consider carefully the condition  
17 studied, and if it appears that there is a severe  
18 imbalance in one direction or another, based on  
19 what we've seen at the end of everything that came  
20 in and at the end of Phase I, I think we're going  
21 to see a pretty nice balance across the conditions.

22 And the same goes with the second one,

1 populations studied. If we saw, you know, some  
2 obvious vulnerable populations just completely left  
3 out, we would, perhaps, look below the pay line to  
4 see if there's a good, high scoring study, that  
5 might bring that population in.

6 But that's what the committee would be  
7 asked to do. We'd be doing it in the next three to  
8 four weeks, and we'll come back to the Board in a  
9 December -- probably our December 18th telephonic  
10 Board meeting, which we'll turn into a webcast, and  
11 we'll present -- the Board/Staff Selection  
12 Committee will present to the Board a proposed  
13 slate of proposals for funding at that time.

14 CHAIRMAN WASHINGTON: Before we go to  
15 questions, Joe, I would just also remind the Board  
16 that we more or less decided that the next  
17 "balancing group" for lack of a better word,  
18 especially with Dr. Normand at the table, would be  
19 composed of a different group of Board members,  
20 that it wouldn't be anyone -- except for possibly  
21 the Chair of the previous round who would come with  
22 some experience from that round.

1            Seriously, that's what we would be  
2 proposing as we think about constituting the second  
3 group.

4            Sigal?

5            MS. SIGAL: Ellen Sigal, Board member.  
6 So, I have a little concern on the balancing and  
7 how we're doing it because we were very specific  
8 that we were disease-agnostic, condition-agnostic,  
9 we wanted a very broad tent. That was what we did.  
10 A lot of us didn't really agree with that, but that  
11 was what the judgment was.

12            Now, we're basically saying, well, if  
13 there are too many from one disease we're going to  
14 kind of reshuffle the deck. And it concerns me  
15 because we were very deliberate, very, very  
16 deliberate in not being specific. And now we are  
17 changing the deck chairs, and I don't know how I  
18 feel about that. You know, maybe if there are one  
19 or two on the edge, but if there were five or ten  
20 outstanding grants on Parkinson's but there are  
21 none in, I don't know, Alzheimer's, so we're going  
22 to give one in Alzheimer's that isn't so good that

1 wouldn't get funded a grant? I don't know how that  
2 works. It just seems to question exactly how we're  
3 doing these things.

4 DR. WEISMAN: The way it was done last  
5 time, Ellen, is they expanded the pool and took the  
6 ones on the border. Is that --

7 DR. SELBY: And we may be able to -- it  
8 may be possible to do that this time.

9 DR. WEISMAN: I thought we voted on it.  
10 [Off microphone discussion.]

11 DR. SELBY: Last time we did -- we were  
12 able to improve the balance some by just taking a  
13 larger number. And I think, you know, the decision  
14 about the exact number to fund is, this time, given  
15 the somewhat smaller than expected total number  
16 submitted, has yet to be made, will be made in  
17 discussions with the committee.

18 But I would just say to Ellen, your -- I  
19 can see how you got to the conclusion that you got,  
20 but I think you could get to the opposite  
21 conclusion. If you wanted to be disease-agnostic,  
22 you'd say, we don't want to focus all of our

1 research in any one area, so disease-agnostic is  
2 maybe the wrong definition, but we did decide we  
3 didn't want to concentrate all of our resources in  
4 one or a few areas, and this would be consistent  
5 with that in saying, you know, if we, by the luck  
6 of the draw, wound up concentrating it all in one  
7 area, we'd like a little spread. So, not  
8 inconsistent.

9 MS. SIGAL: Just a point to that, maybe  
10 that's correct, but if we -- you know, because we  
11 know who the likely candidates are going to be  
12 always by the nature of the population, but if we  
13 really want the diversity, then maybe we need to be  
14 -- and we are getting to that, we need to be a  
15 little bit more specific in getting other diseases  
16 or other rare diseases or other outcomes and be  
17 more proactive about that. That may be another way  
18 to approach it.

19 CHAIRMAN WASHINGTON: Norquist, is your  
20 card up?

21 DR. NORQUIST: Gray Norquist on the Board.  
22 So, what I would say is that we kind of lucked out,

1 you know, the last -- and the other thing, when you  
2 say condition, people are studying chronic, so it's  
3 not as simple as just cancer or something often on  
4 many of these, and so I think you'll find that may  
5 not be an issue. The only thing I would say is  
6 that -- whoever makes up the committee, is that you  
7 be sure that you have some a priori criteria.  
8 Don't just say they didn't hit a severe or whatever  
9 because trust me, the people who don't get funded  
10 are going to have a lot to be upset about, and so I  
11 think we need to be very clear what our line is  
12 there about that.

13 CHAIRMAN WASHINGTON: Douma and then Hunt.

14 DR. DOUMA: The lexicon that Bob keeps  
15 bringing up may be of value here with regard to  
16 what we mean by condition. We can -- I've used it  
17 in a broader sense and a more narrow sense. In the  
18 broader sense, for example, chronic pain or chronic  
19 shortness of breath are conditions. Are we going  
20 to treat them the same way we treat diabetes or  
21 congestive heart failure?

22 DR. SELBY: I think right now they -- if

1 I'm remembering correctly, those are categories, so  
2 if something crossed diseases and was about chronic  
3 pain, yeah, there's pain, so you see, those are  
4 separate categories right now.

5 DR. DOUMA: And those are the same  
6 categories we're going to be using as conditions  
7 and choosing between?

8 DR. SELBY: Except it's a much, much  
9 longer list. But you can see already that there is  
10 pretty good spread among those.

11 CHAIRMAN WASHINGTON: Okay. Hunt?

12 MS. HUNT: Hunt, Gail Hunt, on the Board.  
13 So, to this topic of conditions, are we really  
14 going to be looking at not just the conditions that  
15 are there, or -- I should say, are we just going to  
16 be looking at the conditions that we just saw  
17 listed there, or is it somehow a condition that  
18 sort of ties in with impact or devastation on the  
19 patient or, you know, condition that's broader than  
20 just --

21 DR. SELBY: Now, we would definitely not  
22 try to go after particular conditions that had

1 greater impact because that was already done in the  
2 review. So, our principle last time that we'll  
3 certainly adhere to this time is, we're not going  
4 to second guess the reviews.

5 We look at criteria that were not  
6 considered criteria in that -- those reviews.

7 CHAIRMAN WASHINGTON: [Off microphone.]

8 So, I'm going to summarize where we are at  
9 this point. We've completed two stages of a three-  
10 stage process and we've had quite a bit of debate  
11 and discussion regarding the pros and cons of the  
12 approach that we've executed to date. But at this  
13 point, we are where we are, and with those  
14 comments, I hear more than just the suggestion, a  
15 strong recommendation that we, Joe and Martin, find  
16 a way to more rigorously assess going forward. In  
17 fact, even some retrospective analyses to test some  
18 of these hypotheses, as Mark said, so that we can  
19 have that data going into the future.

20 But looking ahead, there will be this next  
21 smaller group consisting of Board and staff, which  
22 will be looking at the impact scores, essentially,

1 from this phase, to come up with the recommended  
2 list of projects that will be brought to the Board  
3 within the next month, month and a half.

4 DR. SELBY: Month.

5 CHAIRMAN WASHINGTON: Month. Within the  
6 next month. It will be a web telecast.

7 DR. SELBY: December 18th.

8 CHAIRMAN WASHINGTON: Oh, it's December  
9 18th, it would be open to the public. Okay. And  
10 we will ensure that the Board, as soon as the  
11 information is available, that this information is  
12 both put on the web, or can we do that given that  
13 we're talking about specific projects? Maybe we  
14 can't do that before, but we'll get as much  
15 information as we can to the Board as quickly as we  
16 can regarding the outcome of this next phase.

17 DR. SELBY: Last thing I'll say is that we  
18 will be contacting a number of you to invite you to  
19 serve on the Selection Committee, and the last time  
20 we made sure that each of the Board committees was  
21 represented on the Selection Committee, typically  
22 by more than one person.

1           CHAIRMAN WASHINGTON:  Sigal and then  
2 Zwolak has the last comment on this and we're going  
3 to close this session.

4           MS. SIGAL:  So, just a quick question.  
5 So, we're going to get the recommendations.  Are we  
6 going to see the ones right below the line?  One of  
7 the things that I used to take great joy on when I  
8 was at the National Cancer Advisory Board, is that  
9 we got to see things that weren't funded that were  
10 just below the pay line and it was quite  
11 interesting.  Are we going to see that?  Are we  
12 going to see those that almost got there but  
13 didn't?

14           DR. SELBY:  That's an interesting  
15 question.  With respect to choosing those that get  
16 funded, we found last time that it was a very  
17 satisfying and relieving exercise not to have to  
18 look at the proposals themselves or their titles or  
19 inadvertently see the investigators, and just to  
20 look at the distribution of their characteristics  
21 and make decisions about funding on the basis of  
22 characteristics rather than the projects

1 themselves.

2           But I think having said that -- and if we  
3 could get through it this time the same way, we  
4 would have no worries about recusals, we'd have no  
5 worries about conflicts that we missed.

6           But I think having said that, once we  
7 determine which ones we will fund, to take at those  
8 just below with an eye toward identifying promising  
9 projects that should be encouraged to resubmit or  
10 to tool up a little bit and resubmit is a very,  
11 very nice idea and I think that would be -- this is  
12 off the top of my head, but it sounds like a good  
13 idea and a very patient-centered idea to do that.

14           CHAIRMAN WASHINGTON: Zwolak, last  
15 comment.

16           DR. ZWOLAK: Bob Zwolak, Board. I think  
17 at one point in our genesis we were actually  
18 talking about trying to finish two full funding  
19 cycles in calendar 2012. It's going to be one,  
20 it's going to be four and a half months from the  
21 submission of the completed grants to the  
22 announcements.

1           So, the question is, what's -- realizing  
2 this is kind of an alpha, what's the eventual goal  
3 for turnaround from submission of grants to  
4 announcements?

5           DR. SELBY: This is a -- and Carolyn or  
6 Francis, correct me if I'm wrong -- but I think we  
7 have telescoped the NIH/AHRQ process a bit already.  
8 I think this is a bit quicker, four and a half  
9 months from the application deadline to the award  
10 date. That's a little quick.

11           It's tough when you do these broad  
12 announcements because you get so much and so  
13 there's a lot of work to be done just putting the  
14 panels together and getting the reviews done,  
15 especially when there's two phases of review.

16           When we get more targeted announcements,  
17 there will be fewer responses, there will be a  
18 smaller review committee, and I think we could pick  
19 up some ground there, but we haven't had it as one  
20 of our priorities to speed this part of it up even  
21 further.

22           DR. CLANCY: Just one quick comment. Just

1 to be a tiny bit humble, I think any institute or  
2 AHRQ could do it once this rapidly. The challenge  
3 will be when you have to make it a repeatable  
4 process and continue that. So, actually staying on  
5 this timeline I think would be great.

6 CHAIRMAN WASHINGTON: Thanks for all of  
7 your comments and we're going to take a break now.  
8 It's 3:00 o'clock and we will resume at 3:15.

9 [Recess.]

10 CHAIRMAN WASHINGTON: Welcome back to  
11 this, it's the last session of the day, meeting of  
12 the Board of Governors of the Patient-Centered  
13 Outcomes Research Institute.

14 In this session, we are going to address  
15 the question of funding for some initial priority  
16 targeted areas and I've asked our vice chairman to  
17 chair this session and also have the record reflect  
18 that I'm going to recuse myself from the  
19 discussion. It's a personal interpretation of a  
20 potential conflict of interest.

21 VICE CHAIRMAN LIPSTEIN: Joe.

22 DR. SELBY: Yes.

1           VICE CHAIRMAN LIPSTEIN: I just did my  
2 thing.

3           DR. SELBY: It's hard work. Steve, thank  
4 you very much for that and, Gene, thank you. And I  
5 want to reintroduce Dr. Kara Walker, who I had the  
6 pleasure of working with a lot on this particular  
7 budget. Really, the truth is, Kara led much of it  
8 and I'm going to do the Steve/Gene thing of having  
9 Kara sit directly across from me so we can maintain  
10 eye contact and if I need her assistance in  
11 answering a question, she's there.

12           So, what I want to do this afternoon is  
13 present to you a rationale, or review a rationale  
14 with you for why PCORI should move rather quickly  
15 toward some targeted funding announcements. And  
16 targeted funding announcements mean, instead of  
17 submitting a call, a broad call, for research  
18 across a wide range of conditions, any condition,  
19 any treatment, any question, as we do now, that we  
20 dedicate some of our funding to a much more  
21 targeted or specific or focused approach where we  
22 concentrate on one question, which we've determined

1 is very high priority and very suitable for PCORI.

2 I want to say, before going any further,  
3 that we are extremely proud of the announcements  
4 that are out, the standing announcements that I  
5 call broad funding announcements. We think that  
6 they provide an opportunity to get the best ideas  
7 of patients working with -- of researchers working  
8 with patients and stakeholders from across the  
9 country, ideas that we may never have thought of,  
10 ideas about conditions we might not have come up  
11 with, that we simply solicit good research, we  
12 review it, and prioritize it on its merits, not on  
13 the basis of what the question was in the  
14 beginning, not on the basis that they picked the  
15 disease that we favored.

16 So, having said that, we also see a merit  
17 in a targeted approach, which is to identify, in  
18 collaboration with stakeholders, patients,  
19 clinicians, and others, some very high priority  
20 areas that PCORI should concentrate research  
21 funding and resources in.

22 You know and you've heard, at the last

1 meeting in Washington and again earlier today when  
2 we talked about the advisory panels, that we are  
3 building a topic generation and research  
4 prioritization scheme process that we're very  
5 pleased with how it's developing. We're looking  
6 forward to the day when it's functioning and good  
7 ideas are coming out at the end of the process and  
8 coming to the Board -- high prioritized, good  
9 ideas.

10 But we're not going to get there for, I  
11 would say, six months minimum before the advisory  
12 panels have been convened and actually gone through  
13 the prioritization process and generated these  
14 topics for us to consider.

15 And so, in our judgment, we think there's  
16 a need to get on with identifying high priority  
17 topics. I'm going to talk to you about the process  
18 that we've put into place and gone through in this  
19 interim phase. I want to then show you the  
20 proposed topics that we've come up with, have a  
21 discussion with you, give you a little information  
22 about those three topics, and then, in fact, ask

1 for the Board's vote on these topics.

2           There will be a somewhat larger list that  
3 you'll see and I think that we are open to  
4 expanding the number of topics, modestly, that we  
5 could go after. But there are limits on how many  
6 targeted topics one can -- the staff can go after  
7 at one time.

8           So, the rationale, in part we respond to  
9 concerns that we've heard from virtually every  
10 stakeholder group that exists, from patients  
11 through researchers through industry through health  
12 plans and employers, concerns that, in fact, we did  
13 stay at such a high level that it didn't seem to  
14 stakeholders that we were being consistent with the  
15 legislation which said, prioritize high priority  
16 topics and fund in those areas.

17           We're responding to a Board directive,  
18 which we got late in the summer from the Board, to  
19 move forward with identifying several high  
20 priority, stakeholder vetted topics.

21           It gives us a chance to jumpstart and test  
22 -- what we've done allowed us to jumpstart and test

1 the longer-term topic generation and research  
2 prioritization effort that we're putting into  
3 place. And, in fact, I'll say that we're working  
4 on in those workshops I mentioned this morning on  
5 December 4th and 5th.

6           Very importantly, it leverages stakeholder  
7 input that was gathered before PCORI really came on  
8 the scene, and so there were -- and lastly, this  
9 endeavor, allows us to build further on our  
10 engagement work.

11           MS. HUNT: Hunt, I'm on the Board. What  
12 does stakeholder input from before PCORI's  
13 existence -- what does that mean?

14           DR. SELBY: It means that there were other  
15 stakeholder-driven processes that identified high  
16 priority topics.

17           MS. HUNT: Okay.

18           VICE CHAIRMAN LIPSTEIN: I think that will  
19 become apparent, Gail, as we go through the process  
20 -- through the process steps.

21           DR. SELBY: So, you've seen something like  
22 this before, and this is an adaptation of our plan

1 for the long-term prioritization process, but this  
2 is now modified to reflect what we did this time.

3           So, on the left, we began with reports of  
4 prioritized topics that had come from a variety of  
5 stakeholder groups, and we looked specifically for  
6 topics that had been identified by at least two of  
7 these processes or sources. And so, we created a  
8 list, it turned out to be a list of 40 -- 40 or 41,  
9 Kara? -- topics, that had been identified by at  
10 least two of the processes we looked at.

11           Staff. PCORI staff then, we really did  
12 not feel that this prioritization process was ready  
13 to invite patients and stakeholders, non-PCORI  
14 patients and stakeholders into yet because it had  
15 not been vetted at all and there are challenges  
16 about gathering information and prioritizing. So,  
17 we used software that we plan to use going forward,  
18 but there were staff who actually did the review of  
19 these topics, and they reviewed them on two sets of  
20 criteria.

21           The first, and we're in the middle now,  
22 the middle blue chevron, beneath that, the first

1 was PCORI's review criteria, which you're familiar  
2 with, not all eight, but five of them -- patient  
3 centeredness, the impact of the condition, that is  
4 the burden, the innovation and potential for  
5 improvement, that is potential for practice change,  
6 the impact on healthcare, on healthcare  
7 performance, quality, safety, efficiency, and  
8 lastly, inclusiveness, that it either considers  
9 multiple populations or goes after a particular  
10 population that's a vulnerable population.

11           So, those are traditional criteria  
12 reviewed by that, and actually, slightly before we  
13 reviewed by those, we reviewed by four criteria  
14 that I'll talk a little bit more about in a minute,  
15 that were specifically developed for this high  
16 priority, fast tracked process, this targeted  
17 funding.

18           The idea, again, is that the topics that  
19 come out at the top of this list go to the Board.  
20 That's what we're doing today. We hope that you  
21 will approve some high priority topics so that we  
22 can move on to the next step, which is to gather

1 additional expert and stakeholder input in a  
2 process that not only helps us make certain that we  
3 picked the right topics, but more importantly,  
4 helps us zero in on exactly the right questions  
5 within a topic.

6           So, the first filter was looking at the  
7 sources of a stakeholder-vetted list, and we  
8 started with the IOM 100. This had come out just  
9 about a year before PCORI came into existence and  
10 is widely recognized and accepted as a good list  
11 across the whole range of conditions and treatments  
12 and that patients face.

13           We looked at a range of other topic  
14 generation processes, those from AHRQ, those from  
15 NIH, and from other organizations. A total of over  
16 300 topics were considered. We looked for  
17 overlapping topics and I said -- as I said, there  
18 were 40 identified.

19           So, we then applied this second filter,  
20 and these I showed you from the previous slide.  
21 So, the first one is salience, and this meant that  
22 to the staff person or to the prioritizer, this

1 topic has some obvious, recognizable importance,  
2 that is, the question being addressed is known to  
3 represent a fairly common problem. The question  
4 sounds like a legitimate question that you'd  
5 perhaps recognize that people have -- face. The  
6 second is short-term feasibility. We were  
7 interested in projects that would have a relatively  
8 short turn around, possibly within two to three  
9 years, at least for some of the outcomes. The  
10 third is that -- and this last one was -- this  
11 third one was assessed more in subsequent  
12 conversations with other funders, that it was  
13 unlikely to be funded without PCORI support. And  
14 the fourth was resource constraints, just that  
15 moderate investments could suffice or possibly that  
16 PCORI could leverage its resources by identifying  
17 opportunities to co-fund.

18           So, that was the second filter these  
19 targeted funding factors. And the third is, again,  
20 we've already gone through this, these are the  
21 familiar five.

22           And this was the process that six staff

1 reviewers -- four from the science team, two from  
2 the non-science team -- used software to apply  
3 scores on each of these criteria to each of 40  
4 questions.

5           The rankings were independent, the  
6 criteria were weighted, and we actually looked at  
7 several weights and in the end settled on a  
8 weighting scheme that emphasized, to some extent,  
9 the targeted PFA specific filter.

10           As I said, 40 were ranked. We took the  
11 top 25 of those 40, so we did not -- it wasn't that  
12 the filter said absolutely yes or no, it ranked  
13 them, we looked at the distribution and took the  
14 top 25 and discussed that -- those with the PDC.

15           These are the top 25, I apologize, it's  
16 going to be pretty tough to read -- yes, it is  
17 going to be pretty tough to read. We will get to  
18 the ten, I guaranty you, you can read the ten  
19 better than these 25, and those of you on the Board  
20 and the Methodology Committee and staff should have  
21 slides that you can look at to see what they all  
22 are.

1           So, this was discussed with the PDC. It  
2 was also discussed with experts in various fields,  
3 with funders, and it was also considered in terms  
4 of these criteria: we wanted a balance, and  
5 whatever we recommended to the Board, we wanted to  
6 achieve balance on -- again, this will be familiar  
7 to you from our last conversation -- on study  
8 population, on the conditions we addressed, and on  
9 the potential -- and in addition, we wanted it to  
10 have a high potential for impact after all was said  
11 and done and after continued consultation.

12           So, the balance drove us toward a smaller  
13 number and these are the ten. So, starting with --  
14 and these are in rank order, I believe, ranked by  
15 the scores of the staff.

16           VICE CHAIRMAN LIPSTEIN: Joe, can you take  
17 a pause for one second, because we're about to go  
18 into the recommended topics. I wanted to see if  
19 anybody on the Board had any questions or comments  
20 about the process, the process that we followed,  
21 because it's a good time to separate the actual  
22 output of the process from the process to make sure

1 you had any questions or concerns. Dr. Zwolak?

2 DR. ZWOLAK: Zwolak, Board. Just a quick  
3 question, the top 25 were ranked in order? That's  
4 not a random list that was a scored list from  
5 number 1 to number 25?

6 DR. SELBY: That's right.

7 DR. ZWOLAK: Thank you.

8 VICE CHAIRMAN LIPSTEIN: Any other  
9 questions or comments about process? Dr. Douma?

10 DR. DOUMA: Thank you. This is Allen  
11 Douma on the Board. The concern I have about the  
12 process is not the process itself, but it's that I  
13 can't understand it because there's not enough  
14 transparency. It would be really helpful if we had  
15 at each step a list of which diseases or conditions  
16 were in and which came out and the reasons they  
17 came out, and I think that's important for a number  
18 of reasons, one is that we are a transparent  
19 organization. The second reason I think it's  
20 important, because 95 percent, at least, 99 percent  
21 of the people who would like us to fund them,  
22 weren't, and they'd like to understand why not.

1           But it's also important that we want to be  
2 able to have a dialogue with people in the future  
3 who we want them to come forward and we want them  
4 to come forward because they understand our process  
5 and they have a significant possibility of being  
6 funded. So, I would request that we have a greater  
7 amount of information, and I'm not saying that we  
8 have to have it today, but I would certainly like  
9 to see a lot more transparency than we have in our  
10 deck.

11           DR. SELBY: Thanks, Allen. And actually,  
12 we do have the individual scores on each criterion  
13 and, you know, combined using various weighting  
14 approaches that we could prepare into something  
15 that was more presentable than it is right now.

16           DR. DOUMA: And just something as simple  
17 as what were the 400 that were in the original  
18 list.

19           VICE CHAIRMAN LIPSTEIN: Any other  
20 questions on process or comments on process?

21           Okay, Joe.

22           DR. SELBY: Okay. We looked at these 11

1 and discussed them with the PDC again, and out of  
2 this list, we ultimately, taking into account more  
3 intensively this notion of balance, we wanted to be  
4 balanced across populations and conditions, and the  
5 notion of not likely to be funded by others without  
6 our participation, and we have come to three that  
7 we're recommending to you and I will move on to  
8 those at this point.

9           The first one is the treatment of uterine  
10 fibroids. The second is safety and benefits of  
11 treatment options for severe asthma and African-  
12 Americans. And the third is the prevention of  
13 falls in the elderly. And I'm just going to say a  
14 few words about each one.

15           Uterine fibroids occur appear in at least  
16 70 percent of women by the age of 50. The  
17 prevalence is even higher in African-American  
18 women. Many have no symptoms, but those who do can  
19 suffer months, years of pain and bleeding,  
20 interfering with an ability to work, to function in  
21 the family, or in other social situations.

22           Hysterectomy has been the traditional

1 treatment when symptoms get to a certain point, but  
2 there are now both a number of less invasive  
3 surgical procedures, including arterial  
4 embolization, myomectomy, and high-frequency  
5 ultrasound, and there are also a number of  
6 pharmacologic treatments that may be suitable for  
7 particular women who, on the one hand, may be  
8 approaching menopause relatively quickly so that  
9 the duration of time they'd need to take the  
10 therapy may be short and people who can understand  
11 the adverse effects sometimes of these  
12 pharmacologic approaches in the name of avoiding  
13 hysterectomy.

14           Avoiding hysterectomy is obviously  
15 critical if one still hopes to conceive, but even  
16 if a woman is past child bearing age or not  
17 interested in conception any longer, still avoiding  
18 hysterectomy avoids certain amount of morbidity and  
19 risk.

20           So, this is a topic that in our judgment  
21 and in our investigations was unlikely to be funded  
22 elsewhere and it's a topic that has the interesting

1 aspects of comparing a number of new and more time  
2 honored conditions -- treatments. It's really  
3 highly relevant to all women of this age range, so  
4 that was why it is among the top three.

5           Moving on to the second one. Asthma is  
6 one of the most common chronic diseases in the U.S.  
7 It's increasing in prevalence. It's much higher in  
8 prevalence in African-Americans. Mortality in  
9 African-Americans given that they have asthma is  
10 much higher.

11           There's some evidence that particular,  
12 even guideline recommended therapies, may have more  
13 adverse events including mortality in African-  
14 Americans. There's some evidence also that genetic  
15 factors may help to identify those who are  
16 susceptible to adverse effects of treatments.

17           And lastly, there's a strong sense that  
18 system level interventions to improve the quality  
19 and consistency of care and of support for self-  
20 management may be an important factor.

21           So, for those reasons, this second topic  
22 is among the top three.

1           Fall prevention in the elderly. Falls  
2 occur in about 30 to 40 percent of people 65 and  
3 above per year, obviously not the same rate in a  
4 healthy 65 year old as in a frail older person --  
5 frail or older person. Falls are the leading cause  
6 of hospitalization and mortality among trauma in  
7 the elderly -- among types of trauma. And they  
8 often signal an end to the independence -- the  
9 ability to live independently among the elderly.

10           There are a lot of questions these days  
11 about the -- and it's been a recent systematic  
12 review which points to the need for more evidence  
13 on the effectiveness of particularly multi-  
14 factorial screening programs -- screening and  
15 intervention programs in the elderly. And the big  
16 question is, who among the elderly would this be  
17 beneficial for? Obviously, not everybody needs it.  
18 In whom is it beneficial?

19           DR. WEISMAN: Joe, can we pause there for  
20 a second? Harlan. Clarification.

21           VICE CHAIRMAN LIPSTEIN: Clarification,  
22 go.

1 DR. WEISMAN: On the final point, fall  
2 prevention in the elderly, is that including or  
3 excluding patients with known high risk factors  
4 such as orthostatic hypotension from dysautonomia,  
5 you know, from things like Parkinson's disease and  
6 so forth.

7 DR. SELBY: I think that would likely be a  
8 part of the research in those groups -- does  
9 screening -- there may be a group that's so high  
10 risk that it's not even a question, but there are  
11 certainly a large number of patients in whom it's  
12 not certain yet whether this would be a reasonable  
13 approach.

14 VICE CHAIRMAN LIPSTEIN: Joe, could we  
15 pause for a second? What I'd like to do, since the  
16 recommended topics are on the table, is just kind  
17 of take them one at a time and ask Board members if  
18 they -- as Harlan suggested, if they need any more  
19 clarification or comment, I would just highlight  
20 that staff did provide for us a reference manual on  
21 these targeted funding announcements and Leah and I  
22 were commenting that we had a chance to read more

1 about uterine fibroids than either of us had read  
2 before.

3 And so you do have that as background  
4 information at your places, but Ellen, you had a  
5 comment? We're on uterine fibroids right now, is  
6 that okay?

7 MS. SIGAL: Well, it's just a little bit  
8 of a process problem. So, uterine fibroids are  
9 good, okay, you should deal with them. Okay, so  
10 the issue is, we had talked about the possibility  
11 of maybe having five topics that we were going to  
12 look at and then honing down to three just in case,  
13 for whatever reason this -- you know, there was not  
14 consensus on all these three, and I thought we were  
15 going to look at five, although the preference was  
16 going to be three.

17 So, are we going to only talk about these  
18 three or are we going to go back to the other two?  
19 It's just, again, just a process issue.

20 VICE CHAIRMAN LIPSTEIN: So, we will come  
21 back to that. So, let me just put that question on  
22 the parking lot for a second because I think after

1 we get through with the three we can come back to  
2 the five, but I want to see if there are any  
3 questions about any of the three topics or any  
4 concerns that anybody has about these being areas  
5 of priority emphasis and targeted funding for  
6 PCORI.

7 Sharon, you gave me my tutorial on uterine  
8 fibroids, so any comments? Good. And Ellen said  
9 good. Any other concerns about the one on uterine  
10 fibroids? Arnie? You're good. How about on the  
11 second one, on asthma in the African-American  
12 population? Leah.

13 MS. HOLE-CURRY: So, I have just a slight  
14 process question as well. I think it's a  
15 clarification question for you, Joe, and that is,  
16 if you were to move forward with these topics, then  
17 you would work with a team, and I'm not trying to  
18 get into all the details of the next step, it's  
19 just important for me to understand so I know what  
20 we're voting on, and they would help to refine  
21 questions such as the one that Harlan brought up  
22 about where would you exclude certain high-risk

1 population groups? That would be their role in  
2 general, so we're really trying to decide on this  
3 very high level approach. Is that -- I just want  
4 to be --

5 DR. SELBY: That's absolutely right. The  
6 next step -- for those that you approve, and I will  
7 go on record as saying I think we could handle five  
8 if the Board wants to expand it to five.

9 I'll be interested to see your process for  
10 mainly the other two, but we'll take five -- is to  
11 in fact convene an expert-stakeholder panel and in  
12 the Methodology Committee meeting yesterday we  
13 talked about this some as well, and I think that  
14 there is interest in the Methodology Committee in  
15 working with us, crafting that meeting, structuring  
16 that meeting, asking the questions in the right way  
17 is going to be crucial, but it would be great to  
18 have the Methodology Committee's participation in  
19 helping us get to the right study and possibly even  
20 to the right study design.

21 I'll stop there for now.

22 MS. HOLE-CURRY: So, on the topic of

1 briefs -- are the topic briefs what you would start  
2 with? Can we separately provide a few comments on  
3 those apart from just the overall general topic  
4 here?

5 DR. SELBY: Sure.

6 MS. HOLE-CURRY: Okay.

7 DR. SELBY: Got it?

8 MS. HOLE-CURRY: So, now I have a question  
9 on asthma.

10 VICE CHAIRMAN LIPSTEIN: Okay, we have a  
11 question on asthma, so we'll still on asthma.

12 MS. HOLE-CURRY: So, when I was reading  
13 through the background materials related to this,  
14 the systematic review that was conducted also noted  
15 that there was higher prevalence in Puerto Rican  
16 populations, so other ethnic groups, and this topic  
17 says specific to African-Americans. So, I'm  
18 wondering if it would be appropriate to broaden the  
19 topic and then have the sub group -- or the subject  
20 matter expert group go forward in terms of just  
21 African-Americans, or in looking at the systematic  
22 review material, was there a decision already made

1 that this is the place we should focus?

2 DR. SELBY: Kara?

3 MS. ODOM-WALKER: So, to clarify, thank  
4 you so much for that question. The initial  
5 question that came to us was specific to the  
6 African-American population. What we did to work  
7 up the topic was to look at the greater body of  
8 literature that's out there, and so you'll see that  
9 other subpopulations have been identified as also  
10 high-risk groups.

11 What we expect in the next steps, and  
12 maybe, Joe, you could even advance to our slide on  
13 the stakeholder and expert panel process is we  
14 would ask those experts with content knowledge and  
15 talk about study design and what other  
16 subpopulations should be included in a full  
17 proposal for funding.

18 MS. HOLE-CURRY: That would be great. So,  
19 then my only other comment at the topic level is I  
20 think that when you went back to that safety and  
21 benefits of alternatives, I would recommend that  
22 all topics where that's appropriate include safety

1 and benefit, not just option.

2 VICE CHAIRMAN LIPSTEIN: Okay. Other  
3 comments on asthma? Okay, Joe, can you go to the -  
4 -

5 DR. SELBY: Wait, Freda has a comment.

6 DR. LEWIS-HALL: Mine is also a process  
7 clarification and that is, we're talking about this  
8 as a study. Is it possible that at the end of the  
9 day it is not one study, but a suite of studies, if  
10 you would, that would answer one or two critical  
11 questions?

12 DR. SELBY: That's what this slide here is  
13 meant to portray, Freda, that we convened the  
14 stakeholder expert panel and we could come out of  
15 that with a recommendation that what you really  
16 need is to synthesize the evidence that's already  
17 there. We can't move forward until you do an  
18 evidence synthesis, in which case we'd come to the  
19 Board with the proposal that we issue a funding  
20 announcement for an evidence synthesis.

21 They could identify the single study that  
22 is needed. You know, maybe it's a randomized

1 trial, maybe it's a huge cohort study. Or they  
2 could, in fact, suggest just what you said, that  
3 you really need a suite of studies, a portfolio of  
4 study, as we called it, perhaps a randomized trial  
5 and a large database study.

6 DR. FREDA-LEWIS: And just follow up, and  
7 we're prepared to do any of those, none of those  
8 are stops.

9 DR. SELBY: That's right.

10 VICE CHAIRMAN LIPSTEIN: And the third  
11 topic was preventing falls in the elderly. Any  
12 questions or comments about falls in the elderly?  
13 Yes, Dr. Zwolak?

14 DR. ZWOLAK: Bob Zwolak, Board. Sorry  
15 about my voice. I think in this one in particular  
16 if the top 25 were ranked in terms of priority,  
17 somehow number 22 hopped all the way up to  
18 number 3. So, I think it would be crucially  
19 important for us maybe to hear what it is about  
20 falls in the elderly that made it bypass 18 or 19  
21 other high-priority conditions.

22 DR. SELBY: We'll have to get the scores

1 out to see how much of a hopscotch that was, but  
2 you are right, and I think the considerations that  
3 got this moved up were, number one, balance, I  
4 mean, it was among those that was particularly  
5 aimed at the elderly and the other two are not.  
6 So, we thought that it was a good idea to have at  
7 least one that was aimed at -- that was conducted  
8 in that population and addressed a question in that  
9 population.

10 And the other, I think, was the enthusiasm  
11 that we ran into in many quarters for that topic.  
12 It just seemed like there was an awful lot of  
13 enthusiasm for the topic.

14 VICE CHAIRMAN LIPSTEIN: Harlan?

15 DR. WEISMAN: In terms --

16 VICE CHAIRMAN LIPSTEIN: That's Dr. Harlan  
17 Weisman for everybody.

18 DR. WEISMAN: Harlan Weisman, Board  
19 member. I have a question about what this is or  
20 what the PFA is -- RFP. This is actually going to  
21 be where we specify, after the advisory input, in  
22 great detail not only the condition and population,

1 but also at least the broad strokes of design and  
2 that we're asking people not to offer us ideas of  
3 how to approach it as we've done before, but in a  
4 more specific way.

5 We're actually asking for a contract. We  
6 are being very detailed on what we're looking for.  
7 Is that the idea?

8 DR. SELBY: That's the idea of putting RFP  
9 under that single study, yes.

10 DR. WEISMAN: But not under the other one?

11 DR. SELBY: But if it were portfolio  
12 studies, it would -- you know, I guess it could be  
13 a portfolio of two or three very specific studies  
14 or it could be within this narrow area, a call for  
15 best ideas. So, I think, the portfolio, it's a  
16 little unclear whether it would be an RFP or a PFA  
17 type of mechanism.

18 MR. BECKER: Larry Becker. So, I'm not  
19 quite sure if this is an appropriate question or  
20 not, so somebody help me. But you're planning to  
21 do some targeted funding of targeted kinds of  
22 things as opposed to the more general funding that

1 we did.

2           Is someone going to compare these two  
3 approaches and at the end determine which ways were  
4 more effective and in which ways they weren't, so,  
5 that as we go forward, if we go with this kind of a  
6 process, that we sort of have a better idea of how  
7 to proceed next time?

8           DR. SELBY: Well, first of all, I think  
9 that we envision probably doing both processes for  
10 the duration, so I think we always see some value  
11 in having these broad announcements open and an  
12 opportunity for people with good ideas to submit  
13 even outside of those topics that we've labeled as  
14 high priority.

15           But I think the answer is a resounding yes  
16 that we, the staff and I, I predict, you, the  
17 Board, even more than we, the staff, are going to  
18 be watching this process very carefully. I'm sure  
19 or I expect that you, like me, are a bit on the  
20 edge of your seat right now waiting to see what we  
21 in fact do wind up funding through the broad  
22 announcement. What does that look like? And that

1 will be our first glimpse of what a broad  
2 solicitation yields. And over time we'll have a  
3 better and better idea of the kind of portfolio we  
4 get there.

5           The idea with this is that it enables you  
6 to hone in on a smaller, more focused area, you  
7 know, fund one or more studies at the beginning,  
8 keep a close eye on them, because you've named it a  
9 high priority area, consider whether that study  
10 answered it, whether there's a follow on study,  
11 that kind of --

12           VICE CHAIRMAN LIPSTEIN: Dr. Zwolak, are  
13 you still asking to speak?

14           DR. ZWOLAK: Yes, thank you. Bob Zwolak.  
15 I don't mean to push you, but -- so, in response to  
16 my question of how number 22 got up to number 3,  
17 you said, balance, which is great, and enthusiasm.  
18 And so the enthusiasm, that must be internal  
19 enthusiasm, right, because we haven't set this out  
20 for public comment or anything?

21           DR. SELBY: No, it was external because we  
22 did tap the expertise of people in other funding

1 agencies and other experts about this, so we were  
2 persuaded that this was an area of great  
3 importance.

4 VICE CHAIRMAN LIPSTEIN: Dr. Kuntz, are  
5 you over there?

6 DR. KUNTZ: Yeah, just a comment on the  
7 overall process. I like this process a lot. I  
8 think it's really rigorous and it's agnostic, and  
9 it's interesting because I would never guess that  
10 these are the topics that came through and I think  
11 maybe many people around here do.

12 DR. SELBY: I wouldn't either.

13 DR. KUNTZ: One question is, there's an  
14 element there about valuing projects that aren't  
15 being funded and won't be funded, which is a two-  
16 edged sword. I mean, one reason they're not funded  
17 is because they're really not interesting.

18 Did we put a lot of emphasis on that or is  
19 a moderate amount of emphasis? I mean, how much  
20 emphasis did we put on the factor that these are  
21 projects that aren't being funded?

22 DR. SELBY: I think that helped us in the

1 end. You know, that wasn't one of the criteria we  
2 scored on, but afterwards -- and this, Bob, might  
3 be another partial answer to yours, you know, if we  
4 found that something was already substantially  
5 funded, that was different than if we found  
6 something that had no funding or in one case, I  
7 think it was uterine fibroids, I said, this is  
8 unlikely to be funded by others.

9 DR. KUNTZ: Understanding there were two  
10 reasons why that wouldn't be fun -- funded.

11 DR. SELBY: No, no, no. This is a great  
12 idea and it's unlikely that it would be funded by  
13 others.

14 VICE CHAIRMAN LIPSTEIN: So, I'd like to  
15 ask a process question since we have 20 minutes  
16 left in this segment of the agenda. Ellen, help me  
17 out here a little bit. If we were only going to  
18 approve three, would members of the Board, this is  
19 going back to what Allen said, would members of the  
20 Board want to debate these three more carefully  
21 than if they knew we were going to add an  
22 additional two and then they wouldn't feel like we

1 were needing to substitute? Or would these three  
2 emerge as a consensus group for us to begin with?  
3 And so I'm looking around the room for some input  
4 on the -- does everybody understand my question?

5           So, if we were only going to approve  
6 three, would we have a lot more debate about these  
7 three, or if you knew we were going to have two  
8 more, would these three be kind of unanimously in  
9 that group of five and you would want to proceed  
10 with approval at this point?

11           Arnie?

12           DR. EPSTEIN: I guess my preference would  
13 be to have more than three and as many as the  
14 traffic could bear. I think the key issue is what  
15 Joe can learn from an expert panel about the  
16 likelihood that additional dollars will really pay  
17 off with directive information. And I think that  
18 would guide our discussions much more and any  
19 further information about the potential for averted  
20 morbidity or mortality or numbers. So, I go for  
21 more.

22           VICE CHAIRMAN LIPSTEIN: So, let me --

1 Harlan, can you wait? Let me get Larry and then  
2 there's somebody -- Ellen, over there, and then  
3 I'll come back to you, Harlan. Larry?

4 MR. BECKER: And I said this to Joe when  
5 we talked about it, and I support more than three.  
6 At the same time, there's also what I would call  
7 the cost of lost opportunity. So, if we do five,  
8 there's something else that we can't do because we  
9 don't have unlimited resources, unlimited people,  
10 money, et cetera. So, what's the tradeoff that  
11 we're going to make if we decide to go to five  
12 versus three?

13 VICE CHAIRMAN LIPSTEIN: Joe, what's the  
14 tradeoff?

15 DR. SELBY: You don't have to fund five  
16 because --

17 DR. EPSTEIN: Five is a way point to get  
18 back to three.

19 DR. SELBY: Yes.

20 DR. EPSTEIN: Five is, let's get  
21 information from a group of experts and then --

22 DR. SELBY: Arnie, your microphone.

1           VICE CHAIRMAN LIPSTEIN:  What he's saying  
2 is we'll pursue five, but then when we get more  
3 input and more expert guidance and we put this out  
4 for public input, we'll find our way back to three  
5 of the five?  Is that what you said Arnie?

6           DR. EPSTEIN:  [Off microphone.]

7           MR. BECKER:  But I thought your question  
8 was, do we want to do more than three --

9           VICE CHAIRMAN LIPSTEIN:  Well, but he just  
10 clarified my question.

11          DR. SELBY:  We want to process more than  
12 three to get to the best three.  So, we take the  
13 best three out of five.

14          VICE CHAIRMAN LIPSTEIN:  Ellen, it was  
15 Ellen and then I had Harlan and then Francis.  Are  
16 you yielding to Francis?

17          MS. SIGAL:  Yes, I'm yielding, but then I  
18 want to go after.

19          DR. COLLINS:  It was relevant to this  
20 point.  I think the other friendly amendment here  
21 is suppose you look at five and you really love all  
22 five.  Remember, there is a decision we haven't

1 talked about, about how much money do you put into  
2 each one? So, maybe you do all five, but you don't  
3 fund them quite as liberally as if you were just  
4 doing three. That's the other variable we haven't  
5 talked about.

6 UNIDENTIFIED BOARD MEMBER: [Off  
7 microphone.]

8 VICE CHAIRMAN LIPSTEIN: Hold on, I'm  
9 losing control. Joe, can you sit back? Thank you.  
10 Harlan Weisman, Bob -- oh, Ellen. See you made me  
11 -- Gene, can you come back please?

12 MS. SIGAL: I should never have ceded my  
13 voice, but it's okay to do that to Francis, he  
14 actually knows more than I do.

15 So, I think it would be best if we can  
16 look at five, if we have the resources, even if we  
17 choose three. There may be a few in the top three  
18 that are not feasible or we're having problems with  
19 and there may be others that if we do five, may  
20 turn out to be more relevant to what we're trying  
21 to do.

22 So, if we can, even though we may only

1 fund three, I think it would be best if we can look  
2 at five.

3           VICE CHAIRMAN LIPSTEIN: Can I ask for --  
4 is there a general sense that that's okay, just  
5 looking around the room that what we will do is  
6 today we will approve five, realizing that we may  
7 end up wanting to fund five at lower levels or we  
8 may, through the process, find out that we can't  
9 pursue all five and we would come back to three?  
10 Is there anybody that thinks that's a lousy idea?  
11 Harlan, you think that's a lousy idea?

12           DR. WEISMAN: The comment I was going to  
13 make is I don't think it's a lousy idea, but I also  
14 -- and I have no idea whether I would have come up  
15 with the same three as they did, but when I look at  
16 them, they seem like a reasonable three things to  
17 do and could there be better ones or could we spend  
18 a long time discussing, debating, and coming up  
19 with another list of three? Yes. But to me a  
20 better question is, is this an okay list? Are  
21 these okay? Are these important questions? And  
22 should we get on with it? And my vote is, this is

1 as reasonable three conditions as any and I don't  
2 see a reason not to do them.

3           And this is a first attempt to get into  
4 specificity. We have a whole process designed  
5 around getting to specificity over the long-term.  
6 So, why should we draw this out? But maybe I'm --  
7 I could go with five if that's what everybody else  
8 wants.

9           VICE CHAIRMAN LIPSTEIN: I've got a lot of  
10 people -- Bob Jesse.

11           DR. JESSE: So, we've had a lot of  
12 discussion over, I guess, a couple of Board  
13 meetings as we moved into this about whether we're  
14 going to fund specific disease-related topics,  
15 specific condition-related topics versus on and on  
16 and on, and this is kind of our first foray into  
17 that very kind of condition-specific issue.

18           I think that the one comment I would make  
19 is that as we do this, they ought to be conditions  
20 for which the endpoints are driven by relatively  
21 short-term patient-based outcomes, whether it's  
22 pain -- I guess the symptoms of uterine fibroids,

1 the presence and severity of asthma attacks,  
2 however you do that, but, you know, fundamentally  
3 what we want to do as we move into this is to make  
4 sure that we keep it about very specific about the  
5 patient perceived symptoms or outcomes around these  
6 conditions.

7           So, you know, falls in the elderly is  
8 actually a really interesting one and probably out  
9 to have very rapid short-term results, likewise  
10 asthma and the others, but just keeping that in  
11 mind because if we can do these in a relatively  
12 short -- quick fashion, with a lot of specificity,  
13 but poignant outcomes, we can actually do a lot  
14 more than dragging things out into long-term  
15 outcomes that are more -- that are less patient-  
16 specific and more actuarial, I guess is the way to  
17 put it.

18           VICE CHAIRMAN LIPSTEIN: Dr. Selby wants  
19 to respond.

20           DR. SELBY: Well, first of all, I want to  
21 agree with the second part of what you said  
22 completely that -- and, in fact, part of this

1 expert stakeholder advisory panel can be to help us  
2 explore the -- how attractive it is to focus and  
3 how feasible it is to focus on short-term outcomes,  
4 and that should be one of the criteria that help us  
5 decide which directions to go.

6           But I want to make a distinction that you  
7 blurred a little bit, in my mind, and I think it's  
8 a critical decision. To my mind, no one ever said  
9 we were not going to study high-priority, disease-  
10 specific questions. People said we were not going  
11 to name some diseases as high-priority, that is, we  
12 were not going to say that asthma is one of the  
13 five diseases we will study.

14           But to tie our hands and say we're not  
15 going to ask a question in a specific disease cuts  
16 out about, you know, 60 to 70 percent of the things  
17 we can study and about 90 percent of probably what  
18 was intended in the legislation. So, I think the  
19 secret is to get to high-priority questions, not  
20 high-priority conditions.

21           DR. JESSE: No, I agree, and I didn't mean  
22 to infer that.

1           VICE CHAIRMAN LIPSTEIN:   Okay, Dr. Goertz.  
2 I'm just going to go around the room one more time  
3 and if you've already spoken, I'm hoping you'll let  
4 the people who haven't spoken yet go ahead of you.  
5 So, Dr. Goertz.

6           MS. GOERTZ:   Thank you.   Christine Goertz.  
7 I think it would be helpful to put this in a little  
8 bit of a context.   I mean, I'm assuming that these  
9 are not the only five specific PFAs that we're  
10 going to be issuing.   I'm just wondering, what is  
11 the timeline and the process?   I know that we have  
12 a lot of efforts on going to try to figure out how  
13 to better prioritize topics, and Joe, what's the  
14 timeline that you see for -- I mean, are we going  
15 to do this again as a Board or are we going to wait  
16 then after this until we have more information?  
17 How does this all fit together?

18           DR. SELBY:   Our thinking is that this is  
19 the one and only time that we would use this  
20 particular process, that we are working on and  
21 testing and refining our long-term -- longer-term  
22 prioritization process and the next time we

1 consider high-priority topics should be after that  
2 process is in place. And as I intended to say at  
3 the beginning of this, if I didn't, we think that  
4 we could anticipate questions beginning to come to  
5 us somewhat after mid-year, 2013.

6 VICE CHAIRMAN LIPSTEIN: Dr. Levine.

7 DR. LEVINE: Yeah, and my question was, I  
8 mean, I think I agree with Harlan. I worry about  
9 this pushing the decision to add to then go back  
10 and reprioritize three versus four versus five is  
11 going to push out the timeframe and prolong the  
12 process, and I think one of the things that drove  
13 this was an effort to demonstrate some impact that  
14 was valuable and had results that were valuable to  
15 patients. So, I worry about the extension of the  
16 time before we can actually start and wondered,  
17 Joe, what your assessment -- I mean, presumably we  
18 would have to do this again in January at our next  
19 Board meeting. Is that right?

20 DR. SELBY: Well, I don't think we should  
21 discard the three that came up in this process  
22 lightly, so I don't think we should sort of throw

1 it back to 11 or 25. I think we should -- I think  
2 these three have sort of made it to the top and  
3 we've made a good case for each.

4           If there was a process to add one or two  
5 more, that would guard against the possibility that  
6 when we really dig down deep with that expert  
7 stakeholder advisory panel, we don't come up with a  
8 key question. And so, I don't think we're at all  
9 adverse to having four to five total, including  
10 these three.

11           DR. LEVINE: That wasn't the question I  
12 heard. I heard --

13           VICE CHAIRMAN LIPSTEIN: I'm going to try  
14 to get us to a summary point in just a minute  
15 because as Dr. Washington reminded me, we have  
16 public comment in 10 minutes. But let me ask,  
17 Debra and then Carolyn and then I'm going to make a  
18 suggestion.

19           MS. BARKSDALE: Debra Barksdale, Board. I  
20 actually wanted to support Harlan. I think these  
21 three are perfectly fine and that, sure, we could  
22 probably come up with some more. I came up with

1 three more that are my favorites, and if we prolong  
2 this too much, because we all have favorites, so I  
3 just want to stand in agreement with Harlan.

4 VICE CHAIRMAN LIPSTEIN: Carolyn.

5 DR. CLANCY: I, too, want to support  
6 Harlan and now Dr. Barksdale. Carolyn Clancy,  
7 Board member. We've been talking about this and  
8 massaging it and debating it for quite some time.  
9 I am totally confident that we could perfect  
10 anything, but I actually think we need to get  
11 moving, so I actually support the staff  
12 recommendation.

13 VICE CHAIRMAN LIPSTEIN: So, I'm going to  
14 ask for this motion, and see if we can all support  
15 it. The motion would be that we fund up to five  
16 targeted areas, that these be three of the five,  
17 and that we ask staff to return to us in January  
18 with recommendations on the other two. And in the  
19 intervening month and a half or two months, that  
20 would give them an opportunity to either query  
21 individual members of the Board, other stakeholder  
22 groups, in order to identify those two. Because I

1 have a feeling if we were to embark on a discussion  
2 now of what those other two should be, it might be  
3 a pretty prolonged conversation.

4           So, the motion I am asking for somebody to  
5 make is that we approve up to five of these  
6 targeted PFAs, that three of the five will be the  
7 conditions that Dr. Selby identified on the slide  
8 earlier, and that he and staff will return to us in  
9 January to identify the other two targeted  
10 conditions. Dr. Weisman.

11           DR. WEISMAN: So, just for clarity, and I  
12 almost would suggest we do it as two separate  
13 motions, are we voting in -- what you're  
14 suggesting, we're voting to give the go ahead to  
15 proceed on the three --

16           VICE CHAIRMAN LIPSTEIN: Yes.

17           DR. WEISMAN: And in addition, we're  
18 asking them to come back with another two?

19           VICE CHAIRMAN LIPSTEIN: Correct.

20           DR. WEISMAN: Okay. That requires -- you  
21 could support one part of that and not the other  
22 and that's why I'm suggesting maybe we should

1 separate them, but it's up to the group.

2 VICE CHAIRMAN LIPSTEIN: Dr. Sigal.

3 MS. SIGAL: So, just a clarification. If  
4 we were to decide on five rather than three,  
5 wouldn't it be the other two in the top five? How  
6 would we -- or would it just be any other two? How  
7 would that work?

8 VICE CHAIRMAN LIPSTEIN: Well, I think  
9 that since I don't know the answer to that question  
10 and it might take us a while to arrive at that  
11 process, what I think would be better to do would  
12 be to allow staff some time to develop a good  
13 process for identifying those two and to come back  
14 to us in January.

15 Can I have a motion to that effect?

16 MR. BECKER: [Off microphone.]

17 DR. ZWOLAK: [Off microphone.]

18 VICE CHAIRMAN LIPSTEIN: So moved by Mr.  
19 Becker, second by Dr. Zwolak.

20 Okay. Any discussion? All those in  
21 favor?

22 [Hands raised.]

1 VICE CHAIRMAN LIPSTEIN: Any opposed?

2 [Hands raised.]

3 VICE CHAIRMAN LIPSTEIN: Dr. Krumholz is  
4 opposed. Oh, Dr. Douma's opposed two. So, we have  
5 two opposed, all others were in favor.

6 Harlan, do you want to speak in terms of  
7 your reason for voicing opposition?

8 DR. KRUMHOLZ: Well, I think there's room  
9 for dissent on a Board. I didn't do it just for  
10 that reason.

11 Look, this is going to move ahead. I want  
12 to just express a minority opinion, that I don't  
13 feel we're fully leveraging about our vision about  
14 where these PFAs should do it and particularly  
15 where they fit in the overall strategy and how our  
16 approach is going to be to whether we're focusing  
17 on event-driven studies or patient-reported outcome  
18 studies, and how the lessons from these are going  
19 to then leverage into the next ones, and I just  
20 feel that there's an attempt to say, do something,  
21 and so these have come down and I think if you did  
22 it again you'd come up with a different list,

1 probably an equally good list, but I just don't  
2 have a comfort level that this is fully aligned  
3 with what we're trying to accomplish in the bigger  
4 picture, with all due respect to the great work  
5 that's been done by staff.

6           So, I'm just -- I've been silent because I  
7 just have deep respect for the staff work on this,  
8 but it's just -- I can't -- I just don't see it.

9           VICE CHAIRMAN LIPSTEIN: Dr. Krumholz,  
10 thank you for your dissenting view. Dr. Douma?

11           DR. DOUMA: I sort of presaged this  
12 earlier. I don't think there's enough -- I don't  
13 have enough understanding of actually what we did,  
14 the transparency issue, there's a lot of stuff that  
15 went on that's unexplained. I'm not saying it's  
16 not right, but another example of that is -- and  
17 just looking at the Institute of Medicine's list,  
18 on asthma it says, "Compare the effectiveness of an  
19 integrated approach with a non-integrated episodic  
20 care model and managing asthma in children."  
21 That's what they put. Now ours is significantly  
22 different than that and I don't know the process

1 that we used to get from one to the other.

2 So, it's my ignorance that gets in the way  
3 of me being able to vote for it.

4 VICE CHAIRMAN LIPSTEIN: I think those  
5 perspectives are useful and we learn from them as  
6 we go forward.

7 Kara, thank you very, very much. I did  
8 want to say that in counting the votes I forgot to  
9 mention, for the people who are recording the  
10 minutes, that Dr. Washington did recuse himself.  
11 As an obstetrician/gynecologist he didn't feel that  
12 -- since one of the topic areas had to do with his  
13 discipline, that he should participate.

14 CHAIRMAN WASHINGTON: No.

15 VICE CHAIRMAN LIPSTEIN: Is that not  
16 correct.

17 CHAIRMAN WASHINGTON: That's part of my  
18 equation. There are other reasons.

19 VICE CHAIRMAN LIPSTEIN: Okay.

20 DR. COLLINS: Collins, Board. Point of  
21 information. You said that if Board members want  
22 to have some input into the consideration of two

1 more possible projects we should be doing so? By  
2 what path should that information travel?

3 VICE CHAIRMAN LIPSTEIN: I would think Dr.  
4 Selby has the answer to that question.

5 DR. SELBY: As Debra said, we all have our  
6 favorites and so as not to be persuaded by the  
7 first or the last person -- differentially by the  
8 first or the last person that calls with their  
9 favorites, it crossed my mind that we actually  
10 ought to poll the Board and I think people could  
11 refrain if they wanted to just stick with the three  
12 or it might be wiser to choose one or two  
13 additional ones.

14 DR. COLLINS: Great, so that will happen?

15 DR. SELBY: If it suits the Board, we  
16 could certainly make that happen.

17 DR. COLLINS: Thank you.

18 VICE CHAIRMAN LIPSTEIN: Okay, Dr.  
19 Washington, you're back in charge.

20 CHAIRMAN WASHINGTON: Okay. Thank you  
21 Vice Chair Lipstein and thanks also, Kara and Joe  
22 and the other staff for superb work.

1           And we are three minutes away from the  
2 public comment period, so I'm going to ask that we  
3 all stand and sort of walk and wiggle or stretch  
4 your arms in place.

5           [Pause.]

6           CHAIRMAN WASHINGTON: Now we're going to  
7 ask our colleague, Ms. Sue Sheridan, to introduce  
8 this public comment period.

9           MS. SHERIDAN: Good afternoon. I'd like  
10 to welcome those of you who registered to provide  
11 public comment. I am going to just share the  
12 process that we're going to do this afternoon.  
13 We'll take those comments from you, those of you  
14 who registered. After everybody has spoken, we're  
15 going to take comments by phone if there are any.

16           Individuals offering public comment must  
17 limit their remarks to no more than three minutes,  
18 please. We have several of you, so we want to make  
19 sure that everybody has adequate time, and if you  
20 have written testimony, we invite you to submit it  
21 to PCORI via email to [info@pcori.org](mailto:info@pcori.org).

22           So, I am going to call your name and if

1 you could just come up to this mic behind me and  
2 share your comments. We're going to begin with  
3 Aaron Abend [phonetic]? Okay, Aaron, if Aaron  
4 walks in in a little bit we will invite him back.  
5 Next patient or public commenter is Dave  
6 DeBronkhardt, who many of us know is e-Patient Dave  
7 on the Internet.

8 MR. deBRONKHART: I'm going to do the  
9 FedEx commercial. Anybody remember the FedEx  
10 commercials version of --

11 MS. SHERIDAN: Mic.

12 MR. deBRONKHART: Ah. Push the mic  
13 button, folks. All right, the FedEx commercial  
14 version. Thank you for this opportunity. The  
15 Institute of Medicine's new report, "Best Carrot:  
16 Lower Cost" says that of the four pillars of a  
17 learning healthcare system that we need, one is  
18 engaged, empowered patients. It says, "A learning  
19 healthcare system is anchored on" -- anchored on,  
20 not reflects on -- "patient needs and  
21 perspectives." I could go on at more length, but I  
22 want to point out -- so, I ask, are we anchoring

1 our thinking on patient needs and perspectives?

2 And I say this with the greatest respect and  
3 admiration for what this group is doing, but I want  
4 to challenge.

5           This summer at my college reunion I bumped  
6 into a classmate who said, oh, what you're doing in  
7 life, you should meet this guy I used to work with,  
8 Perry Cohen, who has addressed this group before.  
9 Perry and I have met and we have become instant  
10 best friends. Much to our mutual amazement, we  
11 were teaching assistants for the same course in  
12 managerial psychology at the Sloan School many  
13 years ago. We never knew each other. But, you  
14 know, our paths diverged. He went on to get a  
15 doctorate and to be smart, I went into marketing.

16           I learned to understand change and give  
17 speeches about it, Perry says, let's collaborate  
18 because I'm losing my voice. And he and I would  
19 love to engage together in any way we could on  
20 this.

21           Quick examples. Of the three proposed  
22 conditions to study, fibroids, I have two relatives

1 who are significantly affected by fibroids. Do we  
2 know if the endpoints researchers are proposing  
3 studies on match the endpoints that would be  
4 important to those women? We can't do it by asking  
5 surrogates or proxies.

6 Jack Wennberg's research in shared  
7 decision-making has said for decades that the  
8 doctors with the best of intentions are bad at  
9 predicting what their own patients would prefer,  
10 much less people looking at a patient population in  
11 the aggregate.

12 Asthma, do we know if patients want  
13 something different? I understand we're going to  
14 take proposals that researchers have generated and  
15 select from them. Do we know if what patients  
16 would really like is different from what the  
17 researchers have proposed? You're going to have to  
18 interrupt me or knock when my time is almost up.

19 And on falls, are we considering non-  
20 biological interventions like Intel's smart  
21 carpets, things that perhaps would be minimally --  
22 just minimalist intervention but might cause the

1 problem to disappear.

2           In the merit review phase I, phase I as  
3 proposed determines the scientific soundness and  
4 impact, but to make a long story short, my  
5 conversations with Perry make very clear to me that  
6 what research savvy patients think is an important  
7 impact may be substantially different from what the  
8 researchers are thinking, and what I've come to see  
9 -- and then I'll wrap up -- from our background at  
10 MIT, we taught both engineering and science there.  
11 Science is concerned with absolute truth, proposing  
12 a hypothesis and testing it. One of the guys I  
13 knew in college, a guy named Mike Solomon, is the  
14 guy who eventually busted cold fusion. He was such  
15 a pure scientist he just -- he dropped a physics  
16 lab because he didn't understand the electronics in  
17 the instrument that was measuring the stuff.

18           Engineering, on the other hand, is  
19 concerned with developing something that works in a  
20 useful period of time. And in a sense, in addition  
21 to all the good things that scientists do to  
22 develop and test hypotheses, I urge that we also

1 think in terms of engineering relief for people for  
2 whom time is everything.

3 Thanks.

4 MS. SHERIDAN: Thank you, Dave. Our next  
5 is Lewis Kazis. No comment. Thank you, Louis.  
6 Our next is Danny Van Leeuwen.

7 MR. VAN LEEUWEN: Hello. Thank you. I  
8 represent a group of e-Patients here in Boston who  
9 have collaborated to make three recommendations to  
10 this group, and we submitted our recommendations in  
11 writing, so they're either in your packets or  
12 they're available somewhere.

13 So, three minutes. The first one is to  
14 route funding through consumer organizations. The  
15 situations that researchers typically struggle to  
16 include patients and consumers in their research  
17 design, implementation, and dissemination, and the  
18 power dynamic favors the researcher, not the  
19 patient.

20 Our recommendation is to route a defined  
21 proportion of funding through consumer community  
22 organizations with experience recruiting patients

1 for proposal review and other research tasks, and  
2 then allocates that money to researchers and  
3 disseminators.

4           The consumer community organization  
5 enlists the researchers to conduct the patient-  
6 centered outcomes research and publish in academic  
7 journals and allocates a proportion of the funds to  
8 dissemination to the relevant community, so a  
9 different way of doing it.

10           The second thing we recommend -- or we'd  
11 like to suggest has to do with micro grants. The  
12 situation is that patient-driven, patient-centric  
13 research opportunities are less likely to be  
14 prepared to submit high scoring proposals than  
15 traditional research teams. So, our recommendation  
16 is to allocate a defined proportion of funding for  
17 a larger number of smaller projects in the form of  
18 micro grants that either prepare a submitting team  
19 for a high scoring, larger grant, or addresses  
20 research into partnership innovation, cultural  
21 change, social and behavioral determinants, or  
22 dissemination.

1           And the third recommendation that we have  
2 has to do with the scope of research questions.  
3 The medical model paradigm favored by medical  
4 research with its focus on body parts, diagnoses,  
5 and disease labels, is insufficient to meet the  
6 needs of patients.

7           So, our recommendation is to expand the  
8 scope of fundable research questions to include  
9 non-diagnosis related questions, identifying  
10 mechanisms and key success factors of patient-  
11 professional partnership, patient activation, care  
12 coordination and shared decision making, the impact  
13 of peer-to-peer, patient-to-patient, and family-to-  
14 family relationships, and finally, the impact of  
15 social determinants on health.

16           Thank you.

17           MS. SHERIDAN: Thank you, Danny. We'd  
18 like to invite James Rosensweig [phonetic]. Okay.  
19 We'd like to invite Amy Whitcomb-Slemmer.

20           MS. WHITCOMB-SLEMMER: Good afternoon.  
21 I'm Amy Whitcomb-Slemmer, I'm the Executive  
22 Director of Healthcare for All, which is a

1 nonprofit based here in Massachusetts. We're 27  
2 years old and our mission is to create a consumer-  
3 centered healthcare system that provides culturally  
4 competent, high quality, affordable, comprehensive,  
5 high quality care for everybody in Massachusetts,  
6 and our lens is to look for the needs of the most  
7 vulnerable among us.

8 I'm here with Deb Walkenheim who is one of  
9 our policy managers at Healthcare for All, and I  
10 know many of you are familiar with the environment  
11 you find yourselves in here in Massachusetts, but  
12 we take some pride in helping people to understand  
13 what is possible with the Affordable Care Act, and  
14 I wanted this body to understand and know that  
15 we're in the next phase of health reform in  
16 Massachusetts. As we've figured out -- were almost  
17 ready to declare victory on the coverage issue,  
18 we're now really grappling with cost and quality,  
19 and it seems like PCORI has an opportunity to help  
20 be a catalyst for the cost issue from a consumer's  
21 perspective.

22 The foundation that we've laid is we've

1 passed something called Chapter 224, which is our  
2 cost savings and quality care bill, that will help  
3 transform our healthcare delivery system, and I've  
4 heard some conversations today about the  
5 expectation that we want to really change the  
6 delivery system, but I think it would be incredibly  
7 helpful if, as you look at the funding priority  
8 areas that you've laid out, you consider the  
9 opportunities that will come from driving research  
10 from a patient's perspective.

11           And you've heard the Massachusetts, we are  
12 patient advocates and so we're excited to be  
13 organized here in Massachusetts, we will push you  
14 all to consider what truly is patient and consumer  
15 representation on some of the research protocols  
16 that you're supporting.

17           We think, here in this state, we have set  
18 an expectation for what patient-centeredness means,  
19 for changing the dynamic between patients and  
20 providers. We know there's shared responsibility  
21 to go around for all areas of the healthcare  
22 community to work on this change, but again, it

1 feels as though PCORI truly has an opportunity to  
2 push us along, and as we are proud of ourselves for  
3 having shown how you can cover almost all residents  
4 in a state, we'll be very excited to be able to  
5 share the lessons learned that we will figure out  
6 about how to address cost and quality  
7 simultaneously. Thank you.

8 MS. SHERIDAN: Thanks, Amy.

9 CHAIRMAN WASHINGTON: Thank you, Ms.  
10 Whitcomb-Slemmer.

11 MS. SHERIDAN: Okay, we'd like to invite  
12 Cristin Lind, please.

13 MS. LIND: Hi, everybody. Hi, my name is  
14 Cristin Lind, and I am a mom, and I am a caregiver,  
15 and I am here to just share briefly that -- so, in  
16 the course of my son's care I developed a tool to  
17 help to coordinate his care, but I'm not here to  
18 talk about care coordination, although I think  
19 that's important.

20 VICE CHAIRMAN LIPSTEIN: Cristin was one  
21 of our guests at the patient-engagement workshop  
22 and it was wonderful to meet her and she's

1 terrific, so everybody pay really good attention.

2 MS. LIND: Uh-oh. Well, I'm still  
3 recovering from that weekend.

4 So, the tool that I developed for my son  
5 was identified by a pediatrician here in Boston  
6 who's working extensively on the work of care  
7 coordination. He even went so far as to talk about  
8 it as the penicillin of care coordination, which is  
9 really exciting, because even I can understand how  
10 significant that is.

11 So, we're collaborating together and I  
12 really just want to share with you sort of tales  
13 from the field of what it's like to be a patient  
14 doing research about something that we think is  
15 important.

16 So, last night he called me at 11:00  
17 o'clock, we were reaching our deadline to submit an  
18 abstract for the Pediatric Academic Society, and  
19 because I was really busy running a Girl Scout  
20 troop meeting yesterday, he offered to submit the  
21 abstract for us.

22 Because I'm not affiliated with an

1 academic institution, the system would not allow  
2 the submission of our abstract to go through, so we  
3 thought about lots of things and eventually I gave  
4 the name of an organization that I'm affiliated  
5 with to sort of get through that obstacle, and then  
6 later that night I received confirmation from the  
7 PAS, and it was addressed to Dr. Lind, which I  
8 thought was a fantastic promotion that I had gotten  
9 over the course of an evening.

10           So, really what I'm here to tell you -- is  
11 not even to make a recommendation so much as to lay  
12 bare the seismic change of what it is that we're  
13 talking about doing here, of patients identifying  
14 tools that they think would be useful, of  
15 collaborating together with pediatricians or with  
16 providers who really understand that the tools  
17 won't only solve an individual problem, but that  
18 could fill a significant need and gap, and that  
19 this culture is so unused to the idea that patients  
20 and providers could collaborate together that the  
21 basic framework could not comprehend that a patient  
22 or caregiver could have something to contribute,

1 the computer system is just simply not set up that  
2 way.

3           So, I just really -- I'm here to share  
4 that experience with you, to say, don't  
5 underestimate how significant this is, don't  
6 underestimate how much support is going to be  
7 needed to create this really deep and lasting  
8 culture change, to think about how you structure  
9 these projects so that what we're looking for is  
10 not only the answer to what some of these research  
11 questions are, but how do you structure the work  
12 that you're doing so that you can completely upend  
13 a system that doesn't believe that a patient could  
14 have anything significant to say. Thank you.

15           CHAIRMAN WASHINGTON: Thank you.

16           MS. SHERIDAN: Thank you, Cristin. And I  
17 must add that many of our presenters were also at  
18 the workshop that we all got to know and appreciate  
19 the comments.

20           VICE CHAIRMAN LIPSTEIN: I didn't mean to  
21 play favorites, but Cristin and I met at the cash  
22 bar, the cash bar, at the workshop and she's a mom.

1 CHAIRMAN WASHINGTON: Steve, we are live.

2 VICE CHAIRMAN LIPSTEIN: I know. She's a  
3 mom with two kids and has just -- with everything  
4 that she has going in her life, she took the time  
5 to come to our patient workshop and has just  
6 committed herself to improving what we do in a very  
7 meaningful and inspirational way. So, if she's  
8 back there, she was just one of the highlights of  
9 my PCORI experience in telling her story.

10 MS. SHERIDAN: Great. Thank you. I want  
11 to ask our operator if we have anybody on the line  
12 that would like to offer public comment.

13 OPERATOR: If you'd like to make a  
14 comment, please press \*1 on your telephone keypad.  
15 That's a \* and the number 1.

16 CHAIRMAN WASHINGTON: While we're waiting  
17 on the operator, let's go back to the first person  
18 to see if Mr. Abend [phonetic] is in the room.

19 MS. SHERIDAN: Like to see if Aaron  
20 returned to the room?

21 CHAIRMAN WASHINGTON: Okay. Operator,  
22 anyone on?

1 OPERATOR: We have no comments in queue.

2 CHAIRMAN WASHINGTON: Okay, Sue, because  
3 we do have a few minutes left, and we just heard  
4 some great suggestions from our cohort of speakers,  
5 I'm going to ask if there -- if the Board members  
6 have a question that you might want to ask, and I  
7 know that, in fact, we have one that does.

8 DR. DOUMA: Allen Douma, Board. It's not  
9 so much of a question but just an amplification.  
10 At least two of the presenters today or guests  
11 today were from -- identifying themselves as e-  
12 Patients. Just to let you know, for you wonks, "e"  
13 may have at one time -- having to do with  
14 electronic, but now it's much bigger, broader, and  
15 much more important in the work we do, and it  
16 stands for empowered, engaged, equipped, and  
17 enabled, and all of that works together in those  
18 folks being in charge of their own care and also  
19 requiring us to be much more engaged and empowering  
20 them as we go forward.

21 CHAIRMAN WASHINGTON: Okay, great. Thank  
22 you. Any other comments from Board members?

1 Others in the audience who have not commented and  
2 who did not sign up who would like to make a  
3 comment at this point?

4 Okay. Jesse.

5 DR. JESSE: This is Bob Jesse, Board. I'm  
6 sort of intrigued by that last comment that there  
7 may be the expectation from those -- that are  
8 engaging us that they're looking for truly  
9 disruptive innovation in the sense of how we're  
10 going to perform our mission. And just out of  
11 curiosity, did that sense come through at the  
12 engagement meeting in D.C.?

13 CHAIRMAN WASHINGTON: This is really a  
14 question to Board members participating. Why don't  
15 we start with you, Sue? Do you think it came  
16 through?

17 MS. SHERIDAN: You know what, I wasn't  
18 listening to the question because I was speaking  
19 with a patient. Can you repeat it?

20 CHAIRMAN WASHINGTON: Okay.

21 DR. JESSE: Sue, the question was, there's  
22 a sense that the patients are looking for PCORI to

1 really be the force of disruptive innovation, and  
2 did that sense come through in the engagement forum  
3 in D.C.?

4 MS. SHERIDAN: Oh, absolutely, yes. I  
5 mean, patients talked about PCORI being the  
6 paradigm shift, being innovative, creative, bold,  
7 courageous, and being the agency and entity that  
8 they've been waiting for.

9 DR. JESSE: So, that's not an issue that  
10 we've actually kind of taken head on yet. We might  
11 need to talk about that.

12 MS. SHERIDAN: I think we have an  
13 opportunity. I would like to introduce Sally Okun  
14 from Patients Like Me. She's asked to provide a  
15 last minute comment.

16 MS. OKUN: Thank you so much for this  
17 opportunity. I just really want to say, one small  
18 thing that we've actually thought a lot about at  
19 Patients Like Me, and it's a poem. "To learn,  
20 listen well to the impressions voiced by patients  
21 first." I think if you take that and really take  
22 that seriously, the comment that you just made, we

1 will have disruptive innovation and we will make a  
2 difference for patients and their caregivers. So,  
3 thank you very much for the opportunity.

4 CHAIRMAN WASHINGTON: Thank you, Ms. Okun.  
5 Okay.

6 MS. SHERIDAN: We just want to check with  
7 the operator one more time to see if anybody has  
8 called in.

9 OPERATOR: We have no comments in queue.

10 MS. SHERIDAN: Thank you.

11 CHAIRMAN WASHINGTON: Okay, we really have  
12 benefitted from, as I said, great insight and some  
13 terrific suggestions in this comment period today,  
14 so I want to thank our presenters for sharing with  
15 us your thoughts and your suggestions. We are  
16 taking them to heart and we are encouraged by your  
17 sense of what it is that we, in fact, can achieve  
18 and what we should be doing in terms of disrupting  
19 the status quo and creating a new paradigm.

20 MS. SHERIDAN: I think it can be  
21 positively disruptive.

22 CHAIRMAN WASHINGTON: Positively

1 disruptive. Okay. So, and keep pushing us, and I  
2 heard that terminology used once. We'll just get  
3 better with you pushing us.

4 MS. SHERIDAN: Yes, we will.

5 CHAIRMAN WASHINGTON: Okay, so we're going  
6 to move into the last session for today and we're  
7 going to ask our vice chair -- Steve, are you  
8 ready?

9 VICE CHAIRMAN LIPSTEIN: Yup. We're going  
10 to cover the report of the Board Nominating  
11 Committee. There's a tab in your book. I don't  
12 believe we have slides for this presentation, so  
13 we're going to refer to that handout.

14 Just to remind the members of the Board  
15 that the members of the Nominating Committee are  
16 Dr. Jesse, Gail Hunt, Freda Lewis-Hall and Robin  
17 Newhouse, and Dr. Washington and I sit with that  
18 group, and I chair the group.

19 Under the tab you will see that we have  
20 conducted a process where -- as you will remember,  
21 when we set up our committees originally, we asked  
22 our committee chairs and our committee members to

1 serve for two years while we were getting started,  
2 and I would say that our committee chairs have just  
3 done a terrific job. It was way more of a time  
4 commitment than any of them could have imagined and  
5 we are very grateful for all they did to get us up  
6 and running and started.

7           But as you can see, we've asked Dr.  
8 Norquist to chair the Communications, Outreach, and  
9 Engagement Committee beginning in 2013 -- and, by  
10 the way, we are asking that these committee  
11 assignments and chair assignments be for two years,  
12 and I'll explain that in a minute why we think  
13 that's important, but as you can imagine, we've got  
14 good continuity and the only change to the  
15 membership of the COEC we are recommending is that  
16 Ellen Sigal move to the Program Development  
17 Committee, and when we get to that you'll see her  
18 name appear there.

19           We're not replacing Ellen on the COEC. We  
20 did get future draft considerations --

21           CHAIRMAN WASHINGTON: We do have Allen  
22 Douma there.

1           VICE CHAIRMAN LIPSTEIN:  There is, but I  
2 haven't gotten to that trade yet, okay?

3           CHAIRMAN WASHINGTON:  Okay.

4           VICE CHAIRMAN LIPSTEIN:  But as Dr.  
5 Washington pointed out, you can see the addition of  
6 Allen Douma to the COEC coming over from the  
7 Finance, Administration, and Audit Committee.  That  
8 was a request as well as -- I'm going to talk a  
9 little bit about the FAAC in just a minute.  Well,  
10 I'll talk about it right now.

11           You can see we made the Finance,  
12 Administration, and Audit Committee a little  
13 smaller asking Kerry Barnett to continue to chair  
14 the committee, Larry Becker, Dr. Zwolak, but that  
15 Allen, as I mentioned earlier, will be moving over  
16 to the COEC and Freda will be moving over to the  
17 Program Development Committee.

18           We think that now that we've gotten PCORI  
19 up and running and we've put in place a lot of our  
20 administrative policies and procedures.  As I was  
21 explaining to Dr. Zwolak earlier, with each  
22 successive iteration of the budget, it gets clearer

1 and clearer what's in the budget, and while we're  
2 going through some definition and sizing of the  
3 budget this year, a year from now we believe we'll  
4 have, you know, budget comparisons that make it  
5 really much easier for the Board to do that work,  
6 and so we've made the FAAC a little smaller, a  
7 little bit more nimble.

8           We've asked Kerry to continue chairing  
9 that group because, as you know, he was recently  
10 appointed for another six-year term to our Board,  
11 and so we will have good continuity on that  
12 committee for a long, long time.

13           The Program Development Committee, we've  
14 asked Dr. Goertz to chair that committee, and as I  
15 mentioned earlier, Freda and Ellen will be joining  
16 that committee.

17           We've created a committee called the  
18 Executive Compensation Committee, which is the  
19 committee that will address all issues related to  
20 the compensation of our top four officers that Joe  
21 has described -- the executive director position,  
22 the deputy director, the deputy executive director,

1 the chief officer for engagement, and the chief  
2 science officer.

3 We have a Standing Committee on Conflict  
4 of Interest. Larry Becker will continue to chair  
5 that committee. I wanted to ask Larry if he would  
6 briefly mention, since he knows a little bit more  
7 about Silvio than I do, there is one substitution  
8 there related to a new appointment to your  
9 committee.

10 MR. BECKER: So, this is Larry Becker on  
11 the Board. So, Mark Feldstein was at the  
12 University of Maryland and he joined us in the  
13 beginning. He asked to leave the committee based  
14 on commitments and timing. He recommended Silvio,  
15 again, somebody at the University of Maryland, who  
16 has published extensively on public health. And at  
17 this point, that's my memory because it's been  
18 several months since we did that.

19 VICE CHAIRMAN LIPSTEIN: So, if any of you  
20 need to see a résumé on that, we can certainly  
21 circulate that with the minutes of the meeting.

22 And then finally, the Methodology

1 Committee, there are two key changes. We've  
2 already talked about the outgoing vice chair,  
3 Sharon-Lise Normand. The committee is recommending  
4 Robin Newhouse as the new vice chair of the  
5 Methodology Committee. Rest assured that even  
6 though Robin was a member of the Nominating  
7 Committee, she was not party to those deliberations  
8 or discussions. She was the consensus candidate of  
9 the Methodology Committee, so it's always wonderful  
10 when somebody is highly recommended by their peers  
11 and certainly we bring her forward for your  
12 consideration with enthusiastic endorsement.

13 I think as either Joe or Gene have shared  
14 with you before, upon the occasion of Sharon-Lise's  
15 resignation from the committee, we had a meeting at  
16 the General Accounting Office, at the GAO, about  
17 her replacement and at that time we had a good  
18 discussion with the GAO and they kind of  
19 enlightened us as to how labor-intensive and time-  
20 intensive it is to appoint a Methodology Committee  
21 or a Board of Governors like us, and that doing it  
22 one member at a time is not an easy thing or an

1 efficient thing to do, so they've asked that until  
2 there are other vacancies on the Methodology  
3 Committee, that they not necessarily engage in  
4 officially appointing new members of the  
5 Methodology Committee, but we came up with a good  
6 alternative, which is that as you can see, we've  
7 created something called the Methodology Committee  
8 Board Appointed -- and I think there should be a  
9 "c" in that word, I'm not sure -- but I think it's  
10 adjunct members.

11           And the Methodology Committee has  
12 specifically asked that we identify a  
13 biostatistician to fill Sharon-Lise's role, and so  
14 Dr. Washington and Dr. Selby are hard at work with  
15 input from Sherine Gabriel, and the members of the  
16 Methodology Committee on identifying that  
17 individual. And once we've done so, we'll bring  
18 that forward for your consideration.

19           So, those are the -- the only other thing  
20 I will share with you is that we did not renominate  
21 ourselves as a Nominating Committee, but we think  
22 that 2013 should be an off year for the nominating

1 Committee because we shouldn't have many  
2 nominations to make. The committee appointments,  
3 the chair appointments are all two-year  
4 appointments, and barring any other unforeseen  
5 changes, it should be a very, very light year.

6 So, my recommendation would be, stepping  
7 out of the chair for a minute, that we just  
8 continue with the current membership of the  
9 Nominating Committee as constituted.

10 So, Mr. Chairman, those would be our  
11 recommendations and so as the chair of the  
12 Nominating Committee, I would make a motion to the  
13 Board to accept the report of the Nominating  
14 Committee and these appointments.

15 CHAIRMAN WASHINGTON: Okay. First,  
16 thanks, Steve, for your leadership and collecting  
17 all this information and then formulating it and  
18 organizing the deliberations of the committee.

19 But one is, would you comment on the  
20 integration of the dissemination into the COE?

21 VICE CHAIRMAN LIPSTEIN: I will. And Leah  
22 pointed out another thing I forgot to do, so those

1 are two things I meant to mention that I didn't.

2 I skipped over, inadvertently at the top  
3 of the second page, the Scientific Publications  
4 Committee. Debra Barksdale has agreed to continue  
5 to chair that committee. She hasn't yet done her  
6 two-year sentence, and so the Scientific  
7 Publications Committee remains intact.

8 The other recommendation that's coming  
9 forth from the Nominating Committee, and it's  
10 actually also coming forward from the dissemination  
11 work group, is that we combine the two, that we  
12 roll into the charter and the work of the Committee  
13 on Outreach and Engagement and Communications, the  
14 work that we previously had assigned to the  
15 dissemination work group.

16 And so the COEC, then, would begin to  
17 assume that collaborative effort. You'll remember  
18 the dissemination work group was a coordinating  
19 group between the Agency for Healthcare Research  
20 and Quality and PCORI, in terms of the best way to  
21 make sure that we fully align our efforts in  
22 disseminating and communicating the work of our

1 research institute. I think you all are aware that  
2 AHRQ receives 20 percent of the money, I guess it's  
3 the money, before it goes to the PCORI trust fund,  
4 but 20 percent of the proceeds of the revenue  
5 generated by this part of the legislation. And our  
6 Board had asked that we just make sure we are  
7 really well coordinated and integrated with AHRQ so  
8 that we don't duplicate each other's efforts, that  
9 we enhance each other's efforts, and so we think  
10 the time has come, really, to bring that under the  
11 purview of the COEC.

12           So, that's another recommendation coming  
13 forth from our committee.

14           Did I forget anything else? I can ask any  
15 members of the Board, because we've had input from  
16 all of you on these nominations and these  
17 assignments. Any other comments from the  
18 committee?

19           CHAIRMAN WASHINGTON: Just one. There are  
20 a couple of ways to interpret your comment about  
21 the Nominating Committee, but I do think we need in  
22 place over the next year, and at the end your

1 suggestion was that we just continue the same  
2 group, which I certainly would favor, so that we  
3 are in effect putting forth as part of this slate  
4 the same group that's on the Nominating Committee,  
5 correct?

6 VICE CHAIRMAN LIPSTEIN: Correct. And  
7 just so -- for clarity and to -- the members of the  
8 committee in addition to Gene and me would be Bob  
9 Jesse, Gail Hunt, Freda Lewis-Hall, and Robin  
10 Newhouse.

11 CHAIRMAN WASHINGTON: Okay. Can we have a  
12 motion?

13 UNIDENTIFIED BOARD MEMBER: [Off  
14 microphone.]

15 CHAIRMAN WASHINGTON: So moved. Second?

16 UNIDENTIFIED BOARD MEMBER: [Off  
17 microphone.]

18 CHAIRMAN WASHINGTON: Further comments?

19 [No response.]

20 CHAIRMAN WASHINGTON: All in favor of  
21 accepting this slate, aye.

22 [Chorus of ayes.]

1 CHAIRMAN WASHINGTON: All opposed?

2 [No response.]

3 CHAIRMAN WASHINGTON: Okay, any  
4 abstentions?

5 [No response.]

6 CHAIRMAN WASHINGTON: The motion carries  
7 unanimously. Thanks again to Steve and the members  
8 of the Nominating Committee and thanks to the Board  
9 members who are taking on these continued  
10 leadership roles. Okay. And to Robin who's now --  
11 who I thanked again last night and this morning,  
12 will be coming up to the table and working even  
13 more closely with us and the Board.

14 VICE CHAIRMAN LIPSTEIN: And just one  
15 public comment, since I've been on the phone I feel  
16 like every week or every other week with Sharon and  
17 Rick for the better part of two years, we know  
18 where you live -- but in front of the whole Board,  
19 I think we need to acknowledge how much time,  
20 energy, effort, and commitment you both put into  
21 getting us started in your role as committee chairs  
22 for PDC and COEC, so we love you.

1 [Applause.]

2 CHAIRMAN WASHINGTON: Thank you, Steve.  
3 Thank you. Okay, Francis, you're talking about  
4 efficiency, that was efficient. And, Steve, you've  
5 used less than your allotted time. You got carbon  
6 credits here. You want to sell some of them? Or  
7 we're just going to end early.

8 VICE CHAIRMAN LIPSTEIN: I'll take tickets  
9 to the cash bar.

10 CHAIRMAN WASHINGTON: He wants tickets to  
11 the cash bar. Okay, Joe, wrap up comments?

12 DR. SELBY: Good. So, I'm going to go  
13 quickly through each of the topics today because  
14 each one of them did have some next steps and I  
15 want to ask you to please remind us if we don't  
16 have all of them here.

17 So, we adopted the revised standards of  
18 the Methodology Committee today. Checking the  
19 legislation, we do not have to adopt the  
20 recommendations, so that leads to a lot of exciting  
21 next phase work with the Methodology Committee  
22 including work, particularly in partnership with

1 the COEC and staff, on dissemination of the  
2 standards.

3           We heard loud and clear the MC's interest  
4 and willingness in working with us on both training  
5 peer reviewers to incorporate the standards into  
6 the review process, also heard loud and clear  
7 yesterday and today, an interest on the part of the  
8 MC in working with us in helping us to design an  
9 overall evaluation plan for both patient-engagement  
10 and just for the effectiveness of our research.

11           And the last was, I just heard it at the  
12 end of the discussion, but it seems like a great  
13 idea, which would be to convene the Board, staff,  
14 and the Methodology Committee, to carefully go  
15 through the recommended actions, of which there are  
16 a number, and I think I even heard somebody suggest  
17 the word prioritize maybe.

18           So, all of that -- anything else as a  
19 follow up to the methodology -- that's a lot --  
20 that's enough, isn't it?

21           My advancer is not functioning.

22           The next topic we heard about was the

1 advisory panels, and we were instructed by the  
2 Board to proceed with soliciting interest and  
3 preparing slates to propose to the Board for the  
4 three panels that we presented today, that is the  
5 Patient Engagement, the -- let's just -- I hate to  
6 do this, but let's just call it the Comparative-  
7 Effectiveness or Priority I panel, and the  
8 Addressing Disparities Panels. Heard loud and  
9 clear the notion that we need to create a flow  
10 diagram that describes the flow of ideas from  
11 stakeholders through the staff, through the panels,  
12 and ultimately to the Board.

13           And that's a great idea, and we will get  
14 to work on that.

15           We need to make sure, as we're creating  
16 these panels, that we build a structure that  
17 coordinates their work, enables them to communicate  
18 with each other the idea even of their meeting  
19 together when they have face-to-faces was a good  
20 idea -- suggestion that I think we embraced of  
21 changing the composition of the Patient-Engagement  
22 Panel to closer to 50-50 than 75-25 that allows

1 meaningful representation of researchers and other  
2 stakeholders on that engagement panel.

3           The idea that we include a Board member  
4 and possibly -- maybe this is my addition --  
5 possibly an MC member as well on each of these  
6 committees as ex officio members.

7           And lastly, that we may proceed to create  
8 charters for additional advisory panels if time  
9 allows and the need dictates.

10           Anything else on the advisory panels?

11           DR. CLANCY: Carolyn Clancy, Board member.  
12 First of all, I love this summary. Secondly, it  
13 does seem to me that the flow diagram might at  
14 times overlap with some of the Board committees, so  
15 I don't know if that's a footnote or just an  
16 addition to the second bullet.

17           DR. SELBY: Is the word overlap or it  
18 might include -- flow through the committees.

19           DR. CLANCY: I guess it would include flow  
20 through the committees.

21           CHAIRMAN WASHINGTON: Okay. And Joe, I  
22 had one comment. That is, on the 50-50 -- and I

1 think it's important that in that other 50, it be  
2 patients, providers, and other stakeholders. I  
3 think that's a large enough constituency that we've  
4 been hearing from that we need to be a little bit  
5 more explicit about in our deliberations.

6 MS. HUNT: How about caregivers?

7 DR. SELBY: Yes.

8 MS. HUNT: Patients and caregivers.

9 DR. SELBY: It's the other 50 that doesn't  
10 have the patients and caregivers in it.

11 Okay, if there's nothing else --

12 CHAIRMAN WASHINGTON: We have Leah right  
13 here.

14 MS. HOLE-CURRY: As a part of this  
15 process, I heard a lot about evaluation of both  
16 timing and what we're getting from it and  
17 adjustments, so I'm assuming that's built in and  
18 does it need a separate bullet? Was that also your  
19 understanding as well?

20 DR. SELBY: If somebody will please take a  
21 note for me, one of the things I heard was to  
22 change -- reduce the charter of all the committees

1 from two years to one year, which is a corollary of  
2 that, that at one year we have to decide whether we  
3 want to continue all the committees, merge  
4 committees, depending on our evaluation of their  
5 effectiveness.

6 MS. HOLE-CURRY: Thank you.

7 DR. SELBY: The next thing we talked about  
8 was the 2013 budget, and here are the action items  
9 from that. The Board is to communicate as often as  
10 need be with PCORI staff, namely Anne, with your  
11 ideas and your concerns about the budget as it was  
12 presented so that we can incorporate those in the  
13 revision.

14 Staff will continue working with the FAAC,  
15 particularly with the Methodology Committee, that  
16 we haven't worked with on the 2013 budget yet, and  
17 with the COEC to iron out any remaining concerns  
18 and to clarify any still unclear line items from  
19 the perspective of Board members.

20 We will develop an estimate of the  
21 proportion of the total budget that is going  
22 directly to research, and we will bring a revised

1 budget back to the Board either on a public phone  
2 call, to be scheduled, or at February's face-to-  
3 face meeting in San Francisco.

4           Anything else on the budget? Any other --  
5 okay. The next presentation was on -- was Martin's  
6 presentation. I wasn't here, so I didn't hear  
7 next steps on the Pilot Projects. If there are  
8 some, Lori will have them, I'm sure, and I can add  
9 them or I can be reminded of them now.

10           On the upcoming work of identifying the  
11 awardees for the Cycle I of the broad funding  
12 announcements, a Selection Committee will be  
13 comprised very quickly and will meet -- will plan  
14 to meet twice between now and the December 8th  
15 Board meeting. Data on a range of variables will  
16 be considered for the top proposals, not only those  
17 that are above the pay line, that is, that will get  
18 funded, but for those on the other side of the pay  
19 line, those just below it, let's say, that aren't  
20 quite funded, so that we can understand the range  
21 of distribution in these variables for those that  
22 are funded and what's in the -- those just below

1 the line.

2           The Selection Committee will focus  
3 primarily -- and actually I've got a mistake here -  
4 - primarily on the priority score or the overall  
5 score from Phase II, and then on two variables --  
6 the conditions studied and the population studied -  
7 - and based on that we'll recommend a slate of  
8 proposals in each priority and present that to the  
9 Board of Governors at its December 18th meeting,  
10 normally a telephone meeting, but for this purpose  
11 it will be a public and webcast meeting.

12           Any other -- I see somebody's advancing  
13 this for me. Any other comments on this?

14           MS. HUNT: Gail Hunt on the Board. I  
15 thought that we also suggested that there might be  
16 some additional discussion with the committee co-  
17 chairs on the issue of whether the Phase II review,  
18 the people get to see the scores from Phase I.

19           DR. SELBY: Thank you. That's very good.  
20 I think -- we have asked the committee chairs from  
21 the Phase II review of this cycle to meet with us  
22 by phone to debrief and that's -- that's one very

1 good suggestion that we can bring up with them.

2 I think, in general, we need to get their  
3 input on how this review went and whether there's  
4 other modifications we need to make.

5 DR. BEAL: Joe, over here to your left.  
6 Yeah, just a point of clarification, on the  
7 Patient-Engagement Advisory Panel, I think the  
8 feedback that we received was to expand the number  
9 of researchers, but not necessarily to take it down  
10 to 50 percent because the charter itself says that  
11 there would be a super majority of patients on the  
12 panel. So, just a point of clarification.

13 We will definitely expand.

14 DR. SELBY: So, increase the total number  
15 then?

16 DR. BEAL: Increase the total number --

17 DR. SELBY: Increase the total number on  
18 the committee?

19 DR. BEAL: Increase the total number of  
20 scientists on the committee, but not undermine the  
21 supermajority of patients on the committee.

22 DR. SELBY: We also got advised to add

1 some clinicians to the committee.

2 DR. BEAL: Exactly.

3 DR. SELBY: So, we'll have to do the math  
4 and see if we can preserve a super majority, add  
5 those people, and not expand the committee.

6 I don't know what a super majority is,  
7 I'll admit that.

8 Anything else -- I think this notion of  
9 further evaluation of the review process is a point  
10 well taken and will be included. Somebody please  
11 note that for me.

12 Then next, moving on to the targeted PFAs,  
13 the staff will move ahead with further evaluation  
14 of the three topics we identified and convening of  
15 expert stakeholder panels for those topics. Oh, we  
16 will present -- this is to Allen Douma's point --  
17 we will prepare all the data that we've got on how  
18 the prioritization scoring went and present it to  
19 you and make it public as well in the name of  
20 transparency recognizing that this was a first time  
21 prioritization process using this set of criteria.

22 DR. DOUMA: Let me just add, I think you

1 guys did a great job.

2 DR. SELBY: Thank you, Allen. And the  
3 last there is that we will circulate to the entire  
4 Board the longer list of 11 topics for the Board  
5 members to select up to two additional topics per  
6 Board member for our consideration, that's the idea  
7 that we may go to as many as five and then make a  
8 decision later how many of those we have funds for  
9 and are interested in funding.

10 So, anything else on the targeted PFAs?

11 And the next slide, please. Is that it?

12 That's it.

13 CHAIRMAN WASHINGTON: Okay.

14 DR. SELBY: Thank you very much, Gene.

15 CHAIRMAN WASHINGTON: Any further  
16 comments? Well then I'd like to conclude today by  
17 first recognizing our staff, again, for just the  
18 phenomenal job that you've done in moving along our  
19 principle objectives and in positioning us to  
20 continue to build on the success to date. So,  
21 please join me in a round of applause for all of  
22 our staff. Thank you.

1 [Applause.]

2 CHAIRMAN WASHINGTON: And, again, I'd like  
3 to thank our colleagues on the Methodology  
4 Committee for being so actively engaged, and we  
5 know, just a tremendous amount of work that you've  
6 put into developing, first, the draft report, and  
7 then through a series of revisions, eventually, a  
8 final report, which we believe will truly set a new  
9 standard for the nation, in addition to what you do  
10 just from day-to-day.

11 And I think you heard from the discussion  
12 that we are going to find new and even more  
13 creative ways to tap into your expertise and so I  
14 don't think that you will feel like there's going  
15 to be some let down even though you delivered the  
16 report.

17 This is truly where we behave like the  
18 government, more work and no more pay. So, but  
19 here's to the Methodology Committee.

20 [Applause.]

21 CHAIRMAN WASHINGTON: Okay, I know, and  
22 again, to everyone that participated today, both in

1 person and online, thank you. And finally to my  
2 colleagues sitting around the table, really, we  
3 have come a long, long way and this has been a  
4 just, I think, astoundingly productive day in terms  
5 of moving along a very, very meaty agenda that's  
6 been brought forth by Joe and Anne and the rest of  
7 the leadership in our organization. So, thanks to  
8 the Board.

9 [Applause.]

10 CHAIRMAN WASHINGTON: The meeting is  
11 officially adjourned.

12 [Whereupon, at 5:10 p.m. EST, the PCORI  
13 Board of Governors meeting was concluded.]

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